1	Case 2:18-cv-03588-ESW Document	1 Filed 10/30/18 Page 1 of 61		
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4 5				
6		DICEDICE COUDE		
7		DISTRICT COURT ICT OF ARIZONA		
8	Rudy Fuentes,			
9	Plaintiff,	COMPLAINT WITH JURY DEMAND		
10	V.			
11	Monsanto Company,			
12	Defendant.			
13	Plaintiff, Rudy Fuentes, by and through his u	undersigned counsel, for his Complaint against		
14	Defendant Monsanto Company, states:			
15	INTRODUCTION			
16 17	1. In 1970, Defendant Monsanto Company, Inc. ("Monsanto") discovered the herbicidal			
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19				
20	Roundup [®] . Roundup [®] is a non-selective herbicide used to kill weeds that commonly compete			
21	with the growing of crops. In addition to the active ingredient glyphosate, Roundup [®] contains the			
22	surfactant Polyethoxylated tallow amine (POEA) and/or adjuvants and other so-called "inert"			
23	ingredients. In 2001, glyphosate was the mos	st used pesticide active ingredient in American		
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	l de la constante de			

agriculture with 85-90 million pounds used annually. That number grew to 185 million pounds 1 in 2007.¹ As of 2013, glyphosate was the world's most widely used herbicide. 2 2. Monsanto is a multinational agricultural biotechnology corporation based in St. Louis, 3 4 Missouri, and incorporated in Delaware. It is the world's leading producer of glyphosate. As of 5 2009, Monsanto was the world's leading producer of seeds, accounting for 27% of the world seed 6 market.² The majority of these seeds are of the Roundup Ready[®] brand. The stated advantage of 7 Roundup Ready[®] crops is that they substantially improve a farmer's ability to control weeds, 8 because glyphosate can be sprayed in the fields during the growing season without harming the 9 crops. In 2010, an estimated 70% of corn and cotton and 90% of soybean fields in the United 10 11 States were Roundup Ready[®].³ 12 3. Monsanto's glyphosate products are registered in 130 countries and approved for use on 13 over 100 different crops.⁴ They are ubiquitous in the environment. Numerous studies confirm 14 that glyphosate is found in rivers, streams, and groundwater in agricultural areas where Roundup[®] 15 16 17 18 19 ¹ Arthur Grube et al., U.S. Envtl. Prot. Agency, *Pesticides Industry Sales and Usage*, 2006-2007 Market Estimates 14 (2011), available at 20 http://www.epa.gov/pesticides/pestsales/07pestsales/market estimates2007.pdf ² ETC Group, Who Will Control the Green Economy? 22 (2011), available at 21 http://www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf ³ William Neuman & Andrew Pollack, Farmers Cope With Roundup-Resistant Weeds, N.Y. 22 TIMES, May 3, 2010, available at http://www.nytimes.com/2010/05/04/business/energyenvironment/04weed.html?pagewan. ⁴ Monsanto, Backgrounder-History of Monsanto's Glyphosate Herbicides (Sep. 2, 2015), 23 available at http://www.monsanto.com/products/documents/glyphosate-background-24 materials/back_history.pdf.

1	is used. ⁵ It has been found in food, ⁶ in the urine of agricultural workers, ⁷ and even in the urine of					
2	urban dwellers who are not in direct contact with glyphosate. ⁸					
3	4. On March 20, 2015, the International Agency for Research on Cancer ("IARC"), an agency					
4	of the World Health Organization ("WHO"), issued an evaluation of several herbicides, including					
5	glyphosate. That evaluation was based, in part, on studies of exposures to glyphosate in several					
6	countries around the world, and it traces the health implications from exposure to glyphosate since					
7	2001.					
8						
9	5. On July 29, 2015, IARC issued the formal monograph relating to glyphosate. In that					
10	monograph, the IARC Working Group provides a thorough review of the numerous studies and					
11	data relating to glyphosate exposure in humans.					
12	6. The IARC Working Group classified glyphosate as a Group 2A herbicide, which means					
13	that it is probably carcinogenic to humans. The IARC Working Group concluded that the cancers					
14	most associated with glyphosate exposure are non-Hodgkin lymphoma and other haematopoietic					
15	most associated with gryphosate exposure are non-modgkin tymphoma and other naematoporetie					
16	$\frac{1}{5} \sum_{i=1}^{n} \frac{1}{2} \sum_{i=1}^{n} \frac{1}$					
17	⁵ See U.S. Geological Survey, USGS Technical Announcement: Widely Used Herbicide Commonly Found in Rain and Streams in the Mississippi River Basin (2011), available at					
	http://www.usgs.gov/newsroom/article.asp?ID=2909; see also U.S. Envtl. Prot. Agency,					
18	<i>Technical Factsheet on: Glyphosate</i> , available at http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/glyphosa.pdf.					
19	⁶ Thomas Pohn et al. Compositional Differences in Souheans on the Market: Churchesate					
20	at http://www.sciencedirect.com/science/article/pii/S0308814613019201.					
24	⁷ John F. Acquavella et al., <i>Glyphosate Biomonitoring for Farmers and Their Families: Results from the Farm Family Exposure Study</i> , 112(3) ENVTL. HEALTH PERSPECTIVES 321					

(2004), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241861/; Kathryn Z.
 Guyton et al., Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon &

 ²² Guyton et al., Carcinogenicity of Tetrachiorvinphos, Parathion, Malathion, I Glyphosate, 112 IARC Monographs 76, section 5.4 (2015), available at http://dx.doi.org/10.1016/S1470-2045(15)70134-8.
 23 http://dx.doi.org/10.1016/S1470-2045(15)70134-8.

 ⁸ Dirk Brändli & Sandra Reinacher, *Herbicides found in Human Urine*, 1 ITHAKA JOURNAL 270 (2012), available at <u>http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf</u>.

cancers, including lymphocytic lymphoma/chronic lymphocytic leukemia, B-cell lymphoma, and 1 multiple myeloma.9 2

7. The IARC evaluation is significant. It confirms what has been believed for years: that 3 4 glyphosate is toxic to humans.

5 Nevertheless, Monsanto, since it began selling Roundup®, has represented it as safe to 8. 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 8 herbicides, including Roundup[®], create no unreasonable risks to human health or to the environment. 10

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JURISDICTION AND VENUE

12 9. Federal diversity jurisdiction in this Court is proper under 28 U.S.C. § 1332 because 13 Plaintiff is a citizen of Arizona, a different state than the Defendant's place of incorporation 14 (Delaware) and Defendant's headquarters (Missouri), and the aggregate amount in controversy 15 exceeds \$75,000, exclusive of interest and costs.

10. This Court has personal jurisdiction over Monsanto because Monsanto transacts business 17 in Arizona and is a corporation doing business within Arizona. Monsanto knows or should have 18 19 known that its Roundup[®] products are and were sold throughout the state of Arizona, and, more 20 specifically, caused Roundup[®] to be sold to Plaintiff in Arizona.

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⁹ See Guyton et al., Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate, supra. 4

11. In addition, Monsanto maintains sufficient contacts with the State of Arizona such that this
 Court's exercise of personal jurisdiction over it does not offend traditional notions of fair play and
 substantial justice.

4 12. Venue is proper within this District because the events giving rise to this action happened
5 in or are closely related to this District.

PARTIES

PLAINTIFF RUDY FUENTES

9 13. Plaintiff Rudy Fuentes is a natural person, is a citizen of the State of Arizona, and is a
10 resident of Buckeye, Arizona.

14. Mr. Fuentes was exposed to Roundup[®] in or around Peoria, Arizona, from around 2002
through 2004; Surprise, Arizona, from around 2004 through 2009; and Glendale, Arizona, from
around 2009 through 2015. He was diagnosed with Follicular Lymphoma in November 2017.

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DEFENDANT MONSANTO COMPANY

15. Defendant Monsanto Company is a corporation created under the laws of the State of
 Delaware with its headquarters and principal place of business in St. Louis, Missouri.

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FACTS

19 16. At all times relevant to this complaint, Monsanto was the entity that discovered the
20 herbicidal properties of glyphosate and the manufacturer of Roundup[®], which contains the active
21 ingredient glyphosate and the surfactant POEA, as well as adjuvants and other "inert" ingredients.
22 Glyphosate is a broad spectrum, non-selective herbicide used in a wide variety of herbicidal
23 products around the world.

17. Plants treated with glyphosate translocate the systemic herbicide to their roots, shoot 1 regions, and fruit, where it interferes with the plant's ability to form aromatic amino acids 2 necessary for protein synthesis. Treated plants generally die within two to three days. Because 3 4 plants absorb glyphosate, it cannot be completely removed by washing or peeling produce or by 5 milling, baking, or brewing grains.

6 For nearly 40 years, farms across the world have used Roundup[®] without knowing of the 18. 7 dangers its use poses. That is because when Monsanto first introduced Roundup[®], it touted 8 glyphosate as a technological breakthrough: it could kill almost every weed without causing harm 9 either to people or to the environment. Of course, history has shown that not to be true. According 10 to WHO, the main ingredient of Roundup[®] – glyphosate – is a probable cause of cancer. Those 11 12 most at risk are farm workers and other individuals with workplace exposure to Roundup[®], such 13 as garden center workers, nursery workers, and landscapers. Agricultural workers are, once again, 14 victims of corporate greed. Monsanto assured the public that Roundup[®] was harmless. In order 15 to prove this, Monsanto has championed falsified data and has attacked legitimate studies that 16 revealed Roundup[®]'s dangers. Monsanto has led a prolonged campaign of misinformation to 17 convince government agencies, farmers and the general population that Roundup[®] is safe. 18

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The Discovery of Glyphosate and Development of Roundup[®]

20 19. The herbicidal properties of glyphosate were discovered in 1970 by Monsanto chemist 21 John Franz. The first glyphosate-based herbicide was introduced to the market in the mid-1970's 22 23 24 6 25

under the brand name Roundup[®].¹⁰ From the outset, Monsanto marketed Roundup[®] as a "safe" general purpose herbicide for widespread commercial and consumer use. It still markets Roundup[®] as safe today.¹¹ 3

In addition to the active ingredient glyphosate, Roundup[®] formulations also contain 20. 5 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 8 in their own right.

Registration of Herbicides under Federal Law 10

The manufacture, formulation, and distribution of herbicides, such as Roundup[®], are 11 21. 12 regulated under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or "Act"), 7 13 U.S.C. § 136 et seq. FIFRA requires that all pesticides be registered with the Environmental 14 Protection Agency ("EPA" or "Agency") prior to their distribution, sale, or use, except as 15 described by the Act. 7 U.S.C. § 136a(a). 16

22. Because pesticides are toxic to plants, animals, and humans, at least to some degree, the 17 EPA requires as part of the registration process, among other things, a variety of tests to evaluate 18 19 the potential for exposure to pesticides, toxicity to people and other potential non-target 20 organisms, and other adverse effects on the environment. Registration by the EPA, however, is 21

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²² ¹⁰ Monsanto, Backgrounder, History of Monsanto's Glyphosate Herbicide (Sep. 2, 2015), available at http://www.monsanto.com/products/documents/glyphosate-background-23 materials/back history.pdf.

¹¹ Monsanto, What is Glyphosate? (Sep. 2, 2015), available at 24 http://www.monsanto.com/sitecollectiondocuments/glyphosate-safety-health.pdf.

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).

5 23. 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 EPA to make a risk/benefit analysis in determining whether a registration should be granted or a pesticide allowed to continue to be sold in commerce.

11 24. The EPA and the State of Arizona registered Roundup[®] for distribution, sale, and
12 manufacture in the United States and the State of Arizona.

13 25. FIFRA generally requires that the registrant, Monsanto in the case of Roundup[®], conducts
14 the health and safety testing of pesticide products. The EPA has protocols governing the conduct
15 of tests required for registration and the laboratory practices that must be followed in conducting
16 these tests. The data produced by the registrant must be submitted to the EPA for review and
18 evaluation. The government is not required, nor is it able, however, to perform the product tests
19 that are required of the manufacturer.

26. The evaluation of each pesticide product distributed, sold, or manufactured is completed at
21 the time the product in initially registered. The data necessary for registration of a pesticide has
22 changed over time. The EPA is now in the process of re-evaluating all pesticide products through
23 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 recent review and evaluation.

3 27. In the case of glyphosate, and therefore Roundup[®], the EPA had planned on releasing its
4 preliminary risk assessment – in relation to the reregistration process – no later than July 2015.
5 The EPA completed its review of glyphosate in early 2015, but it delayed releasing the risk assessment pending further review in light of the WHO's health-related findings.

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

28. Based on early studies showing that glyphosate could cause cancer in laboratory animals, 9 the EPA originally classified glyphosate as *possibly carcinogenic to humans* (Group C) in 1985. 10 11 After pressure from Monsanto, including contrary studies it provided to the EPA, the EPA 12 changed its classification to evidence of non-carcinogenicity in humans (Group E) in 1991. In so 13 classifying glyphosate, however, the EPA made clear that the designation did not mean the 14 chemical does not cause cancer: "It should be emphasized, however, that designation of an agent 15 in Group E is based on the available evidence at the time of evaluation and should not be 16 interpreted as a definitive conclusion that the agent will not be a carcinogen under any 17 circumstances."12 18

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

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 ¹² U.S. Envtl. Prot. Agency, *Memorandum, Subject: SECOND Peer Review of Glyphosate* 1 (1991), available at <u>http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct-91_265.pdf.</u>

30. 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[®].¹³ IBT performed about 30 tests on glyphosate and glyphosate containing
products, including nine of the 15 residue studies needed to register Roundup[®].

5 31. In 1976, the United States Food and Drug Administration ("FDA") performed an
inspection of IBT that revealed discrepancies between the raw data and the final report relating to
the toxicological impacts of glyphosate. The EPA subsequently audited IBT; it too found the
toxicology studies conducted for the Roundup[®] herbicide to be invalid.¹⁴ 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."¹⁵

12 32. Three top executives of IBT were convicted of fraud in 1983.

13 33. In the second incident of data falsification, Monsanto hired Craven Laboratories in 1991
14 to perform pesticide and herbicide studies, including for Roundup[®]. In that same year, the owner
15 of Craven Laboratories and three of its employees were indicted, and later convicted, of fraudulent
16 laboratory practices in the testing of pesticides and herbicides.¹⁶

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- 19 ¹³ Monsanto, *Backgrounder*, *Testing Fraud: IBT and Craven Laboratories* (Sep. 2, 2015, available at <u>http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf</u>.

22 <u>https://nepis.eps.gov/Exe/ZyPDF.cgi/91014ULV.PDF?Dockey=91014ULV.PDF</u>.

- ²⁴ ¹⁶ Monsanto, *Backgrounder, Testing Fraud: IBT and Craven Laboratories, supra.*
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²¹ ¹⁴ U.S. Envtl. Prot. Agency, *Summary of the IBT Review Program Office of Pesticide Programs* (1983), available at

 ¹⁵ Marie-Monique Robin, *The World According to Monsanto: Pollution, Corruption and the Control of the World's Food Supply* (2011) (*citing* U.S. Envtl. Prot. Agency, *Data Validation, Memo from K. Locke, Toxicology Branch, to R. Taylor, Registration Branch.* Washington, D.C. (August 9, 1978)).

34. Despite the falsity of the tests that underlie its registration, within a few years of its launch,
 Monsanto was marketing Roundup[®] in 115 countries.

3 <u>The Importance of Roundup[®] to Monsanto's Market Dominance Profits</u>

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

In response, Monsanto began the development and sale of genetically engineered Roundup 36. 10 Ready[®] seeds in 1996. Since Roundup Ready[®] crops are resistant to glyphosate, farmers can 11 12 spray Roundup[®] onto their fields during the growing season without harming the crop. This 13 allowed Monsanto to expand its market for Roundup® even further; by 2000, Monsanto's 14 biotechnology seeds were planted on more than 80 million acres worldwide and nearly 70% of 15 American soybeans were planted from Roundup Ready[®] seeds. It also secured Monsanto's 16 dominant share of the glyphosate/Roundup[®] market through a marketing strategy that coupled 17 proprietary Roundup Ready[®] seeds with continued sales of its Roundup[®] herbicide. 18

19 37. Through a three-pronged strategy of increasing production, decreasing prices, and by
 20 coupling with Roundup Ready[®] seeds, Roundup[®] became Monsanto's most profitable product.
 21 In 2000, Roundup[®] accounted for almost \$2.8 billion in sales, outselling other herbicides by a
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margin of five to one, and accounting for close to half of Monsanto's revenue.¹⁷ Today,
glyphosate remains one of the world's largest herbicides by sales volume.

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

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

- a) "Remember that environmentally friendly Roundup herbicide is biodegradable. It
 won't build up in the soil so you can use Roundup with confidence along customers'
 driveways, sidewalks and fences..."
- 14 b) "And remember that Roundup is biodegradable and won't build up in the soil. That
 15 will give you the environmental confidence you need to use Roundup everywhere
 16 you've got a weed, brush, edging or trimming problem."

18 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."

 ¹⁷ 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 <u>http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-killer-is-a-block-for-monsanto-to-build-on.html</u>.

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

f) "You can apply Roundup with 'confidence because it will stay where you put it' it binds tightly to soil particles, preventing leaching. Then, soon after application, soil microorganisms biodegrade Roundup into natural products."

g) "Glyphosate is less toxic to rats than table sale following acute oral ingestion."

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

- "You can feel good about using herbicides by Monsanto. They carry a toxicity category rating of 'practically non-toxic' as it pertains to mammals, birds and fish."
- j) "Roundup can be used where kids and pets will play and breaks down into natural material." This ad depicts a person with his head in the ground and a pet dog standing in an area which has been treated with Roundup[®].¹⁸

17 39. On November 19, 1996, Monsanto entered into an Assurance of Discontinuance with
18 NYAG, in which Monsanto agreed, among other things, "to cease and desist from publishing or
19 broadcasting any advertising [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.

²⁴ ¹⁸ 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).

1	b)	* * * * its glyphosate containing pesticide products or any component thereof
2	-,	manufactured, formulated, distributed or sold by Monsanto are biodegradable.
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4 5		* * *
	c)	its glyphosate containing pesticide products or any component thereof stay where
6 7		they are applied under all circumstances and will not move through the environment
' 8		by any means.
9		* * *
10	d)	its glyphosate containing pesticide products or any component thereof are "good"
11		for the environment or are "known for their environmental characteristics."
12		* * *
13	e)	glyphosate containing pesticide products or any component thereof are safer or less
14	()	
15		toxic than common consumer products other than herbicides;
16	f)	its glyphosate containing products or any component thereof might be classified as
17		"practically non-toxic."
18	40. Monsa	anto did not alter its advertising in the same manner in any state other than New York,
19	and on information and belief it still has not done so as of today.	
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41. 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 judgment that Monsanto had falsely advertised
its herbicide Roundup[®] as "biodegradable" and that it "left the soil clean."¹⁹

4 <u>Classification and Assessments of Glyphosate</u>

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

12 43. The established procedure for IARC Monograph evaluations is described in the IARC
 13 Programme's Preamble.²⁰ Evaluations are performed by panels of international experts, selected
 14 on the basis of their expertise and the absence of actual or apparent conflicts of interest.

44. One year before the Monograph meeting, the meeting is announced and there is a call both
for data and for experts. Eight months before the Monograph meeting, the Working Group
membership is selected and the sections of the Monograph are developed by the Working Group
members. One month prior to the Monograph meeting, the call for data is closed and the various
draft sections are distributed among Working Group members for review and comment. Finally,

23 ¹⁹ *Monsanto Guilty in 'False Ad' Row*, BBC, Oct. 15, 2009, available at <u>http://news.bbc.co.uk/2/hi/europe/8308903.stm</u>.

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²⁴ ²⁰ World Health Org., *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble* (2006), available at <u>http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf</u>.

at the Monograph meeting, the Working Group finalizes review of all literature, evaluates the 1 evidence in each category, and completes the overall evaluation. Within two weeks after the 2 Monograph meeting, the summary of the Working Group findings are published in The Lance 3 4 *Oncology*, and within a year after the meeting, the finalized Monograph is published.

45. 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 by publicly available and 8 have sufficient detail for meaningful review, and reviewers cannot be associated with the underlying study.

11 46. In March 2015, IARC reassessed glyphosate. The summary published in The Lancet 12 *Oncology* reported that glyphosate is a Group 2A agent and probably carcinogenic in humans.

13 47. On July 29, 2015, IARC issued its Monograph for glyphosate, Monograph Volume 112. 14 For Volume 112, a Working Group of 17 experts from 11 countries met at IARC from March 3-15 10, 2015 to assess the carcinogenicity of certain herbicides, including glyphosate. The March 16 meeting culminated a nearly one year review and preparation by the IARC Secretariat and the 17 Working Group, including a comprehensive review of the latest available scientific evidence. 18 19 According to published procedures, the Working Group considered "reports that have been 20 published or accepted for publication in the openly available scientific literature" as well as "data 21 from governmental reports that are publicly available."

48. The studies considered the following exposure groups: (1) occupational exposure of farmers and tree nursery workers in the United States, forestry workers in Canada and Finland

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and municipal weed-control workers in the United Kingdom; and (2) para-occupational exposure in farming families.

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.
50. 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.

9 51. The assessment of the IARC Working Group identified several case control studies of
10 occupational exposure in the United States, Canada, and Sweden. These studies show a human
11 health concern from agricultural and other work related exposure to glyphosate.

12 52. The IARC Working Group found an increased risk between exposure to glyphosate and
 13 NHL and several subtypes of NHL, and the increased risk persisted after adjustment for other
 14 pesticides.

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

19 54. In male CD-1 mice, glyphosate induced a positive trend in the incidence of a rare tumor:
 20 renal tubule carcinoma. A second study reported a positive trend for haemangiosarcoma in male
 21 mice. Glyphosate increased pancreatic islet-cell adenoma in male rats in two studies. A
 22 glyphosate formulation promoted skin tumors in an initiation promotion study in mice.

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55. 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.

56. 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.

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757. The IARC Working Group also noted genotoxic, hormonal, and enzymatic effects in mammals exposed to glyphosate.²¹ Essentially, glyphosate inhibits the biosynthesis of aromatic
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11 secondary product biosynthesis and general metabolic disruption.

12 58. The IARC Working Group also reviewed an Agricultural Health Study, consisting of a
13 prospective cohort of 57,311 licensed pesticide applicators in Iowa and North Carolina.²² While
14 this study differed from others in that it was based on a self-administered questionnaire, the results
15 support an association between glyphosate exposure and multiple myeloma, hairy cell leukemia
17 (HCL), and chronic lymphocytic leukemia (CLL), in addition to several other cancers.

18 Other Earlier Findings About Glyphosate's Dangers to Human Health

19 59. The EPA has a technical fact sheet, as part of its Drinking Water and Health, National
 20 Primary Drinking Water Regulations publication, relating to glyphosate. This technical fact sheet
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 ²¹ Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate, supra* at 77.
 ²³ Glyphosate, Supra at 77.

 ²² Anneclare J. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide* **24** *Applicators in the Agricultural Health Study*, 113 Envt'l Health Perspectives 49-54 (2005), available at <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1253709/pdf/ehp0113-000049.pdf</u>.

predates IARC's March 20, 2015 evaluation. The fact sheet describes the release patterns for glyphosate as follows:

Release Patterns

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Glyphosate is released to the environment in its use as an 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.²³

60. In 1995, the Northwest Coalition for Alternatives to Pesticides reports that in California, the state with the most comprehensive program for reporting of pesticide caused illness, glyphosate was the third most commonly reported cause of pesticide illness among agricultural workers.²⁴

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²³ U.S. Envtl. Prot. Agency, *Technical Factsheet on: Glyphosate, supra*.

 ²⁴ 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 Cal. School of Public Health, Calif. Policy Seminar (1993).

The Toxicity of Other Ingredients in Roundup®

61. In addition to the toxicity of the active ingredient, glyphosate, several studies support the 2 hypothesis that the glyphosate-based formulation in Defendant's Roundup[®] products is more 3 4 dangerous and toxic than glyphosate alone. Indeed, as early as 1991, available evidence 5 demonstrated that glyphosate formulations were significantly more toxic than glyphosate alone.²⁵ 6 62. In 2002, a study by Julie Marc, entitled "Pesticide Roundup Provokes Cell Division 7 Dysfunction at the Level of CDK1/Cyclin B Activation," revealed that Roundup[®] causes delays 8 in the cell cycles of sea urchins but that the same concentrations of glyphosate alone were 9 ineffective and did not alter cell cycles.²⁶ 10

11 63. A 2004 study by Marc and others, entitled "Glyphosate-based pesticides affect cell cycle 12 regulation," demonstrated a molecular link between glyphosate-based products and cell cycle 13 dysregulation. The researchers noted that "cell cycle dysregulation is a hallmark of tumor cells 14 and human cancer. Failure in the cell cycle checkpoints leads genomic instability and subsequent 15 development of cancer from the initial affected cell." Further, "[s]ince cell cycle disorders such 16 as cancer result from dysfunction of a unique cell, it was of interest to evaluate the threshold dose 17 of glyphosate affecting the cells."²⁷ 18

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²¹ ²⁵ 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).

 ²⁶ 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
 ²⁷ http://pubs.acs.org/doi/full/10.1021/tx015543g.

 ²⁷ 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.

64. 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 a potential synergic effect between glyphosate and other ingredients in the Roundup[®] formulation.²⁸

65. 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 study confirmed that the adjuvants present in Roundup[®] are not, in fact, inert and that Roundup[®] is potentially far more toxic than its active ingredient glyphosate alone.²⁹

²⁹ Nora Benachour, et al., *Glyphosate Formulations Induce Apoptosis and Necrosis in Human Ubilical, Embryonic, and Placental Cells*, 22 CHEM. RES. TOXICOL. 97-105 (2008), available at <u>http://big.assets.huffingtonpost.com/france.pdf</u>.

 ¹ ²⁸ Francisco Peixoto, Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation, 61 CHEMOSPHERE 1115, 1122 (2005), available at

https://www.researchgate.net/publications/7504567_Comparative_effects_of_the_Roundup_and glyphosate_on_mitochondrial_oxidative_phosphorylation.

66. 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[®].

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

Recent Worldwide Bans on Roundup[®]/Glyphosate

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68. Several countries around the world have instituted bans on the sale of Roundup[®] and other 9 glyphosate-containing herbicides, both before and since IARC first announced its assessment for 10 11 glyphosate in march 2015, and more countries undoubtedly will follow suit as the dangers of the 12 use of Roundup[®] become more widely known. The Netherlands issued a ban on all glyphosate-13 based herbicides in April 2014, including Roundup[®], which took effect at the end of 2015. In 14 issuing the ban, the Dutch Parliament member who introduced the successful legislation stated: 15 "Agricultural pesticides in user-friendly packaging are sold in abundance to private persons. In 16 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."³⁰

³⁰ *Holland's Parliament Bans Glyphosate Herbicides*, The Real Agenda, April 14, 2014, available at <u>http://real-agenda.com/hollands-parliament-bans-glyphosate-herbicides/</u>.

1	69. The Brazilian Public Prosecutor in the Federal District requested that the Brazilian Justice				
2	Department suspend the use of glyphosate. ³¹				
3	70. France banned the private sale of Roundup [®] and glyphosate following the IARC				
4	assessment for Glyphosate. ³²				
5	71. Bermuda banned both the private and commercial sale of glyphosates, including				
6	Roundup [®] . The Bermuda government explained its ban as follows: "Following a recent scientific				
7	study carried out by a leading cancer agency, the importation of weed spray 'Roundup' has been				
8	suspended " ³³				
9	72. The Sri Lankan government banned the private and commercial use of glyphosate,				
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	workers.				
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16	³¹ Christina Sarich, Brazil's Public Prosecutor Wants to Ban Monsanto's Chemicals Following				
17	Recent Glyphosate-Cancer Link, GLOBAL RESEARCH, MAY 14, 2015, available at <u>http://www.globalresearch.ca/brazils-public-prosecutor-wants-to-ban-monsantos-chemicals-</u>				
18	<u>following-recent-glyphosate-cancer-link/5449440</u> ; see Ministério Público Federal, MPF/DF reforça pedido para que glifosato seja banido do Mercado nacional, April 14, 2015, available at http://noticies.pgr.mpf.mp.br/poticies/poticies.do.sito/conv.of.meio.ambiente.c.pstrimonic				
19	<u>cultural/mpi-di-reforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional.</u>				
20	U.N. Calls it "Probable Carcinogen", NEWSWEEK, JUNE 15, 2015, available at				
21	it-probable-343311. ³³ Health Minister: Importation of Roundup Weed Spray Suspended, Today in Bermuda, May				
22	11, 2015, available at http://www.todayinbermuda.com/news/health/item/1471-health-minister-				
23	May 25, 2015, available at http://sustainable.pulse.com/2015/05/25/sri lapkas now president				
24	puts-immediate-ban-on-glyphosate-herbicides/#. Vedu YK3bKAw.				
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73. 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.³⁵

4 Proposition 65 Listing

5 74. On September 4, 2015, California's Office of Environmental Health Hazard Assessment 6 ("OEHHA") published a notice of intent to include glyphosate on the state's list of known 7 carcinogens under Proposition 65.³⁶ California's Safe Drinking Water and Toxic Enforcement 8 Act of 1986 (informally known as "Proposition 65"), requires the state to maintain and, at least, 9 once a year, revise and republish a list of chemicals "known to the State of California to cause 10 cancer or reproductive toxicity."³⁷ The OEHHA determined that glyphosate met the criteria for 11 12 the listing mechanism under the Labor Code following IARC's assessment of the chemical.³⁸ 13 75. The listing process under the Labor Code is essentially automatic. The list of known 14 carcinogens, at a minimum, must include substances identified by reference in Labor Code § 15 6382(b)(1). That section of the Labor Code identifies "[s]ubstances listed as human or animal 16

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¹⁸ ³⁵ *Columbia to ban coca spraying herbicide glyphosate*, BBC, May 10, 2015, available at http://www.bbc.com/news/world-latin-america-32677411.

 ³⁶ Ĉal. Envtl. Prot. Agency Office of Envtl. Health Hazard Assessment, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015), available at

²⁰ <u>http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_L</u> **21** <u>CSet27.pdf</u>.

²² ³⁸ Cal. Envtl. Prot. Agency Office of Envtl. Health Hazard Assessment, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate

 ²³ Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathlon, Walathlon, Gryphosate (Sept. 4, 2015), available at
 24 <u>http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_L</u> CSet27.pdf.

carcinogens by the International Agency for Research on Cancer (IARC)." IARC's classification
of glyphosate as a Group 2A chemical ("probably carcinogenic to humans") therefore triggered
the listing.

4 76. A business that deploys a listed chemical in its products must provide "clear and reasonable
5 warnings" to the public prior to exposure to the chemical. To be clear and reasonable, a warning
6 must "(1) clearly communicate that the chemical is known to cause cancer, and/or birth defects or
7 other reproductive harm; and (2) effectively reach the person before exposure."³⁹ The law also
9 prohibits the discharge of listed chemicals into drinking water.

10 77. Monsanto disputed the listing decision and, in January 2016, filed a lawsuit against
11 OEHHA and the agency's acting director, Lauren Zeise, in California state court, seeking
12 declaratory and injunctive relief to prevent OEHHA from listing glyphosate.⁴⁰

13 78. Monsanto alleged that OEHHA's exclusive reliance on the IARC decision signified that
14 "OEHHA effectively elevated the determination of an ad hoc committee of an unelected, foreign
15 body, which answers to no United States official (let alone any California state official), over the
16 conclusions of its own scientific experts."⁴¹ Monsanto further alleged that the Labor Code listing
18 mechanism presented various constitutional violations because it "effectively empowers an
19 unelected, undemocratic, unaccountable, and foreign body to make laws applicable in

 ³⁹ Frequently Asked Questions, STATE OF CAL. DEPARTMENT OF JUSTICE, OFFICE OF HE ATTORNEY GENERAL, supra.
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 ⁴⁰ Monsanto Company's Verified Petition for Writ of Mandate and Complaint for Preliminary and Permanent Injunctive and Declaratory Relief, Monsanto Co. v. Office of the Envt'l Health Hazard Assessment, et al., No. 16-CECG-00183 (Cal. Super. Ct.), available at http://www.monsanto.com/files/documents/monvoehha.pdf.

 $^{^{41}}$ *Id.* at 2.

California."⁴² Among other things, Monsanto argued that Proposition 65's requirement to provide 1 a "clear and reasonable warning" to consumers that the chemical is a known carcinogen would 2 damage its reputation and violate its First Amendment rights.⁴³ 3

4 EFSA Report on Glyphosate

5 79. On November 12, 2015, the European Food Safety Authority (EFSA), the European 6 Union's primary agency for food safety, reported on its evaluation of the Renewal Assessment Report (RAR) on glyphosate.⁴⁴ The Rapporteur Member State assigned to glyphosate, the 8 German Federal Institute for Risk Assessment (BfR), had produced the RAR as part of the renewal process for glyphosate in the EU. 10

11 80. BfR sent its draft RAR to EFSA and the RAR underwent a peer review process by EFSA, 12 other member states, and industry groups. As part of the on-going peer review of Germany's 13 reevaluation of glyphosate, EFSA had also received a second mandate from the European 14 Commission to consider IARC's findings regarding the potential carcinogenicity of glyphosate 15 and glyphosate-containing products. 16

81. Based on a review of the RAR, which included data from industry submitted unpublished 17 studies, EFSA sent its own report ("Conclusion") to the European Commission, finding that 18 19 "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support 20 classification with regard to its carcinogenic potential according to Regulation (EC) No 21

⁴³ *Id*. 23

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http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf.

⁴² *Id.* at 3.

European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, available at 24

1272/2008."⁴⁵ EFSA therefore disagreed with IARC: glyphosate was not genotoxic and did not 1 present a carcinogenic threat to humans. 2

82. In explaining why its results departed from IARC's conclusion, EFSA drew a distinction 3 4 between the EU and IARC approaches to the study and classification of chemicals.⁴⁶ Although 5 IARC examined "both glyphosate - an active substance - and glyphosate-based formulations, 6 grouping all formulations regardless of their composition," EFSA explained that it considered 7 only glyphosate and that its assessment focuses on "each individual chemical, and each marketed 8 mixture separately."⁴⁷ IARC, on the other hand, "assesses generic agents, including groups of 9 related chemicals, as well as occupational or environmental exposure, and cultural or behavioural 10 practices."⁴⁸ EFSA accorded greater weight to studies conducted with glyphosate alone than 11 12 studies of formulated products.49

13 83. EFSA went further and noted:

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

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⁴⁵ *Id*. ⁴⁶ EFSA Fact Sheet: Glyphosate, EFSA, available at 22 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate 151112en.pdf. 23 ⁴⁷ *Id.* ⁴⁸ Id. 24 ⁴⁹ Id.

toxicity than that of the active ingredient, presumably because of the presence of co-1 formulants. In its assessment, EFSA proposes that the toxicity of each pesticide 2 formulation and in particular its genotoxic potential should be further considered 3 4 and addressed by Member State authorities while they re-assess uses of glyphosate-5 *based formulations in their own territories*.⁵⁰ (Emphasis added) 6 84. Notwithstanding its conclusion, EFSA did set exposure levels for glyphosate. Specifically, 7 EFSA proposed an acceptable daily intake (ADI) of 0.5 mg/kg of body weight per day; an acute 8 reference dose (ARfD) of 0.5 mg/kg of body weight; and an acceptable operator exposure level 9 (AOEL) of 0.1 mg/kg bw per day.⁵¹ 10 11 Leading Scientists Dispute EFSA's Conclusion 12 85. On November 27, 2015, 96 independent academic and governmental scientists from around 13 the world submitted an open letter to the EU health commissioner, Vytenis Andriukaitis.⁵² The 14 scientists expressed their strong concerns and urged the commissioner to disregard the "flawed" 15 EFSA report, arguing that "the BfR decision is not credible because it is not supported by the 16 evidence and it was not reached in an open and transparent manner."⁵³ 17 18 19 20 ⁵⁰ Id. ⁵¹ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment 21 of the active substance glyphosate, supra. ⁵² Letter from Christopher J. Portier et al. to Commission Vytenis Andriukaitis, Open letter: 22 Review of the Carcinogenicity of Glyphosate by EFSA and BfR (Nov. 27, 2015), available at http://www.seit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf and 23 http://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-ofglyphosate-weedkiller. 24 53 *Id*. 28 25

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

4 87. In an exhaustive and careful examination, the scientists scrutinized EFSA's conclusions
5 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.⁵⁴

17 88. With respect to human data, the scientists pointed out that EFSA agreed with IARC that
18 there was "*limited evidence* of carcinogenicity" for non-Hodgkin lymphoma but EFSA
19 nonetheless dismissed an association between glyphosate exposure and carcinogenicity. IARC
20 applies three levels of evidence in its analyses of human data, including sufficient evidence and
21 limited evidence. EFSA's ultimate conclusion that "there was no unequivocal evidence for a clear
22 and strong association of NHL with glyphosate" was misleading because it was tantamount to

24 $\overline{)}^{54}$ *Id.*

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IARC's highest level of evidence: "sufficient evidence," which means that a causal relationship 1 has been established. However, the scientists argued, "[1]egitimate public health concerns arise when 'causality is credible,' i.e., when there is *limited evidence*."⁵⁵

4 89. Among its many other deficiencies, EFSA's conclusions regarding animal carcinogenicity 5 data were "scientifically unacceptable," particularly in BfR's use of historical control data and in 6 its trend analysis. Indeed, BfR's analysis directly contradicted the Organisation for Economic 7 Co-operation and Development ("OECD") testing guidelines while citing and purporting to 8 follow those same guidelines. For instance, the EFSA report dismisses observed trends in tumor 9 incidence "because there are no individual treatment groups that are significantly different from 10 11 controls and because the maximum observed response is reportedly within the range of the 12 historical control data." However, according to the scientists, concurrent controls are 13 recommended over historical controls in all guidelines, scientific reports, and publications, and, 14 if it is employed, historical control data "should be from studies in the same timeframe, for the 15 same exact animal strain, preferably from the same laboratory or the same supplier and preferably 16 reviewed by the same pathologist." BfR's use of historical control data violated these precautions: 17 "only a single study used the same mouse strain as the historical controls, but was reported more 18 19 than 10 years after the historical control dataset was developed." Further deviating from sound 20 scientific practices, the data used by the BfR came from studies in seven different laboratories. 21 The scientists concluded:

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⁵⁵ Id.

BfR reported seven positive mouse studies with three studies showing increases in renal tumors, two with positive findings for hemangiosarcomas, and two with positive findings for malignant lymphomas. BfR additionally reported two positive findings for tumors in rats. Eliminating the inappropriate use of historical data, the unequivocal conclusion is that these are not negative studies, but in fact document the carcinogenicity of glyphosate in laboratory animals.⁵⁶

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90. 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 BfR relied on unpublished, confidential industry provided studies, it is "impossible for any scientist not associated with BfR to review this conclusion with scientific confidence."⁵⁷

91. On March 3, 2016, the letter was published in the Journal of Epidemiology & Community Health.⁵⁸

18 Statement of Concern Regarding Glyphosate-Based Herbicides

19 92. On February 17, 2016, a consensus statement published in the journal Environmental
 20 Health, entitled "Concerns over use of glyphosate-based herbicides and risks associated with
 21 ⁵⁶ Id.

22 $|_{57} Id.$

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 ⁵⁸ 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, Marc. 3, 2016, available at http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full.

1	exposures: a consensus statement," assessed the safety of glyphosate-based herbicides (GBHs). ⁵⁹		
2	The paper's "focus is on the unanticipated effects arising from the worldwide increase in use of		
3	GBHs, coupled with recent discoveries about the toxicity and human health risks stemming from		
4	use of GBHs." ⁶⁰ The researchers drew seven factual conclusions about GBHs:		
5	1.	GBHs are the most heavily applied herbicide in the world and usage continues to	
6		rise;	
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8	2.	Worldwide, GBHs often contaminate drinking water sources, precipitation, and air,	
9		especially in agricultural regions;	
10	3.	The half-life of glyphosate in water and soil is longer than previously recognized;	
11	4.	Glyphosate and its metabolites are widely present in the global soybean supply;	
12	5.	Human exposures to GBHs are rising;	
13	6.	Glyphosate is now authoritatively classified as a probable human carcinogen; and	
14	7.	Regulatory estimates of tolerable daily intakes for glyphosate in the United States	
15		and European Union are based on outdated science. ⁶¹	
16 17	93. The	researchers noted that GBH use has increased approximately 100-fold since the 1970s.	
18	Furthermor	e, far from posing a limited hazard to vertebrates, as previously believed, two decades	
19 20	of evidence demonstrated that "several vertebrate pathways are likely targets of action, including		
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22	⁵⁹ John P. Myers, et al., <i>Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement</i> , Environmental Health (2016), available at		
23	http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0.		
24	⁶⁰ <i>Id.</i> ⁶¹ <i>Id.</i> 32		
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hepatorenal damage, effects on nutrient balance through glyphosate chelating action and endocrine disruption."62

94. The paper attributed uncertainties in current assessments of glyphosate formulations to the 3 4 fact that "[t]he full list of chemicals in most commercial GBHs is protected as 'commercial 5 business information,' despite the universally accepted relevance of such information to scientists 6 hoping to conduct an accurate risk assessment of these herbicide formulations." Further, the 7 researchers argue, "[t]he distinction in regulatory review and decision processes between 'active' 8 and 'inert' ingredients has no toxicological justification, given increasing evidence that several 9 so-called 'inert' adjuvants are toxic in their own right."63 10

Among various implications, the researchers conclude that "existing toxicological data and 11 95. 12 risk assessments are not sufficient to infer that GBHs, as currently used, are safe." Further, "GBH-13 product formulations are more potent, or toxic, than glyphosate alone to a wide array of non-target 14 organisms including mammals, aquatic insects, and fish." Accordingly, "risk assessments of 15 GBHs that are based on studies quantifying the impacts of glyphosate alone underestimate both 16 toxicity and exposure, and thus risk." The paper concludes that this "shortcoming has repeatedly 17 led regulators to set inappropriately high exposure thresholds."⁶⁴ 18

19 96. The researchers also critique the current practice of regulators who largely rely on 20 "unpublished, non-peer reviewed data generated by the registrants" but ignore "published research 21 because it often uses standards and procedures to assess quality that are different from those 22

- 23 ⁶² Id.
- ⁶³ Id. 24 ⁶⁴ Id.

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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."⁶⁵ 3

97. The researchers also call for greater inclusion of GBHs in government-led toxicology 5 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

The U.S. National Toxicology Program should prioritize a thorough today.

toxicological assessment of the multiple pathways now identified as potentially

12 vulnerable of GBHs.⁶⁶

13 98. The researchers suggest that, in order to fill the gap created by an absence of government

14 funds to support research on GBHs, regulators could adopt a system through which manufacturers 15

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 or routine registration actions and fees. Such funds should then be transferred to appropriate government research institutes, or to an agency experienced in the award of competitive grants. In either case, funds would be made available to independent scientists to conduct the appropriate long-term (minimum 2 years) safety studies in recognized animal model systems. A thorough and modern assessment of GBH toxicity will encompass potential endocrine disruption, impacts on the gut microbiome, carcinogenicity, and multigenerational effects looking at reproductive capability and frequency of birth defects."67

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- ⁶⁶ Id. 24 ⁶⁷ Id.
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FDA Announces Testing of Glyphosate Residue in Foods

99. On February 17, 2016, the U.S. Food and Drug Administration ("FDA") announced that,
for the first time in its history, the agency planned to start testing certain foods for glyphosate
residues. FDA spokeswoman Lauren Sucher explained: "The agency is now considering
assignments for Fiscal year 2016 to measure glyphosate in soybeans, corn, milk, and eggs, among
other potential foods."⁶⁸

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100. In 2014, the U.S. Government Accountability Office (GAO) had severely rebuked the FDA
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for its failures to both monitor for pesticide residue, including that of glyphosate, and to disclose
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the limitations of its monitoring and testing efforts to the public.⁶⁹ The GAO had cited numerous
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undisclosed deficiencies in the FDA's process, specifically highlighting its omission of glyphosate
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testing.

13 101. Indeed, in the past, both the FDA and the U.S. Department of Agriculture (USDA) had
14 routinely excluded glyphosate from their testing for the residues of hundreds of other pesticides,
15 on the rationale that it was too expensive and unnecessary to protect public health. Ms. Sucher,
16 the FDA spokeswoman, however, now states that "the agency has developed 'streamlined
18 methods' for testing for the weed killer."⁷⁰

⁶⁸ Carey Gillam, *FDA to Start Testing for Glyphosate in Food*, TIME, Feb. 17, 2016, available
 ⁶⁹ Ltp://time.com/4227500/fda-glyphosate-testing/?xid=tcoshare.

 $\frac{1}{70}$ Gillam, *supra* note 68.

 ⁶⁹ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-38, FDA AND USDA SHOULD
 STRENGTHEN PESTICIDE RESIDUE MONITORING PROGRAMS AND FURTHER DISCLOSE MONITORING LIMITATIONS (2014), available at http://www.gao.gov/products/GAO-15-38.

102. The FDA's move is significant as the agency possesses enforcement authority and can seek
 action if pesticide residues exceed enforcement guidelines.⁷¹

3 <u>European Union Vote on Glyphosate Renewal</u>

4 103. The license for glyphosate in the European Union (EU) was set to expire on June 30, 2016.
5 104. Without an extension of the license, Monsanto's Roundup[®] and other glyphosate-based herbicides faced a general phase out in EU markets.⁷²

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 105. 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.

106. 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.⁷³ The paper quoted
the Swedish environment minister, Åsa Romson, as stating: "We won't take risks with glyphosate
and we don't think that the analysis done so far is good enough. We will propose that no decision
is taken until further analysis has been done and the Efsa scientists have been more transparent
about their considerations."⁷⁴

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- **20** 7¹ *Id.*; Pesticide Q&A, U.S. FOOD AND DRUG ADMINISTRATION, available at <u>http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm114958.htm.</u>
- ⁷² 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-eu-glyphosate-idUSKCN0ZE25B.

⁷³ 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-torelicense-weedkiller-glyphosate.
- **24** 7^{4} *Id*.

1	107. The Netherlands argued that relicensing should be placed on hold until after a separate
2	evaluation of glyphosate's toxicity can be conducted. ⁷⁵ Leading up to the vote, Italy joined the
3	other EU states in opposing the license renewal, citing health concerns. ⁷⁶
4	108. On June 6, 2016, Member States voted but failed to reach a qualified majority in favor or
5	against the re-authorization of glyphosate. ⁷⁷
6	109. On June 29, 2016, the EU Commission extended the European license for glyphosate for
7	18 months to allow the European Chemical Agency to rule on the safety of the chemical, which
8	is expected by the end of 2017. ⁷⁸
9	is expected by the chd of 2017.
10	110. On July 11, 2016, the EU voted in favor of a proposal to restrict the conditions of use of
11	glyphosate in the EU, including a ban on common co-formulant POE-tallowamine (POEA) from
12	all glyphosate-based herbicides, including Roundup [®] . ⁷⁹
13	111. These restrictions, which are non-binding on the EU states, are expected to apply until the
14	European Chemicals Agency issues an opinion on the chemical's safety. ⁸⁰
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16	⁷⁵ Arthur Neslen, Vote on Controversial weedkiller's European license postponed, THE
17	GUARDIAN, Mar. 8, 2016, available at <u>http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-</u>
18	$\frac{\text{license-postponced-glyphosate}}{^{76} Id.}$
19	⁷⁷ Manon Flausch, <i>Commission prolongs glyphosate license by 18 months</i> , EURACTIV, June 29, 2016, available at http://www.euractiv.com/section/agriculture-food/news/commission-
20	prolongs-glyphosate-license-by-18-months/ ⁷⁸ Arthur Neslen, <i>Controversial chemical in Roundup weedkiller escapes immediate ban</i> , THE
21	GUARDIAN, June 29, 2016, available at http://www.theguardian.com/business/2016/jun/29/controversial-chemical-roundup-weedkiller-
22	escapes-immediate-ban. ⁷⁹ Sarantis Michalopoulos, <i>EU agrees ban on glyphosate co-formulant</i> , EURACTIV, July 11,
23	2016, available at http://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-
	glyphosate-coformulant/?nl_ref=16562829. ⁸⁰ See Arthur Neslen, Controversial chemical in Roundup weedkiller escapes immediate ban,
24	THE GUARDIAN, June 29, 2016.
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Plaintiff Rudy Fuentes' Exposure to Roundup[®]

- Rudy Fuentes used Roundup[®] for at least 13 years on his property in Arizona. 112. 2
- Mr. Fuentes frequently purchased Roundup[®] in its liquid form in Arizona. 113. 3
- 4 114. In November 2017, doctors diagnosed Mr. Fuentes with Follicular Lymphoma.

115. Since his diagnosis, Mr. Fuentes has been treated for the cancer.

During the entire time in which Mr. Fuentes was exposed to Roundup[®], he did not know 116. that exposure to Roundup[®] was injurious to his health or the health of others.

Mr. Fuentes first learned that exposure to Roundup[®] can cause NHL and other serious 117. illnesses sometime after July 29, 2015, when IARC first published its evaluation of glyphosate. 10

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TOLLING OF THE STATUTE OF LIMITATIONS **DISCOVERY RULE TOLLING**

118. Plaintiff had no way of knowing about the risk of serious illness associated with the use of 13 and/or exposure to Roundup[®] and glyphosate. The earliest date one could have learned of the link 14 would have been after IARC released its formal assessment of glyphosate in July 2015. This is 15 16 the quintessential case for tolling.

17 119. Within the time period of any applicable statutes of limitations, Plaintiff could not have 18 discovered, through the exercise of reasonable diligence, that exposure to Roundup® and 19 glyphosate is injurious to human health.

120. Plaintiff did not discover, and did not know of facts that would cause a reasonable person 21 to suspect, the risks associated with the use of and/or exposure to Roundup[®] and glyphosate; nor 22 would a reasonable and diligent investigation by him have disclosed that Roundup[®] and 23 24 glyphosate would cause his illness.

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121. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule with respect to Plaintiff's claim.

3 Fraudulent Concealment Tolling

4 122. All applicable statutes of limitations have also been tolled by Monsanto's knowing and
5 active fraudulent concealment and denial of the facts alleged herein throughout the time period
6 relevant to this action.

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123. Instead of disclosing critical safety information about Roundup[®] and glyphosate, Monsanto
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has consistently and falsely represented the safety of its Roundup[®] products.

10 Estoppel

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

18 126. Based on the foregoing, Monsanto is estopped from relying on any statutes of limitations19 in defense of this action.

COUNT ONE STRICT LIABILITY (DESIGN DEFECT)

22 127. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth
23 herein, and further alleges:

128. Plaintiff brings this strict liability claim against Defendant for defective design.

129. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®] 3 4 products, which are defective and unreasonably dangerous to consumers, users and other persons 5 coming into contact with them, including Plaintiff, thereby placing Roundup[®] products into the 6 stream of commerce. These actions were under the ultimate control and supervision of Defendant. 7 130. At all times relevant to this litigation, Defendant designed, researched, developed, 8 formulated, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold and distributed the Roundup[®] products used by Plaintiff and/or to which Plaintiff was exposed, as described above.

12 At all times relevant to this litigation, Defendant's Roundup[®] products were manufactured, 131. 13 designed and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous 14 for use by or exposure to the public, and, in particular, Plaintiff.

At all times relevant to this litigation, Defendant's Roundup® products reached the intended 132. 16 consumers, handlers, and users or other persons coming into contact with these products in Illinois 17 and throughout the United States, including Plaintiff without substantial change in their condition 18 19 as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

20 Defendant's Roundup[®] products, as researched, tested, developed, designed, licensed, 133. 21 formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant, were 22 defective in design and formulation in that when they left the hands of the Defendant's 23 manufacturers and/or suppliers, they were unreasonably dangerous because they were not as safe 24

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as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

3 134. Defendant's Roundup[®] products, as researched, tested, developed, designed, licensed,
4 formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant, were
5 defective in design and formulation in that when they left the hands of Defendants' manufacturers
6 and/or suppliers, the foreseeable risks associated with these products' reasonably foreseeable uses
7 exceeded the alleged benefits associated with their design and formulation.

9 135. Therefore, at all times relevant to this litigation, Defendant's Roundup[®] products, as
10 researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed,
11 sold and marketed by Defendant, were defective in design and formulation, in one or more of the
12 following ways:

a) When placed in the stream of commerce, Defendant's Roundup[®] products were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would expect.

b) When placed in the stream of commerce, Defendant's Roundup[®] products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner.

 c) When placed in the stream of commerce, Defendant's Roundup[®] products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner.

- d) Defendant did not sufficiently test, investigate, or study its Roundup[®] products and, specifically, the active ingredient glyphosate.
- e) Exposure to Roundup[®] and glyphosate-containing products presents a risk of harmful side effects that outweighs any potential utility stemming from the use of the herbicide.
 - f) Defendant knew or should have known at the time of marketing its Roundup[®] products that exposure to Roundup[®] and specifically, its active ingredient glyphosate, could result in cancer and other severe illnesses and injuries.
 - g) Defendant did not conduct adequate post-marketing surveillance of its Roundup[®] products.
 - h) Defendant could have employed safer alternative designs and formulations.

136. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendant's Roundup[®] products in an intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

137. Plaintiff could not have reasonably discovered the defects and risks associated with
18 Roundup[®] or glyphosate-containing products before or at the time of exposure.

19 138. The harm caused by Defendant's Roundup[®] products far outweighed their benefit,
 20 rendering Defendant's products dangerous to an extent beyond that which an ordinary consumer
 21 would contemplate. Defendant's Roundup[®] products were and are more dangerous than
 22 alternative products and Defendant could have designed its Roundup[®] products to make them less

dangerous. Indeed, at the time that Defendant designed its Roundup[®] products, the state of the 1 industry's scientific knowledge was such that a less risky design or formulation was attainable. 2 139. At the time Roundup[®] products left Defendant's control, there was a practical, technically 3 4 feasible, and safer alternative design that would have prevented the harm without substantially 5 impairing the reasonably anticipated or intended function of Defendant's Roundup[®] herbicides. 6 Defendant's defective design of Roundup[®] amounts to willful, wanton, and/or reckless 140. 7 conduct by Defendant. 8 141. Therefore, as a result of unreasonably dangerous condition of its Roundup[®] products, 9 Defendant is strictly liable to Plaintiff. 10 The defects in Defendant's Roundup[®] products were substantial and contributing factors 11 142. 12 in causing Plaintiff's grave injuries, and, but for Defendant's misconduct and omissions, Plaintiff 13 would not have sustained his injuries. 14 As a direct and proximate result of Defendant placing its defective Roundup[®] products into 143. 15 the stream of commerce, Plaintiff has suffered and continues to suffer grave injuries, and he has 16 endured pain and discomfort, as well as economic hardship, including considerable financial 17 expenses for medical care and treatment. Plaintiff will continue to incur these expenses in the 18 19 future. 20 WHEREFORE, Plaintiff requests that the Court enter judgment in his favor for compensatory and 21 punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other

and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

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COUNT TWO STRICT LIABILITY (FAILURE TO WARN)

Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth 144. herein, and further alleges:

Plaintiff brings this strict liability claim against Defendant for failure to warn. 145.

6 146. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®] 8 products, which are defective and unreasonably dangerous to consumers, including Plaintiff, 9 because they do not contain adequate warnings or instructions concerning the dangerous 10 characteristics of Roundup[®] and specifically, the active ingredient glyphosate. These actions were under the ultimate control and supervision of Defendant.

Defendant researched, developed, designed, tested, manufactured, inspected, labeled, 13 147. 14 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its 15 Roundup[®] products, and in the course of same, directly advertised or marketed the products to 16 consumers and end users, including Plaintiff, and Defendant therefore had a duty to warn of the 17 risks associated with the reasonably foreseeable uses (and misuses) of Roundup[®] and glyphosate-18 containing products and a duty to instruct on the proper, safe use of these products. 19

At all times relevant to this litigation, Defendant had a duty to properly test, develop, 148. 20 21 design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, 22 provide proper warnings, and take such steps as necessary to ensure that its Roundup[®] products 23 did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendant

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had a continuing duty to instruct on the proper, safe use of these products. Defendant, as
manufacturer, seller, or distributor of chemical herbicides, is held to the knowledge of an expert
in the field.

4 149. At the time of manufacture, Defendant could have provided warnings or instructions
5 regarding the full and complete risks of Roundup[®] and glyphosate-containing products because it
6 knew or should have known of the unreasonable risks of harm associated with the use of and/or
7 exposure to these products.

9 150. At all times relevant to this litigation, Defendant failed to investigate, study, test, or
10 promote the safety of its Roundup[®] products. Defendant also failed to minimize the dangers to
11 users and consumer of its Roundup[®] products and to those who would foreseeably use or be
12 harmed by Defendant's herbicides, including Plaintiff.

13 151. Despite the fact that Defendant knew or should have known that Roundup[®] products posed
14 a grave risk of harm, it failed to warn of the dangerous risks associated with their use and exposure.
15 The dangerous propensities of its products and the carcinogenic characteristics of glyphosate, as
16 described above, were known to Defendant, or scientifically knowable to Defendant through
18 appropriate research and testing by known methods, at the time it distributed, supplied, or sold the
19 product, and not known to end users and consumers, such as Plaintiff.

20 152. Defendant knew or should have known that its Roundup[®] and glyphosate-containing
 21 products created significant risks of serious bodily harm to consumers, as alleged herein, and
 22 Defendant failed to adequately warn consumers and reasonably foreseeable users of the risks of
 23 exposure to these products. Defendant 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.

153. At all times relevant to this litigation, Defendant's Roundup[®] products reached the intended 3 4 consumers, handlers, and users or other persons coming into contact with these products 5 throughout the United States, including Plaintiff, without substantial change in their condition as 6 designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

154. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of 8 Defendant's Roundup[®] products in their intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

11 155. Plaintiff could not have reasonably discovered the defects and risks associated with 12 Roundup[®] or glyphosate-containing products before or at the time of Plaintiff's exposure. 13 Plaintiff relied upon the skill, superior knowledge, and judgment of Defendant.

14 Defendant knew or should have known that the minimal warnings disseminated with its 156. 15 Roundup[®] products were inadequate, but it failed to communicate adequate information on the 16 dangers and safe use/exposure and failed to communicate warnings and instructions that were 17 appropriate and adequate to render the products safe for their ordinary, intended, and reasonably 18 19 foreseeable uses, including agricultural and horticultural applications.

20 157. The information that Defendant did provide or communicate failed to contain relevant 21 warnings, hazards, and precautions that would have enabled agricultural workers, horticultural 22 workers and/or at-home users to utilize the products safely and with adequate protection. Instead, 23 Defendant disseminated information that was inaccurate, false, and misleading and which failed 24

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to communicate accurately or adequately the comparative severity, duration, and extent of the risk 1 of injuries associated with use of and/or exposure of Roundup[®] and glyphosate; continued to 2 aggressively promote the efficacy of its products, even after it knew or should have known of the 3 4 unreasonable risks from use or exposure; an concealed, downplayed, or otherwise suppressed, 5 through aggressive marketing and promotion, any information or research about the risks and 6 dangers of exposure to Roundup[®] and glyphosate.

To this day, Defendant has failed to adequately and accurately warn of the true risks of 158. 8 Plaintiff's injuries associated with the use of and exposure to Roundup[®] and its active ingredient 9 glyphosate, a probable carcinogen. 10

159. As a result of their inadequate warnings, Defendant's Roundup[®] products were defective 11 12 and unreasonably dangerous when they left the possession and/or control of Defendant, were 13 distributed by Defendant, and used by Plaintiff.

14 160. Defendant is liable to Plaintiff for injuries caused by its failure, as described above, to 15 provide adequate warnings or other clinically relevant information and data regarding the 16 appropriate use of its Roundup[®] products and the risks associated with the use of or exposure to Roundup[®] and glyphosate. 18

19 The defects in Defendant's Roundup[®] products were substantial and contributing factors 161. 20 in causing Plaintiff's injuries, and, but for Defendant's misconduct and omissions, Plaintiff would 21 not have sustained his injuries.

162. Had Defendant provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Roundup[®] products, Plaintiff could have avoided the

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risk of developing injuries as alleged herein and Plaintiff could have obtained alternative
 herbicides.

3 163. As a direct and proximate result of Defendant placing its defective Roundup[®] products into
4 the stream of commerce, Plaintiff has suffered and continues to suffer severe injuries, and has
5 endured physical pain and discomfort, as well as economic hardship, including considerable
6 financial expenses for medical care and treatment. Plaintiff will continue to incur these expenses
7 in the future.

WHEREFORE, Plaintiff requests that the Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorney's fees, and all such other
and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

COUNT THREE NEGLIGENCE

164. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth
herein, and further alleges:

7 165. Defendant, directly or indirectly, caused Roundup[®] products to be sold, distributed,
8 packaged, labeled, marketed, and/or promoted.

166. Defendant, directly or indirectly, caused Roundup[®] products to be purchased and/or used
by Plaintiff.

167. At all times relevant to this litigation, Defendant 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, and/or sell a product that was not unreasonably dangerous to consumers,
 users, and other persons coming into contact with the product.

3 168. At all times relevant to this litigation, Defendant had a duty to exercise reasonable care in
4 the marketing, advertising, and sale of its Roundup[®] products. Defendant's duty of care owed to
5 consumers and the general public included providing accurate, true, and correct information
6 concerning the risks of using Roundup[®] and appropriate, complete, and accurate warnings
7 concerning the potential adverse effects of exposure to Roundup[®] and, in particular, its active ingredient glyphosate.

169. At all times relevant to this litigation, Defendant knew or, in the exercise of reasonable
11 care, should have known of the hazards and dangers of Roundup[®] and specifically, the
12 carcinogenic properties of the chemical glyphosate.

13 170. Accordingly, at all times relevant to this litigation, Defendant knew or, in the exercise of
14 reasonable care, should have known that use of or exposure to its Roundup[®] products could cause
15 Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to the users of
17 these products, including Plaintiff.

18 171. Defendant knew or, in the exercise of reasonable care, should have known that Roundup[®]
19 is more toxic than glyphosate alone and that safety studies on Roundup[®], Roundup[®]'s adjuvants
20 and "inert" ingredients, and/or the surfactant POEA were necessary to protect Plaintiff from
21 Roundup[®].

172. Defendant knew or, in the exercise of reasonable care, should have known that tests limited to Roundup[®]'s active ingredient glyphosate were insufficient to prove the safety of Roundup[®].

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

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

12 175. Defendant failed to appropriately and adequately test Roundup[®], Roundup[®]'s adjuvants
13 and "inert" ingredients, and/or the surfactant POEA to protect Plaintiff from Roundup[®].

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176. Despite the ability and means to investigate, study, and test its products and to provide
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adequate warnings, Defendant has failed to do so. Indeed, Defendant has wrongfully concealed
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information and has further made false and/or misleading statements concerning the safety and/or
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exposure to Roundup[®] and glyphosate.

19 177. Defendant's negligence included:

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

- b) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, 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, horticulture, and at-home use;
- d) Failing to undertake sufficient studies and conduct necessary tests to determine the safety of "inert" ingredients and/or adjuvants contained within Roundup[®], and the propensity of these ingredients to render Roundup[®] toxic, increase the toxicity of Roundup[®], whether these ingredients are carcinogenic, magnify the carcinogenic properties of Roundup[®], and whether or not "inert" ingredients and/or adjuvants were safe for use;
- e) Failing to use reasonable and prudent care in the design, research, manufacture, formulation, and development of Roundup[®] products so as to avoid the risk of serious harm associated with the prevalent use of Roundup[®]/glyphosate as an herbicide;
 - 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;

- g) Failing to provide adequate instructions, guidelines, and safety precautions to those persons who Defendant could reasonably foresee would use and/or be exposed to its Roundup[®] products;
- h) Failing to disclose to Plaintiff, users, consumers, and the general public that the use of and exposure of Roundup[®] presented severe risks of cancer and other grave illnesses;
- Failing to warn Plaintiff, 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 Plaintiff and other users or consumers;
- j) Systemically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Roundup[®] and glyphosatecontaining products;
- k) Representing that its Roundup[®] products were safe for their intended use when in fact, Defendant knew or should have known that the products were not safe for their intended use;
- Declining to make or propose any changes to Roundup[®] products' labeling or other promotional materials that would alert the consumers and the general public of the risks of Roundup[®] and glyphosate;
 - m) Advertising, marketing, and recommending the use of Roundup[®] products, while concealing and failing to disclose or warn of the dangers known by Defendant to be associated with or caused by the use of or exposure to Roundup[®] and glyphosate;

- Continuing to disseminate information to its consumers, which indicate or imply n) that Defendant's Roundup[®] products are not unsafe for use in the agricultural, horticultural industries, and/or home use; and
- 0) Continuing the manufacture and sale of its products with the knowledge that the products were unreasonably unsafe and dangerous.
- 6 178. Defendant knew and/or should have known that it was foreseeable that consumers and/or 7 users, such as Plaintiff, would suffer injuries as a result of Defendant's failure to exercise ordinary 8 care in the manufacturing, marketing, labeling, distribution, and sale of Roundup[®].
- 179. Plaintiff did not know the nature and extent of the injuries that could result from the 10 intended use of and/or exposure to Roundup[®] or its active ingredient glyphosate. 11
- 12 180. Defendant's negligence was the proximate cause of the injuries, harm, and economic losses 13 that Plaintiff suffered, and will continue to suffer, as described herein.
- 14 181. Defendant's conduct, as described above, was reckless. Defendant regularly risks the lives 15 of consumers and users of its products, including Plaintiff, with full knowledge of the dangers of 16 its products. Defendant has made conscious decisions not to redesign, re-label, warn, or inform 17 the unsuspecting public, including Plaintiff. Defendant's reckless conduct therefore warrants an 18 19 award of punitive damages.
- 20 182. As a proximate result of Defendant's wrongful acts and omissions in placing its defective 21 Roundup[®] products into the stream of commerce without adequate warnings of the hazardous and 22 carcinogenic nature of glyphosate, Plaintiff has suffered and continues to suffer severe and 23 permanent physical and emotional injuries. Plaintiff has endured pain and suffering, has suffered 24

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economic losses (including significant expenses for medical care and treatment) and will continue to incur these expenses in the future.

WHEREFORE, Plaintiff requests that the Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

COUNT FOUR BREACH OF EXPRESS WARRANTY

183. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

184. At all times relevant to this litigation, Defendant engaged in the business of testing,
developing, designing, manufacturing, marketing, selling, distributing, and promoting its
Roundup[®] products, which are defective and unreasonably dangerous to consumers, including
Plaintiff, thereby placing Roundup[®] products into the stream of commerce. These actions were
under the ultimate control and supervision of Defendant.

7 185. At all times relevant to this litigation, Defendant expressly represented and warranted to
8 the purchasers of its Roundup[®] products, by and through statements made by Defendant in labels,
9 publications, package inserts, and other written materials intended for consumers and the general
9 public, that its Roundup[®] products were safe to human health and the environment, effective, fit,
1 and proper for their intended use. Defendant advertised, labeled, marketed, and promoted
1 Roundup[®] products, representing the quality to consumers and the public in such a way as to

induce their purchase or use, thereby making an express warranty that its Roundup[®] products would conform to the representations.

186. These express representations include incomplete warnings and instructions that purport, 3 4 but fail, to include the complete array of risks associated with use of and/or exposure to Roundup[®] 5 and glyphosate. Defendant knew and/or should have known that the risks expressly included in 6 Roundup[®] warnings and labels did not and do not accurately or adequately set forth the risks of 7 developing the serious injuries complained of herein. Nevertheless, Defendant expressly 8 represented that its Roundup[®] products were safe and effective, that they were safe and effective 9 for use by individuals such as Plaintiff, and/or that they were safe and effective as agricultural 10 11 herbicides.

12 187. The representations about Roundup[®], as set forth herein, contained or constituted
 13 affirmations of fact or promises made by the seller to the buyer, which related to the goods and
 14 became part of the basis of the bargain, creating an express warranty that the goods would conform
 15 to the representations.

188. Defendant placed its Roundup[®] products into the stream of commerce for sale and
recommended their use to consumers and the public without adequately warning of the true risks
of developing the injuries associated with the use of and exposure to Roundup[®] and its active
ingredient glyphosate.

189. Defendant breached these warranties because, among other things, its Roundup[®] products were defective, dangerous, unfit for use, did not contain label representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended,

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ordinary, and foreseeable use and purpose. Specifically, Defendant breached the warranties in the following ways:

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

13 190. Defendant had sole access to material facts concerning the nature of the risks associated
14 with its Roundup[®] products as expressly stated within its warnings and labels, and Defendant
15 knew that consumers and users such as Plaintiff could not have reasonably discovered that the
17 risks expressly included in Roundup[®] warnings and labels were inadequate and inaccurate.

18 191. Plaintiff had no knowledge of the falsity or incompleteness of Defendant's statements and
19 representations concerning Roundup[®].

20 192. Plaintiff used and/or was exposed to the use of Roundup[®] as researched, developed,
 21 designed, tested, formulated, manufactured, inspected, labeled, distributed, packaged, marketed,
 22 promoted, sold, or otherwise released into the stream of commerce by Defendant.

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193. Had the warnings and labels for Roundup[®] products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than
a expressly excluding such information and warranting that the products were safe for their intended
4 use, Plaintiff could have avoided the injuries complained of herein.

194. As a direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff has suffered severe injuries. Plaintiff has endured pain and suffering, has suffered economic losses (including significant expenses for medical care and treatment), and will continue to incur these expenses in the future.

10 WHEREFORE, Plaintiff requests that the Court enter judgment in his favor for compensatory and
11 punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other
12 and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the
13 issues contained herein.

COUNT FIVE BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

195. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

196. At all times relevant to this litigation, Defendant engaged in the business of testing,
developing, designing, formulating, manufacturing, marketing, selling, distributing, and
promoting its Roundup[®] products, which are defective and unreasonably dangerous to users and
consumers, including Plaintiff, thereby placing Roundup[®] products into the stream of commerce.
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197. These actions were under the ultimate control and supervision of Defendant.

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198. Before the time that Plaintiff was exposed to the use of the aforementioned Roundup[®]
products, Defendant impliedly warranted to its consumers and users, including Plaintiff, that its
Roundup[®] products were of merchantable quality and safe and fit for the use for which they were
intended; specifically, as horticultural herbicides.

5 199. Defendant, however, failed to disclose that Roundup[®] has dangerous propensities when
6 used as intended and that the use of and/or exposure to Roundup[®] and glyphosate-containing
7 products carries an increased risk of developing severe injuries, including Plaintiff's injuries.

9 200. Upon information and belief, Plaintiff reasonably relied upon the skill, superior knowledge
10 and judgment of Defendant and upon its implied warranties that the Roundup[®] products were of
11 merchantable quality and fit for their intended purpose or use.

12 201. The Roundup[®] products were expected to reach and did in fact reach consumers and users,
13 including Plaintiff, without substantial change in the condition in which they were manufactured
14 and sold by Defendant.

202. At all times relevant to this litigation, Defendant was aware that consumers and users of its products, including Plaintiff, would use Roundup[®] products as marketed by Defendant, which is to say that Plaintiff was the foreseeable user of Roundup[®].

9 203. Defendant intended that its Roundup[®] products be used in the manner in which Plaintiff in
0 fact used them and Defendant impliedly warranted each product to be of merchantable quality,
1 safe, and fit for this use, despite the fact that Roundup[®] was not adequately tested or researched.

1 204. In reliance upon Defendant's implied warranty, Plaintiff used Roundup[®] as instructed and labeled and in the foreseeable manner intended, recommended, promoted and marketed by
3 Defendant.

4 205. Plaintiff could not have reasonably discovered or known of the risks of serious injury **5** associated with Roundup[®] or glyphosate.

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

207. The harm caused by Defendant's Roundup[®] products far outweighed their benefit,
rendering the products more dangerous than an ordinary consumer or user would expect and more
dangerous than alternative products.

208. As a direct and proximate result of Defendant's wrongful acts and omissions Plaintiff has suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, has suffered economic loss (including significant expenses for medical care and treatment) and will continue to incur these expenses in the future.

WHEREFORE, Plaintiff requests that the Court enter judgment in his favor for compensatory and
punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other
and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the
issues contained herein.

COUNT SIX 1 VIOLATION OF ARIZONA CONSUMER FRAUD ACT A.R.S. § 44-1521 et seq. 2 209. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth 3 herein, and further alleges: 4 210. Plaintiff is a person within the meaning of the Arizona Consumer Fraud Act ("the Act"). 5 6 211. Defendant is a person within the meaning of the Act for all purposes herein. 7 212. The false, deceptive, and misleading statements and representations made by Defendant 8 alleged above are unlawful practices within the meaning of the Act. 9 213. Defendant engaged in the unlawful practices alleged above and those unlawful practices 10 occurred or were committed in the course, vocation, or occupation of Defendant's business. 11 214. The unlawful practices engaged in by the Defendant as alleged above significantly impact 12 13 the public as actual or potential customers. 14 215. As a direct and proximate result of the Defendant's unlawful practice committed in 15 violation of the Act, Plaintiff suffered injuries, damages, and losses as alleged herein. 16 216. Plaintiff is entitled to all damages permitted by the A.R.S. § 44-1528 and A.R.S. § 44-1534 17 of this Act, including actual damages sustained, civil penalties, attorneys' fees, and costs of this 18 action. Also, the State of Arizona is entitled to statutory penalties from Defendant for each 19 violation of the Act pursuant to A.R.S. § 44-1531. 20 21 **PRAYER FOR RELIEF** 22 WHEREFORE, Plaintiff requests that the Court enter judgment in his favor and against Monsanto, 23 awarding as follows:

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A. compensatory damages in an amount to be proven at	t trial;
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- B. punitive damages;
- C. costs including reasonable attorneys' fees, court costs, and other litigation expenses;

and

D. any other relief the Court may deem just and proper.

Dated this 30th day of October, 2018.

Respectfully Submitted,

/s/ David J. Diamond David J. Diamond (010842) 698 E. Wetmore Road, Suite 200 Tucson, AZ 85705 Tel: (520) 620-3975 Fax: (520) 620-3991 ddiamond@goldbergandosborne.com

Attorney for Plaintiff Rudy Fuentes

UNITED STATES DISTRICT COURT DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use <u>only</u> in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff (s): Rudy Fuentes	Defendant (s): Monsanto Company	
County of Residence: Maricopa	County of Residence: Outside the State of Arizona	
County Where Claim For Relief Arose: Maricopa		
Plaintiff's Atty(s):	Defendant's Atty(s):	
David J. Diamond, Esq. 698 E. Wetmore Rd., Suite 200 Tucson, Arizona 85705 (520) 620-3975	Martin C. Calhoun, Esq. Hollingsworth LLP 1350 I Street NW Washington, DC 20005 (202) 898-5867	
II. Basis of Jurisdiction: 4. Diversity (compl	ete item III)	
III. Citizenship of Principal		
Parties (Diversity Cases Only)		
Plaintiff:-1 Citizen of This St	tate	
Defendant:-5 Non AZ corp and	l Principal place of Business outside AZ	

IV. Origin :	1. Original Proceeding
V. Nature of Suit:	365 Personal Injury - Product Liability
VI.Cause of Action:	28 U.S.C. § 1332pl diversity, personal injury, product liability

<u>VII. Requested in Complaint</u> Class Action: **No** Dollar Demand: **75000** Jury Demand: Yes

VIII. This case IS RELATED to Case Number MDL No. 2741 assigned to Judge Vince Chhabria.

Signature: /s/ David J. Diamond

Date: 10/30/2018

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014