No. 24-1068

IN THE

Supreme Court of the United States

MONSANTO COMPANY,
Petitioners,
v.
JOHN L. DURNELL,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for Missouri, Eastern District

BRIEF OF FARMWORKER JUSTICE, FARMWORKER ASSOCIATION OF FLORIDA, CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION, MIGRANT CLINICIANS NETWORK, ALIANZA NACIONAL DE CAMPESINAS, AND PESTICIDE ACTION & AGROECOLOGY NETWORK AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF AMICUS CURIAE

Amici Farmworker Justice, Farmworker Association of Florida, California Rural Legal Assistance Foundation, Migrant Clinicians Network, Alianza Nacional de Campesinas, and Pesticide Action & Agroecology Network are nonprofit organizations that represent, serve, and partner with hundreds of thousands of farmworkers across the country to minimize workers' exposures to dangerous pesticides.[1]

As the individuals directly handling pesticides and crops sprayed with pesticides, farmworkers are exposed to pesticides more frequently and in greater concentrations than any other population. The Environmental Protection Agency (EPA) has recognized that "there is strong evidence that [farm]workers and [pesticide] handlers may be exposed to pesticides at levels that can cause adverse effects," including exposures that cause significant long-term health risks. Pesticides; Agricultural Worker Protection Standard Revisions, 80 Fed. Reg. 67496, 67498 (Nov. 2, 2015). Indeed, EPA estimates that about 10,000 to 20,000 physician-diagnosed poisonings occur annually at farms, nurseries, and greenhouses across the country. *Id.* at 67502. Farmworkers and their family members may also be exposed when pesticide dust or droplets move through

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel, party, or any other person or entity—other than amici curiae and their counsel—made a monetary contribution intended to fund the preparation or submission of this brief.

the air to where they live or go to school. *See id.*

Farmworkers depend on the EPA pesticide-registration process to ensure that pesticide labels provide adequate warnings and directions to help minimize harm from exposure. Labels can, for example, prohibit particularly hazardous spraying methods or mandate protective clothing, respirators, or longer periods of time before farmworkers can re-enter fields after pesticide spraying. *See* 80 Fed. Reg. at 67502. The registration process produces adequate label directions only if EPA has up-to-date and complete information about the dangers from the pesticide's use.

State failure to warn litigation plays a critical role in uncovering information that manufacturers have not submitted to EPA or that demonstrates the need for stronger label warnings or directions. Such litigation has spurred manufacturers to modify their pesticide labels to afford workers and their families greater protection from pesticides. Such litigation also provides an avenue for workers to obtain damages to cover their medical expenses and lost wages when they are injured because the manufacturer's label lacks adequate warnings or directions for use to minimize harm.

INTRODUCTION AND SUMMARY OF ARGUMENT

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers pesticides upon determining, among other things, that the pesticide label submitted by the manufacturer complies with FIFRA. 7 U.S.C. § 136a(c)(5)(B). But EPA makes this determination based on the

information on hand at that moment in time. Often EPA lacks sufficient information to assess many ways the pesticide can harm human health. Gaps in the scientific evidence are filled over time and lead manufacturers to change the pesticide label.

Under FIFRA, the label is not cast in stone. Instead, FIFRA establishes an ongoing, iterative scheme that obligates manufacturers to provide EPA with the most up-to-date information about a pesticide's adverse effects, such as its potential to cause cancer. 7 U.S.C. § 136d(a)(2). FIFRA likewise obligates manufacturers to revise pesticide labels to ensure that they avoid misbranding by providing adequate warnings and directions for use to protect health. *See id.* §§ 136(q)(1)(F)-(G), 136j(a)(1)(E). The fact that EPA has registered the pesticide and accepted the manufacturer's label is not a defense for violating FIFRA's misbranding prohibition. *Id.* § 136a(f)(2). And EPA must amend pesticide registrations to reflect label changes made by the manufacturer unless the label change would violate FIFRA. *Id.* § 136a(f)(1). State failure to warn claims impose equivalent obligations and often uncover adverse effects information that leads manufacturers to change their labels to afford adequate health protection.

FIFRA expressly preserves state authority to regulate pesticide use to afford greater protection than EPA. 7 U.S.C. § 136v(a). While EPA approves labels based on FIFRA's unreasonable adverse effects determination—which balances health risks against the pesticide's benefits—a state may impose additional limitations on pesticide use under a more

health-protective standard. Manufacturers can in turn amend their labels to incorporate state use regulations, reinforcing the continuous, adaptive nature of pesticide labels. State failure to warn claims generate additional information that can ensure the EPA-accepted label has adequate directions to protect health and avoid violating FIFRA's misbranding prohibition.

Although FIFRA charges EPA with determining whether the manufacturer's label complies with FIFRA's requirements when registering a pesticide, 7 U.S.C. § 136a(c)(5)(B), EPA reviews the label at a point in time when the agency often lacks complete information about all the ways the pesticide harms people's health. Based on this Court's decision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 450 (2005), the United States concedes that "a pesticide might be misbranded for reasons outside the scope of what EPA assesses during the registration process." U.S. Br. 27. Under FIFRA and EPA's implementing regulations, there often are substantial gaps in the scientific evidence and in what EPA assesses.

FIFRA directs EPA to establish the minimum toxicity data needed for a fully informed unreasonable adverse effects determination, but FIFRA authorizes EPA to allow some pesticide uses without all the required data. FIFRA also allows EPA to complete iterative reviews of pesticide registrations without sufficient studies to assess the pesticide's propensity to cause serious toxic effects. EPA cannot assess such effects until the manufacturer submits the missing studies for the next round of iterative reviews. EPA can also allow voluntarily canceled pesticides to be

used with outdated labels that fail to afford adequate health protection.

In addition, EPA's regulations leave significant gaps in the cancer studies before the agency and cancer warnings. In specifying the data required for registration as FIFRA requires, EPA has required cancer testing of the pesticide's active ingredient but not the whole pesticide product. Moreover, although EPA has promulgated regulations elucidating FIFRA's requirements for classifying pesticides according to their acute toxicity—and providing corresponding warnings—FIFRA establishes no comparable requirements for chronic risks like cancer. EPA therefore does not require tests to address the cancer-causing potential of the pesticide product, and it does not scrutinize labels for the existence or adequacy of cancer warnings.

EPA similarly has insufficient information to assess certain noncancer toxic effects that Congress directed it to address. For instance, EPA has established a statutorily mandated program for testing pesticides for dangerous endocrine disruption effects, yet the agency has still not obtained the required tests. The agency is only beginning to assess the health risks to children from exposure to pesticide dust and vapors that move away from the fields to schools, homes, and playgrounds. EPA has, therefore, made registration decisions and accepted manufacturer labels without assessing potentially serious toxic effects and exposures that Congress directed it to address.

Because EPA has accepted the manufacturer's label based on its assessment of only some harms to

human health, pesticide labels often lack adequate warnings or directions for use. State failure to warn claims address this gap by uncovering scientific studies and adverse effects information that was not before EPA when it accepted the manufacturer's label. Such claims also create incentives for manufacturers to comply with their statutory obligation to ensure that their labels contain adequate warnings and directions to protect health. And failure to warn claims can provide compensation to people who suffer harm to their health because label warnings were inadequate.

ARGUMENT

I. FIFRA Establishes An Iterative Scheme That Requires Manufacturers To Update Pesticide Labels To Provide Adequate Warnings And Directions To Protect Health.

Congress amended FIFRA in 1972 to require pesticide manufacturers to obtain an EPA registration for a pesticide to be sold in the United States. *See* 7 U.S.C. § 136a(a). To obtain a registration, the manufacturer must submit the complete pesticide labeling and laboratory studies required by EPA regulations. *Id.* §§ 136a(c)(1)(C), 136a(c)(2). EPA must in turn find that the label complies with FIFRA's requirements and that use of the pesticide "in accordance with widespread and commonly recognized practice" will not generally cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(B), (D). That standard is defined as "any unreasonable risk to man or the

environment, taking into account the economic, social, and environmental costs and benefits" of the pesticide use. *Id.* § 136(bb).

Once a pesticide is registered, however, the label is not static. Manufacturers have an ongoing duty to update their labels to ensure they contain adequate instructions to protect health and to keep EPA apprised of any information regarding the pesticide's potential to cause adverse effects. For its part, EPA must amend registrations to reflect label changes made by the manufacturer as long as the changes do not violate FIFRA's provisions. 7 U.S.C. § 136a(f)(1). Accordingly, by FIFRA's design, the most recent label accepted by EPA is not set in stone. It must evolve to be sufficient to protect public health.

A. Manufacturers Have An Ongoing Duty To Ensure Their Labels Are Adequate To Protect Public Health.

Pesticide manufacturers have an ongoing duty to ensure that their labels will protect the public. Manufacturers must continually ensure that their labels avoid misbranding, *see* 7 U.S.C. § 136j(a)(1)(E)-(F), and registration is no defense, *id.* § 136a(f)(2). And they must provide EPA emerging science and other information about the pesticide's adverse effects. *Id.* § 136d(a)(2).

1. *EPA's Past Approval Of A Pesticide Label Is No Defense To A Misbranding Violation.*

The fact that EPA has registered a pesticide is "prima facie evidence" of compliance with FIFRA's registration requirements. 7 U.S.C. § 136a(f)(2). But

it is not "a defense for the commission of any offense" under FIFRA. *Id*.

On its face, FIFRA's no-defense provision extends to "any offense" under FIFRA, which includes distributing any pesticide that is misbranded. 7 U.S.C. § 136j(a)(1)(E)-(F). As this Court recognized over twenty years ago, the no-defense provision requires manufacturers to come forward with proposed label changes: "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." *Bates*, 544 U.S. at 438 (citation omitted).

2. *FIFRA Allows Manufacturers To Amend Their Labels To Provide Greater Protection.*

Under FIFRA, it is the manufacturer's prerogative to change its pesticide label. FIFRA mandates that, if a manufacturer changes a pesticide label, "the registration *shall* be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter." 7 U.S.C. § 136a(f)(1) (emphasis added). EPA would have no basis for preventing the manufacturer from providing stronger or more detailed health warnings since EPA's past registration of the pesticide is "no defense" to a violation of FIFRA's misbranding requirement to ensure the label provides adequate health warnings.

It is commonplace for manufacturers to modify their labels to add directions for use to guard against health or environmental harm. Indeed, in *Bates*, Dow

Agrosciences submitted and EPA quickly accepted a modified label, advising against applying the pesticide to certain soils in states where peanut farmers had experienced crop damage. *See* 544 U.S. at 435.

EPA's process of reviewing labels is not onerous. EPA stamps the manufacturer label "accepted" without making written findings. *See* EPA, Label Review Manual at 34 (Dec. 2024), https://perma.cc/SY84-X8NY (Label Review Manual).[2] And FIFRA directs EPA to act "as expeditiously as possible" on an application for a registration amendment that does not require review of scientific data, 7 U.S.C. § 136a(c)(3)(B)(i)(II)—which is often the case with label changes refining the directions for use or adding cancer warnings.

Monsanto raises the specter of EPA preventing it from adding a cancer warning to the Roundup label. But Monsanto never identifies a single instance where EPA has prevented the addition of a cancer warning. Nor has it pointed to a particular provision of FIFRA that would allow EPA to block addition of a cancer warning or further label directions to reduce exposure to a pesticide that has the potential to cause cancer.[3]

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[2] Due to irregular pagination, this brief cites to the PDF page.

[3] In characterizing pesticide labels as somehow inviolate and impossible to change, Monsanto repeatedly quotes a statement in EPA's Pesticide Registration Manual that "[t]he label is the law." Pet. Br. 8, 26, 45. That phrase, however, reflects the fact that it is a violation of FIFRA to *use* a pesticide in a manner inconsistent with its label. *See* 7 U.S.C. § 136j(a)(2)(G); *see also* Label Review Manual at 11 ("label is the law" refers to FIFRA's provision making violations of label requirements

B. Manufacturers Have A Duty To Submit Adverse Effects Information, Including Information Derived From Tort Litigation.

Manufacturers have an ongoing obligation to provide EPA with all information in their possession regarding a pesticide's adverse effects on health and the environment. *See* 7 U.S.C. § 136d(a)(2). This mandate extends to information generated or obtained in tort litigation, including discovery and expert reports. *See* 40 C.F.R. § 159.158(a); *id.* § 159.153(b) (defining "Qualified expert").

The evidence amassed in tort litigation can show how people are being harmed by a pesticide and how labels must be changed to prevent or lessen the harm. Dursban—a residential-use pesticide product containing the acutely toxic pesticide chlorpyrifos—is illustrative. During the 1990s, dozens of people filed lawsuits alleged that spraying Dursban to control insects in their homes caused serious harm, including to children who suffered from seizures, learning impairments, and paralysis. *See* Jim Morris, *The Stuff in the Backyard Shed – The Pesticide Is Effective And Sells Like Mad. But Is It Safe For Everyone?*, U.S. News & World Report, Nov. 8, 1999, https://perma.cc/9E9N-QRPW. DowElanco disclosed in discovery hundreds of incidents of adverse health effects from Dursban that it had failed to report to EPA, leading EPA to impose what was then its largest civil penalty for a violation of FIFRA's adverse effects reporting provision. EPA, EPA Fines DowElanco For

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unlawful).

Failure to Report Pesticide Health Effects (May 2, 1995), https://perma.cc/D7C9-6F66.

Based on the poisoning reports, EPA scientists recommended amending the Dursban label to instruct people to stay out of the area during certain applications and to seek immediate medical attention if they experience headaches, nausea, unusual fatigue, or dizziness. EPA, Memorandum Reviewing Chlorpyrifos Poisoning Data at 6-7, 41 (Jan. 14, 1997), https://perma.cc/H7JA-NC9V. EPA's recommendations led manufacturers to amend Dursban labels to end certain uses and to provide additional instructions to reduce exposures. EPA, Agreement Reached Between EPA and Chlorpyrifos Pesticide Registrants (June 6, 1997), https://perma.cc/4SV2-UYA7. EPA's 2000 human health risk assessment considered the poisonings and found unacceptable risks from residential uses, which spurred DowElanco to voluntarily cancel virtually all residential uses. Carol Browner, Dursban Announcement (June 8, 2000), https://perma.cc/H4ES-G5CP; *see* EPA, Interim Reregistration Eligibility Decision for Chlorpyrifos at viii-ix, 3-6 (2002) (EPA-738-R-01-007) (describing agreement); Chlorpyrifos; Cancellation Order, 65 Fed. Reg. 76233, 76234 (Dec. 6, 2000).

As another example, a district court determined in 2022 that Monsanto had potentially violated FIFRA, 7 U.S.C. § 136d(a)(2), by failing to submit evidence to EPA regarding the conclusions reached by Monsanto's toxicology expert and the company's response. *See Chapman v. Monsanto Co.*, 2022 WL 3971287 at *8-10 (S.D. Tex. 2022). Specifically, Monsanto failed to tell EPA that the expert had advised that glyphosate

could be genotoxic and should be tested for genotoxicity and that Monsanto never conducted the studies the expert recommended, including of the formulated product Roundup. *Id.*

Under FIFRA, manufacturers must inform EPA of any adverse effects from their pesticides, including information uncovered in tort litigation. Such information, including in the form of jury verdicts, furthers FIFRA's requirement that manufacturers ensure their pesticide labels provide adequate warnings and directions to protect health.

II. States Have Authority To Determine Whether EPA-Accepted Labels Are Adequate To Protect Health And To Afford Greater Protection.

Under the cooperative federalism scheme embodied in FIFRA, states can impose more stringent health protection than EPA. *See* 7 U.S.C. § 136v(a). In doing so, states are not bound by FIFRA's unreasonable adverse effects standard, which requires EPA to balance the human health risks against the economic and other benefits of using the pesticide. *See id.* § 136(bb).[4] States can instead decide to afford greater health protection or strike the

[4] For pesticides used on food, FIFRA defines "unreasonable adverse effects" to incorporate the Federal Food, Drug and Cosmetic Act's more health-protective standard. 7 U.S.C. § 136(bb)(2). To promulgate a tolerance regulation allowing residues of a pesticide on food, EPA must find the pesticide "safe," meaning there is reasonable certainty of no harm to the general population and to children. 21 U.S.C. § 346a(b)(2)(A)(i)-(ii); *id.* § 346a(b)(2)(C)(ii)(I).

balance differently.

EPA conducts a series of risk assessments, including for occupational exposures, to determine whether exposures will result in risks that exceed the risk level the agency deems acceptable. *See, e.g.,* EPA, Assessing Human Health Risk from Pesticides (Jan. 23, 2026), https://perma.cc/M59T-46CR. Where EPA finds risks of concern, it assesses the pesticide's benefits to growers and balances the risks against those benefits. *See, e.g.*, EPA, Registration Review Process (Oct. 30, 2025), https://perma.cc/Q7WE-LDN9. The agency can thus decide that avoiding increased costs to growers justifies exposing people to what it deems unacceptable health risks.

For example, EPA decided to allow workers who apply the pesticide paraquat to be exposed to risks of concern from aerial spraying on cotton because it deemed the use critical. EPA, Paraquat Dichloride Interim Registration Review Decision at 29 (July 2021) (EPA-HQ-OPP-2011-0855-0307). It allowed workers to apply paraquat through ground spraying with a respirator, and not in an enclosed cab, to provide growers flexibility. *Id*. at 32-33. And the agency allowed farmworkers to enter treated fields before the risks would be below its acceptable risk level because the longer re-entry prohibition could render the pesticide unusable for the crop. *Id*. at 35.

In striking a different balance, states have banned pesticides that EPA allows to be used, *see, e.g.*, N.Y. Comp. Codes R. & Regs. Tit. 6, § 326.2(c)(17) (2021) (chlorpyrifos cannot be sold or used in New York), or have afforded greater health protections by, for example, prohibiting aerial spraying or imposing

additional requirements to protect workers. *Compare* Or. Admin. R. 603-057-0545(2)(b)-(c) (2026) (Oregon prohibitions on aerial spraying and expansion of time required before returning to fields after spraying) *with* EPA, Interim Reregistration Eligibility Decision for Chlorpyrifos at 81, 82, 85-86 (2002) (EPA-378-R-01-007). And states have imposed limits on pesticide spraying in close proximity to schools and daycare centers. Cal. Code Regs. Tit. 3, § 6691 (limiting pesticide application methods within one-quarter mile of schools and daycare centers in California).

When states adopt stronger safeguards, they are essentially finding that the EPA-accepted label fails to provide adequate warnings and directions to protect health. *See Bates*, 544 U.S. at 442 ("States have ample authority to review pesticide labels to ensure they comply with both federal and state labeling requirements."); *see also* 7 U.S.C. § 136w-1 (states exercising primary enforcement authority may bring misbranding actions before state administrative bodies and courts). EPA, therefore, has no monopoly on deciding what instructions for use are adequate to protect human health.

State limitations on pesticide use can be communicated through the EPA-accepted pesticide label. Indeed, current EPA policies allow manufacturers to add state-specific use prohibitions to the label without notifying EPA, provided the state limitation is phrased as "Not Registered for Use" in the state or registered subject to specified safeguards. *See* EPA, Pesticide Labeling Questions & Answers at 16. Non-notifications (May 25, 2025), https://perma.cc/GE9Z-DU6D; EPA, DRAFT Proposed

PR Notice 2025-NEW (Revised PRN 98-10) at 25-26 (Jan. 5, 2026) (EPA-HQ-OPP-2025-2863-0002).

The word "[u]niformity" in the heading of FIFRA's label preemption provision, 7 U.S.C. § 136v(b), reflects the fact that there is one nationwide label that often includes state-specific content. *See, e.g.,* Label for ACE-jet, EPA Reg. No. 74578-2 at 3 (Jan. 25, 2022), https://perma.cc/V6ZC-BRDX (acephate label lists state use limitation and instructs to check with state authorities for additional use regulations). There is no "crazy-quilt" of conflicting labels, *Bates*, 544 U.S. at 451, just one label incorporating state-specific directions.

State pesticide use restrictions can also spur changes in EPA's pesticide registrations and the manufacturers' labels. For example, states added safeguards beyond EPA's requirements for use of mevinphos after it caused large numbers of worker poisonings. *See, e.g.,* Wash. State Dep't of Agric., Rule-Making Order To Restrict The Use Of Mevinphos (Apr. 15, 1994), https://perma.cc/RA9V-SFZ8.[5] When the manufacturer subsequently agreed to voluntarily cancel the mevinphos registration to avoid an EPA suspension, EPA required amended labels incorporating California's worker protections as a condition of most sales during the phase-out period. *See* Mevinphos; Amendment to Cancellation Order and FIFRA Section 6(g) Notification, 60 Fed. Reg. 17357, 17358 (Apr. 5, 1995) (prohibiting hand-held

[5] Several workers who were poisoned sued the pesticide manufacturer, including for failure to warn of the risks posed by mevinphos. *See Ruiz-Guzman v. Amvac Chemical Corp.*, 7 P.3d 795 (Wash. 2000).

sprayers and requiring respirators, protective eyewear, and chemical-resistant clothing).

As another example, several states limited agricultural uses of chlorpyrifos to address scientific evidence linking exposures during pregnancy with learning and behavioral disorders. *See supra* at 13-14; *see also* EPA, Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review at 6-7, 32-49 (Dec. 29, 2014) (EPA-HQ-OPP-2008-0850-0195) (EPA findings linking exposures during pregnancy to learning and behavioral disorders in children). For example, the California Department of Pesticide Regulation initiated cancellation proceedings, which culminated in Dow Agrosciences (the primary chlorpyrifos maker at the time) agreeing to cancel almost all chlorpyrifos uses in California. Cal. Dep't of Pesticide Reg., Agreement Reached to End Sale of Chlorpyrifos by February 2020 (Oct. 9, 2019), https://perma.cc/GE9Z-DU6D.

FIFRA expressly preserves state authority to afford workers and others greater protection when they find EPA-accepted labels inadequate to protect public health. Indeed, when states adopt more protective pesticide regulations, they often spur EPA to strengthen federal registrations and manufacturers to provide more protective label instructions. Juries deciding state failure to warn claims can likewise spur manufacturers and EPA to improve pesticide labels, while also providing compensation to people who have been harmed by the manufacturer's prior failure to ensure that its labels will protect against harm.

III. FIFRA Allows EPA To Authorize Pesticide Use In Situations Where It Lacks Complete Information To Find The Label Adequate To Protect Health.

FIFRA allows EPA to authorize pesticide use in many situations where, by statutory design, the agency has incomplete information about the pesticide's risks to human health. In these situations, EPA has not made a fully informed judgment that the label contains all necessary warnings and directions.

First, FIFRA allows EPA to conditionally register a new pesticide or additional uses of an already-registered pesticide, even though the manufacturer has not submitted all the studies required for registration. 7 U.S.C. § 136a(c)(7)(A)-(C). EPA must find that the additional uses will not significantly increase the risk of unreasonable adverse effects and that new active ingredients will not cause unreasonable adverse effects during the conditional registration period. EPA, however, makes these findings without the full suite of studies required for registration. *Id.*; *see* GAO, Pesticides: EPA Should Take Steps to Improve Its Oversight of Conditional Registrations at 11-12 (2013) (GAO-13-145) (describing EPA's widespread issuance of conditional registrations, some lasting a decade or more).

Second, FIFRA authorizes EPA to issue emergency exemptions for unregistered uses of pesticides in a defined geographic area where EPA determines an emergency exists, most often because of a pest outbreak. 7 U.S.C. § 136p. EPA can reissue emergency exemptions in successive growing seasons if an application for registration has been filed. *See* 40

C.F.R. § 166.25(b); *id.* § 166.25(b)(2)(ii). EPA allows use of these pesticides often for years without the studies and risk assessment findings needed to register the pesticide use.

Third, FIFRA requires iterative reviews of pesticide registrations to ensure pesticides meet FIFRA's standards, but each review identifies gaps in scientific evidence that must be addressed in future reviews. Pesticide labels reflect only the data on hand and not necessarily all ways the pesticide can harm human health.

The initial round of review entailed re-registering older pesticides that had been allowed to stay on the market without meeting the stronger health and environmental standards incorporated into FIFRA in 1972. *See* FIFRA Amendments, Pub. L. No. 35-396, § 8, 92 Stat. 819, 827 (1978); 7 U.S.C. § 136a-1. Congress recognized, however, that at the end of this one-time review, there would still be gaps in toxicity studies and exposure data (particularly for risks to children from pesticides used on food crops). *See* 21 U.S.C. § 346a(b)(2)(C)-(D); *see infra* at 27.

Registered and re-registered pesticides are subject to ongoing 15-year registration reviews to ensure that the pesticides continue to meet FIFRA's unreasonable adverse effects standard based on evolving science and regulatory requirements. 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40(a); *id.* § 155.53(a). Under EPA's regulations promulgated pursuant to 7 U.S.C. § 136a(g)(1)(A)(ii), EPA can issue interim registration review decisions addressing some, but not all, of the pesticide's risks. 40 C.F.R. § 155.56. The regulations also allow EPA to require new studies at the

culmination of registration review to fill in gaps in information about the pesticide's health effects. *Id.* § 155.58(b)(3). Moreover, the deadline for this round of registration review has been extended to be 19 years and may be extended further.[6] As a result, many pesticide registrations and EPA-accepted labels have not been brought in line with current standards and science. *See* EPA, Upcoming Registration Review Actions (Aug. 26, 2025), https://perma.cc/W9EJ-2XWC.

In addition, FIFRA authorizes the courts of appeals to set aside registration decisions that are not supported by substantial evidence. 7 U.S.C. § 136n(b). When a registration review decision is set aside, as occurred with EPA's 2020 interim registration review decision for glyphosate, the pesticide may continue to be used under the previous registration decision. In *Natural Resources Defense Council v. EPA*, the court of appeals held that EPA's cancer finding for glyphosate was not supported by substantial evidence because EPA discounted studies that correlated glyphosate exposures with cancer. 38 F.4th 34, 45-51 (9th Cir. 2022). The court vacated the human health portion of the interim registration review decision upon finding that "EPA's errors in assessing human-health risk are serious." *Id.* at 52. EPA's cancer finding remains in limbo, as EPA has yet to make a

[6] While Congress set a 2022 deadline for completing the first round of registration review, Congress subsequently extended that deadline to October 2026, and pending legislation would extend the deadline further to October 2031. Fiscal Year 2023 Consolidated Appropriations Act, Pub. L. No. 117-328, § 711(a), 136 Stat. 4459, 6083 (2022); H.R. 7567 § 10204(a)(2), 119th Cong. (2026).

new registration review decision for glyphosate. As a result, no legally valid cancer determination currently underpins the EPA-accepted Roundup label.

Fourth, FIFRA authorizes EPA to allow continued sale and use of existing stocks of a pesticide whose registration has been voluntarily canceled, provided that EPA "determines that such sale or use is not inconsistent with the purposes of" FIFRA. 7 U.S.C. § 136d(a)(1); *see Nat'l Coal. Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 641 (D.C. Cir. 1989) (EPA allowed continued sale and use of existing stocks to avoid time-consuming cancellation proceedings). Often the manufacturer voluntarily cancels a pesticide registration after contesting EPA's risk-assessment findings and stated intention to pursue cancellation of the registration. In these situations, EPA has found that use in accordance with the pesticide label poses unacceptable health risks. *See, e.g.,* 60 Fed. Reg. at 17358 (allowing use of mevinphos pesticide products that lacked the recent label protections for workers); 65 Fed. Reg. at 76238-39 (allowing four years to use existing chlorpyrifos stocks for termite control despite EPA's finding that the use presented unacceptable risks to children); *see supra* at 11, 13.

Merely because EPA has accepted a pesticide label does not mean it has a sufficient basis for determining that the warnings and directions are adequate to protect people from serious harm. FIFRA authorizes EPA to act on the basis of the information it has at a given point in time and to ratchet up health protections in subsequent reviews as informational gaps are filled.

IV. EPA Has Adopted Regulatory Schemes That Fail To Require Comprehensive Cancer Testing Or Warnings.

EPA's implementing regulations do not require cancer testing of the formulated pesticide product or cancer warnings. As a result of these regulatory gaps, EPA lacks sufficient information to make a fully informed finding about the pesticide product's propensity to cause cancer, and the agency has not taken on the task of ensuring pesticide labels have adequate cancer warnings. These deficits reinforce that EPA's acceptance of a pesticide label does not amount to a conclusive cancer determination that could preempt state failure to warn suits.

In *Bates*, this Court concluded it was unlikely that Congress intended to preempt state-law liability for crop damage because EPA does not review pesticide efficacy. 544 U.S. at 450. Acknowledging this statement in *Bates,* the United States concedes that "a pesticide might be misbranded for reasons outside the scope of what EPA assesses during the registration process." U.S. Br. 27. But efficacy is not the only information deficit in EPA's pesticide reviews. EPA similarly lacks sufficient information to assess cancer risks posed by pesticide products and it does not require label warnings for cancer.

A. EPA's Regulations Require Cancer Testing Of A Pesticide's Active Ingredient, But Not Of The Formulated Pesticide Product.

Pursuant to its statutory obligation to specify the information required to support a pesticide-

registration application, 7 U.S.C. § 136a(c)(2)(A), EPA has promulgated regulations setting out the minimum data requirements for registration. Those regulations require chronic testing for carcinogenicity to be assessed by testing only the active ingredient, not the actual end-use product that will be applied in the field. 40 C.F.R. § 158.500(c)-(d). As a result, EPA lacks information to address the cancer-causing potential of the whole pesticide product or the adequacy of the pesticide label to address such risks.

While FIFRA defines "pesticide" to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," 7 U.S.C. §136(u), it differentiates between a pesticide's "active" and "inert" ingredients. An ingredient is considered "active" if it "will prevent, destroy, repel, or mitigate any pest," *id.* § 136(a), while "inert" "means an ingredient which is not active," *id.* § 136(m). A pesticide formulation combines active and inert ingredients into end-use products. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 997 (1984).

For Roundup, this means that EPA has required cancer testing of the active ingredient glyphosate, but not of Roundup's inert ingredients. One of Roundup's "inert" ingredients is a surfactant, which reduces surface tension, allowing the pesticide spray to adhere to and penetrate waxy leaves. RA44 (¶ 33). There is evidence in the trial record that the surfactant makes Roundup more genotoxic than glyphosate alone. RA44-45 (¶¶ 34, 36); RA80.

Since EPA requires cancer testing only of the active pesticide ingredient, the agency is not basing

its registration decisions on the cancer-causing potential of the end-use product. If a failure to warn claim established that an ingredient other than glyphosate increases Roundup's cancer-causing properties, a jury verdict (like the one in this case) could serve an important gap-filling purpose. It would hold Monsanto accountable for failing to warn of the cancer risks associated with the entire product.

FIFRA also does not require *disclosure* of inert ingredients that have the potential to cause cancer or other chronic illnesses. FIFRA deems a pesticide "misbranded" if "the label does not bear an ingredient statement," but the ingredient statement needs to disclose only the total percentage of all inert ingredients, not the names of inert ingredients. 7 U.S.C. § 136(q)(2)(A); *id.* § 136(n)(1).

EPA has classified many commonly used inert ingredients as hazardous. *See e.g. Ctr. for Env't Health v. McCarthy,* 192 F. Supp. 3d 1036, 1040 (N.D. Cal. 2016) (EPA has designated hundreds of inert ingredients as hazardous.). Indeed, there is evidence in the trial record that Roundup contains cancer-causing inert ingredients, including ethylene oxide, 3 Tr. 2007-008, which EPA has classified as a human carcinogen. EPA, Ethylene Oxide Interim Registration Review Decision at 21 (Jan. 2025) (EPA-HQ-OPP-2013-0244-0435).

Because EPA registers pesticides without cancer tests on the end-use product, it makes no determination about the whole product's propensity to cause cancer when it accepts manufacturers' pesticide labels. Similarly, EPA requires no label disclosures of cancer-causing inert ingredients. Endowing such

omissions in EPA-accepted labels with preemptive effect would deprive people of critical information they need to protect themselves from toxic pesticides.

B. EPA's Regulations Require Label Warnings For Acute Toxicity, But Not For Cancer.

EPA has adopted regulations requiring acute toxicity warnings, but not warnings for cancer or other chronic health risks. Its acceptance of a manufacturer label, therefore, cannot be deemed a determination about whether a cancer warning should be provided.

FIFRA directs EPA to classify pesticides as restricted use when use of the pesticide in accordance with its directions for use, warnings, and cautions may generally cause unreasonable adverse effects without additional restrictions. 7 U.S.C. § 136a(d)(1)(C). Restricted use pesticides can only be applied by a certified applicator or under an applicator's direct supervision. *Id*. § 136a(d)(1)(C)(i)-(ii).

To comply with FIFRA's direction to classify acutely toxic pesticides as restricted use, EPA has promulgated regulations establishing a toxicity classification system based on oral, dermal, and inhalation exposures. 40 C.F.R. § 156.62. The most acutely toxic pesticides are classified as restricted use. 7 U.S.C. § 136a(d)(1)(C).

Under FIFRA, a label for a restricted use pesticide is misbranded if it does not bear the skull and crossbones, the word "poison," and first-aid treatments in case of poisonings. *See* 7 U.S.C.

§ 136(q)(2)(D). EPA's regulations add that the pesticide label must display a signal word ("DANGER," "WARNING," and "CAUTION"), reflecting the pesticide's toxicity category, 40 C.F.R. § 156.64, as well as precautionary statements describing the hazard and measures "to be taken to avoid accident, injury or toxic effect or to mitigate the effect," *id.* § 156.70.

FIFRA has no analogous provisions requiring cancer classifications or label disclosures. Nor has EPA promulgated regulations governing cancer classifications or warnings. As the United States has explained, "EPA does not typically use the registration process to address [such] harms by requiring chronic-risk warnings on a pesticide's labeling." U.S. Br. 11, *Monsanto Co. v. Hardeman*, No. 21-241 (filed May 10, 2022), *cert. denied*, 142 S. Ct. 2834 (Mem.).

The fact that some pesticide labels have cancer warnings while others do not is an outgrowth of choices made by the manufacturer, not EPA. Many pesticide manufacturers have added cancer warnings to comply with California's Proposition 65, which requires label warnings for pesticides the state has determined are carcinogenic—even if EPA has not. Cal. Code Regs. Tit. 27, § 25603. *See*, *e.g.*, Label for Kerb 3.3 SC, EPA Reg. No. 62719-578 at 31, 47 (Sept. 18, 2020), https://perma.cc/5G9R-T7Z5; Label for Willowood Pronamide 3.3SC, EPA Reg. No. 87290-22 at 29 (Sept. 18, 2020), https://perma.cc/RKV4-FNQE. EPA expressed concerns when labels making Proposition 65 disclosures used language EPA had assigned a specific meaning in its acute toxicity

regulations. To avoid a conflict, EPA has instructed companies to use "notice" or "attention" instead of "warning" because "warning" is a signal word denoting an acute toxicity classification under EPA's regulations. Label Review Manual at 88. As long as they do not use acute toxicity signal words, manufacturers remain free to add Proposition 65 cancer warnings to their pesticide labels.

When EPA accepts a manufacturer's label, it is not passing on the need for a cancer warning. Its acceptance of the label, therefore, cannot be characterized as EPA's determination that the label is adequate without such a warning.

V. EPA Has Yet To Ensure That Pesticide Registrations And Labels Protect Against Serious Toxic Effects And Exposures That Congress Requires EPA To Address.

As explained above, FIFRA authorizes EPA to allow pesticides to be used in many situations where it lacks sufficient information to ensure pesticide labels contain adequate warnings and directions to protect human health. EPA's regulations also fail to require comprehensive cancer testing of pesticide products or cancer warnings. In addition, EPA lacks sufficient information to protect people from other toxic effects and exposures, as Congress has directed. For this reason as well, the fact that EPA has accepted a pesticide label cannot be deemed to be a conclusive agency determination that the label provides adequate warnings and directions to protect health.

A. EPA Lacks Sufficient Information To Ensure That Labels Protect Against Serious Noncancer Health Effects.

In 1996, Congress directed EPA to develop a program to screen pesticides to determine if they interfere with the body's endocrine system or mimic, block, or alter natural hormones, which can cause fertility, cancer, metabolic, and developmental effects. 21 U.S.C. § 346a(p). When EPA finds such an effect, it must take appropriate action "to ensure the protection of public health." *Id.* § 346a(p)(6). While EPA created the endocrine disruption screening program in 1998, *see* Endocrine Disruptor Screening Program, 63 Fed. Reg. 42852 (Aug. 11, 1998), it has yet to obtain the required tests for most pesticides. *See* EPA Office of Inspector General, EPA's Endocrine Disruptor Screening Program Has Made Limited Progress in Assessing Pesticides at 8-9 (2021) (21-E-0186) https://perma.cc/DT76-JHSN. In a recent consent decree, EPA committed to obtain the overdue testing by 2035. Partial Consent Decree at 4-5, *Alianza Nacional de Campesinas v. EPA*, No. 4:22-cv-09030-JST (N.D. Cal. filed Jan. 21, 2025), Dkt. No. 87. Without such testing, EPA has neither assessed nor ensured pesticide registrations and labels protect people from disruption of the human endocrine system.

In its initial screening, EPA recommended more comprehensive testing of many possible endocrine disruptors, including dacthal. EPA, Endocrine Disruptor Screening Program Tier 1 Screening Determinations and Associated Data Evaluation Records (Sept. 23, 2015), https://perma.cc/X2QW-

XDW4. Years after EPA ordered a thyroid study for dacthal, the manufacturer submitted the required study, which showed that very small exposures during pregnancy can lead to low birth weight and impaired development. EPA issued an emergency suspension order upon finding that dacthal poses an imminent hazard to fetuses even if pregnant farmworkers wear personal protective equipment and use respirators. *See* Pesticides; Emergency Order Suspending the Registrations of All Pesticide Products Containing Dacthal, 89 Fed. Reg. 64445, 64448 (Aug. 7, 2024). The suspension order spurred the company to cancel its dacthal registration. *See* Dacthal; Notice of Receipt of Requests to Voluntarily Cancel Pesticide Registrations, 89 Fed. Reg. 70181, 70181 (Aug. 29, 2024).

For decades after Congress required protection, farmworkers have been exposed to dacthal and other endocrine disrupting pesticides without label directions needed to reduce serious health threats. State failure to warn claims reinforce manufacturers' obligations to ensure pesticide labels will protect against this type of health crisis.

B. EPA Has Failed To Ensure That Pesticide Labels Protect Children From Pesticide Drift.

For many pesticides, EPA has failed to require measures to protect children from toxic pesticide drift, despite congressional direction to do so. As a result, the pesticide labels lack adequate directions to protect children from harm.

Congress has directed EPA to protect children

from aggregate exposures to pesticides used on food, *see* 21 U.S.C. §§ 346a(b)(2)(A)(ii), 346a(b)(2)(C)(ii)(I), which includes exposures to pesticide drift when pesticide dust moves from the fields to homes and schools. In 2014, EPA acknowledged that it had failed to fulfill its legal obligation to address pesticide drift and indicated that it would incorporate drift safeguards in its forthcoming registration reviews. EPA, Agency Response to "Pesticides in the Air - Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift, (2009)" at 32 (Apr. 2, 2014) (EPA-HQ-OPP-2009-0825-0084).

EPA has since conducted risk assessments that identify unacceptable drift risks from many toxic pesticides unless spraying is prohibited in buffer zones around schools, homes, and playgrounds. However, EPA has yet to complete registration review for these pesticides, and as a result, the pesticide labels fail to mandate no-spray buffers. *See* Petition for a Writ of Mandamus at 9-10, *Pesticide Action & Agroecology Network North America v. EPA,* No. 25-3955 (9th Cir. filed June 25, 2025) Dkt. No. 1.1. In addition, prior to July 2024, EPA registered new pesticides without assessing drift or determining whether the pesticide labels should require no-spray buffer zones. *See* EPA, Implementing Chemical Specific Human Health Spray Drift Analysis for Pesticide Registration Actions at 3 (July 2024) (EPA-HQ-OPP-2013-0676-0124).

EPA has also developed a protocol for screening pesticides for volatilization, which occurs when a pesticide converts into a gas or vapor and moves far from the application site. *See* Pesticides;

Consideration of Volatilization in Pesticide Risk Assessment: Notice of Availability and Request for Comment, 79 Fed. Reg. 16791 (Mar. 26, 2012). EPA's protocol requires further testing where the screening indicates potential volatility, but the agency has rarely ordered manufacturers to conduct the follow-up tests. Several *amici* challenged EPA's 2021 interim registration review decision for paraquat, in part, because EPA had not obtained a volatility study required under its policy. In response, EPA ordered the manufacturer to conduct the study, but it will take four years for the study to be completed and inform revisions to the registration-review decision and pesticide label. *See* Decl. of Edward Messina at 6-8, *Cal. Rural Legal Assistance Found. v. EPA,* No. 21-71287 (9th Cir. filed Mar. 17, 2026) Dkt. No. 84-2. Without the full testing and exposure assessments, EPA has insufficient information to ensure pesticide labels protect people from pesticide drift and volatilization.

* * *

In sum, EPA fails to ensure pesticide labels provide adequate warnings and directions to protect people from cancer and other chronic health effects because of gaps in the information before the agency and in the types of warnings it requires. Congress has authorized some registrations without the full testing necessary to ensure the labels will be adequate. EPA's regulatory schemes leave gaping holes in cancer testing and warnings. And EPA has failed to implement congressionally mandated toxicity testing and exposure assessments. Due to these gaps, EPA's acceptance of a manufacturer's pesticide label is no

guarantee that the label is adequate to protect human health. Just as states may adopt use regulations to afford greater health protection, juries may find EPA-accepted labels inadequate to protect health. An uninformed or outdated registration is no defense to a misbranding offense that could spur the manufacturer to provide adequate label warnings to protect health. Nor is it a defense to a state failure to warn claim. Juries deciding such claims can afford an additional remedy for violating FIFRA's misbranding prohibition and compensate people who suffer harm from inadequate label directions that manufacturers can readily change.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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