No. 21-241

In the Supreme Court of the United States

MONSANTO COMPANY, PETITIONER

v.

EDWIN HARDEMAN

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

1. Whether the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, preempts respondent's state-law claims alleging that petitioner tortiously failed to warn of the carcinogenic risks associated with its pesticide product.

2. Whether the district court abused its discretion in admitting expert medical testimony that relied in part on clinical experience.

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or Act), 7 U.S.C. 136 *et seq.*, prohibits the distribution or sale of a pesticide "that is not registered" by the United States Environmental Protection Agency (EPA). 7 U.S.C. 136a(a). To apply for registration, a manufacturer must submit, among other things, the product's "complete formula," "claims to be made for it," proposed labeling, and a "full description of the tests made and the results thereof upon which the claims are based." 7 U.S.C. 136a(c)(1)(C), (D), and (F).

EPA "shall register a pesticide" if the agency determines, *inter alia*, that the pesticide is efficacious; that

its labeling * * * compl[ies] with the requirements of this subchapter"; and that "when used in accordance with widespread and commonly recognized practice[,] it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. 136a(c)(5)(B) and (D). FIFRA defines "unreasonable adverse effects" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). EPA must review a pesticide's registration every 15 years. 7 U.S.C. 136a(g)(1)(A).

"As long as no cancellation proceedings are in effect," registration of a particular pesticide "shall be prima facie evidence that the pesticide, its labeling and packaging comply with [FIFRA's] registration provisions." 7 U.S.C. 136a(f)(2). Registration cannot "be construed as a defense for the commission of any offense under" FIFRA. *Ibid.*

b. FIFRA prohibits the sale or distribution of a pesticide that is "misbranded." 7 U.S.C. 136j(a)(1)(E). A pesticide is misbranded if its labeling "bears any statement * * * which is false or misleading in any particular." 7 U.S.C. 136(q)(1)(A). A pesticide is also misbranded if it "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. 136(q)(1)(G). "Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements," including by seeking EPA approval to amend a label that does not contain all "necessary warnings or cautionary statements." *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 438-439 (2005).

c. "In general," a State may "regulate the sale or use of any federally registered pesticide" within its borders, so long as "the regulation does not permit any sale or use prohibited by" FIFRA. 7 U.S.C. 136v(a) (emphasis omitted). In certain circumstances, a State may also "provide registration for additional uses of federally registered pesticides" in order "to meet special local needs" "within such State." 7 U.S.C. 136v(c)(1). In the interest of "[u]niformity," however, a State may not "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under" FIFRA. 7 U.S.C. 136v(b) (emphasis omitted).

2. Petitioner "Monsanto Company manufactures Roundup, a pesticide with the active ingredient glyphosate." Pet. App. 2a. EPA has registered pesticides containing glyphosate since 1974. *Id.* at 4a. In 1985, EPA classified glyphosate as a possible human carcinogen based on kidney tumors observed in a study of effects on mice. *Ibid.* Since then, however, EPA has repeatedly concluded that glyphosate is unlikely to cause cancer in humans. *Ibid.* Roundup's EPA-approved product label does not currently contain a warning that glyphosate may pose a cancer risk to humans. See *id.* at 14a.

In 2015, a working group at the International Agency for Research on Cancer (IARC) classified glyphosate as a possible human carcinogen. Pet. App. 5a. Under California's Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5, 25249.6, 25249.8-25249.13 (West 2006); *id.* §§ 25249.7, 25249.14 (West Supp. 2022), known as Proposition 65, a substance must be accompanied by a warning "if a body considered to be authoritative by" state experts (which includes IARC) "has formally identified" the substance

"as causing cancer," *id.* § 25249.8(b) (West 2006). In 2017, based on the IARC finding, California "categorized glyphosate as a chemical known to the state to cause cancer." Pet. App. 5a-6a.

In response, several registrants sought EPA approval to amend the labels of glyphosate-containing products to include a statement that California had determined that glyphosate may cause cancer. See Gov't C.A. Amicus Br. 10. EPA initially approved some of these requests, allowing manufacturers to include a cancer warning in the "Optional Marketing Statements" section of those product labels. *Id.* at 10, 18-19 n.14. In 2019, however, the Director of the Registration Division of EPA's Office of Pesticide Programs issued a letter to registrants of glyphosate-containing products addressing the Proposition 65 default language. Pet. App. 195a-197a. The letter stated that, because EPA had determined that glyphosate is "'not likely to be carcinogenic to humans,' * * * pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded" under FIFRA. *Id.* at 196a.

3. In 2015, respondent Edwin Hardeman was diagnosed with non-Hodgkin's lymphoma. Pet. App. 7a. In 2016, he sued petitioner, alleging that his use of Roundup from the mid-1980s to 2012 had caused his cancer. *Ibid.* Respondent alleged, *inter alia*, that petitioner had tortiously failed to warn of cancer risks posed by Roundup.

Before trial, the district court rejected petitioner's argument that FIFRA preempted the failure-to-warn claims. Pet. App. 7a. At trial, over petitioner's objection, the district court admitted medical testimony on disease causation from three of respondent's experts.

Id. at 8a. The jury returned a verdict in respondent's favor on the failure-to-warn claims, concluding that Roundup exposure was a "substantial factor" in causing his cancer and that petitioner had failed to warn of the carcinogenic risks associated with Roundup. *Id.* at 10a.

4. The court of appeals affirmed. Pet. App. 1a-69a.

a. The court of appeals held that FIFRA does not preempt respondent's failure-to-warn claims. The court explained that, "[b]ecause FIFRA's misbranding requirements parallel those of California's common law duty, [respondent's] failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted." Pet. App. 13a. The court rejected petitioner's argument that EPA's registration of Roundup without a cancer warning on the label preempts any state-law rule requiring such a warning. *Id.* at 14a. The court explained that a pesticide can be misbranded even if it has been registered because EPA's approval of a label is prima facie but not conclusive evidence of FIFRA compliance. *Id.* at 14a-15a. The court further held that neither EPA's approval of Roundup's label nor EPA's 2019 letter "carrie[d] the force of law necessary to have preemptive effect." *Id.* at 16a. The court likewise rejected petitioner's implied-preemption argument, holding that petitioner had not established that compliance with both federal and state labeling requirements was impossible. *Id.* at 19a-22a.

b. The court of appeals rejected petitioner's challenge to the admission of respondent's expert medical testimony. The court explained that the district court had "applied the correct legal standard under [*Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),] and did not abuse its discretion by admitting

[respondent's] general and specific causation expert testimony." Pet. App. 22a.

DISCUSSION

The court of appeals correctly held that FIFRA does not preempt respondent's claims, and that decision does not conflict with any decision of this Court or another court of appeals. The court's evidentiary ruling likewise does not conflict with the standards applied by other circuits in considering the admissibility of expert testimony. The petition for a writ of certiorari should be denied.

In the court of appeals, the United States filed an amicus brief that (a) took the position that FIFRA expressly preempts all health-related state pesticide labeling requirements that differ from the labeling approved by EPA and (b) briefly suggested that FIFRA also impliedly preempted respondent's claims. Gov't C.A. Amicus Br. 13-14, 18 n.14, 23-24. In light of the court of appeals' decision and the change in Administration, the United States has reexamined the arguments it made below. Although some aspects of EPA-approved labeling may preempt particular state-law requirements, EPA's approval of labeling that does not warn about particular chronic risks does not by itself preempt a state-law requirement to provide such warnings.

I. THE PREEMPTION QUESTION DOES NOT WARRANT REVIEW

A. The Court Of Appeals Correctly Held That FIFRA Does Not Preempt Respondent's State-Law Failure-To-Warn Claims

Petitioner argues that EPA's approval of pesticide labeling without a chronic-risk warning triggers FIFRA's

express-preemption provision, 7 U.S.C. 136v(b), and categorically preempts any state-law requirement to provide such a warning. That is incorrect. Petitioner likewise has not established that FIFRA impliedly preempts respondent's claims.

1. FIFRA does not expressly preempt respondent's state-law failure-to-warn claims

a. In *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), this Court characterized Section 136v(b)'s preemptive effect as "narrow, but still important." *Id.* at 452. The Court explained that, "[f]or a particular state rule to be pre-empted, it must satisfy two conditions": "[I]t must be a requirement '*for labeling or packaging*,'" and it must impose a labeling or packaging requirement that is "'*in addition to or different from* those required under [FIFRA].'" *Id.* at 444; see 7 U.S.C. 136v(b). The Court held that common-law tort rules that subject manufacturers to potential failure-to-warn liability are "requirements for labeling or packaging" under Section 136v(b). *Bates*, 544 U.S. at 446. It further held, however, that such a "state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447.

In so holding, the *Bates* Court emphasized that FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450. While acknowledging that it would be unworkable to have "50 different labeling regimes prescribing the color, font size, and wording of warnings," the Court construed FIFRA as expressly preempting only those state laws that "would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Id.* at 452.

b. The court of appeals held that California common law parallels FIFRA's misbranding prohibition: California requires a warning against a known or knowable risk, while FIFRA requires a warning "necessary" and "adequate to protect health." Pet. App. 13a (quoting 7 U.S.C. 136(q)(1)(G)). Petitioner has not disputed, in this Court or the court of appeals, that California law is "fully consistent" with the statutory misbranding prohibition. *Bates*, 544 U.S. at 447. Likewise, petitioner does not identify any EPA regulation that "refine[s]" FIFRA's misbranding standard, *id.* at 453 n.27, in a way that bears on the preemption question here.

Instead, petitioner principally asserts that EPA's registration of a specific pesticide and approval of its proposed labeling creates a more particularized FIFRA labeling "requirement" that categorically preempts any State from requiring additional warnings. Pet. 13-14. Accordingly, petitioner argues, EPA's registration of Roundup without a cancer warning on the labeling preempts any imposition of state-law tort liability for failure to provide such a warning. *Ibid.* The court of appeals correctly rejected that argument. Pet. App. 14a-16a.

FIFRA states that registration is not a "defense for the commission of any offense" under FIFRA, but is simply "prima facie evidence that the pesticide, its labeling[,] and packaging comply with the registration provisions" of FIFRA. 7 U.S.C. 136a(f)(2). The Act thus makes clear that a particular pesticide may be found to violate FIFRA's misbranding prohibition even though EPA approved the labeling when registering the pesticide. See Pet. App. 14a-15a. Section 136a(f)(2) does not directly address preemption of state law. But the fact that "EPA's labeling determinations are not dispositive of FIFRA compliance" supports the court of appeals' conclusion

that, for purposes of preemption under Section 136v(b), those determinations "similarly are not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA." *Id.* at 15a (quoting 7 U.S.C. 136v(b)).

Petitioner contends that the court of appeals "assessed FIFRA's requirements at too high a level of generality," Pet. 14, by declining to treat specific EPA pesticide-registration approvals as establishing particularized FIFRA "requirements" under Section 136v(b). But the court's approach is faithful to *Bates*. In remanding the case for further proceedings in the lower courts, the *Bates* Court "emphasize[d] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." 544 U.S. at 453. The Court indicated, however, that in determining whether this equivalence existed, the lower courts should compare the generally applicable state-law standard to the requirements imposed by FIFRA and by EPA's implementing regulations. *Id.* at 453-454. And while the Court recognized that "a manufacturer should not be held liable under a state labeling requirement * * * unless the manufacturer is also liable for misbranding as defined by FIFRA," *id.* at 454, it did not suggest that EPA's prior approval of the manufacturer's labeling would preclude a state-law plaintiff from making that showing. To the contrary, the *Bates* Court allowed the suit before it to go forward even though the plaintiffs' claim was premised on the defendant's failure to provide cautionary language that did not appear on the EPA-approved label. See *id.* at

434-435. That disposition would be inexplicable under petitioner's view of the statute.[1]

That does not mean that EPA registration and labeling decisions are *never* preemptive. FIFRA and EPA regulations identify aspects of EPA-approved pesticide labeling that carry the force of law. For example, FIFRA and its implementing regulations make "use" requirements on EPA-approved labeling mandatory and enforceable against the user. See 7 U.S.C. 136j(a)(2)(G) ("[I]t shall be unlawful for any person * * * to use any registered pesticide in a manner inconsistent with its labeling."); 40 C.F.R. 156.10(i)(2)(ii) ("It is a violation of Federal law to use this product in a manner inconsistent with its labeling."). These enforceable "use" restrictions may operate as FIFRA "requirements" with preemptive effect, generally barring States from permitting uses that EPA-approved labeling prohibits. See *Bates*, 544 U.S. at 453 ("State-law requirements must also be measured against any relevant EPA regulations.").

Neither FIFRA nor its implementing regulations, however, specifically address warnings for chronic health risks like carcinogenicity. No FIFRA provision or EPA

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[1] Petitioner suggests that the Court's analysis in *Bates* was limited to claims about a pesticide's efficacy, because EPA does not review efficacy claims in the registration process. Pet. Reply Br. 4-5. But the *Bates* Court did not suggest that the preemption test it articulated was limited in this manner. The Court discussed the application of its preemption test to a hypothetical "failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION.'" *Bates*, 544 U.S. at 453. The Court found that such a claim "would be preempted," not because it concerned safety rather than efficacy warnings, but "because it is inconsistent with" a specific EPA regulation. *Ibid.*; see pp. 17-18, *infra*.

regulation either requires or precludes warnings about harm a pesticide may cause to human health through long-term exposure. And EPA does not typically use the registration process to address those harms by requiring chronic-risk warnings on a pesticide's labeling. Rather, EPA primarily seeks to control such risks through use limitations or, where appropriate, cancellation proceedings.[2]

EPA regulations likewise do not purport to define the full universe of labeling that might be necessary and adequate "to protect health and the environment." 7 U.S.C. 136(q)(1)(G). EPA guidance allows a manufacturer to propose state-mandated chronic-risk warnings, such as Proposition 65 warnings, so long as the state-law terminology does not conflict with language in the EPA-approved label. See EPA, *Label Review Manual*, Ch. 7, § IV.A.4, at 7-4 (rev. Mar. 2018), https://www.epa.gov/pesticide-registration/label-review-manual; see also, *e.g.*, *id.* Ch. 3 § V.B, at 3-14 (allowing registrants to include "[a]dvisory statements" about "product characteristics and how to maximize safety and efficacy," so long as such statements "do not conflict with mandatory statements, are not false or misleading, and do not otherwise violate statutory or regulatory requirements"). Against that backdrop, EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA "requirement" that no such warning appear. See *Bates*, 544 U.S. at 445 (explaining, with specific reference to Section 136v(b)'s preemptive scope, that "[a] requirement is

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[2] By contrast, EPA regulations specifically address warnings about how products should be handled to avoid acute, rather than chronic, hazards to human health. See 40 C.F.R. 156.70(b), 158.130(d)(1).

a rule of law that must be obeyed"); see also *id.* at 449 (noting "[t]he long history of tort litigation against manufacturers of poisonous substances," and declining to construe Section 136v(b) as "depriv[ing] injured parties of a long available form of compensation").[3]

c. Petitioner also contends that respondent's claims are preempted even if EPA's approval of pesticide labeling does not categorically preempt all state-law tort claims that are premised on the alleged inadequacy of a manufacturer's label-compliant warnings. Petitioner emphasizes (i) EPA's longstanding view that glyphosate is not carcinogenic; and (ii) the 2019 letter in which the Director of the Registration Division of EPA's Office of Pesticide Programs stated that a pesticide would be misbranded if its labeling included a Proposition 65 warning that linked glyphosate to cancer risks. Pet. 13-14. Neither contention alters the preemption analysis.

EPA has long concluded that glyphosate is not likely to be carcinogenic to humans and has repeatedly articulated that view in registration decisions spanning decades. Pet. App. 4a. But inconsistency between state and federal risk assessments does not alone preempt enforcement of state tort law. Rather, Section 136v(b) preempts only those state-law "requirements for labeling or packaging"

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[3] EPA's registration of a particular pesticide is reviewed every 15 years, based in significant part on proposed labeling and scientific studies submitted by the manufacturer. See pp. 1-2, *supra*. Through that periodic-review process, EPA reassesses the risks and benefits of particular pesticides under the "unreasonable adverse effect" standard, 7 U.S.C. 136(bb). Petitioner's preemption theory ignores the possibility that the manufacturer's submissions to EPA may be inaccurate or incomplete, or that evolving science will cast doubt on the adequacy of approved labeling before the next periodic review occurs.

that are "in addition to or different from those *required* under [FIFRA]." 7 U.S.C. 136v(b) (emphasis added). As the court of appeals appeared to recognize, EPA could—either through rulemaking or through some other regulatory action carrying the force of law—make a binding determination that the labels of pesticides containing glyphosate should not contain cancer warnings. See Pet. App. 15a. Such a determination would preempt any state-law tort claim premised on a manufacturer's failure to provide such warnings. But neither EPA's repeated statements that glyphosate is unlikely to be carcinogenic to humans, nor its approval of pesticide labeling without cancer warnings, imposes any such prohibition. See *ibid.*[4]

The 2019 letter issued by the Director of the Registration Division likewise does not change the preemption calculus. No FIFRA provision or EPA regulation authorizes that agency official to impose binding FIFRA "requirements" on manufacturers through an informal letter. And even if that letter could have preemptive effect, it focused solely on the default language required by Proposition 65 and did not address other potential label language that might accommodate both federal and state views. Pet.

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[4] Petitioner emphasizes (Pet. 13) EPA's 2020 *Glyphosate: Interim Registration Review Decision, Case Number 0178* (Jan. 22, 2020) (*Interim Registration Review Decision*), https://www.epa.gov/sites/default/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf, which followed a notice-and-comment process and again concluded that glyphosate presents no "risks of concern." *Id.* at 9. But while that notice-and-comment process could have culminated in binding requirements or prohibitions governing chronic-hazard warnings for glyphosate, it did not. In any event, EPA's 2020 *Interim Registration Review Decision* post-dated the decision below and—by many years—respondent's use of Roundup, this lawsuit, and the jury's verdict.

App. 197a. Indeed, EPA has recently issued a letter identifying a proposed glyphosate warning that would not be considered false or misleading and that EPA could approve if requested for inclusion on glyphosate product labels. See Letter from Michal Freedhoff, Assistant Adm'r, Office of Chem. Safety & Pollution Prevention, EPA, to Lauren Zeise, Dir., Office of Envtl. Health Hazard Assessment, Cal. Envtl. Prot. Agency (Apr. 8, 2022), https://oehha.ca.gov/media/downloads/crnr/usepaaafreedhofftooehhadirzeiseglyphosate40822.pdf. In addition, the 2019 letter postdated the jury verdict here by more than four months and respondent's last use of Roundup by several years, and it was logically inconsistent with prior EPA approvals of manufacturer requests to include cancer warnings on the labels of their glyphosate-containing products. See p. 4, *supra*. If the Court granted certiorari, it therefore might be required to decide difficult retroactivity issues in order to assess the implications of the 2019 letter for the preemption analysis, particularly in light of the clarification in the 2022 letter.

2. FIFRA does not impliedly preempt respondent's state-law claims

Federal law impliedly preempts state law when "it is impossible for a private party to comply with both state and federal law" or when state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372-373 (2000) (citation omitted). In support of its implied-preemption theory, petitioner argues solely that compliance with both federal and California law would have been impossible. See Pet. 20-24. To establish this "demanding defense," a party must present "clear evidence" of

impossibility, *Wyeth* v. *Levine*, 555 U.S. 555, 571, 573 (2009); the "possibility of impossibility [is] not enough," *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 625 n.8 (2011) (citation and internal quotation marks omitted).

The court of appeals applied the correct legal standard in rejecting petitioner's implied-preemption arguments. Pet. App. 18a-22a. And under that standard, petitioner failed to show that federal law prohibited it from implementing a label-based cancer warning between the mid-1980s and 2012, the period during which respondent was exposed to glyphosate.

Petitioner again points to EPA's longstanding assessment that glyphosate is unlikely to be a human carcinogen, and to the 2019 letter issued by the Director of the Registration Division to address the Proposition 65 warnings. See Pet. 21-22. But EPA's assessment that glyphosate does not cause cancer would not necessarily foreclose petitioner from including a warning on Roundup that satisfies California common-law requirements. Neither that general assessment nor EPA's registration decisions for particular pesticides bar manufacturers from including additional chronic-risk warnings. See pp. 10-13, *supra*. Petitioner might have sought to comply with California law while accurately reporting EPA's own glyphosate assessment through (for example) a label advising consumers both of California's determination that Roundup poses cancer risks and of EPA's disagreement with that determination. See p. 14, *supra*.

The 2019 letter expressed the Director's view about the application of FIFRA's misbranding prohibition, but it did not impose an independent legal barrier to inclusion of a cancer warning on petitioner's Roundup label. For that reason, and because the letter was issued long after respondent discontinued his use of Roundup, it does not

establish whether petitioner could have complied with both state and federal law when it made the specific sales that caused respondent's exposure to glyphosate. Moreover, the 2019 letter addressed only the default Proposition 65 warning language—not whether a label could include language that accommodates both federal and state views. As noted, EPA has subsequently clarified that manufacturers may include a proposed glyphosate warning that California could accept as an alternative to the default Proposition 65 warning and that would not contravene FIFRA's misbranding provision. See p. 14, *supra.*

Relying on *PLIVA*, *supra*, petitioner further argues that even if EPA would not have categorically prohibited a cancer warning on Roundup's labeling, compliance with state law was impossible because petitioner could not have changed Roundup's existing label without EPA approval. See Pet. 23-24. But the Court acknowledged in *PLIVA* that "whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine." 564 U.S. at 623. Here, the court of appeals reasonably explained that the approval process under FIFRA is "a far cry from" the approval process at issue in *PLIVA*, which involved a different statute and a different regulatory-approval program. Pet. App. 20a. The court noted that obtaining permission for a chronic-risk warning on a pesticide label does not require the sort of "'special permission and assistance'" from the regulator—as well as negotiations with third-party name-brand manufacturers—that govern generic drug manufacturers' requests for authorization to change their labels. *Ibid.* (quoting *PLIVA*, 564 U.S. at 623-624).

B. Further Review Is Not Warranted

1. The decision below does not conflict with any decision of this Court or another court of appeals.

a. No other circuit has considered whether FIFRA preempts state-law failure-to-warn claims alleging that pesticide labeling should have included a chronic-risk warning. Citing decisions construing other federal statutes, petitioner argues that the decision below "deepens uncertainty over how to apply similarly worded express-preemption provisions." Pet. 18-20 (capitalization and emphasis omitted). But the court of appeals relied heavily on particular features of FIFRA, including Section 136a(f)(2)'s directive that registration is not a defense to a misbranding claim; the label-modification procedures that FIFRA makes available; and the specifics of EPA's registration processes. See Pt. I.A, *supra*. The court's decision therefore is unlikely to have a substantial effect on the development of preemption rules under other federal statutes.

b. The decision below likewise does not conflict with any decision of this Court. Petitioner principally contends that the court of appeals' express-preemption holding conflicts with *Bates*. Pet. 13-18. But as discussed above, the court of appeals correctly applied *Bates* in concluding that EPA's approval of a pesticide label without a chronic-risk warning does not create a FIFRA "requirement" that no such warning appear.

Petitioner emphasizes the *Bates* Court's statement that "a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted." *Bates*, 544 U.S. at 453; see Pet. 14. Petitioner argues that, by using a state-mandated label warning as an example of a preempted state-law requirement, the *Bates*

Court implied that FIFRA preempts *all* state-law labeling rules that require deviation from EPA-approved labeling. Pet. 16. But in explaining *why* the hypothetical state-law claim would be preempted, the *Bates* Court emphasized that an EPA regulation (40 C.F.R. 156.64 (2004)) "specifically assigns these warnings [*i.e.*, "DANGER" and "CAUTION"] to particular classes of pesticides based on their toxicity." 544 U.S. at 453. An additional regulation classifies pesticides into various toxicity categories based on defined hazard indicators. 40 C.F.R. 156.62 (2004). *Bates* thus teaches that labeling constraints established by EPA's FIFRA *regulations* can have preemptive effect. See 544 U.S. at 453. But *Bates* does not support the much broader proposition petitioner advocates: that FIFRA preempts any state-law rule that would require warnings beyond those contained in EPA-approved pesticide labeling.

The decision below likewise does not conflict with this Court's decision in *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), interpreting the preemption provision in the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360k(a). *Riegel* involved "requirements applicable to" use of a particular medical device (an inflatable catheter) that a federal agency had established during the pre-market approval process. 552 U.S. at 321-323. The Court held that those requirements preempted state failure-to-warn claims premised on inconsistent directives. *Id.* at 327-330.

Petitioner asserts that "[t]he 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." Pet. 17. Petitioner overlooks significant differences between the two statutory regimes. FIFRA

specifies that EPA's approval of a pesticide is not conclusive evidence of FIFRA compliance, see pp. 8-9, *supra*, while the MDA contains no similar provision. And the *Riegel* Court emphasized that, in the pre-market approval process, the federal agency had actually and directly addressed the question at issue in the state-law litigation. 552 U.S. at 322-323 ("[T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of *safety and effectiveness*.") (emphasis added). In the FIFRA registration process, by contrast, EPA neither requires nor precludes any specific chronic-risk warnings, through regulation or otherwise. See pp. 10-13, *supra*.

2. Though the petition here arises from consolidated suits in a multidistrict litigation concerning Roundup, similar claims may arise in other circuits involving other glyphosate-based products or similarly situated non-glyphosate products. Even as to Roundup itself, the Eleventh Circuit is currently considering a district court's holding that Section 136v(b) preempts Georgia failure-to-warn claims to the extent those claims are based on defective labeling or packaging of Roundup. See *Carson* v. *Monsanto Co*, No. 21-10994 (11th Cir. argued Nov. 16, 2021). And in state courts across the country, various other plaintiffs have filed failure-to-warn suits challenging Roundup's labeling, as well as suits challenging the California-law labeling requirements established under Proposition 65. There is no sound reason for the Court to grant review unless and until a conflict in authority emerges.

3. The court of appeals determined that, "[b]ecause [respondent's] complaint is based on [petitioner's] failure to provide an adequate warning on a label under California law," Pet. App. 12a, the first part of the *Bates* test (*i.e.*, whether the assertedly preempted state law imposes a requirement "*for labeling or packaging*," 544 U.S. at 444) was satisfied. It is far from clear, however, that California common law actually requires an on-label warning. Proposition 65 identifies several non-labeling mechanisms through which a required chronic-risk warning may be provided. Cal. Health & Safety Code § 25249.11 (West 2006). Future cases involving similar state-law claims may contemplate warnings through non-labeling mechanisms that would not require altering EPA-approved labeling.

II. THE COURT OF APPEALS' EVIDENTIARY RULING DOES NOT WARRANT REVIEW

Petitioner's challenge to the court of appeals' application of Federal Rule of Evidence 702 and *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), likewise does not warrant review. The Ninth Circuit's admissibility standard does not materially differ from the standards applied in other circuits, and its factbound application of that standard here raises no issue of general importance.

A. Relying principally on the Sixth Circuit's decision in *Tamraz* v. *Lincoln Electric Co.*, 620 F.3d 665 (2010), cert. denied, 563 U.S. 988 (2011), petitioner argues that the decision below "departs from the rigorous *Daubert* scrutiny other circuits require," Pet. 28 (capitalization altered; emphasis omitted). See Pet. 30-31. Petitioner asserts that the Sixth Circuit disapproved of expert testimony in which a physician invokes clinical

experience. *Ibid.* But nothing in *Tamraz*'s holding or reasoning is inconsistent with the decision below.

The Sixth Circuit in *Tamraz* disavowed any suggestion that "physicians may not testify to etiology," noting that it had "reversed courts for not allowing such testimony." 620 F.3d at 673. The court's concern in *Tamraz* was the physician's "fail[ure] to cite *any* non-speculative evidence for his conclusion" beyond his clinical experience. *Id.* at 674. Here, by contrast, respondent's experts relied on "epidemiological, animal, and cellular" studies, and they used "clinical experience" only to "supplement the epidemiological studies on which they relied." Pet. App. 28a (footnote omitted); see *id.* at 33a-36a. Although petitioner objects to the experts' interpretation of those studies (Pet. 34-35), that factbound objection does not warrant this Court's review.

The decision below is likewise consistent with the *Tamraz* court's assertion that experts must "rule out 'unknown (idiopathic) causation' as an alternative explanation for [a plaintiff's] illness." Pet. 31 (quoting *Tamraz*, 620 F.3d at 675). The court of appeals in this case articulated the same rule. See Pet. App. 33a. It found, however, that respondent's experts had ruled out idiopathic causation through a "'substantial cause'" analysis based on epidemiological studies that, in the experts' view, showed "a strong association" between glyphosate and non-Hodgkin's lymphoma. *Id.* at 33a-34a. Again, to the extent petitioner contests the Ninth Circuit's application of the legal rule in this case (Pet. 29-30, 32), that factbound challenge does not warrant review.

The Eighth and Tenth Circuit decisions that petitioner cites likewise stand only for the proposition that an expert must rule out idiopathic causation where it

accounts for the majority of cases. See Pet. 31-32 (citing *Hall* v. *Conoco, Inc.*, 886 F.3d 1308, 1315 (10th Cir. 2018); *Bland* v. *Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008)). The decision below articulated and applied the same standard. See Pet. App. 33a-34a.

Petitioner also emphasizes the district court's statement that the Ninth Circuit has adopted a more forgiving *Daubert* standard than other circuits. See Pet. 29-30 (citing Pet. App. 83a-84a). But the court of appeals disavowed the district court's "incorrect assumption that [the Ninth Circuit] is more permissive than others in admitting *Daubert* testimony," Pet. App. 26a, and explained that the Ninth Circuit's approach is consistent with those of its sister circuits, see *id.* at 24a-26a.

B. Petitioner contends that the admissibility standard generally applied by the courts of appeals "clashes with *Daubert* and Rule 702," and that the Court should use this case to provide further guidance. Pet. 32. The record in this case indicates, however, that both the district court and the court of appeals considered whether the opinions of respondent's experts were based on "sufficient facts or data," were "the product of reliable principles and methods," and "reliably applied the principles and methods to the facts of the case," as Rule 702 and *Daubert* require. Pet. App. 9a; *id.* at 107a-137a. Petitioner suggests that the Ninth Circuit's analysis "blurs the boundaries between science and speculation with a third category called 'art.'" Pet. 27 (quoting Pet. App. 26a-27a). But the quoted language referred only to a district court's discretion to permit an expert to rely on "'extensive clinical experience'" when "conducting differential diagnosis to render specific causation opinions," not to any novel category of admissible expert

testimony. Pet. App. 26a-27a (citation omitted). This Court has never suggested that such reliance is impermissible under *Daubert*, particularly where, as here, clinical experience is invoked merely to "supplement the epidemiological studies on which [the experts] relied." *Id.* at 28a.

Petitioner's request for systemic correction of the lower courts' application of Rule 702 is particularly misconceived at the present time, since amendments to Rule 702 may soon provide additional clarification. A proposed amendment to Rule 702(a) clarifies that the proponent of expert testimony bears the burden of demonstrating its admissibility by a preponderance of the evidence. Comm. on Rules of Practice & Procedure, Judicial Conf. of the U.S., *Preliminary Draft: Proposed Amendments to the Federal Rules of Appellate, Bankruptcy, Civil, and Criminal Procedure, and the Federal Rules of Evidence* 308-311 (Aug. 6, 2021).[5] A proposed amendment to Rule 702(d) clarifies that an expert's opinion must "reflect[] a reliable application of the [expert's reliable] principles and methods to the facts of the case." *Id.* at 308-309. The Committee Note describes that amendment as "emphasiz[ing] that a trial judge must exercise gatekeeping authority with respect to the opinion expressed by a testifying expert." *Id.* at 310. The prospect that amendments to Rule 702 will provide the lower courts with additional guidance further reduces any need for this Court to clarify the requirements imposed by the current Rule.

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[5] Available at https://www.uscourts.gov/rules-policies/pending-rules-and-forms-amendments.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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MAY 2022