No. 21-1272

IN THE
Supreme Court of the United States

MONSANTO COMPANY,
Petitioner,

v.

ALBERTA PILLIOD AND ALVA PILLIOD,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeal of California

SUPPLEMENTAL BRIEF FOR RESPONDENTS

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TABLE OF AUTHORITIES

On June 17, 2022, after the briefing had been completed, the Ninth Circuit held that EPA had not adequately considered whether glyphosate causes cancer, vacating the agency's 2020 determination that glyphosate poses no risks to human health. *See Natural Res. Def. Council v. U.S. Env't Prot. Agency*, Nos. 20-70787 & 20-70801, 2022 WL 2184936, at *3 (9th Cir. June 17, 2022) ("*NRDC*"). The court of appeals concluded that EPA had failed to follow its own guidelines when reviewing glyphosate and that substantial evidence did not support the agency's conclusion that glyphosate is not likely carcinogenic to humans. Monsanto's certiorari petition leans heavily on EPA's conclusion, which came after the jury verdict here and which the Ninth Circuit now has vacated. The Ninth Circuit's vacatur provides yet another reason to deny review.

1. FIFRA requires EPA to "periodically review[]" pesticide registrations. 7 U.S.C. § 136a(g)(1)(A). As part of that review, the agency must determine whether the pesticide poses "any unreasonable risk" to human health, among other things. *Id.* § 136(bb); 40 C.F.R. § 155.57.

EPA issued an interim registration decision for glyphosate in January 2020. *NRDC*, 2022 WL 2184936, at *5. That decision explained that the agency had "determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.*

2. The Ninth Circuit vacated EPA's decision. The court held that the agency's determinations were "in tension with parts of the agency's own analysis and with the guidelines it purports to follow," and

thus not supported by substantial evidence. *NRDC*, 2022 WL 2184936, at *8.

First, the court found that EPA's "choice of the 'not likely' descriptor" – as in "not likely carcinogenic" – "conflict[ed] with" its analysis of epidemiological studies. *Id.* EPA uses the "not likely" descriptor when there is "'robust'" data showing "'there is *no* basis for human hazard concern.'" *Id.* at *9 (emphasis added). But here EPA had reason for concern: "most studies EPA examined indicated that human exposure to glyphosate is associated with an at least somewhat increased risk of developing [non-Hodgkin lymphoma]." *Id.* at *8. And in an earlier paper, the agency had concluded that "'the association between glyphosate exposure and risk of [non-Hodgkin lymphoma] cannot be determined based on the available evidence.'" *Id.* The court thus concluded that EPA could not "reasonably treat its inability to reach a conclusion about [non-Hodgkin lymphoma] risk as consistent with a conclusion that glyphosate is 'not likely' to cause cancer." *Id.* at *9.

Second, EPA's "not likely" conclusion did not "withstand[] scrutiny under the agency's own framework." *Id.* For example, EPA guidelines describe how the agency should use historical-control data, which shows how often certain tumors naturally occur in animals. Historical-control data can either "bolster" or "undermine" a study's results: If a study uncovers rare tumors, "'the result is in fact unlikely to be due to chance'"; while if a study turns up only common tumors, that result is of "reduce[d] . . . importance." *Id.* at *9-10. But for glyphosate, "EPA use[d] this type of data *only* to discount studies indicating that glyphosate may cause tumors." *Id.* at *10 (emphasis added). This one-way ratchet drew criticism from an

internal review panel, which said it would "'potentially introduce biases.'" *Id.* Rather than address these concerns, "the agency did not change the way in which it factored those data into its analysis." *Id.* This and other issues, *see*, *e.g.*, *id.* at *11 ("disregard of tumor results occurring at high dosages"), made the "analysis underpinning EPA's 'not likely' descriptor . . . flawed." *Id.* at *9.

Because of EPA's inconsistent and faulty reasoning, its conclusion that glyphosate is "not likely" carcinogenic failed substantial-evidence review. The Ninth Circuit thus vacated "and remand[ed] for further analysis and explanation," *id.* at *13, "including a new public-comment process," *id.*

3. Even setting aside the Ninth Circuit's decision, Monsanto's petition is unworthy of review. That was the United States' conclusion in *Hardeman*: No matter how EPA classifies glyphosate, label-based failure-to-warn claims are "'fully consistent'" with FIFRA, so they are not preempted. Brief for the United States as Amicus Curiae at 8, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. May 10, 2022) (quoting *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 447 (2005)). And the Pilliods' label-based failure-to-warn claims never were about glyphosate in isolation, but about Monsanto's failure to warn of the cancer risks of *formulated Roundup*. *See* Opp. 8, 21, 23. EPA repeatedly has admonished that it has not determined whether glyphosate-based products like Roundup can cause cancer. *See* Opp. 7-8 (collecting examples).

The Pilliods also brought design-defect and off-label failure-to-warn claims that did not require Monsanto to "label or package [its] products in any particular way." *Bates*, 544 U.S. at 444. Those claims fall well

outside the reach of FIFRA's "narrow" preemption provision. *Id.* at 452. Monsanto's petition ignores these claims, and its reply brief fails to substantively address them, but they provide an independent basis to deny review.

Monsanto's certiorari petition never has been worthy of review, and the Ninth Circuit's decision reinforces that conclusion. The petition made EPA's "not likely" conclusion a point of emphasis, highlighting that it came after notice and comment and suggesting that this should somehow weigh in the preemption analysis. Pet. 15. That argument always lacked merit: At the end of its glyphosate review, EPA could have issued binding requirements or prohibitions governing cancer warnings for glyphosate, but it did not. Now that EPA's review decision has been vacated, there is one more reason to deny Monsanto's petition.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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