No. 21-

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Petitioner manufactures the herbicide Roundup. For decades, the Environmental Protection Agency (EPA) has exercised its delegated authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to find that Roundup and its active ingredient, glyphosate, do not cause cancer in humans. EPA has authorized Roundup for sale, repeatedly approved Roundup's labeling without a cancer warning, and recently informed pesticide registrants that including a cancer warning on the labeling of a glyphosate-based pesticide would render it "misbranded" in violation of federal law. And in a provision of FIFRA entitled "Uniformity," Congress explicitly barred States from "impos[ing] ... any requirements for labeling ... in addition to or different from those required under [FIFRA]." 7 U.S.C. §§136v(a)-(b).

This case is one of thousands across the country in which individuals have nonetheless alleged that petitioner violated a state-law duty to warn that exposure to Roundup could cause cancer. The Ninth Circuit concluded that respondent's claims were not preempted by FIFRA and upheld the admission of expert testimony on causation that relied on little more than subjective intuitions rather than the reliable application of scientific principles.

The questions presented are:

1. Whether FIFRA preempts a state-law failure-to-warn claim where the warning cannot be added to a product without EPA approval and EPA has repeatedly concluded that the warning is not appropriate.

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

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CORPORATE DISCLOSURE STATEMENT

Petitioner Monsanto Company is an indirect, wholly owned subsidiary of Bayer AG, a publicly held corporation. No other publicly held corporation owns 10% or more of Monsanto's stock.

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RELATED PROCEEDINGS

Hardeman v. *Monsanto Company*, Nos. 19-16636, 19-16708 (9th Cir.) (opinion and judgment issued May 14, 2021).

Hardeman v. *Monsanto Company*, Nos. 3:16-cv-00525 & 3:16-md-02741 (N.D. Cal.) (final judgment issued May 3, 2019 and amended July 17, 2019).

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PETITION FOR A WRIT OF CERTIORARI

Monsanto Company respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

INTRODUCTION

Monsanto manufactures Roundup, the world's most widely used herbicide. Roundup's active ingredient is glyphosate. Like any herbicide, glyphosate is subject to extensive regulatory scrutiny by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's scrutiny includes reviewing whether glyphosate poses risks to humans and ensuring any risks are communicated to the public.

For decades, EPA has studied the enormous body of science on glyphosate and repeatedly concluded that glyphosate does not cause cancer in humans. As EPA explained below, it has approved 44 versions of Roundup labeling since 1991—all without a cancer warning. And in 2019 it instructed glyphosate manufacturers that no request to add a cancer warning would be approved because that warning would be false and misleading.

Despite EPA's repeated findings—confirmed by national regulators around the world, including in Australia, the E.U., Canada, and New Zealand—a working group at the International Agency for Research on Cancer (IARC) classified glyphosate in 2015 as "probably carcinogenic to humans." EPA and other regulators reviewed and rejected IARC's conclusion, which did not identify either the circumstances under which glyphosate might cause cancer or the amount of exposure required. Still, based on that slender reed, many thousands of litigants (including respondent Edwin Hardeman) sued Monsanto asserting that it failed to warn them about the cancer risks of using Roundup.

The Ninth Circuit's decision here—affirming a $25 million damages award—merits review because it conflicts with this Court's and other circuits' decisions on two important federal questions. *See* S. Ct. R. 10(a), (c).

First, the Ninth Circuit held that FIFRA did not preempt respondent's state-law failure-to-warn claim despite EPA's conclusion that such a cancer warning would be false and therefore prohibited by FIFRA. That contravenes this Court's holding that any state labeling requirement not "*genuinely* equivalent" to a FIFRA labeling requirement is preempted. *Bates* v.

Dow Agrosciences LLC, 544 U.S. 431, 454 (2005). The ruling below also splits with how this Court and others have understood a nearly identical preemption provision in another federal statute.

Second, the Ninth Circuit affirmed the admission of expert opinions that glyphosate can cause non-Hodgkin's lymphoma and caused respondent's cancer specifically, even though those opinions rested on little more than subjective intuitions. That conflicts with *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), which requires trial courts to play "a gatekeeping role" to ensure that expert opinions are reliable, and with Federal Rule of Evidence 702, which requires expert opinions to be the product of "reliable principles and methods," "reliably applied ... to the facts of the case," Fed. R. Evid. 702(c)-(d). The admissibility ruling also departs from other circuits' precedent, which would have likely rejected the testimony at issue.

These deviations merit review, particularly because this case is a "bellwether trial for the [Roundup] cases consolidated in a multidistrict litigation," App.2a—meaning that the decision below will control thousands of other federal suits, and undoubtedly influence still others pending across the country. Together, the Ninth Circuit's errors mean that a company can be severely punished for marketing a product without a cancer warning when the near-universal scientific and regulatory consensus is that the product does not cause cancer, and the responsible federal agency has forbidden such a warning. That is not, and should not be, the law.

OPINIONS BELOW

The Ninth Circuit's decision (App.1a-69a) is reported at 997 F.3d 941. The district court's rulings are reported as follows: on preemption (App.181a-187a, 71a-77a) at 216 F.Supp.3d 1037 and 364 F.Supp.3d 1085 and on expert testimony (App.79a-89a, 91a-180a) at 390 F.Supp.3d 1102 and 358 F.Supp.3d 956.

JURISDICTION

The Ninth Circuit entered judgment on May 14, 2021. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS AND RULE INVOLVED

Reprinted in the appendix are the Supremacy Clause of the U.S. Constitution, 7 U.S.C. §136v, and Federal Rule of Evidence 702. App.191a-194a.

STATEMENT

A. FIFRA's Regulatory Scheme

FIFRA is a "comprehensive regulatory statute" governing "the use, as well as the sale and labeling, of pesticides." *Bates*, 544 U.S. at 437. No pesticide may be sold or distributed domestically without EPA registration. 7 U.S.C. §136a(a). The registration process requires manufacturers to submit voluminous scientific and safety data (including carcinogenicity studies), as well as proposed labeling that includes any precautionary statements regarding potential effects on human health. *E.g.*, *id.* §136a(c); 40 C.F.R. §§156.10(a)(1)(vii), 156.60, 158.500.

To register a pesticide, EPA must determine both that the pesticide poses no unreasonable risk of adverse effects on human health, *see* 7 U.S.C. §§136a(c)(5)(C), 136(bb); 40 C.F.R. §152.122(e), and that its labeling complies with FIFRA's misbranding prohibition, *see* 7 U.S.C. §136a(c)(5)(B). "A pesticide is 'misbranded' if its label contains a statement that is 'false or misleading in any particular,'" *Bates*, 544 U.S. at 438, or "does not contain a warning or caution statement which may be necessary and if complied with ... is adequate to protect health and the environment," 7 U.S.C. §136j. Distributing a misbranded pesticide is unlawful. *Id.* §136j(a)(1)(E).

To "ensure that each pesticide's registration is based on current scientific and other knowledge," 40 C.F.R. §155.40(a)(1), EPA must review a pesticide's registration every 15 years, 7 U.S.C. §136a(g). This process requires EPA to consider whether any "labeling changes" are necessary given new information and whether the product still meets FIFRA's requirements, including not being misbranded. 40 C.F.R. §155.58(b).

Pesticide registrants have a continuing obligation to comply with FIFRA's labeling requirements. It is illegal to distribute a pesticide with labeling substantially different than the EPA-approved labeling. 7 U.S.C. §§136a(c)(1), 136j(a)(1)(B). As the United States explained below, "[t]he label is the law." U.S. C.A. Amicus Br. 1. Once EPA approves a pesticide's labeling, the manufacturer must seek approval for virtually any substantive change thereto. 40 C.F.R. §§152.44, 152.46; 7 U.S.C. §136a(c)(9)(C). Some minor changes may be made through a streamlined "notification" process, 40 C.F.R. §152.46, but any changes to "precautionary statements" require prior EPA approval, *see*

EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10* at 8 (Oct. 22, 1998), https://tinyurl.com/yejwzhkt.

Recognizing that divergent state laws could impair interstate commerce in pesticides, FIFRA limits the "[a]uthority of States" to regulate pesticides. 7 U.S.C. §136v. Specifically, FIFRA provides—in a subsection entitled "Uniformity"—that States may not impose "any requirements for *labeling or packaging* in addition to or different from those required under [FIFRA]." *Id.* §136v(a)-(b) (emphasis added). Congress sought thereby to ensure manufacturers would not have to comply with "50 different labeling regimes." *Bates*, 544 U.S. at 452.

B. Glyphosate's Regulatory History

Glyphosate, Roundup's active ingredient, "is the most important herbicide of [the post-war] era." C.A.E.R.1835. Decades of research have found it to be highly effective, "environmentally benign," and "one of the least toxic pesticides to animals," making it "a precious herbicide resource for world agriculture." C.A.E.R.1835-1836. EPA has registered pesticides containing glyphosate since 1974. *See* EPA, *Glyphosate: Proposed Interim Registration Review Decision* 4 (Apr. 2019), http://tinyurl.com/y6h2u8w6.[1]

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[1] This petition uses "Roundup" and "glyphosate" (Roundup's principal ingredient) interchangeably. Although respondent tried on appeal to draw a distinction between the two—suggesting inert ingredients in Roundup called surfactants made it especially hazardous—nothing in the Ninth Circuit's ruling turned on any such distinction, and the district court expressly rejected it. C.A.E.R.15 n.3, 128. EPA's evaluation of glyphosate-based products, moreover, has encompassed both glyphosate and "any inert ingredients." EPA, *Response from the Pesticide Re-evaluation*

EPA has repeatedly evaluated whether glyphosate is carcinogenic. *See* EPA, *Revised Glyphosate Issue Paper* 12 (Dec. 12, 2017), http://tinyurl.com/eparevdglyphosate. For example, in response to a 1983 study raising concerns about potential carcinogenicity, EPA re-evaluated glyphosate's effects on human health. C.A.E.R.1844; C.A.F.E.R.23-25. EPA considered numerous studies in rodents, none of which showed "convincing evidence" that glyphosate was carcinogenic. C.A.E.R.1845. EPA therefore "classified glyphosate as a Group E carcinogen"—signifying "evidence of non-carcinogenicity in humans." C.A.E.R.1844. EPA has repeatedly reaffirmed that classification, concluding in a 2004 Final Rule, for instance, that "[g]lyphosate has no carcinogenic potential." 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004); *accord* 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) ("Data indicate ... evidence of noncarcinogenicity for studies in humans."). Regulators worldwide have similarly found that glyphosate does not cause cancer in humans. C.A.E.R.1732, 1739, 1863-1870.

Against this global consensus, a working group of the International Agency for Research on Cancer classified glyphosate in 2015 as "probably carcinogenic to humans." C.A.E.R.1819. IARC's classification is merely a "hazard identification," the first step in a public-health assessment designed to "identify cancer hazards even when risks are very low at current exposure levels." C.A.E.R.58. IARC did not determine that glyphosate poses a risk of cancer at real-world exposure levels. *Id.*; C.A.E.R.50.

Division to Comments on the Glyphosate Proposed Interim Decision 6 (Jan. 16, 2020), https://tinyurl.com/426uuejz.

Following IARC's classification, EPA conducted another "systematic review" of the scientific literature on glyphosate, including all studies IARC considered. *See Revised Glyphosate Issue Paper* 13,144. EPA concluded again that glyphosate is "not likely to be carcinogenic to humans." *Id.* at 144. EPA reaffirmed that determination yet again in 2020 when, in connection with its formal glyphosate-registration review, it "thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern," including of "cancer effects." EPA, *Glyphosate: Interim Registration Review Decision* 5, 9 (Jan. 2020), https://tinyurl.com/5b7c8awa. EPA again authorized labeling for glyphosate without any cancer warning. *Id.* at 23-27.

EPA re-confirmed its rejection of IARC's findings in a 2019 letter informing glyphosate registrants that EPA would not approve labels of glyphosate-based products that included a cancer warning. *See* App.195a-197a. "Given EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" the letter stated, EPA considers a warning that glyphosate *is* carcinogenic "to constitute a false and misleading statement" that violates FIFRA's misbranding prohibition. *Id.* The letter was consistent with the fact that EPA has approved 44 versions of Roundup's label without a cancer warning. U.S. C.A. Amicus Br. 26.

EPA has maintained its conclusion that glyphosate is not carcinogenic to this day, explaining to the Ninth Circuit again this Spring that "glyphosate is not likely to be a human carcinogen and poses no human-health risks of concern," stressing that "[t]he record underlying these conclusions is robust, reflecting more than a

decade of analysis and thorough review of the scientific literature." EPA Br. 1, *NRDC* v. *EPA*, Nos. 20-70787, 20-70801 (9th Cir. May 18, 2021).

C. Proceedings Below

1. Respondent used Roundup between 1980 and 2012. App.7a. In 2015, he was diagnosed with non-Hodgkin's lymphoma, a common cancer. *Id.* "Approximately 70% or more of" non-Hodgkin's lymphoma cases "are idiopathic, meaning they develop for unknown reasons." *Id.* Respondent also had hepatitis C—an "established" cause of non-Hodgkin's lymphoma—for 25 to 40 years before developing cancer. *Id.*

Respondent sued Monsanto under diversity jurisdiction alleging that Roundup caused his cancer and that Monsanto had violated its purported California duty to warn him of the cancer risks from exposure to Roundup. C.A.E.R.2279-2308. Monsanto unsuccessfully moved to dismiss and for summary judgment on the ground that respondent's claims were preempted by FIFRA. App.7a.

At trial, the district court admitted expert testimony that exposure to glyphosate can cause non-Hodgkin's lymphoma generally and caused respondent's illness specifically, even though it acknowledged that both questions were close even under the Ninth Circuit's lenient admissibility standard. For example, the court noted that there is no "biomarker or genetic signature" to distinguish glyphosate-caused non-Hodgkin's lymphoma from other cases, nor evidence that non-Hodgkin's lymphoma "presents differently when caused by exposure to glyphosate" rather than by something else. App.83a. The court recognized that expert testimony that nonetheless identified glypho-

sate as the cause was "borderline" and probably inadmissible "[u]nder a strict interpretation of *Daubert*" absent "much stronger epidemiological evidence" that did not exist here. App.83a-84a. The court explained, however, that the Ninth Circuit requires courts to "typically admit" opinions that "lean strongly toward the 'art' side of the spectrum," as opposed to science, and permits "a wider range of expert opinions (arguably much wider)" than other circuits. *Id.*

The jury awarded Hardeman $5.27 million in compensatory damages and $75 million in punitive damages. App.10a. The district court reduced the latter, explaining that Monsanto's culpability was "diminish[ed]" because (1) glyphosate had been "repeated[ly] approv[ed]" by EPA and other regulators, and (2) there was "credible evidence" that glyphosate does not cause non-Hodgkin's lymphoma.[2]

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

a. The court first held that FIFRA neither expressly nor impliedly preempts respondent's failure-to-warn claims. App.11a. As to express preemption, the court recognized that FIFRA preempts state labeling requirements that are "in addition to or different" from those FIFRA requires, 7 U.S.C. §136v(b), but it held that, at a general level, "FIFRA's requirement that a pesticide not be misbranded is consistent with, if not

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[2] Respondent's suit is one of thousands pending in a multidistrict litigation as well as in other federal and state courts across the country. Although some Roundup cases have settled, this one has not, and there remain tens of thousands of filed and unfiled claims that have not settled. Moreover, the district court recently rejected a broad proposed settlement of potential future claimants. Accordingly, the issues here remain live and important for thousands of pending cases, as well as any cases filed in the future.

broader than, California's common law duty to warn." App.11a. The court acknowledged that EPA, applying FIFRA, had concluded no cancer warning was necessary for glyphosate, including by "repeatedly register[ing] Roundup for sale without a cancer warning on the label" and by notifying manufacturers in 2019 that EPA would consider any glyphosate product including a cancer warning to be misbranded. App.6a-7a, 14a. But the court deemed those facts insufficient for express preemption, reasoning that, because registration is not "'a defense for the commission of any [FIFRA] offense,'" EPA's approval of a label "is not conclusive of FIFRA compliance." App.14a-15a (quoting 7 U.S.C. §136a(f)(2)). The court also believed that neither EPA's approval of Roundup nor its 2019 letter "carr[ied] the force of law." App.15a-17a.

As to implied preemption, the Ninth Circuit saw no "irreconcilabl[e] conflict" making it "*impossible*" for Monsanto to comply with both state and federal requirements. App.18a-22a. Specifically, the court thought Monsanto could have unilaterally modified Roundup's label to include a cancer warning through a process for "mak[ing] minor modifications to labeling without prior EPA approval" as long as it subsequently notified EPA. App.20a; *but see supra* pp.5-6 (explaining that regulations prohibit substantive labeling changes without prior EPA approval). The court, however, identified no example of EPA's "'allow[ing] a registrant to use the notification process' where EPA previously 'found the relevant chemical was *not* carcinogenic, much less where [EPA] determined a cancer warning would render a label false and misleading.'" App.21a. The court also rejected Monsanto's argument that, even if Roundup's label could unilaterally be changed, EPA would ultimately reject such a change.

And the court again deemed EPA's repeated finding that glyphosate is non-carcinogenic, its registration of Roundup, and its 2019 letter indicating that a label like the one Hardeman seeks would constitute misbranding all irrelevant because they "do not carry the force of law." App.21a.

b. The Ninth Circuit also affirmed the district court's *Daubert* ruling, acknowledging that the ruling "followed [Ninth Circuit] precedent" under which "slight 'deference to experts' with 'borderline ... opinions' was proper." App.23a, 26a. The court asserted that that precedent was not an "outlier," but it distinguished just a few decisions of other circuits largely based on the facts of each case, ignoring the more rigorous legal standards those courts apply. App.23a-26a.[3]

REASONS FOR GRANTING THE PETITION

I. THE NINTH CIRCUIT'S RULING DEPARTS FROM THIS COURT'S PREEMPTION DECISIONS AND CREATES SIGNIFICANT CONFUSION

A. Express Preemption

Respondent's claims rest on the theory that Monsanto violated a state-law duty to warn consumers that glyphosate is a potential carcinogen. *See* App.7a. But under this Court's precedent, that duty imposes a requirement "'in addition to or different from'" what EPA requires in administering FIFRA. *Bates*, 544 U.S. at 439 (quoting 7 U.S.C. §136v(b)). It is therefore preempted because States may not require a warning

[3] Last week, the California Court of Appeal issued *Pilliod* v. *Monsanto Co.*, -- Cal.Rptr.3d --, 2021 WL 3486893 (Aug. 9, 2021). Although *Pilliod* raises similar issues, its preemption ruling relied heavily on the Ninth Circuit's flawed reasoning and its causation ruling was decided under state law.

label where EPA has decided none is appropriate. *Id.* at 453. That is the case here. EPA—exercising authority delegated under FIFRA—has repeatedly concluded that glyphosate poses no cancer risk in humans and warrants no cancer warning. The Ninth Circuit's decision allowing California juries nonetheless to require a cancer warning on Roundup merits review because it conflicts with *Bates* and other relevant decisions of this Court. *See* S. Ct. R. 10(c). At a minimum, it creates uncertainties regarding how to apply this Court's preemption precedent more broadly. *See Merck Sharp & Dohme Corp.* v. *Albrecht*, 139 S. Ct. 1668, 1676 (2019) (certiorari granted to resolve "uncertainties" regarding "the application of [implied preemption under] *Wyeth*" v. *Levine*, 555 U.S. 555, 571 (2009)).

1. The Decision Below Conflicts With *Bates*

a. *Bates* held that a state-law claim is expressly preempted by §136v(b) if the law (1) imposes a "requirement for labeling or packaging" that is (2) "'in addition to or different from'" a requirement under FIFRA. 544 U.S. at 444. There is no dispute that respondent's claims satisfy the first requirement. They also satisfy the second.

Pursuant to its statutory authority, *see* 7 U.S.C. §136a(c), and based on its repeated conclusion that glyphosate is not carcinogenic, *see supra* pp.7-9, EPA has for decades registered Roundup for sale without a cancer warning. And in 2020 EPA reiterated—following a notice-and-comment process that "thoroughly assess[ed] risks to humans from exposure to glyphosate"—that glyphosate presents no "risks of concern" and requires no cancer warning. *Interim Registration Review Decision* 9. Indeed, EPA has concluded that a cancer warning like the one respondent

sought would be "false and misleading," making the product "misbranded pursuant to" 7 U.S.C. §136j(a)(1)(E). App.196a.

Bates compels the conclusion that any divergent state-law labeling requirement—including the one sought here, imposing a cancer warning EPA has rejected—is expressly preempted. In explaining the contours of express FIFRA preemption, *Bates* "emphasize[d] 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). In other words, "nominal[] equivalen[ce]" is not enough. *Id.* at 454. Only state-law claims that truly parallel a federal requirement survive—a category *Bates* concluded *might* encompass challenges to warnings about the *effectiveness* of a product, since EPA had not taken a position on efficacy. *Id* at 440, 453-454. *Bates* was clear, however, that where EPA determines that a pesticide should be accompanied by one warning (such as "CAUTION") but a jury concludes under state law that the label should include a more aggressive one (such as "DANGER"), state law is preempted. *Id.* at 453. That is the situation here: California would require a cancer warning on Roundup's labeling, yet EPA has determined no such warning is appropriate.

b. The Ninth Circuit held otherwise because it improperly assessed FIFRA's requirements at too high a level of generality—an error that, if uncorrected, could render FIFRA's preemption provision nearly meaningless, and undermine the uniformity in pesticide labeling Congress sought to ensure. The court considered FIFRA and California law "parallel" because both generally "require[] a warning" under certain circumstances: FIFRA when a warning is "necessary" and "adequate" to protect public health, and California

when there is "any health risk that is known or knowable." App.12a-13a.

Bates forecloses that reasoning. As this Court explained, that both FIFRA and state law require warning about risks is not enough; rather, preemption turns on whether state law requires *specific* warnings that EPA, in administering FIFRA, does not. 544 U.S. at 453. The crucial question is thus not whether state and federal law have *generally* similar labeling standards, but whether the labeling requirements that a State applies to a particular pesticide—including those "prescribing the ... wording of warnings" (like DANGER)—are different from what EPA requires for that pesticide (like CAUTION). *Id.* at 452. The Ninth Circuit's contrary ruling directly impedes the uniformity Congress sought to accomplish in §136v(b). Because the basic common-law duty to warn is roughly "parallel" to the misbranding prohibition in FIFRA, under the court of appeals' reasoning a jury is free in applying the common law to impose warning requirements on pesticides dramatically different than those required by EPA. *See Restatement (Third) of Torts: Phys. & Emot. Harm* §18(a)(1) (2010) (duty to warn if defendant "knows or has reason to know ... of that risk").

The Ninth Circuit distinguished *Bates*'s "'DANGER'"-versus-"'CAUTION'" example on the mistaken belief that the EPA warning discussed in that example sprang from a regulation. App.16a n.7. That misunderstands the process for determining what warnings appear on a pesticide's label. While EPA regulations *define* toxicity categories (and associated warnings, *see* 40 C.F.R. §§156.62, 156.64), they do not *assign* toxicity categories (or any warning) to particular pesticides. Rather, EPA determines which warnings to apply by making pesticide-by-pesticide determinations through

the registration process. *See supra* pp.4-5. Accordingly, *Bates*'s example necessarily addressed a situation like this case, where (1) EPA determined the appropriate warnings for the labeling of a "given pesticide," 544 U.S. at 543, through the registration process and (2) state law deviated from that judgment.

The Ninth Circuit also suggested—relying solely on implied-preemption precedent—that "the EPA actions that Monsanto alleges preempt Hardeman's claims do not carry the force of law." App.15a. But the proper focus for express-preemption purposes is the body of statutory and regulatory provisions that prohibit manufacturers from adding safety warnings EPA has not approved (and indeed here has determined would be false). Those provisions impose the federal labeling "requirements" that preempt divergent state law. 7 U.S.C. §136v(b). And as explained, for specific pesticides, requirements imposed "under" FIFRA (*id.*) necessarily include EPA's pesticide-specific determinations, *supra* pp.15-16.

In fact, this Court has held that an agency's product-specific approval constitutes a federal "requirement" for purposes of a nearly identical express-preemption provision. In *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), the Court addressed whether state-law claims regarding a medical device's design and labeling are preempted under the Food Drug and Cosmetic Act's Medical Device Amendments (MDA), *id.* at 320-322. Although the MDA, like FIFRA, generally requires warnings necessary to protect health, *see* 21 U.S.C. §352(f), *Riegel* held the state-law claims preempted to the extent they imposed specific requirements "different from or in addition to" those imposed through the Food and Drug Administration's (FDA) pre-market approval process. 552 U.S. at 323,

330. As the Court explained, "FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. The same reasoning applies here. When EPA registers a product and approves the labeling, it determines that *that* labeling, not labeling more (or less) aggressive, provides appropriate warning. That is precisely why manufacturers cannot substantively change a registered pesticide's labeling unilaterally. *See supra* pp.5-6.

The Ninth Circuit distinguished *Riegel* based on an erroneous interpretation of 7 U.S.C. §136a(f)(2), which states that "registration" of a pesticide under FIFRA is not "a defense for the commission of any offense under this subchapter" but is "prima facie evidence" that a pesticide's labeling "compl[ies] with the registration provisions of the subchapter." App.14a & n.6. The court reasoned that, because "labeling determinations are not dispositive of compliance" with FIFRA, they are not dispositive as to preemption. App.15a. But §136a(f)(2) has "no bearing on" preemption. *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994). It simply "stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration." *Reckitt Benckiser, Inc.* v. *Jackson*, 762 F.Supp.2d 34, 45 (D.D.C. 2011). Monsanto, moreover, has not been charged with an "offense" under FIFRA, and its preemption argument turns not on the mere fact that EPA registered Roundup but on EPA's consistent determinations that no cancer warning is necessary or appropriate. If the Ninth Circuit's reading of §136a(f)(2) were right, then EPA's determination that a warning label is unnecessary (or, as here, false and misleading) would never be preemptive. The result would be the very proliferation of divergent state and federal

labeling requirements Congress sought to avoid. *See infra* pp.24-25.

2. The Decision Below Deepens Uncertainty Over How To Apply Similarly Worded Express-Preemption Provisions

The panel's construction of FIFRA's key preemptive language—"in addition to or different from," 7 U.S.C. §136v(b)—conflicts with this Court's and other circuits' interpretation of virtually identical preemption provisions in other federal laws.

Similar language appears in a wide range of statutes, including those regulating medical devices, meat, poultry, and motor vehicles. *See* 21 U.S.C. §360k(a) (MDA); 21 U.S.C. §467e (Poultry Products Inspection Act); 21 U.S.C. §678 (Federal Meat Inspection Act); 49 U.S.C. §30103(b) (National Traffic and Motor Vehicle Safety Act). And this Court has noted that such preemptive language "sweeps widely." *National Meat Ass'n* v. *Harris*, 565 U.S. 452, 459 (2012). The Ninth Circuit, however, has adopted a restrictive reading, under which state requirements are preempted only if inconsistent with federal requirements at a high level of generality. This reading creates divergence among the courts of appeals, threatening considerable confusion because courts routinely look to decisions interpreting similar statutory language when determining the scope of express preemption provisions. *See Bates*, 544 U.S. at 447-448 (relying on the interpretation of the MDA's similar preemption provision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996)); *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 488-489 (7th Cir. 2005) (relying on *Bates* in applying the MDA's preemption provision); *see also Gomez-Perez* v. *Potter*, 553 U.S. 474, 479 (2008)

(this Court is "guided by [its] prior decisions interpreting similar language in" similar statutes).

Lower courts have diverged regarding whether, to survive preemption, a state-law claim must merely be consistent with federal law at the highest level of generality, or instead must be consistent with how federal law is *actually applied* by the responsible agency. The Ninth Circuit here embraced the first approach, deeming it sufficient that both state and federal law generally require warnings about pesticides' health risks. App.12a-13a. But other courts applying the MDA's virtually identical preemption provision have rejected that approach, holding instead that a state-law claim must establish a *violation* of an existing federal requirement to survive preemption. *See Brooks* v. *Mentor Worldwide LLC*, 985 F.3d 1272, 1279-1280 & n.2 (10th Cir. 2021); *Shuker* v. *Smith & Nephew PLC*, 885 F.3d 760, 776 (3d Cir. 2018); *Bass* v. *Stryker Corp.*, 669 F.3d 501, 509-510 (5th Cir. 2012); *Wolicki-Gables* v. *Arros Int'l, Inc.*, 634 F.3d 1296, 1301-1302 (11th Cir. 2011). This inconsistency reflects confusion among the circuits over what it means for state requirements to "parallel" federal requirements. *See Caplinger* v. *Medtronic, Inc.*, 784 F.3d 1335, 1338 (10th Cir. 2015) (Gorsuch, J.) ("Lower courts have struggled ... when it comes to trying to decide whether particular state claims do or don't 'parallel' putative federal counterparts."); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) ("The contours of the parallel claim exception ... are as-yet ill-defined."). This Court's review is needed to ensure consistent interpretation of language that Congress has adopted to effectuate preemption in numerous federal statutes. *See Rowe* v. *New Hampshire Motor Transport Ass'n*, 552 U.S. 364, 369-370 (2008) ("similar [preemption] lan-

guage" should be applied consistently across federal statutes).

Notably, the unique nature of the multidistrict litigation process makes a more direct split regarding FIFRA less likely than if this and similar cases were adjudicated separately in different courts. This case, for example, is one of thousands consolidated in an MDL in the Northern District of California. *See supra* n.2. That is because the MDL statute authorizes the transfer of civil actions involving "common questions of fact" to "any district for coordinated or consolidated pretrial proceedings" before a single judge. 28 U.S.C. §1407(a). In practical terms, this means that the threshold legal issues in *all* current and future federal Roundup cases alleging that Monsanto failed to warn of the risk of non-Hodgkin's lymphoma will be decided by the same district court, governed by a single circuit standard. *See* Fitzpatrick, *Many Minds, Many MDL Judges*, 84 J. L. & Contemporary Prob. 107, 107-109 (2021). This consolidated resolution of pretrial issues can interfere—and, in this case, has interfered—with the "percolation" through lower courts of important legal issues. *See* Coenen & Davis, *Percolation's Value*, 73 Stan. L. Rev. 363, 385 (2021). Because important federal questions related to Roundup and non-Hodgkin's lymphoma that would otherwise be tested in different courts nationwide are instead being resolved solely in a single district, this Court should not wait to grant review.

B. Conflict Preemption

The decision below is also inconsistent with this Court's holding that state law is impliedly preempted to the extent it "conflict[s] with federal law." *Mutual Pharm. Co.* v. *Bartlett*, 570 U.S. 472, 479-480 (2013).

Such a conflict exists where it is "impossible for a private party to comply with both state and federal requirements." *Id.* at 480. In the context of labeling requirements, that impossibility arises (1) where there is "clear evidence" that the relevant federal agency would not approve a warning required under state law, *see Wyeth*, 555 U.S. at 571; *Merck*, 139 S. Ct. at 1678-1679, *or* (2) where the warning could not have been added without prior federal approval, *see PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 617-619 (2011). Both situations are present here.

1. EPA would unquestionably reject a cancer warning for Roundup's labeling. The state-law warning the jury verdict in this case requires is therefore preempted.

For decades, EPA has (based on repeated reviews of the scientific literature) consistently approved glyphosate, and Roundup's labeling, *without* a cancer warning. *See supra* pp.6-9. Even after the IARC working group's "hazard identification," EPA—following a "systematic review," including of all studies IARC considered—confirmed the conclusion it has reached for years: Glyphosate is "not likely to be carcinogenic to humans." *Supra* pp.8-9. Any remaining doubt about whether EPA might approve a cancer warning for glyphosate dissipated in 2019 when EPA informed all glyphosate registrants that, "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" EPA considers any warning that glyphosate *is* carcinogenic "to constitute a false and misleading statement" that violates FIFRA's prohibition against "misbranded" substances. App.196a. Even the district court—which is intimately familiar with all relevant facts—agreed recently that EPA would not approve the cancer warning California law

imposes. *See* Dkt. 13115, at 3 n.2, *In re Roundup Prods. Liab. Litig.*, No. 3:16-md-02741 (N.D. Cal. May 26, 2021).

The Ninth Circuit rejected all this on the ground that none of EPA's actions carried "the force of law." App.18a-19a, 21a-22a. That is unavailing. EPA's actions approving Roundup's labeling without a cancer warning are comparable to the examples of agency action *Merck* identified as sufficient to "answer the preemption question." *Merck*, 139 S. Ct. at 1679. This Court explained in *Merck* that "agency actions taken pursuant to the [agency's] congressionally delegated authority" can establish that the agency would not have taken a particular action for conflict-preemption purposes. *Id.* The Court listed three ways FDA is authorized to "communicate its disapproval of a warning" and thus "answer the pre-emption question": (1) "notice-and-comment rulemaking setting forth labeling standards," (2) "formally rejecting a warning label that would have been adequate under state law," and (3) "other agency action carrying the force of law." *Id.*[4]

EPA has taken analogous actions in approving Roundup's labeling. *First*, in conducting its statutorily required registration review, EPA engaged in formal notice-and-comment procedures before reaffirming its conclusion that glyphosate is unlikely to be carcinogenic. *See* EPA, *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* (Jan. 13, 2019), https://

[4] As an example of the kind of action satisfying the final category, the Court pointed to a provision requiring the FDA to notify the manufacturer if it "becomes aware of new information ... that [it] determines should be included in the labeling of [a] drug." 21 U.S.C. §355(o)(4)(A).

tinyurl.com/EPACommentResponse; *Interim Registration Review Decision* 5. *Second*, EPA has notified glyphosate registrants in a letter that it would not approve glyphosate labeling containing a cancer warning required under state law. App.195a-197a. And EPA has declined to require a cancer warning through its registration review process—a process that (like the FDA notification requirement discussed in *Merck*) requires EPA to propose "labeling changes" when necessary, 40 C.F.R. §155.58(b)(4).

2. The Ninth Circuit independently erred in concluding that Monsanto could have unilaterally amended its labeling to include a cancer warning.

In *PLIVA*, this Court held that a state-law failure-to-warn claim is preempted where federal law bars a manufacturer from adopting, without prior federal approval, a labeling change that state law requires. 564 U.S. at 617-618. It is irrelevant, *PLIVA* held, whether the manufacturer might have persuaded the relevant agency to approve that change after the fact. *Id.* at 619. Because "[t]he question for 'impossibility' [preemption] is whether the private party could *independently* do ... what state law requires," state law is preempted wherever the manufacturer's ability to comply with state law depends upon prior agency approval. *Id.* at 620-621 (emphasis added).

That is the case here. Selling a pesticide with labeling that makes "any claims" "substantially differ[ent]" from the EPA-approved labeling is unlawful. 7 U.S.C. §136j(a)(1)(B), (2)(G); *see also id.* §136a(c). And pesticide manufacturers may not change substantive aspects of their products' labeling without EPA's prior approval. *See* 40 C.F.R. §§152.44, 152.46. To change labeling, a manufacturer must submit an amended registration

application—a request that EPA re-register the pesticide—including submitting all data relevant to the change. *See id.* §§152.44(a), 152.50. "[T]he application must be approved by [EPA] before the product, as modified, may legally be distributed or sold." *Id.* §152.44(a). Like the manufacturer in *PLIVA*, therefore, Monsanto could not have "independently do[ne] ... what state law require[d]." 564 U.S. at 620.

The Ninth Circuit speculated, however, that Monsanto could have added a cancer warning to Roundup's label via EPA's "notification" procedure (an argument respondent never raised). App.21a. But EPA disagrees: Changes to "precautionary statements" may not be made without prior agency approval. *Pesticide Registration Notice 98-10*, at 8.[5]

C. The Scope Of FIFRA Preemption Is An Issue Of National Importance

FIFRA is a "comprehensive regulatory statute" that grants EPA significant power to ensure uniformity in pesticide labeling requirements. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 991-992 (1984); *see also Bates*, 544 U.S. at 452 n.26. The Ninth Circuit's decision undermines that uniformity.

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[5] The Ninth Circuit noted EPA allowed the addition of a cancer warning to the labeling of a different pesticide, Larvin, via notification. App.21a n.10. But for decades prior, EPA had classified Larvin's active ingredient, thiodicarb, as a "probable human carcinogen." EPA, *Registration Eligibility Decision: Thiodicarb* 13 (Dec. 1998), https://tinyurl.com/5dmctukx. And before the amendment, EPA had already required thiodicarb's labeling to include extensive warnings, including that thiodicarb is "toxic." *Id.* at 100-109. The panel identified *no* example of EPA permitting a registrant to use notification procedures to add a cancer warning where, as here, EPA had previously found that the relevant chemical was not carcinogenic. App.21a.

Indeed, the decision is antithetical to both FIFRA's bedrock uniformity goal and Congress's choice to empower EPA to enforce it. Rather, the decision permits precisely what *Bates* feared: "50 different labeling regimes prescribing the ... wording of warnings," creating "significant inefficiencies for manufacturers," 544 U.S. at 452. Other courts have similarly observed that failure to apply preemption principles properly can lead to "an anarchic patchwork of federal and state regulatory programs." *Engine Mfrs. Ass'n* v. *EPA*, 88 F.3d 1075, 1079 (D.C. Cir. 1996); *accord United Airlines, Inc.* v. *Mesa Airlines, Inc.*, 219 F.3d 605, 611 (7th Cir. 2000) ("applying the conflicting tort principles of 50 different states to ... interstate and international" agreements "would make a mess of things"); *Moss* v. *Parks Corp.*, 985 F.2d 736, 739 (4th Cir. 1993) (preemption alleviates "the impracticality of having the states [require] potentially fifty different labels").

Under the regime the Ninth Circuit endorsed, each State could—based on the tiniest sliver of scientific support—mandate warnings carefully considered and rejected by EPA simply because they were generally consistent with a duty to warn of possible health risks. A single study, even one found unreliable by EPA, could thus spur countless divergent labeling requirements. And even if there was agreement that some kind of warning was necessary, there might not be a single warning a company could adopt to fulfill its state-law obligations. For example, a California district court has held that several potential warnings the State proposed for glyphosate are inaccurate. *See National Ass'n of Wheat Growers* v. *Becerra*, 468 F.Supp.3d 1247, 1259 (E.D. Cal. 2020). Under the decision below, these difficulties could be multiplied by litigation

brought in different States, each potentially requiring a different warning.

Differences in labeling also risk consumer confusion. Following the Ninth Circuit's decision, a Nevadan who visits California may be misled to believe that a pesticide sold in California is more dangerous than the formulation sold in Nevada (or vice versa). And if Nevada itself requires manufacturers to add a glyphosate warning, even a slight difference in wording (for example: "CAUTION: this product contains glyphosate" as opposed to "WARNING: Cancer") could cause consumer confusion about the product's safety. Few things are more likely to cast doubt on the reliability of warnings than state-by-state variances reflecting the vagaries of juries' divergent resolution of duty-to-warn claims. *Cf. Turek* v. *General Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) ("Manufacturers might have to print 50 different labels, driving consumers who buy [pesticides] in more than one state crazy.").

II. The Ninth Circuit's Decision Subverts Trial Courts' Gatekeeping Role In Admitting Expert Testimony

Nearly three decades ago, *Daubert* held that to be admissible, expert testimony must be "not only relevant, but reliable"—*i.e.*, it must impart "'scientific knowledge'" "derived by [a] scientific method" and "supported by appropriate validation." 509 U.S. at 589-590. To ensure that only reliable expert testimony reaches factfinders, this Court directed trial courts to play a "gatekeeping role," screening out expert opinions that are merely "subjective belief or unsupported speculation." *Id.* at 590, 597. For example, a court may find an expert opinion unreliable when "there is simply too great an analytical gap between the data and the

opinion proffered." *General Elec. Co.* v. *Joiner*, 522 U.S. 136, 146 (1997); *see also Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 152 (1999) (reiterating "the importance of *Daubert*'s gatekeeping requirement"). Federal Rule of Evidence 702, which was amended following *Daubert*, *Joiner*, and *Kumho*, thus requires courts to determine not only that expert testimony is "the product of reliable principles and methods," but also that the expert has "reliably applied" those principles and methods to the facts of the case before admitting testimony.

While applying *Daubert* and Rule 702 inherently involves judgment, the Ninth Circuit has distorted the requirements of Rule 702 beyond recognition in ways that diverge from the standards applied by other circuits. Here, the court affirmed the admission of expert testimony that glyphosate could cause non-Hodgkin's lymphoma in the general population and that it caused respondent's lymphoma, even though the experts failed to reliably apply scientific principles and EPA (like regulators worldwide) has consistently found that glyphosate does not cause cancer. As the district court acknowledged, the testimony likely would have been inadmissible under other circuits' *Daubert* standards. *E.g.*, App.83a-84a. The Ninth Circuit blurs the boundaries between science and speculation with a third category called "art," which allows experts to testify based on what are, in effect, unsupported intuitions, as long as they are purportedly rooted in "clinical experience." *See* App.26a-27a. The Ninth Circuit's uniquely lenient admissibility standard has enormous consequences for tens of thousands of pending Roundup cases and for mass-tort and product-liability litigation more generally. Certiorari is warranted to resolve the disagreement

among the circuits and reaffirm trial courts' gatekeeping responsibility in enforcing Rule 702 as written.

A. The Decision Below Departs From The Rigorous *Daubert* Scrutiny Other Circuits Require

1. To prevail on his claims, respondent had to show both that glyphosate can (as a general matter) cause non-Hodgkin's lymphoma at realistic exposure levels, App.91a, and that it specifically caused his illness, App.79a. Both questions involved significant challenges for respondent because the overall epidemiological evidence studying the purported link between glyphosate and non-Hodgkin's lymphoma confirmed what regulators around the world have concluded: Glyphosate does not cause cancer in humans. *E.g.*, App.93a-94a (district court observing that epidemiological studies, "viewed in [their] totality," seem "too equivocal to support any firm conclusion," thereby presenting a "daunting challenge" for respondent).

Indeed, the district court acknowledged that the testimony of respondents' experts would not likely survive robust *Daubert* scrutiny. It noted, for example, that the Ninth Circuit places "great emphasis" on *Daubert*'s "'liberal thrust' favoring admission," requiring courts to exclude only "'nonsense opinions.'" App.101a. As the court explained, that dividing line "has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits," *id.*, a difference the court acknowledged repeatedly, App.83a-84a, 93a. The court also observed—more than a half-dozen times—that even under the Ninth Circuit's heightened "toleran[ce] of borderline expert opinions," App.84a, it was a "close" question whether any of respondent's expert opinions constituted reliable scientific knowledge and thus would

assist the jury in impartial factfinding, App.79a, 91a, 94a, 148a, 154a, 158a, 179a-180a.

Nonetheless, the district court admitted those opinions—and the Ninth Circuit affirmed—because of the Ninth Circuit's impermissibly forgiving standard.

For example, the district court recognized that respondent "barely inched over the [admissibility] line" with his expert testimony that glyphosate caused his illness. App.79a. At least 70% of non-Hodgkin's lymphoma cases are idiopathic—they occur for no known reason—which the district court explained presented the "biggest concern" for respondent. App.82a. In attempting to establish that respondent's case was caused by glyphosate, respondent's only testifying expert on that question, Dr. Dennis Weisenburger, conducted "differential diagnosis," a technique that first rules *in* all potential causes of an illness and then uses the process of elimination to rule *out* all but one. App.80a. Under that method, Weisenburger needed scientific evidence to exclude not only the likelihood that respondent's illness was idiopathic, but also any other non-glyphosate cause (such as respondent's long history with hepatitis C, *see supra* p.9).

That step was key here because although an expert could theoretically account for idiopathy (for example, by statistically ruling out unknown origins based on a sufficiently strong epidemiological link between glyphosate and non-Hodgkin's lymphoma), Weisenburger's testimony did not do so. Instead, the district court rightly found that such epidemiological evidence was lacking and thus, "[u]nder a strict interpretation of *Daubert*, perhaps that would be the end of the line." App.83a; *see also* App.93a. But the court explained that the Ninth Circuit has a unique tolerance for expert

opinions that rest not on science but on "art"—a standardless articulation of an expert's intuitions based on clinical experience or general qualifications. App.83a-84a. According to the Ninth Circuit, "'[m]edicine partakes of art as well as science,'" and so doctors in the circuit "enjoy wide latitude in how they practice their art when offering causation opinions." *Id.*; *see* App.26a. Thus, the district court believed itself required to admit the testimony, noting "courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits," mindful that "a wider range of expert opinions (arguably much wider) will be admissible in this circuit." App.84a. As the Ninth Circuit reiterated, "[w]here, as here, ... doctors who stand at or near the top of their field and have extensive clinical experience with the ... class of disease at issue[] are prepared to give expert opinions supporting causation, ... *Daubert* poses no bar based on their principles and methodology." App.26a-27a; *accord* App.84a.

2. As the district court here recognized, the Ninth Circuit's lenient admissibility standard makes it an outlier among the circuits. *See* App.83a-84a, 101a. So has the chair of the Advisory Rules Committee's Subcommittee on Rule 702, who observed that "Ninth Circuit caselaw appears to interpret *Daubert*" in ways that "set it apart from most" circuits. Thomas Schroeder, *Toward A More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039, 2050 & n.85 (2020). And although the panel here sought to distinguish some conflicting cases in other circuits on their facts, it failed to account for the different *legal standards* those courts apply. App.24a-26a.

The Sixth Circuit, for example, views experts' clinical experience with skepticism, not deference. In

Tamraz v. *Lincoln Electric Co.*, 620 F.3d 665 (6th Cir. 2010), the Sixth Circuit held that the district court abused its discretion in admitting speculative testimony, irrespective of an expert's "'extensive ... experience' with diagnosing" the relevant illness. *Id.* at 673. *Tamraz* explained that in clinical practice, doctors may employ a "low threshold" for identifying a potential cause, since telling a patient to avoid a factor that "*might* cause a disease" "can do little harm" but "a lot of good." *Id.* The court made clear, however, that similar "educated hunch[es]" or "'scientific guesswork, even of the inspired sort,'" have no place in the courtroom. *Id.* at 671, 673.

The Sixth Circuit also requires experts to rigorously account for idiopathy in determining a cause, a requirement not excused by an expert's clinical experience. *Tamraz*, for instance, was much like this case. It involved a disease (Parkinsonism) "occur[ing] commonly in the general population and usually without any known cause," "making it hard to attribute one case to [a particular substance] over ... other possible causes." 620 F.3d at 671. Nonetheless, the court made clear that under *Daubert*, an expert must rule out "unknown (idiopathic) causation" as an alternative explanation for the illness and faulted the expert there for not doing so. *Id.* at 671, 675.

Similarly, the Tenth Circuit would likely have rejected Weisenburger's testimony. As that court has explained, courts generally understand idiopathy to mean that the medical community has a poor understanding of what causes an illness. *Hall* v. *Conoco*, 886 F.3d 1308, 1315 (10th Cir. 2018). Thus, *Hall* explained that differential diagnosis "could be considered inherently unreliable" where (as here) "idiopathy accounts for more than half of the cases of" an illness. *Id.*; *see*

also Bland v. *Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) (doubting that an expert's opinion utilizing a differential diagnosis could be "based upon a reasonable degree of medical certainty" where "the cause of the condition is unknown in [most] cases").

Hall's approach contrasts starkly with the Ninth Circuit's admonition that district courts should liberally allow experts to rely on clinical experience when conducting differential diagnoses, App.27a—even when (as here) reliable epidemiological evidence contradicts the expert's conclusion purportedly based on that experience and the expert fails to reliably grapple with that contradictory epidemiology. *See* App.93a (district court noting that "the largest and most recent" epidemiological study "suggest[s] there is no link at all" between glyphosate and non-Hodgkin's lymphoma); *see also* App.144a. The Tenth Circuit has also held that *Daubert* requires experts to address "a large body of contrary epidemiological evidence" with a "medically reliable and scientifically valid methodology." *Norris* v. *Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005). Weisenburger's differential diagnosis likely would not have satisfied that standard.

B. The Decision Below Contravenes *Daubert* And Federal Rule Of Evidence 702

The Ninth Circuit's lenient admissibility standard clashes with *Daubert* and Rule 702. Despite the regulatory consensus that glyphosate is not carcinogenic, the Ninth Circuit remarkably affirmed a ruling that (1) allowed experts to testify that glyphosate can cause non-Hodgkin's lymphoma and caused respondent's illness even (2) while acknowledging numerous flaws in the experts' opinions. *See* App.85a, 93a, 154a, 156a-158a, 161a-162a; App.35a. Respondent's key expert even

conceded that he could not "identify any peer-reviewed published article" characterizing glyphosate as a "generally accepted" cause of non-Hodgkin's lymphoma, and that he was making a "subjective decision" regarding the level of glyphosate exposure sufficient to cause non-Hodgkin's lymphoma. C.A.E.R.1093-1095, 1099. The Ninth Circuit's blessing of such testimony departs from the law in two ways.

First, the court's approach is inconsistent with the text of Rule 702. *See Daubert*, 509 U.S. at 587 (courts construe the rules of evidence as they "would any statute"). No matter how much clinical experience an expert has, intuition without scientific validation is not "the product of reliable principles and methods." Fed. R. Evid. 702(c). Nor could a court determine that an expert "reliably applied" such intuitions. *Id.* 702(d).

Second, the Ninth Circuit's deference to clinical experience or intuition distorts the inquiry. As *Daubert* explained, "there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory." 509 U.S. at 596-597. Science may progress through "a multitude of hypotheses" and even "[c]onjectures that are probably wrong," but such conjectures are "of little use ... in the project of reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of [past] events." *Id.* at 597. Accordingly, *Daubert* requires excluding unverifiable conjectures, even when they are rooted in the experience of highly credentialed experts. Put simply, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the [expert's] *ipse dixit*." *Joiner*, 522 U.S. at 146.

The Ninth Circuit sought to justify its admissibility standard on the ground that "flexibility is warranted" under *Daubert*. App.34a; *see* App.23a, 26a. But *Daubert*'s observation that Rule 702 has a "liberal thrust" was addressed to the "rigid" standard that preceded it: the test from *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), under which expert testimony was admissible only if the technique used was "'generally accepted' as reliable in the relevant scientific community," *Daubert*, 509 U.S. at 584, 588-589. Whatever "broader range of scientific testimony" *Daubert* allows compared to *Frye*, it also reaffirms trial courts' critical gatekeeping role in screening unreliable expert testimony. *Joiner*, 522 U.S. at 142. And any uncertainty in that regard was resolved by the subsequent amendments to Rule 702, which provide that courts admit only those expert opinions that "reliably appl[y]" principles and methods "to the facts of" each case. Fed. R. Evid. 702(d).

The Ninth Circuit's attempt to justify Weisenburger's testimony on grounds beyond his clinical experience only underscores how far the court has strayed from *Daubert*. To cite one example, the court suggested that his exclusion of idiopathic causes rested partly on epidemiological evidence purportedly showing "a strong association" between glyphosate and non-Hodgkin's lymphoma. App.35a-36a. The court acknowledged, however, that the studies on which Weisenburger principally relied did not adjust for exposure to other pesticides, App.35a, meaning those studies could well have measured the likelihood of non-Hodgkin's lymphoma resulting from pesticides other than glyphosate. Results of epidemiological studies that fail to adjust for confounders (such as other pesticides) are inherently unreliable, and as the district court noted, under a strict *Daubert* standard, respond-

ent would have needed "much stronger epidemiological evidence" overall to reliably rule out idiopathy. App.83a. The Ninth Circuit could not overlook that fundamental flaw while remaining faithful to the principles of scientific rigor that *Daubert* and Rule 702 require.

C. The Proper Admissibility Standard Is A Recurring And Important Question

The Ninth Circuit's distortion of *Daubert* will have significant ramifications if allowed to stand. First, the court's ruling will govern the thousands of cases in the MDL. Indeed, the district court has stated it will apply the Ninth Circuit's *Daubert* standard in *all* the MDL cases (wherever they originated), despite that standard's "relatively higher tolerance for questionable expert testimony." Dkt. 4549 at 3-4, *In re Roundup*, 3:16-md-02741-VC (N.D. Cal. July 10, 2019).

More broadly, the Ninth Circuit's standard will improperly tilt the balance in the multitude of mass-tort and product-liability cases that—like this case—rise or fall on causation. Rule 702 gives trial courts a gatekeeping role precisely because scientific testimony is often difficult to follow and experts inherently carry an aura of authority. By requiring trial courts to admit expert conclusions that are based on clinical experience—even when sound scientific evidence refutes those conclusions—the Ninth Circuit has codified the fallacy that when scientists speak, their views are necessarily rooted in reliable scientific principles.

That approach has deleterious consequences, reducing the broad social benefits that flow from ensuring that mass-tort and product-liability cases are decided based on reliable scientific testimony. "[M]odern life,

including good health as well as economic well-being, depends upon the use of artificial or manufactured substances." *Joiner*, 522 U.S. at 148 (Breyer, J., concurring). Thus, it is "particularly important to see that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones." *Id.* at 148-149; *see also Tamraz*, 620 F.3d at 677-678 ("allowing the law to get ahead of science" would "destroy jobs and stifle innovation unnecessarily").

This case is a good example of what happens when that caution is ignored. For nearly fifty years, glyphosate has (with EPA's consistent approval) brought extraordinary benefits to farmers and consumers. C.A.E.R.1835-1836. But unreliable expert testimony—especially if permitted to stand in the tens of thousands of other pending and future cases—threaten to drive it off the market. This Court should grant certiorari to make clear that *Daubert* and Rule 702 do not permit the abdication of trial courts' gatekeeping responsibility that would lead to such highly undesirable results.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDICES