

**United States District Court
District of Nebraska**

**Larry E. Domina,
Frank Pollard,
Robert L. Dickey, and
Royce D. Janzen**

Plaintiffs,

v.

**Monsanto Company,
Defendant.**

Case No.

**Complaint & Jury Demand
Trial Location Designation**

Overview

1. Defendant Monsanto Company (“Monsanto”) is the world’s largest seller and producer of glyphosate herbicides; it markets the herbicide under the brand name “Roundup[®]”. Roundup[®] is sold for use as a hand-held spray for intermediate uses in intermediate quantities, and also in large industrial volumes for use in row crop and grain crop production and other aspects of agricultural and large scale uses. Roundup[®] is a non-selective herbicide used to kill weeds that commonly compete with growing crops. Roundup[®] contains the active ingredient glyphosate, the surfactant Polyethoxylated tallow amine (POEA), and adjuvants and what Monsanto calls nominally “inert” ingredients. By 2001, glyphosate was the most-used pesticide active ingredient in American agriculture with 85–90 million pounds used annually; this volume grew to 185 million pounds in 2007.¹ As of 2013, glyphosate was the world’s

¹ Arthur Grube et al., U.S. Evtl. Prot. Agency, *Pesticides Industry Sales and Usage, 2006–2007 Market Estimates* 14 (2011), available at http://www.epa.gov/pesticides/pestsales/07pestsales/market_estimates2007.pdf.

most widely used herbicide and Roundup its most widely sold and used brand at the marketplace.

2. Monsanto's glyphosate products are ubiquitous in the environment and are used worldwide on over 100 different crops.² Glyphosate is found in rivers, streams, and groundwater in agricultural areas where Roundup[®] is used.³ It has been found in food,⁴ the urine of exposed persons,⁵ and in the urine of urban dwellers without direct contact with glyphosate.⁶

3. On July 29, 2015, The World Health Organization's International Agency for Research of Cancer ("IARC") issued the formal, peer reviewed, scientific monograph relating to glyphosate. In that monograph, the IARC Working Group of respected scientists from institutions around the world provided its thorough review of the numerous studies and data relating to glyphosate exposure in humans.⁷

4. The IARC Working Group classified glyphosate as a Group 2A herbicide, which means that it is *probably carcinogenic to humans*. The IARC Working Group concluded that the cancers most associated with glyphosate exposure are non-Hodgkin's lymphoma and other haematopoietic cancers, including lymphocytic lymphoma / chronic lymphocytic leukemia, B-cell lymphoma, and multiple myeloma.⁸

² Monsanto, *Backgrounder-History of Monsanto's Glyphosate Herbicides* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf.

³ See U.S. Geological Survey, *USGS Technical Announcement: Widely Used Herbicide Commonly Found in Rain and Streams in the Mississippi River Basin* (2011), available at <http://www.usgs.gov/newsroom/article.asp?ID=2909>; see also U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, available at <http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/glyphosa.pdf>.

⁴ Thomas Bohn et al., *Compositional Differences in Soybeans on the Market: Glyphosate Accumulates in Roundup Ready GM Soybeans*, 153 FOOD CHEMISTRY 207 (2013), available at <http://www.sciencedirect.com/science/article/pii/S0308814613019201>.

⁵ John F. Acquavella et al., *Glyphosate Biomonitoring for Farmers and Their Families: Results from the Farm Family Exposure Study*, 112(3) ENVTL. HEALTH PERSPECTIVES 321 (2004), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241861/>; Kathryn Z. Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, 112 IARC Monographs 76, section 5.4 (2015), available at [http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8).

⁶ Dirk Brändli & Sandra Reinacher, *Herbicides found in Human Urine*, 1 ITHAKA JOURNAL 270 (2012), available at <http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf>.

⁷ The monogram is available at the official website of the WHO, IARC at <http://monographs.iarc.fr/ENG/Monographs/vol112/>

⁸ See Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra*.

5. The IARC research by leading scientists in the world confirms that glyphosate is toxic to humans, and does so on the basis of generally accepted science, tests and methodologies that are respected and used by respected scientists around the world. Despite the IARC findings, Monsanto has continued, and still continues, to engage in the practice of continuing denial of a causal link between its glyphosate products and blood borne and other diseases and harms to humans.

6. Since it began selling Roundup[®], Monsanto has represented it as safe to humans. Indeed, Monsanto repeatedly proclaimed and continues to proclaim to the world, and particularly to United States consumers, that glyphosate-based herbicides, including Roundup[®], create no risks to human health or to the environment. In fact, Monsanto touted “Roundup[®] as “safe enough to drink” in its promotions.

Jurisdiction; Venue

7. This Court has diversity jurisdiction under 28 U.S.C. § 1332 because all Plaintiffs are citizens of Nebraska, a different state than the Defendant’s states of citizenship. The aggregate amount in controversy exceeds \$75,000 exclusive of interest and costs.

8. This Court has personal jurisdiction over Monsanto under *Neb Rev Stat* § 25-536 because Monsanto knows its Roundup[®] products are sold throughout the State of Nebraska, and, more specifically, it caused Roundup[®] to be sold to Plaintiffs in the State of Nebraska. Monsanto delivered Roundup[®] in Nebraska, caused tortious injuries here, and conducts business here. Monsanto maintains substantial contacts within the State of Nebraska and maintains facilities in Nebraska at Gothenberg, Grand Island, Kearney, Lincoln, Omaha, Stromsburg, Waco and York as described on Monsanto’s website.⁹ It has employees and a sales force spread across Nebraska.

9. Venue is proper in the District of Nebraska under 28 U.S.C. § 1391(b)(2) because Plaintiffs live in and were exposed to Defendant’s glyphosate products sold and delivered by Monsanto here. Further, Monsanto, as a corporate entity, is deemed to reside in any judicial district where it is subject to personal jurisdiction.

⁹ <http://www.monsanto.com/whoweare/pages/nebraska.aspx>

Plaintiffs

10. Plaintiff Larry E. Domina is a Nebraska citizen, a resident of Cedar County, Nebraska and a Nebraska farmer. He was diagnosed with non-Hodgkin's lymphoma ("NHL") in Sioux City IA in May, 2012. In view of Monsanto's practice of continuing denial, he was unable to discover the existence of a body of recognized scientific evidence linking his disease to exposure to Roundup[®] prior to issuance and public awareness of the IARC monogram. Mr. Domina was exposed annually to Roundup[®] commencing at about the time it became a widely accepted herbicide in use on crops and promoted in Nebraska by Monsanto. His exposures occurred in Nebraska.

11. Plaintiff Frank Pollard is a Nebraska citizen, a resident of Dodge County, Nebraska and a Nebraska agronomist. He was diagnosed with non-Hodgkin's lymphoma in Omaha NE in 2016. Mr. Pollard was exposed annually to Roundup[®] commencing at about the time it became a widely accepted herbicide in use on crops and promoted in Nebraska by Monsanto. His exposures occurred in Nebraska.

12. Plaintiff Robert L. Dickey is a Nebraska citizen, a resident of Cedar County, Nebraska and a Nebraska farmer. He was diagnosed with non-Hodgkin's lymphoma in Sioux City IA in 2009. In view of Monsanto's practice of continuing denial, he was unable to discover the existence of a body of recognized scientific evidence linking his disease to exposure to Roundup[®] prior to issuance and public awareness of the IARC monogram. Mr. Dickey was exposed annually to Roundup[®] commencing at about the time it became a widely accepted herbicide in use on Nebraska crops and promoted in Nebraska by Monsanto. His exposures occurred in Nebraska.

13. Plaintiff Royce D. Janzen is a Nebraska citizen, a resident of York County, Nebraska and a Nebraska farmer. He was diagnosed with non-Hodgkin's lymphoma ("NHL") in York County in 2013. Mr. Janzen was exposed annually to Roundup[®] commencing at about the time it became a widely accepted herbicide in use on Nebraska crops and promoted in Nebraska by Monsanto. His exposures occurred in Nebraska.

Defendant

14. Defendant Monsanto Company is a Delaware corporation with its headquarters and principal place of business in Missouri at 800 N Lindbergh Blvd, St.Louis MO 63167. Monsanto is authorized to do business in Nebraska. It is assigned account number 10016969 by the Nebraska Secretary of State. Monsanto's registered agent and office in Nebraska is CSC-Lawyers Incorporating Service Co., Suite 1900, 233 S. 13th St., Lincoln, NE 68508.

15. All claims of all Plaintiffs arise from a common nucleus of facts, transactions and occurrences consisting of the actions and conduct of the Defendant and the facts about Roundup® and glyphosate, not to warn of its risks and to engage in continuing denial about those risks. All Plaintiffs were injured in similar ways by the same product, at overlapping times, and as result of Monsanto's actions to distribute and sell Roundup® in Nebraska for the past 25 years or more. The claims joined are logically related and properly joined under *F R Civ P 20*.¹⁰

Facts

16. Monsanto is a multinational agricultural biotechnology with shares traded on public stock exchanges. It is the world's leading producer of glyphosate. As of 2009, it claimed to be the world's leading producer of seeds, accounting for 27% of the world seed market.¹¹ The majority of its seeds are marketed as Roundup Ready®. The stated advantage of Roundup Ready® crops is to substantially improve a farmer's ability to control weeds. This is done by allowing glyphosate to be sprayed on crops grown from Roundup Ready® seed during the growing season without harm. As of 2010 published estimates declared that 70% of corn and cotton and 90% of soybean fields in the United States were planted with Roundup Ready® seed.¹²

¹⁰ “‘Transaction’ is a word of flexible meaning. It may comprehend a series of many occurrences, depending not so much upon the immediateness of their connection as upon their logical relationship.” *Moore v. New York Cotton Exchange*, 270 U.S. 593, 610 (1926); *In re EMC Corp.*, 677 F3d 1351, 1358 (Fed Cir 2012).

¹¹ ETC Group, *Who Will Control the Green Economy?* 22 (2011), available at http://www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf.

¹² William Neuman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, available at <http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewan>.

17. Glyphosate is a broad-spectrum, non-selective herbicide used in a wide variety of herbicidal products around the world. It enters the body of a plant, or a person, through respiration, or absorption.

18. Plants treated with glyphosate translocate the systemic herbicide to their roots, shoot regions, and fruit, where it interferes with the plant's ability to form aromatic amino acids necessary for protein synthesis. Treated plants generally die within two to three days. Plants absorb glyphosate; it cannot be completely removed by washing or peeling produce or by milling, baking, or brewing grains.

19. For nearly 40 years, farmers around the world used Roundup[®] without knowing of the dangers its use poses. That is because when Monsanto first introduced Roundup[®], it touted glyphosate as a technological breakthrough: it was claimed the product could kill almost every weed without causing harm either to people or to the environment. Monsanto representatives routinely explained to farmers in Nebraska and elsewhere that Roundup[®] was, and is, so safe that it can be consumed by humans as a beverage.

20. Monsanto's claims were not true. Monsanto concealed or systematically sought to discredit objective credible research and is still engaged in its practice of continuing denial. But the World Health Organization (WHO), a specialized agency within the terms of Article 57 of the Charter of the United Nations, has found otherwise. The WHO functions for the objective of attainment, by all peoples, of the highest possible level of health.¹³ It is a highly respected medical research organization. Within the WHO, the International Agency on Research of Cancer (IARC) coordinates, commissions, oversees, and reviews the work of scientists in matters concerning cancer. It publishes peer reviewed and approved findings and studies in monographs.

“The *IARC Monographs* identify environmental factors that can increase the risk of human cancer. These include chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and lifestyle factors. National health agencies can use this information as scientific support for their

¹³ Constitution of the World Health Organization, Art I, adopted July 1946, available at <http://www.who.int/about/mission/en/>

actions to prevent exposure to potential carcinogens.

Interdisciplinary working groups of expert scientists review the published studies and evaluate the weight of the evidence that an agent can increase the risk of cancer. The principles, procedures, and scientific criteria that guide the evaluations are described in the Preamble to the *IARC Monographs*.¹⁴

21. The Preamble to the *IARC Monographs* delineates the general principles and procedures, and the scientific review and evaluation that studies undergo prior to approval as an official *IARC Monograph*.¹⁵

22. On July 29, 2015, IARC issued the formal, peer reviewed, scientific monograph relating to glyphosate. In that monograph, the IARC Working Group of respected scientists from institutions around the world provided its thorough review of the numerous studies and data relating to glyphosate exposure in humans.¹⁶ The IARC Working Group classified glyphosate as a Group 2A herbicide, which means that it is *probably carcinogenic to humans*. The IARC Working Group concluded that the cancers most associated with glyphosate exposure are non-Hodgkin's lymphoma ("NHL") and other haematopoietic cancers, including lymphocytic lymphoma / chronic lymphocytic leukemia, B-cell lymphoma, and multiple myeloma.¹⁷ The IARC Working Group's research was conducted in conformity with the principles, procedures, and standards for scientific review and evaluation described in the Preamble.

23. The WHO IARC research reveals scientific confirmation that glyphosate is toxic to humans and does so on the basis of generally accepted science, tests and methodologies that are respected and used by respected scientists around the world. Despite the IARC findings, Monsanto has continued, and still continues, to engage in the practice of continuing denial of a causal link between its glyphosate products and blood borne and other diseases and harms to humans.

¹⁴ <http://monographs.iarc.fr/>

¹⁵ <http://monographs.iarc.fr/ENG/Preamble/index.php>

¹⁶ The monogram is available at the official website of the WHO, IARC at <http://monographs.iarc.fr/ENG/Monographs/vol112/>

¹⁷ See Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra*.

24. According to the WHO, the main chemical ingredient of Roundup[®]—glyphosate—is a probable cause of NHL, a blood cancer. Those most at risk are farmers, farm workers and other individuals with workplace exposure to Roundup[®], such as agronomists. Yet, Monsanto assured the public that Roundup[®] was safe for humans and harmless to them. Monsanto championed falsified data and has attacked legitimate studies that revealed Roundup[®]'s dangers. Monsanto led a campaign of misinformation to convince government agencies, farmers and the general population that Roundup[®] is safe. Its continuing denial extends to the date of this Complaint.

The Discovery of Glyphosate and Development of Roundup[®]

25. Glyphosate's utility as a herbicide was discovered in 1970 by a Monsanto chemist. The first glyphosate-based herbicide was introduced to the market in the mid-1970s under Monsanto's brand name Roundup[®].¹⁸ Monsanto marketed Roundup[®] as a "safe" general-purpose herbicide for widespread commercial and consumer use from its introduction to the public to the present time.¹⁹

Roundup[®] formulations contain adjuvants and other chemicals, such as the surfactant POEA, which are considered "inert" and therefore protected as "trade secrets" in manufacturing; these are in addition to the active ingredient, glyphosate. Growing evidence suggests that these adjuvants and additional components of Roundup[®] formulations are not inert and are toxic in their own right.

Registration of Herbicides under Federal Law

26. The manufacture, formulation, and distribution of herbicides, such as Roundup[®], are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or "Act"), 7 U.S.C. § 136 *et seq.* FIFRA requires that all pesticides be registered with the Environmental Protection Agency ("EPA") prior to their distribution, sale, or use, except as described by the Act. 7 U.S.C. § 136a(a).

¹⁸ Monsanto, *Backgrounder, History of Monsanto's Glyphosate Herbicide* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf.

¹⁹ Monsanto, *What is Glyphosate?* (Sep. 2, 2015), <http://www.monsanto.com/sitecollectiondocuments/glyphosate-safety-health.pdf>.

27. Herbicides are toxic to plants, animals, and humans, at least to some degree. The EPA requires as part of the registration process, among other things, a variety of tests to evaluate the potential for exposure to herbicides, toxicity to people and other potential non-target organisms, and other adverse effects on the environment. Registration by the EPA is not an assurance or finding of safety. The EPA'S decision to register or re-register a product is strictly that use of the product in accordance with its label directions "will not generally cause unreasonable adverse effects on the environment."²⁰ The EPA does not decide that the product is "safe."

28. FIFRA defines "unreasonable adverse effects on the environment" to mean "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"²¹. FIFRA requires EPA to make a risk/benefit analysis to decide whether a registration should be granted or a pesticide allowed to continue to be sold in commerce.

29. The EPA and the State of Nebraska registered Roundup[®] for distribution, sale, and manufacture in the United States and Nebraska. Nebraska, like the EPA, does not determine that a herbicide is "safe" but deals with handling, storing, and proper use of products in accord with their labels.²² FIFRA generally requires that a registrant, like Monsanto in the case of Roundup[®], conduct the health and safety testing of pesticide or herbicide products. The EPA has protocols governing the conduct of tests required for registration and the laboratory practices that must be followed in conducting these tests. Data produced by the registrant must be submitted to the EPA for evaluation. The government does not perform the product tests required of the manufacturer.

30. The evaluation of each herbicide or pesticide product occurs when the product is initially registered. At this time, the EPA is in the process of re-evaluating all pesticide products through a Congressionally-mandated process called "re-

²⁰ 7 U.S.C. § 136a(c)(5)(D).

²¹ The term "pesticides" includes herbicides. 7 U.S.C. § 136 (a).

²² *Neb Rev Stat* § 2-2622 et seq.; 25 Neb Admin Code Ch 2.

registration.”²³ To reevaluate these pesticides, the EPA demands completion of additional tests and submission of data for EPA review and evaluation.

31. In the case of glyphosate and Roundup[®], the EPA delayed releasing its risk assessment pending further review in light of the WHO’s health-related findings. Again, this assessment is not for safety to humans in contact with the herbicide.

Scientific Misrepresentations Underlying Monsanto’s Marketing of Roundup[®]

32. Based on early studies showing that glyphosate could cause cancer in laboratory animals, the EPA originally classified glyphosate as *possibly carcinogenic to humans* (Group C) in 1985. Upon urging by Monsanto, including contrary studies it provided to the EPA, the EPA changed its classification to *evidence of non-carcinogenicity in humans* (Group E) in 1991. In so classifying glyphosate, the EPA made clear that this designation calls into question whether Roundup[®] causes cancer, but does not resolve this issue. EPA officials wrote: “It should be emphasized, however, that designation of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.”²⁴

33. On two occasions, the EPA found that laboratories hired by Monsanto to test Roundup[®] toxicity for registration purposes committed fraud. First, Monsanto hired Industrial Bio-Test Laboratories (“IBT”) to perform and evaluate pesticide toxicology studies relating to Roundup[®].²⁵ IBT performed about 30 tests on glyphosate and glyphosate-containing products, including nine of the 15 residue studies needed to register Roundup[®].

34. In 1976, the United States Food and Drug Administration (“FDA”) performed an inspection of IBT that revealed discrepancies between the raw data and the final report relating to the toxicological impacts of glyphosate. The EPA

²³ 7 U.S.C. § 136a-1.

²⁴ U.S. Env’tl. Prot. Agency, *Memorandum, Subject: SECOND Peer Review of Glyphosate 1* (1991), available at http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct-91_265.pdf.

²⁵ Monsanto, *Backgrounder, Testing Fraud: IBT and Craven Laboratories* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf.

subsequently audited IBT; it too found the toxicology studies conducted for the Roundup[®] herbicide to be invalid.²⁶ EPA review personnel remarked, after finding “routine falsification of data” at IBT, that it was “hard to believe the scientific integrity of the studies when they said they took specimens of the uterus from male rabbits.”²⁷ Three top executives of IBT were convicted of fraud in 1983.

35. Second, Monsanto hired Craven Laboratories in 1991 to perform pesticide and herbicide studies, including for Roundup[®]. In that same year, the owner of Craven Laboratories and three of its employees were indicted, and later convicted, of fraudulent laboratory practices in the testing of pesticides and herbicides.²⁸ Despite these tests that underlie its registration, Monsanto marketed Roundup[®] aggressively around the world.

The Importance of Roundup[®] to Monsanto’s Market Dominance Profits

36. Roundup[®] sales success was key to Monsanto’s solvency, reputation and dominance in the marketplace. Largely due to its Roundup[®] sales, Monsanto’s agriculture division out-performed its chemicals division in operating income year after year. Monsanto’s patent for glyphosate would expire in the United States in the year 2000, creating an incentive for Monsanto to find a way to maintain its Roundup[®] market dominance and ward off competition.

37. Monsanto developed and sold genetically engineered Roundup Ready[®] seeds beginning in about in 1996. Roundup Ready[®] crops are resistant to glyphosate, so farmers can spray Roundup[®] onto their fields during the growing season without harming a growing Roundup Ready[®] crop. By 2000, Monsanto’s biotechnology seeds

²⁶ U.S. Evtl. Prot. Agency, *Summary of the IBT Review Program Office of Pesticide Programs* (1983), *avail. at* <http://nepis.epa.gov/Exe/ZyNET.exe/91014ULV.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1981+Thru+1985&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C81thru85%5CTxt%5C00000022%5C91014ULV.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL>.

²⁷ Marie-Monique Robin, *The World According to Monsanto: Pollution, Corruption and the Control of the World’s Food Supply* (2011) (citing U.S. Evtl. Prot. Agency, *Data Validation, Memo from K. Locke, Toxicology Branch, to R. Taylor, Registration Branch. Washington, D.C. (August 9, 1978)*).

²⁸ Monsanto, *Background, Testing Fraud: IBT and Craven Laboratories, supra*.

were planted on more than 80 million acres worldwide and nearly 70% of American soybeans were planted from Roundup Ready[®] seeds. This new seed allowed Monsanto to expand its Roundup[®] market further; it also secured Monsanto's dominant share of the glyphosate/Roundup[®] market through a marketing strategy that coupled proprietary Roundup Ready[®] seeds with continued sales of its Roundup[®] herbicide.

38. Roundup[®] became Monsanto's most profitable product. In 2000, Roundup[®] is believed to have accounted for almost \$2.8 billion in sales, outselling other herbicides by a margin of five to one, and accounting for close to half of Monsanto's revenue.²⁹ Today, glyphosate remains one of the world's largest herbicides by sales volume.

Monsanto has known for decades that it falsely advertises the safety of Roundup[®]

39. In 1996, the New York Attorney General ("NYAG") sued Monsanto based on its false and misleading advertising of Roundup[®] products. Specifically, the lawsuit challenged Monsanto's general representations that its spray-on glyphosate-based herbicides, including Roundup[®], were "**safer than table salt**" and "**practically non-toxic**" to mammals, birds, and fish. Among the representations the NYAG found deceptive and misleading about the human and environmental safety of glyphosate and/or Roundup[®] are the following:

a) "Remember that environmentally friendly Roundup herbicide is biodegradable. It won't build up in the soil so you can use Roundup with confidence along customers' driveways, sidewalks and fences ..."

b) "And remember that Roundup is biodegradable and won't build up in the soil. That will give you the environmental confidence you need to use Roundup everywhere you've got a weed, brush, edging or trimming problem."

²⁹ David Barboza, *The Power of Roundup; A Weed Killer Is A Block for Monsanto to Build On*, N.Y. TIMES, Aug. 2, 2001, available at <http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-killer-is-a-block-for-monsanto-to-build-on.html>.

c) “Roundup biodegrades into naturally occurring elements.”

d) “Remember that versatile Roundup herbicide stays where you put it. That means there's no washing or leaching to harm customers' shrubs or other desirable vegetation.”

e) “This non-residual herbicide will not wash or leach in the soil. It ... stays where you apply it.”

f) “You can apply Accord with ‘confidence because it will stay where you put it’ it bonds tightly to soil particles, preventing leaching. Then, soon after application, soil microorganisms biodegrade Accord into natural products.”

g) “Glyphosate is less toxic to rats than table salt following acute oral ingestion.”

h) “Glyphosate’s safety margin is much greater than required. It has over a 1,000-fold safety margin in food and over a 700-fold safety margin for workers who manufacture it or use it.”

i) “You can feel good about using herbicides by Monsanto. They carry a toxicity category rating of ‘practically non-toxic’ as it pertains to mammals, birds and fish.”

j) “Roundup can be used where kids and pets will play and breaks down into natural material.” This ad depicts a person with his head in the ground and a pet dog standing in an area which has been treated with Roundup.³⁰

40. On November 19, 1996, Monsanto entered into an “Assurance of Discontinuance” with NYAG, in which Monsanto agreed, among other things, “to cease and desist from publishing or broadcasting any advertisements [in New York] that represent, directly or by implication” that:

³⁰ Attorney General of the State of New York, In the Matter of Monsanto Company, Assurance of Discontinuance Pursuant to Executive Law § 63(15) (Nov. 1996).

a) its glyphosate-containing pesticide products or any component thereof are safe, non-toxic, harmless or free from risk.

b) its glyphosate-containing pesticide products or any component thereof manufactured, formulated, distributed or sold by Monsanto are biodegradable

c) its glyphosate-containing pesticide products or any component thereof stay where they are applied under all circumstances and will not move through the environment by any means.

d) its glyphosate-containing pesticide products or any component thereof are “good” for the environment or are “known for their environmental characteristics.”

e) glyphosate-containing pesticide products or any component thereof are safer or less toxic than common consumer products other than herbicides;

f) its glyphosate-containing products or any component thereof might be classified as “practically non-toxic.”

41. Monsanto did not alter its advertising in the same manner in any state other than New York.

42. In 2009, France’s highest court ruled that Monsanto had not told the truth about the safety of Roundup[®]. The French court affirmed an earlier judgement that Monsanto had falsely advertised its herbicide Roundup[®] as “biodegradable” and that it “left the soil clean.”³¹

Classifications and Assessments of Glyphosate

43. The IARC process for the classification of glyphosate followed IARC’s stringent procedures for the evaluation of a chemical agent. Over time, the IARC Monograph program has reviewed 980 agents. Of those reviewed, it has determined

³¹ *Monsanto Guilty in ‘False Ad’ Row*, BBC, Oct. 15, 2009, available at <http://news.bbc.co.uk/2/hi/europe/8308903.stm>.

116 agents to be Group 1 (Known Human Carcinogens); 73 agents to be Group 2A (Probable Human Carcinogens); 287 agents to be Group 2B (Possible Human Carcinogens); 503 agents to be Group 3 (Not Classified); and one agent to be Probably Not Carcinogenic. The established procedure for IARC Monograph evaluations is described in the IARC Programme's Preamble.³² Evaluations are performed by panels of international experts, selected on the basis of their expertise and the absence of actual or apparent conflicts of interest.

44. One year before the Monograph meeting, the meeting is announced and there is a call both for data and for experts. Eight months before the Monograph meeting, the Working Group membership is selected and the sections of the Monograph are developed by the Working Group members. One month prior to the Monograph meeting, the call for data is closed and the various draft sections are distributed among Working Group members for review and comment. Finally, at the Monograph meeting, the Working Group finalizes review of all literature, evaluates the evidence in each category, and completes the overall evaluation. Within two weeks after the Monograph meeting, the summary of the Working Group findings are published in *The Lancet Oncology*, and within a year after the meeting, the finalized Monograph is published.

45. To perform its assessment, the IARC Working Group reviews: (a) human, experimental, and mechanistic data; (b) all pertinent epidemiological studies and cancer bioassays; and (c) representative mechanistic data. The studies must be publicly available and have sufficient detail for meaningful review, and reviewers cannot be associated with the underlying study.

46. On July 29, 2015, IARC issued its Monograph for glyphosate, Monograph Volume 112. For Volume 112, a Working Group of 17 experts from 11 countries met at IARC from March 3–10, 2015 to assess the carcinogenicity of certain herbicides, including glyphosate. The March meeting culminated a nearly one-year review and preparation by the IARC Secretariat and the Working Group, including a

³² World Health Org., *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble* (2006), available at <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

comprehensive review of the latest available scientific evidence. According to published procedures, the Working Group considered “reports that have been published or accepted for publication in the openly available scientific literature” as well as “data from governmental reports that are publicly available.”

47. The studies considered the two agriculture related exposure groups, including farmers and farm workers, and also related occupations. Glyphosate was identified as the second-most used household herbicide in the United States for weed control between 2001 and 2007 and the most heavily used herbicide in the world in 2012. Exposure pathways for Roundup[®] are identified as air (especially during spraying), water, and food. Community exposure to glyphosate is widespread as it is found in soil, air, surface water, and groundwater, as well as in food.

48. The assessment of the IARC Working Group identified several case control studies of occupational exposure in the United States, Canada, and Sweden. These studies show a human health concern from agricultural and other work-related exposure to glyphosate. The IARC Working Group found an increased risk between exposure to glyphosate and NHL and several subtypes of NHL, and the increased risk persisted after adjustment for other pesticides.

49. The IARC also found that glyphosate caused DNA and chromosomal damage in human cells. One study of community residents reported increases in blood markers of chromosomal damage (micronuclei) after glyphosate formulations were sprayed. In male CD-1 mice, glyphosate induced a positive trend in the incidence of a rare tumor: renal tubule carcinoma. A second study reported a positive trend for haemangiosarcoma in male mice. Glyphosate increased pancreatic islet-cell adenoma in male rats in two studies. A glyphosate formulation promoted skin tumors in an initiation-promotion study in mice.

50. Scientists of the IARC Working Group found that glyphosate has been detected in the urine of agricultural workers, indicating absorption. Soil microbes degrade glyphosate to aminomethylphosphoric acid (AMPA). Blood AMPA detection after exposure suggests intestinal microbial metabolism in humans. In addition, the

IARC found that glyphosate and glyphosate formulations induced DNA and chromosomal damage in mammals, and in human and animal cells in utero. The IARC Working Group connected genotoxic, hormonal, and enzymatic effects in mammals exposed to glyphosate.³³ Essentially, glyphosate inhibits the biosynthesis of aromatic amino acids; this leads to metabolic disturbances, including inhibition of protein and secondary product biosynthesis and general metabolic disruption.

51. The IARC scientific Working Group reviewed an Agricultural Health Study consisting of a prospective cohort of 57,311 licensed pesticide applicators in Iowa and North Carolina.³⁴ While this study, unlike others, was based on a self-administered questionnaire. Results support an association between glyphosate exposure and multiple myeloma, hairy cell leukemia (HCL), and chronic lymphocytic leukemia (CLL), in addition to several other cancers. These illnesses are of the blood as is NHL.

Other Earlier Findings about Glyphosate's Dangers to Human Health

52. The EPA technical fact sheet, part of its Drinking Water and Health, National Primary Drinking Water Regulations publication, relating to glyphosate describes the release patterns for glyphosate as follows:

Release Patterns

Glyphosate is released to the environment in its use as a herbicide for controlling woody and herbaceous weeds on forestry, right-of-way, cropped and non-cropped sites. These sites may be around water and in wetlands.

It may also be released to the environment during its manufacture, formulation, transport, storage, disposal and cleanup, and from spills. Since glyphosate is not a listed chemical in the Toxics Release Inventory, data on releases during its manufacture and handling are not available.

Occupational workers and home gardeners may be exposed to glyphosate by inhalation and dermal contact

³³ Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra* at 77.

³⁴ Anneclaire J. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study*, 113 *Env'tl Health Perspectives* 49–54 (2005), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1253709/pdf/ehp0113-000049.pdf>.

during spraying, mixing, and cleanup. They may also be exposed by touching soil and plants to which glyphosate was applied. Occupational exposure may also occur during glyphosate's manufacture, transport storage, and disposal.³⁵

The Toxicity of Other Ingredients in Roundup®

53. In addition to the toxicity of the active ingredient, glyphosate, several studies noted by the IARC support the hypothesis that the glyphosate-based formulation in Defendant's Roundup® products is more dangerous and toxic than glyphosate alone. During 1991, available evidence demonstrated this danger.³⁶ A 2002 study by Julie Marc, entitled "Pesticide Roundup Provokes Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation," revealed that Roundup® causes delays in the cell cycles of sea urchins but the same concentrations of glyphosate alone did not alter cell cycles.³⁷

54. A 2004 study by Marc and others, entitled "Glyphosate-based pesticides affect cell cycle regulation," demonstrated a molecular link between glyphosate-based products and cell cycle dysregulation. The researchers noted that "cell-cycle dysregulation is a hallmark of tumor cells and human cancer. Failure in the cell-cycle checkpoints leads genomic instability and subsequent development of cancers from the initial affected cell." Further, "[s]ince cell cycle disorders such as cancer result from dysfunction of a unique cell, it was of interest to evaluate the threshold dose of glyphosate affecting the cells."³⁸

55. In 2005, a study by Francisco Peixoto, entitled "Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation," demonstrated that Roundup®'s effects on rat liver mitochondria are far more toxic than equal concentrations of glyphosate alone. The Peixoto study concluded that harmful effects of Roundup® on mitochondrial bioenergetics could not be exclusively attributed to

³⁵ U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate, supra*.

³⁶ Martinez, T.T. and K. Brown, *Oral and pulmonary toxicology of the surfactant used in Roundup herbicide*, PROC. WEST. PHARMACOL. SOC. 34:43-46 (1991).

³⁷ Julie Marc, et al., *Pesticide Roundup Provokes Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation*, 15 CHEM. RES. TOXICOL. 326-331 (2002), available at <http://pubs.acs.org/doi/full/10.1021/tx015543g>.

³⁸ Julie Marc, et al., *Glyphosate-based pesticides affect cell cycle regulation*, 96 BIOLOGY OF THE CELL 245, 245-249 (2004), available at <http://onlinelibrary.wiley.com/doi/10.1016/j.biolcel.2003.11.010/epdf>.

glyphosate but could be the result of other chemicals, such as the surfactant POEA, or in the alternative, due to a potential synergic effect between glyphosate and other ingredients in the Roundup[®] formulation.³⁹

56. In 2009, Nora Benachour and Gilles-Eric Seralini published a study examining the effects of Roundup[®] and glyphosate on human umbilical, embryonic, and placental cells. The study tested dilution levels of Roundup[®] and glyphosate that were far below agricultural recommendations, corresponding with low levels of residue in food. The researchers ultimately concluded that supposed “inert” ingredients, and possibly POEA, alter human cell permeability and amplify toxicity of glyphosate alone. Researchers further suggested that assessments of glyphosate toxicity should account for the presence of adjuvants or additional chemicals used in the formulation of the complete pesticide. The study confirmed that the adjuvants present in Roundup[®] are not, in fact, inert and that Roundup[®] is potentially far more toxic than its active ingredient glyphosate alone.⁴⁰

57. Monsanto knew, or should have known, of these studies. It knew or should have known that Roundup[®] is more toxic than glyphosate alone and that safety studies of Roundup[®], its adjuvants and “inert” ingredients, and/or the surfactant POEA were necessary to protect Plaintiffs from Roundup[®]. Despite this fact, Defendant continued to promote Roundup[®] as safe and did not disclose the dangers of glyphosate or its Roundup[®] formulation

Recent Worldwide Bans on Roundup[®]/Glyphosate

58. Monsanto also knew that several countries around the world instituted bans on sale of Roundup[®] and other glyphosate-containing herbicides, both before and since IARC first announced its assessment for glyphosate in 2015. The Netherlands issued a

³⁹ Francisco Peixoto, *Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation*, 61 CHEMOSPHERE 1115, 1122 (2005), available at https://www.researchgate.net/publication/7504567_Comparative_effects_of_the_Roundup_and_glyphosate_on_mitochondrial_oxidative_phosphorylation.

⁴⁰ Nora Benachour, et al., *Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells*, 22 CHEM. RES. TOXICOL. 97-105 (2008), available at <http://big.assets.huffingtonpost.com/france.pdf>.

ban on all glyphosate-based herbicides in April 2014, including Roundup[®], which will take effect by the end of 2015. In issuing the ban, the Dutch Parliament member who introduced the successful legislation stated:

“Agricultural pesticides in user-friendly packaging are sold in abundance to private persons. In garden centers, Roundup[®] is promoted as harmless, but unsuspecting customers have no idea what the risks of this product are. Especially children are sensitive to toxic substances and should therefore not be exposed to it.”⁴¹

59. The Brazilian Public Prosecutor in the Federal District requested that the Brazilian Justice Department suspend the use of glyphosate.⁴²

France banned the private sale of Roundup[®] and glyphosate following the IARC assessment for Glyphosate.⁴³

60. Bermuda banned both the private and commercial sale of glyphosates, including Roundup[®]. The Bermuda government explained its ban as follows: “Following a recent scientific study carried out by a leading cancer agency, the importation of weed spray ‘Roundup’ has been suspended.”⁴⁴

61. The Sri Lankan government banned the private and commercial use of glyphosate, particularly out of concern that glyphosate has been linked to fatal kidney disease in agricultural workers.⁴⁵

⁴¹ *Holland’s Parliament Bans Glyphosate Herbicides*, The Real Agenda, April 14, 2014, available at <http://real-agenda.com/hollands-parliament-bans-glyphosate-herbicides/>.

⁴² Christina Sarich, *Brazil’s Public Prosecutor Wants to Ban Monsanto’s Chemicals Following Recent Glyphosate-Cancer Link*, GLOBAL RESEARCH, May 14, 2015, available at <http://www.globalresearch.ca/brazils-public-prosecutor-wants-to-ban-monsantos-chemicals-following-recent-glyphosate-cancer-link/5449440>; see Ministério Público Federal, *MPF/DF reforça pedido para que glifosato seja banido do mercado nacional*, April, 14, 2015, available at http://noticias.pgr.mpf.mp.br/noticias/noticias-do-site/copy_of_meio-ambiente-e-patrimonio-cultural/mpf-df-reforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional.

⁴³ Zoe Schlanger, *France Bans Sales of Monsanto’s Roundup in Garden Centers, 3 Months After U.N. Calls it ‘Probable Carcinogen’*, NEWSWEEK, June 15, 2015, available at <http://www.newsweek.com/france-bans-sale-monsantos-roundup-garden-centers-after-un-names-it-probable-343311>.

⁴⁴ *Health Minister: Importation of Roundup Weed Spray Suspended*, Today in Bermuda, May, 11 2015, available at <http://www.todayinbermuda.com/news/health/item/1471-health-minister-importation-of-roundup-weed-spray-suspended>.

⁴⁵ *Sri Lanka’s New President Puts Immediate Ban on Glyphosate Herbicides*, Sustainable Pulse, May 25, 2015, available at <http://sustainablepulse.com/2015/05/25/sri-lankas-new-president-puts-immediate-ban-on-glyphosate-herbicides/#.VeduYk3bKAw>.

62. The government of Colombia announced its ban on using Roundup® and glyphosate to destroy illegal plantations of coca, the raw ingredient for cocaine, because of the WHO's finding that glyphosate is probably carcinogenic.⁴⁶

63. On September 4, 2015, California's Office of Environmental Health Hazard Assessment ("OEHHA") published a notice of intent to include glyphosate on the state's list of known carcinogens under Proposition 65.⁴⁷ California's Safe Drinking Water and Toxic Enforcement Act of 1986 (informally known as "Proposition 65"), requires the state to maintain and, at least once a year, revise and republish a list of chemicals "known to the State of California to cause cancer or reproductive toxicity."⁴⁸ The OEHHA determined that glyphosate met the criteria for the listing mechanism under the Labor Code following IARC's assessment of the chemical.⁴⁹ That section of the Labor Code identifies "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." IARC's classification of glyphosate as a Group 2A chemical ("probably carcinogenic to humans") therefore triggered the listing.

64. A manufacturer like Monsanto that deploys a listed chemical in its products must provide "clear and reasonable warnings" to the public. To be clear and reasonable, and compliant with California state law, a warning must "(1) clearly communicate that the chemical is known to cause cancer, and/or birth defects or other reproductive harm; and (2) effectively reach the person before exposure."⁵⁰ California also prohibits the discharge of listed chemicals into drinking water.

⁴⁶ *Columbia to ban coca spraying herbicide glyphosate*, BBC, May 10, 2015, available at <http://www.bbc.com/news/world-latin-america-32677411>.

⁴⁷ Cal. Env'tl. Prot. Agency Office of Env'tl. Health Hazard Assessment, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015), http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_LCSet27.pdf.

⁴⁸ *Frequently Asked Questions*, STATE OF CAL. DEP'T OF JUSTICE, OFFICE OF THE ATTORNEY GENERAL, <http://oag.ca.gov/prop65/faq> (last visited April 19, 2016).

⁴⁹ Cal. Env'tl. Prot. Agency Office of Env'tl. Health Hazard Assessment, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015), http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_LCSet27.pdf.

⁵⁰ *Frequently Asked Questions*, STATE OF CAL. DEPARTMENT OF JUSTICE, OFFICE OF THE ATTORNEY GENERAL, *supra*.

65. Monsanto responded to California with another chapter of its continuing denials that Roundup[®] is probably carcinogenic and is dangerous to humans. Monsanto alleged California's Agency's reliance on the IARC decision signified that "OEHHA effectively elevated the determination of an ad hoc committee of an unelected, foreign body, which answers to no United States official (let alone any California state official), over the conclusions of its own scientific experts."⁵¹ Monsanto further alleged that the Labor Code listing mechanism presented various constitutional violations because it "effectively empowers an unelected, undemocratic, unaccountable, and foreign body to make laws applicable in California."⁵² Among other things, Monsanto argued that Proposition 65's requirement to provide a "clear and reasonable warning" to consumers that the chemical is a known carcinogen would damage its reputation and violate its First Amendment rights.⁵³ Monsanto's continuing denials in California remain in litigation against the OEHHA. The Agency's position stands as that litigation occurs.

EFSA Report on Glyphosate

66. European scientists, working independently of Monsanto financial influence on research and as objective regulatory agencies, have continued to act to protect the public. On November 12, 2015, the European Food Safety Authority (EFSA), the European Union's primary agency for food safety, reported on its evaluation of the Renewal Assessment Report (RAR) on glyphosate.⁵⁴ This occurred in sequence after the German Federal Institute for Risk Assessment (BfR), published its RAR as part of the registration renewal process for glyphosate in the EU.

67. Within the EFSA the RAR underwent pre-publication scientific peer review by EFSA, non-German member states, and industry groups. As part of the on-going peer review of Germany's reevaluation of glyphosate, EFSA also received a second

⁵¹ *Id.* at 2.

⁵² *Id.* at 3.

⁵³ *Id.*

⁵⁴ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *available at* http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf.

mandate from the European Commission to consider IARC's findings regarding the potential carcinogenicity of glyphosate and Roundup®-like products.

68. After review of the RAR, including review of data from industry-submitted unpublished studies, EFSA published its own report (“Conclusion”) to the European Commission, finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.”⁵⁵ EFSA therefore disagreed with IARC: glyphosate was not genotoxic and did not present a carcinogenic threat to humans.

69. In explaining why its results departed from IARC's conclusion, EFSA drew a distinction between the EU and IARC approaches to the study and classification of chemicals.⁵⁶ Although IARC examined “both glyphosate—an active substance—and glyphosate-based formulations, grouping all formulations regardless of their composition,” EFSA explained that it considered only glyphosate and that its assessment focuses on “each individual chemical, and each marketed mixture separately.”⁵⁷ IARC, on the other hand, “assesses generic agents, including groups of related chemicals, as well as occupational or environmental exposure, and cultural or behavioural practices.”⁵⁸ EFSA accorded greater weight to studies conducted with glyphosate alone than studies of formulated products.⁵⁹ EFSA went further and noted:

[A]lthough some studies suggest that certain glyphosate-based formulations may be genotoxic (i.e. damaging to DNA), others that look solely at the active substance glyphosate do not show this effect. It is likely, therefore, that ***the genotoxic effects observed in some glyphosate-based formulations are related to the other constituents or “co-formulants”***. Similarly, certain glyphosate-based formulations display higher toxicity than that of the active ingredient, presumably because of the presence of co-

⁵⁵ *Id.*

⁵⁶ EFSA Fact Sheet: Glyphosate, EFSA

www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

formulants. In its assessment, *EFSA proposes that the toxicity of each pesticide formulation and in particular its genotoxic potential should be further considered and addressed by Member State authorities while they re-assess uses of glyphosate-based formulations in their own territories.*⁶⁰

70. EFSA did set exposure levels for glyphosate. It proposed an “acceptable daily intake” (ADI) of 0.5 mg/kg of body weight per day; an acute reference dose (ARfD) of 0.5 mg/kg of body weight; and an acceptable operator exposure level (AOEL) of 0.1 mg/kg bw per day.⁶¹ Monsanto is aware of this action but has not warned the public even about these considerations.

Leading Scientists Dispute EFSA’s Conclusion

71. On November 27, 2015, 96 independent academic and governmental scientists from around the world submitted an open letter to the EU Health Commissioner, Vytenis Andriukaitis.⁶² The scientists expressed their strong concerns and urged the commissioner to disregard the “flawed” EFSA report, arguing that “the BfR decision is not credible because it is not supported by the evidence and it was not reached in an open and transparent manner.”⁶³ Signatories to the letter included Dr. Christopher J. Portier, Ph.D., and other renowned international experts in the field, some of whom were part of the IARC Working Group assigned to glyphosate.

72. In an exhaustive and careful examination, the critical community of scientists scrutinized EFSA’s conclusions and outlined why the IARC Working Group decision was “by far the more credible”:

The IARC WG decision was reached relying on open and transparent procedures by independent scientists who completed thorough conflict-of-interest statements and were

⁶⁰ *Id.*

⁶¹ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *supra*.

⁶² Letter from Christopher J. Portier et al. to Commission Vytenis Andriukaitis, Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR (Nov. 27, 2015), <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf>; <http://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-of-glyphosate-weedkiller>.

⁶³ *Id.*

not affiliated or financially supported in any way by the chemical manufacturing industry. It is fully referenced and depends entirely on reports published in the open, peer-reviewed biomedical literature. It is part of a long tradition of deeply researched and highly credible reports on the carcinogenicity of hundreds of chemicals issued over the past four decades by IARC and used today by international agencies and regulatory bodies around the world as a basis for risk assessment, regulation and public health policy.⁶⁴

73. With respect to human data, the scientists pointed out that EFSA agreed with IARC that there was “*limited evidence* of carcinogenicity” for non-Hodgkin’s lymphoma, but they criticized EFSA’s dismissal of the association between glyphosate exposure and carcinogenicity. IARC science applies three levels of evidence in its analyses of human data, including sufficient evidence and limited evidence. The critical scientists submitted that EFSA’s conclusion of “no unequivocal evidence for a clear and strong association of NHL with glyphosate” was misleading because it incorrectly confused scientific standards governing sufficiency of evidence to express different levels of confidence in conclusions. The critical scientists noted that the EFSA’s disagreement mischaracterized the Working Group’s “probably carcinogenic to humans” conclusion about Roundup® with a different IARC scientific confidence and evidence level called “sufficient evidence,” which means a causal relationship has been established...not that it is probable.⁶⁵

74. Among other deficiencies, the scientists noted that EFSA’s conclusions regarding animal carcinogenicity data were “scientifically unacceptable,” particularly in use of historical control data and trend analysis. BfR’s analysis directly contradicted the Organisation for Economic Co-operation and Development (“OECD”) testing guidelines while citing and purporting to follow those same guidelines. The scientists concluded:

⁶⁴ *Id.*

⁶⁵ *Id.* The critical scientists observed that “[l]egitimate public health concerns arise when ‘causality is credible,’ i.e., when there is *limited evidence*.”

BfR reported seven positive mouse studies with three studies showing increases in renal tumors, two with positive findings for hemangiosarcomas, and two with positive findings for malignant lymphomas. BfR additionally reported two positive findings for tumors in rats. Eliminating the inappropriate use of historical data, the unequivocal conclusion is that these are not negative studies, but in fact document the carcinogenicity of glyphosate in laboratory animals.⁶⁶

75. The group of critical scientists condemned EFSA report's lack of transparency and the opacity about data cited in the report: "citations for almost all of the references, even those from the open scientific literature, have been redacted from the document" and "there are no authors or contributors listed for either document, a requirement for publication in virtually all scientific journals." EFSA authors relied on unpublished, confidential industry-provided studies. This made it "impossible for any scientist not associated with BfR to review this conclusion with scientific confidence."⁶⁷ On March 3, 2016, the letter of the group of critical, worldwide scientists was published in the *Journal of Epidemiology & Community Health*.⁶⁸

Statement of Concern Regarding Glyphosate-Based Herbicides

76. On February 17, 2016, a consensus statement of scientists published in the journal *Environmental Health*, entitled "Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement," assessed the

⁶⁶ *Id.* For instance, the EFSA report dismissed observed trends in tumor incidence "because there are no individual treatment groups that are significantly different from controls and because the maximum observed response is reportedly within the range of the historical control data." However, according to the scientists, concurrent controls are recommended over historical controls in all guidelines, scientific reports, and publications, and, if it is employed, historical control data "should be from studies in the same timeframe, for the same exact animal strain, preferably from the same laboratory or the same supplier and preferably reviewed by the same pathologist." BfR's use of historical control data violated these precautions: "only a single study used the same mouse strain as the historical controls, but was reported more than 10 years after the historical control dataset was developed." Further deviating from sound scientific practices, the data used by the BfR came from studies in seven different laboratories.

⁶⁷ *Id.*

⁶⁸ Christopher J. Portier, et al., *Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, *JOURNAL OF EPIDEMIOLOGY & CMTY. HEALTH*, Mar. 3, 2016, available at <http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full>.

safety of glyphosate-based herbicides (GBHs).⁶⁹ The paper's "focus is on the unanticipated effects arising from the worldwide increase in use of GBHs, coupled with recent discoveries about the toxicity and human health risks stemming from use of GBHs."⁷⁰

77. The researchers announced these factual conclusions:

77.1 GBHs are the most heavily applied herbicide in the world and usage continues to rise;

77.2 Worldwide, GBHs often contaminate drinking water sources, precipitation, and air, especially in agricultural regions;

77.3 The half-life of glyphosate in water and soil is longer than previously recognized;

77.4 Glyphosate and its metabolites are widely present in the global soybean supply;

77.5 Human exposures to GBHs are rising;

77.6 Glyphosate is now authoritatively classified as a probable human carcinogen; and

77.7 Regulatory estimates of tolerable daily intakes for glyphosate in the United States and European Union are based on outdated science.⁷¹

78. The consensus statement researchers observed that GBH use increased approximately 100-fold since the 1970s. Further, far from posing a limited hazard to vertebrates, as previously believed, two decades of evidence demonstrated that "several

⁶⁹ John P. Myers, et al, *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, Environmental Health (2016), available at <http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>.

⁷⁰ *Id.*

⁷¹ *Id.*

vertebrate pathways are likely targets of action, including hepatorenal damage, effects on nutrient balance through glyphosate chelating action and endocrine disruption.”⁷²

79. Among various implications, the researchers conclude that “existing toxicological data and risk assessments are not sufficient to infer that GBHs, as currently used, are safe.” Further, “GBH-product formulations are more potent, or toxic, than glyphosate alone to a wide array of non-target organisms including mammals, aquatic insects, and fish.” Accordingly, “risk assessments of GBHs that are based on studies quantifying the impacts of glyphosate alone underestimate both toxicity and exposure, and thus risk.” The paper concludes that this “shortcoming has repeatedly led regulators to set inappropriately high exposure thresholds.”⁷³

80. The researchers also critique the current practice of regulators who largely rely on “unpublished, non-peer reviewed data generated by the registrants” but ignore “published research because it often uses standards and procedures to assess quality that are different from those codified in regulatory agency data requirements, which largely focus on avoiding fraud.” In the researchers’ view, “[s]cientists independent of the registrants should conduct regulatory tests of GBHs that include glyphosate alone, as well as GBH-product formulations.”⁷⁴ The researchers also call for greater inclusion of GBHs in government-led toxicology testing programs:

[A] fresh and independent examination of GBH toxicity should be undertaken, and . . . this re-examination be accompanied by systematic efforts by relevant agencies to monitor GBH levels in people and in the food supply, none of which are occurring today. The U.S. National Toxicology Program should prioritize a thorough toxicological

⁷² *Id.* The paper attributes uncertainties in current assessments of glyphosate formulations to the fact that “[t]he full list of chemicals in most commercial GBHs is protected as ‘commercial business information,’ despite the universally accepted relevance of such information to scientists hoping to conduct an accurate risk assessment of these herbicide formulations.” Further, the researchers argue, “[t]he distinction in regulatory review and decision processes between ‘active’ and ‘inert’ ingredients has no toxicological justification, given increasing evidence that several so-called ‘inert’ adjuvants are toxic in their own right.”

⁷³ *Id.*

⁷⁴ *Id.*

assessment of the multiple pathways now identified as potentially vulnerable to GBHs.⁷⁵

FDA Announces Testing of Glyphosate Residue in Foods

81. On February 17, 2016, the U.S. Food and Drug Administration (“FDA”) announced that it would begin testing certain foods for glyphosate residues. The FDA explained: “The agency is now considering assignments for Fiscal Year 2016 to measure glyphosate in soybeans, corn, milk, and eggs, among other potential foods.”⁷⁶

In 2014, the U.S. Government Accountability Office (GAO) rebuked the FDA for its failures to both monitor for pesticide residue, including that of glyphosate, and to disclose the limitations of its monitoring and testing efforts to the public.⁷⁷ The GAO cited numerous undisclosed deficiencies in the FDA’s process, specifically highlighting its omission of glyphosate testing. In the past, both the FDA and the U.S. Department of Agriculture (USDA) routinely excluded glyphosate from their testing for residues of hundreds of other pesticides. The FDA however, now states that “the agency has developed ‘streamlined methods’ for testing for the weed killer.”⁷⁸ The FDA possesses enforcement authority and can seek action if pesticide residues exceed enforcement guidelines.⁷⁹

⁷⁵ *Id.* The researchers suggest that, in order to fill the gap created by an absence of government funds to support research on GBHs, regulators could adopt a system through which manufacturers fund the registration process and the necessary testing:

“[W]e recommend that a system be put in place through which manufacturers of GBHs provide funds to the appropriate regulatory body as part of routine registration actions and fees. Such funds should then be transferred to appropriate government research institutes, or to an agency experienced in the award of competitive grants. In either case, funds would be made available to independent scientists to conduct the appropriate long-term (minimum 2 years) safety studies in recognized animal model systems. A thorough and modern assessment of GBH toxicity will encompass potential endocrine disruption, impacts on the gut microbiome, carcinogenicity, and multigenerational effects looking at reproductive capability and frequency of birth defects.”⁷⁵

⁷⁶ Carey Gillam, *FDA to Start Testing for Glyphosate in Food*, TIME, Feb. 17, 2016, available at <http://time.com/4227500/fda-glyphosate-testing/?xid=tcoshare>.

⁷⁷ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-15-38, FDA AND USDA SHOULD STRENGTHEN PESTICIDE RESIDUE MONITORING PROGRAMS AND FURTHER DISCLOSE MONITORING LIMITATIONS (2014), available at <http://www.gao.gov/products/GAO-15-38>.

⁷⁸ Gillam, *supra* note 46.

⁷⁹ *Id.*; Pesticide Q&A, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm114958.htm> (last visited April 19, 2016).

EU Delays Vote on Glyphosate Renewal

82. On March 7 and 8, 2016, experts from the 28 European Union member states met to vote on reapproving a 15-year license for glyphosate. The current license for glyphosate is scheduled to expire at the end of June 2016.⁸⁰

83. On March 4, 2016, *The Guardian* reported that France, the Netherlands, and Sweden did not support EFSA's assessment that glyphosate was harmless.⁸¹ The paper reported the Swedish environment minister, Åsa Romson, as stating: "We won't take risks with glyphosate and we don't think that the analysis done so far is good enough. We will propose that no decision is taken until further analysis has been done and the EFSA scientists have been more transparent about their considerations."⁸²

84. The Netherlands, in particular, argued that the relicensing should be put on hold until after a separate evaluation of glyphosate's toxicity can be conducted.⁸³ Leading up to the vote, Italy joined the other EU states in opposing the license renewal, citing health concerns.⁸⁴

85. On March 8, 2016, the EU ultimately decided to delay its vote and is scheduled to meet again on May 18–19, 2016.⁸⁵

86. Growing public awareness and concern over the chemical "led 1.4 million people to sign a petition against glyphosate in the biggest online campaign since neonicotinoid pesticides were banned during the last commission."⁸⁶

⁸⁰ Arthur Neslen, *Vote on Controversial weedkiller's European licence postponed*, THE GUARDIAN, Mar. 8, 2016, available at <http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate>.

⁸¹ Arthur Neslen, *EU states rebel against plans to relicence weedkiller glyphosate*, THE GUARDIAN, Mar. 4, 2016, available at <http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicence-weedkiller-glyphosate>.

⁸² *Id.*

⁸³ Arthur Neslen, *Vote on Controversial weedkiller's European licence postponed*, THE GUARDIAN, Mar. 8, 2016, available at <http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate>.

⁸⁴ *Id.*

⁸⁵ *Id.* *The Guardian* quoted a commission spokesperson as stating: "We would like a solid majority to take a decision on this kind of issue and some member states had sceptical [*sic*] observations that we will have to answer, so it [a postponement] was the wise thing to do."

⁸⁶ *Id.*

Claims I – IV.

Claim I. Plaintiff Larry E. Domina

87. Plaintiff Larry E. Domina has used Roundup, and been exposed to it when used by others, in his Cedar County, Nebraska corn, soybean and alfalfa farming operation. For more than 25 years, he applied Roundup[®] with sprayer pulled or carried by a tractor or by commercially sold or rented sprayers or applicators. At times he also applied the product with a hand-held sprayer. He did so following label directions. Mr. Domina did not know that Roundup[®] was injurious to his health; he did not wear any protective gear while spraying. Mr. Domina purchased Roundup[®] for his farming operation. He continued to be exposed into and through the 2015 farming season. All allegations above, and all theories below, are incorporated here.

88. On May 12, 2012, Mr. Domina was diagnosed with follicular non-Hodgkin's lymphoma by a physician at Sioux City IA. He was treated with chemotherapy. Mr. Domina was born in 1954.

89. During the entire time that Mr. Domina was exposed to Roundup[®], he did not know that exposure to Roundup[®] was injurious to his health or the health of others. Mr. Domina first learned that exposure to Roundup[®] can cause non-Hodgkin's lymphoma and other serious illnesses sometime after July 29, 2015, when IARC first published its evaluation of glyphosate. Monsanto continued throughout his use of Roundup[®] to deny its health risks.

90. Mr. Domina has suffered general and special damages, personal injuries, illness, debilitations, disruption of his life, and necessity for treatment for his NHL. Both his general and special damages are accruing. He does not know the full amount damages and requests leave to specify all special damages at the time of the final pretrial conference.

Claim II: Plaintiff Frank Pollard

91. Plaintiff Frank Pollard is a Nebraska agronomist. He studied the science of agronomy, and devoted his life to helping farmers, primarily in Nebraska, produce better crops. Mr. Pollard worked in direct contact with soils and growing crops, side by

side with farmer customers and clients. He managed, and worked for, cooperative organizations and businesses that purchased Roundup® from Monsanto, and resold it to farmers like the other plaintiffs. Annually, since approximately 1988 when he was first exposed to it, Mr. Pollard estimates his exposures to Roundup were more than 3000 gallons per year. Each year, his exposures included inhalation and direct contact with the skin. Mr. Pollard knows that Roundup® is virtually ubiquitous in the Nebraska farm community and, Roundup Ready® seed was and is, the most widely sold and used herbicide in corn and soybean producing areas of the Midwest. All allegations above, and all theories below, are incorporated here.

92. Mr. Pollard used Roundup® in accord with labeling directions, and as instructed by representatives of Monsanto. As a professional agronomist, Mr. Pollard carefully, and regularly, uses pesticides, herbicides and chemicals in connection with agricultural activities, strictly in accord with label instructions. He often aids and helps educate farm customers about label requirements and how to follow them. When explaining Roundup® and its use, Mr. Pollard consistently followed, and used, what Monsanto taught him and other agronomist like him about the product. Mr. Pollard stayed abreast of developments affecting corn production, including matters related to Roundup and Roundup Ready® seed. He knows Monsanto has consistently engaged in the practice of continuing denial that Roundup® is harmful to human health, probably carcinogenic, and linked to the occurrence of NHL.

93. Mr. Pollard did not know that Roundup® was injurious to his health; he did not wear any protective gear while around Roundup®. Monsanto's continuing positions on the product's safety induced him to handle the product as he did. No warnings were given that Roundup® posed any dangers to him, members of his family, his farmer customers or clients, or other persons exposed to it. To the contrary, Mr. Pollard remembers that when Roundup® was a new product, and for some time thereafter, Monsanto representatives affirmatively represented that Roundup® was completely safe for human use and, in fact, so safe that it could be consumed as a beverage. Mr. Pollard is aware of no withdrawal, retraction, denial of those statements. He knows Monsanto

continues to promote the product as safe, and it continues to deny that Roundup[®] is probably carcinogenic to humans.

94. Mr. Pollard, who was born in 1952, was diagnosed with marginal zone non-Hodgkin's lymphoma by a physician at Omaha NE in 2016. Mr. Pollard first learned of risks of Roundup[®] after July 2015 and after news of the WHO's IARC's scientific studies came to light. He continued to be exposed into and through the 2015 farming season.

95. Mr. Pollard has suffered general and special damages, personal injuries, illness, debilitations, disruption of his life, and necessity for treatment for his NHL. Both his general and special damages are accruing. He does not know the full amount damages and requests leave to specify all special damages at the time of the final pretrial conference.

Claim III: Plaintiff Robert L. Dickey

96. Plaintiff Robert L. Dickey first encountered Roundup[®] when it was presented as a new product by company officials and he was urged to purchase it as the newest, best herbicide. Mr. Dickey was told that the product was safe to use on his corn, soybeans and around his crop and buildings; he distinctly recalls being told Roundup[®] was so safe "you can drink it". Mr. Dickey used Roundup[®] thereafter in his Cedar County farming operation. Mr. Dickey stayed abreast of developments affecting corn production, including matters related to Roundup and Roundup Ready[®] seed. He knows that Monsanto has consistently engaged in the practice of continuing denial that Roundup[®] is harmful to human health, probably carcinogenic, and linked to the occurrence of NHL. All allegations above, and all theories below, are incorporated here.

97. For more than 25 years, Mr. Dickey applied Roundup[®] with sprayer pulled or carried by a tractor or by commercially sold or rented sprayers or applicators. At times he also applied the product with a hand-held sprayer. He did so following label directions. Mr. Dickey did not know that Roundup[®] was injurious to his health; he did not wear any protective gear while spraying. Monsanto's continuing positions on the

product's safety induced him to do so. No warnings were given that Roundup[®] posed any dangers to him, members of his family, or other persons exposed to it. He continued to be exposed into and through the 2015 farming season.

98. Mr. Dickey was diagnosed with non-Hodgkin's lymphoma by a physician at Omaha NE in 2009. Mr. Dickey was born in 1939. He was unable to discover the existence of a body of recognized scientific evidence linking his disease to exposure to Roundup[®] prior to issuance and public awareness of the IARC monogram. Mr. Dickey was exposed annually to Roundup[®] commencing at about the time it became a widely accepted herbicide in use on Nebraska crops and promoted in Nebraska by Monsanto. His exposures occurred in Nebraska.

99. Mr. Dickey has suffered general and special damages, personal injuries, illness, debilitations, disruption of his life, and necessity for treatment for his NHL. Both his general and special damages are accruing. He does not know the full amount damages and requests leave to specify all special damages at the time of the final pretrial conference. Mr. Dickey is now a Medicare recipient; notice of this fact is given.

Claim IV: Plaintiff Royce D. Janzen

100. Plaintiff Royce D. Janzen first encountered Roundup[®] when it was presented as a new product by company representatives. He was urged to buy Roundup[®] as the newest, best herbicide. Mr. Janzen was told that the product was safe to use on his corn, soybeans and around his crop and buildings. Janzen used Roundup[®] thereafter in his York County farming operation. He did so following label directions. Mr. Janzen did not know that Roundup[®] was injurious to his health; he did not wear any protective gear while spraying. Monsanto's continuing positions on the product's safety induced him to do so. No warnings were given that Roundup[®] posed any dangers to him, members of his family, or other persons exposed to it. All allegations above, and all theories below, are incorporated here.

101. For more than 25 years, Mr. Dickey applied Roundup[®] with sprayer pulled or carried by a tractor or by commercially sold or rented sprayers or applicators. At times he also applied the product with a hand-held sprayer. He Mr. Janzen was exposed

annually to Roundup[®] commencing at about the time it became a widely accepted herbicide in use on Nebraska crops and promoted in Nebraska by Monsanto. Mr. Janzen, who was born in 1949, was diagnosed with non-Hodgkin's lymphoma ("NHL") in York County in 2013. He continued to be exposed into and through the 2015 farming season.

102. Mr. Janzen first learned that exposure to Roundup[®] can cause non-Hodgkin's lymphoma and other serious illnesses sometime after July 29, 2015, when IARC first published its evaluation of glyphosate.

103. Mr. Janzen has suffered general and special damages, personal injuries, illness, debilitations, disruption of his life, and necessity for treatment for his NHL. Both his general and special damages are accruing. He does not know the full amount damages and requests leave to specify all special damages at the time of the final pretrial conference.

Tolling: Statute of Limitations

Discovery Rule Tolling; Equitable Estoppel

104. Plaintiffs had no reasonable no way of knowing about the risk of serious illness associated with the use of, or exposure to, Roundup[®] and glyphosate until the WHO IARC formal assessment was announced and reached the public after July 2015. They could not have discovered, through the exercise of reasonable diligence, that exposure to Roundup[®] and glyphosate is injurious to human health before that time. Monsanto engaged in two separate but parallel actions including:

104.1. Monsanto affirmatively claimed and claims that Roundup[®] and glyphosate are safe to human users like Plaintiffs and including them. It affirmatively denies the probability that Roundup[®] and glyphosate are probably carcinogenic to humans and are linked to blood born cancers including NHL.

104.2. Monsanto continues its campaign of denial of the scientific data amassed by the WHO. This continuing denial is designed to cause confusion, create credibility concerns, and cause users to continue to use Roundup[®]

105. Monsanto is equitably estopped to assert a statute of limitations defense. It made, and continues to make, statements intended to be relied upon by farmers and agronomists and the public that Roundup[®] is safe and harmless to humans. Plaintiffs relied on those statements.

106. Plaintiffs did not discover, and did not know of facts that would cause a reasonable person to suspect, the risks associated with the use of and/or exposure to Roundup[®] and glyphosate; nor would a reasonable and diligent investigation by them have disclosed that Roundup[®] and glyphosate would cause their illnesses. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule and its invocation is estopped by Monsanto's actions.

107. Monsanto was under a continuous duty to disclose to consumers, users and other persons coming into contact with its products, including Plaintiffs, accurate safety information concerning its products and the risks associated with the use of and/or exposure to Roundup[®] and glyphosate. Instead, Monsanto knowingly, affirmatively, and actively concealed safety information concerning Roundup[®] and glyphosate and the risks associated with the use of and/or exposure to its products.

108. As a proximate result of Monsanto's wrongful acts and omissions in placing its defective Roundup[®] products into the stream of commerce without adequate warnings of the hazardous and carcinogenic nature of glyphosate, and in breach of its warranties, negligence and strict liability, Plaintiffs each suffered and continue to suffer severe and permanent physical and emotional injuries. Plaintiffs each endured the anguish of a cancer diagnosis, pain and suffering, and economic losses and special damages, which are accruing and not now known.

First Theory: Design Defect

109. All allegations above are renewed here. Plaintiffs bring their strict liability claims against Monsanto for defective design.

110. At all times relevant to this litigation, Monsanto engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®] products, which are defective and unreasonably dangerous to

consumers and users and other persons coming into contact them, including Plaintiffs, thereby placing Roundup[®] products into the stream of commerce. These actions were under Monsanto's ultimate control and supervision. At all times relevant to this litigation, Monsanto designed, researched, developed, formulated, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the Roundup[®] products used by the Plaintiffs, and/or to which the Plaintiffs were exposed, as described above.

111. At all times relevant to this litigation, Defendant's Roundup[®] products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public, and, in particular, the Plaintiffs.

112. Monsanto's Roundup[®] products reached the intended farmers, consumers, handlers, and users or other persons coming into contact with these products in Nebraska including Plaintiffs, without substantial change in their condition and as designed, manufactured, sold, distributed, labeled, and marketed.

113. Monsanto's Roundup[®] products, as researched, tested, developed, designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Monsanto were defective in design and formulation when they left Monsanto's control; they were unreasonably dangerous to foreseeable human users, including Plaintiffs. These dangers could not be discovered by reasonable users.

114. Defendant's Roundup[®] products were defective in design and formulation in that when they left the hands of Defendant's manufacturers and/or suppliers, the foreseeable risks associated with these products' reasonably foreseeable uses exceeded the alleged benefits associated with their design and formulation. Defendant's Roundup[®] products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendant, were defective in design and formulation, in one or more of the following ways:

- 114.1 When placed in the stream of commerce, Defendant's Roundup[®] products were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate.
- 114.2 When placed in the stream of commerce, Defendant's Roundup[®] products were unreasonably dangerous in that they were hazardous and posed a grave risk of NHL, cancer and other serious illnesses when used in a reasonably anticipated manner.
- 114.3 When placed in the stream of commerce, Defendant's Roundup[®] products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner.
- 114.4 Defendant did not sufficiently test, investigate, or study its Roundup[®] products and, specifically, the active ingredient glyphosate.
- 114.5 Exposure to Roundup[®] and glyphosate-containing products presents a risk of harmful side effects that outweighs any potential utility stemming from the use of the herbicide.
- 114.6 Defendant knew or should have known at the time of marketing its Roundup[®] products that exposure to Roundup[®] and specifically, its active ingredient glyphosate, could result in cancer and other severe illnesses and injuries.
- 114.7 Defendant did not conduct adequate post-marketing surveillance of its Roundup[®] products.
- 114.8 Defendant could have employed safer alternative designs and formulations.

115. At all times relevant, Plaintiffs used and/or was exposed to the use of Defendant's Roundup[®] products in an intended or reasonably foreseeable manner without knowledge of their dangerous characteristics. Plaintiffs could not have reasonably discovered the defects and risks associated with Roundup[®] or glyphosate-containing products before or at the time of exposure.

116. Harms caused by Monsanto's Roundup[®] products outweighed their benefit, rendering Defendant's products dangerous to an extent beyond that which an ordinary consumer would contemplate. Monsanto's Roundup[®] products were and are

more dangerous than alternative products and Defendant could have designed its Roundup[®] products to make them less dangerous. At the times relevant to that Monsanto's original and updated events of design and manufacture of its Roundup[®] products, the industry's scientific knowledge included awareness of less risky designs or formulations.

117. At the time Roundup[®] products left Monsanto's control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Monsanto's Roundup[®] herbicides. As a result of the unreasonably dangerous condition of its Roundup[®] products, Defendant is strictly liable to Plaintiffs.

118. Monsanto's defective design, its perpetuation, and the continuing denial by Monsanto of safety risks of Roundup[®] amounts to willful, wanton, and/or reckless conduct. The defects in Monsanto's Roundup[®] products were substantial and proximate causes of Plaintiffs' grave injuries, illness and damages. Plaintiffs are each permanently injured. Each has suffered pain, anguish, anxiety, disability, impairment and disability.

Second Theory: Strict Liability. Failure to Warn

119. All allegations above are renewed here. Plaintiffs bring their strict liability claims against Monsanto for failure to warn.

120. At all times relevant to this litigation, Monsanto engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®] products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Roundup[®] and glyphosate. These actions were under the ultimate control and supervision of Monsanto.

121. Monsanto researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Roundup[®] products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs.

Monsanto had a duty to warn of the risks associated with the reasonably foreseeable uses (and misuses) of Roundup[®] and glyphosate-containing products but failed to do so.

122. At all times relevant to this litigation, Monsanto, an expert in its field, had a duty to provide proper warnings, and take steps as necessary to ensure that its Roundup[®] products did not cause users and consumers to suffer from unknown, undiscoverable and unreasonable risks. Monsanto had a continuing duty to warn Plaintiffs of dangers associated with use of Roundup[®].

123. At the time of manufacture, Monsanto could have provided warnings or instructions regarding the full and complete risks of Roundup[®] and glyphosate-containing products because it knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to these products. But, Monsanto failed, on an ongoing basis, to investigate, study, test, or promote the safety or to minimize dangers to users of Roundup[®] products,, including Plaintiffs.

124. Monsanto knew or should have known that Roundup[®] products posed a grave risk of harm, it failed to warn of the dangerous risks associated with their use and exposure. It failed to warn of those risks, and denied their existence. It continues to do so. The dangerous propensities of its products and the carcinogenic characteristics of glyphosate, as described above, were known to Monsanto, or scientifically knowable to Monsanto through appropriate research and testing by known methods.

125. Monsanto knew or should have known that its Roundup[®] and glyphosate-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Monsanto failed to adequately warn consumers and reasonably foreseeable users of the risks of exposure to these products. Monsanto wrongfully concealed information concerning the dangerous nature of Roundup[®] and its active ingredient glyphosate, and further made false and/or misleading statements concerning the safety of Roundup[®] and glyphosate.

126. At all times relevant to this litigation, Monsanto's Roundup[®] products reached the Plaintiffs as intended consumers, handlers, and users, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and

marketed by Monsanto. Plaintiffs used and/or were exposed to the use of Roundup[®] products in a reasonably foreseeable manner without knowledge of dangers. These dangers were not reasonably discoverable by Plaintiffs.

127. Monsanto knew or should have known that the minimal warnings disseminated with its Roundup[®] products were inadequate, but it failed to communicate adequate information on the dangers and safe use/exposure and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses, including agricultural and horticultural applications.

128. As a result of their inadequate warnings and otherwise, Monsanto's Roundup[®] products were defective and unreasonably dangerous when they left the possession and/or control of Monsanto, were distributed by Monsanto, and used by Plaintiff, and Plaintiffs were each injured as alleged above.

129. Had Monsanto provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Roundup[®] products, Plaintiffs could have avoided the risk of developing injuries as alleged herein and Plaintiffs' employers could have obtained alternative herbicides.

Third Theory: Negligence

130. All allegations above are renewed here. Monsanto was negligent in its acts practices and methods to design, test, package, label, promote, market and distribute its Roundup[®] products. Plaintiffs assert their negligence claims.

131. Monsanto had, but breached, its duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of its Roundup[®] products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to Plaintiffs as consumers and users of them.

132. Monsanto knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Roundup[®] and specifically, the carcinogenic properties of the chemical glyphosate. Monsanto knew or, in the exercise of reasonable care, should

have known that use of or exposure to its Roundup[®] products could cause Plaintiffs' injuries and thus create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

133. Monsanto knew or, in the exercise of reasonable care, should have known that Roundup[®] is more toxic than glyphosate alone and that safety studies on Roundup[®], Roundup[®]'s adjuvants and "inert" ingredients, and/or the surfactant POEA were necessary to protect Plaintiffs from Roundup[®] and it knew or, in the exercise of reasonable care, should have known that tests limited to Roundup's active ingredient glyphosate were insufficient to prove the safety of Roundup.

134. Monsanto also knew or, in the exercise of reasonable care, should have known that users and consumers of Roundup[®] were unaware of the risks and the magnitude of the risks associated with the use of and/or exposure to Roundup[®] and glyphosate-containing products.

135. Monsanto breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of its Roundup[®] products, in that Monsanto manufactured and produced defective herbicides containing the chemical glyphosate, knew or had reason to know of the defects inherent in its products, knew or had reason to know that a user's or consumer's exposure to the products created a significant risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of these risks and injuries.

136. Monsanto failed to appropriately and adequately test Roundup[®], Roundup[®]'s adjuvants and "inert" ingredients, and/or the surfactant POEA to protect Plaintiffs from Roundup[®]. Indeed, Monsanto has wrongfully concealed information and has further made false and/or misleading statements concerning the safety and/or exposure to Roundup[®] and glyphosate. Monsanto's negligence included:

136.1 Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing its Roundup[®] products without thorough and adequate pre- and post-market testing;

- 136.2 Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Roundup[®] while negligently and/or intentionally concealing and failing to disclose results of trials, tests, and studies of exposure to glyphosate, and, the risk of serious harm associated with human use of and exposure to Roundup[®];
- 136.3 Failing to undertake sufficient studies and tests to determine whether or not Roundup[®] products and glyphosate-containing products were safe for their intended use in agriculture, horticulture, and at-home use;
- 136.4 Failing to conduct reasonable tests and studies to determine the safety of “inert” ingredients and/or adjuvants contained within Roundup[®], and propensity of these ingredients to render Roundup[®] toxic, increase the toxicity of Roundup[®], and magnify carcinogenic its properties and whether or not “inert” ingredients and/or adjuvants were safe for use;
- 136.5 Failing to use reasonable and prudent care in the design, research, manufacture, formulation, and development of Roundup[®] products so as to avoid the risk of serious harm associated with the prevalent use of Roundup[®]/glyphosate as an herbicide;
- 136.6 Failing to design and manufacture Roundup[®] products so as to ensure they were at least as safe and effective as other herbicides on the market;
- 136.7 Failing to provide adequate instructions, guidelines, and safety precautions to those persons who Monsanto could reasonably foresee would use and/or be exposed to its Roundup[®] products;
- 136.8 Failing to disclose to Plaintiffs, users, consumers, and the general public that the use of and exposure to Roundup[®] presented severe risks of cancer and other grave illnesses;
- 136.9 Failing to warn Plaintiffs, users, consumers, and the general public that the product’s risk of harm was unreasonable and that there were safer and effective alternative herbicides available to Plaintiffs and other users or consumers;
- 136.10 Systematically suppressing or belittling contrary evidence about the risks, incidence, and prevalence of the side effects of Roundup[®] and glyphosate-containing products;

- 136.11 Representing that its Roundup[®] products were safe for their intended use when, in fact, Monsanto knew or should have known that the products were not safe for their intended use;
- 136.12 Declining to make or propose any changes to Roundup[®] products' labeling or other promotional materials that would alert the consumers and the general public of the risks of Roundup[®] and glyphosate;
- 136.13 Advertising, marketing, and recommending the use of Roundup[®] products, while concealing and failing to disclose or warn of the dangers known by Monsanto to be associated with or caused by the use of or exposure to Roundup[®] and glyphosate;
- 136.14 Continuing denial of risks and continuing dissemination of information to its consumers that Monsanto's Roundup[®] is safe as marketed for use in the agricultural, horticultural industries, and/or home use; and
- 136.15 Continuing the manufacture and sale of its products with the knowledge that the products were unreasonably unsafe and dangerous.

137 Monsanto knew and/or should have known it was foreseeable that consumers and/or users, such as Plaintiffs, would suffer injuries as a result of Monsanto's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Roundup[®]. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Roundup[®] or its active ingredient glyphosate. Monsanto's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiffs suffered, and will continue to suffer.

138 Monsanto made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiffs. Monsanto's reckless conduct warrants an award of punitive damages payable to the State common school fund.

Fourth Theory: Breach of Express Warranty

139 All allegations above are renewed here. Monsanto has special knowledge skill and expertise germane to herbicides and their design, manufacture testing, and marketing. At all times relevant, Monsanto engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting

its Roundup® products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing Roundup® products into the stream of commerce. These actions were under the ultimate control and supervision of Monsanto. Plaintiffs assert their breach of express warranty claims.

140 Monsanto had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of its Roundup® products, including a duty to:

140.1 Reasonable assure that its products did not cause the user unreasonably dangerous side effects;

140.2 Warn of dangerous and potentially fatal side effects; and

140.3 Disclose adverse material facts, such as the true risks associated with use of Roundup® and glyphosate-containing products, when making representations to consumers and the general public, including Plaintiffs.

141 Monsanto expressly represented and warranted matters to Plaintiffs and other consumers and users, and through statements made by Monsanto in labels, publications, package inserts, and other written materials. These representations included assurances that its Roundup® products were safe to human health and the environment, effective, fit, and proper for their intended use and posed no risks of harm to humans. Monsanto advertised, labeled, marketed, and promoted Roundup® products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that its Roundup® products would conform to the representations.

142 These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Roundup® and glyphosate. Monsanto knew and/or should have known that the risks expressly included in Roundup® warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Monsanto expressly represented that its Roundup®

products were safe and effective, that they were safe and effective for use by individuals such as Plaintiffs, and/or that they were safe and effective as agricultural herbicides.

143 The representations about Roundup®, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations. Monsanto placed its Roundup® products into the stream of commerce for sale and recommended use without adequately warning of the true risks of developing the injuries associated with the use of and exposure to Roundup® and its active ingredient glyphosate.

144 Monsanto breached these warranties. Its Roundup® products were defective, dangerous, unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Monsanto breached the warranties as follows:

- 144.1 Monsanto represented through its labeling, advertising, and marketing materials that its Roundup® products were safe, and intentionally withheld and concealed information about the risks of serious injury and disease associated with use of and/or exposure to Roundup® and glyphosate by expressly limiting the risks associated with use and/or exposure within its warnings and labels; and
- 144.2 Monsanto represented that its Roundup® products were safe for use and fraudulently concealed information that demonstrated that glyphosate, the active ingredient in Roundup®, had carcinogenic properties, and that its Roundup® products, therefore, were not safer than alternatives available on the market.

145 Plaintiffs justifiably and detrimentally relied on the express warranties and representations of Monsanto in the purchase and use of its Roundup® products. When Plaintiffs made the decision to purchase Roundup®, they reasonably relied upon Monsanto to disclose known risks, dangers, and effects of Roundup® and glyphosate and they relied on Monsanto's continuing representations that the product is safe.

146 Plaintiffs had no knowledge of the falsity or incompleteness of Monsanto's statements and representations concerning Roundup[®].

Fifth Theory: Breach of Implied Warranties

147 All allegations of both are renewed here. Plaintiffs assert their breach of implied warranty claims.

148 Before the time that Plaintiffs were exposed to the use of the aforementioned Roundup[®] products, Monsanto impliedly warranted to its consumers and users—including Plaintiffs and Plaintiff Sanders's employers—that its Roundup[®] products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as herbicides to be used in Nebraska corn, soybean and crop production agriculture by farmers, agronomists, and related persons.

149 Monsanto failed to disclose that Roundup[®] has dangerous propensities when used as intended and that the use of and/or exposure to Roundup[®] and glyphosate-containing products carries an increased risk of developing severe injuries, including Plaintiffs' injuries. Monsanto was a merchant with respect to herbicides, and Roundup[®]. Each Plaintiff is an intended third-party beneficiary of Monsanto's implied warranties, and each relied on Monsanto to supply Roundup[®] as a safe product that was not probably carcinogens. They relied on the goods to be fit for their intended purpose and of merchantable quality, but herbicides that are sold without disclosure that they are probably carcinogenic to humans are not so fit. Plaintiffs used Roundup[®] as directed by Monsanto. None of them knew or could have known of the concealed risks.

150 Monsanto breached its implied warranty to Plaintiffs in that its Roundup[®] products were not of merchantable quality, safe, or fit for their intended use, or adequately tested. Roundup[®] has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

Requests for Relief

On the foregoing basis each Plaintiff requests judgment in his favor and against Monsanto for:

1. General Damages.

2. Accruing Special Damages, and leave of court to state the amount of the Special Damages at the time of the final pretrial conference.
3. Punitive damages to the extent permitted by law to be paid to Nebraska's common schools fund;
4. Taxable costs, and attorney's fees to the extent permitted by law.

Jury Demand; Trial Location Request.

Each Plaintiff demands trial by jury on all issues so triable. Trial is requested in Lincoln NE.

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