

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<p>JACK LEWIS,</p> <p style="text-align: center;">Plaintiff,</p> <p>v.</p> <p>MONSANTO COMPANY,</p> <p style="text-align: center;">Defendant.</p>	<p>Civil Action No.:</p> <p>Judge:</p> <p>Magistrate Judge:</p> <p><b>JURY TRIAL DEMANDED</b></p>
---	---

**COMPLAINT**

COMES NOW Plaintiff Jack Lewis (“Mr. Lewis”, or “Plaintiff”), by and through his attorneys of record, and shows unto the Court the following:

**INTRODUCTION**

1. In 1970, Defendant Monsanto Company (hereinafter “Monsanto” or “Defendant”) discovered the herbicidal properties of glyphosate and began marketing it in products in 1974, under the brand name Roundup®. Roundup® is a non-selective herbicide used to kill weeds that commonly compete with the growing of crops. In addition to the active ingredient glyphosate, Roundup® contains the surfactant Polyethoxylated tallow amine (“POEA”) and/or adjuvants and other so-called “inert” ingredients. In 2001, glyphosate was the most-used pesticide active ingredient in American agriculture with 85–90 millions of pounds used annually. That number grew to 185 million pounds by 2007.<sup>1</sup> As of 2013, glyphosate was the world’s most widely used herbicide.

2. Monsanto is a multinational agricultural biotechnology corporation based in St. Louis, Missouri, and incorporated in Delaware. It is the world’s leading producer of glyphosate.

---

<sup>1</sup> Grube, et al., on behalf of EPA, *Pesticides Industry Sales and Usage, 2006-2007 Market Estimates*, 14, (2011) available at [http://www.epa.gov/pesticides/pestsales/07pestsales/market\\_estimates2007.pdf](http://www.epa.gov/pesticides/pestsales/07pestsales/market_estimates2007.pdf).

As of 2009, Monsanto was the world's leading producer of seeds, accounting for 27% of the world seed market.<sup>2</sup> The majority of these seeds are of the Roundup® Ready® brand. The stated advantage of Roundup® Ready® crops is that they substantially improve a farmer's ability to control weeds, since glyphosate can be sprayed in the fields during the growing season without harming the crops. In 2010, an estimated 70% of corn and cotton, and 90% of soybean fields in the United States were Roundup® Ready®.<sup>3</sup>

3. Monsanto's glyphosate products are registered in 130 countries and approved for use on over 100 different crops.<sup>4</sup> They are ubiquitous in the environment. Numerous studies confirm that glyphosate is found in rivers, streams and groundwater in agricultural areas where Roundup® is used.<sup>5</sup> It has been found in food,<sup>6</sup> in the urine of agricultural workers,<sup>7, 8</sup> and even in the urine of urban dwellers who are not in direct contact with glyphosate.<sup>9</sup>

---

<sup>2</sup> 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](http://www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf).

<sup>3</sup> William Neuman and 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>.

<sup>4</sup> Monsanto, *Backgrounder - History of Monsanto's Glyphosate Herbicides*, (Sept. 2, 2015), available at [http://www.monsanto.com/products/documents/glyphosate-background-materials/back\\_history.pdf](http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf).

<sup>5</sup> See: USGS, *USGS Technical Announcement: Widely Used Herbicide Commonly Found in Rain and Streams in the Mississippi River Basin*, 2011, <http://www.usgs.gov/newsroom/article.asp?ID=2909>; see also: U.S. Evtl. Prot. Agency, *Technical Factsheet on: Glyphosate*, available at <http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/glyphosa.pdf>.

<sup>6</sup> 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>.

<sup>7</sup> Acquavella, et al., *Glyphosate Biomonitoring for Farmers and their Families: Results from the Farm Family Exposure Study*, 112(3) *Environmental Health Perspective*, 321, (2004) available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241861/>.

<sup>8</sup> Guyton, et al. *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon and 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).

<sup>9</sup> Brändli D, Reinacher S, *Herbicides found in Human Urine*, 1 *Ithaka Journal*, 270 (2012), available at <http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf>.

4. On March 20, 2015, the International Agency for Research on Cancer (“IARC”), an agency of the World Health Organization (“WHO”), issued an evaluation of several herbicides, including glyphosate. That evaluation was based, in part, on studies of exposures to glyphosate in several countries around the world, and it traces the health implications from exposure to glyphosate since 2001.

5. On July 29, 2015, IARC issued the formal monograph relating to glyphosate. In that monograph, the IARC Working Group provides a thorough review of the numerous studies and data relating to glyphosate exposure in humans.

6. 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 Hematopoietic cancers, including Lymphocytic Lymphoma, Chronic Lymphocytic Leukemia, B-cell Lymphoma and Multiple Myeloma.<sup>10</sup>

7. The IARC evaluation is significant. It confirms what has been believed for years: that glyphosate is toxic to humans.

8. Nevertheless, Monsanto, since it began selling Roundup®, has represented it as safe to humans and the environment. Indeed, Monsanto has repeatedly proclaimed and continues to proclaim to the world, and particularly to United States consumers, that glyphosate-based herbicides, including Roundup®, do not create unreasonable risks to human health or to the environment.

---

<sup>10</sup> See Guyton, et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon and Glyphosate*, *supra*.

**JURISDICTION & VENUE**

9. This Court has diversity jurisdiction over the claims in this Complaint because the aggregate amount in controversy exceeds the sum of \$75,000.00 and is between citizens of different states. 28 U.S.C. § 1332(a)(1).

10. Venue is proper within this District under 28 U.S.C. § 1391 because injuries sustained by the Plaintiff, as described herein, occurred within the Northern District of Ohio.

**THE PARTIES**

11. Plaintiff Jack Lewis, a citizen of the State of Ohio whose principal place of residence is in Wooster, Ohio, brings this action due to injuries he has sustained as a direct and proximate result of his use of Defendant's Roundup® product and subsequent NHL, chronic lymphocytic leukemia/small lymphocytic lymphoma diagnosis.

12. Defendant Monsanto is a Delaware corporation with its headquarters and principal place of business in St. Louis, Missouri, and is licensed to do and does business in the State of Ohio. Defendant Monsanto Company is in the business of researching, testing, developing, designing, formulating, manufacturing, producing, assembling, packaging, labeling, advertising, promoting, marketing, selling, supplying and distributing herbicides, including Roundup® products.

13. At all times relevant to this Complaint, Monsanto was the entity that discovered the herbicidal properties of glyphosate and the manufacturer of Roundup® products, which contain the active ingredient glyphosate and the surfactant POEA, as well as adjuvants and other "inert" ingredients.

**STATEMENT OF THE FACTS**

14. Glyphosate is a broad-spectrum, non-selective herbicide used in a wide variety of herbicidal products around the world.

15. 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. Because plants absorb glyphosate, it cannot be completely removed by washing or peeling produce or by milling, baking or brewing grains.

16. For nearly 40 years, farms across the world have 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 could kill almost every weed without causing harm either to people or to the environment. According to the WHO, the main chemical ingredient of Roundup®—glyphosate—is a probable cause of cancer. Those most at risk are farm workers and other individuals with workplace exposure to Roundup®, such as workers in garden centers, nurseries and landscapers. Monsanto assured the public that Roundup® was harmless. In order to prove this, Monsanto championed falsified data and attacked legitimate studies that revealed its dangers. Monsanto led a prolonged campaign of misinformation to convince government agencies, farmers and the general population that Roundup® is safe.

***The Discovery of Glyphosate and Development of Roundup®***

17. The herbicidal properties of glyphosate were discovered in 1970 by Monsanto chemist John Franz. The first glyphosate-based herbicide was introduced to the market in the mid-1970s under the brand name Roundup®.<sup>11</sup> From the outset, Monsanto marketed Roundup®

---

<sup>11</sup> Monsanto, *Backgrounder-History of Monsanto's Glyphosate Herbicide*, Monsanto, (Sept. 2, 2015), [http://www.monsanto.com/products/documents/glyphosate-background-materials/back\\_history.pdf](http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf).

as a “safe” general-purpose herbicide for widespread commercial and consumer use. It still markets and advertises Roundup® as safe today.<sup>12</sup>

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

***Registration of Herbicides under Federal Law***

19. 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” or “Agency”) prior to their distribution, sale or use, except as described by the Act. 7 U.S.C. § 136a(a).

20. Because pesticides 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 pesticides, toxicity to people and other potential non-target organisms and other adverse effects on the environment. Registration by the EPA, however, is not an assurance or finding of safety. The determination the Agency must make in registering or re-registering a product is not that the product is “safe,” but rather that use of the product in accordance with its label directions “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(D).

---

<sup>12</sup> Monsanto, *What is Glyphosate?*, (Sept. 2, 2015), available at <http://www.monsanto.com/sitecollectiondocuments/glyphosate-safety-health.pdf>.

21. 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.” 7 U.S.C. § 136(bb). FIFRA thus requires the EPA to make a risk/benefit analysis in determining whether a registration should be granted or allowed to continue to be sold in commerce.

22. The EPA and the State of Ohio registered Roundup® for distribution, sale and manufacture in the United States and the State of Ohio.

23. FIFRA generally requires that the registrant, Monsanto in the case of Roundup®, conduct the health and safety testing of pesticide 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. The data produced by the registrant must be submitted to the EPA for review and evaluation. The government is not required, nor is it able to perform the product tests that are required of the manufacturer.

24. The evaluation of each pesticide product distributed, sold or manufactured is completed at the time the product is initially registered. The data necessary for registration of a pesticide has changed over time. The EPA is now in the process of re-evaluating all pesticide products through a Congressionally-mandated process called “re-registration.” 7 U.S.C. § 136a-1. In order to reevaluate these pesticides, the EPA is demanding the completion of additional tests and the submission of data for the EPA’s review and evaluation.

25. In the case of glyphosate, and therefore Roundup®, the EPA had planned on releasing its preliminary risk assessment—in relation to the reregistration process—no later than July 2015. The EPA completed its review of glyphosate in early 2015, but it delayed

releasing the risk assessment pending further review in light of the World Health Organization's health-related findings.

***Scientific Fraud Underlying the Marketing and Sale of Glyphosate/ Roundup®***

26. Based on early studies that glyphosate could cause cancer in laboratory animals, the EPA originally classified glyphosate as *possibly carcinogenic to humans* (Group C) in 1985. After pressure from 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, however, the EPA made clear that the designation did not mean the chemical does not cause cancer: “[i]t 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.”<sup>13</sup>

27. On two occasions, the EPA found that the laboratories hired by Monsanto to test the toxicity of its Roundup® products for registration purposes committed fraud.

28. In the first instance, Monsanto, in seeking initial registration of Roundup® by the EPA, hired Industrial Bio-Test Laboratories (“IBT”) to perform and evaluate pesticide toxicology studies relating to Roundup®.<sup>14</sup> IBT performed about thirty (30) tests on glyphosate and glyphosate-containing products, including nine (9) of the fifteen (15) residue studies needed to register Roundup®.

---

<sup>13</sup> 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-Oct91\\_265.pdf](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct91_265.pdf).

<sup>14</sup> Monsanto, Backgrounder. *Testing Fraud: IBT and Craven Laboratories*, (Sept. 2, 2015), [http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt\\_craven\\_bkg.pdf](http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf).



29. In 1976, the United States Food and Drug Administration (“FDA”) performed an inspection of Industrial Bio-Test Industries (“IBT”) that revealed discrepancies between the raw data and the final report relating to the toxicological impacts of glyphosate. The EPA subsequently audited IBT; it too found the toxicology studies conducted for the Roundup® herbicide to be invalid.<sup>15</sup> An EPA reviewer stated, 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.”<sup>16</sup>

30. Three top executives of IBT were convicted of fraud in 1983.

31. In the second incident of data falsification, 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.<sup>17</sup>

### ***The Importance of Roundup® to Monsanto’s Dominance Profits***

32. Despite the falsity of the tests that underlie its registration, within a few years of its launch, Roundup® was being marketed in 115 countries.

---

<sup>15</sup> U.S. Env’tl. Prot. Agency, *Summary of the IBT Review Program Office of Pesticide Programs*, (1983), available 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%7CMaximumDocuments=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>.

<sup>16</sup> Marie-Monique Robin, *The World According to Monsanto: Pollution, Corruption and the Control of the World’s Food Supply* (2011) (citing U.S. Env’tl. Prot. Agency, Data Validation, Memo from K. Locke, Toxicology Branch, to R. Taylor, Registration Branch. Washington, D.C. (August 9, 1978.)).

<sup>17</sup> Monsanto, Backgrounder. *Testing Fraud: IBT and Craven Laboratories*, supra.

33. The success of Roundup® was key to Monsanto's continued reputation and dominance in the marketplace. Largely due to the success of Roundup® sales, Monsanto's agriculture division was out-performing its chemicals division's operating income, and that gap increased yearly. But with its patent for glyphosate expiring in the United States in the year 2000, Monsanto needed a strategy to maintain its Roundup® market dominance and to ward off impending competition.

34. In response, Monsanto began the development and sale of genetically engineered Roundup® Ready® seeds in 1996. Since Roundup® Ready® crops are resistant to glyphosate, farmers can spray Roundup® onto their fields during the growing season without harming the crop. This allowed Monsanto to expand its market for Roundup® even further; by 2000, Monsanto's biotechnology seeds were planted on more than 80 million acres worldwide and nearly 70% of American soybeans were planted from Roundup® Ready® seeds. 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.

35. Through a three-pronged strategy of increased production, decreased prices and by coupling with Roundup® Ready® seeds, Roundup® became Monsanto's most profitable product. In 2000, Roundup® 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.<sup>18</sup> Today, glyphosate remains one of the world's largest herbicides by sales volume.

---

<sup>18</sup> 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-weedkiller-is-a-block-for-monsanto-to-build-on.html>.

*Monsanto has known for decades that it falsely advertised the safety of Roundup®*

36. In 1996, the New York Attorney General (“NYAG”) filed a lawsuit against 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 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.”
- 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) “Glyphosate is less toxic to rats than table salt following acute oral ingestion.”
- g) “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.”

- h) “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.”
- i) “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®.<sup>19</sup>

37. On November 19, 1996, Monsanto entered into an Assurance of Discontinuance with the 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:

- 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."
- ...

---

<sup>19</sup> 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).

- 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."

38. Monsanto did not alter its advertising in the same manner in any state other than New York, and on information and belief still has not done so today.

39. 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."<sup>20</sup>

#### *Classifications and Assessments of Glyphosate*

40. The IARC process for the classification of glyphosate followed the 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 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.

41. The established procedure for the IARC Monograph evaluations is described in the IARC Programme's Preamble.<sup>21</sup> 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.

---

<sup>20</sup> *Monsanto Guilty in 'False Ad' Row*, BBC, Oct. 15, 2009, available at <http://news.bbc.co.uk/2/hi/europe/8308903.stm>.

<sup>21</sup> 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>.

42. One year before the Monograph meeting, the meeting is announced and there is a call both for data and for experts. Eight (8) 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 (1) 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 (2) weeks after the Monograph meeting, the summary of the Working Group findings are published in *The Lancet Oncology*, and within one (1) year after the meeting, the finalized Monograph is published.

43. In assessing an agent, the IARC Working Group reviews the following information: (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 studies.

44. In March 2015, IARC reassessed glyphosate. The summary published in *The Lancet Oncology* reported that glyphosate is a Group 2A agent and probably carcinogenic in humans.

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

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.”

46. The studies considered the following exposure groups: (a) occupational exposure of farmers and tree nursery workers in the United States, forestry workers in Canada and Finland and municipal weed-control workers in the United Kingdom; and (b) para-occupational exposure in farming families.

47. 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.

48. Exposure pathways are identified as air (especially during spraying), water and food. Community exposure to glyphosate is widespread and found in soil, air, surface water and groundwater, as well as in food.

49. 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.

50. 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.

51. The IARC Working Group also found that glyphosate caused DNA and chromosomal damage in human cells. One study in community residents reported increases in

blood markers of chromosomal damage (micronuclei) after glyphosate formulations were sprayed.

52. 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.

53. The IARC Working Group also noted 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.

54. The IARC Working Group further found that glyphosate and glyphosate formulations induced DNA and chromosomal damage in mammals, and in human and animal cells in utero.

55. The IARC Working Group also noted genotoxic, hormonal and enzymatic effects in mammals exposed to glyphosate.<sup>22</sup> Essentially, glyphosate inhibits the biosynthesis of aromatic amino acids, which leads to several metabolic disturbances, including the inhibition of protein and secondary product biosynthesis and general metabolic disruption.

56. The IARC Working Group also reviewed an Agricultural Health Study, consisting of a prospective cohort of 57,311 licensed pesticide applicators in Iowa and North Carolina. While this study differed from others in that it was based on a self-administered questionnaire, the results support an association between glyphosate exposure and multiple myeloma, hairy cell

---

<sup>22</sup> Guyton, et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, supra at 77.



leukemia (“HCL”) and chronic lymphocytic leukemia (“CLL”), in addition to several other cancers.

***Other Earlier Findings About Glyphosate’s Dangers to Human Health***

57. The EPA has a technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water Regulations publication, relating to glyphosate. This technical fact sheet predates the IARC March 20, 2015, evaluation. The fact sheet 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 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.<sup>23</sup>

58. In 1995, the Northwest Coalition for Alternatives to Pesticides reported that in California, the state with the most comprehensive program for reporting of pesticide-caused

---

<sup>23</sup> U.S. Env’tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, supra.

illness, glyphosate was the third most commonly-reported cause of pesticide illness among agricultural workers.<sup>24</sup>

***The Toxicity of Other Ingredients in Roundup®***

59. In addition to the toxicity of the active ingredient, glyphosate, several studies support the hypothesis that the glyphosate-based formulation in Defendant's Roundup® products is more dangerous and toxic than glyphosate alone. Indeed, as early as 1991, available evidence demonstrated that glyphosate formulations were significantly more toxic than glyphosate alone.<sup>25</sup>

60. In 2002, a 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 that the same concentrations of glyphosate alone were ineffective and did not alter cell cycles.<sup>26</sup>

61. 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 to genomic instability and subsequent development of cancers from the initial affected cell." Further, "[s]ince cell cycle

---

<sup>24</sup> Caroline Cox, *Glyphosate, Part 2: Human Exposure and Ecological Effects*, 15 J. Pesticide Reform 4 (1995); W.S. Peas, et al., *Preventing Pesticide-Related Illness in California Agriculture: Strategies and Priorities. Environmental Health Policy Program Report*, Univ. of Calif. School of Public Health, Calif. Policy Seminar (1993).

<sup>25</sup> 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).

<sup>26</sup> 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>.

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.”<sup>27</sup>

62. 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 further suggested that the harmful effects of Roundup® on mitochondrial bioenergetics could not be exclusively attributed to glyphosate but could be the result of other chemicals, such as the surfactant POEA, or in the alternative, due to the potential synergistic effect between glyphosate and other ingredients in the Roundup® formulation.<sup>28</sup>

63. 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. The 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 Benachour/Seralini Study confirmed that the

---

<sup>27</sup> 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>.

<sup>28</sup> 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](https://www.researchgate.net/publication/7504567_Comparative_effects_of_the_Roundup_and_glyphosate_on_mitochondrial_oxidative_phosphorylation).

adjuvants present in Roundup® are not, in fact, inert and that Roundup® is potentially far more toxic than its active ingredient glyphosate alone.<sup>29</sup>

64. The results of these studies were at all times available to Defendant. Defendant thus knew or should have known that Roundup® is more toxic than glyphosate alone and that safety studies of Roundup®, Roundup®’s adjuvants and “inert” ingredients, and/or the surfactant POEA were necessary to protect Plaintiff from Roundup® products.

65. Despite its knowledge that Roundup® is considerably more dangerous than glyphosate alone, Defendant continued to promote Roundup® as safe.

### ***The EPA’s Review of Glyphosate***

66. On September 12, 2016, EPA’s OPP submitted a report on the carcinogenic potential of glyphosate, wherein it issued a “proposed conclusion” that glyphosate is “‘not likely to be carcinogenic to humans’ at doses relevant to human health risk assessment.”<sup>30</sup> There are no authors listed on this issue paper, which reiterates and adopts the conclusions of the October 2015 leaked assessment. The issue paper is based upon a review of industry-sponsored articles and studies. The OPP acknowledged that it rejected all studies that considered Roundup®—the formulated product—instead of studies that isolated glyphosate because “[g]lyphosate formulations contain various components other than glyphosate and it has been hypothesized these components are more toxic than glyphosate alone.”<sup>31</sup>

---

<sup>29</sup> 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>.

<sup>30</sup> See EPA’s Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (Sept. 12, 2016), available at [https://www.epa.gov/sites/production/files/201609/documents/glyphosate\\_issue\\_paper\\_evaluation\\_of\\_carcinogenic\\_potential.pdf](https://www.epa.gov/sites/production/files/201609/documents/glyphosate_issue_paper_evaluation_of_carcinogenic_potential.pdf).

<sup>31</sup> *Id.*

67. Thus, the OPP notes dozens of studies considered by IARC were not reviewed by the OPP because the OPP's "evaluation focused on studies on the active ingredient glyphosate" and "additional research could also be performed to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations."<sup>32</sup>

68. From December 13 to 16, 2016, the EPA held FIFRA Scientific Advisory Panel ("SAP") meetings to consider issues raised by the OPP's evaluation of glyphosate. Again, OPP only allowed the SAP to consider studies of glyphosate alone, and not any study of the formulated product. In its Charge to the FIFRA SAP, the OPP noted that "[a]lthough there are studies available on glyphosate-based pesticide formulations, the agency is soliciting advice from the FIFRA Scientific Advisory Panel ("SAP") on this evaluation of human carcinogenic potential for the active ingredient glyphosate only at this time."<sup>33</sup>

69. The OPP draft assessment therefore does not actually consider the product at issue in this litigation or, more importantly, how glyphosate, in conjunction with surfactants and other chemicals, affects carcinogenicity.

70. On March 16, 2017, the final SAP meeting minutes and report were released, revealing disagreement and lack of consensus among the scientists on whether there was a positive association between glyphosate exposure and NHL.<sup>34</sup>

---

<sup>32</sup> *Id.*

<sup>33</sup> EPA OPP, *Glyphosate: Evaluation of Carcinogenic Potential*, Charge to the FIFRA SAP for the October 18-21, 2016 Meeting, available at, [https://www.epa.gov/sites/production/files/201611/documents/glyphosate\\_sap\\_charge\\_questions\\_final.pdf](https://www.epa.gov/sites/production/files/201611/documents/glyphosate_sap_charge_questions_final.pdf).

<sup>34</sup> FIFRA Scientific Advisory Panel Meeting Minutes and Final Report No. 2017-01, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: EPA's Evaluation of the Carcinogenic Potential of Glyphosate*, available at [https://www.epa.gov/sites/production/files/2017-03/documents/december\\_13-16\\_2016\\_final\\_report\\_03162017.pdf](https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf).

***Recent Worldwide Bans on Roundup®/Glyphosate***

71. Several countries around the world have instituted bans on the sale of Roundup® and other glyphosate-containing herbicides, both before and since the IARC first announced its assessment for glyphosate in March 2015, and more countries undoubtedly will follow suit as the dangers of the use of Roundup® become more widely known. The Netherlands issued a ban on all glyphosate-based herbicides in April 2014, including Roundup®, which took effect at 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.”<sup>35</sup>

72. The Brazilian Public Prosecutor in the Federal District requested that the Brazilian Justice Department suspend the use of glyphosate.<sup>36</sup>

73. France banned the private sale of Roundup® and glyphosate following the IARC assessment for glyphosate.<sup>37</sup>

---

<sup>35</sup> *Holland’s Parliament Bans Glyphosate Herbicides*, The Real Agenda, 14 April 2014, available at <http://real-agenda.com/hollands-parliament-bans-glyphosate-herbicides/>.

<sup>36</sup> 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-recentglyphosate-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-dfreforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional](http://noticias.pgr.mpf.mp.br/noticias/noticias-do-site/copy_of_meio-ambiente-e-patrimonio-cultural/mpf-dfreforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional).

<sup>37</sup> 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-banssale-monsantos-roundup-garden-centers-after-un-names-it-probable-343311>.

74. Bermuda banned both the private and commercial sale of glyphosate, including Roundup®. The Bermuda government explained its ban as follows: “[f]ollowing a recent scientific study carried out by a leading cancer agency, the importation of weed spray ‘Roundup®’ has been suspended.”<sup>38</sup>

75. The Sri Lankan government banned the private and commercial use of glyphosates, particularly out of concern that glyphosate has been linked to fatal kidney disease in agricultural workers.<sup>39</sup>

76. The government of Columbia 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.<sup>40</sup>

#### ***EFSA Report on Glyphosate***

77. On November 12, 2015, the European Food Safety Authority (“EFSA”), the European Union’s (“EU”) primary agency for food safety, reported on its evaluation of the Renewal Assessment Report (“RAR”) on glyphosate.<sup>41</sup> The Rapporteur Member State assigned to glyphosate, the German Federal Institute for Risk Assessment (“BfR”), had produced the RAR as part of the renewal process for glyphosate in the EU.

---

<sup>38</sup> *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-weedspray-suspended>.

<sup>39</sup> *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>.

<sup>40</sup> *Columbia to Ban Coca Spraying Herbicide Glyphosate*, BBC, May 10, 2015, available at <http://www.bbc.com/news/world-latin-america-32677411>.

<sup>41</sup> European Food Safety Auth., *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, EFSA Journal (2015), available at [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/4302.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf).

78. The BfR sent its draft RAR to the EFSA and the RAR underwent a peer review process by the EFSA, other member states and industry groups. As part of the on-going peer review of Germany's re-evaluation of glyphosate, the EFSA had also received a second mandate from the European Commission to consider the IARC's findings regarding the potential carcinogenicity of glyphosate and glyphosate-containing products.

79. Based on a review of the RAR, which included data from industry-submitted, unpublished studies, the EFSA sent 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."<sup>42</sup> The EFSA therefore disagreed with the IARC: glyphosate was not genotoxic and did not present a carcinogenic threat to humans.

80. In explaining why its results departed from the IARC's conclusion, the EFSA drew a distinction between the EU and the IARC approaches to the study and classification of chemicals.<sup>43</sup> Although the IARC examined "both glyphosate—an active substance—and glyphosate-based formulations, grouping all formulations regardless of their composition," the EFSA explained that it considered only glyphosate and that its assessment focuses on "each individual chemical, and each marketed mixture separately."<sup>44</sup> The IARC, on the other hand, "assesses generic agents, including groups of related chemicals, as well as occupational or

---

<sup>42</sup> *Id.*

<sup>43</sup> European Food Safety Auth., *The EFSA Fact Sheet: Glyphosate*, available at [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/efsaexplainsglyphosate15112en.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate15112en.pdf).

<sup>44</sup> *Id.*



environmental exposure, and cultural or behavioral practices.”<sup>45</sup> The EFSA accorded greater weight to studies conducted with glyphosate alone than studies of formulated products.<sup>46</sup>

81. The EFSA went further and noted:

Although 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-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 reassess uses of glyphosate-based formulations in their own territories.*<sup>47</sup> (Emphasis added.)

82. Notwithstanding its conclusion, the EFSA did set exposure levels for glyphosate. Specifically, the EFSA 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 of body weight per day.<sup>48</sup>

### ***Leading Scientists Dispute EFSA’s Conclusion***

83. 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.<sup>49</sup> The scientists expressed their strong concerns and urged the commissioner to

---

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> European Food Safety Auth., Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance *Glyphosate*, EFSA Journal (2015), *supra*.

<sup>49</sup> Letter from Christopher J. Portier, et al. to Commissioner Vytenis Andriukaitis, *Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR* (Nov. 27, 2015), available at <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-scientists-in-row-over-safety-of-glyphosate-weedkiller>.

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.”<sup>50</sup>

84. Signatories to the letter included Dr. Christopher J. Portier, Ph.D., and other renowned international experts, some of whom were part of the IARC Working Group assigned to glyphosate.

85. In an exhaustive and careful examination, the scientists scrutinized the 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 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.<sup>51</sup>

86. With respect to human data, the scientists pointed out that the EFSA agreed with the IARC that there was “*limited evidence* of carcinogenicity for NHL, but the EFSA nonetheless dismissed an association between glyphosate exposure and carcinogenicity. The IARC applies three (3) levels of evidence in its analyses of human data, including sufficient evidence and limited evidence. The EFSA’s ultimate conclusion that “there was no unequivocal evidence for a clear and strong association of NHL with glyphosate” was misleading because it was tantamount to IARC’s highest level of evidence: “sufficient evidence,” which means that a causal

---

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

relationship has been established. However, the scientists argued, “[legitimate public health concerns arise when ‘causality is credible,’ i.e., when there is *limited evidence*.”<sup>52</sup>

87. Among its many other deficiencies, the EFSA’s conclusions regarding animal carcinogenicity data were “scientifically unacceptable,” particularly in BfR’s use of historical control data and in its trend analysis. Indeed, 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. For instance, the EFSA report dismisses 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 the 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. The scientists concluded:

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,

---

<sup>52</sup> *Id.*

but in fact document the carcinogenicity of glyphosate in laboratory animals.<sup>53</sup>

88. The letter also critiqued the EFSA report's lack of transparency and the opacity surrounding the 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." Because the BfR relied on unpublished, confidential industry-provided studies, it is "impossible for any scientist not associated with the BfR to review this conclusion with scientific confidence."<sup>54</sup>

89. On March 3, 2016, the letter was published in the *Journal of Epidemiology & Community Health*.<sup>55</sup>

***Statement of Concern Regarding Glyphosate-Based Herbicides***

90. On February 17, 2016, a consensus statement published in the journal *Environmental Health*, entitled "Concerns Over Use of Glyphosate-based Herbicides and Risks Associated with Exposures: a Consensus Statement," assessed the safety of glyphosate-based herbicides ("GBHs").<sup>56</sup>

- a) GBHs are the most heavily applied herbicide in the world and usage continues to rise;

---

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> 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>.

<sup>56</sup> 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>.

- b) Worldwide, GBHs often contaminate drinking water sources, precipitation and air, especially in agricultural regions;
- c) The half-life of glyphosate in water and soil is longer than previously recognized;
- d) Glyphosate and its metabolites are widely present in the global soybean supply;
- e) Human exposures to GBHs are rising;
- f) Glyphosate is now authoritatively classified as a probable human carcinogen; and
- g) Regulatory estimates of tolerable daily intakes for glyphosate in the United States and EU are based on outdated science.

91. The researchers noted that GBH use has 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 vertebrate pathways are likely targets of action, including hepatorenal damage, effects on nutrient balance through glyphosate chelating action and endocrine disruption.”<sup>57</sup>

92. 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.”<sup>58</sup>

93. 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.”

---

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

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.”<sup>59</sup>

94. 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.”<sup>60</sup>

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

96. 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

---

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

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.

### ***European Union Vote on Glyphosate Renewal***

97. The license for glyphosate in the EU was set to expire on June 30, 2016.

98. Without an extension of the license, Monsanto's Roundup® and other glyphosate-based herbicides faced a general phase out in EU markets.<sup>61</sup>

99. In the months leading up to the license expiration date, protracted meetings and votes among national experts from the 28 EU Member States failed to produce agreement on an extension.

100. For instance, on March 4, 2016, The Guardian reported that France, the Netherlands, and Sweden did not support EFSA's assessment that glyphosate was harmless.<sup>62</sup> The paper quoted the Swedish environment minister, Åsa Romson, as stating: "[w]e 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's scientists have been more transparent about their considerations."<sup>63</sup>

---

<sup>61</sup> Philip Blenkinsop, Alissa de Carbonnel & Barbara Lewis European, *Commission to Extend Glyphosate License for 18 Months*, REUTERS, June 28, 2016, available at <http://www.reuters.com/article/us-health-euglyphosate-idUSKCN0ZE25B>

<sup>62</sup> Arthur Neslen, *EU States Rebel against Plans to Relicense Weedkiller Glyphosate*, THE GUARDIAN, Mar. 4, 2016, available at <http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicenseweedkiller-glyphosate>.

<sup>63</sup> *Id.*

101. The Netherlands argued that relicensing should be placed on hold until after a separate evaluation of glyphosate's toxicity can be conducted.<sup>64</sup> Leading up to the vote, Italy joined the other EU states in opposing the license renewal, citing health concerns.<sup>65</sup>

102. On June 6, 2016, Member States voted but failed to reach a qualified majority in favor or against the re-authorization of glyphosate.<sup>66</sup>

103. On June 29, 2016, the EU Commission extended the European license for glyphosate for 18 months to allow the European Chemical Agency to rule on the safety of the chemical, which is expected by the end of 2017. 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."<sup>67</sup>

104. On July 11, 2016, the EU voted in favor of a proposal to restrict the conditions of use of glyphosate in the EU, including a ban on common co-formulant POE-tallowamine ("POEA") from all glyphosate-based herbicides, including Roundup®.<sup>68</sup>

---

<sup>64</sup> 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-weedkillerlicence-postponed-glyphosate>

<sup>65</sup> *Id.*

<sup>66</sup> Manon Flausch, *Commission Prolongs Glyphosate License by 18 Months*, EURACTIV, June 29, 2016, available at <http://www.euractiv.com/section/agriculture-food/news/commission-prolongs-glyphosate-licence-by-18-months/>.

<sup>67</sup> Arthur Neslen, *Controversial Chemical in Roundup Weedkiller Escapes Immediate Ban*, THE GUARDIAN, June 29, 2016, available at <https://www.theguardian.com/business/2016/jun/29/controversial-chemical-roundupweedkiller-escapes-immediate-ban>.

<sup>68</sup> Sarantis Michalopoulos, *EU Agrees Ban on Glyphosate Co-formulant*, EURACTIV, July 11, 2016, available at [http://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-glyphosate-coformulant/?nl\\_ref=16562829](http://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-glyphosate-coformulant/?nl_ref=16562829).



105. These restrictions, which are non-binding on the EU states, are expected to apply until the European Chemicals Agency issues an opinion on the chemical's safety.<sup>69</sup>

***Jack Lewis's Exposure to Roundup®***

106. Jack Lewis was exposed to Roundup® from approximately 2001 to approximately 2005 while tending to the backyard of his residence in Wooster, Ohio. Specifically, Mr. Lewis sprayed Ready-to-Use Roundup® on the property at least once a month, generally during the months of April through September.

107. On or about August 8, 2008, Mr. Lewis was diagnosed with chronic lymphocytic leukemia/small lymphocytic lymphoma in Akron, Ohio at Summa Health System, and suffered the effects attendant thereto, as a direct and proximate result of the unreasonably dangerous and defective nature of Roundup® and Defendant's wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, advertising and sale of Roundup®.

108. During the entire time that Jack Lewis was exposed to Roundup®, he did not know that exposure to Roundup® was injurious to his health or the health of others.

**COUNT I**

**DESIGN DEFECT**

109. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

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

---

<sup>69</sup> See Arthur Neslen, *Controversial Chemical in Roundup Weedkiller Escapes Immediate Ban*, THE GUARDIAN, June 29, 2016.

including the Plaintiffs, thereby placing Roundup® products into the stream of commerce. These actions were under the ultimate control and supervision of Monsanto. At all times relevant to this litigation, Monsanto designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the Roundup® products used by Mr. Lewis, as described above.

111. At all times relevant to this litigation, Monsanto's Roundup® products were defectively designed by causing an increased risk of cancer and by containing additives that, when combined with glyphosate, significantly increased the risk of developing cancer.

112. These design defects rendered Roundup® unreasonably dangerous.

113. The dangers posed by Roundup® go beyond that which would be contemplated by the ordinary consumer with ordinary knowledge common to the community as to its characteristics.

114. Additionally, the benefits of the Roundup® design are outweighed by the design's inherent risk of danger in causing cancer.

115. At all times relevant to this litigation, Roundup® products reached the intended consumers, handlers, and users or other persons coming into contact with these products in the State of Ohio and throughout the United States, including Mr. Lewis, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Monsanto.

116. At all times relevant to this action, Monsanto knew or had reason to know that its Roundup® products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Monsanto.

117. Monsanto could have employed a safer alternative design to render Roundup® safe or, in the alternative, provided proper instructions for use on how to limit the potential risk associated with Roundup®'s defective design. Monsanto's Roundup® products were and are more dangerous than alternative products and Monsanto could have designed its Roundup® products to make them less dangerous. At the time Monsanto designed its Roundup® products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable. Thus, 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 herbicides.

118. Mr. Lewis was exposed to Monsanto's Roundup® products while caring for his property, as described above, without knowledge of Roundup®'s dangerous characteristics.

119. At all times relevant to this litigation, Mr. Lewis used and/or was exposed to the use of Monsanto's Roundup® products in an intended or reasonably foreseeable manner, without knowledge of Roundup®'s dangerous characteristics.

120. Mr. Lewis could not reasonably have discovered the defects and risks associated with Roundup® or glyphosate-containing products before or at the time of exposure due to Monsanto's suppression of scientific information linking glyphosate to cancer.

121. The defects in Monsanto's Roundup® products were substantial and contributing factors in causing Mr. Lewis's injuries, and but for Monsanto's misconduct and omissions, he would not have sustained said injuries.

122. Monsanto's defective design of its Roundup® products was willful, wanton, fraudulent, malicious, and conducted with reckless disregard for the health and safety of users of the Roundup® products, including Mr. Lewis herein.

123. Monsanto's conduct, as described above, was reckless. Monsanto risked the lives of consumers and users of its products, including Mr. Lewis, with knowledge of the safety problems associated with Roundup® and glyphosate-containing products, and suppressed this knowledge from the general public. Monsanto made conscious decisions not to redesign, warn or inform the unsuspecting public. Monsanto's reckless conduct warrants an award of punitive damages.

124. As a direct and proximate result of the Defendant's overt unlawful acts regarding the nature of the Roundup® products, including, but not limited to, placing its defective Roundup® products into the stream of commerce, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **COUNT II**

### **INADEQUATE WARNING**

125. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

126. 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 Jack Lewis, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Roundup® and specifically, the active ingredient glyphosate. These actions were under the ultimate control and supervision of Monsanto.

127. 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 Mr. Lewis, and therefore had a duty to warn of the risks associated with the use of Roundup® and glyphosate-containing products.

128. At all times relevant to this litigation, Monsanto had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure its Roundup® products did not cause users and consumers to suffer from unreasonable and dangerous risks. Monsanto had a continuing duty to warn Mr. Lewis of the dangers associated with Roundup® use and exposure. Monsanto, as manufacturer, seller, or distributor of chemical herbicides is held to the knowledge of an expert in the field.

129. At the time of manufacture, Monsanto could have provided the 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 such products. Such warnings could have been disclosed in circumstances not limited to the Roundup® labeling.

130. At all times relevant to this litigation, Monsanto failed to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of its product and to those who would foreseeably use or be harmed by Monsanto's herbicides, including Mr. Lewis.

131. Despite the fact that Monsanto knew or should have known that Roundup® posed a grave risk of harm, it failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. 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, at the time it distributed, supplied or sold the product, and not known to end users and consumers, such as Mr. Lewis.

132. Monsanto knew or should have known that its products created significant risks of serious bodily harm to consumers, as alleged herein, and Monsanto failed to adequately warn consumers, i.e., the reasonably foreseeable users, of the risks of exposure to its products. Monsanto has 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.

133. At all times relevant to this litigation, Monsanto's Roundup® products reached the intended consumers, handlers, and users or other persons coming into contact with these products in Ohio and throughout the United States, including Mr. Lewis, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Monsanto.

134. Jack Lewis was exposed to Monsanto's Roundup® products while tending to his property, as described above, without knowledge of their dangerous characteristics.

135. At all times relevant to this litigation, Mr. Lewis used and/or was exposed to the use of Roundup® products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

136. Mr. Lewis could not have reasonably discovered the defects and risks associated with Roundup® or glyphosate-containing products prior to or at the time of his exposure. Mr.

Lewis relied upon the skill, superior knowledge, and judgment of Monsanto to know about and disclose serious health risks associated with using the products.

137. Monsanto knew or should have known that the minimal warnings disseminated with its Roundup® products were inadequate, 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.

138. This alleged failure to warn is not limited to the information contained on Roundup®'s labeling. Monsanto was able, in accord with federal law, to comply with Ohio law by disclosing the known risks associated with Roundup® through other non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public information sources. Monsanto, however, did not disclose these known risks through any medium.

139. To this day, Monsanto has failed to adequately and accurately warn of the risks of cancer associated with the use of and exposure to Roundup® and its active ingredient glyphosate.

140. As a result of their inadequate warnings, 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 Mr. Lewis as described herein.

141. Monsanto is liable to Plaintiff for his injuries caused by its negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of its products and the risks associated with the use of or exposure to Roundup® and glyphosate.

142. Had Monsanto provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Roundup® products, Mr. Lewis could have avoided the risk of developing injuries and could have obtained or used alternative herbicides.

143. As a direct and proximate result of the Defendant's overt unlawful acts regarding the nature of the Roundup® products, including, but not limited to, placing its defective Roundup® products into the stream of commerce, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

### **COUNT III**

#### **NEGLIGENCE**

144. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

145. At all times relevant to this litigation, Monsanto had a 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, advertise, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

146. At all times relevant to this litigation, Monsanto had a duty to exercise reasonable care in the marketing, advertisement, and sale of the Roundup® products. Monsanto's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Roundup® and appropriate, complete, and accurate warnings concerning the potential adverse effects of exposure to Roundup®, and, in particular, its active ingredient glyphosate.



147. At all times relevant to this litigation, 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.

148. Accordingly, at all times relevant to this litigation, Monsanto knew or, in the exercise of reasonable care, should have known that use of or exposure to its Roundup® products could cause or be associated with Mr. Lewis's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of these products, including Mr. Lewis.

149. 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 use of and/or exposure to Roundup® and glyphosate-containing products.

150. As such, 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.

151. Monsanto was negligent in its promotion of Roundup®, outside of the labeling context, by failing to disclose material risk information as part of its promotion and marketing of Roundup®, including the internet, television, print advertisements, etc. Nothing prevented Monsanto from being honest in its promotional activities, and in fact, Monsanto had a

duty to disclose the truth about the risks associated with Roundup® in its promotional efforts, outside of the of the context of labeling.

152. Monsanto had and has the ability and means to investigate, study, and test its products and to provide adequate warnings, Monsanto has failed to do so. 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.

153. Monsanto's negligence included:

- a) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising and/or distributing its Roundup® products without thorough and adequate pre- and post-market testing;
- b) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising and/or distributing Roundup® while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of exposure to glyphosate, and, consequently, the risk of serious harm associated with human use of and exposure to Roundup®;
- c) Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Roundup® products and glyphosate-containing products were safe for their intended use in agriculture and horticulture;
- d) Failing to use reasonable and prudent care in the design, research, manufacture, 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;
- e) 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;

- f) Failing to provide adequate instructions, guidelines, and safety precautions to those persons Monsanto could reasonably foresee would use and be exposed to its Roundup® products;
- g) Failing to disclose to Mr. Lewis, users/consumers, and the general public that use of and exposure to Roundup® presented severe risks of cancer and other grave illnesses;
- h) Failing to warn Mr. Lewis, 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 Mr. Lewis and other consumers;
- i) Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Roundup® and glyphosate-containing products;
- j) Representing that its Roundup® products were safe for their intended use when, in fact, Monsanto knew or should have known the products were not safe for their intended purpose;
- k) Declining to make or propose any changes to Roundup® products' labeling or other promotional materials that would alert consumers and the general public of the risks of Roundup® and glyphosate;
- l) Advertising, marketing, and recommending the use of the 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;

- m) Continuing to disseminate information to its consumers, which indicate or imply that Monsanto's Roundup® products are safe for use in the agricultural and horticultural industries; and
- n) Continuing the manufacture and sale of its products with the knowledge that the products were unreasonably unsafe and dangerous.

154. Monsanto knew and/or should have known that it was foreseeable consumers such as Mr. Lewis would suffer injuries as a result of Monsanto's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Roundup®.

155. Jack Lewis 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 Mr. Lewis's injuries, i.e., absent Monsanto's negligence, Mr. Lewis would not have developed NHL.

156. Monsanto's conduct, as described above, was reckless. Monsanto regularly risks the lives of consumers and users of its products, including Mr. Lewis, with full knowledge of the dangers of its products. Monsanto has made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Mr. Lewis. Monsanto's reckless conduct therefore warrants an award of punitive damages.

157. WHEREFORE, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT IV**

**FRAUD**

158. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

159. Monsanto has defrauded the agricultural and gardening communities in general and Mr. Lewis in particular by misrepresenting the true safety of Roundup® and by failing to disclose known risks of cancer.

160. Monsanto misrepresented and/or failed to disclose, inter alia, that: glyphosate and its major metabolite aminomethylphosphonic acid (“AMPA”) could cause cancer; glyphosate and AMPA are known to be genotoxic in humans and laboratory animals because exposure is known to cause DNA strand breaks (a precursor to cancer); glyphosate and AMPA are known to induce oxidative stress in humans and laboratory animals (a precursor to cancer); glyphosate and AMPA interfere with the aromatic amino acids within the human gut, leading to downstream health conditions including cancer; exposure to glyphosate and AMPA is causally associated with NHL; and the laboratory tests attesting to the safety of glyphosate were flawed and/or fraudulent.

161. Due to these misrepresentations and omissions, at all times relevant to this litigation, Roundup® was misbranded under 7 U.S.C. § 136(g) and its distribution within Ohio and around the United States was a violation of 7 U.S.C. § 136(j) and 40 C.F.R. § 156.10(a)(5).

162. When Jack Lewis used Roundup® from approximately 2001 through approximately 2005, neither the labeling on the product nor Monsanto’s general promotion warned or disclosed the true safety risks of Roundup® or that the product could cause cancer, as described above. Since the true risk information was known to Monsanto and was not reasonably knowable to reasonable consumers, Mr. Lewis was unaware of these material facts and/or omissions prior to using the product.

163. Jack Lewis relied on Monsanto’s misrepresentations and/or material omissions regarding the safety of Roundup® and its active ingredient glyphosate in deciding whether to use the product. Mr. Lewis did not know, nor could he reasonably have known, of the

misrepresentations and/or material omissions by Monsanto concerning Roundup® and its active ingredient glyphosate.

164. The misrepresentations and/or material omissions that form the basis of this fraud claim is not limited to statements made on the Roundup® labeling, as defined under federal law, but also involve Monsanto's representations and omissions made as part of its promotion and marketing of Roundup®, including on the internet, television, in print advertisements, etc. Nothing prevented Monsanto from disclosing the truth about the risks associated with Roundup® in its promotional efforts outside of the labeling context, using the forms of media and promotion Monsanto traditionally used to promote the product's efficacy and benefits.

165. When Monsanto made the misrepresentations and/or omissions as alleged in this pleading, it did so with the intent of defrauding and deceiving the public in general and with the intent of inducing the public to purchase and use Roundup®.

166. Monsanto made these misrepresentations and/or material omissions with malicious, fraudulent, and/or oppressive intent toward Mr. Lewis and the public generally. Monsanto's conduct was willful, wanton, and/or reckless. Monsanto deliberately manufactured, produced, marketed, sold, distributed, merchandized, packaged, promoted and advertised the dangerous and defective herbicide Roundup®. This constitutes an utter, wanton, and conscious disregard of the rights and safety of a large segment of the public including Jack Lewis, and by reason thereof, Monsanto, is liable for reckless, willful, and wanton acts and omissions which evidence a total and conscious disregard for the safety of Mr. Lewis and others which proximately caused the injuries as set forth herein.

167. Jack Lewis sustained injuries as a proximate result of Monsanto's fraudulent and deceitful conduct, advertisements, and representations.

168. WHEREFORE, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT V**

**BREACH OF EXPRESS WARRANTY**

169. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

170. Monsanto expressly warranted that Roundup® was safe and accepted by consumers.

171. Roundup® does not conform to these express representations, because Roundup® is not safe and carries with it an increased risk of cancer by containing additives that, when combined with glyphosate, significantly increased the risk of developing cancer.

172. Jack Lewis relied on Monsanto's express warranties. Furthermore, the express warranties represented by Monsanto were a part of the basis for Mr. Lewis's use of Roundup®, and he relied upon these warranties in deciding to use Roundup®.

173. At the time of the making of express warranties, Monsanto had knowledge of the purpose for which Roundup® was to be used, and warranted same to be in all respects safe, effective, and proper for such use.

174. Monsanto expressly represented to Mr. Lewis that Roundup® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other herbicides, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

175. Monsanto knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue in that Roundup® was not safe and fit for the use intended, and, in fact, Roundup® produced serious injuries to the users that were not accurately identified and represented by Monsanto.

176. As a result of the foregoing acts and omissions, Monsanto caused Jack Lewis to suffer serious and dangerous side effects, severe and personal injuries, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; mental anguish; severe and debilitating emotional distress; physical and mental pain, suffering, and discomfort; and loss and impairment of the quality and enjoyment of life.

177. WHEREFORE, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **COUNT VI**

### **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

178. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

179. At the time Monsanto manufactured, marketed, labeled, promoted, distributed and/or sold Roundup® products, Monsanto knew of the uses for which the Roundup® products were intended, and impliedly warranted the Roundup® products were merchantable and fit for the ordinary purposes for which they were intended.

180. Members of the consuming public, including consumers such as Mr. Lewis, were intended third-party beneficiaries of the warranty.

181. The Roundup® products were not merchantable or fit for their ordinary purposes,



because they had a propensity to lead to the serious personal injuries described herein.

182. Mr. Lewis reasonably relied on Monsanto's representations that Roundup® products were safe and free of defects.

183. Monsanto's breach of the implied warranty of merchantability was the direct and proximate cause of Mr. Lewis's injuries.

184. Monsanto's conduct, as described above, was extreme and outrageous. Monsanto risked the lives of the consumers and users of their Roundup® products, including Mr. Lewis, with knowledge of the safety and efficacy problems, and suppressed this knowledge from Mr. Lewis and the general public. Monsanto made conscious decisions not to redesign, relabel, warn or inform Mr. Lewis or the unsuspecting consuming public.

185. As a direct and proximate result of Monsanto's implied warranties of merchantability concerning the Roundup® products, as described herein, Plaintiff suffered and continues to suffer from the injuries and damages warranting an entitlement to recovery.

186. WHEREFORE, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **COUNT VII**

### **BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE**

187. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

188. Monsanto manufactured, supplied and sold Roundup® products with an implied warranty that they were fit for the particular purpose for which they were warranted.

189. Members of the consuming public, including Mr. Lewis, were the intended third-party beneficiaries of the warranty.

190. The Roundup® products were not fit for the particular purpose for which they were warranted without serious risk of personal injury, which risk is much higher than other products designed to perform the same function.

191. Mr. Lewis reasonably relied on Monsanto's representations that the Roundup® products were safe and effective for use.

192. Monsanto's breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Mr. Lewis's injuries.

193. Monsanto's conduct, as described above, was extreme and outrageous. Monsanto risked the lives of the consumers and users of their Roundup® products, including Mr. Lewis, by having knowledge of the safety and efficacy problems associated with the Roundup® products, but suppressing this knowledge from the public. Monsanto made a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public. Monsanto's outrageous conduct warrants an award of punitive damages.

194. As a direct and proximate result of Monsanto's implied warranties of fitness concerning Roundup® products, as described herein, Plaintiff suffered and continues to suffer from the injuries and damages warranting an entitlement to recovery.

195. WHEREFORE, Plaintiff demands judgment against the Defendant, and requests compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

### **COUNT VIII**

#### **DISCOVERY RULE AND EQUITABLE TOLLING**

196. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including the discovery rule, delayed discovery, equitable tolling, and fraudulent concealment.

197. The discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known of the cause of Plaintiff's injury, and the tortious nature of the wrongdoing that caused Plaintiff's injury.

198. Despite diligent investigation by Plaintiff into the cause of his injury, he did not and could not have discovered the cause until recently. Accordingly, his claim has been filed within the applicable statutory period. In fact, Defendant continues to deny any causal connection between Roundup® and NHL, and thus should be estopped from asserting a statute of limitations defense based on Plaintiff's failure to discover the cause of his injury until recently.

199. The running of the statute of limitations in this cause should also be tolled due to equitable tolling based on Defendant's fraudulent concealment. Defendant is estopped from asserting a statute of limitations defense due to its fraudulent concealment, through affirmative misrepresentations and deliberate omissions, regarding the true risks associated with Roundup®, which were known by Defendant.

200. Defendant's affirmative misrepresentations were known by Defendants to be false and were calculated to mislead or deceive and to induce inaction by Plaintiff and others harmed by Roundup®. The information Defendant misrepresented was material to consumers and Plaintiff with regard to their decision to use Roundup®. Defendant made these material misrepresentations knowing they were false, unfair, fraudulent, deceptive, and misleading and made them intending to defraud, deceive, and mislead.

201. Because of the fraudulent acts of concealment of the true risks of Roundup® to users, Plaintiff was unaware, and could not reasonably have known, ascertained, or learned

through the exercise of reasonable due diligence, the true cause of his injuries until recently. Accordingly, Plaintiff's claim has been filed within the applicable statutory period.

### **PUNITIVE DAMAGES ALLEGATIONS**

202. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

203. Monsanto's conduct as alleged herein was done with oppression, fraud, and malice. Monsanto was fully aware of Roundup®'s safety risks. Nonetheless, Monsanto deliberately crafted its label, marketing, and promotion to mislead farmers and consumers.

204. This was not done by accident or through some justifiable negligence. Rather, Monsanto knew that it could turn a profit by convincing the agricultural industry and the general population that Roundup® was harmless to humans, and that full disclosure of Roundup®'s true risks would limit the amount of money Monsanto would make selling Roundup® in the State of Ohio. This was accomplished not only through its misleading, deceptive, fraudulent and unfair labeling, but also through a comprehensive scheme of selective fraudulent research and testing, misleading advertising, and deceptive omissions as more fully alleged throughout this pleading. Jack Lewis was robbed of his right to make an informed decision about whether to use an herbicide, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Mr. Lewis's rights.

205. There is no indication that Monsanto will stop its deceptive, unfair, fraudulent, misleading and unlawful marketing practices unless it is punished and deterred. Accordingly, Plaintiff Jack Lewis requests treble damages and punitive damages against Monsanto for the harms caused to him.

**DAMAGES**

206. For all the reasons stated herein, Jack Lewis is entitled to recover those damages consequential to the events complained of in this Complaint. The damages sought to be recovered include, but are not necessarily limited to, any mental or physical pain and suffering endured by Plaintiff; for all general damages reasonable in the premises; for all medical services incurred as a result of Jack Lewis's exposure to Roundup®; for all ascertainable losses, for all special expenses reasonable in the premises; for all general and equitable relief under the circumstances; legal interest from date of judicial demand; and any expenses incurred or to be incurred and for which Jack Lewis is responsible that are consequential to the events complained of in this action, and for such other damages as may be established at the trial of this action.

**JURY TRIAL DEMAND**

207. Plaintiff demands a trial by jury on all of the triable issues within this pleading.

**PRAYER FOR RELIEF**

208. WHEREFORE, Plaintiff requests that the Court enter judgment in his favor and against Monsanto, awarding:

- a) Special and general damages, and ascertainable losses in such amount to be determined at trial and as provided by applicable law;
- b) Exemplary, treble and punitive damages sufficient to punish and deter Monsanto and others from future deceptive, fraudulent, unfair, misleading, illegal and fraudulent practices;
- c) Pre-judgment and post-judgment interest;
- d) Costs including reasonable attorneys' fees and costs, court costs, and other litigation expenses; and
- e) Any other relief the Court may deem just and proper.

Dated: September 11, 2019

Respectfully Submitted,

By: *s/Peter H. Weinberger*

Peter H. Weinberger (0022076 )  
Spangenberg Shibley & Liber LLP  
1001 Lakeside Avenue East, Suite 1700  
Cleveland, Ohio 44114  
Phone: (216) 696-3232  
Fax: (216) 696-3924  
pweinberger@spanglaw.com

*Attorney for Plaintiff*