THE "ROUNDUP" CONTROVERSY: GLYPHOSATE LITIGATION, NON-HODGKIN'S LYMPHOMA, AND LESSONS FOR TOXICS REGULATION GOING FORWARD

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INTRODUCTION

In December 2017, the media reported that residues of glyphosate, the main ingredient in the widely used herbicide, Roundup, had been found in oatmeal and baby food.[1] These findings came alongside regulatory disagreements about just how dangerous glyphosate is—controversies that began in earnest in 2015.[2] That year, the International Agency on Cancer Research, part of the World Health Organization, labeled glyphosate as "probably carcinogenic to humans."[3] Despite this finding, the United States Environmental Protection Agency (EPA) has since stated that glyphosate presents no risk to public health when used as intended.[4] Likewise, the European Union's Food Safety Authority (EFSA), has approved glyphosate

[1] *See* Carey Gillam, *FDA Tests Confirm Oatmeal, Baby Foods Contain Residues of Monsanto Weed Killer*, HUFFINGTON POST (Dec. 6, 2017), http://www.huffingtonpost.com/carey-gillam/fda-tests-confirm-oatmeal_b_12252824.html.

[2] *See IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides*, INT'L AGENCY FOR RSCH. ON CANCER (Mar. 20, 2015), https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf.

[3] *See id.*; Corbin Hiar, *Under Fire by U.S. Politicians, World Health Organization Defends its Claim that an Herbicide Causes Cancer*, SCIENCE (Feb. 7, 2018), https://www.sciencemag.org/news/2018/02/who-rebuts-house-committee-criticisms-about-glyphosate-cancer-warning.

[4] *See Glyphosate*, EPA, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (last visited Sept. 24, 2021); Cameron English & Jon Entine, *'Children Killer' Glyphosate Found in Cheerios? Experts Dismantle Environmental Working Group's Herbicide Food Residue Study*, GENETIC LITERACY PROJECT (June 17, 2019), https://geneticliteracyproject.org/2019/06/17/children-killer-glyphosate-found-in-cheerios-experts-dismantle-environmental-working-groups-glyphosate-study.

for use until December 15, 2022.[5] This article explores the controversy around glyphosate and the Roundup herbicide,[6] produced by the corporation formerly known as Monsanto, now acquired by Bayer.[7]

The sale of glyphosate-based herbicide products (GBHs) is "big business," reportedly netting Monsanto/Bayer $5 billion per year, [8] and in the last decade, GBH sale and use has increased sixteen-fold.[9] Usage statistics show that in the forty years prior to 2016, two thirds of all glyphosate used in the United States was used from 2006 to 2016, and only one third of total usage occurred from 1976 to 2006.[10]

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[5] *See Glyphosate*, EUR. FOOD SAFETY AUTH., https://www.efsa.europa.eu/en/topics/topic/glyphosate (last visited Sept. 24, 2021).

[6] The Roundup website lists many products with "caution" warnings on the front of the product with a note that additional warnings can be found on the back panel. The back panel generally contains additional, generic warnings about keeping products out of reach of children, eye and skin irritants, and not applying directly to water. *See Roundup Ready-To-Use Weed & Grass Killer III with Sure Shot Wand*, ROUNDUP, https://www.roundup.com/en-us/products/landscape-weeds/roundup-ready-use-weed-grass-killer-iii-sure-shot-wand (last visited Sept. 24, 2021).

[7] *See* Nathan Bomey, *Monsanto Shedding Name: Bayer Acquisition Leads to Change for Environmental Lightning Rod*, USA TODAY (June 4, 2018), https://www.usatoday.com/story/money/2018/06/04/monsanto-bayer-name/668418002; Greg Roumeliotis & Ludwig Burger, *Bayer Clinches Monsanto with Improved $66 Billion Bid*, REUTERS (Sept 14, 2016), https://www.reuters.com/article/us-monsanto-m-a-bayer-deal-idUSKCN11K128. Given the multiple lawsuits related to Roundup and resulting negative jury verdicts, Bayer's acquisition of Monsanto may be a disastrous decision. *See* Sarah Randazzo & Jacob Bunge, *Inside the Mass-Tort Machine that Powers Thousands of Roundup Lawsuits*, WALL ST. J. (Nov. 25, 2019), https://www.wsj.com/articles/inside-the-mass-tort-machine-that-powers-thousands-of-roundup-lawsuits-11574700480. Hereinafter, Monsanto will be called "Monsanto" in litigation naming it as such and "Monsanto/Bayer" or "Bayer" when referred to generally post-merger.

[8] *See* Carey Gillam, *Tests Show Monsanto Weed Killer in Cheerios, Other Popular Foods*, HUFFINGTON POST (Dec. 6, 2017), http://www.huffingtonpost.com/carey-gillam/tests-show-monsanto-weed_b_12950444.html.

[9] *See* Charles M. Benbrook, *Trends in Glyphosate Herbicide Use in the United States and Globally*, ENV'T. SCI. EUR., 2016 at 1, 5; GAIL P. THELIN & WESLEY W. STONE, U.S. GEOLOGICAL SURVEY, ESTIMATION OF ANNUAL AGRICULTURAL PESTICIDE USE OF COUNTIES OF THE CONTERMINOUS UNITED STATES, 1992–2009 (2013).

[10] *See id.* From 2014 to 2016, 70% of adults had trace amounts of glyphosate in their urine, compared to only 12% tested between 1993 to 1996. ENV'T WORKING GRP., PETITION TO MODIFY THE TOLERANCE OF GLYPHOSATE IN OATS TO .1 PPM AND REQUIRE GLYPHOSATE-CONTAINING PRODUCT LABELS TO

Against this background of increasing sales and use of GBHs, and rising concerns regarding their effect on human health, three juries have held Monsanto liable for astronomical verdicts in Roundup-related tort cases, including one California state court verdict for over $2 billion,[11] another for $289 million,[12] and another for $80 million.[13] In all three suits, the juries found that Monsanto had acted so callously in continuing to sell and market Roundup, despite significant evidence of its toxicity, that the corporation's behavior called for an award of punitive damages.[14] In these cases regarding Monsanto's liability for its manufacture and sale of Roundup, the plaintiffs alleged that they had been regular users of Roundup and that the herbicide caused their cancers. Plaintiffs have put forth legal theories for this liability that include failure to warn, false advertising, and design defect claims.[15] Despite large verdicts, in each case

EXPLICITLY PROHIBIT THE USE OF GLYPHOSATE AS A PRE-HARVEST DESICCANT 2 (Sept. 27, 2018), https://www.ewg.org/sites/default/files/Glyphosate%20Petition%20Final%20.pdf [hereinafter EWG RULE CHANGE PETITION 2018].

[11] *See* Verdict Form for Alva Pilliod, Pilliod v. Monsanto Co., No. RG1786702 (Cal. Super. Ct. May. 13, 2019); Verdict Form for Alberta Pilliod, Pilliod v. Monsanto Co., No: RG1786702 (Cal. Sup. Ct. May 13, 2019).

[12] *See* Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 136 (Cal. Dist. Ct. App. 2020) (noting $289 million dollar verdict).
The appellate court later reduced the Johnson verdict to $20.5 million. *See id.* at 136.

[13] *See* Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021); Verdict form for Edwin Hardeman, Hardeman v. Monsanto Co., No. 16-cv-00525-VC (N.D. Cal. Mar. 9, 2019); *see infra* note 259 and accompanying discussion.

[14] *See id.* at 121; Verdict Form for Alberta Pilliod, Pilliod v. Monsanto Co., No. RG1786702 (Cal. Super. Ct. May. 13, 2019); Verdict Form for Alberta Pilliod, Pilliod v. Monsanto Co., No: RG1786702 (Cal. Sup. Ct. May 13, 2019); *In re* Roundup Prods. Liab. Litig., 385 F. Supp. 3d 1042, 1044 (N.D. Cal. 2019).

[15] In addition to the plaintiffs suing because they allege Roundup caused their cancers, plaintiffs have brought suit urging that products containing trace amounts of glyphosate are deceptively labeled and that defendants have thus been unjustly enriched. The 11th Circuit affirmed a dismissal of such a case in *Doss v. General Mills, Inc.*, 816 Fed. Appx. 312 (11th Cir. 2020) (noting that plaintiff had not shown that she had bought any box of Cheerios containing glyphosate and certainly not any box containing an unsafe amount of glyphosate). *See also* Order Granting Mot. to Dismiss, Parks v. Ainsworth Pet Nutrition, LLC, 18 Civ. 6936 (LLS), 2020 WL 832863, at *1–2 (S.D.N.Y. Feb. 20, 2020) (dismissing suit alleging dog food labeled "natural" could not contain trace amounts of glyphosate and noting that natural does not mean the utter absence of pesticides); Yu v. Dr Pepper Snapple Grp., No. 5:2018cv06664, 2019 WL 2515919, at *2 (N.D. Cal. June 18, 2019).

and in public, Monsanto (now Bayer)[16] has maintained that Roundup does not present unreasonable risk to human health or the environment,[17] and it continues to market and sell GBH products, including Roundup.[18]

The controversy over whether Roundup/glyphosate causes cancer in humans and whether to regulate it, the accompanying legal proceedings, and related regulatory activity provide lessons about our toxics regulatory system and how the United States can more effectively regulate potentially toxic chemicals about which there exists considerable scientific evidence. The Roundup litigation, while similar to recent litigation involving talc-based baby powder,[19] Zantac,[20] and other potentially toxic consumer products, is particularly noteworthy because the herbicide's use is so widespread and millions are exposed.[21]

This Article uses the current status of GBH litigation and regulation to contend that using litigation to curb the sale of products about which there exists strong suspicion of grave harm is not effective, ethical, or cost-saving. We should learn from the limitations of ongoing glyphosate litigation and move past our reluctance to regulate toxic substances where reliable evidence suggests unreasonable danger to human health. Litigation does not serve adequately as a check because jury awards to individual plaintiffs do

16 *See* Bomey, *supra* note 7.

17 *See infra* notes 135–46 and accompanying text discussing FIFRA. FIFRA allows a pesticide to be labeled and sold in the United States if it does not cause "unreasonable adverse effects on the environment," meaning, in part, "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb); 7 U.S.C. § 136a(c)5(d).

18 *See, e.g.*, Monsanto Co.'s Notice of Motion to Dismiss and Memorandum of Points and Authorities in Support of Motion to Dismiss at 3–5, Hardeman v. Monsanto Co., 216 F. Supp. 3d 1037 (N.D. Cal. 2016).

19 *See* Tiffany Hsu & Roni Caryn Rabin, *Johnson & Johnson to End Talc-Based Baby Powder Sales in North America,* N.Y. TIMES (July 27, 2021), https://www.nytimes.com/2020/05/19/business/johnson-baby-powder-sales-stopped.html.

20 *See* Transfer Order, *In re* Zantac (Ranitidine) Prods. Liab. Litig., 20-MD-2924, (S.D. Fla. Feb. 6, 2020) (consolidating 15 actions in 9 districts in MDL litigation). The FDA pulled Zantac from the shelves in April 2020. *See* Katie Thomas, *Zantac Products Should Not Be Sold or Used, FDA Warns, Citing Cancer Danger*, N.Y. TIMES (Apr. 1, 2020), https://www.nytimes.com/2020/04/01/health/zantac-cancer-fda.html.

21 *See infra* Part I.B; *supra*, notes 8–10; *infra* notes 51–61, 196–212 and accompanying discussion.

not account for the widespread social harms caused by these chemicals; it has not had enough of a deterrent effect on sales; and it is designed to settle claims between two parties, not for intervening in the market when products are lucrative but have high human health costs.

Instead of relying on litigation, this Article suggests we should take a focused precautionary approach to regulating GBHs and other chemical substances for which there exists reliable, if not definitive, scientific evidence of grave risk to human health. A more protective regulatory stance aimed at this group of substances would safeguard human health, prevent pain and suffering, save judicial and medical resources, and allow expert regulators to purposefully act. Moving U.S. toxics regulation toward a more targeted and precautionary stance based on existing science would also help make the United States an international leader in the regulation of toxic substances.

This argument has four parts. Part I of this Article includes a brief overview of the relationship between cancer rates, environmental factors, and GBH use. Next, it discusses the contrast between the World Health Organization finding that glyphosate is a probable human carcinogen and the contrary findings of other international, federal, and state agencies.[22] Part II discusses the current federal approach to the regulation of pesticides, herbicides, and fungicides under the U.S. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[23] the Federal Food, Drug, and Cosmetic Act (FFDCA),[24] and the approach[25] to regulating other potentially toxic chemicals under the Lautenberg Chemical Safety Act of 2016 (the "Lautenberg Act" or the "Act"). [26] Next, Part II explores Canadian and European decisions not to ban or significantly restrict glyphosate, noting that this is surprising given that E.U. and Canadian regulators have generally taken a more precautionary approach to toxics regulation than that taken by regulators in the United States.[27] In Part III, the Article contextualizes the thousands of GBH-related tort lawsuits against Monsanto, focusing on the three which have already gone to trial before juries who have granted some of the largest

22 *See infra* Part I.B.
23 *See infra* Part II.B.
24 *See infra* Part II.C.
25 *See infra* Part II.A.
26 *See* Lautenberg Chemical Safety Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified as amended at 15 U.S.C. §§ 2601–2609).
27 *See infra* Part II.A and II.E.

awards to plaintiffs ever recorded.[28] Part IV explains why relying on litigation in lieu of more protective regulation is not most advantageous for protecting human health or efficiently using judicial and other resources.[29] This Part also touches on recent industry attempts to make health-protective toxics regulation more difficult to implement.[30] Finally, Part V suggests that even though science involves judgment and has built-in ambiguity, we need to integrate greater, more targeted reliance on science into our chemical regulatory approach, particularly for a subset of chemicals for which there exists significant evidence of potential, grave risk to human health.

With the Lautenberg Act now in place and FIFRA's existing robust labeling scheme, we have the legislative frameworks in place to support paradigm shifts that will allow us to regulate a number of potentially toxic chemicals expeditiously. However, this will require great shifts in expectations from the public and from regulators themselves. Such shifts will allow EPA to promptly evaluate a short list of suspect or "high priority"[31] synthetic chemicals for which there exists reliable evidence of the potential for great harm.[32] This new, more precautionary regulatory approach will allow the United States to move forward toward a more ethical, cost-efficient paradigm and become a global leader in regulating and labeling glyphosate and other potentially toxic substances.

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28 *See infra* Part III.

29 *See infra* Part IV.

30 *See infra* notes 105–10 and accompanying discussion.

31 15 U.S.C. § 2605(b)(1)(B) calls for the regulation of existing, high priority non-pesticidal chemicals.

32 *See infra* Part V. Under 15 U.S.C. § 2602(B)(ii), pesticide substances are exempt from the Lautenberg Act. The Act sets up a model for regulating new chemicals suspected of grave harm at a faster pace than existed before the Act's passage. *See* Valerie J. Watnick, *The Lautenberg Chemical Safety Act of 2016: Cancer, Industry Pressure and a Proactive Approach*, 43 HARV. ENV'T. L. REV. 373, 393 (2019); 15 U.S.C. § 2605(c)(2) (Administrator must propose a rule regarding a chemical that is slated for "high priority" review within one year of a risk evaluation). The Act also calls for more stringent review of new chemicals and new chemical uses. *See id*. at 392–93; 15 U.S.C. § 2604(e) (allowing EPA to issue an order if data is insufficient to determine if a chemical or use will present unreasonable risk; that the chemical will be produced in large volume; or that, without regard to cost or non-risk factors, the chemical or use may present a risk of injury to health or the environment under the planned "conditions of use").

I. THE GLYPHOSATE CONTROVERSY: GLYPHOSATE IN ROUNDUP

A. *Background on Cancer Rates, Environmental Factors, and Glyphosate-Based Herbicide Use* [33]

Cancers such as Non-Hodgkin's Lymphoma (NHL), as suffered by many of the plaintiffs who had used glyphosate, tallied approximately seventy-seven thousand new cases and caused almost twenty thousand deaths in 2020 in the United States alone.[34] Cancer statistics show that at least one in three Americans will develop some type of cancer in their lifetime.[35] Indeed, cancer continues to be one of the leading causes of death in the world,[36] and the National Cancer Institute predicts that worldwide cancer incidence will increase over the next twenty-two years by more than fifty percent.[37] For example, cancer rates in cancers most common in children have steadily increased since 1975, with rates increasing by approximately 0.8 percent yearly from 2007 to 2016.[38] Experts believe environmental exposures pose significant risk in development of these cancers.

In 2010, the President's Cancer Panel, the official advisors to the President on the National Cancer Program,[39] noted that many

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[33] The following section is partially adapted and updated from Watnick, *The Lautenberg Chemical Safety Act*, *supra* note 32. *See also infra* Part V.

[34] *See* AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2020, at 10 fig.3 (2020), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf.

[35] According to the National Cancer Institute, 606,520 people in the United States will have died from cancer in 2020, and 1,806,590 new cases will have been diagnosed. *See Cancer Statistics*, NAT'L CANCER INST. (Sept. 25, 2020), https://www.cancer.gov/about-cancer/understanding/statistics. Far more Americans will die in 2021 from cancer than from gun violence. For reference, cancer deaths in the United States in 2016 were 595,690. Deaths from gun violence in 2016 numbered 38,658 people. *See Gun Violence in America*, EVERYTOWN RSCH. & POL'Y (May 19, 2020), https://everytownresearch.org/gun-violence-by-the-numbers (citing CDC statistics).

[36] *See Cancer*, WORLD HEALTH ORG. (February 2018), http://www.who.int/mediacentre/factsheets/fs297/en; NAT'L CANCER INST., *supra* note 35.

[37] *See* NAT'L CANCER INST., *supra* note 35.

[38] *See* AM. CANCER SOC'Y, *supra* note 34, at 9.

[39] *See* Roxanne Nelson, *President's Cancer Panel: Environmental Cancer Risk Under Estimated*, MEDSCAPE (May 13, 2010), https://www.medscape.com/viewarticle/721766#vp_1; PRESIDENT'S CANCER PANEL, ACCELERATING HPV

more cancers were environmentally related than previously recognized in a controversial report calling for more precautionary measures to prevent cancers in the United States.[40] The American Cancer Society criticized the Report for focusing on environmental factors, claiming that more cancers are due to lifestyle, rather than environmental causes.[41] However, medical experts, including the expert Cancer Panel, suggested that while lifestyle plays a part in cancer and other disease development, environmental factors are significant and have historically been underestimated by the medical community.[42]

In addition, cancer and other diseases linked to environmental causes exact a tremendous emotional and economic toll on affected families.[43] The American Cancer Society reported that in 2015, medical costs for cancer care in the United States amounted to $80.2 billion.[44] In addition, the American Cancer Society estimates that Americans lost $94 billion in earnings in 2015 due to cancer deaths.[45]

VACCINE UPTAKE: URGENCY FOR ACTION TO PREVENT CANCER (2014), https://www.medscape.com/viewarticle/721766#vp_1.

[40] *See* SUZANNE H. REUBEN, PRESIDENT'S CANCER PANEL REPORT, REDUCING CANCER RISK vi–ix (2010), https://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf. The Panel made headlines, calling the environmental risk of the cancer "grossly underestimated." Daniel DeNoon, *Environmental Cancer Risk 'Grossly Underestimated'?* WEBMD: CANCER CENTER (May 6, 2010), https://www.webmd.com/cancer/news/20100506/environmental-cancer-risk-grossly-underestimated.

[41] *See* Kate Sheridan*, Americans Are Giving Themselves Cancer—Half of Cases Caused by Lifestyle*, NEWSWEEK (Nov. 22, 2017), http://www.newsweek.com/americans-are-giving-themselves-cancer-half-cases-caused-lifestyle-719512.

[42] *See* Marla Cone, *Doctors Underestimate Environment as Cause for Cancer*, SCI. AMERICAN (May 6, 2010), https://www.scientificamerican.com/article/environment-as-cause-for-cancer; *id.*

[43] *See generally* Peeranuch LeSeure & Supaporn Chongkham-ang, *The Experience of Caregivers Living with Cancer Patients: A Systematic Review and Meta-Synthesis*, 5 J. PERSONLIZED MED. 406 (2015). The National Cancer Institute estimated that national expenditures for cancer care in the United States in 2018 totaled $150.8 billion. NAT'L CANCER INST., *supra* note 35. The World Health Organization estimates that in 2010, the economic worldwide cost of cancer was $1.16 trillion. WORLD HEALTH ORG., WORLD CANCER REPORT 2014 576 (Bernard W. Stewart & Christopher P. Wild eds.), https://publications.iarc.fr/Non-Series-Publications/World-Cancer-Reports/World-Cancer-Report-2014.

[44] *See* AM. CANCER SOC'Y, *supra* note 34, at 9.

[45] *See id.*

Even prior to the 2010 President's Cancer Panel Report, leading scientists and public policy experts argued for a paradigm shift in our general toxics regulatory system to make it more precautionary in approach.[46] These expert opinions[47] suggested the need for a regulatory approach different than the existing Toxics Substances Control Act and more stringent than FIFRA: one that would test chemicals thoroughly or require industry testing, as is required by other countries, before they are brought to market.[48] The experts urged a more precautionary approach in the United States,[49] where chemical manufacturers produce and market approximately eighty thousand synthetic chemicals, the vast majority of which were not tested before they came to market and remain untested for their effects on human health.[50]

Despite these expert warnings, the use of synthetic pesticides in the United States continues to skyrocket,[51] particularly the use of GBHs.[52] GBHs are broad spectrum herbicides that kill a variety of weeds and grasses.[53] They are used agriculturally and in homes and parks via sprays, droplets and injections, and are now widely used

46 *See* Richard W. Clapp, *Environmental and Occupational Causes of Cancer Re-visited*, 27 J. PUB. HEALTH POL'Y 61, 73–74 (2006).

47 *See id.*

48 *See, e.g.*, Commission Regulation 1907/2006, art. 5, 2006 O.J. (L 396). This section of European chemical regulations, commonly known as "no data, no market," requires E.U. manufacturers to comply with testing requirements for their products before they go to market. Jeanne Rizzo, CEO of the Breast Cancer Fund and RN, stated at the time of the President's 2010 Cancer Panel Report that the Panel "level[s] a hefty critique of failed regulation [of environmental contaminants], undue industry influence, and inadequate research and funding." Jeanne Rizzo, *It's Time for Breast Cancer Prevention Month*, HUFFINGTON POST (Oct. 12, 2010, 12:27 PM), https://www.huffingtonpost.com/jeanne-rizzo/its-time-for-breast-cance_b_759556.html.

49 *See* Rizzo, *supra* note 48 and accompanying discussion.

50 *See* U.S. GOV'T ACCOUNTABILITY OFF., TOXIC SUBSTANCES 12–17 (2013); John Wargo, *Pervasive Plastics: Why the U.S. Needs New and Tighter Controls*, YALE ENV'T 360 (Nov. 12, 2009), https://e360.yale.edu/features/pervasive_plastics_why_the_us_needs_new_and_tighter_controls.

51 *See* Emily Marquez, *In the U.S. and the World, Pesticide Use is Up*, PESTICIDE ACTION NETWORK (Aug. 2, 2018), http://www.panna.org/blog/us-and-world-pesticide-use; Valerie Matozzo et al., *The Effects of Glyphosate and Its Commercial Formulations to Marine Invertebrates: A Review*, J. MAR. SCI. ENG., June 2020, at 29 (noting that U.S. glyphosate usage has increased 300% from 1974 to 2014). Pesticides are regulated mainly under FIFRA. *See infra* Part II.B.

52 *See* Benbrook, *supra* note 9, at 10.

53 *See Glyphosate*, *supra* note 4.

on corn, soybeans, and other crops.[54] Increases in GBH usage occurred largely after the introduction of glyphosate-resistant "Roundup ready" crops, which have been genetically modified to survive broad-spectrum Roundup application.[55] In addition, since the mid-2000s, GBHs have been widely used not just to kill weeds, but as desiccants (drying agents) on crops ready for harvest.[56] As GBH usage has broadened and increased, some weeds have become resistant, requiring the application of additional amounts of the herbicide.[57]

In 2014, in the United States alone, GBH usage stood at 276 million pounds,[58] and global usage of GBHs topped 1,800 million pounds.[59] In 2016, Newsweek wrote: we are literally "awash in glyphosate."[60] Rather than imposing stricter safety requirements for GBHs in response to this increased and expanded usage, EPA has instead allowed greater herbicide residues on crops as they are brought to market.[61]

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54 *See id.*

55 *See* Myers et al., *Concerns Over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement*, ENV'T HEALTH, 2016, at 10; THELIN & STONE, *supra* note 9.

56 *See* Benbrook, *supra* note 9, at 9.

57 *See* THELIN & STONE, *supra* note 9; Benbrook, *supra* note 9, at 2 nn.11–13 ("To combat weeds less sensitive to glyphosate, farmers typically increase glyphosate application rates and spray more often."); Stephen Tan & Brian Epley, *Much Ado About Something: The First Amendment and Mandatory Labeling of Genetically Engineered Foods*, 89 WASH. L. REV. 301, 317 (2014).

58 *See* Luoping Zhang et al., *Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence*, 781 MUTATION RSCH. 186, 187 fig.1 (2019); Alexis Tempkin, *Breakfast With a Dose of Roundup?*, YWECARE (Aug. 15, 2018), https://www.ywecare.org/health/77-breakfast-with-a-dose-of-roundup.

59 *See* Zhang et al., *supra* note 58, at 187.

60 Douglas Main, *Glyphosate Now the Most-Used Agricultural Chemical Ever*, NEWSWEEK (Feb. 2, 2016), https://www.newsweek.com/glyphosate-now-most-used-agricultural-chemical-ever-422419. This article begins: "The world is awash in glyphosate, the active ingredient in the herbicide Roundup, produced by Monsanto." *See also* Zhang et al., *supra* note 58, at 187 (noting "ubiquitous exposure" in humans to glyphosate); Carey Gillam, *USDA Drops Plan to Test for Monsanto Weed Killer in Foods*, HUFFPOST, March 27, 2017, https://www.huffpost.com/entry/usda-drops-plan-to-test-for-monsanto-weed-killer-in_b_58d2db4ee4b062043ad4af84.

61 *See, e.g.*, 40 C.F.R. § 180.364 (July 1, 2017) (increasing tolerance on oats from 0.1 in 1993 to 30 parts per million); 40 C.F.R. § 180.41(c)(24)(ii); Gibson v. Quaker Oats Co., No. 16 CV 4853, 2017 WL 3508724, at *1 (N.D. Ill. 2017) (noting that EPA changed the maximum allowed amount for glyphosate on oats from

Amidst this growing exposure to GBHs, a large body of literature suggests potential negative effects on environmental and human health.[62] For example, with regard to the link between glyphosate and cancer, scientists have studied the teratogenic[63] effects of GBHs on vertebrates,[64] occupational exposure and its relation to NHL,[65] and the induction of growth in human breast cancer cells.[66] However, cancer is widely considered by experts to be exponentially complex, "of [varying] typology, genetics, environmental factors, and idiosyncrasies."[67] In other words, cancer causation is extremely challenging to definitely prove. In turn, this difficulty in connecting a chemical such as glyphosate or any synthetic chemical with cancer development makes it hard for U.S. regulators to ever gather enough proof to effectively regulate. Rather, researchers tend to look for long-term relationships and statistical associations using meta-analyses of epidemiological research done over protracted periods.[68] At least partially due to this complexity in cancer causation, the regulation of glyphosate to protect human health has been

20 parts per million in 1997 to 30 parts per million in 2008); Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25396, 25399 (May 1, 2013) (affecting crops such as okra and strawberries, among others).

62 *See* Benbrook, *supra* note 9, at 11; *infra* notes 63–80 and accompanying text.

63 The study of teratogenic effects involves a study of whether a substance affects embryological development. *See generally* Alejandra Paganelli et al., *Glyphosate-Based Herbicides Products Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling*, 23 CHEM. RSCH. TOXICOLOGY 1586 (2010).

64 *See id.* at 1586–95.

65 *See* Leah Schinasi & Maria E. Leon, *Non-Hodgkin Lymphoma and Occupational Exposure to Agricultural Pesticide Chemical Groups and Active Ingredients: A Systematic Review and Meta-Analysis*, 11 INT. J. ENV'T. RSCH. PUB. HEALTH 4449 (2014) (meta-analysis studying 44 papers published over three decades).

66 *See* Siriporn Thongprakaisang et al., *Glyphosate Induces Human Breast Cancer Cells Growth via Estrogen Receptors*, 59 FOOD & CHEM. TOXICOLOGY 129 (2013).

67 *See* Douglas Hanahan & Robert A. Weinberg, *The Hallmarks of Cancer*, 100 CELL 57, 57 (2000); Jacob Sherkow, *Cancer's IP*, 96 N.C. L. REV. 297 (2018) (encouraging public-private partnerships in cancer research).

68 *See, e.g.*, Schinasi & Leon, *supra* note 65; Zhang et al., *supra* note 58, at 187. For a discussion of how scientists use meta-analysis and why synthesizing the data across studies to reach an "overall understanding" is crucial for scientific inquiry, *see generally* Jessica Gurevitch et al., *Meta-analysis and the Science of Research Synthesis*, 55 NATURE 175 (2018).

controversial, as reflected in the different stances taken by key international and U.S. agencies.

B. *United States and Global Governmental Responses to Glyphosate-Based Herbicides and the Regulation of Glyphosate as a Potential Environmental Factor in Cancer Rates*

In 2015, the World Health Organization, through its arm, the International Agency for Research on Cancer (IARC), labeled glyphosate a probable human carcinogen based on existing research.[69] In reaching this finding, the IARC monograph working group on glyphosate, which is comprised of seventeen scientists from eleven countries, had studied available evidence and determined that GBHs are associated with NHL.[70] At least one expert has called the IARC the "number one arbiter in the world of whether something is carcinogenic."[71] By contrast, in that same year, EPA declared that glyphosate was "not likely to be carcinogenic to humans."[72] EPA has gone further and states that there are "no risks of concern" to public health from glyphosate when used as labeled and that the herbicide is not a human carcinogen.[73]

Dr. Charles Benbrook has put forth multiple explanations for the well-regarded agencies' disparate findings in a highly-reviewed paper. In that paper, Benbrook noted that while EPA and the IARC looked at some of the same studies, EPA relied mainly on "unpublished regulatory studies, many of them industry-funded."[74] The

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[69] *See* Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 118 (Cal. Dist. Ct. App. 2020); *see also* Int'l Agency for Rsch. On Cancer, *IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides*, WORLD HEALTH ORGANIZATION [WHO] (Mar. 20, 2015), https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf.

[70] *See IARC Monograph on Glyphosate,* INT'L AGENCY FOR RSCH. ON CANCER (Mar. 1, 2016), https://www.iarc.who.int/featured-news/media-centre-iarc-news-glyphosate; 112 INT'L AGENCY FOR RSCH. ON CANCER, SOME ORGANOPHOSPHATE INSECTICIDES AND HERBICIDES 398 (2017); Kathryn Z. Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon, and Glyphosate*, 16 LANCET ONCOLOGY 490, 490 (2015).

[71] *Johnson,* 266 Cal. Rptr. 3d at 118.

[72] OFF. OF PESTICIDE PROGRAMS, EPA, GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL 13 (2016).

[73] *Glyphosate*, *supra* note 4.

[74] *See* Charles M. Benbrook, *How Did the US EPA and IARC Reach Diametrically Opposed Conclusions on the Genotoxicity of Glyphosate-Based Herbicides?*, 31 ENV'T SCI. EUR. 1, 1 (2019) ("EPA relied mostly on registrant-commissioned, unpublished regulatory studies, 99% of which were negative, while IARC

IARC, on the other hand, looked at "'mostly peer-reviewed studies,' including three in humans that suggested glyphosate might indeed be toxic."[75] Benbrook, in analyzing this discrepancy, posited that there are two other reasons for EPA and the IARC's different conclusions.[76] He asserts that not only did EPA rely more on "regulatory studies" commissioned by chemical industry registrants, but it also did not account for cancers related to the main metabolite of glyphosate, aminomethylphosphonic acid (AMPA). EPA also did not take into account additional exposures for occupational use of GBHs.[77] Instead, EPA focused on exposure of the general population and dietary exposure, assuming legal uses of glyphosate.[78] These different supporting documents and differing exposure foci may explain why EPA virtually found no "regulatory" assay that said that glyphosate caused cancer, while the WHO/IARC found that the vast majority of assays suggested positive associations between glyphosate and cancer in humans.[79] EPA's reliance on industry studies and failure to account for occupational exposure in this case exemplifies its over-reliance on industry inputs. While decisions about toxicity of useful products are inherently complicated and difficult, this heavy reliance by EPA on industry-provided data demonstrates how the regulatory system is not well designed to protect human health.

To add fuel to the controversy about whether glyphosate is safe for use, and whether it should be further regulated, California declared glyphosate a known human carcinogen in 2017.[80] The State then filed a "Notice of Intent to List" glyphosate as a substance

relied mostly on peer-reviewed studies of which 70% were positive."); Hilary Brueck, *The EPA Says a Chemical in Monsanto's Weed-Killer Doesn't Cause Cancer — But There's Compelling Evidence the Agency Is Wrong*, BUS. INSIDER (June 17, 2019), https://www.businessinsider.com/glyphosate-cancer-dangers-roundup-epa-2019-5; *Johnson*, 266 Cal. Rptr. 3d at 119.

75 Brueck, *supra* note 74.

76 *See* Benbrook, *supra* note 74, at 14.

77 *See id.*

78 *See id.*

79 *Id.*; INT'L AGENCY FOR RSCH. ON CANCER, *supra* note 70, at 1.

80 *Glyphosate Listed Effective July 7, 2017, Known to the State of California to Cause Cancer*, OFF. ENV'T HEALTH HAZARD ASSESSMENT (June 26, 2017), https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer.

known to the state to cause cancer under Proposition 65.[81] Under California's Proposition 65, this declaration brought glyphosate within Proposition 65 listing requirements, which, if implemented, would impose strict warning labels on all products containing glyphosate.[82] Such labels, under Proposition 65, conspicuously warn that the product contains a chemical(s) "known [to the State of California] to cause cancer, birth defects or other reproductive harm."[83]

Following this "Notice of Intent to List" by the State, Monsanto sued the Office of Environmental Health Hazard Assessment to enjoin labeling of Roundup in 2016.[84] The California state court held that in requiring labeling that warned that the product could cause cancer in humans, the State had not violated Monsanto's due process rights and had not unconstitutionally delegated responsibilities to the California Office of Environmental and Health Hazard Assessment (OEHHA).[85] In so holding, the California Court of Appeal noted that the IARC is an internationally recognized agency in cancer research that had published a 2015 monograph regarding

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[81] *See* Notice of Intent to List Glyphosate, CAL. CODE REGS tit. 27, § 25904 (2017), https://oehha.ca.gov/media/downloads/crnr/finallistingnoticeglyphosate07072017.pdf; *see also* Monsanto v. Off. Of Env't Health Hazard Assessment, 231 Cal. Rptr. 3d 537, 542 (Cal. Ct. App. 2018).

[82] *See Glyphosate Listed Effective July 7, 2017, supra* note 80; *Monsanto*, 231 Cal. Rptr. 3d at 561 (finding no error in failure of trial court to dismiss Monsanto's claim that the Proposition 65 and accompanying requirements were an "improper delegation of authority"); *Proposition 65 Warnings*, CAL. OFF. ENV'T HEALTH HAZARD ASSESSMENT, www.p65warnings.ca.gov (last visited Oct. 18, 2021).

[83] Responsibility to Provide Consumer Product Exposure Warnings, 27 CAL. CODE REGS § 25600.2; *Proposition 65 Warnings*, *supra* note 82 (containing detailed information on California's Proposition 65 warnings). Indeed, California toxics warning requirements have spawned a cottage industry. One internet search reveals that companies are readily willing and able to provide warning stickers for a business's products. *See, e.g.*, *California Prop 65 Labels*, ULINE, https://www.uline.com/BL_2483/California-Prop-65-Labels.

[84] Petition for Writ of Mandate and Complaint, Monsanto Co. v. Office of Env't Health Hazard Assessment, No. 16CECG00183, 2017 Cal. Super. LEXIS 3 (Cal. Super. Ct. Mar. 10, 2017). The California Supreme Court declined to review the decision in the case on August 15, 2018. *Appellate Courts Case Information*, CALIFORNIA COURTS, https://appellatecases.courtinfo.ca.gov/search/case/mainCaseScreen.cfm?dist=0&doc_id=2252820&doc_no=S249056&request_token=NiIwLSEmTkw2W1BdSSFdTEtIQDw0UDxTJyBORz9SUCAgCg%3D%3D (last visited Sept. 24 2021).

[85] *See* Monsanto Co. v. Office of Env't. Health Hazard Assessment, 231 Cal. Rptr. 3d 537, 560 (2018).

glyphosate,[86] and that California could rely on IARC as an authoritative body in making its determination regarding glyphosate.[87] Monsanto subsequently brought a federal action, after the California Supreme Court declined to hear the case on the basis that the Proposition 65 warning would violate Monsanto's free speech rights and would expose Bayer, the parent company, to litigation.[88] Finally, in summer 2020, the federal court blocked California's attempt to label GBHs under Proposition 65.[89]

C. *Scientific Support for Increased Glyphosate-Based Chemical Regulation*

Despite this federal court decision and EPA's finding that glyphosate is not a human carcinogen, many activists and scientists nonetheless have persuasively asserted that the relationship between GBHs and NHL needs priority attention because glyphosate is so widely used in agriculture.[90] The Agricultural Health Study, a huge prospective cohort study begun in the 1990s, continues to produce ongoing, important data regarding the relationship between

[86] *See Monsanto*, 231 Cal. Rptr. 3d at 541. A monograph is "a detailed written study of a single specialized topic." *Monograph*, OXFORD ENGLISH DICTIONARY, https://www.oed.com/view/Entry/121419 (last visited Sept. 24, 2021).

[87] *See Monsanto*, 231 Cal. Rptr. 3d at 556–57 (noting that "the Agency [IARC] is an international agency created specifically to scientifically investigate potentially carcinogenic compounds. Its reputation and authority on the world stage—and relatedly its funding—is dependent, in part, on its work being accepted as scientifically sound."). Since the state court case, Monsanto has sought relief in federal court on constitutional grounds. Nat'l Ass'n of Wheat Growers v. Lauren Zeise, 309 F. Supp. 3d 842, 845–46 (E.D. Cal. 2018) (preliminarily enjoining labeling in that it was not purely factual and uncontroversial).

[88] *See generally Nat'l Ass'n of Wheat Growers*, 309 F. Supp. 3d at 854 (preliminarily enjoining labeling in that it was not purely factual and uncontroversial); Joel Rosenblatt, *Bayer Wins Ruling Blocking California's Roundup Warning*, BLOOMBERG (June 22, 2020), https://www.bloomberg.com/news/articles/2020-06-22/bayer-wins-court-ruling-blocking-california-s-roundup-warning?sref=eJaRTK7q.

[89] *See Nat'l Ass'n of Wheat Growers*, 309 F. Supp. 3d at 854 (group of farming organizations joined Monsanto to oppose the labeling).

[90] *See* Elizabeth Ward, *Glyphosate Use and Cancer Incidence in the Agricultural Health Study: An Epidemiologic Perspective*, 110 J. NAT'L CANCER INST. 446 (2018); Benbrook, *supra* note 74; Nat. Res. Def. Council, Comments on Glyphosate Proposed Interim Registration Review Decision (Sept. 3, 2019), https://www.agri-pulse.com/ext/resources/pdfs/g/nrdc-glyphosate-cancer-comments-20190903.pdf.

exposure to GBHs and carcinogenic effects.[91] The dataset used in the study includes 57,310 licensed pesticide applicators and 32,347 spouses in Iowa and North Carolina. Scientists continue to analyze this data prospectively to see if there are relationships between glyphosate use and various cancers.[92]

In 2019, researchers published a noteworthy meta-analysis in *Mutation Research* that statistically analyzed all human studies to date that had considered the relationship between glyphosate and NHL.[93] In this meta-analysis, the authors concluded that GBH exposure is associated with increased risk of NHL in humans.[94] The scientists set out to explore the controversy over glyphosate by testing the a priori hypothesis that exposure to GBHs at higher levels and for longer durations or with a sufficient lag and latency period would lead to higher levels of NHL.[95] In conducting their meta-analysis, the authors evaluated past studies, including a significant 2018 data update to the Agricultural Health Study.[96] The scientists noted that a cohort study such as the Agricultural Health Study[97] is the "gold standard" for "their ability to estimate exposure before disease occurrence."[98] In conducting their research, the scientists found that the 2018 update to the Agricultural Health Study was significant because the latency period between exposure to GBHs and NHL could

[91] *See* Michael C. R. Alavanja et al., *The Agricultural Health Study*, 104(4) ENV'T HEALTH PERSPECTIVES 362 (1996).

[92] *See* Anneclaire J. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide Health Applicators in the Agricultural Health Study*, 113(1) ENV'T HEALTH PERSPS. 49 (2005); Lianne Sheppard & Rachel Shaffer, *Re:Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 111(2) J. OF NAT'L CANCER INST. 214 (2019); Pamela J. Mink et al., *Epidemiologic Studies of Glyphosate and Cancer: A Review,* 63 REGUL. TOXICOLOGY & PHARMACOLOGY 440, 440–52 (2012).

[93] *See* Zhang et al., *supra* note 58, at 188; *see generally* Alavanja, *supra* note 91.

[94] *See* Zhang et al., *supra* note 58, at 202.

[95] *See id.* at 188.

[96] *See* Gabriella Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 J. NAT'L. CANCER INST. 509 (2018); Alavanja, *supra* note 91.

[97] A cohort study involves following a large group over time rather than analyzing existing NHL cases. *See Prospective Cohort Study*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/prospective-cohort-study (last visited Feb. 1, 2022).

[98] Zhang et al., *supra* note 58, at 199.

be as short as two and as long as fifteen years.[99] Thus, in 2018, researchers identified 575 cases of NHL after exposure to GBHs,[100] whereas researchers using the 2005 data had only identified 92 cases among the cohort.[101] The *Mutation Research* scientists in turn asserted that their current meta-analysis of human epidemiological studies, including the updated Agricultural Health Study, suggests a "compelling" link between exposures to GBHs and NHL.[102] These scientists concluded, "[t]ogether, all of the meta-analyses conducted to date, including our own, consistently report the same key finding: exposure[s] to GBHs is associated with an increased risk of NHL."[103]

While the Agricultural Health Study meta-analysis has been referred to as the "gold standard," it is noteworthy from a regulatory point of view that its use may have been imperiled by a 2019 EPA "transparency" rule.[104] The rule, which is no longer in effect, would

99 *See id.* at 201.

100 *See* Andreotti et al., *supra* note 96.

101 *See* De Roos et al., *supra* note 92.

102 Zhang et al. *supra* note 58, at 204.

103 *Id.* Scientists involved in the above Mutation Research Study noted that they did not have any financial conflicts of interest. *Id.* at 204. Other studies have also considered the Agricultural Health Study. Scientists Sheppard and Shaffer criticized the regression analysis of the Study data in that it failed to account for NHL and multiple myelomas as serious health outcomes for those exposed to glyphosate. In this way, the Agricultural Health Study had found no relationship—or a null relationship—between glyphosate use and cancer. Shepard and Shaffer explain that this failure to consider these health factors leads to bias against a finding of increased risk. Sheppard and Shaffer in particular call for the Agricultural Health Study investigators to refine their approach: "[we] encourage the AHS investigators to refine their approach and improve our ability to understand the true impacts of pesticide exposures, which—particularly for glyphosate—could have tangible consequences for public health policy." Sheppard & Shaffer, *supra* note 92. Past statistics have also shown that regression analysis done without these health effects is regression analysis with "missing X's" that leads to bias in the results. Roderick J.A. Little, *Regression with Missing X's: A Review*, 87 J. AM. STAT. ASS'N 1227 (1992).

104 *See* Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469, 473 (Jan. 6, 2021) (to be codified at 40 C.F.R. pt. 30) [hereinafter Strengthening Transparency in Pivotal Science]; EARTHJUSTICE, Comments for the Science Advisory Board's Consideration in Advance of its June 2019 Meeting (May 19, 2019), https://yosemite.epa.gov/sab/sabproduct.nsf/C8DC97CD16CBF8808525840B0068C228/$File/Public+comments+from+Earthjustice.pdf; *see* Order Granting Motion to Vacate and Remand at 2, Env't Def. Fund v. EPA, No. 4:21-cv-00003-BMM (D. Mont. Feb. 1, 2021) (vacating the rule).

have required scientists to submit all backup data to public scrutiny, even if it includes confidential, personal, medical information.[105] Essentially, the rule would have allowed regulators to ignore large-scale studies unless they are shared such that the personal data of study participants is available "in a manner sufficient for independent validation."[106] The rule would concomitantly have allowed the Agency to "give greater consideration to studies where the underlying data and models were available . . . either because they were publicly available" or because they had been made available on a limited basis.[107] Touted as a rule that would increase transparency as denoted by its name, "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Decisions and Influential Scientific Information," the rule would in actuality have made it more difficult for scientists to access health records that could support more health protective regulatory measures in general and with regard to glyphosate in particular. In commenting on the proposed regulatory changes at the time, the public interest group Earthjustice noted that the rule was inconsistent with best practices and that there was "no valid scientific basis to ignore epidemiological health studies and other peer-reviewed scientific information that reflect the best-available science when conducting rulemakings."[108] In 2021, a federal district judge in the District of Montana struck down the effort to decrease transparency when he "scrapped"[109] the

105 *See* Strengthening Transparency in Pivotal Science, 86 Fed. Reg. at 469–70; Lisa Friedman, *A Plan Made to Shield Big Tobacco From Facts Is Now E.P.A. Policy*, N.Y. TIMES (Jan. 4, 2021), https://www.nytimes.com/2021/01/04/climate/trump-epa-science.html. The U.S. Court of Appeals for the Second Circuit, in *EPA v. General Electric Co.*, 197 F.3d 592, 595 (2d Cir. 1999), found that "the Federal Housekeeping Statute, 5 U.S.C. 301, authorizes government agencies such as the EPA to adopt regulations regarding 'the custody, use, and preservation of [agency] records, papers, and property.'" *See also* Strengthening Transparency in Regulatory Science, 85 Fed. Reg. 15,396, 15,397 (proposed Mar. 18, 2020) (to be codified at 40 C.F.R. pt. 30) ("Courts have considered EPA to be an agency with section 301 housekeeping authority"); Lisa Friedman, *EPA to Limit Science Used to Write Public Health Rules*, N.Y. TIMES (Nov. 11, 2019), https://www.nytimes.com/2019/11/11/climate/epa-science-trump.html?smid=nytcore-ios-share.

106 Strengthening Transparency in Pivotal Science, 86 Fed. Reg. at 470.

107 *Id.* at 483.

108 EARTHJUSTICE, *supra* note 104, at 1.

109 Asher Jones, *A Federal Judge Ditches EPA's Science Transparency Rule*, SCIENTIST (Feb. 8, 2021), https://www.the-scientist.com/news-opinion/a-federal-judge-ditches-epas-science-transparency-rule-68432; Order Granting Motion to Vacate and Remand, *supra* note 104, at 1.

"Strengthening Transparency" rule, finding that EPA had not properly engaged in rulemaking in this area and had no authority to do so.[110]

II. CURRENT REGULATION OF PESTICIDE SUBSTANCES

A. *Overview of Federal Statutes Regulating Synthetic Chemicals*

FIFRA regulates the use and sale of all pesticides, which includes herbicides, insecticides, and rodenticides,[111] while FFDCA[112] regulates pesticide use on food products. The Food Quality Protection Act of 1996 (FQPA),[113] which amended both FIFRA and FFDCA, regulates the *amount* of pesticide residue allowed on foods.[114] FIFRA only minimally regulates pesticides to protect human health in that it is primarily a marketing and labeling statute. In turn, FFDCA and FQPA allow EPA to set limits on the amount of toxic residue allowed in food, but without true accounting for the complex and varied exposure humans face every day. These regulatory weaknesses are discussed further below. In addition to FIFRA and FFDCA, Congress designed the Toxic Substances Control Act (TSCA)[115] as a catch-all act to regulate all other chemical substances not otherwise covered by regulation. TSCA, however, has suffered

110 *See* Order Granting Motion to Vacate and Remand, *supra* note 104, at 1 (explaining that the motion for vacatur was unopposed by EPA under the Biden administration).

111 *See* 7 U.S.C. § 136(u) (defining "pesticide" for the purposes of FIFRA).

112 *See* 21 U.S.C. § 346a(a) (defining tolerance requirements and exemptions for pesticide chemical residues). The Food Quality Protection Act of 1996 amended FFDCA. Food Quality Protection Act of 1996, Pub. L.104-170, 1101 Stat. 1489 (1996).

113 *See* Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in scattered sections of 7 U.S.C. and 21 U.S.C. and amending FIFRA and FFDCA); *see also The Food Quality Protection Act (FQPA) of 1996*, EPA, https://perma.cc/8J6W-6JDT (last visited Sep. 21, 2021) (providing background information on the functions and history of FQPA).

114 *See generally* 21 U.S.C. § 346a.

115 *See* H.R. REP. NO. 114-176, at 12 (2015) ("In 1971, the President's Council on Environmental Quality proposed comprehensive Federal legislation to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes."); Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2629).

from shortcomings as well in that it contained a major regulatory loophole.[116]

While truly intended as a regulatory safeguard, TSCA[117] had proven largely ineffective at regulating the over eighty thousand[118] non-pesticidal chemicals on the market.[119] This failure has been mainly due to a "catch-22" provision embedded in the regulatory framework, alongside the grandfathering of more than sixty thousand existing chemicals at the time of TSCA's passage.[120] TSCA's "catch-22" provision did not allow EPA to require testing of a chemical if it did not have adequate data, but it also did not allow EPA to request such information from industry unless it already believed the chemical presented an unreasonable risk to public health or the environment.[121] This "unreasonable risk" assertion was difficult to make without data.[122] Thus, EPA could only request information if it already had some data suggesting that a chemical was a danger to human health or the environment.[123] As a result, in the more than forty years since the enactment of TSCA, the federal government has only called for testing of approximately two hundred chemicals and has restricted the use of less than ten chemicals under TSCA.[124]

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116 *See* Charles Schmidt, *TSCA 2.0: A New Era in Chemical Risk Management*, 124 ENV'T HEALTH PERSPS. 182, 183–84 (2016); Watnick, *supra* note 32, at 385.

117 The text and accompanying notes in this section are partially adopted from Watnick, *supra* note 32, at 381–85.

118 *See* U.S. GOV'T ACCOUNTABILITY OFF., TOXIC SUBSTANCES: EPA HAS INCREASED EFFORTS TO ASSESS AND CONTROL CHEMICALS BUT COULD STRENGTHEN ITS APPROACH 10 n.12 (2013).

119 *See id*.

120 *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825, 4826 (Jan. 17, 2017) (discussing background on and need for recent 2016 amendments to TSCA); Charles Schmidt, *TSCA 2.0: A New Era in Chemical Risk Management*, 124 ENV'T HEALTH PERSPS. 182, 183–84 (2016).

121 *See* Schmidt, *supra* note 116, at 183–84; Eve Gartner, *Weak Laws and Weaker Governance Keep Toxic Chemicals on the Market*, EARTHJUSTICE (Apr. 7, 2016), https://earthjustice.org/blog/2016-april/weak-laws-and-weaker-governance-keep-toxic-chemicals-on-the-market.

122 *See* Schmidt, *supra* note 116, at 183–84.

123 *See* David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 355–59 (2010); Schmidt, *supra* note 116, at 183–84.

124 *See* Schmidt, *supra* note 116; U.S. GOV'T ACCOUNTABILITY OFF., GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 18 (2005).

Congress finally amended TSCA[125] to address these failings by passing the Lautenberg Act of 2016.[126] The Act, for the first time, calls for review of all new chemicals[127] for safety[128] before they are brought to market and for phased review of existing "high priority" chemicals.[129] The Lautenberg Act has great potential to improve the regulation of toxic substances in the United States. However, due to enforcement challenges regarding new chemicals, as well as unrealistic and glacially slow planned reviews for existing chemicals, the Act has yet to effect major improvements in our toxics regulatory scheme.[130] The regulation of potentially toxic substances in the United States remains a patchwork of federal efforts under FIFRA,[131] FQPA,[132] and TSCA,[133] the interplay and effects of which are further discussed in the next section.[134]

[125] *See* Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2629).

[126] *See* Pub. L. No. 114-182, 130 Stat. 448 (2016) (to be codified at 15 U.S.C. §§ 2601–2629); *see generally* Sheldon Krimsky, *The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act*, PLOS BIOLOGY, Dec. 18, 2017, at 1–5 (discussing how the current regulatory structure has not resulted in the comprehensive federal regulation of toxic substances).

[127] *See* 15 U.S.C. § 2604.

[128] *See* 15 U.S.C. § 2604(a)(3)(A) (calling for the Administrator to determine if a new chemical or new chemical use presents unreasonable risk without regard to costs or other "nonrisk" factors).

[129] 15 U.S.C. §§ 2604(a)(3)(A), 2604(e)–(f) (requiring review of new chemicals before they are brought to market); 15 U.S.C. § 2605(c) (requiring that for high priority chemicals, the Administrator propose a rule within one year of the final risk evaluation and publish a final rule within two years of the risk evaluation); H.R. REP. NO. 114-176, at 22–23 (2016) (stating general performance goals of the Act and need for EPA to have greater authority to order testing).

[130] *See* Watnick, *supra* note 32, at 397–408. The full shortcomings in the implementation of the new Lautenberg Act, while beyond the scope of this paper, are fully addressed in Watnick, *supra* note 32, at 391–408.

[131] *See* 7 U.S.C. §§ 136–136y.

[132] *See* Food Quality Protection Act of 1996, Pub. L. No. 104-70, 110 Stat. 1489 (codified as amended in scattered sections of 7 U.S.C. and 21 U.S.C.) (amending FIFRA and FFDCA); *see also Food Quality Protection Act (FQPA) of 1996*, EPA, https://perma.cc/8J6W-6JDT (last visited Sept. 16, 2021) (providing background information on the functions and history of FQPA).

[133] *See* Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2629).

[134] *See infra* Part II.B.

B. *Pesticide Registration and Sale Under FIFRA*

Under FIFRA, all pesticides must be registered for use, except those subject to an exemption within the act.[135] However, in registering a pesticide, and thus allowing its sale and marketing, EPA does not determine that a pesticide such as glyphosate is safe. Instead, EPA determines that its use in accord with label instructions will not "generally cause unreasonable adverse effects on the environment."[136] FIFRA states that "unreasonable adverse effects on the environment" includes "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[137] In other words, FIFRA calls for EPA to conduct a cost-benefit analysis when approving pesticides for sale.[138] And although FIFRA requires the registrant to provide a variety of tests to accompany a registration application, the tests are not designed to guarantee safety. Environmental health scientists and healthcare professionals have criticized EPA for its failure to consider many potential ill effects of pesticides, particularly effects found at low levels of exposure.[139]

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135 *See* 7 U.S.C. § 136a(a).

136 7 U.S.C. §§ 136a(c)(5)(D), 136a(d)(1)(B).

137 7 U.S.C. § 136(bb).

138 *See id*.

139 *See, e.g.*, Tyrone B. Hayes et al., *Atrazine Induces Complete Feminization and Chemical Castration in Male African Clawed Frogs (Xenopus laevis)*, 107 PROCEEDINGS NAT'L ACAD. SCI. 4612 (2010); Michelle K Manske et al., *Low-level Atrazine Exposure Decreases Cell Proliferation in Human Fibroblasts*, 46 ARCHIVES ENV'T CONTAMINATION & TOXICOLOGY 438 (2004); Valerie J. Watnick, *Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point*, 2004 UTAH L. REV. 1305, 1322–23 (2004) [hereinafter *Toxics Regulatory System*]; Env't Health Scientists & Healthcare Pros., Comment Letter on EPA's 2016 Revised Human Health Risk Assessment and the 2015 Proposed Tolerance Revocation for Chlorpyrifos (Jan. 17, 2017), https://www.regulations.gov/comment/EPA-HQ-OPP-2015-0653-0587 (showing that chlorpyrifos remains on the market despite suspected serious health concerns at low doses); Valerie Watnick, *Federal Preemption of Tort Claims Under FIFRA: The Erosion of a Defense*, 36 MICH. J.L. REFORM 419, 422 (2003) [hereinafter *Federal Preemption*]. FIFRA requires that before the pesticide is sold for use, it must be found not to present unreasonable risks to humans or the environment when used as labeled. *See* 7 U.S.C. § 136(bb); *Pesticide Registration Manual: Chapter 1 - Overview of Requirements for Pesticide Registration and Registrant Obligations*, EPA, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide. Registrants are responsible for their pesticide and its labeling. *See generally* 40 C.F.R. §§ 152, 169 (2021).

Most importantly, EPA does not typically conduct any testing of a product itself.[140] Rather, as is true for almost all chemicals undergoing regulatory review, the registrant—the business seeking approval to market and sell the product[141]—must conduct the testing and then provide its data to EPA.[142] Essentially, FIFRA is a marketing and labeling statute that allows a seller to register and then sell its product in accord with EPA-required labeling restrictions.[143] In addition, FIFRA preempts state labeling that is inconsistent with federal requirements and preempts some state tort actions related to failure to warn of harm from pesticide products.[144] This is so even though EPA itself has stated that "no pesticide can be considered 'safe'" and that all pesticide use creates some risk to human health or the environment.[145]

[140] Some scholars have noted that FIFRA has proactive aspects in that it requires manufacturers to provide basic information before marketing and also requires mandatory federal labeling. *See* John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle,* 6 HUM. & ECOLOGICAL RISK ASSESSMENT 413, 427–28 (2000). However, FIFRA does not require major safety testing before a pesticide goes to market. *See Federal Preemption*, *supra* note 139, at 422.

[141] *See* 40 C.F.R. § 152.15 (laying out when a substance must be registered for use as a pesticide); 7 U.S.C. § 136a (requiring that a pesticide be registered before it is sold for use).

[142] *See* 7 U.S.C. § 136a(c)(1)(F) (2018).

[143] *See Federal Preemption*, *supra* note 139, at 422.

[144] *See* 7 U.S.C. § 136v(b) (preempting labeling that is different or in addition to those required by FIFRA); Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 38–41 (Cal. Dist. Ct. App. 2020) (for a discussion of when federal preemption would occur but not finding it in *Johnson*); *see also Federal Preemption*, *supra* note 139, at 424.

[145] N.Y. STATE DEP'T. OF LAW, PESTICIDES IN SCHOOLS: REDUCING THE RISKS 3 (1996).

C. *Regulation of Pesticide Use on Food Under FQPA*[146]

FQPA[147] regulates the amount of pesticide residue or deleterious substances that may be found on fresh and processed food.[148] The 1996 FQPA amended FIFRA and FFDCA, both of which continue to regulate the use of pesticides on food crops in the United States.[149]

FIFRA requires that all pesticides must be registered for use in the United States,[150] but for food uses, EPA must establish a legal limit on a pesticide residue, known as a tolerance, or an exemption from a tolerance,[151] pursuant to FFDCA.[152] Federal law also prohibits the sale of food that is "adulterated,"[153] which would include a food tainted with pesticide residue beyond the allowed tolerance.[154]

Tolerances, however, are set for the food use on a single crop without sufficient regard for multiple routes of exposure to a

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146 Partially adapted from Valerie J. Watnick, *Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children*, 31 ARIZ. STATE L.J. 1315, 1319, 1336–41 (1999) [hereinafter *Risk Assessment*].

147 Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in various sections of 7 U.S.C. and 21 U.S.C.) [hereinafter FQPA]. FQPA amends the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–473 [hereinafter FFDCA] and FIFRA, 7 U.S.C. §§ 136–136y. FIFRA regulates the registration of pesticides for all uses, and FFDCA regulates their use on food.

148 *See* Watnick, *Risk Assessment*, *supra* note 146, at 1337.

149 *See id.* at 1319; 7 U.S.C. § 136a(a) (2018); 21 U.S.C. § 346a(b)(2) (2021).

150 *See* 7 U.S.C. § 136a(a) (2018).

151 *See* 21 U.S.C. § 342 (2005); 21 U.S.C.§ 346a(a)(1)(A) (2019); EPA, *Summary of the Federal Food, Drug, and Cosmetic Act* (Sept. 28, 2021), https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act (defining tolerance as a legal limit on a pesticide residue); Consumer Reports Food Safety and Sustainability Center, Pesticide Report: From Crop to Table 15 (2015), https://advocacy.consumerreports.org/wp-content/uploads/2015/08/CR_FSASC_FromCroptoTablePesticides_Mar2015-4.pdf; Kate Graham, *Federal Regulation of Pesticide Residues: A Brief History and Analysis*, 15 J. FOOD L. & POL'Y 98, 108–13 (2019).

152 *See* 21 U.S.C. § 346a(a)(1).

153 21 U.S.C. § 331(a). The allowed tolerance level for glyphosate is 30 parts per million on certain grains. 40 C.F.R. § 180.364(a)(1) (1980).

154 *See* 21 U.S.C. § 342(a) (defining adulterated food as that containing an unsafe pesticide chemical residue); *see also* 21 U.S.C. § 346a(a) (laying out framework for tolerance regulations); *see* Complaint, Tabler v. Panera, 19-CV 1646 (N.D. Cal. Mar. 29, 2019); Tabler v. Panera, 19-CV 1646 (N.D. Cal. June 20, 2020) (dismissing deceptive advertising complaint claiming glyphosate residues on food sold as "clean" on motion to dismiss with leave to replead).

substance or its breakdown products, or to substances that act similarly.[155] Additionally, these tolerances are set based on limited toxicity information, including available epidemiological studies, animal studies, and exposure information.[156] FQPA also calls for the EPA Administrator to apply additional safety factors generally known as "3X" to "10X" factors to account for a lack of data or the particular susceptibility of children.[157] Risk assessors may thus make tolerances a number of times safer in an effort to protect vulnerable populations.[158] However, the assessors often lack basic toxicity data and must perform their assessments making multiple assumptions and judgments.[159]

Moreover, once the risk assessor performs the analysis and the tolerance is set, actual enforcement of these "tolerable" residue levels is inconsistent at best,[160] and potentially very misleading in that there is no guarantee that tolerance levels are safe or are actually met in practice.[161] While the U.S. Department of Agriculture (USDA) performs periodic residue testing, it does so on a per crop

155 *See Toxics Regulatory System*, *supra* note 139, at 1320–24.

156 *See id.* at 1323–24; *Setting Tolerances for Pesticide Residues*, EPA, https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#food-safety (last visited Sept. 24, 2021).

157 *See* 21 U.S.C. § 346a(b)(2)(C)(ii)(II) (providing that the Administrator may use a different margin of safety if such will be safe for children and prescribing 10X safety factor for children in some cases); *see, e.g.*, *Evaluation of the FQPA Safety Factor for Pyrethrins and Pyrethroids*, EPA, https://www.epa.gov/ingredients-used-pesticide-products/evaluation-fqpa-safety-factor-pyrethrins-and-pyrethroids (Mar. 13, 2021) (reducing 3X safety factor for pyrethins to 1X).

158 *See* 21 U.S.C. § 346a(b)(2)(C).

159 *See About Risk Assessment*, EPA, https://www.epa.gov/risk/about-risk-assessment (last visited Sept. 15, 2021) ("[R]isk assessors often must estimate exposures and use judgment to calculate risks. Consequently, all risk estimates include uncertainty."); *Toxics Regulatory System, supra* note 139, at 1318–20.

160 *See* Valerie Watnick, *The Organic Foods Production Act, the Process/Product Distinction, and a Case for More End Product Regulation in the Organic Foods Market*, 32 UCLA J. ENV'T L. & POL'Y 40, 68 (2014); *Eat the Peach, Not the Pesticide*, CONSUMER REPORTS, Mar. 19, 2015, https://www.consumerreports.org/cro/health/natural-health/pesticides/index.htm (detailing and analyzing U.S. data on pesticide residues in food).

161 *See Eat the Peach, Not the Pesticide*, *supra* note 160 (noting that more than half the crops tested by the USDA had pesticide residues on them, with the majority below tolerance levels).

basis.[162] In USDA testing for the period ending in 2016,[163] the majority of crops contained pesticide residues, and many contained residues from multiple pesticides.[164] When various pesticides are mixed together, the effect on human health is largely untested and unknown.[165] Because the original tolerance is based on single-chemical risk assessment, with limited accounting for multiple pathways of exposure, and chemicals that act in similar manners,[166] it does not adequately account for real-life risk.[167] Pursuant to FQPA, the risk assessor is to use "available" information on aggregate risk and common mechanisms of toxicity.[168] However, these factors do

[162] *See* Press Release, USDA Releases 2016 Annual Pesticide Date Program Summary, USDA (Feb. 8, 2018) (noting that 78% of crops tested contained pesticide residues and listing individual crops tested); *see Eat the Peach, Not the Pesticide*, *supra* note 160.

[163] *See* USDA, *supra* note 162.

[164] One survey found that many Americans believe that there is a legal limit to how many different residues may be found on a food product, when no such legal limit exists. *See Eat the Peach, Not the Pesticide*, *supra* note 160. An industry group in 2016 maintained that crop residue testing proved crop safety in that only 0.36% of crops had pesticide residues exceeding allowable tolerance levels. *See USDA Pesticide Data Program Report Confirms Food Safety*, CROPLIFE AMERICA, https://www.croplifeamerica.org/news-releases/2wq93rzq8q0ih-bntr1s3sknh9tvjfs (last visited Jan. 19, 2022). A U.S. government study of pesticide residues on organic foods in 2014 likewise found that residue levels on many crops exceeded even those allowable tolerances for conventional crops. On November 8, 2012, the National Organic Program (NOP) formally required organic certifiers to test products for prohibited substances and pesticide residues. The memorandum followed a 2010–2011 pilot study by the NOP that tested 571 samples for pesticide residues. Memorandum from Miles McEvoy, Deputy Administrator, National Organic Program, to the National Organic Program Standards Board (Sept. 27, 2012). 57% of those samples tested had no residue at all, and 96% complied with existing organic regulations. *See 2010-2011 Pilot Study: Pesticide Residue Testing of Organic Produce*, USDA (Nov. 2012), https://www.ams.usda.gov/reports/2010-2011-pilot-study-pesticide-residue-testing-organic-produce.

[165] *See Eat the Peach, Not the Pesticide*, *supra* note 160.

[166] *See* 21 U.S.C. § 346a(b)(2)(D)(iv)(v) (calling for consideration of aggregate exposures to a pesticide as well as consideration of chemicals that have a common mechanism of toxicity). "Under th[e current U.S.] approach, the safety of an individual pesticide is largely evaluated on its single use in a specific crop." Wallter Beckwith, *Experts Call for Overhaul of Pesticide Regulations*, ASS'N FOR THE ADVANCEMENT OF SCI. (Jan. 23, 2020), https://www.aaas.org/news/experts-call-overhaul-pesticide-regulations.

[167] *See* Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2324 (2017).

[168] 21 U.S.C. § 346a(b)(2)(D)(iv)(v).

not account for the synergistic effects of a chemical or combined effects of multiple, daily chemical exposures to a variety of chemicals (cumulative risk),[169] nor fully account for individual human differences and reactions to chemical exposure (intra-species risk).[170]

D. *Pesticide Registration and Reregistration of Glyphosate; Testing and Tolerance Setting*

Within this overall federal regulatory context and pursuant to FIFRA, EPA put in place a re-registration program to review every pesticide every fifteen years.[171] As part of the re-registration process, if EPA determines that an existing chemical now requires more information, it may request such information from the registrant.[172] However, it bears note that EPA may allow the registration to remain in place pending a later "Data Call-In."[173] A "Data Call-In" thus allows a registrant to sell and market its product based on existing data, pending submission of additional testing data.[174]

EPA re-registered glyphosate as an existing pesticide in January 2020 as required by federal regulations.[175] As part of this re-

[169] *See* Knudsen, *supra* note 167, at 2315–17, 2320, 2322, 2360–61 (making the important case that cumulative risk assessments must take "center stage" in regulation in that we are bombarded daily with synthetic chemicals and that individuals cannot control their personal chemical exposures); *see also* Adam Abelkop & John Graham, *Regulation of Chemical Risks: Lessons for Reform of the Toxic Substances Control Act from Canada and the European Union*, 32 PACE ENV'T L. REV. 108, 120 (2015).

[170] "[Risk] assessments rely heavily on data extrapolated from human epidemiology, animal testing and cell culture/*in vitro* laboratory studies that fail to account for multiple routes of exposure, mixture effects, transgenerational epigenetic effects or individual human risk factors such as age, gender, genetics, nutrition, psychosocial determinants and comorbidities." Nicole Bijlsma & Marc M. Cohen, *Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Feb. 2, 2016, at 5.

[171] *See Registration Review Process*, EPA, https://www.epa.gov/pesticide-reevaluation/registration-review-process (Mar. 4, 2021).

[172] *See* 7 U.S.C. 136a(c)(7)(B) (allowing reregistration pending receipt of additional data).

[173] *Id.*; *see, e.g.*, EPA, OPP-2005-0231, REREGISTRATION ELIGIBILITY DECISION FOR METALDEHYDE 38–39 (2006), https://nepis.epa.gov/Exe/ZyPDF.cgi/P100L3BC.PDF?Dockey=P100L3BC.PDF (allowing reregistration of certain metaldehyde uses while pending data call-in).

[174] *See* 7 U.S.C. 136a(c)(7)(B).

[175] *See* EPA, GLYPHOSATE INTERIM REGISTRATION REVIEW DECISION (2020), https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-

registration process, EPA published a paper evaluating the carcinogenic potential of glyphosate in 2017,[176] and in 2019, the Agency announced a proposed interim registration decision for glyphosate open for sixty-day public comment.[177] EPA received over 238 thousand comments on the decision, reflecting the importance of the chemical to agricultural groups and the public.[178]

In April 2019, EPA announced in a proposed interim rule that it would re-register glyphosate under FIFRA, maintaining that the chemical is "not likely to be carcinogenic to humans." [179] This controversial decision, finalized in January 2020,[180] was criticized for failing to take into account the comments of EPA's Scientific Advisory Panel (SAP), which did not fully agree with EPA's Office of Pesticide Programs (OPP) in its safety assessment.[181] According to OPP, there exist five levels of assessment of a pesticide, ranging from the lowest risk, not likely carcinogenic to humans, to the highest risk, carcinogenic to humans.[182] The SAP did not favor the

interim-reg-review-decision-case-num-0178.pdf; *Registration Review Process*, *supra* note 171.

176 *See* EPA, REVISED GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL (2017), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487&Lab=OPP.

177 *See* Glyphosate Proposed Interim Registration Review Decision; Notice of Availability, 84 Fed. Reg. 19,782 (May 6, 2019).

178 *See* EPA, GLYPHOSATE PROPOSED INTERIM REGISTRATION REVIEW DECISION, 6 (2019), https://www.epa.gov/sites/default/files/2019-04/documents/glyphosate-pid-signed.pdf; *see, e.g.*, Nat. Res. Def. Council, Comments on Glyphosate Proposed Interim Registration Review Decision (Sept. 3, 2019), at 3, https://www.agri-pulse.com/ext/resources/pdfs/g/nrdc-glyphosate-cancer-comments-20190903.pdf ("Monsanto, now Bayer's, goals are to: support glyphosate registration and approval worldwide; defend itself against litigation claims by farmers who were once Monsanto customers and are now cancer patients; and, prevent labeling of glyphosate-containing products as containing a carcinogen in the State of California and everywhere else. The mission of EPA is to protect human health and the environment. EPA cannot do this if it is 'cozy' with the industries it is supposed to regulate . . . .").

179 EPA, *supra* note 178, at 19.

180 *See* EPA, *supra* note 175.

181 *See* Nat. Res. Def. Council, *supra* note 178, at 5 ("Science Advisory Panel disagree with the Pesticide Office, says evidence supports a 'suggestive' link to cancer.").

182 EPA Cancer Guidelines classifications have five levels: 1. "Carcinogenic to humans"; 2. "Likely to be carcinogenic to humans"; 3. "Suggestive evidence of carcinogenic potential"; 4. "Inadequate information to assess carcinogenic potential"; and 5. "Not likely to be carcinogenic to humans." *Guidelines for Carcinogen Risk Assessment*, EPA (Mar. 2005), https://www.epa.gov/sites/default/files/2013-

highest level risk ranking, but it did not reach consensus as to a least toxic characterization.[183] OPP, however, seemed only to consider the two disparate ends of the spectrum, carcinogenic or not, and dismissed SAP's concerns. Instead, the OPP found that glyphosate was not likely to pose a cancer risk, labeling it with the lowest possible risk level—essentially as safe.[184]

Adding to the body of scientific data and regulatory debate, the Agency for Toxic Substances and Disease Registration (ATSDR), a federal health agency under the Department of Health and Human Services, released its draft toxicological profile on glyphosate for public comment in 2019.[185] The ATSDR draft profile links glyphosate to some cancers in humans, finding epidemiological links, as well as links in animal studies.[186]

Despite ASTDR's profile, EPA has adjusted tolerances upward[187] and has not required regular widespread residue testing for glyphosate, which aligns with EPA's view that glyphosate is generally safe for use as intended.[188] EPA has remained steadfast in this stance, despite evidence that many food products are contaminated with glyphosate. In 2011, for example, in what EPA labeled a "special project," it tested 300 samples of soybeans for glyphosate and

09/documents/cancer_guidelines_final_3-25-05.pdf. EPA did not have to characterize the choice as either glyphosate causes cancer or it does not. *See* E-mail from Vincent Cogliano, EPA, to Norman Birchfield, EPA (Dec. 7, 2015, 12:01 EST), https://assets.documentcloud.org/documents/4641115/Cogliano-Memo.pdf; *Summary of ORD Comments on OPP's Glyphosate Cancer Assessment*, EPA (Dec. 14, 2015), https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf.

183 *See* EPA, FIFRA SAP MINUTES AND FINAL REPORT NO. 2017-01, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: EPA'S EVALUATION OF THE CARCINOGENIC POTENTIAL OF GLYPHOSATE 22 (2016).

184 *See Glyphosate Proposed Interim Registration Review Decision*, *supra* note 178, at 19; EPA, GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL 140 (Sept. 12, 2016), https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcinogenic_potential.pdf.

185 *See* U.S. Dep't of Health & Hum. Servs., Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Glyphosate: Draft for Public Comment* (2019).

186 *See id.*

187 *See infra* notes 200–02 and accompanying text (regarding tolerances for glyphosate).

188 *See* U.S. Food & Drug Admin., *Questions and Answers on Glyphosate* (2020).

found that more than 90 percent (271) of the samples contained glyphosate residues.[189] However, EPA said these levels did not exceed the tolerance level, or allowed amount, on the soy crop.[190] EPA again in 2016 and 2017 tested 879 samples of corn, soybeans, milk, and eggs for glyphosate and found, again, that although 59 percent of corn and soybeans contained glyphosate residues, the levels found did not exceed tolerance levels.[191] It is worth noting, though, that in a relevant trend that coincides with increasing glyphosate usage, EPA has adjusted pesticide tolerances upward. In 2008, it increased the glyphosate tolerance for soybeans,[192] and did the same for additional crops in 2013.[193] In 1993, EPA had likewise increased the tolerance of pesticide residue for glyphosate on oats from 0.1 to 30 parts per million.[194]

Within this landscape, the Environmental Working Group (EWG), a nonprofit public interest group, had also engaged in its own testing of various foods for glyphosate residues and publicly announced that it had found residues both to have widespread presence and to exist at unacceptable levels.[195] EWG likely chose oat-based food for testing because it is common practice to spray oats with glyphosate prior to harvest so that the glyphosate can act as a

189 *See* U.S. Dep't of Agric., *Pesticide Data Program Ann. Summary* (2011).

190 *See id.*

191 *See* U.S. Food & Drug Admin., *supra* note 188; U.S. Food & Drug Admin., *Pesticide Residue Monitoring Program Fiscal Year 2016 Pesticide Report* (2016); U.S. Food & Drug Admin., *Pesticide Residue Monitoring Program Fiscal Year 2017 Pesticide Report* (2017).

192 *See* EPA, Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).

193 *See* EPA, Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25,396 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).

194 *See, e.g.*, 40 C.F.R. § 180.364 (2017) (increasing tolerance on oats from 0.1 in 1993 to 30 parts per million in 2007); 40 C.F.R. § 180.41(c)(24)(ii); Gibson v. Quaker Oats Co., No. 16 CV 4853, 2017 WL 3508724, at *1 (N.D. Ill. Aug. 14, 2017) (noting that EPA has changed the maximum allowed amount (tolerance) for glyphosate on oats from 20 parts per million in 1997 to 30 parts per million in 2008).

195 *See* ENV'T WORKING GRP., *Roundup for Breakfast, Part 2: In New Tests, Weed Killer Found in All Kids' Cereals Sampled* (Oct. 24, 2018), https://www.ewg.org/news-insights/news-release/roundup-breakfast-part-2-new-tests-weed-killer-found-all-kids-cereals.

desiccant,[196] and oats are frequently marketed for children.[197] EWG, in a study that tested more than a dozen brands of oat-based foods,[198] set a health benchmark for glyphosate using a cancer risk assessment developed by California State scientists.[199] The benchmark included additional safety factors in line with FQPA's legislative requirement to protect vulnerable populations such as children.[200] Based on its calculations and assessment, EWG set the health benchmark for glyphosate a child could ingest daily at 0.01 milligrams per day.[201] The nonprofit group found glyphosate on most samples of the tested food and at levels that exceeded this health benchmark it believed was appropriate based on available science and the FQPA requirement to protect children.[202]

After making these findings, EWG, joined by many organic and health food companies, had petitioned EPA to lower the tolerance for glyphosate on oats and to prohibit the pre-harvest use of the chemical in September 2018.[203] EWG urged that the current

196 *See* Robert Coleman, *How Does the EWG Set A 'Health Benchmark' for Glyphosate Exposure*, ENV'T WORKING GRP. (Aug. 16, 2018), https://www.ewg.org/news-and-analysis/2018/08/how-does-ewg-set-health-benchmark-glyphosate-exposure.

197 *See* ENV'T WORKING GRP., *supra* note 195.

198 *See id.*

199 *See id.*

200 FQPA calls for safety factors of 10X to make pesticide tolerances many times safer to account for the special vulnerabilities of children. 21 U.S.C. § 346a(b)(2)(c)(ii)(II). Other groups have advocated for an even higher tolerance for glyphosate according to these statutory mandates. *See generally* Nat. Res. Def. Council, *supra* note 178.

201 *See* ENV'T WORKING GRP., *supra* note 195.

202 *See id.* (noting that just because a tolerance was legal when made, it does not mean that current science means it is "safe" for children as required by FQPA); *see also* 21 U.S.C. § 346a(b)(2) (requiring EPA to revoke a tolerance level if the Agency later determines it to be unsafe).

203 *See* EWG RULE CHANGE PETITION 2018, *supra* note 10. The EWG filed this rule change petition under the Administrative Procedure Act, 5 U.S.C § 553(e), which allows anyone to petition for a rule change, and under the Food Quality Protection Act, 21 U.S.C. § 346a(c)(d), requesting a reduction in a tolerance, and under 40 C.F.R. § 180.32, to request a label modification so that glyphosate products are labeled so as to prohibit the use of the product as a pre-harvest desiccant. *Id.* at 4. The EWG submitted an amended petition on March 28, 2019. ENV'T WORKING GRP., PETITION TO MODIFY THE TOLERANCE OF GLYPHOSATE IN OATS TO .1 PPM AND REQUIRE GLYPHOSATE-CONTAINING PRODUCT LABELS TO EXPLICITLY PROHIBIT THE USE OF GLYPHOSATE AS A PRE-HARVEST DESICCANT (Mar. 28, 2019), https://www.ewg.org/sites/default/files/u352/EWG%20Amended%20Glyphosate%20Petition%203.28.19%20.pdf.

tolerance for glyphosate does not take into account cancer as an endpoint and does not adequately account for the risk to children from glyphosate.[204] The group called for EPA to therefore make the tolerance for glyphosate on oats many times safer than the current level.[205] In October 2018, EWG commissioned a second round of testing that also found glyphosate in every sample of popular oat-based cereal and other oat-based products marketed to children.[206]

E. *European Union and Canadian Findings on Glyphosate*

Similar to EPA, the Canadian Food Inspection Agency tested 3,188 samples of domestic and imported food products and found glyphosate in more than thirty percent of the infant food and cereal tested.[207] The testing did not, however, include oats, as tested by EWG.[208] The Canadian agency's results showed that forty-seven percent of all bean products, seven percent of all fresh fruit, and twelve percent of all processed fruit samples tested contained glyphosate residues.[209] However, despite this evidence of widespread glyphosate contamination, only 1.3 percent of samples contained residues above Canadian pesticide residue limits, and "no human health concerns were identified."[210] In attempting to cross-

204 *See* EWG RULE CHANGE PETITION 2018, *supra* note 10, at 15–17.

205 *See* EPA dietary exposure limit for glyphosate; *id.* (pending decision per email on file with author from EWG). FQPA calls for increased safety calculations of 3X or 10X where appropriate to account for the special susceptibilities of children. *See* 21 U.S.C. § 346a(b)(2)(C)(ii). In 2018, the nonprofit Right to Know obtained FDA emails that showed that indeed the U.S. government had engaged in a non-public and ongoing testing program since 2016 for glyphosate in food samples. *FDA FOIA Documents Regarding Glyphosate Residue Testing*, U.S. RIGHT TO KNOW (May 10, 2018), https://usrtk.org/pesticides/fda-foia-documents-regarding-glyphosate-residue-testing (containing emails discussing ongoing nature of work in 2016 and 2017 to test for glyphosate).

206 *See* Environmental Working Group, *supra* note 195.

207 *See Safeguarding with Science: Glyphosate Testing in 2015-2016*, CANADIAN FOOD INSPECTION AGENCY (Apr. 11, 2017), https://www.inspection.gc.ca/food-safety-for-industry/food-chemistry-and-microbiology/food-safety-testing-bulletin-and-reports/executive-summary/glyphosate-testing/eng/1491846907641/1491846907985.

208 *See id.*

209 *See id.*

210 *Id.* at 4; *see also NIST Researchers Advance Efforts to Accurately Measure Glyphosate Pesticide in Common Foods*, NIST (Nov. 2, 2020) https://www.nist.gov/news-events/news/2020/11/nist-researchers-advance-efforts-accurately-measure-glyphosate-pesticide (noting that glyphosate is often found in oats and discussing efforts to design better testing mechanisms).

reference this testing to U.S. testing, the Canadian agency used a maximum contaminant level for soybeans of twenty parts per million, which appears consistent with the current U.S. tolerance for whole soybeans, also set at twenty parts per million for glyphosate and its degradates.[211]

In line with this testing by the Canadian Food Inspection Agency, neither Canada nor Europe have, to date, labeled glyphosate a probable carcinogen. Yet, these governments' approach to toxics regulation in general tends to be more precautionary and protective of human health than that of the United States. Overall, the European Union has banned pesticides that are still used in the United States due to concerns about harm to the environment or human health. In fact, a quarter of all pesticides currently used in the United States are banned in the European Union.[212] As one example, the European Union has banned the controversial pesticide atrazine for use on food crops, citing health concerns, while the United States continues to allow its use while the chemical undergoes a "special review."[213]

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211 *See* 40 C.F.R. § 180.364 (2021) (setting tolerance for glyphosate and its degradates for many crops). A 2016 WHO report states that glyphosate is unlikely to be carcinogenic through diet. European Chemicals Agency [ECHA], *CLH Report*, EC Number: 213-997-4 CAS Number: 1071-83-6 Index Number: 607-315-00-8 (May 2016) at 8, https://echa.europa.eu/documents/10162/c0864db4-d5e7-81dc-8042-0e2c72bfa7dd.

212 *See* Nathan Donley, *USA Lags Behind other Agricultural Nations in Banning Harmful Pesticides*, 18 ENV'T HEALTH 39 n.44 (2019).

213 *See* Jennifer B. Sass & Aaron Colangelo, *European Union Bans Atrazine, While the United States Negotiates Continued Use*, 12 INT'L J. OCCUP. ENV'T. HEALTH 260 (2013) (citing evidence that Atrazine interferes with endocrine activity and may cause cancer); EPA, ATRAZINE: PROPOSED INTERIM REGISTRATION REVIEW DECISION (2019), https://www.epa.gov/sites/production/files/2019-12/documents/atrazine_pid_signed_12_18_19.pdf; Nat. Res. Def. Council, *supra* note 178 ("Monsanto, now Bayer's, goals are to: support glyphosate registration and approval worldwide; defend itself against litigation claims by farmers who were once Monsanto customers and are now cancer patients; and, prevent labeling of glyphosate-containing products as containing a carcinogen in the State of California and everywhere else. The mission of EPA is to protect human health and the environment. EPA cannot do this if it is 'cozy' with the industries it is supposed to regulate . . . ."); Hakluyt Rep., Pilliod v. Monsanto, Case No. RG17862702, Exhibit A, (Cal, Sup. Alameda 2019) (characterizing the relationship between Monsanto and EPA as cozy and showing emails in which OPP says it has "Monsanto's back"). Whether Atrazine benefits global food production and the economy is in debate. *Compare* Frank Ackerman, *The Economics of Atrazine*, 13 INT'L J. OCCUP. & ENV'T HEALTH 437 (2013) (noting that atrazine does not benefit agricultural production or the economy), *with* Paul Mitchell, *Market-Level*

Despite this generally more precautionary stance, in 2017, in a close vote, the EFSA voted to license glyphosate for use until late 2022.[214] However, critics have noted that the EFSA was opaque as to the studies it reviewed and the origin of the supporting scientific work.[215] At least one expert has publicly criticized the European Union's decision to continue to allow glyphosate use on crops, saying that the EFSA decision was based on plagiarized work from a Monsanto consultant and did not comport with good scientific practice.[216] In particular, criticism of the EFSA's decision condemned the use of text written by a former Monsanto employee, now a consultant to the industry, without attribution.[217]

Overall, under Europe's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) initiative, and under the Canadian Environmental Protection Act (CEPA),[218] the continued authorization of glyphosate seems anomalous.[219] Under REACH, chemicals are generally not presumed safe unless proven otherwise.[220] Rather, the European toxics regulatory systems calls

Assessment of the Economic Benefits of Atrazine in the United States, 70 PEST MGMT. SCI. 1864 (2014) (concluding that atrazine generates economic benefits).

214 *See* Philip Blenkinsop, *Germany Swings EU Vote in Favor of Weed-Killer Glyphosate*, REUTERS (Nov. 27, 2017), https://perma.cc/7QCZ-HAMM; Danny Hakim, *Glyphosate, Top-Selling Weed Killer Wins E.U. Approval for 5 Years*, N.Y. TIMES (Nov. 27, 2017), https://perma.cc/9ZVT-3BZ5.

215 *See* Ignacio Carreno & Tobias Dolle, *The Regulatory Framework on Plant Protection Products in the United Kingdom After Brexit*, 8 EUR. J. RISK REG. 766, 768 (2017). "The IARC considered in its assessment the extent of possible damage (hazard potential), while the EFSA goes beyond this approach and assesses how likely it is that this damage may occur (ie the extent of the risk). The latter is, for example, dependent on the extent to which someone is exposed to a potential 'hazard.'" *Id*. at 768–69.

216 *See* STEPHEN WEBER, EXPERT OPINION ON ADHERENCE TO THE RULES OF GOOD SCIENTIFIC PRACTICE IN THE SUBSECTIONS "B.6.4.8 PUBLISHED DATA (RELEASED SINCE 2000)", "B.6.5.3 PUBLISHED DATA ON CARCINOGENICITY (RELEASED SINCE 2000)" AND "B.6.6.12 PUBLISHED DATA (RELEASED SINCE 2000)" IN THE REPORT "FINAL ADDENDUM TO THE RENEWAL ASSESSMENT REPORT. RISK ASSESSMENT […] FOR THE ACTIVE SUBSTANCE GLYPHOSATE […]" (Oct. 2015), https://www.nrdc.org/sites/default/files/expert-opinion-glyphosate-plagiarism_2017-10-06.pdf.

217 *See id.* at 2–9.

218 Canadian Environmental Protection Act, S.C. 1999, c 33 (Can.).

219 *See* Alex Sauerwein, *The Shortcomings of Regulating Pesticides Internationally and How Disadvantaged Communities Pay the Price*, 25 HASTINGS ENV'T L.J. 319, 333 (2019).

220 *See* Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of Oct. 21, 2009, Concerning the Placing of Plant Protection Products on

for the application of the precautionary principle and requires that, at least for new chemicals, manufacturers submit safety testing to show that the chemical is safe before it goes to market.[221] Under such a precautionary system and given the controversy over glyphosate, such relicensing is perplexing and perhaps surprising.[222] Indeed, concerns that European authorities might prohibit glyphosate use in the European Union are said to have prompted U.K. farmers to support Brexit.[223] In the United Kingdom, as in the United States, Roundup is the most widely used agricultural herbicide.[224]

Likewise, Health Canada generally takes a more precautionary stance to toxics regulation under CEPA.[225] Part 64 of CEPA requires that a substance be deemed toxic where it either enters the environment in quantity or concentration in which it "may have" long-term effect on the environment or "may constitute a danger" to the environment or human life.[226] CEPA also calls for "virtual elimination" of toxic substances.[227] Nonetheless, Canadian health authorities also appear to support the U.S. stance with regard to glyphosate and say it is unlikely that glyphosate is carcinogenic to humans. [228]

the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, 2009 O.J. (L 309) 5, 6 and 13.

221 *See id.* at 6.

222 *See supra* notes 214–26 and accompanying discussion.

223 *See* Ignacio Carreno & Tobias Dolle, *The Regulatory Framework on Plant Protection Products in the United Kingdom After Brexit*, 8 EUR. J. RISK REG. 766, 769 (2017).

224 *See id.* at 769. "More than 2 million hectares of land were treated with glyphosate in England and Wales in 2014. Without it, winter wheat and barley production would likely decline by about 12% and would reduce the cultivation of oilseed rape (used for oil and animal feed) by about 10%, according to the National Farmers Union." *Id.*

225 *See generally* Canadian Environmental Protection Act, S.C. 1999, c 33 (Can.), pt. 5.

226 *Id.* § 64.

227 *Id*. § 65.

228 *See Statement from Health Canada on Glyphosate*, HEALTH CAN. (Jan. 11, 2019), https://www.canada.ca/en/health-canada/news/2019/01/statement-from-health-canada-on-glyphosate.html.

III. TORT LAWSUITS RELATED TO GLYPHOSATE-BASED HERBICIDE SUGGEST WIDESPREAD PUBLIC HARMS AND CORPORATE INDIFFERENCE

A. *Ongoing GBH Litigation*

The ongoing, worldwide controversy around and continued use of glyphosate reveals how economically important the chemical is to agriculture and to industry.[229] In a parallel legal universe, however, the pesticide has led to the creation of a cottage industry for plaintiffs' lawyers and their beleaguered and gravely ill clients.[230] In what has been called a "legal ecosystem,"[231] plaintiffs' lawyers have recruited thousands of victims who claim grave harm from glyphosate usage. Plaintiffs assert various strict liability and negligence theories of failure to warn, false advertising, and deceptive practices.[232] In the first three such cases to go to trial, juries have awarded plaintiffs huge verdicts and stoked continued public controversy about GBHs. Yet, allowing litigation to drive the regulation of GBHs to protect human health has ethical, practical, and financial implications explored in Part IV, *infra*, that hasten the call for the development of a new regulatory paradigm.

In *Johnson vs. Monsanto*, one of the first Roundup cases to go to trial, the jury originally awarded the plaintiff $289 million in compensatory and punitive damages,[233] finding that Monsanto acted with a "willful and conscious disregard of others' safety" and with "corporate malice" in continuing to market GBH products notwithstanding the possible link to NHL.[234] Plaintiff Johnson was a certified pesticide applicator who worked at schools and used Monsanto products two to five hours a day for approximately three years,

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229 *See supra* notes 52–68 and accompanying discussion.

230 *See* Sarah Randazzo & Jacob Bunge, *Inside the Mass Tort Machine that Powers Thousands of Roundup Lawsuits*, WALL ST. J. (Nov. 25, 2019), https://www.wsj.com/articles/inside-the-mass-tort-machine-that-powers-thousands-of-roundup-lawsuits-11574700480.

231 *Id.*

232 Monsanto makes two glyphosate-based products, Roundup Pro and Ranger Pro, which the Johnson appellate court referred to collectively as "Roundup products." *See* Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 114 (Cal. Dist. Ct. App. 2020).

233 *See* Order Den. Reh'g & Modifying Op. at 13, Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111 (Cal. Dist. Ct. App. 2020) (No. CGC-16-550128). The jury's award of $289 million was later reduced by the court to $78 million. *Id.* at 14.

234 *Id.* at 77, 79.

suffering one bad accident and exposure to the chemical prior to his diagnosis with NHL.[235] The plaintiff took safety precautions, such as wearing a protective suit, but testified that spray would drift to his face depending on the winds.[236] Johnson suffered from skin lesions, skin cancer, and a great deal of pain.[237] Diagnosed with NHL in 2014, Johnson contacted Monsanto about his diagnosis and condition to see if they could be related to Monsanto's products and never received a response.[238] Johnson sought recovery for design defect and failure to warn in strict liability and for negligent failure to warn.[239]

The scientific evidence in the case showed that from 1997 to 1991, researchers published at least four papers that suggested that glyphosate was genotoxic, or damaged the cell DNA in such a way that might lead to mutation and cancer, and that an in-house Monsanto toxicologist suggested further testing.[240] Additionally, Monsanto internal emails stated that the company "want[s] to find/develop someone who is comfortable with the genotox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genotox[] issues arise. My read is that [the expert who wrote the 1999 reports] is not currently such a person, and it would take quite some time and $$$/studies to get him there. We simply aren't going to do the studies that [the expert] suggests."[241] The email continued by stating that the company had not had much success in recruiting such an expert and that it "remained very vulnerable in this area."[242]

While the California trial court agreed that the company had acted maliciously and that Johnson had proven strict liability, on due process grounds, the judge reduced the overall damages to $78 million, and the parties cross-appealed.[243] Monsanto argued on appeal

235 *See id.* at 3–5.
236 *See id.* at 4.
237 *See id.* at 6.
238 *See id.* at 5–6.
239 *See id*. at 7.
240 *See id.* at 2–3.
241 *Id.* at 3.
242 *Id*.
243 *See id.* at 14.

that the risk from glyphosate was not known.[244] The company insisted that glyphosate is safe for use as intended and labeled.[245]

In July 2020, the California appellate court finally ruled on the *Johnson* appeal, holding that the danger of glyphosate was "knowable" in light of the best scientific or medical knowledge available at the time of the manufacture and distribution.[246] The appellate court noted that it was not a "minority" opinion that glyphosate caused NHL, in light of the IARC's findings and other studies done in the late 1990s.[247] In a noteworthy and meticulously detailed opinion, the *Johnson* appellate court confirmed that the jury could have concluded that the company acted with a "conscious disregard for public safety by discounting legitimate questions surrounding glyphosate's genotoxic effect and in failing to conduct adequate studies."[248] The court specifically mentioned that Monsanto had been faced with many studies showing that Roundup might be genotoxic. It also noted that Monsanto had, since the 1980s, been aware of studies that potentially implied Roundup was genotoxic, but that it had been trying to "combat" such information.[249] The appellate court thus found that the jury could have inferred that Monsanto tried to discount legitimate questions regarding glyphosate in that (1) it had failed to do its own studies; (2) it was unconcerned when the plaintiff reached out to it with safety concerns; and (3) it had promoted its products without regard to public safety, and without regard to a possible link between GBHs and NHL.[250] In sum, the

244 *See id.* at 16.
245 *See id.* at 3.
246 *Id.* at 20.
247 *Id.* at 16–19. The *Johnson* appellate court also found that there was nothing unusual about how Johnson applied the products, and they had not worked safely as would be expected so that Monsanto would also be liable on a design defect claim. *Id.* at 26. The appellate court noted: "Johnson presented abundant—and certainly substantial—evidence that glyphosate, together with the other ingredients in Roundup products, caused his cancer. Expert after expert provided evidence that Roundup products are both capable of causing non-Hodgkin's lymphoma (general causation) and caused Johnson's cancer in particular (specific causation)." *Id.* at 29.
248 *Id.* at 74.
249 *Id.* at 75–76.
250 *See id.* at 79–80.

appellate court agreed that Monsanto's behavior constituted corporate malice.[251]

A similar result to that in *Johnson* occurred in multi-district federal litigation in California in spring 2019. In this first bellwether trial, the *Hardeman v. Monsanto Co.* trial court also found that it was reasonable for the jury to have concluded that Monsanto acted with willful disregard for the rights or safety of others.[252] In that case, the jury awarded the plaintiff, who had also contracted NHL after prolonged use of Roundup, $80 million total: $5 million for compensatory damage and $75 million in punitive damages.[253] As in *Johnson*, the court found that while "Monsanto deserves to be punished,"[254] the punitive damages award was too large at fifteen times the size of the other damages. The *Hardeman* court thus reduced the punitive damages award to $20 million, for an overall award of $25 million.[255]

Moreover, the court addressed the issue of federal preemption with regard to the plaintiff's failure to warn claim under FIFRA. The *Hardeman* district court noted that to be preempted under the law, the action or claim must impose a labeling or packaging requirement, and it must impose one that is *in addition to or different from* those under FIFRA.[256] The court then held that a failure to warn tort

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[251] *See id.* at 79–80. While the appellate court also saw fit to further reduce the overall award to $20 million, it also noted that "there was overwhelming evidence that Johnson has suffered, and will continue to suffer for the rest of his life, significant pain and suffering." *Id.* at 64, 71, 84. The court noted that damages for past pain and suffering, future economic loss and other damages amounted to approximately $10 million, in that the life expectancy for Johnson was not consistent with the original trial court award of $78 million. *Id.* at 71.

[252] *See* Hardeman v. Monsanto Co., 16-Cv-00525-VC, MDL No. 2741 (N.D. Cal. Mar. 27, 2019); Hardeman v. Monsanto Co., MDL No. 2741, Case No. 16-md-02741, at 5 (N.D. Cal, July 15, 2019).

[253] The Hardeman court later reduced this award to $5 million in compensatory damages and $20 million in punitive damages. *See In re* Roundup Prods. Liab. Litig., 385 F. Supp. 3d 1042, 1044 (N.D. Cal. 2019).

[254] *Id.* at 1046.

[255] *See id.* In May 2021, a three-judge appellate panel in the case upheld a $25 million verdict. *See* Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021). Bayer filed a petition for a writ of certiorari. *See Bayer Announces Filing of Petition to U.S. Supreme Court for Review of* Hardeman *Decision*, BUSINESSWIRE (Aug. 16, 2021), https://www.businesswire.com/news/home/20210816005461/en/Bayer-Announces-Filing-of-Petition-to-U.S.-Supreme-Court-for-Review-of-Hardeman-Decision.

[256] *See* Hardeman v. Monsanto Co., 216 F. Supp. 3d 1037, 1037, 1039 (N.D. Cal. 2016); Bates v. Dow Agrosciences LLC., 544 U.S. 431, 444 (2005).

action would not impose such a requirement.[257] Likewise, the *Johnson* court "rejected the premise that an occurrence, such as an adverse jury verdict, that 'merely motivates an optional decision' to change a pesticide label was not a 'requirement' [preempted] under federal law."[258] In addition to finding no federal preemption under FIFRA,[259] *Hardeman* teaches that a federal court, as the state court had in *Johnson*, saw compelling evidence that Monsanto tried to cover up the dangers of glyphosate use. Both courts also found that a jury could have inferred that the company acted in a purposefully wrongful manner deserving of punishment.[260]

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[257] *See Hardeman*, 216 F. Supp. 3d at 1040; *In re* Roundup Prods. Liab. Litig., 385 F. Supp. 3d 1042 (N.D. Cal. 2019); 7 U.S.C. § 136v(b); Bates v. Dow Agrosciences LLC., 544 U.S. 431, 451 (2005).

[258] *See* Order Den. Reh'g & Modifying Op. at 44, 50, Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111 (Cal. Dist. Ct. App. 2020) (No. CGC-16-550128). It is interesting to note that Monsanto also argued in *Johnson* and *Hardeman* that it would have been "impossible" for it to label its product with a cancer warning since EPA would not have approved it because EPA does not find that glyphosate causes cancer. However, the Johnson court stated that this defense, first raised on appeal, is a difficult one to meet and would require proof that the manufacturer had tried to use a label that had been rejected by EPA under FIFRA. "Impossibility pre-emption is a demanding defense." *Id*. at 50; *see Hardeman*, 216 F. Supp. 3d at 1038–39 (citing *Bates*, 544 U.S. 442, 444; 7 U.S.C. § 136v(b) (prohibiting labeling or packaging different than required under FIFRA (express preemption)); Hardeman v. Monsanto Co., MDL No. 2741, Case No. 16-md-02741, at 3–5 (N.D. Cal. 2019) (citing *Wyeth*, 555 U.S. at 573; Risperdal & Invega Cases, B284315, at 960 (Cal. Ct. Ap. 2020) (defendant drug maker had not submitted evidence that the FDA had rejected a label change). Since Hardeman has filed his appeal, EPA has said that it will not approve a label with a cancer warning. *See* Letter from Michael L. Goodis, EPA, Office of Pesticide Programs, at 2 (Aug. 7, 2019).

[259] The Ninth Circuit Court of Appeals rejected Bayer's argument that plaintiff Hardeman's failure to warn claims were preempted under FIFRA. *See* Hardeman v. Monsanto Co., 997 F.3d 941, 954 (9th Cir. 2021). On August 16, 2021, Bayer petitioned the U.S. Supreme Court for a writ of certiorari, arguing in the *Hardeman* case that, among other errors at trial, the plaintiff's failure to warn claim is preempted under federal law. *See* Carey Gillam, *Bayer Seeks U.S. Supreme Court Review of Roundup Trial Loss*, U.S. RIGHT TO KNOW (Aug. 16, 2021), https://usrtk.org/monsanto-roundup-trial-tracker/bayer-seeks-u-s-supreme-court-review-of-roundup-trial-loss; Lawrence Hurley & Ludwig Burger, *Supreme Court Asks U.S. Government for Views on Bayer Weedkiller Case*, REUTERS (Dec. 13, 2021), https://www.reuters.com/legal/government/supreme-court-asks-us-government-views-bayer-weedkiller-case-2021-12-13. For a discussion of the history of preemption cases under FIFRA, see *Federal Preemption*, *supra* note 139, at 419.

[260] *See* Pretrial Order No. 180, at 4–5, *Hardeman v. Monsanto Co.* (No. 16-Md-02741) (N.D. Cal. 2019). In May 2021, the three-judge appellate panel in the case upheld a $25 million verdict. *See Judge Rejects Bayer Proposal to Settle*

In the third case to go to trial, *Pilliod v. Monsanto Company*, the California state court jury awarded a couple *two billion dollars* in punitive damages and fifty-five million dollars in compensatory damages in late 2019.[261] Alva and Alberta Pilliod had used Roundup in their grounds-keeping work and both developed NHL. As in *Johnson*, the trial court likewise reduced this overall jury award to eighty-seven million dollars for the couple.[262]

B. *GBH Settlements to Date*

As of 2020, Monsanto/Bayer faces over 125 thousand cases related to Roundup.[263] With a deluge of litigation and three large verdicts to date, in June 2020, Bayer agreed to pay more than ten billion dollars to more than ninety-five thousand existing plaintiffs, mostly professional groundskeepers and homeowners.[264] The settlement originally attempted to include $1.25 billion to cover future plaintiffs, a scientific commission to study whether glyphosate is safe, and payments of $5,000 to $250,000 to plaintiffs.[265] So structured,

Future Roundup Claims, BEYOND PESTICIDES (June 2, 2021), https://beyondpesticides.org/dailynewsblog/2021/06/judge-rejects-bayer-proposal-to-settle-future-roundup-claims.

261 *See* Verdict Form, Pilliod v. Monsanto Company, No. RG1786702 (Cal. App. Dep't Super. Ct. 2019). The Pilliod case was tried as part of the California Roundup Judicial Council Coordinated Proceedings.

262 *See* Pilliod v. Monsanto Company, No. RG1786702, at 25–6 (Cal. App. Dep't Super. Ct. 2019) (Trial Order).

263 *See* Tom Hals, *Bayer to Rethink Roundup in U.S. Residential Market After Judge Nixes $2 Bln Settlement*, REUTERS (May 27, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/us-judge-rejects-bayers-2-bln-deal-resolve-future-roundup-lawsuits-2021-05-26 (noting the existence of 125,000 claims related to glyphosate and NHL); Patricia Cohen, *Roundup Maker to Pay $10 Billion to Settle Cancer Suits*, N.Y. TIMES (June 24, 2020), https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html; *see also* Tina Bellon, *U.S. Judge Stands by Ruling to Limit Evidence in Roundup Cancer Trials*, REUTERS (Jan. 4, 2019), https://www.reuters.com/article/us-bayer-glyphosate-lawsuit/us-judge-stands-by-ruling-to-limit-evidence-in-roundup-cancer-trials-idUSKCN1OY1RY; Leora Friedman, *Litigating the Alleged Carcinogenicity of Glyphosate in Monsanto's Roundup: The Fairness (and Unfairness) of Deciding Causation Independent of Liability*, GEO. ENV'T L. REV. BLOG at 1 (Jan. 17, 2019), https://www.law.georgetown.edu/environmental-law-review/blog/litigating-the-alleged-carcinogenicity-of-glyphosate-in-monsantos-roundup-the-fairness-and-unfairness-of-deciding-causation-independent-of-liability (noting that 620 cases are currently before Federal District Judge Chhabria).

264 *See* Cohen, *supra* note 263.

265 *See id.*

the settlement attempted to address future litigation.[266] As part of this proposed settlement, Monsanto/Bayer had thus originally set aside $1.25 billion dollars of the approximately $10 billion to establish a "Science Panel" to study the safety of glyphosate and settle a class action suit to be filed in a U.S. District Court in San Francisco on behalf of plaintiffs who may have future health concerns.[267]

In May 2021, however, District Judge Chhabria rejected the proposed settlement of future claims regarding Roundup, calling the proposal "clearly unreasonable."[268] Judge Chhabria rejected the proposal to settle future claims and subject all those who did not opt out to the findings of the planned Science Panel.[269] The Court noted that the Science Panel benefitted mostly Bayer as the Company had lost the battle of the experts in three prior trials, that the medical monitoring proposed by Bayer was only vaguely useful as it would just last four years and medical experts do not actually have tests to detect NHL before onset, and that the potential cash amounts provided to plaintiffs were too small relative to past trials.[270]

> In sum, [the Court noted that] the settlement proposed by these [defense] attorneys would accomplish a lot for Monsanto. It would substantially diminish the company's settlement exposure and litigation exposure at the back end, eliminating punitive damages and potentially increasing its chances of winning trials on compensatory damages. It would accomplish far less for the Roundup users who have not been diagnosed with NHL—and not nearly as much as the attorneys pushing this deal contend.[271]

It is worth mentioning that in rejecting the proposed settlement of future claims, Judge Chhabria actually suggested that Bayer

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266 *See id.*

267 *See* Press Release, Christopher Loder, Global Media Relations, Bayer Announces Agreements to Resolve Major Legacy Glyphosate Litigation (June 24, 2020), https://media.bayer.com/baynews/baynews.nsf/id/Bayer-announces-agreements-to-resolve-major-legacy-Monsanto-litigation.

268 Benedikt Kammel & Joel Rosenblatt, *Bayer Request to Settle Future Roundup Claims Is Denied by Judge*, BLOOMBERG (May 26, 2021), https://www.bloomberg.com/news/articles/2021-05-26/bayer-roundup-request-to-settle-future-claims-denied-by-judge; *Judge Rejects Bayer Proposal to Settle Future Roundup Claims, Beyond Pesticides*, BEYOND PESTICIDES (June 2, 2021) https://beyondpesticides.org/dailynewsblog/2021/06/judge-rejects-bayer-proposal-to-settle-future-roundup-claims; Hals, *supra* note 263.

269 *See* Kammel & Rosenblatt, *supra* note 268.

270 *See* Pretrial Order No. 235, *In re* Roundup Prods. Liab. Litig., No. 16-md-02741-VC, at 2, 4, 5 (N.D. Cal. 2019).

271 *See id.* at 5.

consider labeling its products with a warning that the World Health Organization has found that glyphosate is probably carcinogenic to humans as a way to protect it from future litigation.[272]

In light of the rejection of the proposed settlement, it is interesting to note that Bayer says instead it will reconsider its use of residential Roundup made with glyphosate in the U.S. market,[273] and will reformulate the residential product in 2023.[274] However, Bayer has stated that this is not due to safety concerns,[275] and that it remains committed to the Roundup brand and will continue to supply glyphosate products for agricultural and other users.[276]

Additionally, critics of the settlement of the existing claims include lawyers representing current plaintiffs who have not signed onto the deal.[277] One lawyer representing five thousand non-settling plaintiffs said it was like "putting out part of a house fire" and walking away.[278] The settlement also notably involves no admission of liability or wrongdoing,[279] but is one of the largest settlements ever

[272] *See* Hals, *supra* note 263. In suggesting a warning label, it is not clear whether Judge Chhabria was attempting to warn consumers so they would not have future claims or to protect consumers from actual harm.

[273] *See id.*

[274] *See* Tim Loh & Jef Feeley, *Bayer's Roundup Costs Could Top 16 Billion*, BLOOMBERG (July 29, 2021), https://www.bloomberg.com/news/articles/2021-07-29/bayer-to-set-aside-4-5-billion-for-potential-roundup-claims.

[275] *See id.*

[276] *See* Hals, *supra* note 263. While one might argue that this action by Bayer means litigation works to change company behavior, one still has to ask: at what cost? There has been a tremendous cost to the court system in the over 125,000 suits filed and to the families that have suffered in the face of grave illness. *See supra* note 263 and accompanying discussion. Additionally, Bayer plans to continue to supply the agricultural market with GBH products. *See* Hals, *supra* note 263.

[277] *See* Cohen, *supra* note 263. Other Litigation of note related to glyphosate includes the "No Injury Product Liability"—wherein plaintiffs allege that products containing trace amount of glyphosate cannot be labeled natural under federal law. These cases have not succeeded, noting that the reasonable consumer would not assume that a label of natural would mean that the product therefore did not contain any trace amounts of a pesticide or other toxic substance. *In re* Gen. Mills Glyphosate Litig., No. 16-2869, at *5–6 (D. Minn. 2017) ("The Court concludes that it is not plausible to allege that the statement 'Made with 100% Natural Whole Grain Oats' means that there is no trace glyphosate in Nature Valley Products or that a reasonable consumer would so interpret the label.").

[278] Cohen, *supra* note 263 (quoting Fletch Trammell, a Houston-based lawyer representing 5,000 claimants).

[279] *See* Press Release, *supra* note 267.

announced in civil litigation in the United States.[280] Roundup remains on the market until at least 2023 for residential use and indefinitely for agricultural use.[281]

IV. LITIGATION IN PLACE OF PROTECTIVE REGULATION IS NOT ETHICAL, EFFICIENT, OR PRACTICAL

The controversy over whether glyphosate causes human cancers and the related U.S. tort litigation to date offers significant lessons. It suggests that the U.S. toxics regulatory system is broken, and that litigation does not work effectively to protect consumers from widely used, potentially toxic products that are economically beneficial to industry. In the current system, regulators rely on industry data inputs that are not readily forthcoming, and face pushback at every turn. The result is an almost complete lack of restrictions on the chemical industry, and, when litigation does exist, largely one-sided settlements and continued marketing of the products at issue. Overall, continuing to allow litigation to drive the regulation of glyphosate and other chemical substances about which there exists significant scientific data to suggest grave harm to human health presents ethical, financial, and practical challenges. These challenges are explored in turn below.

A. *Ethical Considerations*

The facts suggest that the most serious risks of glyphosate use fall on those who may not have a choice in avoiding them, which raises ethical questions.[282] Since it is grounds-workers or "professional weed-whackers," who are repeatedly exposed to Roundup, and now filing cases against Bayer,[283] exposure to glyphosate highlights that pesticide workers and those most exposed may not have

280 *See* Cohen, *supra* note 263 (noting that the settlement is one of the largest civil litigation settlements ever reached in the United States).

281 *See supra* notes 273–76 and accompanying discussion.

282 *See* Donald A. Brown, *Superfund Cleanups, Ethics and Environmental Risk Assessment*, 16 B.C. ENV'T AFFS. L. REV. 181, 194 (1998) ("Ethical questions also arise if a particular hazard is not equally distributed among subgroups in a population."). Additionally, scientists remain concerned that children are exposed to glyphosate residues on food.

283 Hillary Brueck, *The EPA Says a Chemical in Monsanto's Weed-Killer Doesn't Cause Cancer—But There's Compelling Evidence the Agency is Wrong*, BUS. INSIDER (June 17, 2019), https://www.businessinsider.com/glyphosate-cancer-dangers-roundup-epa-2019-5.

occupational choice.[284] Additionally, as noted above, there exist large bodies of scientific evidence that suggest GBHs present a serious danger to human health.[285] This is especially true in light of the most recent federal agency profile by the ATSDR.[286] In this context, the continued use and sale of glyphosate often exposes lower-socioeconomic, and potentially, minority populations disproportionately to risk and presents thorny environmental justice and ethics issues.[287]

Ethical considerations are prescriptive by nature, calling for us to do right or wrong whereas science attempts to objectively describe a given risk from a potentially toxic substance.[288] Science informs the ethical decision-making by laying out the risks posed.[289] The science regarding GBH products indicates that occupational exposure among groundskeepers, as well as agricultural workers, presents a potential risk of grave harm, and the continued marketing and sale of GBH products therefore presents serious environmental justice issues.

The continued sale of glyphosate products thus may impose widespread, material costs on occupational and residential users of

284 Dewayne Johnson, for example, worked as a grounds manager for a school district that used a lot of herbicides. *See* Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 114 (Cal. Dist. Ct. App. 2020).

285 *See supra* notes 69–71, 80–85.

286 *See* U.S. Dep't of Health & Human Services, ATSDR Toxicological Profile for Glyphosate Draft for Public Comment, Docket No. ATSDR-2019-0001 (March 2019).

287 Multiple scholars have commented on racial and socioeconomic injustices related to occupation, historically, and as a result of the pandemic. *See, e.g.*, Sauerwein, *supra* note 219, at 320–21; Human Rights Council, *Rep. of the Special Rapporteur on the Right to Food on Its Thirty-Fourth Session,* U.N. Doc. A/HRC/34/48, at 1–9, 14–31 (2017); Lisa Sun-Hee Park & David N. Pellow, *Racial Formation, Environmental Racism, and the Emergence of Silicon Valley*, 4(3) ETHNICITIES 410-11 (Sept. 2004). In their carefully drawn critique of racist practices in Silicon Valley, Park and Pellow detail the environmental justice issues often suffered by people of color and immigrants, noting that they may have little choice in occupation. *Id.* ("[I]mmigrants [were] forced to labor and live in environmentally unhealthy and socially hazardous areas, with little control . . . ."). *See also* Marina Hund-Mejean & Marcla Escobari, *Our Employment System has Failed Low-Wage Workers*, BROOKINGS INST. (April 28, 2020), https://www.brookings.edu/blog/up-front/2020/04/28/our-employment-system-is-failing-low-wage-workers-how-do-we-make-it-more-resilient.

288 *See* Brown, *supra* note 282, at 184–85.

289 *See id.* at 186, 198 (noting that environmental decisions must be viewed more as ethical than scientific decisions).

Roundup as well as material costs on society. Cancer, when it occurs, is expensive to treat,[290] and can result in financial and emotional strain,[291] and untimely death.[292] NHL in particular, as suffered by Johnson, the Pilliods, and Hardeman, and allegedly caused by their glyphosate use, is a serious and deadly disease, often resulting in pain, extreme discomfort, and toxic treatment regimens.[293] In addition, for plaintiffs that cannot bear the medical cost of their treatment or who are uninsured, society may have to bear these medical costs[294] as well as suffer the lost input and tax revenues of an otherwise healthy person in the work force.[295] Families of victims likewise also suffer alongside the patient,[296] and the illness can result in breakdowns of the family structure that impact current and future generations.[297]

In addition to the infliction of serious harm to human health on those who may not have the means to avoid such harm, great suffering to this same group, and societal damage noted above, glyphosate is also suspected of grave harm to aquatic and other wildlife as

290 *See supra* notes 43–45 and accompanying discussion.

291 *See* Tamaki Hosoda, *The Impact of Childhood Cancer on Family Functioning: A Review*, 15 GRAD. J. PSYCH. 18, 19 (2014) (noting that a case of childhood cancer can lead to financial strain and family life disruption); *see supra* notes 43–45 and accompanying discussion.

292 *See supra* notes 35–38 and accompanying discussion.

293 *See, e.g.*, Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 125 (Cal. Dist. Ct. App. 2020). Johnson suffered from painful lesions and plaques on his skin, stayed in bed for one month following one chemotherapy treatment, was depressed, had trouble sleeping, and testified that "[t]he lesions were so painful that it was sometimes difficult for him to put on shoes or wear certain clothes, and he told his family he would wear a loose bed-sheet if he could because he did not want anything to touch his skin." *Id.*

294 *See, e.g.*, COLO. DEP'T HEALTH CARE POL'Y & FIN., COLORADO HOSPITAL COST SHIFT ANALYSIS 8 (Jan. 2020), https://www.colorado.gov/pacific/sites/default/files/Colorado%20Hospital%20Cost%20Shift%20Analysis%20Report-January%202020.pdf; Austin B. Frakt, *How Much Do Hospitals Cost Shift? A Review of the Evidence*, 89(1) MILBANK Q. 90-130 (Mar. 2011) (discussing whether private companies and insureds pay more for health care to supplement the uninsured).

295 *See Johnson v. Monsanto Co.*, 266 Cal. Rptr. 3d at 123 (lost past and future economic damages).

296 *See* Joan Patterson & Ann Garwick, *The Impact of Chronic Illness on Families: A Family Systems Perspective*, 16 ANNALS BEHAVIORAL MED. 131, 131 (Jan. 1994) (noting that a chronic illness in a family affects the whole family and also the surrounding community); *supra* notes 43–45 and accompanying discussion.

297 *See* Hosoda, *supra* note 291, at 19 (noting that a case of childhood cancer can lead to divorce, changes in job, financial worry, and disruption).

it does not dissipate easily in the environment.[298] EPA has begun to attempt to mitigate the risks to terrestrial and aquatic plants, birds, and honeybees in 2020 with "drift management"[299] and required non-target organism labeling.[300] When considering the moral and ethical obligations, as informed by science, to curtail the sale and use of glyphosate, these environmental and wildlife effects, alongside the potential for human harm, must enter the calculus.

B. *Mass Tort Litigation Wastes Governmental Resources*

The common law system of plaintiffs suing to recover for injuries from toxic torts wastes judicial resources and makes it incredibly difficult for plaintiffs to recover.[301] The trials of Johnson, Hardeman, and the Pilliods against Monsanto lasted many months. All three trials were preceded by protracted motion practice and then continued with ongoing, lengthy appeals. In Hardeman, for

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[298] *See* Ignacio Carreño &Tobias Dolle, *The Regulatory Framework on Plant Protection Products in the United Kingdom After Brexit*, 8 EUR. J. RISK REGUL. 766, 769 (2017) ("The [European] Commission also included in its proposal the following aspects: (1) specific provisions that EU Member States have to take into account when considering applications for glyphosate-products (ie protection of groundwater and terrestrial animals and non-target plants) . . . ."); Valerio Matozzo et al., *The Effects of Glyphosate and Its Commercial Formulations to Marine Invertebrates: A Review*, J. MARINE SCI. & ENG'G, June 1, 2020, at 1, 2, 12; Austin Price, *New Study Shows Roundup Kills Bees: Glyphosate Targets Undesired Weeds—As Well as Honeybees,* SIERRA (Oct. 3, 2018), https://www.sierraclub.org/sierra/new-study-shows-roundup-kills-bees.

[299] Drift pesticide management involves managing how much pesticide moves unintentionally from where it is applied to other areas that may include wildlife habitats or neighboring farms. Taking steps to mitigate the risk of such drifting might include not spraying pesticides on windy days or in certain other weather conditions and using different application equipment or methods. *See, e.g.*, *Management of Pesticide Spray Drift*, GOV'T OF CAN. (May 1, 2020), https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/growers-commercial-users/drift-mitigation/management-pesticide-spray-drift.html.

[300] *See* EPA, Case No. 0178 Docket No. EPAHQOPP20090361, Glyphosate Interim Registration Review Decision 1517, 17–18 (2020), https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

[301] *See* Howard F. Chang, *Developments in the Law - Toxic Waste Litigation*, 99 HARV. L. REV. 1631, 1632 (1986). In particular, it is difficult for plaintiffs to prove causation.

example, filings numbered in the hundreds,[302] in a case that spanned a number of years to reach a trial verdict which the parties have now appealed.[303] At least partially owing to the fact that cancer causation is complicated and inordinately difficult to show, toxic tort cases require enormous inputs of judicial resources over a course of years.[304] Moreover, settlement negotiations to date show that there exist over 125 thousand existing claims related to Roundup and that 620 cases alone are currently before Judge Chhabria in multi-district litigation in California.[305] These cases drain judicial resources and clog the court system so that it is less available to other disputes.

C. *Allowing Toxic Tort Litigation to Drive Reform is Not Effective*

Much has been written about the inefficiency of tort litigation in driving actors to proceed with socially optimal caution.[306] One premise is that incorporating litigation costs into the standard of due care could deter the continued sales of potentially toxic products.[307] However, allowing the court system to be the sole regulator in cases where we *already have reliable evidence that a substance is potentially, seriously harmful to human health* may not have the desired social outcomes where the economic benefit of production is great.[308] That is, a lucrative product such as Roundup may remain on the market despite litigation, large verdicts, and mass settlements if it is worth the cost of potential tort exposure.

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302 *See Monsanto Papers*, U.S. RIGHT TO Know, https://usrtk.org/monsanto-papers/federal-court (last visited Sept. 23, 2021) (showing hundreds of filings in Hardeman v. Monsanto, 216 F.Supp.3d 1037 (N.D. Cal. 2016)).

303 *See* First Step Brief for Monsanto Co., Hardeman v. Monsanto, 997 F.3d 941 (9th Cir. 2021) (Nos. 19-16636, 19-16708), https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/12/Hardeman-appeal-by-Monsanto.pdf.

304 *See supra* notes 67–68 and accompanying discussion.

305 *See* Cohen, *supra* note 263; *see also* Tina Bellon, *U.S. Judge Stands by Ruling to Limit Evidence in Roundup Cancer Trials*, REUTERS (Jan. 4, 2019), https://www.reuters.com/article/us-bayer-glyphosate-lawsuit/us-judge-stands-by-ruling-to-limit-evidence-in-roundup-cancer-trials-idUSKCN1OY1RY; Friedman, *supra* note 263 (noting that 620 cases are currently before Federal District Judge Chhabria).

306 *See* GUIDO CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS 239 (1970); Keith N. Hylton, *Litigation Costs and the Economic Theory of Tort Law*, 46 U. MIA. L. REV. 111, 112–13 (1991).

307 *See* Keith N. Hylton, *Costly Litigation and Legal Error Under Negligence,* 6 J. L. ECON. & ORG. 433, 445 (1990).

308 *See supra* notes 8–10, 51–61 and accompanying discussion (regarding the size of the glyphosate industry).

While it is true that plaintiffs' successes may have prompted Monsanto/Bayer to proceed to end residential sales of Roundup as it is currently formulated, to attempt to settle all existing and future cases, and to study the effects of GBH use, the company remains currently committed to the agricultural sale and use of Roundup.[309] Moreover, the results of its efforts to further study GBHs are not yet known. In light of this uncertainty, one might argue that it may even be in the corporation's best interests to avoid litigation and accompanying reputation problems by not selling a product for agricultural or residential use with so much evidence against it.

Monsanto/Bayer will still face remaining non-settling plaintiffs and plaintiffs with future illnesses, and it remains to be seen how the courts will manage future cases brought by those not yet sick and by non-settling current plaintiffs. Additionally, Monsanto's ten billion dollar settlement appears to benefit plaintiffs' attorneys in GBH cases, more than the victims, as each individual settling plaintiff—Johnson, the Pilliods, and Hardeman excepted—is only slated to receive between $5,000 and $250,000.[310] In sum, the glyphosate settlement includes no admission of wrongdoing,[311] paltry settlement amounts for the vast majority of plaintiffs,[312] and does not require Monsanto/Bayer to restrict the manufacture and future sales of most glyphosate uses.[313]

Moreover, litigation may also result in inequitable damage awards as to those similarly situated.[314] Plaintiffs may lack the

309 *See* Hals, *supra* note 263.

310 *See* Cohen, *supra* note 263. Bayer's stock tumbled amid large verdicts against it, and the long-term damage to its reputation remains to be known. *Bayer Tumbles After $2BN Roundup Award in US*, IRISH TIMES (May 14, 2019), https://www.irishtimes.com/business/agribusiness-and-food/bayer-tumbles-after-2bn-roundup-award-in-us-1.3891729.

311 *See* Press Release, *supra* note 267.

312 *See* Cohen, *supra* note 263.

313 *See supra* note 11 (announcing glyphosate litigation settlement). It is worth noting that courts have historically deferred to legislative and regulatory bodies to lay down and enforce the law. *See, e.g.*, Chevron v. Nat. Res. Def. Council, 467 U.S. 837 (1984); Ruckelshaus v. Nat. Res. Def. Council, 464 U.S. 810 (1983) (giving deference to the Agency's reasonable statutory interpretation); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 450 (2005) (determining Congressional intent in interpreting statute rather than substituting its own judgment regarding FIFRA preemption). Given this historical deference, litigation and related settlements are not designed, nor will they result in, large scale judicial intervention to restrict widely sold products suspected of grave danger.

314 *See, e.g.*, *supra* notes 11–14, 310 and accompanying discussion.

concomitant resources or research capacity of corporate defendants,[315] which makes proving their cases more difficult, and results uneven.[316] All three verdicts against Monsanto, for example, while large and in favor of plaintiffs, differ greatly in the damages awarded by the juries. While Johnson and Hardeman both claimed glyphosate usage had caused their NHL, Johnson came away from the trial court with $78 million, while Hardeman was awarded only $25 million, and the Pilliods left the courthouse with a combined $87 million after the trial court reduced the initial damage awards.[317] This inconsistency seems to lack fairness and is more evidence that costly and time-consuming litigation does not necessarily result in just outcomes.

V. THE ROUNDUP CONTROVERSY CALLS FOR A SHIFT IN EPA'S TOXICS REGULATORY PARADIGM

A. *Glyphosate and Our Toxics Regulatory Challenges*

Even in light of the new Lautenberg Act,[318] our toxics regulatory system remains skewed toward allowing the production and sale of existing chemicals without proof of their safety. This has historically been the regulatory approach in the United States to all synthetic chemicals unless and until definitive evidence of potential harm to human health is available.[319] In the meantime, while proof is sought, large scale toxic tort litigation serves as the only public remedy or redress for any resulting harm from toxic substances, including pesticides.

The current glyphosate litigation and controversy recalls our failed regulatory treatment and continued sale of many known

315 *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 774–75 (1997) (noting that corporations possess the information about their products, can limit liability through their research programs, and are disincentivized to conduct research on their products).

316 *See supra* notes 11–14 and accompanying discussion.

317 *See* Pilliod v. Monsanto Co., No. RG-17-862702 (Cal. App. Dep't Super. Ct. 2019) (Trial Order).

318 *See* Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601–2629); Frank R. Lautenberg Chemical Safety for the 21st Century Act, 3. Pub. L. No. 114-182, 130 Stat. 448 (2016) (to be codified at 15 U.S.C. §§ 2601–2629).

319 *See supra* notes 111–70 and accompanying discussion.

carcinogens that remain in use today.[320] These chemicals and products include formaldehyde, in use and a byproduct in many manufactured products such as furniture, despite its categorization as a known carcinogen,[321] cigarettes, on the market without cautionary labeling, long after the cigarette industry had indication that cigarettes caused lung cancer, and PCBs,[322] still used today in specific situations[323] and previously widely used in light fixtures, sealants, and caulking long after Monsanto had evidence that PCBs were extremely toxic to human health.[324] Even the ongoing controversy and related litigation involving talc in baby powder and its relationship to ovarian cancer were not enough to make regulators require Johnson & Johnson to stop selling its iconic baby powder.[325] Rather, while the company agreed to pull its talc products off the market after a large 2018 verdict against it, Johnson & Johnson did so

320 *See infra* notes 321–28 and accompanying discussion. In *Hardeman*, the court stated: "Monsanto's behavior betrayed a lack of concern about the risk that its product might be carcinogenic. Despite years of colorable claims in the scientific community that Roundup causes NHL, Monsanto presented minimal evidence suggesting that it was interested in getting to the bottom of those claims." Pretrial Order No. 160, *In re* Roundup Prods. Liab. Litig., 385 F. Supp. 3d 1042, 1047 (N.D. Cal. 2019).

321 *See* Wagner, *supra* note 315, at 1645–46 (regarding formaldehyde regulation).

322 *See* Valerie Watnick, *PCBs in Schools and Corporate Responsibility for Remediation: Yorktown Central School District v. Monsanto Company*, 33 ENV'T. L. & POL'Y 231, 245–48 (2010) (discussing formaldehyde PCB, asbestos regulation, and cigarettes); Ernest L. Wynder & Evarts A. Graham, *Tobacco Smoking as a Possible Etiologic Factor in Bronchogenic Carcinoma: A Study of Six Hundred and Eighty-Four Proved Cases*, 143 J. AM. MED. ASS'N 329, 329 (1950); Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (requiring warnings on cigarette packages).

323 *See* 15 U.S.C. § 2605(e); 40 C.F.R. § 761.30.

324 As early as 1937, Harvard researcher Cecil Drinker raised concerns about the health effects of PCBs. *See* Cecil K. Drinker et al., *The Problem of Possible Systemic Effects from Certain Chlorinated Hydrocarbons*, 19 J. INDUS. HYGIENE & TOXICOLOGY 283 (1937) (discussing PCBs). It was not until 1982 that regulators first effected a construction ban on PCB use. *Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes*, 47 Fed. Reg. 46,980 (1982) (banning most uses of PCBs with the exception of uses in a "totally enclosed manner"). PCBs may still be used today in a non-totally enclosed manner in certain electrical equipment. 40 C.F.R. § 761.30.

325 *See* Vanessa Romo, *Johnson and Johnson Stops Selling Talc-Based Baby Powder in U.S. and Canada*, NPR (May 19, 2020), https://www.npr.org/2020/05/19/859182015/johnson-johnson-stops-selling-talc-based-baby-powder-in-u-s-and-canada.

because it said that demand had waned for the products, not because the U.S. government had required it to do so.[326] Despite a settlement of $100 million and a jury verdict of $2 billion for twenty-two plaintiffs,[327] Johnson & Johnson has still made no admission of wrongdoing with reference to the production and sale of its powders, nor has it admitted that they have caused harm to human health.[328]

To force more proactive industry action as to existing chemicals, including pesticides such as glyphosate, a significant shift in regulatory framing is required. The economic importance of a product should not fully determine future regulatory status and sales. History shows that for economically important products, restriction and/or labeling has taken too long. In the cases of cigarettes and PCBs, for example,[329] use, and often virtually unrestricted use, continues as long as industry wants to sell the products. These products

326 *See id.*

327 *See* Ingham v. Johnson & Johnson, 608 S.W.3d 663, 724–25 (Mo. Ct. App. 2020), reh'g and/or transfer denied (July 28, 2020), transfer denied (Nov. 3, 2020), cert. denied, No. 20-1223, 2021 WL 2194948 (U.S. June 1, 2021); Ronald V. Miller, Jr., *$2 Billion Verdict in Missouri Motivates J&J to Settle Talcum Powder Lawsuit*, LAWSUIT INFO. CTR. BLOG (May 20, 2021), https://www.lawsuit-information-center.com/2-billion-verdict-in-missouri-motivates-jj-to-settle-talcum-powder-lawsuits.html.

328 *See* Richard J. Dolesh, *Weeding Through the Thorny Debate on Glyphosate*, NAT'L RECREATION & PARK ASS'N, (Jan. 23, 2020), https://www.nrpa.org/parks-recreation-magazine/2020/february/weeding-through-the-thorny-debate-on-glyphosate (noting that more than 280 million pounds per year are used in parks and other public spaces); Kori Hale, *Johnson & Johnson's $100 Million Baby Powder Lawsuit Settlement Is Overdue for Black & Hispanic Women*, FORBES (Oct. 14, 2020), https://www.forbes.com/sites/korihale/2020/10/14/johnson—johnsons-100-million-baby-powder-lawsuit-settlement-is-overdue-for-black—hispanic-women/?sh=343b9a2463b3 ("Bloomberg Intelligence estimated in July that settling all the outstanding cases could cost J&J as much as $10 billion."). While parallel in some ways, talcum powder and glyphosate have vast differences. While consumers choose to use baby powder, glyphosate is largely sprayed and used widely in all sorts of agriculture and around public spaces such as on school grounds and in parks, without consumer knowledge or choice. *See* Dolesh*, supra*. In addition, unaware consumers eat food with glyphosate residues daily. *See supra* notes 163–70, 189–204 and accompanying discussion.

329 Cigarettes remained largely unregulated until 1965, when Congress mandated warning labels in the face of definitive proof that cigarettes cause lung cancer. *See* Federal Cigarette Labeling and Advertising Act, Pub. Act 89-92, 79 Stat. 282 (1965). PCBs remain in use today in "non-totally enclosed" uses, and past legacy uses remain in place in schools, public buildings, and homes throughout the United States. *See supra* notes 323–24 and accompanying discussion.

remain in use long after there is evidence of the potential for grave harm, and while regulators fight an uphill battle for necessary public health information.[330] Toxics litigation and our existing regulatory mindset simply do not get us to where we need to be: a system designed to protect human health and the environment and one that also promotes safe industry practices. We must shift direction and call for more targeted, achievable efforts to regulate toxic chemicals like glyphosate, about which there exists reliable scientific evidence that suggests the potential for grave harm to human health.[331]

B. *The Lautenberg Act, FIFRA, and Political Environment Herald a More Targeted, Precautionary Approach*

This Article argues that current law and the current political environment present opportunities for implementing a precautionary and targeted approach to existing synthetic chemical and pesticide regulation. Simply put, if the science reliably indicates that an existing chemical product potentially causes grave danger, the substance should *not* remain on the market without restriction, absent proactive safety data from the manufacturer to show the product does not present an unreasonable risk to man or the environment. In this vein, scholar Sheldon Krimsky has described the existence of two potential theses in chemical regulation.[332] Krimsky writes: "There are 2 fundamental ways to address the risks of a . . . substance (or technology): Thesis 1 assumes the substance is unsafe, unless it can be proven safe, and Thesis 2 assumes the substance is safe, unless it can be proven unsafe."[333] While the new Lautenberg Act moves the needle somewhat toward Thesis 1 for existing, non-pesticidal chemicals in the United States, the pace of review is still glacially slow, and according to Krimsky, the Act still "bear[s] . . . many of the impediments" of the old TSCA.[334] The sixty thousand plus chemicals grandfathered into the Toxics Inventory at the time

330 *See supra* notes 320–28 and accompanying discussion.

331 *See infra* notes 355–68 and accompanying discussion.

332 *See generally* Sheldon Krimsky, *The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act*, 15 PLOS BIOLOGY 1, 1–5 (Dec. 18, 2017).

333 *Id.* at 2–3.

334 *Id.* at 3. Under the Lautenberg Act, pesticides are exempted from TSCA and regulated under FIFRA. *See* 15 U.S.C. § 2602(2)(B).

of the original TSCA are still assumed safe.[335] While under the Lautenberg Act, EPA can and will review new chemicals for unreasonable risk,[336] the Agency still has to prioritize and then review the over eighty thousand existing chemicals now on the TSCA Inventory and designate them as low or high priority, with high priority chemicals slated for expedited review.[337] Yet, under the current system, manufacturers are responsible for developing and sharing relevant toxicity data,[338] and thus remain disincentivized from creating unfavorable data regarding their products. Due to this disincentive and a lack of agency resources to create its own data, EPA lacks the information it needs to properly prioritize and then assess the eighty-five thousand existing chemicals to see if they present "unreasonable risk" in a timely manner.[339] At every turn, as it tries to regulate, EPA encounters industry push-back, including lobbying[340]

335 *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825, 4826 (Jan. 17, 2017) (discussing background on and need for recent 2016 amendments to TSCA).

336 *See* 15 U.S.C. § 2604(a)(3).

337 *See* Krimsky, *supra* note 332, at 4, 8; 15 U.S.C. § 2605(b)(1)(B)(ii) (stating that without negative data, the Agency can designate a chemical as low priority under the Lautenberg Act and postpone its review indefinitely).

338 *See* 7 U.S.C. § 136a(c)(F) (noting that the procedure for registration of a pesticide requires the applicant to provide data to support the application); 15 U.S.C. § 2605(b)(1)(B)(ii); Krimsky, *supra* note 332, at 6 ("considerable hurdles in data acquisition and building the requisite human resources to analyze the massive amounts of data"). Applegate summed up the problems in the toxics regulatory system that assumes chemicals safe unless proven otherwise as far back as 1992 in John Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 282–87, 304–05, 352–53 (1992) (noting that agencies suffer a serious lack of information as to the extent of health effects of a given substance, resource constraints and controversy regarding decisions and must therefore prioritize regulation). *See also* U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT 2 (2009) (noting that EPA has had difficulty restricting existing chemicals).

339 15 U.S.C. § 2605(a); Krimsky, *supra* note 332, at 2.

340 *See, e.g.*, *Dow Chemical Urges Trump Administration to Ignore Pesticide Findings*, USA TODAY (Apr. 20, 2017), https://www.usatoday.com/story/news/2017/04/20/ap-exclusive-pesticide-maker-tries-to-kill-risk-study/100709990 (detailing how Dow pushed the administration to ignore studies about Dow products are fundamentally flawed); *How Dow Chemical Influenced the EPA to Ignore the Scientific Evidence on Chlorpyrifos*, UNION OF CONCERNED SCIENTISTS (Oct. 11, 2017), https://www.ucsusa.org/resources/how-dow-chemical-influenced-epa-ignore-scientific-evidence-chlorpyrifos; U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-696T, CHEMICAL REGULATION: OBSERVATIONS ON THE TOXIC SUBSTANCES CONTROL ACT 7–9 (June 13, 2013).

to stop restrictive rule-making, and a reluctance to provide toxicity data sufficient for the agency to make an "unreasonable risk" determination under FIFRA or the Lautenberg Act.

With regard to pesticides, however, FIFRA empowers EPA with labeling discretion in applying the cost-benefit statute to register pesticides and require pesticide labeling.[341] In requiring pesticide labeling, the Act thus allows EPA to include a "poison" designation or a "skull and crossbones" if it considers a pesticide chemical "highly toxic to man."[342] Given the existing and powerful evidence against glyphosate, EPA could move swiftly in this political climate to restrict or at least require labeling of GBHs as potentially toxic to humans.[343]

Likewise, the Lautenberg Act suggests a new plan and direction for our general toxics regulatory approach to existing chemicals.[344] In making its initial assessment and prioritization for review, EPA does not have to even consider costs and benefits.[345] Once EPA designates an existing chemical as "high priority," it must then conduct a risk evaluation, propose a rule within one year to ameliorate

341 *See* 7 U.S.C. § 136(q)(2)(D); Mary Jane Angelo, *Embracing Uncertainty, Complexity, and Change: An Eco-Pragmatic Reinvention of a First-Generation Environmental Law*, 33 ECOLOGY L.Q. 105, 161–63. While FIFRA's legislative history indicates that negative effects were not supposed to be tolerated in the absence of overriding benefits, the Act has been interpreted to give EPA much discretion in conducting cost-benefit analysis to determine pesticide registration. *See id.*

342 7 U.S.C. § 136(q)(2)(D).

343 A decidedly more informative approach as to labeling is not so far-fetched, considering that Judge Chhabria went so far as to suggest much more impactful poison labeling to defendants possibly as a way to warn users of the potential dangers associated with Roundup use or to protect against future liability. *See* Bellon, *supra* note 263 and accompanying discussion.

344 *See* H.R. REP. NO. 114-176, at 22 (2015) (House Report on Toxic Substances Control Act Modernization Act of 2015) (noting that "EPA should have the information necessary to fill knowledge gaps before making regulatory decisions" and that "[th]e Committee believes that the broader and simpler manner of requiring new test information by order or consent agreement, the new authority given to EPA to compel the creation of new data . . . will enable EPA to close knowledge gaps"); *see also id*. (statement of general performance goals and objectives recognizing the need for EPA to increase its access to information); Valerie J. Watnick, *The Lautenberg Chemical Safety Act of 2016: Cancer, Industry Pressure, and a Proactive Approach*, 43 HARV. ENV'T L. REV. 373, 390 n.115.

345 *See* 15 U.S.C. § 2605(b)(1)(B); Applegate, *supra* note 338, at 285 (describing the vague nature of EPA's "unreasonable risk" standard).

any unreasonable risk, and publish a final rule within two years.[346] In creating a rule to reduce risk as to an existing chemical, EPA may consider costs and benefits, but such are not determinative.[347] EPA also has the ability to require protective labeling on existing chemicals. It should thus move expeditiously to regulate existing chemicals about which there exists reliable, if not definitive, evidence of potential unreasonable risk to human health or the environment, to quickly restrict their sale and use; or require comprehensive, prominent labeling on an emergency basis.

Such a plan is not so far off. EPA has also already developed a targeted list of potentially toxic chemicals that could be the starting place for a more precautionary regulatory paradigm. In 2014, EPA prepared a 2014 workplan that contained ninety chemicals for highest priority review.[348] EPA had selected these chemicals because the chemicals had both exposure and hazard concerns, as well as the potential to persist and bioaccumulate in the environment.[349] It then limited its priority review to ten chemicals in 2017,[350] and now to

[346] 15 U.S.C. § 2605(b)(1)(A)(B), (c). "In designating high-priority substances, the Administrator shall give preference to (i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and (ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity." 15 U.S.C. § 2605(b)(2)(D).

[347] *See* 15 U.S.C. § 2605(c)(2).

[348] *See* Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 Fed. Reg. 91,927, 91,928 (Dec. 19, 2016). In comments in response to the 2014 Workplan made after passage of the Lautenberg Act, the Environmental Working Group specifically said EPA's list of chemicals to prioritize assessment was not sufficiently broad and should consider production volumes, proximity to drinking water, and broader groups of potentially vulnerable subpopulations. *See* MELANIE BENESH ET AL., ENV'T WORKING GRP., ENVIRONMENTAL WORKING GROUP COMMENTS ON EPA TSCA PRIORITIZATION WHITE PAPER: A WORKING APPROACH FOR IDENTIFYING POTENTIAL CANDIDATE CHEMICALS FOR PRIORITIZATION 10 (Nov. 15, 2018), https://cdn3.ewg.org/sites/default/files/testimony/FINAL%20EWG%20Comments%20Prioritization%20White%20Paper%20Nov%202018.pdf.

[349] *See* 81 Fed. Reg. 91,927, 91,928; 15 U.S.C.A. § 2605(c)(2)(A) (stating that the Administrator shall select chemicals based on conditions of use, chemicals' volume of production, hazard and exposure potential, persistence and bioaccumulation, and potential to expose susceptible sub-populations).

[350] *See* EPA, *Chemical Substances Undergoing Prioritization: High-Priority*, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemical-substances-undergoing-prioritization-high (Apr. 2, 2021); EPA, *Chemicals Undergoing Risk Evaluation Under TSCA*, https://www.epa.gov/assessing-and-

twenty.[351] However, in an industry blog written in 2017, corporate lawyers note that none of the initial ten chemicals have been banned, labeled, or significantly restricted in their use and sale.[352] Thus, while the Lautenberg Act and FIFRA both present frameworks within which EPA can begin to regulate in a more proactive, expeditious manner, the Agency has not done so.[353] As Krimsky puts it, "[p]ast experience shows that legal authority without the requisite resources is a recipe for inaction or glacial progress."[354]

The antidote appears clear: increased agency resources and a change in regulatory mindset that calls for swift, proactive agency action. First, empower EPA to create its own data under FIFRA for pesticides and under the Lautenberg Act for all high-priority chemicals. EPA should be allocated the resources necessary for contracting out its chemical testing needs so that data inputs can be secured more expeditiously and without bias. Second, and most importantly, shift the burden to industry by regulating where there exists reliable evidence of the potential for great harm absent proof from the producer of product safety. The Lautenberg Act, FIFRA, and the new political reality under President Biden just might allow such a shift.[355]

As a starting place, history shows that warning labels can act as powerful tools to prompt changes in business behavior and increase public awareness,[356] even where definitive proof of harm is not available. Rather than looking for definitive evidence that a

managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca (Sept. 8 2021); 15 U.S.C. § 2605(b)(2)(B).

351 *See id*.

352 *See* Lynne L. Bergeson & Margaret R. Graham, *EPA Opens Comment Period on Risk Evaluations for First Ten Chemicals Under Revised TSCA,* TOXIC SUBSTANCES CONTROL ACT BLOG (June 21, 2017), http://www.tscablog.com/entry/epa-opens-comment-period-on-risk-evaluations-for-first-ten-chemicals-under.

353 The current speed of review of the 90 workplan chemicals under the Lautenberg Act lags: to date, the Agency has only completed risk evaluation on four of the 90 chemicals on the workplan, finding two worthy of restriction. *See* Krimsky, *supra* note 332.

354 Krimsky, *supra* note 332, at 6.

355 *See infra* notes 356–81 and accompanying discussion.

356 *See* Lauren Sherman, *A Warning for Environmental Warnings: Regulatory Uncertainty in the Face of First Amendment Litigation*, 27 N.Y.U. ENV'T L.J. 241, 261 (2019*)*; Michael P. Vandenbergh, *From Smokestack to SUV: The Individual as Regulated Entity in the New Era of Environmental Law*, 57 VAND. L. REV. 515, 610 (2004).

substance is toxic or carcinogenic, regulators can act proactively to put warning labels on high-priority chemicals like glyphosate. Such a decision by EPA would comport with a health protective approach under the Lautenberg Act,[357] and under FIFRA, which already calls for prominent and powerful labeling where there is evidence of potential, grave danger to humans.[358] This is especially true considering that proof of disease causation is difficult to develop and often not within the resources of the public or EPA.[359] California's Proposition 65 is just one powerful example of how warning labels can act as deterrents.[360] Additionally, warning labels, when required, can cause manufacturers to change their planned production schedules of suspect products, especially where consumers garner their collective purchasing power in the face of a warning.

In addition to requiring more conspicuous warning labels, EPA also has the authority under existing law to prohibit the sale of chemicals for which there is reliable evidence of unreasonable risk to human health or the environment.[361] However, we must also be mindful of a potential pitfall of this approach. In banning existing chemicals, regulators must ensure that the replacement product is not a worse substitute.[362] If a product is cast aside, industry typically decides whether to replace it and what replacement chemical to

357 *See* 15 U.S.C. § 2605(c).

358 *See* 7 U.S.C. § 136(q)(2)(D); Angelo, *supra* note 341, at 162 (noting that the legislative history of FIFRA suggests that EPA was not ever to tolerate adverse effects from a pesticide "in the absence of 'overriding benefits'" and that Congress did not direct the Agency to "conduct a strict cost/benefit analysis" in registering a pesticide).

359 *See, e.g.*, Watnick, *supra* note 322, at 245–47; EPA, *Polychlorinated Biphenyls (PCBs)*, https://www.epa.gov/pcbs (providing general PCB information); *see supra* notes 67–68 (noting difficulty of proving cancer causation and citing studies).

360 *See* Haileigh Haffner, *Amendments to California's Proposition 65: Clarity for Consumers, Less Confusion for Businesses*, 31 LOY. CONSUMER L. REV. 128, 140 (2018) (arguing that recent amendments improve the law's effectiveness as to consumers and businesses).

361 *See* 15 U.S.C. § 2605(a).

362 *See* Steve C. Gold & Wendy E. Wagner, *Filling Gaps in Science Exposes Gaps in Chemical Regulation*, SCIENCE (2020), https://www.science.org/doi/full/10.1126/science.abc1250; Miranda Goot, *Emerging Thoughts: A Principled Framework for Regulating GenX as an Emerging Contaminant*, 98 N.C. L. REV. 629, 632, 634 (2020) (describing GenX as a replacement for the largely phased out PFOA).

use.[363] If, however, the replacement chemical is later suspected of grave harm, and had been in commercial use for some time, the whole process of existing chemical review might begin anew for the replacement chemical. In the case of bisphenol A (BPA), for example, consumer outcry and litigation[364] prompted manufacturers to move away from its use.[365] In response, industry has often replaced BPA with chemicals not necessarily safer than BPA, but which were already in use at the time of the outcry.[366] A better system would instead apply the Lautenberg Act strictly to ensure that any replacement product be considered a "new chemical substance" or "significant new use" subject to the Act's requirements for data input showing safety for such uses before commercialization.[367] Under this type of approach, expert regulators would first decide whether a product would remain on the market and then would decide if the industry's proposed replacement is safe to market, based on data that the industry would be required to provide for the new chemical use.[368]

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[363] *See, e.g.*, Nathaniel Rich, *The Lawyer Who Became Dupont's Worst Nightmare*, N.Y. TIMES MAG. (Jan. 6, 2016). Dupont had the opportunity to replace PFOA with a substitute in 1993 but chose not to do so because the economic risk was too great. *See id.*

[364] *See In re* Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig, 687 F. Supp. 2d 897 (W.D. Mo. 2009) (order allowing some claims to stand); 18 Broadway v. Avent America, Case No. 08-00997 (W.D. Mo.) (No. 4:08-1967-MD-WODS) (stipulation of class action settlement).

[365] *See* Warren Cornwall, *To Replace Controversial Plastic Additive BPA, a Chemical Company Teams Up with Unlikely Allies*, SCIENCE (Jan. 23, 2020), https://www.science.org/news/2020/01/replace-controversial-plastic-additive-bpa-chemical-company-teams-unlikely-allies (noting that BPA has been linked to breast cancer, prostate cancer, reduced fertility, diabetes, birth defects, and other problems).

[366] *See id.* ("[T]he alternatives have flaws. Some substitutes—often related chemicals in the bisphenol family—appear to have similar hormone-mimicking properties."); Robert F. Service, *BPA Substitutes May Be Just as Bad as the Popular Consumer Plastic*, SCIENCE (Sep. 13, 2018), https://www.science.org/news/2018/09/bpa-substitutes-may-be-just-bad-popular-consumer-plastic.

[367] *See* 15 U.S.C. § 2604(a)(1), (b)(2)(e). Generally, the Act allows the Administrator to require additional data before commercialization where data is "insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance" or where in the absence of enough data to make a determination the new chemical or use may present an unreasonable risk to health or the environment (without consideration of costs or non-risk factors) or where the chemical will be produced in substantial quantities. 15 U.S.C. § 2604(b)(2)(e).

[368] *See* 15 U.S.C. § 2604(b)(2)(e).

C. *The Argument to Move Swiftly Comes at a Perfect Time in History*

U.S. regulation of toxic substances does not occur in a vacuum: federal toxics regulation is influenced by the politics of the current administration and by the public will. Under the Trump administration, the executive branch sought to cut regulation, no matter the cost.[369] The election of a democratic president concerned about the environment signals a shift in politics that likely favors greater environmental regulation to protect human health.[370] In his January 20, 2020, executive order, President Biden expressly required a renewed focus on public health, including the limitation of dangerous chemicals and pesticides alongside greater environmental equity.[371] Under a new administration, the opportunity is ripe to make the regulation of a small list of potentially dangerous chemicals a focus.

This political shift, combined with the pressure of many potential cases on behalf of non-settling GBH plaintiffs, and with expanded regulatory authority under the Lautenberg Act,[372] offers a chance to shift our framework for regulating glyphosate and other "high-priority" chemicals. We must demand EPA act to protect human health. EPA can act with a greater reliance on existing scientific research to make forward-looking regulatory decisions to expeditiously limit, remove, or at least label products suspected of widespread and grave harm to human health and the environment, including glyphosate. This moment in history, with recent political shifts that arguably reflect the populace's and the president's concern about the environment and environmental regulation, calls for

369 *See* Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Feb. 3, 2017); *see also* Lisa Heinzerling, *How Not to Regulate*, 85 U. CHI. L. REV. 2015 (2018) (reviewing THOMAS LAMBERT, HOW TO REGULATE: A GUIDE FOR POLICYMAKERS (2017)).

370 *See* Exec. Order No. 13,990, 86 Fed. Reg. 7037 (Jan. 25, 2021); Marianna Sotomayor & Mike Memoli, *In A Nod to Sanders, Biden Looks to Adopt More Progressive Policies*, NBC NEWS (Apr. 8, 2020), https://www.nbcnews.com/politics/meet-the-press/blog/meet-press-blog-latest-news-analysis-data-driving-political-discussion-n988541/ncrd1180516#blogHeader.

371 *See* Exec. Order No. 13,990, 86 Fed. Reg. 7037 (Jan. 25, 2021) ("It is, therefore, the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities . . . .").

372 *See supra* notes 353–59.

such a change.[373] If the United States moves quickly to fund EPA to prioritize; evaluate; and then restrict, ban, or label chemicals that appear to present an unreasonable risk of danger to the public based on solid evidence, we can lead in this regulatory area.[374] We have the legislative framework to support a targeted precautionary approach, and the political will also appears to be in place.[375]

Overall, toxics regulation presents challenging and thorny cost-benefit and ethical problems that may be pushed aside in the face of a pandemic, pressing economic needs, and racial strife. However, the current lack of regulation when substances are strongly suspected to cause serious illness has dire consequences as well.[376] The public needs to engage with the government to act expeditiously to restrict, ban, *or at least label* a substance strongly suspected of unreasonable risk of harm to human health or the environment according to reliable, unbiased scientific research, even absent definitive proof. Public pressure has worked many times in history to force governmental oversight regarding potentially dangerous toxic substances. Such substances have included Alar on apples,[377] BPA,[378] and flame retardants,[379] to name a few chemicals about which there existed public outcry which then motivated governmental and

373 *See* Exec. Order No. 13,990, 86 Fed. Reg. 7037 (Jan. 25, 2021).

374 *See* EPA, TSCA WORK PLAN FOR CHEMICAL ASSESSMENTS: 2014 UPDATE (Oct. 2014), https://www.epa.gov/sites/production/files/2015-01/documents/tsca-_work_plan_chemicals_2014_update-final.pdf. EPA has the opportunity to identify the most potentially toxic substances and regulate swiftly, as its 2014 work plan included 90 chemicals for prioritization under 15 U.S.C.A. § 2605 et seq. Since the plan was initially developed, EPA has completed its assessment of four chemicals and issued final rules that two did not present concern for their intended use. With the addition of glyphosate and atrazine, the list would again total 90. *See id.* (noting that the Agency has completed assessments for four of the 90 chemicals and that two do not present concern: 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[γ]-2-benzopyran (HHCB) and Antimony Trioxide).

375 *See supra* notes 348–55 and accompanying discussion.

376 *See* Part IV.A.

377 *See* Wendy Gordon, *The True Alar Story IV*, HUFFPOST (July 12, 2011), https://www.huffpost.com/entry/food-chemicals-_b_859179.

378 *See* NOAH SACHS ET AL., PROTECTING THE PUBLIC FROM BPA: AN ACTION PLAN FOR FEDERAL AGENCIES, CTR. FOR PROGRESSIVE REFORM 5 (Jan. 2012) (stating the Center for Progressive Reform's belief that "people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment").

379 *See* Michael Hawthorne, *EPA Vows Investigation of Flame Retardants, Which Tribune Investigated*, CHICAGO TRIBUNE (July 18, 2012), https://www.chicagotribune.com/ct-met-flame-retardants-hearing-20120718-story.html.

corporate action. Public pressure, alongside an existing legislative framework, in the right political environment can clearly force more health-protective regulation by EPA. One could see the regulation or restriction of glyphosate use in a similar vein as was done with Alar and BPA, given glyphosate's widespread use and the controversy surrounding its safety.[380] What is needed is public awareness and pressure to instigate this new regulatory paradigm. Such a paradigm will place greater reliance on existing scientific research to make regulatory decisions in favor of protecting human health and the environment. It will also shift the burden to industry to prove a chemical is safe—much as was anticipated by Congress when it passed the 2016 Lautenberg Act, heralding a new dawn in toxics regulation.[381]

CONCLUSION

The controversy over the health effects of Monsanto/Bayer's Roundup GBH products is ongoing, and scientists continue to debate and study the issue. Yet, plaintiffs have successfully sued Monsanto and won large verdicts that include sizable compensatory awards and awards for punitive damages. The sheer size of the GBH industry and the ubiquitous nature of the herbicide make this controversy and resulting litigation important illustrations of the current toxics regulatory system's failures. The ongoing glyphosate litigation wastes judicial resources, does not always result in fair awards, and does not achieve desired outcomes—regulatory or other action or consequences designed to protect human health and the environment and promote safer industry practices. Overall, litigation is especially ineffective where, as with Roundup, there is evidence that the chemical in question presents a grave risk to human health, but where the product is economically important.

The totality of this controversy shows that there is a required shift in our toxics regulatory mindset to expect a more targeted, ethical, and efficient system. Such a system would call for EPA to move swiftly under the Lautenberg Act and FIFRA to severely limit, restrict, or at least label the most likely toxic chemicals, including those in EPA's 2014 workplan, as well as glyphosate. For these chemicals, there already exists reliable, scientific research that suggests the potential for grave, unreasonable risk to human health or

380 *See supra* notes 8–18, 58–89.
381 *See supra* Part V.B and accompanying discussion.

the environment. Under a new, targeted precautionary framework, the manufacturers of these chemicals would in turn have the right to countermand EPA's speedy "unreasonable risk" determinations, under FIFRA or the Lautenberg Act and resulting restrictions, by testing and providing reliable data to show their products are safe. In the case of glyphosate, this shift of the burden to industry would prompt more industry-funded research and greater research transparency. In the current political climate and armed with the Lautenberg Act and FIFRA labeling and other provisions, we can move toward a more precautionary, targeted toxics regulatory system for synthetic chemicals, including pesticides. In so doing, the United States would lead the developed world in the toxics regulatory arena.