Nos. 19-16636, 19-16708

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee / Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant / Cross-Appellee.

On Appeal from the United States District Court for the Northern District of California, Nos. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

AMICI CURIAE BRIEF OF CENTER FOR FOOD SAFETY AND CENTER FOR BIOLOGICAL DIVERSITY IN SUPPORT OF PLAINTIFF-APPELLEE EDWIN HARDEMAN

/s/ Ryan D. Talbott
RYAN D. TALBOTT
Center for Food Safety
2009 NE Alberta Street
Suite 207
Portland, OR 97211
971-271-7372
rtalbott@centerforfoodsafety.org

Counsel of record

March 23, 2020

CORPORATE DISCLOSURE STATEMENT

Amici curiae Center for Food Safety and Center for Biological Diversity are nonprofit corporations, have no parent corporations, and do not issue stock.

Dated: March 23, 2020

/s/ *Ryan D. Talbott*
RYAN D. TALBOTT
CENTER FOR FOOD SAFETY
2009 NE Alberta Street, Suite 207
Portland, OR 97211
T: (971) 271-7372
Email:
rtalbott@centerforfoodsafety.org

TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE* 1

INTRODUCTION AND SUMMARY OF ARGUMENT 3

ARGUMENT 4

I. Glyphosate's destructive effects on the environment, agriculture, and human health. 4

II. There is no preemption because "glyphosate" and "Roundup" are not synonymous. 9

A. Toxicity of co-formulants 11

B. Surfactants increase dermal absorption of glyphosate 15

C. Respiratory exposure to glyphosate 17

D. Aggregate exposure to glyphosate formulations 19

III. Flaws and Bias Undermined EPA's Evaluation of Glyphosate During Registration Review. 20

A. Dubious studies biased OPP's assessment 21

B. EPA violated cancer assessment guidelines to discount evidence of carcinogenicity in animal studies 24

C. EPA improperly dismissed epidemiology 29

D. Glyphosate persists in bone and bone marrow 32

E. Glyphosate triggers cancer-causing changes in genotoxicity assays involving bone marrow,

lymphocytes and other tissues 36

F. Integration of animal, human and mechanistic data points to glyphosate's carcinogenicity 39

G. EPA scientists in its research science division regard glyphosate as likely carcinogenic 41

CONCLUSION 42

TABLE OF AUTHORITIES

Page(s)

Cases

Ctr. for Food Safety v. Vilsack,
718 F.3d 829 (9th Cir. 2013) 5

Federal Statutes

7 U.S.C. § 136(bb) 10

7 U.S.C. § 136a(a) 10

7 U.S.C. § 136a(g) 10

Rules

Fed. R. App. P. 29(a)(2) 1

Fed. R. App. P. 29(a)(4)(E) 1

Other Authorities

A.J. De Roos et al., *Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men*, 60 Occup. & Envtl. Med. 5 (Sept. 2003), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740618/pdf/v060p00e11.pdf 29

A. Jauhiainen et al., *Occupational exposure of forest workers to glyphosate during brush saw spraying work*, 52 Am. Indus. Hygiene Ass'n J. 61-64 (1991), https://www.ncbi.nlm.nih.gov/pubmed/2011980 18

Alkyl Amine Polyalkoxylates; Exemption from the Requirement of a Tolerance, 74 Fed. Reg. 28616-24 (June 17, 2009) 13

Other Authorities (Cont'd) **Page(s)**

American Cancer Society, *What is Non-Hodkgin Lymphoma*? (last revised Aug. 1, 2018), https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html 33

Association of American Pesticide Control Officials, 1999 Pesticide Drift Enforcement Survey, AAPCO (Nov. 30, 1999), https://www.centerforfoodsafety.org/files/aapco-survey-1999_90996.pdf 18

Association of American Pesticide Control Officials, *2005 Pesticide Drift Enforcement Survey*. AAPCO (2005), https://www.centerforfoodsafety.org/files/aapco-2005_29712.pdf 18

B. Keim, *New generation of GM crops puts agriculture in a 'crisis situation,'* Wired, (Sept. 25, 2014), https://www.wired.com/2014/09/new-gm-crops/ 8

B.X. Semmens et al., *Quasi-extinction risk and population targets for the Eastern, migratory population of monarch butterflies* (Danaus plexippus), 6 Nature Sci. Rep. 23265 (2016), https://www.researchgate.net/publication/299267766_Quasi-extinction_risk_and_population_targets_for_the_Eastern_migratory_population_of_monarch_butterflies_Danaus_plexippus 7

C. Bento et al., *Glyphosate and AMPA distribution in wind-eroded sediment derived from loess soil*, 220 Envtl. Pollution 1079-1089 (Jan. 2017), https://www.researchgate.net/publication/310749189_Glyphosate_and_AMPA_distribution_in_wind-eroded_sediment_derived_from_loess_soil 19

Other Authorities (Cont'd) **Page(s)**

C. Bolognesi et al., *Biomonitoring of genotoxic risk in agricultural workers from five colombian regions: association to occupational exposure to glyphosate*, 72 J. Toxicology & Envtl. Health, Part A 986-997 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19672767 37

C. Cox and M. Surgan, *Unidentified inert ingredients in pesticides: implications for human and environmental health*, 114 Envtl. Health Perspectives 1803-06 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1764160/ 14

C. Dewey, *This miracle weed killer was supposed to save farms. Instead, it's devastating them*, The Washington Post (Aug. 29, 2017), https://www.washingtonpost.com/business/economy/this-miracle-weed-killer-was-supposed-to-save-farms-instead-its-devastating-them/2017/08/29/33a21a56-88e3-11e7-961d-2f373b3977ee_story.html 8

CFS, Comments to EPA's Scientific Advisory Panel reviewing EPA's *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential,* Sections 3.1, 4.1 (Oct. 12, 2016) (CFS 2016a), https://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments--cfs-20161_35863.pdf 22, 23, 26, 27, 28, 29

CFS, Supplemental Comments to EPA's Scientific Advisory Panel reviewing EPA's *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential,* Section 1.2 (Nov. 28, 2016) (CFS 2016b), http://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments-supplemental-corrected--cfs-2016_35425.pdf 26, 27

Other Authorities (Cont'd) **Page(s)**

C. Gustin et al., *Clustering glyphosate formulations with regard to the testing for dermal uptake*, Monsanto Company, at 4 (July 2001) (Monsanto 2001), https://www.centerforfoodsafety.org/files/monsanto-paper-clustering-glyphosate-formulations-with-regard-to-testing-for-dermal-uptake_86864.pdf 15, 16

C.M. Benbrook, *How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?*, 31 Envtl. Scis. Europe 1 (2019), https://enveurope.springeropen.com/track/pdf/10.1186/s12302-018-0184-7 38

C.J. Portier, *A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies*, 19 Environmental Health Table 2 (Feb. 12, 2020) (Portier 2020), https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00574-1 23

C. Paz-Y-Miño et al., *Evaluation of DNA damage in an Ecuadorian population exposed to glyphosate*, 30 Genetics & Molecular Biology 456-460 (2007), http://www.scielo.br/pdf/gmb/v30n2/a26v30n2.pdf 37

D.A. Mortensen et al., *Navigating a critical juncture for sustainable weed management,* 62 Bioscience 75-84 (Jan. 2012), https://academic.oup.com/bioscience/article/62/1/75/295845 9

Department of Health and Human Services, *Toxicological Profile for Glyphosate: Draft for Public Comment*, at 86 (Apr. 2019), https://www.atsdr.cdc.gov/toxprofiles/tp214.pdf 30

Other Authorities (Cont'd) **Page(s)**

D. Tush et al., *Characterization of polyoxyethylene tallow amine surfactants in technical mixtures and glyphosate formulations using ultra-high performance liquid chromatography and triple quadrupole mass spectrometry*, 1319 J. Chromatography A 80-87 (2013), https://www.ncbi.nlm.nih.gov/pubmed/24188997 12

D.W. Brewster et al., *Metabolism of glyphosate in Sprague-Dawley rats: tissue distribution, identification, and quantitation of glyphosate-derived materials following a single oral dose*, 17 Fundamental & Applied Toxicology 43-51 (1991), https://www.ncbi.nlm.nih.gov/pubmed/1916078 34

Endangered and Threatened Wildlife and Plants; 90-day Findings on Two Petitions, 79 Fed. Reg. 78775-78778 (Dec. 31, 2014) 6

EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system 41

EPA, Biological and Economic Analysis Division, *Pesticides Industry Sales and Usage: 2008-2012 Market Estimates*, at 14 (2017), https://www.epa.gov/sites/production/files/2017-01/documents/pesticides-industry-sales-usage-2016_0.pdf 5

EPA, Data Evaluation Record – Glyphosate: Pharmacokinetics, at pdf 3-6 (May 29, 1984), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-167.pdf 35

Other Authorities (Cont'd) **Page(s)**

EPA, email exchange between ORD scientists Vincent Cogliano and Norman Birchfield, at 2 (Dec. 7, 2015) (Cogliano 2015), https://assets.documentcloud.org/documents/4641115/Cogliano-Memo.pdf 41, 42

EPA, *Glyphosate: Response to Comments, Usage, and Benefits*, at 13, 17 (Apr. 18, 2019), https://www.epa.gov/sites/production/files/2019-04/documents/glyphosate-response-comments-usage-benefits-final.pdf 5

EPA, *Guidelines for Carcinogen Risk Assessment*, at 2-19 (Mar. 2005) (EPA 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf ..... *passim*

EPA, Health Effects Division, *Alkyl amine polyalkoxylates (JITF CST 4 inert ingredients)*, (Apr. 3, 2009) (EPA 2009), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0738-0005 12

EPA, Health Effects Division, *Glyphosate: Tier II Incident Report*, at 7 (Feb. 6, 2014), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0069 10

EPA, Health Effects Division, *Iprovalicarb – Report of the Cancer Assessment Review Committee*, at vi (Apr. 11, 2002) (EPA 2002), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/098359/098359-008.pdf 26

Other Authorities (Cont'd) **Page(s)**

EPA, Office of Pesticide Programs, Health Effects Division, *Glyphosate: Draft Human Health Risk Assessment in Support of Registration Review*, at 12 (Dec. 12, 2017) (EPA 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068 ..... 17, 19

EPA, Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 73-93 (Sept. 12, 2016) (OPP 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf 21

EPA, Office of Pesticide Programs, Health Effects Division, *Hazard Identification: Toxicology Endpoint Selection Process*, at 14 (Aug. 11, 1998), http://cfs.center/epahazardid 17

EPA, Office of Pesticide Programs, *Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and its Salts*, at 31 (June 5, 2009), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0007 14

EPA, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 70, 99 (December 12, 2017) (OPP 2017), https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=OPP&dirEntryId=337935 10

Other Authorities (Cont'd) **Page(s)**

EPA, Office of Prevention, Pesticides and Toxic Substances, *Glyphosate Reregistration Eligibility Decision (RED)*, at 18 (Sept. 1993) (EPA 1993), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf 35, 36

EPA, Office of Prevention, Pesticides and Toxic Substances, *Health Effects Test Guidelines: OPPTS 870.4200 Carcinogenicity*, at 4 (Aug. 1998) (emphasis added), https://nepis.epa.gov/Exe/ZyPDF.cgi/P100J73B.PDF?Dockey=P100J73B.PDF 25

EPA, Pesticide Re-Evaluation Division, *Glyphosate: Proposed Interim Registration Review Decision – Case Number 0178*, at 38 (Apr. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344 15

EPA, Pesticide Re-Evaluation Division, *Glyphosate: Report of the Cancer Assessment Review Committee*, at 39-57 (Oct. 1, 2015) (CARC 2015), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014 21

EPA, *Summary of ORD comments on OPP's glyphosate cancer assessment,* at 1, 3 (Dec. 14, 2015) (ORD 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf 41

E.T. Chang and E. Delzell, *Systematic review and meta-analysis of glyphosate exposure and risk of lymphohematopoietic cancers*, 51 J. Envtl. Sci. & Health, Part B, 402-434 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4866614/pdf/lesb-51-402.pdf 30

Other Authorities (Cont'd) **Page(s)**

European Commission, Health and Food Safety Directorate-General, *Addendum to the review report for the active substance glyphosate*, SANTE/11051/2016 rev 0 (July 11, 2016), https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1438 13

European Food Safety Authority, *Request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine*, 13 EFSA J. 4303 (Nov. 12, 2015), Section 2.5 (EFSA 2015), https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4303 ..... 12, 13

F. Chang et al., *Occurrence and fate of the herbicide glyphosate and its degradate aminomethylphosphonic acid in the atmosphere*, 30 Envtl. Toxicology & Chemistry 548-555 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21128261..... 18

FIFRA Scientific Advisory Panel, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding EPA's Evaluation of the Carcinogenic Potential of Glyphosate*, at 50, 51, 60-62, 72-74 (Dec. 13-16, 2016), https://apirs.plants.ifas.ufl.edu/site/assets/files/376003/376003.pdf 28

H.H. McDuffie et al., *Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health*, 10 Cancer Epidemiology, Biomarkers & Prevention 1155-63 (Nov. 2001), https://cebp.aacrjournals.org/content/10/11/1155.full-text.pdf..... 30

Other Authorities (Cont'd) **Page(s)**

Int'l Agency for Research on Cancer, *Some Organophosphate Insecticides and Herbicides*. In: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112, at 350 (IARC 2017), https://monographs.iarc.fr/wp-content/uploads/2018/07/mono112.pdf 30

J.A. van Burgsteden, *In vitro percutaneous absorption study with [^{14}C]glyphosate using viable rat skin membranes*, TNO Nutrition & Food Res., at 2 (June 14, 2002), https://baumhedlundlaw.com/pdf/monsanto-documents/70-b-TNO-Study-on-Dermal-Absorption-Referenced-in-Email-Correspondence.pdf 16

J.M. Pleasants and K.S. Oberhauser, *Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population,* 6 Insect Conservation & Diversity 135-144 (Mar. 12, 2012), https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1752-4598.2012.00196.x 6

J. Pucci, *The war against weeds evolves in 2018*, CropLife (Mar. 20, 2018), https://www.croplife.com/crop-inputs/the-war-against-weeds-evolves-in-2018/ 7

K. Schneider, *Faking It: The Case against Industrial Bio-Test Laboratories*, The Amicus Journal, Natural Resources Defense Council (Spring 1983), http://planetwaves.net/contents/faking_it.html 22

L.H. Nowell et al., *Complex mixtures of dissolved pesticides show potential aquatic toxicity in a synoptic study of Midwestern U.S. streams*, 613-614 Sci. Total Env't 1469-88 (2018), https://www.sciencedirect.com/science/article/pii/S0048969717315735 8

Other Authorities (Cont'd) **Page(s)**

L. Schinasi et al., *Non-Hodgkin Lymphoma and Occupational Exposure to Agricultural Pesticide Chemical Groups and Active Ingredients: A Systematic Review and Meta-Analysis*, 11 Int'l J. Envtl. Res. & Pub. Health, 4449-4527 (Apr. 2014), https://www.mdpi.com/1660-4601/11/4/4449/htm 30

L. Zhang et al., *Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence*, 781 Mutation Res. 186-206 (2019), https://www.ncbi.nlm.nih.gov/pubmed/31342895 32

M.E. Leon et al., *Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USA: a pooled analysis from the AGRICOH consortium*, 48 Int'l J. Epidemiology 1519-1535 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6857760/pdf/dyz017.pdf 32

M. Eriksson et al., *Pesticide exposure as risk factor for non-Hodking lymphoma including histopathological subgroup analysis*, 123 Int'l J. Cancer 1657-63 (2008), https://onlinelibrary.wiley.com/doi/epdf/10.1002/ijc.23589; 29

N. Donley, *Lost in the Mist: How Glyphosate Disproportionally Threatens California's Most Impoverished Counties*, Center for Biological Diversity (Nov. 2015), https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/LostInTheMist.pdf 3

Pesticide Registration Review; Interim Decision for Glyphosate; Notice of Availability, 85 Fed. Reg. 5957 (Feb. 3, 2020) 10

Other Authorities (Cont'd) **Page(s)**

P.J. Lennon et al., *Novel Surfactants and Formulations*, U.S. Patent Application No. US 2010/0234228 A1, assignee: Monsanto Technology, LLC paragraphs 0407 to 0613 (Sept. 16, 2010), http://appft.uspto.gov/netacgi/nph-Parser?p=1&u=%2Fnetahtml%2FPTO%2Fsearch-adv.html&r=1&f=G&l=50&d=PG01&s1=20100234228.PN.&OS=PN/20100234228&RS=PN/20100234228 14

Proposed Interim Registration Review Decision – Case Number 0178 15

R.A. Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 Ecol. Adaptations 1118-24 (2005), https://www.nrc.gov/docs/ML1434/ML14345A564.pdf 6

Registration Review; Glyphosate Docket Opened for Review and Comment, 74 Fed. Reg. 36217 (July 22, 2009) 20

S. Kilman, *Superweed outbreak triggers arms race*, Wall Street Journal (June 4, 2010), https://www.wsj.com/articles/SB10001424052748704025304575284390777746822 7

S.M. Bradberry et al., *Glyphosate Poisoning*, 23 Toxicological Reviews 159-167 (2004), https://www.ncbi.nlm.nih.gov/pubmed/15862083 12

Sulfosate; Pesticide Tolerance, 63 Fed. Reg. 48597 (Sept. 11, 1998) 22

USDA, *Final Environmental Impact Statement for Determination of Nonregulated Status of 2,4-D-Resistant Corn and Soybean Varieties*, at 134 (Aug. 2014), https://www.aphis.usda.gov/brs/aphisdocs/24d_feis.pdf 8

Other Authorities (Cont'd) **Page(s)**

U.S. Fish and Wildlife Service, https://www.fws.gov/savethemonarch/SSA.html 6

U.S. Right To Know, Glyphosate: 4/5/16 meeting between EPA and Monsanto – notes, https://usrtk.org/wp-content/uploads/2017/08/EPA-notes-from-April-2016-meeting-with-Monsanto.pdf 10

W. Neuman & A. Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. Times, May 3, 2010, https://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?_r=1&pagewanted=all 5

World Health Organization, *Pesticide Residues in Food - 2004*, at 100-103, 164 (2004), https://apps.who.int/iris/bitstream/handle/10665/43624/9241665203_eng.pdf?sequence=1&isAllowed=y 34, 35

W.P. Ridley, *A study of the plasma and bone marrow levels of glyphosate following intraperitoneal administration in the rat*, Study No. 830109, Monsanto Envtl. Health Lab., at pdf p. 49 (Oct. 24, 1983), https://www.centerforfoodsafety.org/files/monsanto-tissue-distribution-bone-marrow--1983_90955.pdf 36

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

Center for Food Safety (CFS) is a nonprofit whose mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture.[2] CFS has nearly a million members nationwide.

CFS and its members have strong interest in this appeal: CFS is a leading U.S. public interest organizing working on the issue of pesticides in industrial agriculture. A pillar of CFS's mission is protecting the public health and environment from toxic pesticides like glyphosate. CFS has a major program area specific to pesticides, and numerous staff members – scientific, policy, campaign, and legal – whose work encompasses the topic. CFS staff are recognized experts in the field, intimately familiar with the issue of pesticides, the

---

[1] No party's counsel authored the brief in whole or part; no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and no person—other than *Amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief. *See* Fed. R. App. P. 29(a)(4)(E). All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2).

[2] *See* CFS, www.centerforfoodsafety.org.

inadequacy of their oversight, their health risks, and their adverse environmental impacts.

Center for Biological Diversity (CBD) is a non-profit organization whose mission is to ensure the preservation, protection, and restoration of biodiversity, native species, ecosystems, public lands and water, and public health through science, policy, and law. CBD has more than 1.7 million members and online activists throughout the world, including in areas affected by the use of glyphosate. Based on the understanding that the health and vigor of human societies, plants and wildlife, and the natural environment are deeply intertwined, CBD works to protect and to secure a future for animals and plants hovering on the brink of extinction, for the ecosystems they need to survive, and for the people that interact with, depend on, and cherish these ecosystems.

CBD's Environmental Health Program is focused on protecting biodiversity and human health from toxic substances, including pesticides and glyphosate. For example, in 2015 CBD published the report Lost in the Mist: How Glyphosate Disproportionally Threatens

California's Most Impoverished Counties[3], which found that more than half the glyphosate sprayed in California is applied in the state's eight most impoverished counties. The analysis also found that the populations in these counties are predominantly Latinx, indicating that glyphosate use in California is distributed unequally along both socioeconomic and racial lines.

Amici respectfully submit this brief in support of Plaintiff-Appellee Hardeman.

INTRODUCTION AND SUMMARY OF ARGUMENT

The purpose of this brief is to provide this Court further context regarding the carcinogenicity of glyphosate. First, this brief lays out the profound costs to our environment, agriculture, and human health caused by widespread use of glyphosate. Second, we distinguish between glyphosate and glyphosate pesticide product formulations. Despite the fact that glyphosate formulations are even more likely to be

[3] Dr. Nathan Donley, *Lost in the Mist: How Glyphosate Disproportionally Threatens California's Most Impoverished Counties*, Center for Biological Diversity (Nov. 2015), https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/LostInTheMist.pdf.

carcinogenic than the glyphosate active ingredient in isolation, the Environmental Protection Agency (EPA) has never evaluated glyphosate formulations, such as the Roundup used by Edwin Hardeman, for carcinogenicity. Finally, we explain how EPA undermined its cancer evaluation of glyphosate due to fatal flaws and bias.

ARGUMENT

This Court should affirm the jury's verdict. Glyphosate and Roundup have caused major harms to our environment, agriculture, and human health. Contrary to Monsanto's claims, Mr. Hardeman's case is not preempted by EPA's conclusion relative to glyphosate because Roundup is a glyphosate formulation that EPA has never evaluated for carcinogenicity. Moreover, significant flaws and biases undermined EPA's evaluation of glyphosate's carcinogenicity and the district court was correct in allowing testimony to that effect.

I. Glyphosate's destructive effects on the environment, agriculture, and human health.

This case is about the weed-killer Roundup, which contains the active ingredient glyphosate, the most heavily used conventional

pesticide in the United States. Glyphosate use has increased dramatically over the past quarter-century in tandem with the increased cultivation of Monsanto's "Roundup Ready" corn, soybeans, and other crops, which are genetically engineered (GE) to be resistant to glyphosate.[4] EPA estimates that 280 million pounds of glyphosate are applied to 298 million acres annually in agriculture,[5] four times that of the second-leading pesticide, atrazine.[6]

This massive, unprecedented spraying of Roundup and other glyphosate-based herbicides has serious adverse effects on our environment, agriculture, and human health. Certain Roundup

---

[4] W. Neuman & A. Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. Times, May 3, 2010, https://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?_r=1&pagewanted=all; *see also Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 836 (9th Cir. 2013) (describing Monsanto's Roundup Ready "crop system" of the GE crop and pesticide).

[5] EPA, *Glyphosate: Response to Comments, Usage, and Benefits*, at 13, 17 (Apr. 18, 2019), https://www.epa.gov/sites/production/files/2019-04/documents/glyphosate-response-comments-usage-benefits-final.pdf.

[6] EPA, Biological and Economic Analysis Division, *Pesticides Industry Sales and Usage: 2008-2012 Market Estimates*, at 14 (2017), https://www.epa.gov/sites/production/files/2017-01/documents/pesticides-industry-sales-usage-2016_0.pdf.

formulations are extremely toxic to aquatic life and are thought to be among the factors driving the worldwide decline in amphibians.[7] Glyphosate has also contributed to the recent precipitous decline (80%) of the iconic monarch butterfly. Monarch caterpillars feed only on milkweed plants, once common in corn and soybean fields. Glyphosate has nearly eradicated milkweed from Midwest cropland, the monarch's major breeding range, depriving monarch caterpillars of their chief food source.[8] In 2014, the Fish and Wildlife Service (FWS) concluded that Endangered Species Act protections may be warranted for monarchs. 79 Fed. Reg. 78775 (Dec. 31, 2014).[9] Scientists estimate that the migratory

[7] R.A. Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 Ecol. Adaptations 1118-24 (2005), https://www.nrc.gov/docs/ML1434/ML14345A564.pdf.

[8] J.M. Pleasants and K.S. Oberhauser, *Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population*, 6 Insect Conservation & Diversity 135-144 (Mar. 12, 2012), https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1752-4598.2012.00196.x.

[9] FWS is expected to make a listing decision on Monarch butterflies in December 2020, https://www.fws.gov/savethemonarch/SSA.html.

monarch population faces up to a 57% risk of quasi-extinction over the next two decades.[10]

Roundup Ready crops are also responsible for an epidemic of "superweeds" that have evolved resistance to glyphosate on 120 million acres of U.S. cropland.[11] The pesticide industry's "solution" is a new generation of GE crops "stacked" with resistance to glyphosate and other toxic herbicides, such as Agent Orange component 2,4-D or the closely related dicamba.[12] Yet far from providing any panacea, these new GE crops will instead lead to vastly increased herbicide use, such

---

[10] B.X. Semmens et al., *Quasi-extinction risk and population targets for the Eastern, migratory population of monarch butterflies* (Danaus plexippus), 6 Nature Sci. Rep. 23265 (2016), https://www.researchgate.net/publication/299267766_Quasi-extinction_risk_and_population_targets_for_the_Eastern_migratory_population_of_monarch_butterflies_Danaus_plexippus.

[11] J. Pucci, *The war against weeds evolves in 2018*, CropLife (Mar. 20, 2018), https://www.croplife.com/crop-inputs/the-war-against-weeds-evolves-in-2018/.

[12] S. Kilman, *Superweed outbreak triggers arms race*, Wall Street Journal (June 4, 2010), https://www.wsj.com/articles/SB10001424052748704025304575284390777746822.

as a three- to seven-fold rise in agricultural use of 2,4-D,[13] increasingly intractable weeds resistant to multiple herbicides,[14] and crop damage from drift. Indeed, massive use of dicamba to kill resistant weeds has resulted in unprecedented drift damage to millions of acres of crops over the past three years.[15] The introduction of more GE herbicide-resistant crops will only further boost unsustainable herbicide use, increase pollution of our soils and rivers,[16] and make American agriculture even less sustainable than it is today.[17]

---

[13] USDA, *Final Environmental Impact Statement for Determination of Nonregulated Status of 2,4-D-Resistant Corn and Soybean Varieties*, at 134 (Aug. 2014), https://www.aphis.usda.gov/brs/aphisdocs/24d_feis.pdf.

[14] B. Keim, *New generation of GM crops puts agriculture in a 'crisis situation,'* Wired, (Sept. 25, 2014), https://www.wired.com/2014/09/new-gm-crops/.

[15] C. Dewey, *This miracle weed killer was supposed to save farms. Instead, it's devastating them*, The Washington Post (Aug. 29, 2017), https://www.washingtonpost.com/business/economy/this-miracle-weed-killer-was-supposed-to-save-farms-instead-its-devastating-them/2017/08/29/33a21a56-88e3-11e7-961d-2f373b3977ee_story.html.

[16] L.H. Nowell et al., *Complex mixtures of dissolved pesticides show potential aquatic toxicity in a synoptic study of Midwestern U.S. streams*, 613-614 Sci. Total Env't 1469-88 (2018), https://www.sciencedirect.com/science/article/pii/S0048969717315735.

II. There is no preemption because "glyphosate" and "Roundup" are not synonymous.

Monsanto wants this Court to believe that "glyphosate" is synonymous with "Roundup." Monsanto Br. 5, n.1. The reason is simple: if the terms are interchangeable, then, they argue, EPA's finding that glyphosate is "not likely to be carcinogenic" would apply to Roundup and might preempt Mr. Hardeman's case.

However as the evidence presented at trial demonstrated, "glyphosate" and "Roundup" are very much *not* synonymous, and Roundup is far more toxic than glyphosate. Hardeman Br. 24-26, 42, 48. Moreover, EPA has never evaluated Roundup for carcinogenicity. *Id*. 42. Glyphosate formulations, like Roundup, contain additional ingredients (co-formulants) to improve performance in some way. EPA understands these formulations are more toxic than glyphosate alone, yet nevertheless focused its cancer evaluation on pure glyphosate, and

[17] D.A. Mortensen et al., *Navigating a critical juncture for sustainable weed management,* 62 Bioscience 75-84 (Jan. 2012), https://academic.oup.com/bioscience/article/62/1/75/295845.

excluded animal feeding trials and genotoxicity tests involving the formulated products that people actually use.[18]

During registration review[19] for glyphosate, EPA also acknowledged that different glyphosate formulations pose different health risks.[20] Yet rather than require formulation-specific testing, in 2016 EPA asked Monsanto to provide any data it might happen to have on the subject.[21] EPA's belated proposal to explore the carcinogenic

---

[18] EPA, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 70, 99 (December 12, 2017) (OPP 2017), https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=OPP&dirEntryId=337935.

[19] The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA registration of pesticides "to prevent unreasonable adverse effects on the environment[,]" which includes human health. 7 U.S.C. §§ 136a(a); 136(bb). EPA must review a pesticide's registration every 15 years. *Id*. § 136a(g). EPA commenced registration review for glyphosate in 2009 and issued an interim registration review decision in January 2020. 85 Fed. Reg. 5957 (Feb. 3, 2020).

[20] EPA, Health Effects Division, *Glyphosate: Tier II Incident Report*, at 7 (Feb. 6, 2014), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0069. *See also* OPP 2017, at 145.

[21] U.S. Right To Know, Glyphosate: 4/5/16 meeting between EPA and Monsanto – notes, https://usrtk.org/wp-content/uploads/2017/08/EPA-notes-from-April-2016-meeting-with-Monsanto.pdf. ("In an effort to resolve questions about the potential toxicity of glyphosate, glyphosate

risks of glyphosate formulations with the National Toxicology Program[22] further undermines its deeply flawed cancer evaluation of glyphosate alone.

Among the co-formulants in glyphosate herbicides are a class of compounds known as surfactants, which increase plants' absorption of glyphosate and thus its weed-killing efficacy. Surfactants and other co-formulants can be toxic in their own right, or increase the risk posed by glyphosate.

A. Toxicity of co-formulants

The best-known surfactants in glyphosate formulations are polyoxyethylene tallow amines (POEAs), a class of related compounds derived from fat (also known as polyethoxylated tallowamine and POE-tallowamine).[23] POEAs are known to be quite toxic to aquatic

---

formulations, and any co-formulants (inert ingredients and surfactants), EPA was interested in any data or information Monsanto may have on how the formulations may differ from data on the active ingredient and surfactants independently of one another.").

[22] OPP 2017, at 145-146.

[23] D. Tush et al., *Characterization of polyoxyethylene tallow amine surfactants in technical mixtures and glyphosate formulations using ultra-high performance liquid chromatography and triple quadrupole*

organisms, but human toxicology is sparse. Based on the limited studies that are available, POEAs are more acutely toxic than pure glyphosate,[24] have adverse reproductive and developmental impacts at low doses,[25] and are nearly seven-fold more toxic on a long-term basis than pure glyphosate.[26] EPA also found that POEAs pose risks to children and occupational users, but dismissed these risks on the grounds that its assessment was conservative.[27]

---

mass spectrometry, 1319 J. Chromatography A 80-87 (2013), https://www.ncbi.nlm.nih.gov/pubmed/24188997.

[24] S.M. Bradberry et al., *Glyphosate Poisoning*, 23 Toxicological Reviews 159-167 (2004), https://www.ncbi.nlm.nih.gov/pubmed/15862083.

[25] European Food Safety Authority, *Request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine*, 13 EFSA J. 4303 (Nov. 12, 2015), Section 2.5 (EFSA 2015), https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4303.

[26] EPA, Health Effects Division, *Alkyl amine polyalkoxylates (JITF CST 4 inert ingredients)*, (Apr. 3, 2009) (EPA 2009), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0738-0005. Note that the class of compounds assessed encompasses POEAs, also known as MON 0818 (p. 10) and the chronic oral reference dose (cRfD) is 0.15 mg/kg/day (p. 16), nearly seven-fold lower than the cRfD for glyphosate of 1 mg/kg/day.

[27] *Id.* at 29-30 (aggregate MOE < 100 in Table 7.2 indicates risk to children); 31, 34-37 (occupational scenarios in Tables 8.1.1, 8.1.2 & 8.1.3

Despite this known toxicity, neither EPA nor the European Food Safety Authority has any animal studies on the carcinogenic hazard posed by POEAs.[28] In part for this reason, the European Commission banned POEAs for use in glyphosate products in 2016.[29] In contrast, EPA renewed a pre-existing exemption from the requirement of a tolerance in 2009, permitting POEAs and related surfactants to comprise up to 25% of herbicide products, with no limit on the amount of POEA residues permitted in food.[30]

---

for which the total MOE < 100, highlighted in bold, indicate increasing risk with decreasing MOE).

[28] *Id*. at 17 (Table 4.5), stating lack of animal carcinogenicity data; EPA merely assumed lack of carcinogenicity based on computer modeling (at 15-16); *see also* EFSA 2015, at Section 2.4.

[29] European Commission, Health and Food Safety Directorate-General, *Addendum to the review report for the active substance glyphosate*, SANTE/11051/2016 rev 0 (July 11, 2016), https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1438 (*see* "Addendum 2016" link).

[30] Alkyl Amine Polyalkoxylates; Exemption from the Requirement of a Tolerance, 74 Fed. Reg. 28616-24 (June 17, 2009).

There is even less toxicity data on non-POEA co-formulants, the identities of which are considered trade secrets, as is true of pesticides generally.[31] A Monsanto patent describes 166 co-formulants (mostly surfactants) and thousands of co-formulant combinations developed for use in glyphosate formulations.[32] Although EPA is supposed to have complete compositional information on all glyphosate formulations, when it began registration review for glyphosate in 2009, it stated that "[t]here are many formulated products for glyphosate and the surfactants used in these products that [sic] must first be identified."[33]

---

[31] C. Cox and M. Surgan, *Unidentified inert ingredients in pesticides: implications for human and environmental health*, 114 Envtl. Health Perspectives 1803-06 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1764160/.

[32] P.J. Lennon et al., *Novel Surfactants and Formulations*, U.S. Patent Application No. US 2010/0234228 A1, assignee: Monsanto Technology, LLC paragraphs 0407 to 0613 (Sept. 16, 2010), http://appft.uspto.gov/netacgi/nph-Parser?p=1&u=%2Fnetahtml%2FPTO%2Fsearch-adv.html&r=1&f=G&l=50&d=PG01&s1=20100234228.PN.&OS=PN/20100234228&RS=PN/20100234228.

[33] EPA, Office of Pesticide Programs, *Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and its Salts*, at 31 (June 5, 2009), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0007.

Seven years later, EPA was still trying to gather this information from Monsanto, asking the company to "provide in writing any information that documents the changes of glyphosate formulations over time and across the globe[.]"[34]

EPA thus has significant knowledge gaps regarding the composition of the 555 glyphosate-containing products registered in the U.S.,[35] and still less understanding of the toxicity – including carcinogenic potential – of their various co-formulants.

B. Surfactants increase dermal absorption of glyphosate

In addition to being toxic in their own right, surfactants increase the amount of glyphosate that is absorbed via skin contact. *See* Hardeman Br. 26. Surfactants increase absorption in several ways. First, they remove lipids from the surface of the skin.[36] Second, they

---

[34] Gillam 2017.

[35] EPA, Pesticide Re-Evaluation Division, *Glyphosate: Proposed Interim Registration Review Decision – Case Number 0178*, at 38 (Apr. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[36] C. Gustin et al., *Clustering glyphosate formulations with regard to the testing for dermal uptake*, Monsanto Company, at 4 (July 2001)

spread out droplets of glyphosate solution on skin, increasing the area of skin contact.[37] Third, they decrease evaporation of water from the glyphosate solution, increasing the time of skin contact.[38] Finally, the skin irritation effect of surfactants also increases blood flow in blood vessels just below the epidermis, increasing absorption of glyphosate in this way as well.[39]

Tests conducted in 2001 illustrate the wide range of dermal absorption that occurs with different formulations. With just two formulations, each tested at two different concentrations, dermal absorption of glyphosate ranged from 1.3% to 10.3% of the applied dose.[40] Even Monsanto acknowledged that "all of the different

---

(Monsanto 2001), https://www.centerforfoodsafety.org/files/monsanto-paper-clustering-glyphosate-formulations-with-regard-to-testing-for-dermal-uptake_86864.pdf.

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] J.A. van Burgsteden, *In vitro percutaneous absorption study with [^{14}C]glyphosate using viable rat skin membranes*, TNO Nutrition & Food Res., at 2 (June 14, 2002), https://baumhedlundlaw.com/pdf/monsanto-

glyphosate formulations would have to be tested for dermal uptake" to better understand absorption rates in humans.[41] Nevertheless, EPA has not required any such dermal absorption testing.[42]

Without formulation-specific dermal absorption data, EPA's risk assessments for occupational or residential use of glyphosate are incomplete at best.[43]

C. Respiratory exposure to glyphosate

Inhalation is another important exposure pathway for glyphosate and its chief breakdown product, aminomethylphosphonic acid (AMPA). Given its high-volume use, glyphosate has ranked among the three top

---

documents/70-b-TNO-Study-on-Dermal-Absorption-Referenced-in-Email-Correspondence.pdf.

[41] Monsanto 2001, at 3.

[42] EPA, Office of Pesticide Programs, Health Effects Division, *Glyphosate: Draft Human Health Risk Assessment in Support of Registration Review*, at 12 (Dec. 12, 2017) (EPA 2017) ("A dermal absorption study is not available in the toxicity database."), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0068.

[43] EPA, Office of Pesticide Programs, Health Effects Division, *Hazard Identification: Toxicology Endpoint Selection Process*, at 14 (Aug. 11, 1998) ("Dermal absorption is a significant factor in occupational or residential exposure risk assessments."), http://cfs.center/epahazardid.

pesticides in spray drift episodes in the U.S. over a six-year period,[44] subjecting farmers, farmworkers and bystanders to frequent exposure. Glyphosate and its AMPA metabolite were detected in over 60% of air samples taken in Iowa and Mississippi in 2007 and 2008.[45] A one-week study of silvicultural workers spraying glyphosate in Finland revealed that the workers' breathing zone contained glyphosate levels orders of magnitude higher than found elsewhere in ambient air.[46] Studies in Argentina have revealed a high potential for inhalation of glyphosate and AMPA adhering to wind-blown particles of soil, with the highest

---

[44] Association of American Pesticide Control Officials, 1999 Pesticide Drift Enforcement Survey, AAPCO (Nov. 30, 1999), https://www.centerforfoodsafety.org/files/aapco-survey-1999_90996.pdf; Association of American Pesticide Control Officials, *2005 Pesticide Drift Enforcement Survey*. AAPCO (2005), https://www.centerforfoodsafety.org/files/aapco-2005_29712.pdf.

[45] F. Chang et al., *Occurrence and fate of the herbicide glyphosate and its degradate aminomethylphosphonic acid in the atmosphere*, 30 Envtl. Toxicology & Chemistry 548-555 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21128261.

[46] A. Jauhiainen et al., *Occupational exposure of forest workers to glyphosate during brush saw spraying work*, 52 Am. Indus. Hygiene Ass'n J. 61-64 (1991), https://www.ncbi.nlm.nih.gov/pubmed/2011980.

concentrations in the finest particles that penetrate furthest into the respiratory system.[47] Despite this evidence, EPA did not assess inhalational exposure to glyphosate during registration review.[48]

D. Aggregate exposure to glyphosate formulations

For those who apply glyphosate, an aggregate risk assessment is needed to account not only for glyphosate residues they encounter in food and water (dietary), but also for the amount that enters their system from dermal contact with glyphosate formulations or inhalation of Roundup spray droplets or glyphosate-bearing dust particles. EPA did not conduct such an aggregate risk assessment during registration review and never collected the data needed to do so, either for residential or occupational users.[49] Without knowledge of aggregate

---

[47] C. Bento et al., *Glyphosate and AMPA distribution in wind-eroded sediment derived from loess soil*, 220 Envtl. Pollution 1079-1089 (Jan. 2017), https://www.researchgate.net/publication/310749189_Glyphosate_and_AMPA_distribution_in_wind-eroded_sediment_derived_from_loess_soil.

[48] EPA 2017, at 8.

[49] *Id.* at 25 (EPA conducted only a "short-term aggregate risk assessment" that entirely excluded dermal or inhalational exposure).

exposure, EPA cannot conduct a true risk assessment of glyphosate, and that includes an assessment of glyphosate's cancer risk.

III. Flaws and Bias Undermined EPA's Evaluation of Glyphosate During Registration Review.

EPA began reviewing the current registration of glyphosate in 2009.[50] As part of that process, EPA's Office of Pesticide Programs (OPP) evaluated glyphosate for carcinogenicity. To the extent assessments of pure glyphosate are relevant at all, OPPs' most recent evaluation was compromised by several factors. First, OPP included inappropriate animal feeding trials in its review. Second, OPP violated its carcinogenicity testing and evaluation guidelines in assessing the animal feeding trials that were valid. Third, OPP dismissed human epidemiology in assessing glyphosate's carcinogenicity. Fourth, OPP miscalculated glyphosate distribution data and disregarded critical genotoxicity tests. Fifth, EPA failed to conduct an integrative assessment of animal, human and mechanistic data.

[50] Registration Review; Glyphosate Docket Opened for Review and Comment, 74 Fed. Reg. 36217 (July 22, 2009).

A. Dubious studies biased OPP's assessment

As part of the registration review process, EPA's Cancer Assessment Review Committee (CARC) evaluated eleven animal feeding trials to assess glyphosate's carcinogenicity.[51] However, when OPP later concluded that glyphosate is "not likely to be carcinogenic to humans," that decision was based not just on the eleven studies that CARC reviewed, but four additional studies not included in the CARC evaluation.[52]

While there are concerns with each of these studies, the four additional studies OPP considered are especially problematic. One study involved rats that were not even fed glyphosate.[53] EPA had

---

[51] EPA, Pesticide Re-Evaluation Division, *Glyphosate: Report of the Cancer Assessment Review Committee*, at 39-57 (Oct. 1, 2015) (CARC 2015), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014.

[52] EPA, Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 73-93 (Sept. 12, 2016) (OPP 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf.

[53] After CFS exposed this error (*see infra* n.54), EPA removed this study from its revised evaluation in OPP 2017 (at 74, n.15) but left in the other three.

previously invalidated a second study with mice.[54] Monsanto contracted with Industrial Bio-Test Laboratories (IBT) in the 1970s to conduct these two studies.[55] In the 1970s, IBT falsified and fabricated data on hundreds of animal feeding studies on pesticides and other chemicals submitted to federal agencies.[56]

Two additional feeding studies (rat and mouse) from the 1980s involved sulfosate, the trimesium salt of glyphosate that has different toxicological properties. For that reason, EPA regulated sulfosate distinct from all other glyphosate salts.[57] None of the separate suite of

---

[54] CFS, Comments to EPA's Scientific Advisory Panel reviewing EPA's *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential,* Sections 3.1, 4.1 (Oct. 12, 2016) (CFS 2016a), https://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments--cfs-20161_35863.pdf.

[55] *Id.*, Sections 3.1, 4.1; *see also* OPP 2017, at 148, 156, documenting IBT as testing firm for Burnett et al., 1979 and Reyna and Gordon, 1973.

[56] K. Schneider, *Faking It: The Case against Industrial Bio-Test Laboratories*, The Amicus Journal, Natural Resources Defense Council (Spring 1983), http://planetwaves.net/contents/faking_it.html.

[57] Sulfosate; Pesticide Tolerance, 63 Fed. Reg. 48597 (Sept. 11, 1998).

toxicology studies EPA collected for sulfosate had ever before been utilized for any health or carcinogenicity assessment of glyphosate. In 2004, EPA cancelled the registration of sulfosate, making it still more irrelevant to EPA's carcinogenicity evaluation of glyphosate.[58]

OPP evaluated these four dubious studies despite the fact that they were excluded from both CARC's 2015 evaluation and from EPA's last comprehensive assessment of glyphosate in 1993. Unlike most of the other eleven studies, these four provided no evidence of treatment-related tumors. Thus, in 2016 when OPP illegitimately included these four studies during the glyphosate registration review process, it skewed OPP's "weight-of-the-evidence" assessment to the faulty conclusion that glyphosate is "not likely to be carcinogenic." The remaining 11 studies and one that EPA did not review are discussed below.

---

[58] CFS 2016a, Sections 3.6, 4.6. These four studies were also excluded from the evaluation in: C.J. Portier, *A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies*, 19 Environmental Health Table 2 (Feb. 12, 2020) (Portier 2020), https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00574-1.

B. EPA violated cancer assessment guidelines to discount evidence of carcinogenicity in animal studies

Rodent studies to assess carcinogenicity involve feeding different amounts of the substance (here, glyphosate) to three "treatment groups" each day for 18-24 months, and a fourth control group that receives none. The animals that develop tumors in each group are counted, with tumors grouped and counted separately based on the organ or tissue in which they appear. In determining whether the substance accounts for observed tumors, EPA is supposed to consider two major criteria: first, whether there is a statistically significant increase in the number of tumors in a treatment group compared to the control group;[59] second, whether there is a statistically significant trend of increasing tumors with rising doses.[60] Only one of the two criteria need be met for a presumption of cancer-causing potential.[61]

---

[59] EPA, *Guidelines for Carcinogen Risk Assessment*, at 2-19 (Mar. 2005) (EPA 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[60] *Id.*

[61] *Id.*

OPP discounts the evidence of carcinogenicity provided by the eleven glyphosate animal feeding trials at issue here in three ways.

First, OPP discounted the significantly higher number of tumors in high-dose versus control animals in many studies on grounds that the dose was *too* high, exceeding EPA's "limit dose" of 1,000 milligrams per kilogram body weight per day (mg/kg/day).[62] EPA's test guidelines, however, do not prohibit feeding more than this amount; rather the test guidelines only provide that "[t]he highest dose *need not* exceed 1,000 mg/kg/day."[63] In fact, EPA Guidelines reflect more concern that the high dose be *high enough* to provide a sufficiently stringent test of the compound's carcinogenic potential.[64] Moreover, EPA previously found two other pesticides, isoxaflutole and iprovalicarb, to be likely carcinogenic based primarily on tumor incidences in groups receiving

---

[62] OPP 2017, at 69, 71.

[63] EPA, Office of Prevention, Pesticides and Toxic Substances, *Health Effects Test Guidelines: OPPTS 870.4200 Carcinogenicity*, at 4 (Aug. 1998) (emphasis added), https://nepis.epa.gov/Exe/ZyPDF.cgi/P100J73B.PDF?Dockey=P100J73B.PDF.

[64] EPA 2005, at 2-17.

more than the "limit dose."[65] Contrary to EPA, none of the glyphosate studies involved an excessively high dose.[66]

Second, OPP dismissed many studies that showed a statistically significant trend of increasing number of tumors with a rising dose of glyphosate. Instead of relying on the prescribed statistical trend test, OPP insisted that the proportion of tumor-bearing animals in each group fit a perfect "monotonic dose-response" pattern of stepwise increase, from control to low- to mid- to high-dose groups.[67] This standard, not mentioned in EPA's Guidelines, "suggests a serious lack

---

[65] CFS, Supplemental Comments to EPA's Scientific Advisory Panel reviewing EPA's *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential,* Section 1.2 (Nov. 28, 2016) (CFS 2016b), http://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments-supplemental-corrected--cfs-2016_35425.pdf. *See also* EPA, Health Effects Division, *Iprovalicarb – Report of the Cancer Assessment Review Committee*, at vi (Apr. 11, 2002) (EPA 2002) ("Most of these tumors [in rats] were induced [by iprovalicarb] above the limit dose which was not excessively toxic"), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/098359/098359-008.pdf.

[65] CFS 2016b, at Section 1.1.

[66] Portier 2020, at 12; *see also* CFS 2016a, at Section 2.2.

[67] OPP 2017, at 71-72.

of understanding of statistical variation in tumor responses."[68] Again, there was no mention of "monotonic dose-response" as a criterion of significance for tumors in EPA's review of isoxaflutole or iprovalicarb.[69]

Third, OPP dismissed the significance of tumors in glyphosate-treated animals by making improper comparisons to the incidence of tumors in untreated animals from entirely different studies – so-called "historical controls." EPA Guidelines, however, emphasize that the control group that is part of the study takes precedence over historical controls in providing a baseline for deciding whether the test substance is responsible for tumors.[70] EPA violated its Guidelines by using historical control comparisons only to deny, and never support, glyphosate as the cause of tumors in treated rodents.[71]

---

[68] Portier 2020, at 12; *see also* CFS 2016a, Section 2.3.

[69] CFS 2016b, at Section 2.1.

[70] EPA 2005, at 2-20 to 2-21.

[71] CFS 2016a, at Section 2.4.

Importantly, an EPA-appointed Scientific Advisory Panel leveled the very same criticisms of OPP's glyphosate evaluation.[72]

Had EPA excluded the four studies that CARC did not evaluate, included another study that was improperly excluded,[73] and assessed them according to its Guidelines, then glyphosate-treated rodents had statistically significant tumor increases in at least four of seven rat studies and five of five mouse studies.[74] According to EPA Guidelines, particular tumor types that appear in more than one study, strain, sex and/or species are accorded greater weight, as are rare and severe (malignant) tumors.[75] Liver tumors appeared at statistically elevated rates in males in two rat studies; kidney tumors were found at statistically increased rates in males in two strains of mouse; and

---

[72] FIFRA Scientific Advisory Panel, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding EPA's Evaluation of the Carcinogenic Potential of Glyphosate*, at 50, 51, 60-62, 72-74 (Dec. 13-16, 2016), https://apirs.plants.ifas.ufl.edu/site/assets/files/376003/376003.pdf.

[73] CFS 2016a, at Section 4.7.

[74] CFS 2016a, at Sections 3.10, 4.8.

[75] EPA 2005, at 2-21 to 2-22.

haemongiosarcomas were found at elevated rates in males of two mouse studies. Finally, malignant lymphomas were found at statistically elevated rates in males of three mouse studies involving two strains.[76] This evidence clearly demonstrates that glyphosate is carcinogenic in animals.

C. EPA improperly dismissed epidemiology

EPA's assessment of epidemiology studies was marked by consistent efforts to discount results showing clear associations between exposure to glyphosate formulations and non-Hodgkin lymphoma (NHL). Three studies in the U.S., Canada, and Sweden showed that those who used glyphosate herbicides were roughly twice as likely to contract NHL.[77] While it is true that not all epidemiology studies linked

---

[76] CFS 2016a, at Section 5.0; *see also* Portier 2020, at 13-14, Table 6.

[77] A.J. De Roos et al., *Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men*, 60 Occup. & Envtl. Med. 5 (Sept. 2003), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1740618/pdf/v060p00e11.pdf; M. Eriksson et al., *Pesticide exposure as risk factor for non-Hodking lymphoma including histopathological subgroup analysis*, 123 Int'l J. Cancer 1657-63 (2008), https://onlinelibrary.wiley.com/doi/epdf/10.1002/ijc.23589; H.H. McDuffie et al., *Non-Hodgkin's Lymphoma and Specific Pesticide*

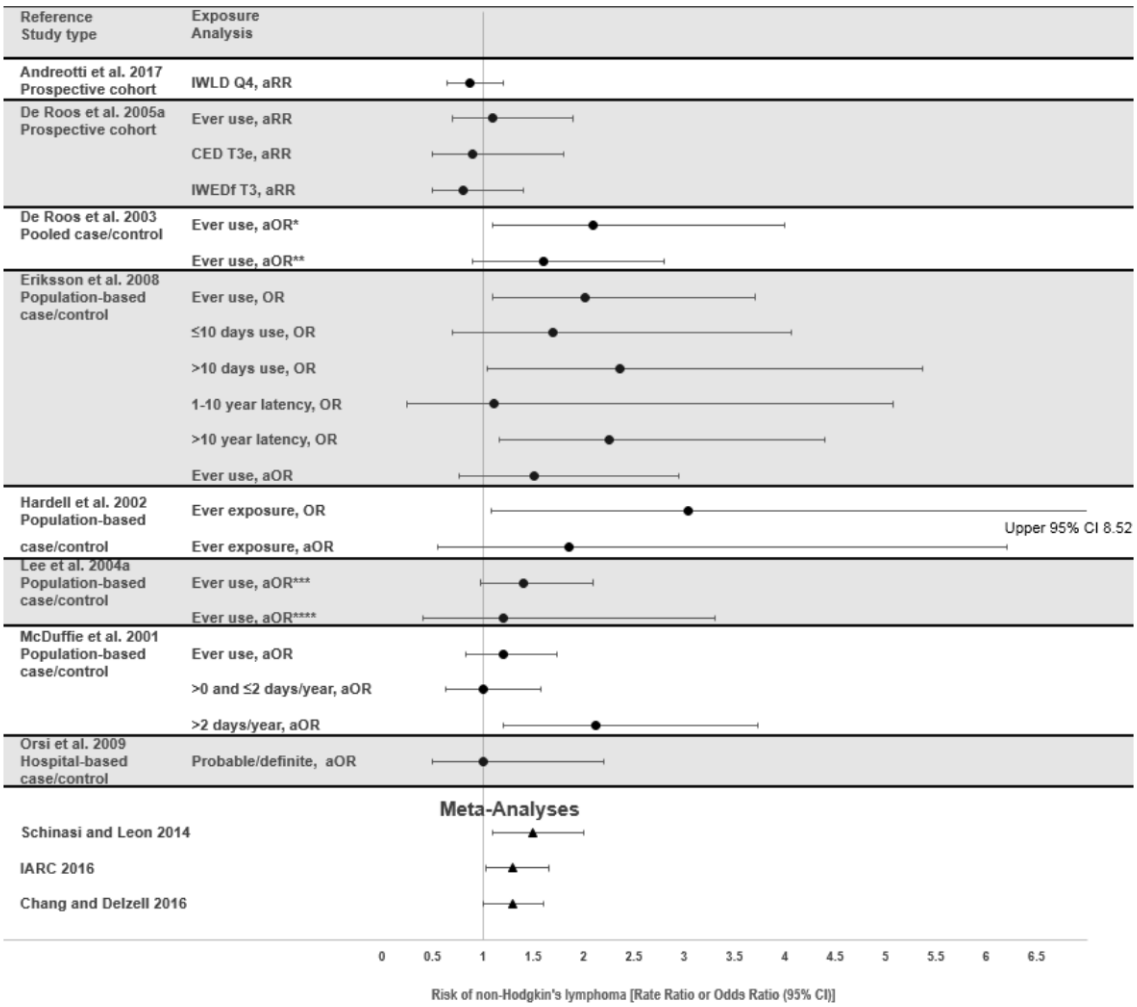
glyphosate formulation exposure to NHL, three meta-analyses – studies that analyze, aggregate and provide the central tendency of numerous relevant individual studies – found 30% to 50% higher risk of NHL among those who used glyphosate formulations.[78] The risks of NHL determined by these three meta-analyses and their underlying epidemiology studies are portrayed in Figure 2-4[79] below.

Exposures in Men: Cross-Canada Study of Pesticides and Health, 10 Cancer Epidemiology, Biomarkers & Prevention 1155-63 (Nov. 2001), https://cebp.aacrjournals.org/content/10/11/1155.full-text.pdf. *See infra* Figure 2-4.

[78] L. Schinasi et al., *Non-Hodgkin Lymphoma and Occupational Exposure to Agricultural Pesticide Chemical Groups and Active Ingredients: A Systematic Review and Meta-Analysis*, 11 Int'l J. Envtl. Res. & Pub. Health, 4449-4527 (Apr. 2014), https://www.mdpi.com/1660-4601/11/4/4449/htm; Int'l Agency for Research on Cancer, *Some Organophosphate Insecticides and Herbicides*. In: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112, at 350 (IARC 2017), https://monographs.iarc.fr/wp-content/uploads/2018/07/mono112.pdf; E.T. Chang and E. Delzell, *Systematic review and meta-analysis of glyphosate exposure and risk of lymphohematopoietic cancers*, 51 J. Envtl. Sci. & Health, Part B, 402-434 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4866614/pdf/lesb-51-402.pdf.

[79] Embedded in: Department of Health and Human Services, *Toxicological Profile for Glyphosate: Draft for Public Comment*, at 86 (Apr. 2019), https://www.atsdr.cdc.gov/toxprofiles/tp214.pdf. This figure displays risk estimate in glyphosate epidemiology studies and meta-

Figure 2-4. Risk of non-Hodgkin's Lymphoma Relative to Self-Reported Glyphosate Use or Exposure



*Logistic Regression; **Hierarchical regression; ***Non-Asthmatic farmers; ****Asthmatic farmers

a = adjusted; CED = cumulative exposure; IWED = intensity-weighted exposure days; IWLD = intensity-weighted lifetime days; OR = odds ratio; Q4 = 4th quartile; RR = rate ratio; T3 = 3rd tertile

Two more recent meta-analyses reached similar conclusions. In one study, the 2,430 cases of NHL diagnosed in over 300,000 farmers in

---

analyses. Filled circles to the right of the vertical line indicate that risk is increased by the corresponding factor on the x-axis.

the U.S., France, and Norway were pooled and analyzed, with glyphosate exposure associated with a 36% greater risk of diffuse large B-cell lymphoma, the most common subtype of NHL. The large number of farmers and NHL cases is a great strength of this study.[80] A fifth meta-analysis included six epidemiology studies, and using the risk estimates for applicators most highly exposed to glyphosate when available, found a 41% increased risk of NHL.[81] Based on this evidence, glyphosate exposure is credibly linked to NHL.

D. Glyphosate persists in bone and bone marrow

Another element of a cancer assessment is investigation of where a compound travels once it is in the body and how long it persists in various tissues before being eliminated. EPA briefly discussed such

---

[80] M.E. Leon et al., *Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USA: a pooled analysis from the AGRICOH consortium*, 48 Int'l J. Epidemiology 1519-1535 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6857760/pdf/dyz017.pdf.

[81] L. Zhang et al., *Exposure to glyphosate-based herbicides and risk for non-Hodgkin lymphoma: A meta-analysis and supporting evidence*, 781 Mutation Res. 186-206 (2019), https://www.ncbi.nlm.nih.gov/pubmed/31342895.

data for glyphosate because they "may provide valuable insights into the likelihood of human cancer risk from exposure."[82]

As discussed above, the cancer most associated with glyphosate exposure in both animal feeding trials and human epidemiology studies is lymphoma: malignant lymphomas in three mouse studies, and NHL in glyphosate applicators.[83] NHL is a cancer that begins in lymphocytes, which are infection-fighting white blood cells produced by lymph tissue. NHL can originate anywhere lymph tissue is found – including the lymph nodes, spleen, thymus and bone marrow – and spread to other parts of the lymphatic system.[84] Several studies in rodents show that glyphosate persists longer in bone and bone marrow than in other tissues.

---

[82] OPP 2017, at 93 (discussing absorption, distribution, metabolism, and excretion (ADME) data).

[83] *See* Zhang 2019.

[84] American Cancer Society, *What is Non-Hodkgin Lymphoma*? (last revised Aug. 1, 2018), https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html.

A Monsanto study found 4.7% of the glyphosate fed to rats was in their bones 6.3 hours later, while 1.1% was still present in bones after seven days.[85] Elimination followed a two-phase pattern, with a very short period of rapid elimination followed by a second phase in which glyphosate levels in bone declined much more slowly.[86] Three similar studies found that the highest levels of glyphosate remaining in rats after 72 hours were likewise in bone tissue.[87]

Glyphosate also lingers specifically in bone marrow. Seven days after administration to rats, "[t]he highest concentration of glyphosate was found in bone, with lower concentrations in bone marrow, kidney,

---

[85] D.W. Brewster et al., *Metabolism of glyphosate in Sprague-Dawley rats: tissue distribution, identification, and quantitation of glyphosate-derived materials following a single oral dose*, 17 Fundamental & Applied Toxicology 43-51 (1991), https://www.ncbi.nlm.nih.gov/pubmed/1916078.

[86] *Id.*

[87] Results of regulatory studies submitted by Syngenta Crop Protection AG to the World Health Organization, as reported in *Pesticide Residues in Food - 2004*, at 100-103 (Table 9) and 164 (reporting results of Davies 1996a, 1996b, 1996c) (Sept. 20-29, 2004), https://apps.who.int/iris/bitstream/handle/10665/43624/9241665203_eng.pdf?sequence=1&isAllowed=y.

liver, lungs and the residual carcass[.]"[88] Similarly, another rat test showed that bone and bone marrow were among the tissues with the highest levels of glyphosate 10- and 24-hours after administration.[89]

Glyphosate's relative persistence in bone marrow raises the possibility that it exerts carcinogenic effects on developing lymphocytes. OPP, however, neglected this possibility because of its botched calculations in a key Monsanto rat experiment.[90] EPA asserted that just 0.0044% and 0.0072% of the glyphosate injected into male and female rats, respectively, reached bone marrow thirty minutes later,[91] when in fact their bone marrow contained 200-fold more, approximately 1% of

---

[88] *Id*. at 99-100 (*see also* Table 7 at 101) and 168 (reporting results for Powles (1992b)).

[89] *Id*. at 99 and 168 (reporting results for Powles (1992a)).

[90] EPA, Data Evaluation Record – Glyphosate: Pharmacokinetics, at pdf 3-6 (May 29, 1984), https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-167.pdf.

[91] EPA, Office of Prevention, Pesticides and Toxic Substances, *Glyphosate Reregistration Eligibility Decision (RED)*, at 18 (Sept. 1993) (EPA 1993), https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf.

the administered dose.[92] EPA's faulty calculations underlie its false conclusions that "very little glyphosate reaches bone marrow" and that "it is rapidly eliminated."[93] In contrast, Monsanto scientists state that "significant concentrations" reach the bone marrow, and remain "more constant" than glyphosate in plasma over the 10 hour experimental period.[94]

E. Glyphosate triggers cancer-causing changes in genotoxicity assays involving bone marrow, lymphocytes and other tissues

There is also strong mechanistic evidence that glyphosate and its formulations are genotoxic (damage DNA) and exert oxidative stress, two pathways to cancer. Particularly compelling is the evidence in

---

[92] EPA vastly understated glyphosate in bone marrow because it confused the amount of glyphosate in small bone marrow *samples* with the amount in rats' *total bone marrow*.

[93] EPA 1993, at 18.

[94] W.P. Ridley, *A study of the plasma and bone marrow levels of glyphosate following intraperitoneal administration in the rat*, Study No. 830109, Monsanto Envtl. Health Lab., at pdf p. 49 (Oct. 24, 1983), https://www.centerforfoodsafety.org/files/monsanto-tissue-distribution-bone-marrow--1983_90955.pdf.

human beings exposed to aerial spraying of glyphosate formulations: chromosomal damage in the lymphocytes of Columbians[95] and DNA strand breaks in the blood cells of Ecuadorians.[96] Glyphosate and its formulations have also proven to be genotoxic to human lymphocytes in a number of *in vitro* assays[97] and to cause chromosomal damage in the bone marrow of rodents.[98] Genotoxicity assays in bovine lymphocyte cell cultures have likewise demonstrated that glyphosate and its formulations can trigger chromosomal damage.[99]

The World Health Organization's International Agency for Research on Cancer (IARC) has found strong mechanistic evidence of

---

[95] C. Bolognesi et al., *Biomonitoring of genotoxic risk in agricultural workers from five colombian regions: association to occupational exposure to glyphosate*, 72 J. Toxicology & Envtl. Health, Part A 986-997 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19672767.

[96] C. Paz-Y-Miño et al., *Evaluation of DNA damage in an Ecuadorian population exposed to glyphosate*, 30 Genetics & Molecular Biology 456-460 (2007), http://www.scielo.br/pdf/gmb/v30n2/a26v30n2.pdf.

[97] IARC 2017, at 366, 369-70 (Table 4.2).

[98] *Id*. at 366-368, 372-74 (Table 4.3).

[99] *Id*. at 368, 375 (Table 4.4).

glyphosate's cancer-causing potential, while EPA's more restricted assessment did not. There are three critical differences between the IARC and EPA assessments. First, EPA relied mostly on unpublished pesticide industry assays, 99% of which came up negative, while IARC focused more on the results of published, peer-reviewed studies, 70% of which produced positive findings of genotoxicity.[100] Second, EPA centered its assessment on assays conducted with pure glyphosate, while IARC placed more weight on tests involving exposure to glyphosate formulations used by farmers and homeowners.[101] Finally, EPA's evaluation focused on typical dietary exposure of the general population, assuming legal applications to food crops, while IARC considered dietary exposure as well as higher exposure levels common among farmers, groundskeepers and applicators.[102]

---

[100] *See* C.M. Benbrook, *How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?*, 31 Envtl. Scis. Europe 1 (2019), https://enveurope.springeropen.com/track/pdf/10.1186/s12302-018-0184-7.

[101] *Id.*

[102] *Id.*

F. Integration of animal, human and mechanistic data points to glyphosate's carcinogenicity

The final and most important assessment step is the integration of the animal, human, and mechanistic data, followed by assignment of the compound into one of five categories depending on the overall strength of the evidence: carcinogenic to humans; likely to be carcinogenic to humans; suggestive evidence of carcinogenic potential; inadequate information to assess carcinogenic potential; and not likely to be carcinogenic to humans.[103] Glyphosate meets and exceeds EPA's criteria for "likely to be carcinogenic to humans."[104] EPA Guidelines describe five situations that result in a "likely" designation, and glyphosate fits at least three. First, it applies when the human epidemiological association is "plausible (but not definitively causal)," with some supporting biological evidence that need not even include carcinogenicity data from animal experiments. A "likely" designation is also indicated when there are two or more positive findings in animal experiments, even without evidence of carcinogenicity in humans.

---

[103] EPA 2005, at 2-53 to 2-58.

[104] *Id.* at 2-54 to 2-55.

Finally, inducement of a "rare animal tumor response in a single experiment" also merits a "likely" classification. For glyphosate, the epidemiological link to NHL is certainly plausible. Glyphosate induces several tumor types in different rat and mouse strains, including renal adenomas and carcinomas that are rare in CD-1 mice; and there is also supporting biological evidence in the form of positive genotoxicity assays and ADME data.

That the same tumor "site" or type is associated with glyphosate exposure in both animal studies (malignant lymphomas) and epidemiology (NHL) strengthens the evidence for glyphosate's carcinogenicity in humans.[105] The various lines of evidence – animal studies, human epidemiology, ADME data and genotoxicity assays – are mutually reinforcing for glyphosate as a carcinogen that affects the lymphatic system and causes NHL.

[105] *Id.* at 2-3 to 2-4.

G. EPA scientists in its research science division regard glyphosate as likely carcinogenic

In 2015, EPA's scientific research arm – the Office of Research and Development (ORD) – reviewed a draft of OPP's glyphosate cancer evaluation. ORD "develop[s] impartial toxicity information independent of its use by EPA's program" offices like OPP.[106] ORD's epidemiologists agreed with IARC on the epidemiological evidence for glyphosate, and noted that this alone would rule out "not likely to be carcinogenic," the classification OPP eventually chose.[107] ORD explained that "OPP insisted on dichotomizing this [epidemiology studies] to be either 'causal' or 'not 'causal[,]'"[108] directly contradicting EPA Guidelines, which call for assessments that account for "gradations of causality."[109]

---

[106] EPA, *Basic Information about the Integrated Risk Information System*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

[107] EPA, *Summary of ORD comments on OPP's glyphosate cancer assessment,* at 1, 3 (Dec. 14, 2015) (ORD 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf.

[108] EPA, email exchange between ORD scientists Vincent Cogliano and Norman Birchfield, at 2 (Dec. 7, 2015) (Cogliano 2015), https://assets.documentcloud.org/documents/4641115/Cogliano-Memo.pdf.

ORD noted OPP's deviations from the Guidelines in its interpretation of animal studies as well (neglecting to test for significant tumor trends), and described the criteria for the different carcinogenic hazard categories.[110] One ORD scientist concluded that ORD scientists would be split between classifying glyphosate as "[l]ikely to be carcinogenic" and "[s]uggestive evidence" of carcinogenicity.[111]

CONCLUSION

EPA OPP's conclusion that glyphosate is "not likely to be carcinogenic" does not apply to glyphosate formulations actually used by people like Mr. Hardeman. Glyphosate formulations are more toxic than pure glyphosate. Surfactants like POEAs have considerable toxicity in their own right, but have not been tested for carcinogenicity. Residential and occupational users of Roundup inevitably get the herbicide on their skin and surfactants enhance dermal absorption of glyphosate. To this must be added inhalation of glyphosate in spray

---

[109] ORD 2015, at 1.

[110] *Id.* at 1-3.

[111] Cogliano 2015, at 3.

droplets and adhering to dust particles, as well as glyphosate residues in food and water. EPA lacks the data to assess aggregate exposure to glyphosate, and hence cannot perform a true risk assessment for the herbicide's cancer or other health risks.

Monsanto's reliance on EPA OPP's conclusions that glyphosate is "not likely to be carcinogenic" is misplaced. OPP included four suspect studies in its most recent assessment of glyphosate that biased its weight-of-the-evidence conclusion. OPP also flouted its cancer assessment Guidelines and discounted evidence of glyphosate's carcinogenic potential on the basis of evidence quite similar to that which merited "likely to be carcinogenic" classifications of two other pesticides. Significantly, EPA's impartial scientific research arm, ORD, favored a classification of "likely to be carcinogenic" or at least "suggestive evidence" of carcinogenicity.

The evidence is clear that glyphosate causes animal tumors, particularly lymphomas. The weight of evidence from epidemiology points to glyphosate as the cause of human NHL, consistent with study results in rodents. Distribution studies further show that glyphosate lingers in lymphocyte-generating bone marrow, while glyphosate and its

formulations are genotoxic in many assays, including those in lymphocytes and bone marrow.

For these reasons, the Court should affirm the jury's verdict.

Respectfully submitted,

/s/ Ryan D. Talbott
RYAN D. TALBOTT
Center for Food Safety
2009 NE Alberta Street
Suite 207
Portland, OR 97211
971-271-7372
rtalbott@centerforfoodsafety.org

Counsel of record

March 23, 2020

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 19-16636, 19-16708

I am the attorney or self-represented party.

This brief contains 6,956 **words**, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- ○ complies with the word limit of Cir. R. 32-1.
- ○ is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ◉ is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ○ is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ○ complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one):*
  - ○ it is a joint brief submitted by separately represented parties;
  - ○ a party or parties are filing a single brief in response to multiple briefs; or
  - ○ a party or parties are filing a single brief in response to a longer joint brief.
- ○ complies with the length limit designated by court order dated _____.
- ○ is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/Ryan D. Talbott **Date** Mar 23, 2020

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

CERTIFICATE OF SERVICE

I certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on March 23, 2020.

All Participants in the case are registered CM/ECF users, and they will be served by the appellate CM/ECF system.

s/Ryan D. Talbott