No. 21-241

In The
Supreme Court of the United States

MONSANTO COMPANY,

Petitioner,

v.

ED HARDEMAN,

Respondent.

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

RESPONDENT HARDEMAN'S BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

In *Bates* v. *Dow Agrosciences LLC*, this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not preempt state-law causes of action that parallel or are narrower than the federal statute's misbranding standard. 544 U.S. 431, 447 (2005). That is so even if "properly instructed juries might on occasion reach contrary conclusions" than the Environmental Protection Agency (EPA) "on a similar issue of misbranding." *Id.* at 452.

The district court found that California's failure-to-warn law is narrower than the federal misbranding standard, and it properly instructed the jury on that claim. The Ninth Circuit affirmed. Petitioner does not challenge the lower courts' interpretation of California law or the jury instruction on the failure-to-warn claim.

The questions presented are:

1. Did the Ninth Circuit correctly apply *Bates* in holding that California's failure-to-warn requirement is not preempted where state law is equivalent to or narrower than FIFRA's misbranding provision?

2. Does the Ninth Circuit, like all other circuits, follow Rule 702 in requiring every expert to utilize reliable methodologies, and to reliably apply those methodologies to the facts of the case?

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INTRODUCTION

Monsanto is asking this Court to review the first and only federal appellate decision arising from the first and only federal trial of state-law claims involving Roundup, the herbicide manufactured and sold by Petitioner Monsanto.

This request for error correction is unworthy of review. Petitioner cannot identify any appellate decision—state or federal—that disagrees with the Ninth Circuit's fact-bound application of governing precedent of this Court. If, as Petitioner claims, the issues are so important, they will arise again. Further percolation is likely to yield agreement rather than discord among the Courts of Appeals because the Ninth Circuit's judgment is plainly correct. Regardless, this Court should not depart from its normal practice of eschewing review of decisions that no other appellate court disagrees with.

1. As to the first question (regarding federal preemption), all appellate courts agree that, under this Court's decision in *Bates* v. *Dow Agrosciences*, 544 U.S. 431 (2005), there is no express preemption of failure-to-warn claims involving Roundup.

That is no surprise, given *Bates*' holding that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not preempt state-law failure-to-warn claims that are substantively equivalent to, or narrower than, federal misbranding requirements. *See id.* at 447. As the lower court recognized, the core teaching of *Bates* is that EPA's approval of a pesticide's label

does *not* mean the pesticide satisfies federal misbranding requirements. App.14a. To the contrary, where, as here, a plaintiff proves that a herbicide is dangerous to human health, the manufacturer can be found in violation of *both* state and federal law.

And there is no split of authority at all as to whether federal law impliedly preempts such claims—all courts agree: it does not. That, too, is no surprise, given that the text of FIFRA forecloses any inquiry into implied preemption. *See Bates*, 544 U.S. at 459 (Thomas, J., concurring in judgment and dissenting in part).

Even if implied preemption did exist under FIFRA, Monsanto's argument would fail because, as the Ninth Circuit held, it principally rests on a two-page, post-verdict letter from EPA's Office of Pesticide Program (OPP Letter) that lacks the force of law. App.16a. That aside, the letter has no bearing here because it merely told pesticide registrants that—*contrary to EPA decisions from a few months earlier*—they cannot change their product labels "where the *only* basis for the warning is glyphosate." App.197a (emphasis added). The letter says nothing about the unique risks posed by glyphosate and various other ingredients that combine to form Roundup.

Monsanto's other implied preemption argument relates to EPA's pre-approval authority over changes to pesticide labels, which Monsanto says creates a basis for a finding of impossibility preemption under *PLIVA* v. *Mensing*, 564 U.S. 604 (2011), because EPA

would supposedly *never* approve a cancer warning on Roundup—even though it has already approved cancer warnings on glyphosate-based formulations like Roundup several times in the past and might do so again in the future.

Putting aside the counterfactual premise at the core of this argument, Monsanto's argument fails because *Bates* itself involved a situation where, as here, the EPA had approved a pesticide label, yet this Court found that the plaintiffs' failure-to-warn claims would not be preempted so long as the state-law tort standard was equivalent to FIFRA's misbranding requirement (an issue left for remand). *See* 544 U.S. at 453-454.

Monsanto also ignores that FIFRA includes a provision stating that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under" FIFRA. 7 U.S.C. § 136a(f)(2). If registration of "an article" under FIFRA—which necessarily includes approval of the product's label—doesn't mean the pesticide complies with federal law, then why should a lawsuit challenging that label as inadequate under state law necessarily conflict with FIFRA? Short answer: it doesn't.

2. The second question presented by Monsanto—whether the Ninth Circuit applied a "uniquely lenient" standard when affirming the district court's admission of certain expert testimony (in purported conflict with Federal Rule of Evidence 702 and *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993))—is equally unworthy of this Court's review.

First, contrary to Monsanto's argument, there is no split of authority as to the proper standard for evaluating the admissibility of the expert testimony at issue here. What Monsanto fails to tell the Court is that the Ninth Circuit itself explicitly rejected Monsanto's suggestion that its *Daubert* approach is more lenient than that of other jurisdictions, holding that "[it] is not an outlier following a more flexible *Daubert* approach than other circuits." App.24a-25a.

Monsanto also fails to acknowledge that, in upholding the district court's admissibility determinations, the Ninth Circuit found support for its ruling in decisions issued by the other, supposedly "stricter," jurisdictions cited by Monsanto. *Id*. That alone defeats Monsanto's effort to transform the Ninth Circuit's ruling into a vehicle worthy of this Court's review.

Monsanto's *Daubert* arguments are also fatally flawed as a factual matter. Monsanto repeatedly insists that Respondent's experts "relied on little more than subjective intuitions rather than the reliable application of scientific principles." Pet.(i); *see also* Pet.27. In fact, as the district court determined in its *Daubert* rulings (which are chronicled in over a hundred pages of written decisions on both general and specific causation, *see* App.91a; App.79a), the expert testimony at issue was grounded in reliable scientific principles and passed the *Daubert* threshold of reliability. *Id.* As the Ninth Circuit held, there was no error in the admission

of this testimony, let alone an error of such dimensions as to warrant review by this Court.

COUNTERSTATEMENT OF FACTS

A. Statutory Framework

FIFRA requires pesticide manufacturers to register their products with the EPA. 7 U.S.C. § 136a(a). But registration of a pesticide does not confer an unconditioned right to sell a federally registered pesticide. Rather, FIFRA gives states the authority to "regulate the sale or use of any federally registered pesticide." 7 U.S.C. § 136v(a). This broad delegation includes the authority to "ban the sale of a pesticide if [such a state] finds, for instance, that one of the pesticide's label-approved uses is unsafe." *Bates*, 544 U.S. at 446 (citing 7 U.S.C. § 136v(a)).

Nor does federal registration mean that a pesticide and its labeling comply with FIFRA. FIFRA states that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." 7 U.S.C. § 136a(f)(2). Under FIFRA, registration of a pesticide is merely "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." *Id.*

EPA can bring various enforcement actions against the manufacturer of a registered pesticide if it determines that the product is "misbranded," including

seeking civil and criminal penalties. *Bates*, 544 U.S. at 439 & n.11 (citation omitted). A duly registered pesticide is misbranded if, inter alia, the label "does not contain adequate instructions for use, or if its label omits necessary warnings or cautionary statements." *Id*. at 438 (citation omitted).

FIFRA's only relevant limitation on state authority is set forth in the Act's preemption clause: 7 U.S.C. § 136v(b). As *Bates* explained, this provision is "narrow." 544 U.S. at 452. Although Section 136v(b) "reaches beyond positive enactments . . . to embrace common-law duties," *id.* at 443, it "prohibits only state-law labeling and packaging requirements that are 'in addition to or different from' the labeling and packaging requirements under FIFRA." *Id.* at 447 (quoting 7 U.S.C. § 136v(b) (emphasis in original)).

B. Regulatory History

Monsanto's Petition contains two central errors regarding the nature of Roundup and its regulatory history that warrant discussion at the outset.

1. The Petition tries to obscure the distinction between Roundup, which is a combination of glyphosate and other chemicals, with its active ingredient glyphosate, suggesting that the two terms can accurately be used "interchangeably." Pet.6 n.1.

But, as Respondent proved at trial, Monsanto's own scientists understood that Roundup and glyphosate have vastly disparate toxicological profiles. *See*

App.44a-45a; *see also* App.42a & n.18. In fact, a 2003 internal email from a Monsanto toxicologist admitted that "[t]he terms glyphosate and Roundup cannot be used interchangeably." C.A.P.E.R.257.[1] The toxicologist, who also served as Monsanto's chief glyphosate spokesperson, likewise admitted that "you cannot say that Roundup is not a carcinogen . . . [because] we have not done the necessary testing on the formulation to make that statement." App.45a. Years later, in 2009, the same toxicologist again acknowledged that "you cannot say that Roundup does not cause cancer . . . [because] we have not done carcinogenicity studies with 'Roundup'." App.42a n.18.

Accordingly, Monsanto's contentions that the terms "Roundup" and "glyphosate" can be used interchangeably, and that studies regarding glyphosate are dispositive as to the carcinogenicity of Roundup, were specifically disproven at trial. As explained below, those contentions are also contrary to EPA's own views on the matter.

2. Monsanto also falsely contends that "EPA has repeatedly concluded that [a cancer warning on Roundup] is not appropriate." Pet.(i); *see also* Pet.3 (EPA "has forbidden" a cancer warning on Roundup); Pet.21 ("EPA would unquestionably reject a cancer warning for Roundup's labeling.").

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[1] "E.R." refers to Monsanto's Excerpts of Record filed in this Court. "C.A.E.R." refers to Monsanto's Excerpts of Record in the Court of Appeals. "C.A.P.E.R." refers to Petitioner's Excerpt of Record in the Court of Appeals.

In truth, Monsanto has never proposed any warning on Roundup regarding the potential carcinogenicity of glyphosate-based formulations, and EPA has never rejected one. The OPP Letter at the center of Monsanto's argument actually establishes that EPA has *allowed* cancer warnings to be included on various glyphosate-based formulations like Roundup—a fact the United States confirmed in its amicus brief to the Ninth Circuit. *See* Brief for United States as Amicus Curiae Supporting Defendant-Appellant at 17, *Monsanto Co.* v. *Hardeman*, No. 19-16636 (9th Cir. Dec. 20, 2019).[2]

The OPP Letter, moreover, merely concerns *glyphosate*, Roundup's active ingredient, not Roundup itself. As explained below, EPA has never made any formal findings as to the carcinogenicity of Roundup. Instead, over the past 40 years, EPA has only reviewed and considered the carcinogenicity of glyphosate, and it has repeatedly stated that it lacks sufficient data to determine whether glyphosate-based formulations—such as Roundup—pose any risk to human health.[3]

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[2] The OPP Letter can be found at App.195a-197a. It specifically stated that EPA will "*no longer approve* labeling that includes the Proposition 65 warning statement on glyphosate-containing products." *Id*. (emphasis added).

[3] In 1985, an EPA review of a mouse study found "[g]lyphosate was oncogenic in male mice," causing rare tumors, and classified glyphosate as a possible human carcinogen. App.4a. EPA later changed that classification based in part on new evidence submitted by Monsanto—evidence that turned out to have been falsified, as Respondent proved at trial. *See* Edwin Hardeman's

Thus, in 2017, as part of its re-registration review of glyphosate, EPA acknowledged this distinction, noting that "farmers and other applicators apply *formulations*, *not the active ingredient alone*." EPA, *Revised Glyphosate Issue Paper* 137 (Dec. 12, 2017) (emphasis added), http://tinyurl.com/eparevdglyphosate. The agency acknowledged a need for additional research "*to determine whether formulation components, such as surfactants, increase the toxicity of glyphosate formulations*." *Id.* at 144 (emphasis added).

EPA said the same thing in April 2019—shortly after the jury verdict in this case—when the agency published its 2019 Interim Glyphosate Review. EPA, *Glyphosate: Proposed Interim Registration Review Decision* 11 (Apr. 2019), http://tinyurl.com/y6h2u8w6. There, EPA again acknowledged that it had not made any conclusions as to whether glyphosate "formulations," like Roundup, pose any risks to human health. *See id.* at 11 (emphasis added).

To this day, EPA still has not reached any conclusions as to the carcinogenicity of glyphosate-based formulations like Roundup.

C. District Court Proceedings

This appeal arises out of the only federal trial regarding Roundup. After regularly spraying concentrated Roundup for 26 years, Respondent Edwin

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Principal and Response Brief at 33-35, *Hardeman* v. *Monsanto Co.*, Nos. 19-16636, 19-16708 (9th Cir. Mar. 16, 2020).

Hardeman, was diagnosed with diffuse large B-cell lymphoma, a subtype of non-Hodgkin's lymphoma ("NHL"). Hardeman sued Monsanto in February 2016, alleging his cancer was caused by his long-term exposure to Roundup.

1. The *Daubert* Hearings

After denying Monsanto's pre-trial motion to dismiss based on federal preemption, the district court conducted a week of *Daubert* hearings on whether Roundup can cause cancer generally (general causation), which were videotaped so they could be used by judges in other cases against Monsanto involving Roundup. App.98a n.4.

In July 2018, the court issued a comprehensive, 67-page opinion on general causation. ER49-116. The court examined each discrete line of evidence in detail, and individually evaluated the strengths and weaknesses of every epidemiological study. The court ultimately held that "the plaintiffs have presented evidence from which a reasonable jury could conclude that glyphosate can cause NHL at human relevant doses." App.179a-180a.

After defeating summary judgment at the general-causation stage, Monsanto moved for summary judgment again, arguing that Hardeman's specific-causation experts' opinions did not satisfy *Daubert*. In response, the district court *again* held *Daubert* hearings with live testimony from three specific causation experts. Based on the evidence presented, the district

court denied Monsanto's motion for summary judgment. App.79a.

2. The Trial

At Monsanto's request, the trial was "reverse-bifurcated" into two phases: the first limited to scientific causation (whether Roundup caused Hardeman's NHL); the second on liability and damages. App.7a-8a.

After Phase One, the jury found that "Mr. Hardeman prove[d] by a preponderance of the evidence that his exposure to Roundup was a substantial factor in causing his non-Hodgkin's lymphoma." C.A.E.R.1710.

After Phase Two, the jury found Monsanto failed to warn of Roundup's risks, that "Monsanto was negligent by not using reasonable care to warn about Roundup's [non-Hodgkin's lymphoma] risk," that Roundup was defectively designed, and that Mr. Hardeman proved by "clear and convincing evidence that he is entitled to punitive damages." C.A.E.R.1680-1681.

The jury awarded Hardeman roughly $5 million in compensatory damages and $75 million in punitive damages—later remitted to $20 million, bringing the total verdict to roughly $25 million. App.10a-11a.

D. The Decision Below

The Ninth Circuit affirmed. App.1a-69a.

The panel first held that FIFRA neither expressly nor impliedly preempts Hardeman's failure-to-warn claims. App.11a.

As to express preemption, the court 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." App.13a.

In so ruling, the panel held that "EPA's approval of a label—one step in a larger registration process—is not conclusive of FIFRA compliance." App.14a. Rather, the court observed, "FIFRA specifies: In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." *Id.*

Nor, in the panel's view, did the 2019 OPP Letter from a subdivision of EPA possess any power to trigger express preemption under FIFRA, because that letter "was issued without any written notice, gave no hearing or opportunity to respond, and lacked any sort of dispute-resolution process"—and thus lacked any force of law. App.17a.

As to implied preemption, the Ninth Circuit held that "[b]ecause Monsanto could comply with both FIFRA and California law, FIFRA did not impliedly

preempt Hardeman's state failure-to-warn claims." App.18a.

On this point, the court did not address Hardeman's argument that FIFRA itself, as construed in *Bates*, entirely forecloses any inquiry into implied preemption. Instead, the Court addressed the merits of the issue, rejecting Monsanto's effort to shoehorn this case into *PLIVA* v. *Mensing*, 564 U.S. 604 (2011), which found impossibility preemption based on FDA's exclusive control over generic-drug labeling. App.20a.

Regarding *PLIVA*, the court observed, first, that FIFRA's concurrent state/federal pesticide labeling regime is a "far cry" from the strict regulatory regime applicable to prescription drugs under the Federal Food Drug and Cosmetic Act (FDCA). App.20a. Unlike the FDA, which forbids generic drug manufacturers from making *any* label changes without prior agency authorization, EPA "permits pesticide manufacturers to make certain changes to labels without prior approval"—including adding cancer warnings. App.20a & n.10. Indeed, the panel emphasized, "EPA has repeatedly permitted pesticide manufacturers to use the notification procedure to add notices related to cancer to their products' labels." App.21a. "Thus," the court concluded, "unlike the generic drug manufacturers in *PLIVA*, pesticide manufacturers '*can* act sufficiently independently under federal law' when amending a label." App.21a (citing *PLIVA*, 564 U.S. at 623; emphasis added).

The court also rejected Monsanto's argument that EPA's 2017 Revised Glyphosate Issue Paper and the 2019 OPP Letter created a basis for impossibility preemption, finding that the OPP Letter lacked the force of law and that neither action "divert[s] Monsanto to a different process for amending a label beyond those normally followed by pesticide manufacturers under FIFRA and its regulations." App.21a.

The panel ultimately concluded that "[c]onsidering the responsibility FIFRA places on manufacturers to update pesticide labels and [the fact] that EPA has allowed pesticide manufacturers to add cancer warnings to labels through the notification process without prior approval, it is not impossible for Monsanto to add a cancer warning to Roundup's label." App.21a-22a (citations omitted).

2. As to the district court's *Daubert* rulings, the Ninth Circuit unanimously held that it is "not an outlier following a more flexible *Daubert* approach than other circuits." App.24a. The panel applied the universal standard for admissibility under Rule 702 and *Daubert*: "expert testimony must be reliable to be admissible." App.22a. It then conducted a detailed review of the general and specific causation opinions of multiple experts. App.22a. The panel held that the district court applied the correct legal standard for evaluating the admissibility of expert testimony but was incorrect in its belief that the Ninth Circuit applies a more flexible *Daubert* approach than other circuits. App.26a.

The panel also rejected the district court's suggestion that the Ninth Circuit is more deferential to expert opinions in close cases. App.24a; 26a. To illustrate this point, the panel compared its own precedent to cases from other circuits involving injuries with high background rates of idiopathy, finding that the different outcomes owed to different facts, not a disparity in the *Daubert* standard or its application. App.24a-25a.

On the merits, the panel performed an exhaustive review of the general causation evidence, concluding that Hardeman's experts' opinions "were sufficiently supported by reliable epidemiological evidence" and were therefore properly admitted. App.33a. The court observed that Hardeman's multiple experts relied upon epidemiological studies showing statistically significant associations, fully adjusted for the possibility of confounding by other pesticides. App.31a; 82a. The panel then found that the reliability of the epidemiological studies was further corroborated by the experts' reliance upon animal studies showing glyphosate causes cancer in rodents and cell studies showing Roundup is genotoxic to human lymphocytes. App.28a.

The panel also found that Hardeman's experts reliably discounted the one epidemiological study Monsanto's experts predicated their defense upon. App.29a. The court observed that the study was criticized by Monsanto's own scientists (prior to litigation) on grounds that "resemble[d] those from Hardeman's experts." App.30a. The panel concluded that these

opinions fell within "the range where experts might reasonably differ." App.30a.

On specific causation, the panel held that Dr. Dennis Weisenburger's differential diagnosis, including his opinion "ruling out" idiopathy, was reliable. App.33a; 36a. The court reasoned that Dr. Weisenburger reliably "ruled in" Roundup as a potential cause of Hardeman's NHL on the basis of the epidemiological evidence (including studies adjusted for confounding by other pesticides), toxicology studies, cell studies, his review of the medical records, and his own clinical experience. App.36a. The court held that, "as a whole," the evidence Dr. Weisenburger relied upon provided a sufficient basis for reliably ruling out idiopathy." App.36a. The court likewise found that Dr. Weisenburger's exclusion of hepatitis C to be reliable. *Id*. The court ultimately found that, as with general causation, the district court did not err in allowing the testimony of Hardeman's specific-causation experts.

REASONS FOR DENYING REVIEW

I. THE NINTH CIRCUIT'S PREEMPTION DECISION IS NOT WORTHY OF THIS COURT'S REVIEW

A. There is No Conflict On the Preemption Question

1. The preemption issue decided below has only been the subject of a single federal appellate decision:

the Ninth Circuit's decision here. No state high courts have yet weighed in.

And as to whether FIFRA expressly preempts a state-law failure-to-warn claim (the first part of the first question presented by Monsanto), this Court resolved that question in *Bates*. There is no conflict between the circuits on that point. In fact, every circuit to consider this question is in agreement: EPA approval of a pesticide label does not preempt parallel warnings claims. *See Schoenhofer* v. *McClaskey*, 861 F.3d 1170, 1175 n.4 (10th Cir. 2017) ("It is not clear that EPA-approved labels can preempt state laws on their own; if anything, *Bates* suggests the opposite. It identified only two sources of preemption: FIFRA itself and any implementing regulations."); *Indian Brand Farms, Inc.* v. *Novartis Crop Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010) ("[T]he remand [in *Bates*] established that mere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration did not necessarily mean that the state law duty was preempted.").

Recognizing that there is no split in authority, Monsanto pivots to the curious argument that this Court should grant review because all future federal cases will necessarily be decided as part of the MDL. *See* Pet.20.

That argument is both misguided and self-centered. It is misguided because an assurance of uniformity in the law is a ground for *denying* rather than granting certiorari. It is self-centered because

it presumes that whether failure-to-warn claims involving Roundup are preempted is a question of great national significance worthy of this Court's attention. While that question is surely important to *Monsanto*, this Court does not serve one company or show special concern for one product. If the application of *Bates* to products like Roundup is truly of great national significance, the issue will recur in other cases, in other courts, as applied to other companies' products. And in the unlikely event a split in authority emerges, this Court can step in at that time. There is no "MDLs-are-special" reason to depart from this Court's normal standards for cert-worthy petitions.[4]

2. Without a split in authority, Monsanto tries to manufacture one by hypothesizing that the Ninth Circuit's application of FIFRA might affect application of wholly unrelated federal statutes involving medical devices. *See* Pet.18-19.

This argument is naked conjecture, not an actual conflict that requires this Court's present attention. And it is incorrect.

It is self-evident that different textual provisions, read within the context of disparate statutory schemes (involving medical devices), may well command

[4] Federal district courts largely agree that claims like Respondent's are not preempted. *See Holyfield* v. *Chevron U.S.A., Inc.*, No. 1:20-CV-00165-JAR, 2021 WL 1380280, at *2 (E.D. Mo. Apr. 12, 2021) (collecting cases and noting that, "[s]ince *Bates*, courts have generally held that FIFRA does not preempt state law claims . . . "). Moreover, there are many cases similar to Respondent's being litigated in state courts around the country.

different preemption outcomes than FIFRA. But different preemption outcomes hardly qualify as a *future* split in *judicial* authority. Instead, any disparity merely reflects a split in how Congress chose to regulate products with vastly different benefits and safety profiles—here, to regulate medical devices (which save and improve lives) more extensively than pesticides (which are poisons designed to kill living things).

It is obvious why Congress chose to regulate Class III medical devices more extensively than pesticides. These devices are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Thus, human health concerns weigh on both sides of the scale concerning whether to allow additional state regulation. Hence, in *Riegel* v. *Medtronic, Inc*., 552 U.S. 312 (2008), this Court concluded that Congress deliberately chose to foreclose compensation of injured persons through the state tort system to encourage the manufacture of federally approved devices. *Id*.

FIFRA's structure represents a different legislative choice; it stems from the fact that the products regulated by the statute—insecticides, fungicides, and rodenticides—*cannot*, by their very nature, be tested on humans. That fact necessarily limits the ability of regulatory entities (like EPA) to predict, in advance, whether any given product will be hazardous to *human* health. And in the context of pesticides, unlike medical devices and pharmaceutical drugs, there is no

public health concern that can spring from over-warning about the dangers of pesticides.

These disparate concerns are reflected in the respective preemption provisions of each statute: the preemptive reach of the Medical Device Amendments (the statute at issue in *Riegel*) encompasses *all* state regulation of "the safety or effectiveness of the device or . . . any other matter included in a [federal] requirement," 21 U.S.C. § 360k(a)(2). And under the MDA, preemption occurs whenever there are "*specific requirements* applicable to a *particular device*." *Riegel*, 522 U.S. at 322 (emphasis added) (citing 21 C.F.R. § 808.1). Therefore, this Court found that "when Congress enacted 21 C.F.R. § 360k, it was primarily concerned with the problem of *specific*, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." *Medtronic, Inc.* v. *Lohr* 518 U.S. 470, 489 (1996) (emphasis added). By contrast, FIFRA's preemptive reach is limited by its text to only *general* labeling or packaging requirements. 7 U.S.C. § 136v(b).

And in any event, if there is confusion about application of preemption for medical devices, that confusion should be addressed in a case involving the MDA, not FIFRA.

B. The Ninth Circuit's Express Preemption Decision Does Not Conflict With Any Rulings of This Court

Monsanto also argues that the Ninth Circuit's express preemption ruling conflicts with prior preemption rulings of this Court, including (remarkably) *Bates* and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008). *See* Pet.13-19. Monsanto is wrong on both counts.

1. The Ninth Circuit's express preemption ruling is a textbook application of *Bates*. Just as *Bates* instructed, the court compared "elements of California's duty to warn and FIFRA's misbranding provision" to determine whether "they impose parallel requirements fully consistent with each other . . . " App.12a (citing *Bates*, 544 U.S. at 454). The court found that "because FIFRA's requirement that a pesticide not be misbranded is consistent with, if not broader than, California's common law duty to warn," Hardeman's claims are not preempted. App.11a; *see also* App.12a-13a.

Monsanto argues, however, that because *Bates* itself said that "a state-law labeling requirement must *in fact* be equivalent to a requirement under FIFRA in order to survive pre-emption," 544 U.S. at 453 (emphasis added by Monsanto), the Ninth Circuit erred by not considering OPP's 2019 Letter and EPA's registration of glyphosate to be "federal requirements" within the meaning of FIFRA.

Here again, Monsanto's argument cannot be squared with *Bates*' actual holding that, pursuant to

FIFRA's text, the *only* federal "requirements" that have the power to preempt are FIFRA's misbranding standard and duly promulgated "regulations." *See* 544 U.S. at 543; *see also* 544 U.S. at 445 (holding that "[a] requirement is a rule of law that must be obeyed.").[5]

Bates' holding makes sense because it limits FIFRA's preemptive reach to agency actions that actually possess the force of law. If Monsanto were correct, a court confronted with a FIFRA preemption argument would have to consider *any* agency action, no matter how informal or tentative, that "in fact" might be undermined by the plaintiff's state-law claims, even if that action does not possess any force of law.

Put another way, Monsanto's reading would give unelected officials the power to preempt without following any formal procedure, sometimes even through mere inaction. Not only is that contrary to *Bates* itself, but it also violates this Court's repeated holdings that informal agency actions do not possess the power to preempt. *See, e.g.*, *Merck Sharp & Dohme Corp.* v.

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[5] The example from *Bates* that Monsanto cites in its brief (at 14) concerns a specific EPA *regulation*, not an informal agency action like the OPP Letter, which clearly lacks the power to preempt. *See Bates*, 544 U.S. at 453 (citing 40 C.F.R. § 156.64 (2004)); App.17a (holding that OPP Letter lacks force of law). EPA's determination regarding glyphosate likewise lacks the power to preempt; as the Ninth Circuit held, "[e]ven if [that determination] stems from more formal procedures, it . . . was made as part of EPA's registration decision, which only supports presumptive (not conclusive) compliance with FIFRA." *Id*.

Albrecht, 139 S. Ct. 1668, 1679 (2019); *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 65 (2002).

2. The Ninth Circuit's express preemption ruling is also consistent with this Court's ruling in *Riegel*, 552 U.S. 312, which involved a Class III medical device. Monsanto argues that the Ninth Circuit ran afoul of *Riegel* because, there, this Court, interpreting the MDA, held that *device-specific* federal requirements regarding a medical device—the FDA's pre-market approval of a specific pacemaker—preempted state tort claims. In Monsanto's view, *Riegel* should apply with equal force in the pesticide context, where it would have mandated a finding of preemption based on EPA's *pesticide-specific* decision to approve Roundup without a cancer warning.

This argument, if correct, would mean that *Bates* itself was wrongly decided, because *Bates* found that EPA's approval of a specific herbicide did *not* preempt state-law failure-to-warn claims challenging the herbicide's label. That aside, Monsanto's argument fails because pesticides are governed by FIFRA, not the MDA. And FIFRA—unlike the MDA—says that EPA's registration of a pesticide merely constitutes "prima facie" evidence that the pesticide is not misbranded (7 U.S.C. § 136v(a))—evidence that can be overcome in a federal misbranding or registration-cancellation proceeding.

There is no comparable provision in the MDA; instead, under that statute, FDA's pre-market approval of a device is dispositive as to the device's statutory compliance. *Riegel*, 522 U.S. at 323. So—as the Ninth

Circuit held here (App.14a n.6)—Monsanto's effort to import *Riegel* into the pesticide context is like trying to fit a square peg into a round hole.

C. The Ninth Circuit's Implied Preemption Decision Does Not Conflict With Any Rulings of this Court

Monsanto has two arguments as to why the Ninth Circuit's implied-preemption ruling conflicts with prior rulings of this Court, both are equally flawed.

1. Monsanto's first argument—that the lower court's implied preemption ruling conflicts with *Merck*, 139 S. Ct. 166 (*see* Pet.21-23)—is easily answered.

First, as noted above, *Bates* itself construed the text of FIFRA as foreclosing any inquiry into implied preemption. *See* 544 U.S. at 459 (Thomas, J., concurring in judgment and dissenting in part) (noting that the majority's decision "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied preemption.").

That aside, Monsanto's contention is predicated on the assertion that it presented "clear evidence" to the Ninth Circuit that EPA will "never" approve a cancer warning on Roundup—evidence that Monsanto says should have triggered a finding of impossibility preemption under *Merck*.

The argument fails for all the reasons discussed above: (1) EPA allowed such warnings in the past (*see*

supra **B. Regulatory History** 6-9 & n.1); (2) EPA has never formally rejected any such warnings or conducted any misbranding or registration-cancellation proceedings as to any product containing such a warning, as FIFRA requires (*see* App.14a-15a; App.17a & n.8); and (3) EPA has never reached any conclusions carrying the force of law as to whether Roundup, a glyphosate-based *formulation*, as opposed to glyphosate alone, poses any risk to human health; instead, it merely found, in its 2020 Interim Registration Review Decision, that "*glyphosate* is not likely to be carcinogenic to humans." EPA, *Glyphosate: Interim Registration Review Decision* 7 (Jan. 2020) (emphasis added), https://tinyurl.com/wnklu3d. And even *that* decision was tentative: EPA added that it "will continue to monitor the open literature for studies . . . that have the potential to impact the risk evaluation of glyphosate." *Id.* at 7.

Accordingly, even if the Court wanted to address the scope of conflict preemption under FIFRA, this case is a poor vehicle for doing so because the question as to which Monsanto seeks review—"whether FIFRA preempts a state-law failure-to-warn claim where . . . EPA has repeatedly concluded that the warning is not appropriate," (Pet.(i))—is not even presented in this case.

And, based on this record, the most that can be said is that EPA *might* reject a cancer warning on Roundup. Even assuming that impossibility preemption exists under FIFRA, the mere "possibility of impossibility is not enough." *Merck*, 139 S. Ct. at 1679; *see*

also id. at 1679 (requiring a showing that federal and state laws "irreconcilably conflic[t]").

Monsanto tries to overcome this defect by taking aim at the Ninth Circuit's conclusion that the OPP Letter does not have force of law. That is wrong for all the reasons stated by the Ninth Circuit. *See* App.16a-17a.

But even if the OPP Letter *did* have the force of law, it still could not preempt Hardeman's claim (or answer the question as to which Monsanto seeks review) because the letter, by its plain text, speaks only to glyphosate and not Roundup. The letter merely says that EPA will not approve Proposition 65 warnings "where the *only* basis for the warning is glyphosate." App.197a (emphasis added). But Hardeman's theory of the case was always that Roundup, which is *mixture* of glyphosate and other chemicals, "is more toxic than glyphosate alone." C.A.E.R.2289. And EPA itself has repeatedly said that it lacks sufficient data to determine whether glyphosate-based formulations like Roundup cause cancer. *See supra* at 8. Thus, the OPP Letter, and EPA's underlying decisions, even taken at face value, do not conflict with the jury's verdict in this case.

2. Monsanto also argues (Pet.23) that the Ninth Circuit "independently erred in concluding that Monsanto could have unilaterally amended its labeling to include a cancer warning."

Here again, Monsanto does not claim that there is any conflict on this point among the federal appellate or state high courts; instead, it argues that the Ninth

Circuit misread the EPA's "notification" procedures, which allow changes to be made to a pesticide label without prior agency approval. Pet.24 & n.5. Respondent disagrees, but because the Ninth Circuit's opinion did not turn on this point, it is not worth discussing. The issue is obviously not worthy of this Court's review.

Ironically, Monsanto tries to overcome that fact by suggesting that this part of the Ninth Circuit's ruling conflicts with *PLIVA* v. *Mensing*, which expressly cautioned against exactly what Monsanto encourages here: "distort[ing] the Supremacy Clause in order to create similar pre-emption across dissimilar statutory schemes." 564 U.S. at 626. *PLIVA* merely held that federal law preempts state-law failure-to-warn claims involving generic drugs because generic drugs are required to have the same label as brand name drugs. *See* 564 U.S. at 617-619. As the Ninth Circuit recognized, however, FIFRA, unlike the FDCA, provides that EPA's mere approval of a drug label does not insulate the drug manufacturer from a federal misbranding action. *See* App.14a (citing 7 U.S.C. § 136a(f)(2)). Accordingly, as this Court recognized in *Bates*, mere approval of a label cannot prevent states from providing a damages remedy for conduct that violates FIFRA. 544 U.S. at 448.

D. Both *Bates* and FIFRA Itself Disprove the Uniformity Concerns Cited by Monsanto

Monsanto also argues (Pet.24) that "the scope of FIFRA preemption" is an issue of "national importance" because the lower court's ruling threatens FIFRA's overriding goal of ensuring "uniformity" of pesticide labeling—and thus review is warranted even in the absence of a lower-court split of authority on preemption.

Once again, Monsanto's argument rests on a demonstrably false premise: that the main goal of FIFRA is to prevent a patchwork of state-law labeling regimes for pesticides. *Bates* itself rejected that argument outright, stating that FIFRA's "clear text" demonstrates that Congress intended to tolerate even a "crazy quilt" of different labeling standards in order to protect the public from dangerous pesticides. *See* 544 U.S. at 448.

What FIFRA prohibits are disparate state requirements relating to aspects of labels like "color" and "font size," not rules of law that parallel misbranding requirements. *Bates*, 544 U.S. at 452. Accordingly, Monsanto's claim that FIFRA rests on a "bedrock uniformity goal" (Pet.25) is disproven by *Bates*. *See also* 40 C.F.R. § 162.153(e)(5) (delegating labeling authority to states including authority to require supplemental labeling).

Moreover, as Justice Breyer wrote in *Bates*, to the extent "state tort liability rules" threaten "a counterproductive 'crazy-quilt of anti-misbranding requirements,"

it is EPA, not the courts, that should take appropriate measures. *See* 544 U.S. at 455 (Breyer, J., concurring). Yet in the 15 years since *Bates* was decided, EPA has not issued a single regulation or taken any other action with the force of law to suggest that state tort actions are causing a "crazy quilt" of misbranding standards. *Id.* at 453. That fact alone speaks volumes.

* * *

In short, the first question presented is not worthy of this Court's review. There is no conflict as to the preemption issue, and because it relates to FIFRA—a singularly unique statute—there is no risk that the Ninth Circuit's decision will cause confusion among the lower courts as to other statutory schemes. And the uniformity concerns cited by Monsanto are belied by FIFRA itself, which was designed to tolerate—and, indeed, encourage—state tort suits that "help to expose new dangers associated with pesticides." *Id*. at 451 (citation omitted). That is exactly what the jury verdict accomplished in this case. The decision below should stand.

II. THE NINTH CIRCUIT'S FACT-SPECIFIC EVIDENTIARY DECISION TO ADMIT RESPONDENT'S EXPERT TESTIMONY IS NOT WORTHY OF THIS COURT'S REVIEW

The second question presented rests on an incorrect premise: that the Ninth Circuit's standard for admitting expert testimony "departs from other circuits' standards." That's incorrect as a matter of law, as the

Ninth Circuit held in its decision below. *See* App.24a (stating that "this court is not an outlier following a more flexible *Daubert* approach than other circuits.").

In reality, the Ninth Circuit applies the same *Daubert* standard as all other circuits—a fact that Monsanto itself argued in its opening brief below. *See* First Step Brief of Monsanto Co. at 41, *Hardeman* v. *Monsanto Co.*, Nos. 19-16636, 19-16708 (9th Cir. Dec. 13, 2019) (arguing that "[the Ninth Circuit] does not employ a lower *Daubert* standard than other circuits."). As explained *infra* at II(A), Monsanto was right

With no substantive split to point to, Monsanto's argument devolves into a contention that the Ninth Circuit applies *Daubert* more leniently than other circuits. But that is not true either. As explained *infra* at II(C), the Ninth Circuit was not more permissive in its application of the universal *Daubert* standard than the other circuits cited by Monsanto. The panel reached that conclusion as well. App.24a.

So the split that Monsanto claims is worthy of this Court's review does not actually exist. And without its imagined split, Monsanto is left to hypothesize that the Ninth Circuit either does not mean what it says or misapplied its own rules. This amounts to a request for error correction at best.—That is not a reason for this Court to grant review.

A. The Panel Did Not Apply an "Impermissibly Forgiving" *Daubert* Standard.

Monsanto's first argument is that the Ninth Circuit applies an "impermissibly forgiving" *Daubert* standard, in contrast to other federal appellate courts. Pet.29; *see also* Pet.30 (stating that "the Ninth Circuit's lenient admissibility standard makes it an outlier among the circuits."). In particular, Monsanto argues that the testimony of Hardeman's specific causation expert—Dr. Weisenburger—would have been excluded under the Sixth and Tenth Circuits' application of the *Daubert* standard. *See* Pet. at 30-31 (citing *Tamraz* v. *Lincoln Electric Co.*, 620 F.3d 665 (6th Cir. 2010) and *Hall* v. *Conoco*, 886 F.3d 1308 (10th Cir. 2018)).[6]

What is most striking about Monsanto's argument is that it fails to address what the Ninth Circuit actually held. As noted above, the panel held that its approach to *Daubert* is no different from other circuits. *See* App.24a. Monsanto ignores this holding, citing instead to statements from the district court that the Ninth Circuit expressly rejected. *See id.*

Monsanto tries to bolster its position by pointing to decisions from other circuits that supposedly apply a different standard. *See* Pet.30 (citing *Tamraz* and *Hall*). In reality, there is no disparity in the legal standards applied in those cases. The standard

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[6] Monsanto's argument that Dr. Weisenburger based his testimony on "unsupported intuitions," and that the Ninth Circuit deviated from other circuits in admitting that testimony, is based on a mischaracterization of the record, as explained *infra* at II(B).

under *Daubert* is always the same: whether "the principles and methodology used by an expert are grounded in the methods of science." App.22a (citing *Clausen* v. *M/V New Carissa*, 339 F.3d 1049, 1056 (9th Cir. 2003)).

Instead, Monsanto points to different *outcomes* in the cases, as though they demonstrate that the Ninth Circuit applies an "impermissibly forgiving" approach. App.29a. But the difference in outcomes is simply due to *factual* differences among the cases—in particular the absence of epidemiology and other lines of evidence—not disparate standards.

Consider *Tamraz*, 620 F.3d 670 (6th Cir. 2010), which Monsanto points to as evidence of other circuits' allegedly stricter approaches to *Daubert.* Pet.31. After citing Rule 702 and *Daubert*—the same substantive rules the Ninth Circuit cited to here—the Sixth Circuit rejected the expert's testimony based on a fact-intensive evaluation of whether the expert in that case had offered reliable evidence that manganese exposure caused the plaintiff's injuries. *See* 620 F.3d at 668-669.

The *Tamraz* expert came up short, in the Sixth Circuit's view, "because the scientific literature had only hypothesized but did not find a link between chemical and disease," App.24a (citing *Tamraz* at 667-668). There, unlike this case, there was *no* epidemiological evidence supporting an association between exposure and disease, leading that expert to admit that "he knew of no studies finding a link between [exposure and disease]" and the expert admitted that a key

step in his methodology was based on "speculation." *Tamraz* at 670. Here, by contrast, the experts' opinions were based on reliable epidemiology supporting an association between exposure and disease *and* with other powerful lines of evidence, including studies showing that glyphosate-based formulations like Roundup caused chromosomal damage to human lymphocytes and that glyphosate causes cancer in rodent studies. App.8a; *see also* App.128a-135a (discussing animal and cell studies). Each of Hardeman's experts' testimony was found to be reliably based on sound epidemiology, toxicology, and cell studies, a much different factual scenario than *Tamraz*.

The result in the other case Monsanto relies upon, *Hall* v. *Conoco*, 886 F.3d 1308, 1315 (10th Cir. 2018), likewise owes its outcome to different facts. There, as in *Tamraz*, the Tenth Circuit applied the same substantive *Daubert* standard as the Ninth Circuit here. *See Hall*, 866 F.3d at 1311 ("Before expert testimony can be admitted, the district court must determine that the proposed testimony is reliable.") (citing *Daubert*). The difference in result was due to the fact that the expert's method of calculating dose was clearly and demonstrably erroneous, resulting in an opinion that incorrectly doubled the plaintiff's exposure. *Id*. at 1313-1314. Beyond that, and unlike Dr. Weisenburger here (*see* App.33a-34a), the expert in *Hall* did not even purport to rule out idiopathy. *Id*. His opinions ultimately failed at *both* stages of his differential diagnosis: he failed to reliably rule *in* benzene as a cause and failed to reliably rule *out* the possibility of idiopathic

causes. *Id*. That's entirely different from what happened in this case where Dr. Weisenburger used reliable methods to *both* rule in Roundup *and* rule out alternative causes including idiopathy. *See* App.33a-36a.

Monsanto mischaracterizes the record when it insists, based on *Hall*, that the Ninth Circuit, unlike the Tenth, does not "require[] experts to address 'a large body of contrary epidemiological evidence.'" Pet.32. Not only did Hardeman's experts consider and analyze the single large cohort study Monsanto predicated its entire scientific defense upon, *see* App.124a-128a, but the district court required an *additional* round of experts reports, depositions, and *Daubert* briefing dedicated exclusively to that study. App.124a. As the Ninth Circuit observed, moreover, Hardeman's experts considered the study but afforded it less weight on account of the same glaring flaws that led Monsanto's own scientists to disparage the same study before litigation. App.29a-30a.

In sum, *Tamraz* and *Hall* merely stand for the unremarkable proposition that experts must reliably account for alternative causes of an injury when employing a differential diagnosis. Here, Hardeman's experts did just that, relying upon an abundance of scientific evidence, and expressly ruling out idiopathy. The difference in outcomes stems from different facts, not different legal standards for evaluating the admissibility of expert testimony.

B. The Panel Did Not Allow or Endorse the Admission of "Unsupported Intuitions" Founded Only on "Clinical Experience."

Because there is no real circuit split as to the applicable *Daubert* standard, Monsanto tries to manufacture one by misrepresenting the Ninth Circuit's ruling as a factual matter. Monsanto predicates the entirety of its *Daubert* arguments on a demonstrably false premise—that the Ninth Circuit allows experts to testify based only upon "unsupported intuitions" so long as those intuitions are "purportedly rooted in 'clinical experience.'" Pet.27 (citing App.26a-27a). That is not the Ninth Circuit's rule in this or any other.

In reality, the panel did not even purport to admit testimony based solely upon clinical experience or "intuitions," especially not "as a separate, standalone category, divorced from logic and science." App.26a. Rather, as both the district court and the Ninth Circuit observed, all of Hardeman's experts based their opinions upon multiple lines of reliable scientific evidence, including epidemiology, toxicology, and cell studies. App.8a; App.107a-137a (discussing each line of evidence). In fact, only one expert, Dr. Weisenburger, relied upon clinical experience at all, and he did so merely to *supplement* the larger body of evidence he relied upon including epidemiology, toxicology, and cell studies. App.28a.

Monsanto itself eventually concedes this point. Despite repeatedly suggesting that Hardeman's experts relied on nothing more than clinical experience,

Monsanto admits that the Ninth Circuit, by its own terms, "justif[ied] Weisenburger's testimony on grounds beyond his clinical experience." Pet.34. This justification included, as Monsanto admits, epidemiological evidence showing "a strong association" between glyphosate-based formulations like Roundup and NHL. *Id.* (citing App.35a).

Knowing that the *Daubert* portion of its petition falls apart without this misrepresentation, Monsanto tries to save its argument by contending that Weisenburger's opinion "rested partly" on epidemiological studies "that did not adjust for exposure to other pesticides." Pet.34. Thus, according to Monsanto, even though Dr. Weisenburger's opinions were based on more than "intuition" rooted in "clinical experience," they are unreliable. *Id.*

Monsanto's argument ignores that, in addition to two limited studies that did not adjust for confounding, Dr. Weisenburger also relied upon epidemiological studies fully adjusted for the possibility of confounding by other pesticides, including findings that people exposed to glyphosate-based formulations like Roundup developed NHL at double the rate of the unexposed. App.35a; 31a; 82a.[7] And in any event, the Ninth Circuit

[7] Monsanto argued below that a statistically significant more than doubling of risk (*e.g.*, an odds ratio over 2.0) is an important threshold for proving specific causation. As Monsanto put it, "[a]n odds ratio exceeding 2.0 can provide evidence that an individual contracted the disease 'more likely than not' because of the substance." *See* Monsanto Br. 52, *Hardeman* v. *Monsanto Company*, Nos. 19-16636, 19-16708 (9th Cir. Dec. 13, 2019). In other words, a statistically significant odds ratio over 2.0 is reliable evidence

specifically addressed the Petition's argument, noting that if Dr. Weisenburger had "relied only on" unadjusted studies, his opinions would likely "have been unreliable." App.35a. But the panel correctly found that Monsanto's version of events "is not what happened here." App.35a.

In sum, the second question presented rests on a mischaracterization of what actually happened below. Because Hardeman's experts relied upon valid epidemiological studies that *did* adjust for confounders, and were merely supplemented with clinical experience, the Ninth Circuit did not permit scientific testimony based solely on "unsupported intuitions." Its approach to *Daubert* is no different from other circuits, leaving no evidentiary question worthy of this Court's review.

C. The Panel's Decision Adhered Faithfully to *Daubert* and Federal Rule of Evidence 702.

Monsanto's final point—that the decision below "contravenes" *Daubert* and/or Rule 702 (*see* Pet.32-33)—is based on the same factual misrepresentations that dooms the foregoing arguments. Monsanto argues that, by allowing Hardeman's experts to testify based solely on their "unverifiable conjecture," the Ninth

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of both the capacity of an agent to cause a disease (general causation) *and* the probability that an agent caused an individual's disease (specific causation). *See* App.87a n.5. Here, Hardeman's experts relied upon epidemiological studies with statistically significant odds ratio exceeding 2.0. *See, e.g.*, App.163a; App.82a.

Circuit endorsed "intuition without scientific validation." Pet.33. This is simply wrong. As explained above, Dr. Weisenburger's testimony (and all of the other experts who did not purport to rely upon clinical experience) was supported by a large body of evidence, including epidemiology, toxicology, and cell studies. App.28a; *see also* App.33a (noting that Respondent's experts' testimony was based *in part* on epidemiological evidence). Thus, the notion that the Ninth Circuit allows expert testimony based on "intuition without scientific validation" (Pet.33) is incorrect as a matter of fact.

In reality, the Ninth Circuit, like every other circuit, always requires experts to employ a reliable methodology, no matter their clinical experience or other qualifications, just as *Daubert* requires. *See Daubert* v. *Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1315 (9th Cir. 1995) (finding testimony inadmissible because of the expert's unreliable methodology despite their "impressive qualifications"). Indeed, the Ninth Circuit has consistently held that qualifications like clinical experience does not transmogrify unreliable opinions into admissible testimony. *See, e.g.*, *Domingo ex rel. Domingo* v. *T.K.*, 289 F.3d 600, 607 (9th Cir. 2002) (upholding the exclusion of a qualified expert because his opinion was connected to existing data only by the *ipse dixit* of the expert.").

The Ninth Circuit's approach is no different in the context of differential diagnoses—reliable methodologies are always required for "ruling in" and "ruling out" potential causes of an injury. In particular, the Ninth

Circuit holds that "[w]hen an expert rules out a potential cause in the course of a differential diagnosis, the 'expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation.'" *Messick* v. *Novartis Pharms. Corp*, 747 F.3d 1193, 1198 (9th Cir. 2014) (quoting *Clausen*, 339 F.3d at 1058). In other words, unsupported intuition is *never* admissible in the Ninth Circuit. *See also Nelson* v. *Matrixx Initiatives, Inc*., 592 F. App'x 591, 592 (9th Cir. 2015) (excluding expert for failing to reliably rule out alternative causes of the plaintiff's injury); *Avila* v. *Willits Envtl. Remediation Tr.*, 633 F.3d 828, 839 (9th Cir. 2011) (excluding an expert report when, among other reasons, it "does not actually consider confounding factors" and "failed to consider and rule out other sources [of injury] at all"); *Newkirk* v. *ConAgra Foods Inc*., 438 F. App'x 607, 609 (9th Cir. 2011); *Whisnant* v. *United States*, 274 F. App'x 536, 537 (9th Cir. 2008) (excluding differential diagnosis for "fail[ing] to account for possible alternate causes of the plaintiff's symptoms.").

Monsanto also errs in arguing that the Ninth Circuit "strayed from *Daubert*" by endorsing a flexible approach to evaluating expert testimony. Pet.34. As this Court held in *Kumho Tire Co.* v. *Carmichael*, "the test of reliability is 'flexible.'" 526 U.S. 137, 141 (1999). Thus, not only is some degree of flexibility appropriate, it is *essential*. And here, the Ninth Circuit correctly

held that it is no more flexible in its approach to *Daubert* than any other circuit. *See* App.26a.

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In sum, Monsanto's second question presented rests on misstatements of law and misrepresentations of the record. There is no conflict among the circuits as to the appropriate *Daubert* standard and the panel here did not allow scientific testimony based on "unsupported intuition."

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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