

Roundup Litigation: Using Discovery to Dissolve Doubt

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ABSTRACT

In 2015, the International Agency for Research on Cancer (“IARC”) classified glyphosate, the most heavily used agricultural pesticide in the world, as a Group 2A carcinogen. This Article reviews reasons for conflicting scientific evidence relating to potential risks of glyphosate and glyphosate-based herbicides (“GBH”), pertinent differences between IARC’s Monograph 112 and EPA’s Risk Assessment, and corporate strategies designed to influence the balance of evidence and refute allegations of potential product risk. Building on product liability precedent, this Article summarizes three current lawsuits against Monsanto by consumers who allege injuries from Roundup, including Johnson v. Monsanto, Blitz v. Monsanto, and In re Roundup Products Liability Litigation. In areas of scientific controversy, discovery documents obtained pursuant to litigation may serve as a tool to provide transparency, discern credibility of conflicting narratives, and inform policy in a manner that prioritizes public health.

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INTRODUCTION

Glyphosate, the active ingredient in Roundup, has become the most heavily used agricultural pesticide in the world.¹ In 2015, the International Agency for Research on Cancer (“IARC”) classified glyphosate as a Group 2A probable human carcinogen,² and some studies have linked glyphosate or glyphosate-based herbicides (“GBH”) such as Roundup, to an increased risk of cancer,³ endocrine disruption,⁴ birth defects,⁵ and potential hepatorenal dysfunction.⁶ Hundreds of lawsuits have emerged against Monsanto, alleging a variety of

1. See ENVTL. PROT. AGENCY OFFICE OF PESTICIDE PROGRAMS, GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL (2016), <https://perma.cc/Y6TU-Y639>.

2. WORLD HEALTH ORG. INT’L AGENCY FOR RESEARCH ON CANCER, IARC MONOGRAPHS VOLUME 112: EVALUATION OF FIVE ORGANOPHOSPHATE INSECTICIDES AND HERBICIDES 1 (2015) [hereinafter IARC MONOGRAPH 112].

3. Helen 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, 1160–62 (2001); Lennart Hardell & Mikael Eriksson, *A Case-Control Study of Non-Hodgkin Lymphoma Exposure to Pesticides*, 85 *CANCER* 1353, 1355 (1999); Mikael Eriksson et al., *Pesticide Exposure as Risk Factor for Non-Hodgkin Lymphoma Including Histopathological Subgroup Analysis*, 123 *INT’L J. OF CANCER* 1657, 1660–62 (2008).

4. Robin Mesnage et al., *Transcriptome Profile Analysis Reflects Rat Liver and Kidney Damage Following Chronic Ultra-Low Dose Roundup Exposure*, ENVTL. HEALTH, Aug. 2015, at 4; Céline Gasnier et al., *Glyphosate Based Herbicides are Toxic and Endocrine Disruptors in Human Cell Lines*, 262 *TOXICOLOGY* 184, 189 (2009); Jorgelina Vayaroud et al., *Effects of a Glyphosate-Based Herbicide on the Uterus of Adult Ovariectomized Rats*, 32 ENVTL. TOXICOLOGY 1191 (2017).

5. Vincent Gary et al., *Birth Defects, Season of Conception, and Sex of Children Born to Pesticide Applicators Living in the Red River Valley of Minnesota, USA*, 110 ENVTL. HEALTH PERSP. 441, 441–49 (2002); MEDARDO ÁVILA VAZQUEZ & CARLOS NOTA, 1ST NATIONAL MEETING OF PHYSICIANS IN THE CROP-SPRAYED TOWNS (2010).

6. Gasnier et al., *supra* note 4, at 184–89; Laura Vandenberg et al., *Is It Time to Reassess Current Safety Standards for Glyphosate Based Herbicides?*, 71 *J. OF EPIDEMIOLOGY AND COMMUNITY HEALTH* 613–18 (2017).

claims related to cancer or death from Roundup use. Monsanto swiftly defended glyphosate's status, asserting it has a long "history of safe use"⁷ and noted its compliance with the Environmental Protection Agency's ("EPA") requirements set forth in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). In Part I, this Article will provide an overview of EPA's regulatory framework for pesticides such as glyphosate, describe the cost-benefit analysis set forth in FIFRA, and summarize evidence of potential health risks. Part II of this Article will address how IARC's hazard assessment differs from EPA's registration review process, and will describe how discovery documents obtained in litigation revealed a series of calculated public relations strategies by Monsanto specifically designed to tip the scales of scientific evidence and discredit IARC. Finally, Part III of this Article will summarize the allegations made in recent lawsuits pertaining to Roundup—*Johnson v. Monsanto*, *Blitz v. Monsanto*, and *In re Roundup Products Litigation*—to illustrate the significance of litigation as a means of addressing public health concerns pertaining to environmental risk. In areas of scientific controversy, litigation can serve as an important tool to increase transparency and discern credibility of conflicting narratives.

I. GLYPHOSATE REGISTRATION AND THE IMPACT OF A COST-BENEFIT ANALYSIS STANDARD

When the EPA registered glyphosate in 1974, it concluded that glyphosate did not pose an unreasonable adverse effect to human health or the environment. Since its registration, application of glyphosate-based products has increased a hundredfold, increasing in both scale and scope. This section will introduce the competing narratives pertaining to GBH risk: According to multiple scientists, additional research has revealed that glyphosate may increase the risk of multiple diseases, such as cancer, birth defects, hepatorenal damage, and chronic disease, whereas Monsanto denies such risks and maintains that glyphosate has been safely used for forty years.

A. FIFRA AND EPA'S INITIAL ASSESSMENTS

In 1974, the EPA registered glyphosate as an herbicide, concluding that glyphosate does not pose an "unreasonable adverse effect" to human health or the environment.⁸ Public health scientists and legal scholars have levied two important criticisms of the registration process by which pesticide manufacturers and agribusiness may heavily influence regulatory outcomes: reliance on industry data and the weight assigned during cost-benefit analysis.⁹

7. IARC's *Report on Glyphosate*, MONSANTO (Apr. 21, 2017), <https://perma.cc/7ACU-2MB6> [hereinafter *Monsanto's Response to IARC*].

8. See 7 U.S.C. § 136 (b)(b).

9. Sanne Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2376–87 (2017).

First, the EPA's registration process reviews data submitted by the manufacturer, which has a direct financial stake in facilitating the registration of the product.¹⁰ Second, the cost-benefit analysis integrated into FIFRA's registration standard balances economic considerations for beneficial commercial use against the potential risk to human health or the environment. Monsanto has unquestionably demonstrated its significant commercial potential—by volume, application of glyphosate-based products has increased a hundredfold since the 1970s as its uses have diversified and expanded.¹¹ In 2014, approximately 280–290 million pounds of glyphosate were used in the United States,¹² corresponding to four billion dollars in annual revenue. In both corporate website postings¹³ and legal documents, Monsanto equates the EPA's licensing of glyphosate to its “safety” without acknowledging this important nuance.¹⁴

B. EVIDENCE OF INCREASED RISKS TO HUMAN HEALTH

Scientific literature provides robust evidence on the role of pesticides as a preventable risk factor in the development of multiple pathologies, including cancer, birth defects, reproductive disorders, hepatorenal damage, and chronic disease.¹⁵ Current research suggests that exposure to glyphosate or GBH elevates risk of non-Hodgkin's lymphoma (“NHL”),¹⁶ induces genotoxicity to human cells, and may act as a tumor promoter in human tissue.¹⁷ Studies in cell culture have shown that glyphosate generates endocrine-mediated effects¹⁸ and that GBH may disrupt endocrine signaling systems, both of which can impact sexual differentiation, reproduction, and formation of sexual organs, as well as contribute to hormone-dependent diseases.¹⁹

In Argentina, researchers at the National University of Cordoba assembled a coalition of scientists and physicians to investigate reports demonstrating a

10. Joan Flocks, *The Environmental and Social Injustice of Farmworker Pesticide Exposure*, 19 GEO. J. ON POVERTY L. AND POL. 255, 266 (2012).

11. John Peterson Myers et al., *Concerns Over Use of Glyphosate-Based Herbicides and Risks Associated with Exposure: A Consensus Statement*, 15 ENVTL. HEALTH, Feb. 2016, at 5–6, 10.

12. ENVTL. PROT. AGENCY OFFICE OF PESTICIDE PROGRAMS, *supra* note 1, at 16.

13. *Monsanto's Response to IARC*, *supra* note 7.

14. Answer, In re Roundup Products Liab. Litig., No. 16-md-02741-VC, MDL No. 2741 (N.D. Cal. 2017) [hereinafter In re Roundup Products Liab. Litig. Answer].

15. Sara Mostafalou & Mohammad Abdollahi, *Pesticides and Human Chronic Disease: Evidence, Mechanisms, and Perspectives*, 268 TOXICOLOGY AND APPLIED PHARMACOLOGY 157, 158–63 (2013).

16. McDuffie et al., *supra* note 3, at 1155; Hardell & Eriksson, *supra* note 3, at 1355; Eriksson et al., *supra* note 3, at 1660–62.

17. Shala Hosseini Bai & Steven M. Ogbourne, *Glyphosate: Environmental Contamination, Toxicity, and Potential Risks to Human Health via Food Contamination*, 23 ENVTL. SCI. AND POLLUTION RES. 18988, 18994–97 (2016).

18. Gasnier et al., *supra* note 4, at 189.

19. *Id.*; Mesnage et al., *supra* note 4, at 4; Vandenberg et al., *supra* note 6, at 614–18; Myers et al., *supra* note 11, at 10.

fourfold increase in birth defects from 1998 to 2008.²⁰ Subsequent research by Carrasco and colleagues demonstrates that glyphosate and GBH interfere with molecular mechanisms regulating early development, which can lead to the types of congenital malformations reported in Argentina.²¹ Toxicity studies in rodents reveal adverse effects of GBH on kidney and liver function, leading some public health scientists to suggest glyphosate-based herbicides may contribute to the epidemic of occupational chronic kidney disease of unknown origin plaguing farmworkers globally—especially in Sri Lanka and Central America.²²

In 2016, Myers and colleagues published a Statement of Concern, calling for a re-assessment of acceptable daily intake of GBH residue and noting the increase in total glyphosate use, increase in potential dietary exposure, and adverse effects occurring at “safe” doses.²³ Vandenberg and colleagues echo these concerns, indicating that current assessments may underestimate toxicity if studies only examine glyphosate, because GBH mixtures can enhance adhesion, facilitate penetration, and reveal effects that would otherwise not be observable.²⁴

C. REFUTING INCREASED RISK AND INFLUENCING THE SCALES OF EVIDENCE

Monsanto maintains that glyphosate has forty years of safe use and poses little risk to human health because glyphosate’s primary mode of activity inhibits the plant enzyme 5-enolpyruvylshikimate-3-phosphate synthase (“EPSPS”), which does not exist in vertebrate cells.²⁵ Monsanto also points to Williams and colleagues’ research that found “no convincing evidence” of genotoxicity, carcinogenicity, or developmental toxicity.²⁶

Yet Monsanto’s claims require further scrutiny. First, emerging evidence suggests that GBH may impact EPSPS present in the human microbiome as a means to affecting human health,²⁷ an argument also proffered by plaintiffs in *Blitz v. Monsanto*. Current evidence also suggests that focusing on one mode of action to the exclusion of other impacts misses significant potential health risks.²⁸ Second, discovery documents assist with contextualizing the Williams and colleagues

20. See VAZQUEZ & NOTA, *supra* note 5, at 1, 3–4.

21. Alejandra Paganelli et al., *Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling*, 23 CHEMICAL RES. IN TOXICOLOGY 1585, 1593 (2010).

22. See Channa Jayasumana et al., *Glyphosate, Hard Water, and Nephrotoxic Metals: Are They the Culprits Behind the Epidemic of Chronic Kidney Disease of Unknown Etiology in Sri Lanka?* 11 INT’L RES. AND PUB. HEALTH 2125 (2014); Vandenberg et al., *supra* note 6, at 614; Myers et al., *supra* note 11, at 5 (noting the global use of GBH and observations of chronic kidney disease in regions “in which there is a combination of heavy GBH use and ‘hard’ water”).

23. Myers et al., *supra* note 11, at 5–6, 10.

24. Vandenberg et al., *supra* note 6, at 615.

25. *Monsanto’s Response to IARC*, *supra* note 7.

26. See Gary M. Williams et al., *Safety Evaluation and Risk Assessment of Herbicide Roundup and Its Active Ingredient, Glyphosate for Humans*, 31 REG. TOXICOLOGY AND PHARMACOLOGY 117 (2000).

27. Myers et al., *supra* note 11, at 2, 10.

28. *Id.*

study: Monsanto not only funded the study, but also stated in internal documents that it authored its contents.²⁹ Journalist Carey Gillam combed through hundreds of documents released in conjunction with current litigation,³⁰ including internal e-mail communications within Monsanto. Gillam contends that Monsanto did not merely produce or influence a few studies but “dozens or hundreds,” which were subsequently re-cited in other publications as evidence refuting risk.³¹ This practice drastically skews the consensus of available literature. As historians Naomi Oreskes and Erik Conway note, corporations manufacture doubt by directing and manufacturing research for a counternarrative not only to convince the public, but also scientists and regulatory bodies that the weight of scientific evidence demonstrates its product is not harmful.³²

II. DISCERNING THE DIFFERENCE BETWEEN IARC’S MONOGRAPH 112 AND EPA REGISTRATION REVIEW

In March 2015, IARC published its hazard assessment of Monograph 112, concluding that glyphosate is “probably carcinogenic to humans,”³³ which on its surface appeared to contradict both the EPA’s initial registration and the Registration Review that concluded glyphosate is not likely to be carcinogenic. This section will explain the differences in these conclusions by discerning hazard versus risk, the scope of evidence evaluated, and the potential role of industry-funded studies and public relations strategies in influencing the weight of scientific evidence.

A. IARC: GLYPHOSATE IS “PROBABLY CARCINOGENIC TO HUMANS”

In IARC’s hazard assessment concluding that glyphosate is “probably carcinogenic to humans,” the Working Group found there was limited evidence of carcinogenicity in humans for NHL, convincing evidence that glyphosate can cause cancer in laboratory animals, and that glyphosate caused DNA and chromosomal damage in human cells.³⁴ This publication followed a year-long review process and represented the consensus of seventeen members from eleven countries. Importantly, the Working Group members are independent experts free from vested interests, and the deliberative process excludes private industry data by design.

29. E-mail from William Heydens, Chief Scientist, Monsanto, to Donna Farmer, Toxicologist, Monsanto (Feb. 19, 2015, 07:53), <https://perma.cc/8JN4-F7PB>.

30. See generally THE MONSANTO PAPERS—MASTER CHART, <https://perma.cc/T5LQ-2ZYY>.

31. CAREY GILLAM, THE STORY OF A WEED KILLER, CANCER, AND THE CORRUPTION OF SCIENCE (Island Press 2017).

32. NAOMI ORESKES & ERIK M. CONWAY, MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING (Bloomsbury Press 2010).

33. IARC MONOGRAPH, *supra* note 2, at 112.

34. *Id.*

B. MONSANTO'S ATTEMPTS TO DISCREDIT IARC

Monsanto quickly initiated an aggressive attack on IARC's finding, employing a series of public relations strategies to neutralize public perception, discredit IARC, and tip the scales beyond confusion to paint a counternarrative that IARC's conclusion rests upon "junk science."³⁵

1. Neutralizing Public Perception

Specifically anticipating IARC's finding, Monsanto coordinated contact with Henry Miller of Stanford University's Hoover Institute prior to IARC's publication in order to solicit Miller to write an article in *Forbes*. Miller agreed to participate on the condition that Monsanto would supply him a "high quality draft," and, unsurprisingly, the article reiterated Monsanto's position that "glyphosate is not a human health risk."³⁶ Miller's article relied on explaining the hazard-risk distinction and comparing glyphosate to water or salt, which could also be dangerous if consumed in high quantities, but poses a negligible risk. Other media articles echoed Miller's dismissal of the impact of the hazard classification, avowing "it bears no real relationship to anything in the real world."³⁷ These assurances rely on the "menace of daily life" public relations strategy adopted by Big Tobacco: There are many potential hazards, but none, including *our* product, is sufficient to produce real health risks.³⁸

Beyond neutralizing the impact of IARC's classification in the media, Monsanto facilitated additional scientific publications relating to glyphosate. *Critical Reviews in Toxicology* published a review of "independent expert panels," finding that available data does not support the conclusion that glyphosate is a "probable human carcinogen."³⁹ Documents released as part of the discovery process revealed that the review did *not* consist of independent experts. Intertek, a consulting firm that facilitated the review, communicated with authors who were paid Monsanto consultants as well as Monsanto executives during, and prior to, publication.⁴⁰ The Declaration of Interest following the publication acknowledged funding from Monsanto, but incorrectly stated that Monsanto employees did not review the contents of the manuscript before submission. Several internal e-mails document a Monsanto executive writing the introductory paragraph,

35. THE MONSANTO PAPERS, *supra* note 30, at 166; see Monsanto, Preparedness and Engagement Plan for IARC Carcinogen Rating of Glyphosate, BAUM HEDLUND ARISTEI GOLDMAN PC (Feb. 17, 2015), <https://perma.cc/PQW7-4GRY> [hereinafter Monsanto Preparedness and Engagement Plan].

36. THE MONSANTO PAPERS, *supra* note 30, at 25.

37. Derek Lowe, *Glyphosate and Cancer*, SCI. TRANSLATIONAL MED. BLOG (May 18, 2016), <https://perma.cc/86YK-R5KQ>.

38. See Elisa K. Ong & Stanton A. Glantz, *Constructing "Sound Science" and "Good Epidemiology" Tobacco, Lawyers, and Public Relations Firms*, 91 AM. J. OF PUB. HEALTH 1749 (2001).

39. Gary Williams et al., *A Review of the Carcinogenic Potential of Glyphosate by Four Independent Expert Panels and Comparison to IARC Assessment*, 46 CRITICAL REVS. IN TOXICOLOGY 3, 16 (2016).

40. See THE MONSANTO PAPERS, *supra* note 30, at 40–46.

editing the entire manuscript, and adding his own text, which directly contradicts the veracity of the Declaration of Interest.⁴¹ Thus, a review labeled “independent” was in reality initiated and overseen by Monsanto.

2. Sound Science v. Junk Science: Using Trade and Front Groups to Discredit IARC

Monsanto further coordinated an effort to discredit IARC through a variety of channels, primarily by facilitating misleading media reports and employing trade groups and front groups to rally for sound science and lobby Congress to investigate allegedly inappropriate methodology and outcomes.⁴² Monsanto directly repudiated IARC’s findings, arguing IARC’s outcome represented junk science and cherry-picking of data.⁴³ Reuters published several pieces alleging that IARC “edited out non-carcinogenic findings,” IARC’s decision constituted an outlier, and the classification needlessly confused consumers.⁴⁴ Attacking IARC constitutes an “archetypical [strategy] for creating ‘doubt’ about scientific evidence that has policy implications” with the intent to undermine confidence in the integrity of the process and outcome.⁴⁵ In 2015, Pearce and colleagues addressed similar allegations of impropriety against IARC, concluding that such criticisms are unconvincing, opposition stems from a vocal minority, and IARC’s processes represent a balanced evaluation.⁴⁶

The trade association, American Chemistry Council (“ACC”), of which Monsanto is a member, extended Monsanto’s narrative that the deliberative process involved omission of critical evidence, alleged that IARC “has shown a lack of objectivity, credibility, and integrity,” and called for a third-party investigation.⁴⁷ The ACC initiated The Campaign for Accuracy in Public Health Research, a front group with a deceptive-sounding name, to address “fake news” stories that mislead and confuse the public.⁴⁸

As Ong and Glantz have noted, the sound science movement and labeling studies as “junk science” do not originate from a genuine desire to improve

41. *Id.*

42. Monsanto Preparedness and Engagement Plan, *supra* note 35.

43. See *Monsanto’s Response to IARC*, *supra* note 7.

44. Kate Kelland, *In Glyphosate Review, WHO Cancer Agency Edited Out “Non-Carcinogenic” Findings*, REUTERS, (Oct. 19, 2017), <https://perma.cc/G2GN-CJKN>; Kate Kelland, *Special Report: How The World Health Organization’s Cancer Agency Confuses Consumers*, REUTERS (Apr. 18, 2016), <https://perma.cc/6KML-MASZ>.

45. Jonathan Samet, *The IARC Monographs: Critics and Controversy*, 36 CARCINOGENESIS 707, 708 (2015).

46. See Neil Pearce et al., *IARC Monographs: 40 Years of Evaluating Carcinogenic Hazards to Humans*, 123 ENVTL. HEALTH PERSP. 507 (2015).

47. Press Releases from Cal Dooley, President and CEO, American Chemistry Council, ACC Calls upon Global Leaders to Take Action Against IARC Over Deliberate Manipulation of Data (Oct. 19, 2017), <https://perma.cc/96VG-T9G5>.

48. ACC Launches Campaign to Promote Credibility in Public Health Research, AM. CHEMISTRY COUNCIL (Jan. 25, 2017), <https://perma.cc/SC8S-PTK8>.

epidemiological standards, but instead represents a calculated appeal to refute research that reveals health risks connected to a product.⁴⁹ Public health law attorney Michelle Simon clarifies that each of these tactics follows a common and identifiable set of objectives: Industry shapes public discourse by forming front groups that appear to benefit the public and will “debunk” myths and confusion.⁵⁰ The front group aggressively discredits critics—highly respected scientists—by attacking their credibility, alleging bias, and averring that these experts are merely fear-mongering. Finally, front groups appeal to our culture’s desire for reason and balance, and its belief that each story has an equal perspective and weight in the debate.⁵¹ Sifting through misrepresentations and discerning bias becomes immensely challenging, particularly when a corporation masks the extent of its involvement as a facilitator of media articles, social media campaigns, academic research, and front group activity.

3. Persuading Congress to Pressure IARC

Days after the ACC issued a call to action, U.S. Representatives Smith and Biggs of the Congressional Committee on Science, Space, and Technology sent a letter to the Director of IARC alleging concern over “blatant manipulations” of Monograph 112 and other media reports that “revealed troubling evidence of data deletion, manipulation, and potential conflicts of interest.”⁵² The letter demanded to know who was responsible for final editing, reminded IARC that the NIH funds a portion of its budget, and indicated that the Committee would be convening a hearing to “ensure sound science.”⁵³ The Director of IARC replied to Representatives Smith and Biggs to correct repeated misrepresentations and clarify that draft deliberations are both private and based on independent scientific reviews precisely to insulate independent experts from interference by vested interests.⁵⁴

In February 2018, the Congressional Committee on Science, Space, and Technology held a hearing, during which Representative Smith alleged that IARC’s conclusion resulted from “unsubstantiated claims” that were “not backed by reliable data” and questioned why IARC should receive any federal funding.⁵⁵

49. Ong & Glantz, *supra* note 38, at 1753–54.

50. MICHELLE SIMON, THE BEST PUBLIC RELATIONS THAT MONEY CAN BUY: A GUIDE TO FOOD INDUSTRY FRONT GROUPS, CTR. FOR FOOD SAFETY 6 (May 2013), <https://perma.cc/HEN2-UH7E>; see also Jean Macchiaroli Eggen, *The Synergy of Toxic Tort Law and Public Health, Lessons from a Century of Cigarettes*, 41 CONN. L. REV. 561, 571–73 (2008).

51. ORESKES & CONWAY, *supra* note 32, at 16–19.

52. Letter from Lamar Smith and Andy Biggs, House of Representatives, U.S. Cong., to Christopher Wild, Dir., IARC (Nov. 1, 2017), <https://perma.cc/9Y76-DNDG>.

53. *Id.*

54. Letter from Christopher Wild, Dir., IARC, to Lamar Smith and Andy Biggs, House of Representatives, U.S. Cong. (Nov. 20, 2017), <https://perma.cc/6KDY-UQUT>.

55. *In Defense of Scientific Integrity: Examining the IARC Monograph Programme and Glyphosate Review: Hearing Before the H. Comm. on Science, Space, and Technology*, 115th Cong. 6–7 (2018)

A Minority Staff Report prepared for the Committee documented Monsanto's extensive attempts to influence scientific literature by "ghostwriting" articles, and documented evidence of how Monsanto influenced an editor of a prominent scientific journal to retract an unfavorable publication and of how Monsanto solicited the assistance of experts to attack critics and their credibility.⁵⁶

It is incumbent on members of Congress in addition to the public health community, to discern the motivations of the attacks on IARC and to examine the compelling evidence demonstrating the source of informational manipulation. Politics invariably shapes scientific perception. As legal scholar Holly Doremus notes, the involvement of politics is not the problem, but rather the problem is using the weight of political authority to legitimize scientific evidence as a neutral truth when it in fact has been skewed by special interests.⁵⁷

C. EPA REGISTRATION REVIEW

Currently, the EPA is in the process of Registration Review to reevaluate potential risks to human health and the environment based on new science. In 2016, the EPA published *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, which concluded that the weight of the evidence does not support a finding that glyphosate is carcinogenic or likely to be carcinogenic to humans.⁵⁸ The *Glyphosate Issue Paper* also concluded that the risk of NHL cannot be determined based on available data due to conflicting results and limitations in studies; in addition, it concluded that although "positive responses were observed in a limited number of genotoxicity assays evaluating chromosomal and primary DNA damage, the overall weight of the evidence indicates there is no convincing evidence that glyphosate induces mutations in vivo via the oral route."⁵⁹ In December 2017, the EPA published its *Draft Human Health Risk Assessment in Support of Registration Review for Glyphosate*, similarly concluding that glyphosate is not likely to be carcinogenic.⁶⁰ The EPA's final review is scheduled for completion in 2019.

Despite these conclusory statements, the minutes of the Scientific Advisory Panel meeting ("SAP"), that were held prior to these publications and reviewed scientific issues associated with the carcinogenic potential of glyphosate, reveal pervasive dissent and disagreement with multiple conclusions set forth in the

(statement of Rep. Lamar Smith, Chairman, H. Comm. on Science, Space, and Technology), <https://perma.cc/2WA7-SKGC>.

56. MINORITY STAFF REPORT, SPINNING THE SCIENCE & SILENCING SCIENTISTS: A CASE STUDY OF HOW THE CHEMICAL INDUSTRY ATTEMPTS TO INFLUENCE SCIENCE, HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY, 115th Cong. (2018), <https://perma.cc/DB2D-8NQU>.

57. Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, UC DAVIS LEGAL STUDIES RESEARCH PAPER SERIES, Apr. 2008, at 15–17.

58. ENVTL. PROT. AGENCY OFFICE OF PESTICIDE PROGRAMS, *supra* note 1, at 137–40.

59. *Id.* at 138.

60. EPA, DRAFT HUMAN HEALTH RISK ASSESSMENT IN SUPPORT OF REGISTRATION REVIEW FOR GLYPHOSATE (Dec. 12, 2017), <https://perma.cc/C7XX-AJWR>.

Issue Paper and Draft Risk Assessment. First, some members of the SAP agreed that a meta-analysis shows a “scientifically important and statistically significant elevated NHL risk,” indicating the Agency “cannot exclude the possibility that observed positive associations between glyphosate exposure and risk of NHL suggest carcinogenic potential of glyphosate.”⁶¹ Second, when analyzing the laboratory animal carcinogenicity studies for glyphosate, some SAP members expressed that the totality of the data supports the hypothesis that glyphosate may act as a weak tumor promoter and questioned why the Agency discounted statistically significant trends.⁶² Finally, and most notably, some SAP members asserted that the current evidence is consistent with and suggestive of the positive carcinogenic potential of glyphosate.⁶³ Each of these conclusions stand in stark contrast to the published findings in the *Draft Human Health Risk Assessment*.

There are several reasons why these discrepancies may exist. The EPA’s review includes industry data, which means corporate-funded or allegedly “ghostwritten” studies influence the scales of evidence that the EPA reviews. Manufacturing evidence to tip the scales necessarily injects corporate bias into the decision-making process, particularly when a corporation attempts to mask the extent of its involvement. Plaintiffs in *In re Roundup Products Litigation* raise a more serious allegation of regulatory capture, charging that Monsanto officials exerted inappropriate influence on EPA officials. One official promised Monsanto over text that “you can count on me.”⁶⁴ According to Monsanto e-mails, a separate EPA official told a Monsanto employee that he “deserved a medal if he could ‘kill’ another proposed review [referring to a review by the Agency for Toxic Substances and Disease Registry].”⁶⁵ Supporting the plaintiff’s theory, discovery uncovered a letter written by EPA senior scientist Marion Copley to the same EPA official in 2013, submitting her analysis of why the Cancer Assessment Review Committee should change glyphosate’s designation to a “probable human carcinogen.” In the same letter, Copley pleaded with this official to “do the right thing” instead of “playing games with the science to favor the registrants.”⁶⁶ In May 2017, the Office of the Inspector General at the EPA announced it would investigate allegations of collusion between Monsanto executives and EPA officials.⁶⁷

61. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT SCIENTIFIC ADVISORY PANEL, MEETING MINUTES AND FINAL REPORT NO. 2017-01 16–17 (Dec. 13–16, 2016), <https://perma.cc/GUZ2-AERY> [hereinafter FIFRA MEETING MINUTES AND FINAL REPORT].

62. Letter from Marion Copley, Senior Scientist, EPA, to Jesudoss Rowland, Deputy Dir., Office of Pesticide Programs, EPA (Mar. 4, 2013), <https://perma.cc/WZU6-GYNC>.

63. FIFRA MEETING MINUTES AND FINAL REPORT, *supra* note 61, at 22.

64. THE MONSANTO PAPERS, *supra* note 30, at 111.

65. *Id.* at 119.

66. Letter from Marion Copley, *supra* note 62.

67. Letter from Arthur Elkins, Inspector Gen., EPA, to Ted Lieu, U.S. House of Representatives (May 31, 2017), <https://perma.cc/TAW6-FY2U>.

III. PRODUCT LIABILITY LITIGATION AS A STRATEGY TO DEMONSTRATE CONSUMER HARM

Regulatory law, by its nature, strikes a balance between weighing relative risks of products while permitting the sale of useful consumer goods. In some cases, however, additional time in the marketplace reveals multiple consumers who allege the product increases risk of disease or injury. First, this section will describe how product liability tort law can serve as a mechanism to raise awareness of environmental health risks, explain the standards required for scientific evidence to establish legal causation, and evaluate strategies used by the defense to dispute causation. Second, this section will describe three representative lawsuits by consumers against Monsanto alleging health harms arising from using GBH and will analyze the impact of critical corporate documents obtained during the discovery process to discern the industry's internal knowledge of potential risks. Finally, this section will explain the public health significance of product liability litigation—how it can serve as a tool to identify preventable risks associated with a product and promote corporate accountability.

A. PRODUCT LIABILITY HIGHLIGHTS INSUFFICIENCIES IN REGULATORY LAW

Litigation alleging injury from consumer products such as Roundup illustrates the vastly different functions of regulatory law and tort law. The EPA's mandate from Congress entails assessing relative risk of glyphosate, Roundup's active ingredient, to prevent harm to human health, while also balancing economic considerations. This standard does not account for the health impact of the final Roundup formulation, nor does it require preventing or reducing all harms to human health. Tort litigation across multiple sectors involving consumer products illustrates how a properly approved product may subsequently reveal serious and unacceptable risks to the public's health and safety.⁶⁸

As patterns of disease or injury emerge, parties may form a class action lawsuit, which enables injured parties to leverage common resources to bring attention to the broader impact on similarly situated consumers.⁶⁹ Multiple plaintiffs exposed to the same product and who each suffer from the same type of injury illustrate potential public health implications of the product that allegedly increase risk of disease or injury.⁷⁰ Unlike the regulatory system designed to minimize harm before it occurs, the tort system is designed to compensate and remediate where regulation was insufficient or where new information related to

68. See generally Lucinda Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 339–45 (2008); Carl Cranor et al., *Judicial Boundary Drawing and the Need for Context Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals*, 16 VA. ENVTL. L.J. 1, 7–9, 14–15 (1996).

69. Eggen, *supra* note 50, at 583; 600–601.

70. *Id.*

product risk has emerged.⁷¹ The judicial system provides a powerful mechanism to initiate dialogue of potential product risk,⁷² investigate allegations of special interest manipulation or regulatory capture,⁷³ and utilize the discovery process to obtain otherwise confidential corporate documents to discern an industry's internal knowledge of potential risks and corporate strategy.⁷⁴ Each of these goals of litigation, however, hinges on the ability of plaintiffs to present evidence in the form of expert testimony before the court. Judicial discretion to accept evidence as admissible and sufficient in current Roundup litigation has been strongly influenced by evolving evidentiary standards in product liability precedent.

1. Product Liability Precedent

Three product liability cases, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, *General Electric Co. v. Joiner*, and *Kuhmo Tire Co. v. Carmichael*, each set forth prescriptive standards for judicial admission of expert testimony.⁷⁵ The court's role in permitting certain types of evidence and testimony directly impacts the scope and weight of the evidence plaintiffs may use to bolster their allegations, thus influencing whether a jury has sufficient evidence to arrive at a finding of liability.⁷⁶

In the early 1990s, women who ingested the anti-nausea drug Bendectin during pregnancy began to allege that the drug was the cause of birth defects in their infants.⁷⁷ Existing epidemiological studies demonstrated Bendectin did not increase the risk of birth defects during pregnancy.⁷⁸ Despite a paucity of existing scientific evidence, multiple plaintiffs in litigation relating to Bendectin proffered expert testimony reanalyzing previously published human statistical studies which showed that Bendectin more than doubled the risk of birth defect development.⁷⁹ The scientific community, defense attorneys, and judges questioned jury verdicts in favor of plaintiffs, leading some courts to hold the plaintiffs' evidence insufficient as a matter of law, thereby issuing a judgment notwithstanding the verdict ("JNOV").⁸⁰ These discrepancies raised the question of what constitutes the exact standards for admissible evidence and sufficient scientific evidence to support plaintiffs' theories of causation.

71. *Id.* at 564–565.

72. *Id.* at 607.

73. Adam Abelkop, *Tort Law as an Environmental Policy Instrument*, 92 OR. L. REV. 381, 433–34, 448–49 (2013).

74. Eggen, *supra* note 50, at 578–579.

75. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146–47 (1997); *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 148 (1999).

76. Finley, *supra* note 68, at 341.

77. *Id.* at 338–41.

78. *Id.*

79. *Id.*

80. *Id.*

The Supreme Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals* clarified the role of the trial judge as gatekeeper to ensure the reliability and relevance of expert testimony before the jury.⁸¹ In *Daubert*, the plaintiffs appealed the exclusion of expert testimony, including animal studies, chemical structure analyses, and unpublished reanalysis of previously published human statistical studies.⁸² The Court set forth four factors for a judge to consider in deciding whether to admit expert testimony; a court should assess whether the evidence supporting the testimony: (1) is based upon the scientific method, (2) was published and subject to peer review, (3) has any known error rate of the technique, and (4) is "generally accepted" in the scientific community.⁸³ Despite these guidelines, the Court emphasized the flexibility of these factors by noting that peer review or even publication does not necessarily correlate with reliability because "some propositions . . . are too particular, too new or of too limited interest to be published."⁸⁴ Each of these factors, the Court held, are designed as non-dispositive guidelines for the judge for assessing the relevance and reliability of the expert testimony.⁸⁵

Notably, *Daubert* cautioned that judicial determinations must focus on the expert's principles and methodology rather than on the expert's conclusions.⁸⁶ However, subsequent precedent following *Daubert* began to erode this directive. *General Electric Co. v. Joiner* held that trained experts may extrapolate and provide expert opinion, but that too great of a gap between the current data and expert opinion may signal unreliability.⁸⁷ Legal scholars assert that the holding in *Joiner* opened the door for judicial determinations based on extrapolation and uncertainty, which entail normative judgments about areas of scientific controversy.⁸⁸ In *Kuhmo Tire Co. v. Carmichael*, the Eleventh Circuit scrutinized how an expert applied methods and principles in reaching a conclusion, stating that when an expert's "factual basis, data, principles, [and] methods of their application are sufficiently called into question . . . the trial judge must determine whether the testimony has a reliable basis in knowledge and experience of the relevant discipline."⁸⁹ *Kuhmo Tire* extended judicial examination of methodological reliability to assessing the expert's conclusion, which directly impacts whether the judge permits expert testimony to be heard by the jury.

81. *Daubert*, 509 U.S. at 589; see also Finley, *supra* note 68, at 339–40; Cranor et al., *supra* note 68, at 8–9.

82. *Daubert*, 509 U.S. at 583.

83. *Id.* at 592–94.

84. *Id.* at 593.

85. *Id.* at 594–95.

86. *Id.* at 595.

87. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

88. Finley, *supra* note 68, at 343–44.

89. *Carmichael v. Samyang Tire, Inc.*, 131 F.3d 1433 (11th Cir. 1997).

Following these cases, the Federal Rules Advisory Committee revised Federal Rule of Evidence 702 to instruct the court when considering admission of expert testimony to assess whether:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.⁹⁰

Despite this revision, the language still permits significant judicial discretion to determine what types of scientific evidence meet these standards, the strength of the scientific evidence, and what constitutes reliable methods, particularly if methodology integrates unpublished data reanalysis. If the court permits the expert testimony, both product liability precedent and the standard for admitting testimony under Rule 702 may also influence whether the expert testimony is sufficient to support a finding of causation.⁹¹

2. Establishing Causation

In product liability cases alleging health injury from a consumer product, the plaintiff must produce expert testimony to support both general and specific causation. First, plaintiffs must show that the product in question is capable of causing the type of injury from which the plaintiff suffers.⁹² This includes a hypothesis, testing, and some evidence to suggest that exposure to a product can result in the disease or condition at issue, with some courts prioritizing, or even requiring, epidemiological evidence.⁹³ Some courts adopt the standard that evidence must show that exposure doubles the risk of injury (a relative risk of 2.0 or greater), reasoning that it is fifty percent likely that any particular case of the disease is attributable to the exposure rather than unexplained causes or to “background risk.”⁹⁴ According to some courts, this threshold is sufficient to support a jury finding that a preponderance of the evidence demonstrates the product in question caused the plaintiff's injury.⁹⁵ After establishing general causation, the plaintiff must provide expert medical testimony to rule out other potential causes

90. FED. R. EVID. 702.

91. See Joseph Sanders & Michael Green, *Do Courts Engage in Sufficiency Analysis When Making Daubert Rulings in Toxic Tort Cases?*, 50 CONN. L. REV. 443, 458 (2018).

92. Eggen, *supra* note 50, 588–90; Christopher Ogolla, *What Are the Policy Implications of Use of Epidemiological Evidence in Mass Torts and Public Health Litigation?*, 23 ST. THOMAS L. REV. 157, 177–78 (2010).

93. Ogolla, *supra* note 92, at 177; Finley, *supra* note 68, at 360.

94. Ogolla, *supra* note 92, at 182.

95. *Id.*

and support the finding that the plaintiff's exposure to the product—rather than an alternate source or confounding variable—was the cause of the injury or disease.⁹⁶

Defense counsel may argue that epidemiological evidence is required to support the plaintiffs' claims because scientific evidence requires "subjective leaps" from other methods of study to support general causation in humans, asserting studies demonstrating a 2.0 relative risk merely show a "weak association."⁹⁷ The defense may introduce competing evidence to undermine arguments of causation, such as evidence that criticizes the period of latency (too long or too short a time from exposure to disease), emphasizes confounding variables (exposure to other harmful products or alternate risk factors), or invokes the argument that the cause of disease is unknown or idiopathic in nature.⁹⁸

Yet, legal scholars contend that by requiring a specific relative risk standard of 2.0, some courts may be adopting too rigid a view of the science that may result in false negatives; that is, these courts may reject the evidence even in cases of a product that is truly harmful.⁹⁹ Early studies examining the impact of radiation, for example, showed a relative risk of cancer from radiation exposure of less than 2.0.¹⁰⁰ Despite this, radiation is a known carcinogen and may cause multiple types of cancer in some people, but other people may never develop cancer from exposure.¹⁰¹ Judicial determination of both the admissibility and sufficiency of evidence entails normative judgments of who bears the burden of harms allegedly caused by dangerous products in the marketplace.

3. The Impact of a Heightened Standard for Causation

Legal scholars note that limiting types of testimony or precluding expert testimony has raised the threshold of scientific proof, amounting to determinations by the trial judge of whether the evidence is *sufficient* to support causation of product harm, rather than whether it should merely be *admissible*.¹⁰² By assessing the reliability of scientific studies and scrutinizing or criticizing the methodology of expert witnesses, judges can rule the testimony as inadmissible, preventing a jury from hearing certain expert testimony and narrowing of the scope of evidence that even reaches jury consideration. Alternatively, if the court admits testimony but perceives the testimony as insufficient as a matter of law to support general

96. *Id.* at 177–78; Eggen, *supra* note 50, at 589–91.

97. Joe Hollingsworth & Eric Lasker, *The Case Against Differential Diagnosis: Daubert, Medical Causation Testimony, and the Scientific Method*, 37 J. OF HEALTH L. 85, 88–93 (2004).

98. Eggen, *supra* note 50, at 570–71, 590–91.

99. Finley, *supra* note 68, at 360; Cranor et al., *supra* note 68, at 38–41.

100. Eggen *supra* note 50, at 589–91; Cranor et al., *supra* note 68, at 22–23.

101. *Known and Probable Human Carcinogens*, AM. CANCER SOC'Y, <https://perma.cc/K7VQ-TK3A> (last visited Oct. 4, 2019).

102. Cranor et al., *supra* note 68, at 16–17; Finley, *supra* note 68, at 335; Sanders & Green, *supra* note 91, at 14.

and specific causation, the judge may issue a JNOV.¹⁰³ In some instances, these determinations exert a prohibitively high bar for plaintiffs attempting to recover for their injuries despite presenting evidence of both specific and general causation.¹⁰⁴

A recent high profile product liability case, *Lloyd v. Johnson & Johnson*, illustrated the powerful impact of product liability precedent on judicial determinations of what constitutes sufficient evidence and defense counsel's strategy to request a JNOV following an unfavorable verdict.¹⁰⁵ In *Lloyd*, a Johnson & Johnson Talcum Powder case, the plaintiffs' experts provided scientific studies to support general causation, including studies showing a relative risk ratio over 2.0 and a scientific study showing a 1.7 relative risk ratio, reanalyzed evidence showing higher risk ratios than the original study conclusion, and provided testimony for specific causation ruling out alternate risk factors that could have caused the lead plaintiff's ovarian cancer.¹⁰⁶ The jury returned a verdict for the plaintiffs, awarding \$68 million in non-economic damages and \$340 million in punitive damages against Johnson & Johnson.¹⁰⁷ The presiding judge granted Johnson & Johnson's motion for a JNOV, characterized the evidence as "limited at best" and the subject of ongoing controversy, and held that the outcome represented a "misreading of the evidence."¹⁰⁸ By granting the defendant's JNOV despite extensive evidence presented by the plaintiffs, this outcome suggests that some courts may be establishing a new interpretation that inflates a plaintiff's burden of proving causation beyond a preponderance of evidence to a significantly higher standard.

4. The Impact of Product Liability Precedent on Roundup Litigation

Product liability precedent set the foundation for the course of litigation against Monsanto by establishing standards for what constitutes admissible expert testimony for a jury to hear, what constitutes sufficient expert testimony to support a verdict for the plaintiff, and, finally, specific defense strategies to undermine the strength of a plaintiff's evidence and undercut reliability of a plaintiff's experts to refute causation. In addition to well established precedent that heightened standards for admissibility, in ongoing litigation Monsanto is strongly relying on the strategy used in the

103. Finley, *supra* note 68, at 340; *see also* Order Granting Judgment Notwithstanding the Verdict, *Lloyd v. Johnson & Johnson*, No. BC628228 (Cal. App. Dep't Super. Ct. Oct. 20 2017) [hereinafter *Lloyd v. Johnson & Johnson Order*].

104. *Id.*

105. *See* Alison Frankel, *Dismissal of \$472 Million Verdict v. J&J Disaster for Talc Plaintiffs*, REUTERS (Oct. 23, 2017), <https://perma.cc/QAV8-BRFW>.

106. *Lloyd v. Johnson & Johnson Order*, *supra* note 103, at 28; *see also* Katherine Drabiak, *Dying to Be Fresh and Clean? Assessing Regulatory Shortcomings Governing Personal Care Products, Cancer Risk, and Epigenetic Damage*, 35 PACE ENVTL. L. REV. 75 (2018) (describing allegations against Johnson & Johnson relating to the Talcum Powder cases).

107. *Lloyd v. Johnson & Johnson Order*, *supra* note 103, at 7.

108. *Id.* at 30–31.

early Bendectin litigation and *Lloyd v. Johnson & Johnson* to raise the standard for both the admissibility and sufficiency of the evidence to avoid liability.

B. LITIGATION AGAINST MONSANTO

There are currently hundreds of both federal and state lawsuits pending against Monsanto relating to Roundup. This section will briefly describe three representative cases: (1) *Johnson v. Monsanto*, (2) *Blitz v. Monsanto*, and (3) *In re Roundup Products Liability*. This section will provide an overview of the factual circumstances of each case and each plaintiff's claims, Monsanto's responses and defense strategy, each case's current status, and each case's significance.

During the process of litigation, the plaintiffs may gain access through discovery to otherwise confidential corporate documents, such as internal e-mails or memoranda between corporate employees and outside parties. These documents can be instrumental in discerning a corporation's intent, knowledge of product risks, and corporate strategy for shaping public perception of those risks. Litigation can force the hand of manufacturers who may control potentially damaging information, such as by forcing manufacturers to reveal relevant product risks they previously concealed or omitted, which may change how the product is marketed, used by consumers, or regulated.

1. *Johnson v. Monsanto*

In *Johnson v. Monsanto*, a California state court case, Dewayne Johnson worked as a groundskeeper beginning in 2012 in Benicia Unified California School District where he sprayed GBH around school grounds for weed control several hours each day.¹⁰⁹ Johnson was diagnosed with NHL in 2014, which he alleged was proximately caused by his exposure to GBH.¹¹⁰ Registration of glyphosate does not equate to or assure product safety, and the plaintiff alleged Monsanto "led a prolonged campaign of misinformation to convince government agencies, farmers, and the general population that Roundup was safe."¹¹¹ Johnson described how Monsanto hired two independent corporations to conduct early product testing to support its application to the EPA for initial registration.¹¹² An FDA inspection of one corporation with which Monsanto contracted to conduct testing for submission to the EPA revealed discrepancies between raw data and the final report on the toxicological impact of glyphosate, wherein one EPA reviewer stated that this corporation's "routine falsification of data" undermined the scientific integrity of the corporation's findings supporting the application

109. Sam Levin & Patricia Greenfield, *Monsanto Ordered to Pay \$289m as Jury Rules Weedkiller Caused Man's Cancer*, THE GUARDIAN (Aug. 11, 2018), <https://perma.cc/WNL2-5ZTG>.

110. Complaint, *Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. App. Dep't Super. Ct. 2016).

111. *Id.* at 7–8.

112. *Id.* at 10–11.

for registration.¹¹³ Johnson alleged Monsanto knew that GBH increased consumer risk of cancer, specifically NHL, yet continued to market, advertise, and sell an unreasonably dangerous product.

Johnson alleged four claims: (1) strict liability for design defect; (2) strict liability for failure to warn; (3) negligence; (4) breach of implied warranty; and (5) demand for punitive damages.¹¹⁴

First, the plaintiff asserted that Roundup's products were "unsafe, defective, and inherently dangerous" beyond what an ordinary consumer would contemplate and that the foreseeable risks outweighed the benefits because they posed a grave risk of cancer or other serious illness.¹¹⁵ The first claim relating to design defect highlighted the asymmetry of information between manufacturers and the ordinary consumer, wherein the manufacturer has a duty to adequately test the product against unreasonable adverse health risks, stay abreast of scientific literature to actively monitor product safety, and employ an alternate design or formulation should evidence of serious risks emerge. Johnson argued that Monsanto not only failed to conduct additional testing to assess the safety of Roundup but also actively suppressed its knowledge of risks from the general public, which constituted "reckless conduct" supporting consideration of punitive damages.¹¹⁶

Second, based on this imbalance of information, Johnson alleged Monsanto knew of Roundup's "dangerous propensities and carcinogenic characteristics" but "concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion" information relating to the risks and dangers of product exposure rather than warning consumers.¹¹⁷ Further, Johnson alleged that had he known the danger of using Roundup, he would not have continued to use Roundup or spray it around school children.¹¹⁸

Third, Johnson alleged negligence arising from insufficient testing, failure to warn consumers, "systematically suppressing or downplaying" evidence of risks, representing product safety, and continuing to market Roundup knowing it was unreasonably unsafe and dangerous.¹¹⁹

Fourth, Johnson alleged that despite its knowledge of Roundup's dangerous propensities, Monsanto warranted its safety, causing foreseeable injury to Johnson.¹²⁰

Finally, the plaintiff requested punitive damages arising from Monsanto's alleged conduct, averred Monsanto misrepresented facts of product safety, knowingly withheld material information from the public, knew and recklessly

113. *Id.*

114. *Id.* at 1.

115. *Id.* at 23–24.

116. *Id.* at 25–28.

117. *Id.* at 32.

118. *Id.* at 28–32.

119. *Id.* at 36–38.

120. *Id.* at 39–42.

disregarded that Roundup can cause NHL, and continued to aggressively market Roundup to the public.¹²¹

Monsanto denied these allegations and raised a variety of defenses, including that the product was not unreasonably dangerous, lack of proximate cause, regulatory compliance, and preemption.¹²² In August 2018, the jury returned a verdict for the plaintiff on all five counts, awarding \$289 million in damages.¹²³ Defendants filed for a motion for a new trial and requested a JNOV in October 2018.

In the motion for a JNOV and new trial, Monsanto maintained that evidence of causation is insufficient because multiple epidemiological studies did not show an increased risk of NHL.¹²⁴ Monsanto also argued that the plaintiff improperly relied on animal and mechanistic studies, which required extrapolation to human effects, arguing such studies are “legally irrelevant,” “not evidence of causation,” and “not linked to human outcomes.”¹²⁵ The defense heavily relied on product liability precedent’s heightened standards for evidence to demonstrate sufficient causation and favor toward epidemiological evidence and epidemiological studies that establish relative risk of at least 2.0.¹²⁶

Notably, Monsanto repeatedly cited *Lloyd v. Johnson & Johnson* to support the proposition that mixed epidemiological data disproves causation. In *Lloyd*, the judge discarded both evidence of relative risk less than 2.0 and reanalysis of data showing a relative risk of 2.0 or greater, and found this evidence legally insufficient to support a finding of causation.¹²⁷ Based on this finding, Monsanto requested that presiding Judge Bolanos similarly reject multiple types of scientific evidence, including epidemiological studies showing a relative risk of less than 2.0 and reanalysis of data showing a relative risk of 2.0 or greater.¹²⁸ Monsanto further adopted a similar argument from *Lloyd* pointing to idiopathic causes of the disease, arguing the plaintiff did not meet the burden of demonstrating specific causation, namely, that the plaintiff did not provide sufficient evidence to rule out a different, unknown factor as the cause of plaintiff’s NHL.¹²⁹ The defense maintained that multiple documents and memoranda were “taken out of context;”¹³⁰ denied it knew, or should have warned, of any risk; and stated

121. *Id.* at 43–45.

122. Answer, *Johnson v. Monsanto Co.*, No. CGC-16-550128 at 1–2 (Cal. App. Dep’t Super. Ct. 2016).

123. Verdict Form, *Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. App. Dep’t Super. Ct. 2018); *see also* Levin & Greenfield, *supra* note 109.

124. Defendant’s Proposed Order for Judgment Notwithstanding the Verdict, *Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. App. Dep’t Super. Ct. 2018) [hereinafter *Johnson v. Monsanto Defendant’s Proposed Order*].

125. *Id.* at 3–9.

126. *Id.* at 3–5.

127. *Lloyd v. Johnson & Johnson Order*, *supra* note 103, at 30.

128. *Johnson v. Monsanto Defendant’s Proposed Order*, *supra* note 124, at 5, 14.

129. *Id.* at 15.

130. *Id.* at 25.

the court should not punish Monsanto for the “honestly held scientific conclusion it shared with the world’s regulatory scientists”¹³¹ of the virtually uniform belief that glyphosate and GBH do not cause NHL.¹³² Finally, Monsanto challenged the jury’s finding of punitive damages, denied employees engaged in ghostwriting scientific studies, and argued that employee communications with EPA officials amounted to “participation in science.”¹³³

In October 2018, Judge Bolanos reduced the jury verdict to approximately \$39 million and denied Monsanto’s motion for both a new trial and a request for a JNOV.¹³⁴

The outcome and defense strategies in the *Johnson v. Monsanto* litigation highlight three pertinent considerations. First, reliance on compliance with the regulatory standard does not equate to product safety, and, in some instances, litigation functions to bring transparency and publicity to scientific evidence by linking product use and exposure to health harms.¹³⁵ If the court would have adopted the *Lloyd* approach, the judge would have discarded significant evidence that formed the basis of the plaintiff’s claims. In this case, reanalysis of existing data to support general causation adjusted for dose-response established statistically significant relationships *in excess* of 2.0 when adjusting for persons exposed to GBH for more than two days.¹³⁶ For persons whose exposure constitutes not merely two *days* of spraying but *years* of exposure to GBH, as in Johnson’s case based on his occupation, reanalysis of data to model dose-response outcomes constituted potentially powerful evidence of the biological plausibility for general causation in excess of 2.0. Moreover, Judge Bolanos clarified that plaintiff’s experts need not rule out every possible alternate cause of cancer, including idiopathic causes, but let the jury consider the weight of expert testimony that Johnson’s exposure to GBH was a substantial factor in causing his NHL.¹³⁷ Finally, the plaintiff noted that issuing a JNOV would fundamentally usurp the jury’s function.¹³⁸ These determinations fall squarely within the jury’s purview to weigh the credibility of each party’s evidence, including the plaintiff’s evidence, that supports allegations of ghostwriting, knowledge of product risk, and suppression of evidence against Monsanto’s claims of engagement in science and “scientific disagreement.”

131. *Id.* at 26.

132. *Id.* at 21.

133. *Id.* at 30–31.

134. Order Denying Defendant’s Motion for Judgment Notwithstanding the Verdict, *Johnson v. Monsanto Co.*, 2018 WL 5246323, No. CGC-16-550128 (Cal. App. Dep’t Super. Ct. Oct. 22, 2018) [hereinafter *Johnson v. Monsanto Order Denying Defendant’s Motion*].

135. Plaintiff’s Proposed Order Denying Defendant’s Motion, *Johnson v. Monsanto Co.*, No. CGC-16-550128 at 9–10 (Cal. Super. Ct. 2018) [hereinafter *Johnson v. Monsanto Plaintiff’s Proposed Order*].

136. Plaintiffs cite relative risk adjusted for more than two days exposure to GBH demonstrated relative risk at 2.2, 2.26, and 2.36. *See id.* at 5–6.

137. *Johnson v. Monsanto Order Denying Defendant’s Motion*, *supra* note 134, at 4.

138. *Johnson v. Monsanto Plaintiff’s Proposed Order*, *supra* note 135, at 2, 9.

2. *Blitz v. Monsanto*

Blitz v. Monsanto was a class action federal court lawsuit in which a group of consumers sued Monsanto and alleged, among other claims, that each person who purchased Roundup or GBH relied on Monsanto's promise that the herbicide targets the enzyme EPSPS not found in pets or people.¹³⁹ The plaintiffs based their allegations on various state consumer protection laws, which are designed to prohibit manufacturers from representing properties of its product in a misleading, deceptive, or untruthful manner.¹⁴⁰ The plaintiffs maintained that Monsanto's advertising claims are false and misleading because GBH *does* target an enzyme found in pets and people.¹⁴¹ This case rested on the novel approach of introducing emerging science that suggests EPSPS is present in beneficial intestinal bacteria that is "critical to health and wellbeing, including [their] immune system, digestion, allergies, metabolism, and even brain function," and, had the plaintiffs known, they would not have made the same purchase.¹⁴² Similar to *Johnson*, *Blitz* also highlighted the asymmetry in scientific knowledge: Discovering the true nature of the product would require extensive scientific knowledge that the average consumer could not, and would not, undertake.¹⁴³ The plaintiffs requested restitution for unjust enrichment, disgorgement of profits, and economic damages for pecuniary losses.¹⁴⁴

Monsanto denied the allegations and offered defenses including preemption and the preclusion of *Blitz's* claim on a factual basis.¹⁴⁵ As a legal strategy, Monsanto argued that the plaintiffs' claims were preempted by federal law—that is, courts do not have the authority to address the state law claims because the EPA already made a determination through registration that glyphosate is "safe" and does not cause cancer. Monsanto asserted that the court should dismiss the plaintiffs' claims because glyphosate is appropriately registered pursuant to FIFRA and bears EPA-approved labeling.¹⁴⁶ Next, Monsanto stated that GBH's method of action is selectively toxic to plants and that EPSPS is not found in people.¹⁴⁷ Monsanto subsequently filed a motion to dismiss.¹⁴⁸

In April 2018, Judge Conley denied Monsanto's motion to dismiss and held *Blitz's* state law claims are not preempted by federal law.¹⁴⁹ Citing *Bates v. Dow Agrosciences LLC*, the court explained that FIFRA does not preempt potential

139. Complaint, *Blitz v. Monsanto Co.*, No. 3:17-cv-00473 (W.D. Wis. June 20, 2017).

140. *Id.*

141. *Id.* at 1–2, 6–7.

142. *Id.* at 1–3.

143. *Id.* at 12.

144. *Id.* at 32.

145. *Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042, 1048, 1051 (W.D. Wis. 2018).

146. *Id.* at 1048.

147. *Id.* at 1051.

148. *Id.* at 1046.

149. *Id.* at 1050.

plaintiff's claims for design defect, defective manufacturing, negligent testing, or breach of express warranty.¹⁵⁰ Judge Conley clarified that court verdicts finding untrue, deceptive, or misleading statements on EPA-approved labeling for pesticides do not mandate or require by law that the manufacturer change its product label, even if they serve to prompt manufacturer changes.¹⁵¹ Thus, although likely motivating manufacturers to modify their products or warning labels, the statements are not prohibited under FIFRA's preemption statement.¹⁵² Further, the court examined the specific statement that EPSPS is found in plants but not in pets or people.¹⁵³ A reasonable consumer, according to the court, may interpret this statement to mean EPSPS is not found *at all* in people, including within human intestinal bacteria. Adopting a position that relies on linguistic parsing, Monsanto argued that no reasonable consumer considers "in people" to include human intestinal bacteria and that it refers specifically to *human cells*.¹⁵⁴ In denying Monsanto's motion to dismiss, Judge Conley noted that interpretation of this claim depends on the perception of the reasonable consumer and, thus, is a matter for jury determination.¹⁵⁵

At the time of this writing, *Blitz v. Monsanto* is scheduled to move forward to trial. Unlike *Johnson v. Monsanto* and *In re Roundup Products Liability*, *Blitz* relies on newer emerging scientific evidence to allege that Monsanto made false, misleading, or deceptive claims. This strategy builds on the straightforward proposition that manufacturers have a duty to accurately represent the characteristics of products they place into the marketplace and on the corresponding function of consumer protection laws to prohibit practices that would confuse or deceive reasonable consumers. To support such claims, the plaintiffs will need to introduce evidence on the existence and function of EPSPS in the intestinal microbiome, describe how GBH could disrupt the microbiome's functioning, and explain why whether a product disrupts microbiome functioning constitutes a material fact about which a reasonable consumer would want to know.

Blitz centered on the truthfulness of the product claims, unlike the claims in *Johnson* and *In re Products Liability* that alleged a particularized injury. Indeed, for the plaintiffs to allege injuries arising from disrupted intestinal microbiome functioning would present extraordinary causation hurdles, requiring the plaintiffs to explain baseline microbiome function and the impact of GBH and to connect altered microbiome function to concrete and particularized injuries.

Independent of whether the jury finds the plaintiffs' evidence for misleading product claims compelling, *Blitz* raised public attention to the existence of EPSPS in the human intestinal microbiome and the plaintiffs' assertion that GBH

150. *Id.* at 1048–49 (citing *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 444, 453–54 (2005)).

151. *Id.* at 1050.

152. *Id.*

153. *Id.* at 1052–53.

154. *Id.*

155. *Id.* at 1051–52.

interferes with the microbiome, which results in adverse health effects. Accordingly, even without alleging injury from intestinal microbiome disruption, the plaintiffs still brought this issue into scientific, legal, and policy discourse.

3. In re Roundup Products Liability

In *In re Roundup Products Liability* hundreds of consumers who used Roundup alleged it constitutes a fundamentally unsafe product and was a substantial contributing factor in causing them to develop NHL.¹⁵⁶ Based on the massive number of similar factual claims, multiple cases were combined into a single district for pretrial proceedings.

In one complaint, the plaintiffs alleged five claims, including (1) negligence; (2) strict liability for a design defect; (3) strict liability for failure to warn; (4) breach of warranty; and (5) breach of warranty of merchantability.¹⁵⁷

Similar to the plaintiffs in *Johnson*, these plaintiffs alleged that Monsanto has a duty to test its product to ensure it will not cause unreasonable adverse side effects, failed to conduct adequate testing, and concealed and misrepresented information pertaining to product safety. The plaintiffs alleged that Monsanto breached its duty to consumers of ensuring its products would not cause users to suffer unreasonable adverse health effects.¹⁵⁸ According to the plaintiffs, Monsanto knew GBH was more dangerous than a reasonable consumer would expect and posed a grave risk of cancer and illness.¹⁵⁹ This strategy offered scientific evidence demonstrating that the formulation of Roundup inclusive of adjuvants and inert ingredients is “more toxic and harmful” than the effects of glyphosate alone. Part of these arguments relied on the nuances between EPA registration of glyphosate and Roundup’s safety for consumer use, because glyphosate and Roundup are distinct *and* the standards underlying each determination (EPA registration of glyphosate and Roundup’s safety) are distinct.

The plaintiffs alleged Monsanto had knowledge of genotoxicity, potential carcinogenicity, and, instead of revising its label with the EPA when it learned of unfavorable research, Monsanto engaged in actions to suppress and downplay unfavorable research while implementing strategies to create favorable research.¹⁶⁰ Discovery uncovered a timeline of e-mails from Monsanto employees discussing the strategy to hire consultants to counter growing genotoxicity publications and how to manage a hired expert who concluded “glyphosate is capable of producing genotoxicity . . . based on the production of oxidative damage,” such as finding a different scientist “who would be comfortable” and “influential with regulators.”¹⁶¹

156. Complaint, *In re Roundup Products Liab. Litig.*, No. 16-md-02741-VC, MDL No. 2741 (N.D. Cal. 2017).

157. *Id.*

158. *Id.* at 24–25.

159. *Id.* at 28–29.

160. *Id.* at 34–35.

161. THE MONSANTO PAPERS, *supra* note 30, at 49.

Plaintiffs also alleged Monsanto placed GBH into commerce with knowledge of its carcinogenicity, which amounted to a breach of implied warranty because GBH is not safe and fit for its intended use.¹⁶² The plaintiffs further alleged that by advertising claims of product safety and failing to disclose risks of Roundup's "dangerous propensities" when used as intended, Monsanto breached its express warranty to consumers.¹⁶³

Monsanto denied these allegations, using the defense that glyphosate's compliance with the EPA standard set forth in FIFRA undermines claims that Roundup is unreasonably dangerous¹⁶⁴ and that there is no reliable scientific evidence of genotoxicity or carcinogenicity.¹⁶⁵ Monsanto maintains there is no reliable scientific evidence that exposure to Roundup causes NHL, and it continues to promote the safety of its product.¹⁶⁶ Utilizing the same defense strategy seen in *Johnson* and *Blitz*, Monsanto argued the plaintiffs' claims were preempted by federal law.¹⁶⁷

The presiding judge disagreed with Monsanto, held that most claims were not preempted, and denied Monsanto's motion to dismiss. Proceedings for the case began in summer 2018, which included presiding Judge Chhabria issuing a pre-trial order ruling on *Daubert* motions for the admissibility of expert testimony.¹⁶⁸ At that juncture, Judge Chhabria opined that "the evidence in its totality seems too equivocal to support any firm conclusion that glyphosate causes NHL. This calls into question the credibility of some of the plaintiff's experts, who have confidently identified a causal link."¹⁶⁹ Moreover, this assessment illustrates the impact of moving from *Daubert*, which instructed the court to focus on reliability and methodology, to *Joiner* and *Kuhmo Tire*, where the court expanded the focus to the appropriateness of the expert's conclusion based on the evidence. Yet the expert's conclusion may rely on explaining data or on reanalysis of data using a different methodology and rationale.

Similar to the plaintiffs in *Johnson*, the plaintiffs presented specific evidence at the *Daubert* hearing in July 2018 that focused on reanalysis of the data to demonstrate relative risk and general causation.¹⁷⁰ By adjusting exposure rates, exposure to glyphosate more than two days per year corresponded to a 2.12 relative risk of developing NHL, whereas exposure to glyphosate more than ten days per year corresponded to 2.36 relative risk.¹⁷¹ Notably, some original analysis presented

162. *Id.* at 35–40.

163. *Id.*

164. In re Roundup Products Liab. Litig. Answer, *supra* note 14.

165. *Id.*

166. *Id.*

167. *Id.*

168. Pretrial Order No. 45: Summary Judgement and *Daubert* Motions, In re Roundup Products Liab. Litig., 390 F. Supp. 3d 1102 (N.D. Cal. July 10, 2018) (No. 16-md-02741-VC, MDL No. 2741).

169. *Id.* at 2.

170. *Id.* at 20.

171. *Id.* at 40.

data showing a relative risk of less than 2.0 or even *no* increased risk.¹⁷² Allowing expert reanalysis to proceed to trial will permit the jury to determine the strength of the plaintiffs' argument that adjusting days of exposure leads to statistically significant risk.¹⁷³ Adjusted days of exposure are particularly salient for certain occupations, such as farmworkers or groundskeepers, that include frequent and repeated contact with GBH.

Monsanto also sought to exclude expert plaintiff testimony on the basis that some studies relied on a period of time ranging from five to ten years from exposure to diagnosis.¹⁷⁴ Monsanto argued that these cases of NHL were likely caused by another factor because cancer in most cases takes many years to develop.¹⁷⁵ Judge Chhabria permitted the plaintiffs' expert testimony relating to latency but cautioned that the plaintiffs would need to account for confounding variables, such as their exposure to other pesticides during that timeframe.¹⁷⁶ Markedly, the plaintiffs' experts put forward a distinct conclusion regarding the short latency period: It should signal an "alarm bell" that heavy exposure may increase risk of fast and aggressive cancer development.¹⁷⁷

At the time of this writing, the trial is scheduled to begin in early 2019.¹⁷⁸

C. LESSONS FROM LITIGATION

Each of these representative cases illustrates the nuance that corporate regulatory compliance with FIFRA does not equate to product safety but instead clarifies the unique function of regulatory law compared to product liability litigation. When additional evidence begins to suggest a product may indeed pose unreasonable adverse effects to human health, product liability claims can constitute a critical strategy not only to assess the weight of scientific evidence but also to address corporate influence on the creation of scientific evidence and evaluate corporate strategies to direct how regulatory bodies, courts, and the public view the evidence as a whole. Litigation is a crucial tool for promoting transparency and corporate accountability.

As a consistent defense strategy, Monsanto argued in each case that federal law set forth in FIFRA preempted the plaintiffs' claims. States retain the police power right to protect the health and safety of the public, which includes addressing when members of the public allege they have been injured using an EPA-registered pesticide. Although states cannot undermine federal requirements in FIFRA, such as mandating a modification to the product's label, tort and

172. *Id.* at 18–19, 25–26, 40.

173. *See id.*

174. *Id.* at 22.

175. *Id.*

176. *Id.* at 24.

177. *Id.* at 23.

178. Pretrial Order No. 53: Revised Trial Schedule – Group 1 Plaintiffs, In re Roundup Products Liab. Litig., No. 16-md-02741-VC, MDL No. 2741 (N.D. Cal. Oct. 3, 2018).

consumer protection litigation against manufacturers of potentially risky substances can serve several important goals. Under the EPA's cost-benefit analysis, even an appropriately registered pesticide that has significant economic benefit may pose what society deems to be an unacceptable health risk. Manufacturers have a duty to design reasonably safe products, which includes diligence in testing and labeling that should evolve over time as more research about the product becomes available. Tort and consumer law claims can serve as a catalyst for identifying new dangers associated with product use and can spur product safety improvements.

Each of the three representative cases highlights the influence of product liability precedent that, over time, substantially increased the standards for both admissible and sufficient evidence. In cases such as *Johnson v. Monsanto* and *In re Roundup Product Liability*, evidence such as data reanalysis demonstrating dose-response relationships provides vital support for plaintiffs who face risks arising from frequent occupational exposure. Courts presiding over product liability claims, such as *Lloyd v. Johnson & Johnson*, that grant defense motions for JNOV and reject the sufficiency of extensive evidence from plaintiffs are not only potentially incorrectly discarding a plaintiff's evidence based on an expert's conclusions but are also problematically usurping the jury's role of considering the weight of the evidence, as noted by Judge Bolanos in *Johnson v. Monsanto*. The outcome of litigation both affects public perception of the legitimacy of a plaintiff's claim and, furthermore, affects whether and how the product continues to exist in the marketplace. If the jury concludes a preponderance of evidence demonstrates a plaintiff's exposure to GBH was a substantial factor in causing NHL, then a court's decision to issue a JNOV impacts justice for plaintiffs in addition to affecting the greater public health.

Finally, these representative lawsuits, corresponding media coverage, and the publication of discovery documents functioned as a spotlight to promote transparency of corporate practices. By uncovering memoranda, e-mails, and strategic communications, plaintiffs proffered powerful evidence to support serious and troubling allegations of corporate behavior that entailed claims of suppression of evidence, ghostwriting, inappropriately influencing regulators, and misleading the media. The jury in *Johnson v. Monsanto* found such evidence so compelling that it also awarded punitive damages, finding sufficient evidence that Monsanto intentionally misrepresented and concealed pertinent product risks and recklessly disregarded that human exposure to Roundup poses serious health hazards, including increased risk of NHL.¹⁷⁹ Documents from litigation raise public awareness to the potential gaps in our regulatory framework; call attention to how even appropriately registered pesticides such as glyphosate and GBH may pose risk of harm to consumers; and provide the public access to and insight into

179. Verdict Form, *Johnson v. Monsanto Co.*, 2018 WL 3830050, No. CGC-16-550128 (Cal. App. Dep't Super. Ct. 2018).

specific corporate strategies designed to sway public opinion, regulatory outcomes, and scientific debate. Although the outcome of pending litigation remains to be seen, the jury's verdict for the plaintiffs in *Johnson v. Monsanto* and Judge Bolanos's order denying Monsanto's motion to dismiss in *Johnson v. Monsanto* signal a strong message of corporate accountability.

CONCLUSION

Sifting through conflicting narratives pertaining to potential risks from glyphosate and GBH presents an onerous and confusing task to scientists, the public health community, and regulators. EPA registration and reregistration of glyphosate do not equate to definitive safety but instead reflect the weight of the evidence assessing risk that includes industry-funded or -directed studies and includes consideration of economic benefit, both of which may heavily tip the scale in favor of reregistration. Attempts to undermine IARC's hazard assessment must be recognized as a concerted public relations strategy to create doubt rather than a genuine desire for greater scrutiny of scientific standards. Independent of pending litigation outcomes, discovery documents provide transparency to the extent of corporate influence over scientific research, the media, congressional investigations, and allegations of inappropriate influence on the EPA. Discovery documents provide essential insight into determining credibility and assessing weight of the scientific evidence to inform future regulatory and policy decisions that prioritize public health over corporate interests.