No. 24-1068

In the Supreme Court of the United States

MONSANTO COMPANY, PETITIONER,
v.
JOHN L. DURNELL, RESPONDENT.

ON WRIT OF CERTIORARI TO THE MISSOURI COURT OF APPEALS

BRIEF FOR *AMICI CURIAE* CENTER FOR FOOD SAFETY, CONSUMER FEDERATION OF AMERICA, BREAST CANCER PREVENTION PARTNERS, RURAL COALITION, ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS, CENTER FOR BIOLOGICAL DIVERSITY, BEYOND PESTICIDES, AND FOOD & WATER WATCH, IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*[1]

Center for Food Safety (CFS) is a nonprofit, public interest organization dedicated to empowering people, supporting farmers, and protecting the earth from the harmful impacts of industrial agriculture. Founded in 1997, CFS represents over a million consumer and farmer members nationwide. Since its inception over twenty-five years ago, CFS has had a flagship program on improving pesticide risk assessment and regulation with dedicated legal, policy, and science staff, and including public interest litigation when necessary. Among other cases CFS was counsel in *Rural Coalition/NRDC v. EPA*, 38 F.4th 34 (9th Cir. 2022) (*Rural Coalition/NRDC*), which held EPA's glyphosate cancer risk assessment unlawful and vacated it.

Consumer Federation of America (CFA) is an association of nonprofit consumer organizations that was established in 1968 to advance consumer interest through research, advocacy, and education.

Breast Cancer Prevention Partners (BCPP) is the nation's leading nonprofit organization working to eliminate toxic chemicals and other environmental exposures linked to the disease. BCPP translates science into action, encourages businesses to make safer products, educates and protects consumers from unsafe

[1] No counsel for any party in this case authored this brief in whole or in part, and no person or entity other than *Amici Curiae* made a monetary contribution to its preparation or submission.

chemical exposures, and champions health-protective laws.

Rural Coalition is a nonprofit membership organization that has worked for over 40 years to assure just and sustainable food systems for small farmers and ranchers, fair and save working conditions for farmworkers, and safe and healthy food for all.

Alliance of Nurses for Healthy Environments is the only national nursing organization focused on the intersection of health and the environment. The Alliance's mission is to support nurses in promoting planetary health and equity globally by educating and leading the nursing profession, advancing research, incorporating planet-safe practice, and influencing policy.

Beyond Pesticides is a nationwide nonprofit organization founded in 1981 which works with allies in protecting public health and the environment to lead the transition to a world free of toxic pesticides.

Center for Biological Diversity (CBD) is a nonprofit membership organization with a mission of securing a future for all species through science, policy, education, and environmental law. One of CBD's flagship programs is its environmental health program, which focuses on, among other things, the adverse impacts of pesticides.

Food & Water Watch (FWW) is a national, nonprofit membership organization that mobilizes regular people to build political power to move bold and uncompromised solutions to the most pressing food,

water, and climate problems of our time. FWW works to protect people's health, communities, and democracy from the growing destructive power of the most powerful economic interests.

INTRODUCTION AND SUMMARY OF ARGUMENT

Monsanto's arguments are all predicated on the core claim that EPA has "determined" that glyphosate does not cause cancer. That reliance is legally, factually, and scientifically incorrect: the glyphosate registration review and its "not likely to be carcinogenic" finding on which Monsanto so heavily relies was held unlawful and judicially vacated four years ago because it was contrary to EPA's own basic cancer risk assessment standards in multiple ways.

More broadly, Monsanto also claims that state law cancer warnings are unnecessary—despite FIFRA otherwise being a prime example of cooperative federalism—because EPA's risk assessment in pesticide registration is "exhaustive," and thus sufficient to protect farmers, farmworkers, and everyday Americans. But EPA's registration process is the antithesis of robust: it is a narrow review system rife with data gaps, limitations, loopholes, delays, and lack of enforcement. And the EPA's Office of Pesticide Products is a paradigmatic example of a captured agency, which has required decades of dogged public interest litigation to force it to comply with its most basic duties.

Not only is EPA's risk assessment inadequate, but the agency almost never requires a cancer risk warning on labels, even when it finds a pesticide poses a risk of cancer. Monsanto's hyperbolic claims of "over-

warning" on pesticides are the antithesis of reality: 2026 analyses of EPA's historic and current pesticide assessments reveal that even when EPA admits pesticides are linked to cancer, the agency still does not warn users. Of the 570 unique pesticide chemicals assessed by EPA, *over one-third* (35%) have carcinogenic potential: 127 are "possible human carcinogens" or exhibit "suggestive evidence of carcinogenicity," while 73 are "likely" or "probable" human carcinogens. Yet, in a comprehensive review of more than 93,000 pesticide product labels, *only 1%* had any cancer warning for active ingredients that EPA itself designated a "probable" or "likely" carcinogen.

And new product labels do not constitute any new risk assessment or EPA determination; they simply rely on work done at the registration review level. In practice, product label content is determined by the registrant; EPA only stamps its approval. Monsanto could at any time seek label amendments to add cancer warnings on its glyphosate-based products, and EPA would oblige.

Cancer is an epidemic, afflicting more than 1 in 3 Americans within their lifetimes. The Court should not afford Monsanto immunity for its products' risks, nullify the important role that States play in the FIFRA cooperative federalism model, and deny Americans their right to know the risks of an inherently dangerous product, particularly given the severe limitations of EPA's pesticide risk assessment structure, implementation, and track record.

ARGUMENT

I. Monsanto Relies Heavily on EPA's Glyphosate Registration Review That Was Held Unlawful, Contrary to Core Cancer Science, and Vacated.

To both claim preemptive effect and assure the Court of EPA's purported rigor and comprehensiveness in pesticide risk assessment, Monsanto heavily relies on EPA's registration process, claiming it is "exhaustive," "rigorous," and "comprehensive." Monsanto Br. at 7, 23, 25. Specifically, Monsanto relies—over and over again—on EPA's 2020 glyphosate registration review decision and the 2017 "not likely" cancer classification on which that registration was based. *Id.* at 11, 12, 14, 15. Indeed, Monsanto's brief quotes the 2017 EPA Cancer Paper's conclusions as setting forth the "strongest support" for its claim that glyphosate is not carcinogenic. *Id.* at 15. State law cancer warnings are not needed, Monsanto assures the Court, because EPA is ensuring glyphosate is not causing cancer or other harm it considers unreasonable with its registration review.

What Monsanto glosses over is that the EPA decision that it relies so heavily on was *judicially vacated four years ago* specifically because of the fundamental flaws in its evaluation of glyphosate's carcinogenic potential.

That decision, by a three-judge panel comprised of Judges Friedland and Wallace of the Ninth Circuit, and Judge Boggs of the Sixth Circuit, was unanimous. In it, the panel undertook an exhaustive examination of the evidentiary record and underlying, intertwined

EPA risk assessments, resulting in a decision supported by numerous factual record findings. And contrary to Monsanto's gross mischaracterization of the decision's holdings as based on EPA's mere failure to adequately explain, the court held EPA's human health risk assessment was fundamentally flawed in its substance, as well as contrary to law and violative of well-settled cancer science standards in at least five ways, set forth below. *Rural Coalition/NRDC*, 38 F.4th at 45-51.

A. EPA's Irreconcilable Inconsistency in its "Not Likely to Cause Cancer" Classification.

EPA said it could not reach a conclusion about whether glyphosate causes the type of cancer (non-Hodgkin lymphoma (NHL)) to which glyphosate is most strongly linked, but nevertheless concluded that it was overall "not likely" to cause cancer, an irreconcilable inconsistency.[2] With respect to cancer, EPA's registration review decision is *based entirely* on its *2017 Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* ("Cancer Paper"),[3] which the court held "contravened [EPA's] Cancer Guidelines it purported to follow." *Rural Coalition/NRDC*, 38 F.4th at 45. Again, this is the very same cancer assessment

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[2] EPA, GLYPHOSATE: INTERIM REGISTRATION REVIEW DECISION 10 (2020), https://www.epa.gov/sites/default/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

[3] EPA, REVISED GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL (2017), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0385-0528.

on which Monsanto so heavily relies. Monsanto Br. at 11, 12, 14, 15, 17, 31, 48, 49.

EPA's 2005 Guidelines for Carcinogen Risk Assessment[4] ("Cancer Guidelines") set the standards for how EPA is supposed to undertake cancer risk assessment, and EPA's 2020 registration decision, its 2017 Human Health Risk Assessment,[5] and the Cancer Paper all expressly rely on those Guidelines. *Rural Coalition/NRDC*, 38 F.4th at 45. Further, EPA "tie[d] itself to the Cancer Guidelines" in the registration decision, repeatedly saying it was following them in its approach, but instead flouting them in fundamental ways. *Id.*

The Cancer Guidelines classification of "not likely to be carcinogenic to humans" applies *only* when the data is "*robust*" to support there is "no basis for human hazard concern." *Id.* at 46-47. Yet in the Cancer Paper, EPA concluded that "the association between glyphosate exposure and risk of NHL *cannot be determined* based on the available evidence." *Id.* at 46. (emphasis added). EPA was unable to rule out NHL because "some epidemiological studies . . . provide evidence of an exposure-response relationship between

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[4] EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[5] EPA, DRAFT HUMAN HEALTH RISK ASSESSMENT IN SUPPORT OF REGISTRATION REVIEW (2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0068 (citing Cancer Paper with no changes to assessment).

glyphosate and NHL." *Id.*[6] The court highlighted this irreconcilable inconsistency, holding that EPA "cannot reasonably treat *its inability to reach a conclusion* about NHL risk as consistent with a *conclusion that glyphosate is "not likely"* to cause cancer within the meaning of the Cancer Guidelines." *Id.* at 47 (emphases added).

The panel then went on to analyze at length how the "analysis underpinning EPA's 'not likely' descriptor is also flawed in various other ways." *Id.* The decision took apart EPA's rationales, unpacking them in detailed analysis, concluding that they did not "withstand[] scrutiny" even applying the "agency's own framework." *Id.*

B. Four Ways EPA Improperly Discounted Study Results.

In evaluating animal carcinogenicity studies, EPA relied on key interpretive indicia when it helped dismiss cancer findings, but never when it would support them. EPA discounted all tumors observed in animal studies as not being "treatment-related" by improperly tipping the scales in favor of glyphosate. *Id.* In so doing EPA's approach and conclusions again conflicted with the Cancer Guidelines it purported to follow. *Id.* at 47-49.

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[6] EPA elsewhere improperly discounted these epidemiological studies showing increased NHL risk—ostensibly to avoid a conclusive determination on glyphosate's potential to cause NHL—by attributing the associations to "chance and/or bias," despite that also being inconsistent with the Cancer Guidelines framework. *Id.* at 46-47.

First, as to the interpretative indicium of "historical-control data,"[7] EPA applied it "selectively" and in a manner "inconsistent with the Cancer Guidelines." *Id.* at 47. Specifically, EPA used the historical-control data "only to *discount* studies indicating glyphosate may cause tumors," rather than applying the data even-handedly to either *bolster* or *weaken* the case for glyphosate causing observed tumors. *Id.* at 48 (emphasis added).

But the Cancer Guidelines instructed EPA should apply the historical-control factor when it could both *add* weight to study findings (like a given tumor was rare and thus unlikely to be due to chance), and when it *reduces* likelihood (if a type of tumor was common in the specific test animal). *Id.* Instead, EPA used this indicium only on one side of the scale, to discount studies indicating glyphosate may cause tumors. *Id.* The FIFRA Scientific Advisory Panel (SAP), tasked by EPA with providing a critical review of the agency's draft Cancer Paper, had similarly concluded there were "numerous instances in which historical-control data could *add* weight to tumor findings, but EPA never used the data in that manner." *Id.* (emphasis in the original). Yet EPA did not remedy the failings in the final assessment.

Second, EPA misused another "treatment-related" indicator—lack of pairwise statistical significance—applying it "inconsistent[ly] with the Cancer Guidelines." *Id.* at 48. EPA applied a more demanding

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[7] These are data that show the natural frequency of different types of tumors. *Id.*

statistical threshold than it should have and thus systematically minimized evidence of cancer risk.

Pairwise comparison and trend tests are two different tests, both assessing statistical significance, "which is an indication that a particular result is unlikely due to chance." 38 F.4th at 48.[8] For glyphosate, EPA required significance "in both types of tests" to conclude tumor results were treatment-related, making it much harder for any tumor finding to count. *Id.* at n.9. But pursuant to the Cancer Guidelines "significance in *either* kind of test is sufficient to reject the hypothesis that chance accounts for the result." *Id.* at 48 (emphasis in original). Accordingly, "EPA's flawed use of two of the indicia to infer a lack of treatment-related effects is sufficient to undermine the agency's assessment" of the studies examined. *Id.* at n.7.

Both EPA's Office of Research and Development (ORD) and the SAP had pointed out to EPA that its draft assessments had improperly discounted tumor incidences only because they were not statistically significant in pairwise comparison tests, "when those same tumor incidences were apparently statistically significant using trend tests." *Id.* at 48. SAP told EPA in no uncertain terms that "requiring a significant pairwise comparison . . . *in addition to* a significant trend is neither consistent with the [Cancer

[8] A *pairwise comparison* test asks whether tumor incidence in a treatment group was higher than in the control group, whereas a *trend test* asks whether tumor incidences follow a pattern of more tumors in groups of animals fed higher doses. *Id.*

Guidelines] nor a conservative approach for public health protection." *Id.* (emphasis the SAP's).

EPA's misuse of interpretative indicia was not a limited failing; it was systemic, decisively shaping the agency's evaluation and conclusion: "EPA relied upon these indicia *so often* throughout the Cancer Paper that it is *impossible to know* what conclusion EPA would have reached without them." *Id.* at n.7 (emphases added). In contrast EPA's ORD did reach a conclusion–suggestive evidence of carcinogenic potential–based only on epidemiology linking glyphosate to NHL, and without regard to animal studies showing glyphosate causes cancer in animals.[9] EPA could only discount tumors as unrelated to glyphosate by violating core tenets of the Cancer Guidelines to which it professed adherence.

Third, EPA improperly disregarded high-dose tumor results. When lab animals developed tumors at higher doses of glyphosate, EPA ignored those results in its assessment. That is, EPA improperly discounted animal studies with high-dose tumors by claiming that the tumor results were "not considered relevant to human health risk assessment based on the currently registered use pattern." *Rural Coalition/NRDC*, 38 F.4th at 49.

Again, EPA's conclusions conflicted with its own Cancer Guidelines; worse, the agency's approach was even "contrary to the 'purpose' of a hazard

[9] EPA, OFF. OF RSCH. & DEV., EPIDEMIOLOGIC EVIDENCE [OF GLYPHOSATE] (2016), https://www.documentcloud.org/documents/20786671-doc101719.

assessment," which is to first identify carcinogenic effects and mode of action, so that later steps can determine the risk of cancer based on human exposure levels. *Id.* at 50, 51.[10]

"The Cancer Guidelines do not support disregarding results simply because they are based on exposures that exceed typical human-exposure levels." *Id.* at 50. Indeed, "in order to obtain the most relevant information from a long-term carcinogenicity study, it is important to maximize exposure conditions…"[11] and "in general . . . effects seen at the highest dose tested are assumed to be appropriate for assessment." 38 F.4th at 50. The Cancer Guidelines explain that results may be excluded from the carcinogenicity assessment "only if *adequate data demonstrate* that the effects are *solely the result of excessive toxicity* rather than the carcinogenicity of the tested agent *per se*." *Id.* (emphasis added). That is, under the Guidelines, EPA should only disregard the results if the dose was so excessively high that any tumor effects were secondary to severe sickness rather than due directly to the agent. But EPA had provided "no evidence" of that. *Id.*

Fourth, EPA improperly relied on a purported "limit dose" of 1,000 mg/kg/day, that neither the Cancer Guidelines nor EPA's Health Effects Test Guidelines supported. *Id.* at 49-52. Still *another*

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[10] EPA first determines the likelihood a chemical can cause cancer (*e.g.,* known, likely or possible carcinogen), and only when it is classified as known or likely does it go on to "integrate human-exposure patterns into the risk assessment," that is, determine the risk of it causing cancer in real-world situations. *Id.* at 50.

[11] EPA, *supra* note 4 at p. 2-17.

unauthorized exclusion of important data. The SAP, in its comments on the draft Cancer Paper, also concluded that EPA improperly discounted study results above that threshold. *Id.* at 51. Yet again, despite this criticism from its own expert scientific body, EPA failed to change its approach in its final decision or meaningfully respond. *Id.*

C. EPA Contravened Its Cancer Guidelines, Office of Research and Development, and Expert Scientific Advisory Panel.

EPA repeatedly "invoke[d]," "purport[ed] to follow," indeed "tie[d]," itself to its Cancer Guidelines. *Id.* at 45, 49. Yet its "not likely" analysis and conclusion was contrary to them, repeatedly. *Id.* at 45, 46, 47, 48, 49, 50, 51. And both the agency's expert SAP and its ORD criticized many of these same fundamental risk assessment errors, which EPA ignored. *Id.* at 41-42, 48, 51 (explaining that "ORD's criticisms did not change EPA's overall 'not likely' determination" and that EPA ignored the SAP's concern regarding "improperly discounted study results," among other things).

So, when Monsanto incessantly cites the glyphosate registration review and its underlying risk assessments in support of its claims, it is relying on EPA action held to be irreconcilably contradictory, fundamentally flawed, and contrary to basic scientific standards, as EPA's own expert bodies told it, but which EPA chose to ignore.

Summing up, the court held that for all the reasons explained above, "EPA's choice of a hazard descriptor [not likely to be carcinogenic to humans] is

not supported by substantial evidence." *Id.* at 51. The registration decision "fails to abide by the [Cancer] Guidelines," despite EPA's repeated invocation of them. *Id.*[12] And because of EPA's "[in]consistent reasoning," the decision "cannot survive substantial-evidence review." 38 F.4th at 51.

D. Vacating the Registration Review Because of its Serious Errors.

In view of these flaws, the panel vacated the registration. The administrative law remedy of vacatur renders agency actions null and void, without legal force or effect.[13] The first factor in the vacatur test is the seriousness of the agency's legal violations. 38 F.4th at 52. In the registration review case, this factor "clearly weigh[ed] in favor of vacatur" because "EPA's errors in assessing human-health risks are serious." *Id.*

Monsanto (Br. at 17, 31) grossly mischaracterizes the record, making it seem like the errors held by the court were procedural and minor and could be cured simply by better drafting after remand. That is contradicted by the panel opinion, as explained above. The court identified at least five specific substantive

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[12] Even Monsanto acknowledges the importance of the cancer guidelines despite attempting to still rely on the registration review. Monsanto Br. at 24.

[13] *E.g.*, Monsanto v. Geertson Seed Farms, 561 U.S. 139, 165-66 (2010); Corner Post, Inc. v. Board of Governors of Federal Reserve System, 603 U.S. 799, 826-43 (2024) (Kavanaugh, J., concurring); *Vacate,* Black's Law Dictionary (2nd ed.), https://thelawdictionary.org/vacate (last visited Mar. 30, 2026) ("To annul; to cancel or rescind; to rend an act void").

errors that cut to the core of EPA's cancer assessment and methodology, infecting its conclusions. *E.g.*, 38 F.4th at n.7 ("EPA relied upon these indicia *so often* throughout the Cancer Paper that it is *impossible to know* what conclusion EPA would have reached without them.") (emphases added). EPA's systemic violations decisively shaped how the agency evaluated the record and scientific evidence and were not mere problems in how it communicated its conclusions. Monsanto's position is also belied by EPA's own actions, or lack thereof: it has been four years, and EPA has yet to issue even a proposed new registration review decision.

The court used harshly critical language to describe these EPA violations and errors, such as "flawed use," *id.* at n.7, "bare assertion," *id.* at 49, "fails to account coherently for the evidence," *id.*, "disregarding results," *id.* at 50, "discounted" studies, *id.* at 46, 51, "unsupported" reliance, *id.* at 51, and "inconsistent" reasoning, *id.* at 46-48. Expert bodies ORD and the SAP pointed out many of these same errors to EPA, yet they went uncorrected in the final risk assessment. *See supra.*

After discussing the other remedy test factors, the Court concluded and held: "we vacate the human-health portion of EPA's Interim Decision and remand for further analysis and explanation." *Id.* at 52. Vacating the human-health portion of the registration review decision thus rendered it null and void.

As a result of the Court's vacatur and EPA's subsequent actions,[14] the 2020 registration review decision is without legal force or effect. Accordingly, glyphosate's current product registrations rely on the last legally operative assessment: the 1993 Reregistration Eligibility Decision (RED), based on 1986 (now superseded) cancer guidelines and data before glyphosate use exploded in U.S. agriculture. EPA has not made a court-upheld carcinogenicity determination for over thirty-three years.[15] This is what the individual pesticide product labels are left to rely on because, as explained below, they include no risk assessments themselves.

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[14] Instead of completing the registration decision by the deadline on remand, EPA notified the court in September 2022 that it was withdrawing the remaining parts of the registration that the court had not already vacated (*e.g.,* the ecological risk assessment and cost-benefit determination). Rural Coalition/NRDC, No. 20-70787, Dkt. 144-1 & 144-2 (Sep. 22, 2022).

[15] Monsanto relies on a 2019 EPA letter (Monsanto Br. at 16-17, 33) but that letter lacks the force of law and contains no *new* cancer risk analysis; instead, it simply refers back to the 2017 assessment that was eviscerated in judicial review. EPA also issued a 2022 memo Monsanto claims "re-affirmed" EPA's registration review findings. Monsanto Br. at 18, 49. But agencies cannot "re-affirm" vacated actions any more than one can "re-affirm" that a corpse is alive. They no longer exist legally. That memo similarly contained no new risk analysis, was not a final agency action with the force of law, and even admitted that EPA had to issue a future registration decision addressing glyphosate's cancer risks "following reconsideration in accordance with the court's decision," which EPA has not yet done.

II. Monsanto's Undue Influence Tainted EPA's Assessment.

Taken together, EPA's multiple risk assessment violations in the 2009-2020 glyphosate registration review reveal a systematic choice to depart from EPA's own bedrock standards to minimize cancer risk evidence. This was not random: EPA's Office of Pesticide Programs has long been a paradigmatic example of "regulatory capture."[16] But even given that longstanding institutional problem, Monsanto's glyphosate efforts are unprecedented: it is now well-documented that Monsanto spent many years influencing the scientific environment that shaped the registration review's cancer risk assessment.[17]

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[16] Where the regulatory agency that is created to act in the public interest instead advances the commercial concerns of the special interest groups that the agency is charged with regulating. Sharon Lerner, *The Department of Yes,* THE INTERCEPT (June 30, 2021), https://theintercept.com/2021/06/30/epa-pesticides-exposure-opp ("Interviews with more than two dozen experts on pesticide regulation – including 14 who worked at the EPA's Office of Pesticide Programs, or OPP – described a federal environmental agency that is often unable to stand up to the intense pressures from powerful agrochemical companies, which spend tens of millions of dollars on lobbying each year and employ many former EPA scientists once they leave the agency. The enormous corporate influence has weakened and, in some cases, shut down the meaningful regulation of pesticides in the U.S. and left the country's residents exposed to levels of dangerous chemicals not tolerated in many other nations.").

[17] Carey Gillam, *Monsanto Exec Reveals $17 Million Budget For Anti-IARC, Pro-Glyphosate Efforts,* U.S. RIGHT TO KNOW (Mar. 27, 2019), https://usrtk.org/monsanto-roundup-trial-

The public record reveals numerous examples of Monsanto's efforts to influence EPA's glyphosate risk assessments and eventual final decision, the scientific evidence and opinion on glyphosate, and public opinion, including: ghostwriting purportedly independent scientific papers;[18] enlisting EPA officials in charge of the registration review to undermine the 2015 International Agency for Research on Cancer (IARC) "probably carcinogenic to humans" cancer risk determination[19] and achieve "not likely to be carcinogenic" and "no risks to human health" determinations from EPA;[20] working to "kill" or suppress other independent

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tracker/monsanto-executive-reveals-17-million-for-anti-iarc-pro-glyphosate-efforts.

[18] Sean Rossman, *Emails show Monsanto tried to 'ghostwrite' research*, USA TODAY (Mar. 16, 2017), https://www.usatoday.com/story/news/nation-now/2017/03/16/emails-show-monsanto-tried-ghostwrite-research/99248950; Dan Charles, *Emails Reveal Monsanto's Tactics To Defend Glyphosate Against Cancer Fears*, NPR (Mar. 15, 2017), https://www.npr.org/sections/thesalt/2017/03/15/520250505/emails-reveal-monsantos-tactics-to-defend-glyphosate-against-cancer-fears.

[19] Despite Monsanto's reliance on agreement by other world regulatory bodies, 94 medical scientists from the U.S. and abroad support IARC's classification of glyphosate as "probably carcinogenic to humans." Christopher Portier *et al.*, *Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, 70 J. EPIDEMIOLOGY & CMTY. HEALTH 741 (2016), https://doi.org/10.1136/jech-2015-207005.

[20] Danny Hakim, *Monsanto Weed Killer Roundup Faces New Doubts on Safety in Unsealed Documents*, N.Y. TIMES (Mar. 14, 2017), https://www.nytimes.com/2017/03/14/business/monsanto-roundup-safety-lawsuit.

scientific research;[21] and extraordinarily broad efforts to influence the public and media discourse.[22]

A 2021 academic study published in the peer-reviewed journal *Research Policy* undertook a "systematic inquiry" of Monsanto's actions during registration review and concluded that "it is now generally recognized that Monsanto engaged in research misconduct to distort the scientific record with the goal of preventing proper regulatory oversight by the US Environmental Protection Agency."[23] To give one high profile example, in December 2025, a scientific journal formally retracted the ghostwritten "Williams study" over "serious ethical concerns." That study was not just any study: it had been the cornerstone of Monsanto's glyphosate defense, cited by regulators and academics more than 99.9% (*top 0.1%)* of all studies in

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[21] *Id.*; Michael Hytha et al., *Ex-EPA official allegedly bragged about killing investigation*, FARMFUTURES/BLOOMBERG (Mar. 16, 2017), https://www.farmprogress.com/farm-business/ex-epa-official-allegedly-bragged-about-killing-investigation; Joel Rosenblatt et al., *EPA official accused of helping Monsanto 'kill' cancer study,* BLOOMBERG (Mar. 14, 2017), https://www.bloomberg.com/news/articles/2017-03-14/monsanto-accused-of-ghostwriting-papers-on-roundup-cancer-risk#xj4y7vzkg.

[22] Stacy Malkan, *Attacks on Scientists: Lessons from the Monsanto papers,* COLLABORATIVE FOR HEALTH & ENV'T (July 9, 2024), https://www.healthandenvironment.org/latest-research/blog/attacks-on-scientists-lessons-from-the-monsanto-papers.

[23] Leland Glenna et al., *Suborning science for profit: Monsanto, glyphosate, and private science research misconduct*, 50 RSCH. POL'Y 104290 (2021), https://doi.org/10.1016/j.respol.2021.104290.

glyphosate-related research and risk review,[24] including of course EPA relying heavily on the now-retracted study in the registration review.[25]

III. Registrant Pesticide Product Labels Approved by EPA Carry No Preemptive Weight.

The glyphosate registration review fatally belies any claims that EPA has assured glyphosate's cancer safety. But even when EPA *does* find pesticides pose cancer risks, public records reveal EPA *still* does not require warnings on the manufacturer-drafted labels it approves. *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 435, 438 (2005); 7 U.S.C. §§ 136a(c)(1)(C), (c)(9) (it is the *manufacturer* (here Monsanto) that drafts labels, EPA merely approves them). Additionally, approval of individual product labels does not trigger any further risk assessment but merely relies back on past assessments of the active ingredient, further

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[24] Warren Cornwall, *Journal retracts weed killer study backed by Monsanto, citing 'serious ethical concerns,'* SCI. (Dec. 5, 2025), https://www.science.org/content/article/journal-retracts-weed-killer-study-backed-monsanto-citing-serious-ethical-concerns; Hiroko Tabuchi, *A Study Is Retracted, Renewing Concerns About the Weedkiller Roundup*, N.Y. TIMES (Jan. 2, 2026), https://www.nytimes.com/2026/01/02/climate/glyphosate-roundup-retracted-study.html; Alexander Kaurov et al., *The afterlife of a ghost-written paper: How corporate authorship shaped two decades of glyphosate safety discourse*, 171 ENV'T SCI. & POLICY 104160 (2025), https://doi.org/10.1186/s12940-019-0488-0.

[25] EPA, *supra* note 3 at 22 and 99; EPA, GLYPHOSATE: REPORT OF THE CANCER ASSESSMENT REVIEW COMMITTEE, 8-9, 58-63 (2015), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0385-0014 (citing the Williams study eleven times).

proof that state failure to warn claims are not preempted. *Bates,* 544 U.S. at 449.

A. EPA Frequently Approves Potentially Carcinogenic Pesticides but Virtually Never Requires Cancer Warnings.

Two new 2026 analyses of EPA's pesticide regulation concluded EPA *frequently approves* potentially carcinogenic pesticides, but *virtually never requires* cancer warnings on labels drafted by registrants. Not only has EPA abdicated its duty by approving labels that "omit necessary warnings or cautionary statements," 7 U.S.C. §§ 136(q)(1)(F), (G), but Monsanto's hyperbolic claims (Br. at 42, 52) of the cost of "excessive" or "unnecessary" warnings has the problem exactly reversed. *Bates*, 544 U.S. at 451-52 ("Dow and the United States exaggerate the disruptive effects of using common-law suits to enforce the prohibition on misbranding.").

The first study analyzed EPA's regulation at the active ingredient level, including current and legacy pesticides.[26] Specifically, of the 570 unique pesticide

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[26] CTR. FOR FOOD SAFETY, ANALYSIS OF FEDERAL RECORDS REGARDING THE CANCER HAZARDS & RISKS OF EPA-APPROVED PESTICIDES (Mar. 2026), https://www.centerforfood-safety.org/files/cfs-pesticide-preemption-and-cancer-warning-analysis--march-2026_68842.pdf. The analysis is based on the EPA Office of Pesticide Program's latest listing (October 2024) of the cancer hazard classifications assigned to pesticides and related chemicals. EPA, CHEMICALS EVALUATED FOR CARCINOGENIC POTENTIAL BY OFFICE OF PESTICIDE PROGRAMS (2024), https://npic.orst.edu/chemicals_evaluated.pdf. Of the 692 entries, 122 represent alternate names, leaving 570 unique pesticide chemicals.

chemicals EPA has assessed for carcinogenic potential since 1985, EPA classified over one-third (35%) as "possible human carcinogens"/"suggestive evidence of carcinogenic potential" (127) or as "probable/likely" human carcinogens (73). *Id.* [And belying the Petitioners' masquerade of the "comprehensive" nature of EPA's review, the status of 62 others (11%) is shockingly uncertain, because EPA lacks sufficient data to even make a determination. *Id.*]

A second comprehensive review at the pesticide product level found EPA failed to put pesticide cancer warnings in place for thousands of pesticide products even *when EPA's own assessments found links to cancer*.[27] The assessment reviewed more than 93,000 historic and currently approved pesticide labels for all active "end-use" pesticide products currently available. *Id.*

The study found that *only 69 of 4,919 pesticide labels* (*or 1.4%)* containing an active ingredient that EPA designated a "probable" or "likely" human carcinogen included a cancer warning. *Id.* Cancer warnings appeared on *only 242 of the 22,147* pesticide labels *(1%)* that contain an ingredient the agency has designated as having "possible" or "suggestive" evidence of carcinogenic potential. *Id.*[28]

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[27] CTR. FOR BIOLOGICAL DIVERSITY, EPA'S FAILURE TO WARN (2026), https://biologicaldiversity.org/programs/environmental_health/pdfs/Failure-to-Warn.pdf.

[28] The reality is even worse than it sounds: The 311 total labels with cancer warnings actually represent a far smaller number of products and active ingredients. First, the total count includes

Notably, EPA approves likely carcinogenic pesticides whose various uses lead to substantial risks of cancer far higher than its "benchmark level of concern" of 1 additional cancer among 1 million exposed.[29] EPA predicts drinking water contaminated with certain fungicides can cause cancer in up to 4 in 10,000 of those exposed, while residential and occupational uses of certain pesticides can cause cancer in 7 of 1,000, a 7,000-fold higher risk than EPA supposedly finds concerning.[30]

EPA also approves many hazardous pesticides on the assumption users will mitigate risks by wearing "personal protective equipment" (PPE),[31] like chemical-resistant gloves, rubber boots, double-layer clothing, aprons and/or respirators. While studies show

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multiple label iterations for individual products over time, with each iteration correcting slight (*e.g.,* typographical) errors or making minor revisions. Second, the labels represent products containing *only 6 of 125* currently registered active ingredients EPA has linked to cancer, as either likely/probable or possible/suggestive evidence carcinogens. Finally, the few cancer warnings are themselves haphazard: Some products containing the same active ingredient include indication of carcinogenicity on the label and others do not, despite being formulated with the same amount of active ingredient and approved for the same uses. *Id.*

[29] CTR. FOR FOOD SAFETY, *supra* note 26 at 1.

[30] *Id.* at 2.

[31] Alain Garrigou et al., *Critical Review of the Role of PPE in the Prevention of Risks Related to Agricultural Pesticide Use,* 123 SAFETY SCI. 104527 (2020), https://doi.org/10.1016/j.ssci.2019.104527.

workers do not always wear required PPE,[32] research also confirms the common-sense notion that workers who are informed a pesticide can cause cancer or other serious (*e.g.,* reproductive) harm—for instance through "government warning stickers or labels"—are far more likely to wear risk-reducing PPE.[33]

Where EPA has failed, states have filled the gap, in the robust cooperative federalism model FIFRA contemplates. *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991); 7 U.S.C. §§ 136t(b), 136u, 136v(a) ("[s]tate[s] may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter"); 136w-1 (states with adequate laws have primary enforcement authority). States can be *more* protective than EPA, just not less protective. *Id.* § 136v(a).

Crucially, just because pesticides are *registered* does not mean they are not *misbranded*, hence registrants' continuing duty to comply with labeling requirements and "report incidents involving a pesticide's toxic effects that may not be adequately reflected in its label's warnings." *Bates*, 544 U.S. at 439. And whether a particular product is "misbranded" is a factual determination dependent on whether the

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[32] Melissa Perry et al., *Compliance with required pesticide-specific protective equipment use*, 41 AM. J. INDUS. MED. 70-73 (2002), https://doi.org/10.1002/ajim.10026.

[33] Gregory Kearney et al., *Assessment of Personal Protective Equipment Use Among Farmers in Eastern North Carolina: A Cross-sectional Study,* 20 J. AGROMEDICINE 43 (2015), https://doi.org/10.1080/1059924X.2014.976730.

label warnings are sufficient to protect public and environmental health. S. REP. NO. 92-838, at 14 (1972) *as reprinted in* 1972 U.S.C.C.A.N. 3993, 3995. Registration with the information submitted concurrently does not preclude a finding of misbranding based on later findings.

Not only does FIFRA explicitly grant the States various powers in its plain text, it also "leaves ample room for States and localities to supplement federal efforts even absent the express regulatory authorization of § 136v(a)." *Mortier*, 501 U.S. at 613. "FIFRA nonetheless leaves substantial portions of the field vacant, including the area at issue in this case . . . Whatever else FIFRA may supplant, it does not occupy the field of pesticide regulation in general . . . ." *Id.* at 613-14.

For example, California requires warnings for products (including pesticides) that contain significant levels of chemicals that cause cancer, birth defects, or reproductive harm. *See* Cal. Health & Safety Code §§ 25249.5–.14. A recent analysis found more than 1,250 pesticide product labels indicated compliance with California's Proposition 65, including many deemed carcinogenic by EPA.[34] For example, California (but not EPA) lists fungicides chlorothalonil (EPA-designated "likely to be carcinogenic to humans") and mancozeb (an EPA "Group B probable human

[34] CTR. FOR BIOLOGICAL DIVERSITY, *supra* note 27 at 5.

carcinogen") as chemicals subject to the law's warning requirements.[35]

Warning labels give users critical information, and the means to make their own independent, informed decisions regarding whether and if so how to use inherently dangerous products. In this way, products a state might otherwise prohibit can remain on the market.

If this Court preempts states from providing the public the right to know about cancer risks from pesticides and instead makes EPA the sole authority to implement warnings, the American public will be left completely in the dark. And EPA's track record shows without a doubt that it will not provide such warnings, even when it agrees the pesticide's use poses cancer risks.

B. Pesticide Product Labels Do Not Include Any Cancer Risk Assessment.

To conjure the result it needs to escape liability for the harm its products cause, Monsanto admits that it must find preemptive force in not just the registration but *also* the pesticide *product label*. It claims EPA's approval of Monsanto-created glyphosate product labels equals EPA having "considered and rejected" a cancer warning. Monsanto Br. at 1, 39 n.6 (Monsanto

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[35] *Id.* at 7; State of California, Off. of Env't Health Hazard Assessment, *Chemicals Considered or Listed Under Proposition 65: Chlorothalonil*, https://oehha.ca.gov/proposition-65/chemicals/chlorothalonil; State of California, Off. of Env't Health Hazard Assessment, *Mancozeb*, https://oehha.ca.gov/proposition-65/chemicals/mancozeb.

does not rely solely on the "bare fact of registration" for preemption, but instead, "relies on both registration *and* EPA's specific determination that a cancer warning for glyphosate-based products is not required under FIFRA."); 7 U.S.C. § 136a(f)(2) (registration alone may not be construed as a defense).

But EPA only conducts scientific assessments of toxicity, including carcinogenicity, at the *active ingredient level*. Contrary to Monsanto's misrepresentations, EPA's approval of registrant-drafted pesticide product labels does not include a cancer risk assessment, let alone any "findings" by EPA of cancer safety. They simply refer back to the underlying registration decision (here, from 33+ years ago). Under EPA's regulations, registrants effectively control the label, not EPA, and if they don't ask for a cancer warning, EPA never evaluates whether one is warranted. 40 C.F.R. § 152.44(a) (for labels, the applicant must only submit information "applicable to the change requested").

Carcinogenicity studies and risk assessment are conducted at the active ingredient level of registration, *not* at the product and product label stage. 40 C.F.R. §§ 158.500 (carcinogenicity studies assigned by active ingredient), 152.85 (product applicants exempt from independently submitting active ingredient risk data), 152.111 (data reviews on a "chemical-by-chemical" basis not in response to new product application). For individual products and their labels, except for a new active ingredient, EPA simply relies on the existing database; it does not undertake any new review. 40 C.F.R. § 152.111. Monsanto *has never asked* EPA to add a cancer warning; thus, EPA has never "determined" that a cancer warning is not required or

disallowed by FIFRA. Monsanto Br. at 1. In each glyphosate product label "approval," EPA simply relies on the underlying registration and otherwise only considers the scope which Monsanto requests.

The product label system itself shows it is not set up to include cancer risk warnings. *Notably, not a single word* in EPA's entire, 299-page Label Review Manual speaks to cancer warnings.[36] Pesticide labels routinely indicate only "acute" harms, the immediate effects of significant, one-time exposures. One prominent acute toxicity indicator is the median lethal dose (LD_{50}): the amount of a substance required to kill 50% of test rats.[37] But acute toxicity has nothing to do with chronic toxicity, the adverse effects of repeated, low-level exposure to a toxin over years, such as cancer.[38]

The real work to assess the risks of an active ingredient, including cancer risk, is only done during initial active ingredient registration or registration review, which only happens every 15 years. 7 U.S.C. § 136a(g)(1) (and even that 15-year deadline is merely theoretical, *see infra*). And for glyphosate, as discussed above, the last such review before the vacated-

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[36] EPA, LABEL REVIEW MANUAL (2024), https://www.epa.gov/pesticide-registration/label-review-manual.

[37] *Id.* at CH. 7: PRECAUTIONARY STATEMENTS, 7-2 to 7-3.

[38] NAT'L PESTICIDE INFO. CTR., SIGNAL WORDS 2 (July 2008), https://npic.orst.edu/factsheets/signalwords.pdf ("However, the LD_{50}/LC_{50} does not reflect any effects from long-term exposure (i.e. cancer, birth defects or reproductive toxicity) that may occur at levels below those that cause death.").

2020 registration was way back in 1993.[39] And the agency has not attempted to address the fundamental failings that required vacatur since.

IV. EPA's Pesticide Risk Review Is Neither Rigorous nor Continuous, Contrary to Monsanto's Claims.

Monsanto and the pesticide industry claim registered pesticides have been thoroughly assessed by EPA, more "proof" no further warnings are needed. The truth is EPA's review is the antithesis of their portrayal. Instead, the agency's approach leaves major data gaps; weakly applies regulatory thresholds; fails to weigh and account for significant risks/costs; and lacks transparency, public process, and accountability.[40]

A. Conditional Registration: the Exceptional Exception that Swallowed the Rule.

EPA's major risk assessment limitations begin with its heavy reliance on "conditional" registrations, meaning registration without all required data. 7

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[39] The 1993 registration, in addition to being decades out of date on usage and science, was also highly problematic and unduly influenced by Monsanto. *See, e.g.,* Carey Gilliam, *Of mice, Monsanto and a mysterious tumor*, ENV'T HEALTH NEWS (June 7, 2017), https://:www.ehn.org/of_mice_monsanto_and_a_mysterious_tumor.

[40] For longer treatment, *see generally* George Kimbrell et al., *Will Regulators Catch the Drift?* NFFC v. EPA *& Breathing New Life into Pesticide Regulation,* 51 ENV'T L. 667, 672-81 (2021) (and citations therein).

U.S.C. §§ 136a(c)(7)(A)-(C). While Congress intended this as very narrow exception,[41] EPA instead treats it as the rule: approximately 65%-70% of pesticides are conditionally registered, although due to lack of public transparency in EPA's oversight it is hard to gauge the actual number.[42] The U.S. Government Accountability Office (GAO) found EPA lacked a system to track these registrations, as well as whether the registrants *eventually ever even submitted the missing data*, or to enable adequate review of that data, an egregious lack of accountability and transparency.[43] While EPA claims to be improving these systems, its database shows that from 2011 to 2023, 49% of EPA-issued product registrations were still conditional.[44] EPA continues to conditionally register dangerous pesticide products that go on to cause significant

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[41] S. REP. NO. 95-334, at 10 (1977); *see also* 123 CONG. REC. 25,706 (daily ed. July 29, 1977) (statement of Sen. Leahy) ("I want to stress this use of conditional registration would only be in exceptional cases.").

[42] GAO, PESTICIDES: EPA SHOULD TAKE STEPS TO IMPROVE ITS OVERSIGHT OF CONDITIONAL REGISTRATIONS 3 (2013), https://www.gao.gov/assets/gao-13-145.pdf ("EPA's Office of Pesticide Programs Information Network (OPPIN) data system showed that conditional registrations represented the majority of active registrations."); JENNIFER SASS & MAE WU, NRDC, SUPERFICIAL SAFEGUARDS: MOST PESTICIDES ARE APPROVED BY FLAWED EPA PROCESS 2 (2013), https://www.nrdc.org/sites/default/files/flawed-epa-approval-process-IB.pdf.

[43] GAO, *supra* note 42 at 13, 19.

[44] EPA, *APPRIL Database*, https://ordspub.epa.gov/ords/pesticides/f?p=APPRIL_PUBLIC:2 (search conducted for first registration dates between Jan. 1, 2011 and March 27, 2026, 20,985 total active products, 10,248 (49%) conditional).

harm. *National Family Farm Coalition v. EPA,* 960 F.3d 1120 (9th Cir. 2020) (vacating three dicamba product conditional registrations because EPA substantially understated or ignored numerous risks, resulting in millions of acres harmed from off-field pesticide drift).

B. Major EPA Risk Assessment Limitations and Gaps.

Conditional or unconditional, EPA's pesticide registration process and structure is rife with other major gaps and structural limitations, a far cry from the "comprehensive" picture Monsanto paints.

Whole Formulations vs Active Ingredients: In its data requirements and risk assessment approach, EPA assesses only the active ingredient (*e.g.*, glyphosate), not the whole pesticide formulation (*e.g.*, Monsanto's "Roundup").[45] But a pesticide formulation has many *additional* ingredients (*e.g.*, solvents, surfactants) that can be toxic themselves, and which very often increase the active ingredient's toxicity.[46] Nonetheless, EPA narrowly focuses its data requirements

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[45] *See generally* CTR. FOR FOOD SAFETY, RULEMAKING PETITION SEEKING REVISED TESTING REQUIREMENTS OF PESTICIDES PRIOR TO REGISTRATION (July 10, 2017), https://www.centerforfoodsafety.org/files/2017-7-9-whole-formula-petition-to-epa-final_18181.pdf; Caroline Cox & Michael Surgan, *Unidentified Inert Ingredients in Pesticides: Implications for Human & Environmental Health*, 114 ENV'T HEALTH PERSPECTIVES 1803, 1803-05 (2006).

[46] Cox & Surgan, *supra* note 45.

on active ingredients *alone*—largely ignoring adverse effects of whole formulations.[47]

Example: In the 2020 registration review EPA failed to assess the *over 550 individual glyphosate formulations* for chronic harm, focusing instead narrowly on the active ingredient,[48] despite the admission of Monsanto's chief toxicologist:

> The terms glyphosate and Roundup cannot be used interchangeably nor can you use "Roundup" for all glyphosate-based herbicides any more. For example you cannot say that Roundup is not a carcinogen...we have not done the necessary testing on the formulation to make that statement. The testing on the formulations are not anywhere near the level of the active ingredient.[49]

Dermal Exposures: Testing is urgently needed to assess pesticides' dermal effects, the chief route of

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[47] 40 C.F.R. § 158.500; Karoly Nagy, *et al.*, *Systematic review of comparative studies assessing the toxicity of pesticide active ingredients and their product formulations*, ENVIRON RES. (2020), https://pubmed.ncbi.nlm.nih.gov/31791711/.

[48] EPA, *supra* note 5 at 9 ("Consistent with Agency policy, this evaluation focuses on studies performed with the active ingredient glyphosate and not studies performed with pesticide formulations containing glyphosate.").

[49] Email from Donna Farmer, Toxicology Programs Manager, Monsanto, to Sekhar Natarajan, Monsanto (Nov. 22, 2003, 4:46 AM), https://corporateeurope.org/sites/default/files/attachments/27-internal-monsanto-email-you-cannot-say-that-roundup-is-not-a-carcinogen.pdf.

exposure for residential and occupational users.[50] Surfactants in some glyphosate formulations cause severe burns[51] and increase dermal absorption of glyphosate upon skin contact but vary depending on formulation. Monsanto[52] and European regulators[53] agree on the need for formulation-specific dermal absorption tests, but EPA has failed to collect even one glyphosate dermal absorption study.[54]

Acute vs Chronic harms: To the limited extent that EPA assesses formulations at all, it is only for acute toxicity of no relevance to diseases like cancer that ensue from low-level chronic exposure.[55]

Waiver of Required Studies: Even for the narrow data it does require, EPA often waives data requirements. EPA has waived an astonishing number of otherwise required health-related studies, including

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[50] EPA, HAZARD IDENTIFICATION: TOXICOLOGY ENDPOINT SELECTION PROCESS 14 (1998), http://cfs.center/epahazardid (emphasis added).

[51] EPA, GLYPHOSATE: TIER II INCIDENT REPORT 6-11 (2014), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0069.

[52] C. Gustin et al., *Clustering glyphosate formulations with regard to the testing for dermal uptake*, Monsanto St. Louis, Monsanto Brussels (July 2001), https://usrtk.org/wp-content/uploads/2017/10/Glyphosate-formulations-testing-for-dermal-uptake-Monsanto-Brussels.pdf.

[53] Eur. Food Safety Auth. et al., *Guidance on dermal absorption*, 15 EFSA J. 1, 9 (2017), https://doi.org/10.2903/j.efsa.2017.4873.

[54] EPA, *supra* note 5 at 12.

[55] *Id.* at 47; 40 C.F.R. § 158.500 ("EP" = formulated "end product" while TGAI is the "pure" active ingredient).

most company-requested waivers for studies assessing harm to the developing fetal brain, cancer, and the immune system.[56]

C. EPA's Delay, Inaction, and Enforcement Failure.

Monsanto (Br. at 8-9, 38) paints a rosy picture of registrants continuously providing EPA with new information and EPA reviewing pesticides regularly to determine whether a pesticide still meets the FIFRA safety standard and cancelling them when they don't. But the regulatory reality is very different.

Glyphosate's last registration was 1993. EPA started registration review in 2009, issued its now vacated decision in 2020. Review is still unfinished and without a lawful carcinogenicity determination in 2026. Despite its first approval in 1974, and a drastic increase in use and critical scientific evidence since 1993, EPA has yet to complete even one (lawful) registration review for the most widely used pesticide on the planet.

And glyphosate is representative, not singular: EPA has similarly failed to meet the registration review timeline for *many* major pesticides (*e.g.,* imidacloprid (32 years), atrazine (20 years), chlorothalonil (28 years), and paraquat (29 years)), despite

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[56] Anna Lowit, *Waiving studies for human risk assessment of pesticides at USEPA, Office of Pesticide Programs*, Slide 19, EPA (Feb. 18, 2020), https://risk21.org/wp-content/uploads/2020/03/Lowit-RISK21-Summit-2020.pdf; Lerner, *supra* note 16 (noting EPA held a party to celebrate the 1000th waived study).

increasing and overwhelming evidence of their harm to human health and the environment.[57]

Monsanto cites FIFRA's duty that registrants report adverse effects, but that does not include a warning trigger or even label review. 7 U.S.C. § 136d(a)(2), 40 C.F.R. § 159.152. This duty is only as useful as what the registrants choose to submit and includes no affirmative mechanism to update labeling.

Finally, EPA very rarely cancels pesticides: EPA cancelled only one active ingredient between 2010-2020, four between 2000-2010, and a total of 37-40 ever.[58] Last year EPA issued its first emergency suspension of a pesticide in over 40 years.[59] In contrast, the pesticide industry has introduced over 16,000 products and 1,200 active ingredients.[60] The U.S. lags behind the rest of the world: At least 85 pesticides banned in China, Brazil, or Europe are still used in the U.S.[61]

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[57] EPA, *Upcoming Registration Review Actions*, https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions (listing numerous examples); Kimbrell, *supra* note 40 at 673-74 (same).

[58] Lerner, *supra* note 16.

[59] EPA, *EPA Issues Emergency Order to Stop Use of Pesticide Dacthal to Address Serious Health Risk* (Aug. 6, 2024), https://www.epa.gov/newsreleases/epa-issues-emergency-order-stop-use-pesticide-dacthal-address-serious-health-risk-4.

[60] Lerner, *supra* note 16.

[61] Nathan Donley, *The USA lags behind other agricultural nations in banning harmful pesticides*, 18 ENV'T HEALTH 44 (2019), https://doi.org/10.1186/s12940-019-0488-0.

In sum, these agency actions neither have preemptive effect nor can be relied upon as the sole arbiter of cancer safety for the American public.

CONCLUSION

Monsanto's heavy reliance on the registration review is like relying on a house for shelter after the building inspector declared it unsafe and razed it to the ground. It provides no form of preemption or assurance of public health protection. Nor do the individual pesticide product labels, which do not encompass cancer risk assessments or determinations by EPA. The regulatory record reveals that even for active ingredients EPA admits are linked to cancer risks, registrants do not provide and EPA does not require cancer warnings on product labels, providing no preemptive support. EPA's overall review is limited, leaving an important and robust role for states, which has been the settled status quo for decades.

The decision below should be affirmed.

Respectfully submitted,

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