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15 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
16 **FOR THE COUNTY OF ALAMEDA**

17 COORDINATION PROCEEDING
SPECIAL TITLE (Rule 3.550)
18 ROUNDUP PRODUCTS CASES

JCCP NO. 4953

ASSIGNED FOR ALL PURPOSES TO
JUDGE WINIFRED SMITH
DEPARTMENT 21

19 THIS DOCUMENT RELATES TO:

20 PILLIOD, ET AL. v. MONSANTO CO.,
21 ET AL., CASE NO. RG17862702
22

**DEFENDANT MONSANTO COMPANY'S
SEPARATE STATEMENT OF
UNDISPUTED MATERIAL FACTS IN
SUPPORT OF MOTION FOR SUMMARY
JUDGMENT OR, IN THE ALTERNATIVE,
SUMMARY ADJUDICATION**

Hearing Date: March 7, 2019

Time: 10:00 a.m.

Department: 21

Reservation No.: R-2048303

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UNDISPUTED MATERIAL FACTS IN SUPPORT OF SUMMARY JUDGMENT

Pursuant to California Rule of Court Rule 3.1350, Defendant Monsanto Company submits this separate statement of undisputed material facts, together with references to supporting evidence, in support of its Motion for Summary Judgment or, in the Alternative, Summary Adjudication.

ISSUE ONE

The first cause of action in the Second Amended Complaint (“SAC”) for strict liability – design defect on the grounds that it is preempted by federal law and there are no disputed issues of material fact.

	<u>Moving Party’s Undisputed Material Facts and Supporting Evidence:</u>		<u>Opposing Party’s Response and Supporting Evidence</u>
1.	Roundup® is an herbicide manufactured and sold by Monsanto. First Amended Complaint (“FAC”) ¶¶ 1, 2.	1.	
2.	Roundup’s active ingredient is glyphosate. <i>Id.</i>	2.	
3.	The U.S. Environmental Protection Agency (“EPA”) first approved glyphosate-based herbicides for sale in 1974. Request for Judicial Notice (“RJN”) Exhibit 9 at p. 12; <i>see also</i> FAC ¶ 1.	3.	
4.	EPA provides express regulatory limitations as to what types of label changes can be made without prior approval. RJN Exh. 1(EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998)).	4.	

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5.	<p>Pesticide Registration Notice (“PRN”) 98-10 prohibits a “change in the ingredients statement, signal word, use classification, <i>precautionary statements</i>, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.”</p> <p><i>Id.</i> at p. 8.</p>	5.	
6.	<p>Warnings about health hazards, like cancer, are required to appear in the “Precautionary Statements” section of the label.</p> <p>40 C.F.R. § 156.70(a).</p>	6.	
7.	<p>PRN 98-10 does not list health warnings as label changes that can occur without EPA approval.</p> <p>RJN Exh. 1; <i>see also</i> Declaration of Eugene Brown (“Brown Decl.”) Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 248:8-13 (agreeing that “in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve”); 249:10-16 (agreeing that a “registrant can’t make a unilateral label change except for minor adjustments to the label”)).</p>	7.	
8.	<p>Changes to EPA-approved product formulations are governed by the same criterion as label changes.</p> <p>40 C.F.R. §§ 152.44, 152.46; RJN Exh. 1; <i>see also</i> Brown Decl. Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 242:17-21 (agreeing that “[e]very time that Monsanto changes a glyphosate-based formulation, it has to submit an application to EPA to get approval of that new formulation”)).</p>	8.	

1	9.	EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.”	9.	
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4		RJN Exh. 2, at p. 8, 39 (EPA, <i>Reregistration Eligibility Decision (RED) Glyphosate</i> at 14 (Sept. 1993)).		
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6	10.	On June 26, 1991, EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.”	10.	
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10		RJN Exh. 2, at 7, 38.		
11	11.	In 1993, glyphosate was registered again, and EPA again concluded in its Reregistration Eligibility Decision (“RED”) that there was “evidence of non-carcinogenicity in humans.”	11.	
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14		<i>Id.</i> at 21.		
15	12.	In 1997, EPA again found that “[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans . . .).”	12.	
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19		RJN Exh. 3 (<i>Glyphosate; Pesticide Tolerances</i> , 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 180, 185 and 186)).		
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21	13.	In 2002, in response to a challenge to glyphosate’s safety, the EPA found “[n]o evidence of carcinogenicity” of glyphosate.	13.	
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25		RJN Exh. 4 (<i>Glyphosate; Pesticide Tolerances</i> , 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180)).		
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1	14.	In 2004, the EPA found that “[g]lyphosate has no carcinogenic potential.”	14.	
2		RJN Exh. 5 (<i>Glyphosate; Pesticide Tolerance</i> , 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180)).		
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6	15.	In 2008, EPA found that “[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.”	15.	
7		RJN Exh. 6 (<i>Glyphosate; Pesticide Tolerances</i> , 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).		
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13	16.	In 2013, “EPA . . . concluded that glyphosate does not pose a cancer risk to humans.”	16.	
14		RJN Exh. 7 (<i>Glyphosate; Pesticide Tolerances</i> , 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180)).		
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18	17.	In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA’s Office of Pesticide Programs re-evaluated the chemical and again classified it as “[n]ot [l]ikely to be [c]arcinogenic to [h]umans.”	17.	
19		RJN Exh. 8 (EPA, Office of Pesticide Programs, <i>Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate</i> at 10, 77 (Oct. 1, 2015) (“CARC”)).		
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25	18.	In September 2016, EPA concluded that “the available data and weight-of-evidence clearly do not support the descriptors ‘carcinogenic to humans,’ ‘likely to be carcinogenic to humans,’ or ‘inadequate information to assess	18.	
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1		carcinogenic potential” and that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”		
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4		RJN Exh. 9 (Glyphosate Issue Paper at 137, 141).		
5	19.	In December 2017, EPA concluded that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	19.	
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8		RJN Exh. 10 (EPA, Office of Pesticide Programs, <i>Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 143-44 (Dec. 12, 2017)).		
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11	20.	EPA thus concluded in that report that glyphosate is “not likely to be carcinogenic to humans.”	20.	
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14		<i>Id.</i>		
15	21.	In February 2018, the Science Advisor of EPA’s OPP testified before the House Committee on Science, Space, and Technology that “[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is ‘not likely to be carcinogenic to humans.’”	21.	
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20		RJN Exh. 11 (Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)).		
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23	22.	Regulatory agencies like EPA, the European Food Safety Authority (“EFSA”), and the European Chemicals Agency (“ECHA”) have evaluated the safety of glyphosate numerous times and continually found it to be safe.	22.	
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27		RJN Exh 17 (December 21, 2018 U.S.		
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1		EPA letter to the Australian Senate).		
2				
3	23.	Prior to Plaintiffs' NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans.	23.	
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6		<i>Id.</i>		
7	24.	In July 2015, the International Agency for Research on Cancer ("IARC") issued a monograph that classified glyphosate as Group 2A (probably carcinogenic to humans).	24.	
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11		Brown Decl. Exh. 9 (IARC Monograph); <i>see also</i> FAC ¶¶ 5-6.		
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13	25.	IARC found "limited evidence" that glyphosate causes cancer in humans.	25.	
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16		Brown Decl. Exh. 9 (IARC Monograph).		
17	26.	"Limited evidence" means that IARC found a positive association between glyphosate and cancer that could have resulted from "chance, bias, or confounding."	26.	
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21		<i>Id.</i>		
22	27.	Since IARC came out with its classification of glyphosate, EPA re-reviewed the data and again determined that glyphosate is "not likely to be carcinogenic to humans."	27.	
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25		RJN Exhs. 8, 9, 10, 14, 15, 16, 17.		
26	28.	EPA again reiterated that "it is confident" that "glyphosate is not likely	28.	
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1		to be carcinogenic” and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators.		
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3		RJN Exh. 17.		
4	29.	IARC’s assessment prompted EPA’s Cancer Assessment Review Committee (“CARC”) to begin its own reassessment of glyphosate’s safety. Based on its assessment of all available epidemiological data, 11 animal studies, and 54 mutagenicity and genotoxicity studies, CARC concluded that glyphosate should continue to be classified as “not likely to be carcinogenic to humans.”	29.	
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11		RJN Exh. 8 (CARC).		
12	30.	EFSA likewise reevaluated glyphosate and concluded that it was not carcinogenic to humans.	30.	
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14		RJN Exh. 17.		
15	31.	The European Chemicals Agency concluded in 2017 that “[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted.”	31.	
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20		Brown Decl. Exh. 10 (European Chemical Agency’s glyphosate report dated March 15, 2017).		
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22	32.	The New Zealand Environmental Protection Authority, weighing all the available evidence, found: “glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen.”	32.	
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27		Brown Decl. Exh. 11, at p. 16 (New Zealand Environmental Protection Authority’s glyphosate report dated August 2016).		
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33.	<p>In 2016, the Joint Meeting on Pesticides Residues Report concluded “glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.”</p> <p>Brown Decl. Exh. 12, at p. 13 (2016 Joint FAO/WHO Meeting on Pesticides Residues Report).</p>	33.	
34.	<p>In 1994, the International Programme on Chemical Safety (“IPCS”) conducted an Environmental Health Criteria and concluded that “no adverse effects were found” in workers using GBFs, and in 2005, the WHO Guidelines for Drinking-Water Quality concluded in 2005 that “the presence of glyphosate . . . in drinking-water does not represent a hazard to human health.”</p> <p>Brown Decl. Exh. 13, 14 (International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); Ex. 20 World Health Organization (WHO), <i>Glyphosate and AMPA in Drinking-water: Background Document for Development of WHO Guidelines for Drinking-water Quality</i>, WHO/SDE/WSH/03.04/97 (June 2005)).</p>	34.	
35.	<p>The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study (“AHS”), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer risk in farmers and pesticide applicators.</p> <p>Brown Decl. Exh. 15 (Andreotti, G. et al., <i>Glyphosate Use and Cancer Incidence in the Agricultural Health Study</i>, 110 J. Nat’l Cancer Inst (2017) (“AHS Study”)).</p>	35.	

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36.	AHS followed more than 54,000 professional pesticide applicators and continued to track their progress for more than 20 years. <i>Id.</i>	36.	
37.	It represents the largest population of glyphosate users ever studied and the largest study in which researchers controlled for other pesticide use in order to isolate the effects of glyphosate on the study population. <i>Id.</i>	37.	
38.	The paper grouped participants into four tiers based on exposure levels. Each tier showed a risk ratio less than 1.0 and there was no dose-response trend to suggest that cancer was associated with greater glyphosate exposure. <i>Id.</i>	38.	
39.	When researchers first published results from this population in 2005, they concluded that “[t]here was no association between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes we evaluated, including NHL.” <i>Id.</i>	39.	
40.	Based on the AHS study, the prestigious <i>Journal of the National Cancer Institute</i> in 2018 (“JNCI 2018”) published data showing “no associations between glyphosate use and NHL risk overall or any of its subtypes.” <i>Id.</i>	40.	

1	41.	The North American Pooled Project (“NAPP”) is a project also funded by the National Institute of Health specifically addressing the hypothesis of glyphosate and NHL risk.	41.	
2		Brown Decl. Exh. 5 (Expert Report and Supplemental Expert Report of Dr. Lorelei Mucci), Exh. 16 (Manisha Pahwa et al., <i>An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin’s Lymphoma Major Histological Sub-types in the North American Pooled Project</i>).		
3	42.	NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis.	42.	
4		<i>Id.</i>		
5	43.	Like JNCI 2018, the results of NAPP showed “no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL.”	43.	
6		<i>Id.</i>		
7	44.	When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL.	44.	
8		Brown Decl. Exh. 5 (Supplemental Expert Report of Dr. Lorelei Mucci).		
9	45.	The acknowledgements section of Williams (2000) thanks “the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions.” It then names the	45.	
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1		specific toxicologists who had assisted the authors and gives credit to the company for giving the authors “complete access” to a large volume of valuable data.		
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4		Brown Decl. Ex. 17 (Gary Williams, Robert Kroes, and Ian Munro, <i>Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans, Regulatory Toxicology and Pharmacology</i> (2000)).		
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8	46.	The Williams (2012) publication also acknowledges Monsanto for “funding and for providing its unpublished glyphosate and surfactant toxicity study reports.”	46.	
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12		Brown Decl. Exh. 18 (Amy Lavin Williams, Rebecca E. Watson, John M. DeSesso, <i>Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis</i> , <i>Journal of Toxicology and Enviro. Health, Part B</i> (2012)).		
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16	47.	The acknowledgement section for Kier and Kirkland (2013) references the contributions of “David Saltmiras (Monsanto Company)” for “his invaluable service in providing coordination with individual companies and the Glyphosate Task Force.”	47.	
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21		Brown Decl. Exh. 19 (Larry D. Kier and David J. Kirkland, <i>Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations</i> , <i>Critical Reviews in Toxicology</i> (2013)).		
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23	48.	In response to Dr. Parry’s recommendations, Monsanto completed tests in an accredited laboratory and either submitted them to the EPA or, in some instances, published the results in peer-reviewed journals.	48.	
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27		Brown Decl. Exh. 6 (Martens Dep. 128:23-129:4; 216:16-217:21; 218:18-		
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	25); <i>see also</i> Brown Decl. Exh. 20 (Heydens, W. et al., <i>Genotoxic Potential of Glyphosate Formulations: Mode-of-Action Investigations</i> , 56 J. Agric. Food Chem. 1517 (2008); Hotz, K., <i>A Study of the Short-Term Effects of Mon 3050 in Male CD-1 Mice</i> , Monsanto Study MSL-16949, Monsanto Co. (July 26, 2002) (unpublished study on file with Monsanto)).		
49.	The evidence shows that upon review of the results of those tests, Dr. Parry agreed that GBHs were not genotoxic. Brown Decl. Exh. 6 (Martens Dep. 224-28).	49.	
50.	NHL is a cancer that consists of over 60 different subtypes, each of which can have different risk factors. Brown Decl. Exh. 3 (Nabhan Dep. 27:6-8; 28:14-18).	50.	
51.	The majority of NHL cases are idiopathic, meaning there is no known cause. <i>Id.</i> (Nabhan Dep. 313:23-25); <i>see also</i> Brown Decl. Exh. 4 (Expert Report of Chadi Nabhan); Brown Decl. Exh. 7 (Gupta Dep. 114:18-20).	51.	
52.	The risk of getting NHL, like most cancers, dramatically increases as people age. A man in his 70's is six times more likely to be diagnosed with diffuse large B-cell lymphoma ("DLBCL"), the most common subtype of NHL, than a man in his 50's. Brown Decl. Exh. 3 (Nabhan Dep. 21:16-17; 28:3-5; 35:13-16).	52.	

1	53.	Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012.	53.	
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3		Brown Decl. Exh. 4, p. 22-23 (Expert Report of Dr. Chadi Nabhan); Exh. 1 (Alva Pilliod Dep. 100:14-18).		
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6	54.	He was [REDACTED]	54.	
7		<i>Id.</i> ; see also Brown Decl. Exh. 3 (Nabhan Dep. 43:12-14).		
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9	55.	Mrs. Pilliod was diagnosed with primary CNS lymphoma (“PCNSL”), a rare subtype of lymphoma, in April 2015, though her symptoms started a few months earlier.	55.	
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12		Brown Decl. Exh. 4, p. 4-5 (Expert Report of Dr. Chadi Nabhan); Brown Decl. Exh. 3 (Nabhan Dep. 37:8-10); Exh. 2 (Alberta Pilliod Dep. 156:17-19).		
13				
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15	56.	She was [REDACTED]	56.	
16		<i>Id.</i>		
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18	57.	None of Plaintiffs’ treating doctors told them that their NHL was caused by Roundup.	57.	
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20		Brown Decl. Exh. 1, 2 (Alva Pilliod Dep. 107:14-18, 107:24-108:2; Alberta Pilliod Dep. 159:1-4).		
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ISSUE TWO

The second cause of action in the SAC for strict liability – failure to warn on the grounds that it is preempted by federal law and there are no disputed issues of material fact.

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	<u>Moving Party’s Undisputed Material Facts and Supporting Evidence:</u>		<u>Opposing Party’s Response and Supporting Evidence</u>
1.	Roundup® is an herbicide manufactured and sold by Monsanto. First Amended Complaint (“FAC”) ¶¶ 1, 2.	1	
2.	Roundup’s active ingredient is glyphosate. <i>Id.</i>	2.	
3.	The U.S. Environmental Protection Agency (“EPA”) first approved glyphosate-based herbicides for sale in 1974. Request for Judicial Notice (“RJN”) Exhibit 9 at p. 12; <i>see also</i> FAC ¶ 1.	3.	
4.	EPA provides express regulatory limitations as to what types of label changes can be made without prior approval. RJN Exh. 1(EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998)).	4.	
5.	Pesticide Registration Notice (“PRN”) 98-10 prohibits a “change in the ingredients statement, signal word, use classification, <i>precautionary statements</i> , statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.” <i>Id.</i> at p. 8.	5.	

1	6.	Warnings about health hazards, like cancer, are required to appear in the “Precautionary Statements” section of the label.	6.	
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4		40 C.F.R. § 156.70(a)).		
5				
6	7.	PRN 98-10 does not list health warnings as label changes that can occur without EPA approval.	7.	
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8		RJN Exh. 1; <i>see also</i> Declaration of Eugene Brown (“Brown Decl.”) Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 248:8-13 (agreeing that “in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve”); 249:10-16 (agreeing that a “registrant can’t make a unilateral label change except for minor adjustments to the label”)).		
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14	8.	Changes to EPA-approved product formulations are governed by the same criterion as label changes.	8.	
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16		40 C.F.R. §§ 152.44, 152.46; RJN Exh. 1; <i>see also</i> Brown Decl. Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 242:17-21 (agreeing that “[e]very time that Monsanto changes a glyphosate-based formulation, it has to submit an application to EPA to get approval of that new formulation”)).		
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21	9.	EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.”	9.	
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23		RJN Exh. 2, at p. 8, 39 (EPA, <i>Reregistration Eligibility Decision (RED) Glyphosate</i> at 14 (Sept. 1993)).		
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25				
26	10.	On June 26, 1991, EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate	10.	
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1	studies.”		
2	RJN Exh. 2, at 7, 38.		
3	11.	11.	
4	In 1993, glyphosate was registered		
5	again, and EPA again concluded in its		
6	Reregistration Eligibility Decision		
7	(“RED”) that there was “evidence of		
8	non-carcinogenicity in humans.”		
9	<i>Id.</i> at 21.		
10	12.	12.	
11	In 1997, EPA again found that “[d]ata		
12	indicate that glyphosate is a group E		
13	carcinogen (evidence of		
14	noncarcinogenicity for studies in		
15	humans . . .).”		
16	RJN Exh. 3 (<i>Glyphosate; Pesticide</i>		
17	<i>Tolerances</i> , 62 Fed. Reg. 17,723, 17,728		
18	(Apr. 11, 1997) (to be codified at 40		
19	C.F.R. pts. 180, 185 and 186)).		
20	13.	13.	
21	In 2002, in response to a challenge to		
22	glyphosate’s safety, the EPA found		
23	“[n]o evidence of carcinogenicity” of		
24	glyphosate.		
25	RJN Exh. 4 (<i>Glyphosate; Pesticide</i>		
26	<i>Tolerances</i> , 67 Fed. Reg. 60,934,		
27	60,935-43 (Sept. 27, 2002) (to be		
28	codified at 40 C.F.R. pt. 180)).		
29	14.	14.	
30	In 2004, the EPA found that		
31	“[g]lyphosate has no carcinogenic		
32	potential.”		
33	RJN Exh. 5 (<i>Glyphosate; Pesticide</i>		
34	<i>Tolerance</i> , 69 Fed. Reg. 65,081, 65,086		
35	(Nov. 10, 2004) (to be codified at 40		
36	C.F.R. pt. 180)).		
37	15.	15.	
38	In 2008, EPA found that “[t]here is [an]		
39	extensive database available on		
40	glyphosate, which indicate[s] that		
41	glyphosate is not mutagenic, not a		
42	carcinogen, and not a developmental or		
43	reproductive toxicant.”		

1		RJN Exh. 6 (<i>Glyphosate; Pesticide Tolerances</i> , 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).		
2	16.	In 2013, “EPA . . . concluded that glyphosate does not pose a cancer risk to humans.”	16.	
3		RJN Exh. 7 (<i>Glyphosate; Pesticide Tolerances</i> , 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180)).		
4	17.	In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA’s Office of Pesticide Programs re-evaluated the chemical and again classified it as “[n]ot [l]ikely to be [c]arcinogenic to [h]umans.”	17.	
5		RJN Exh. 8 (EPA, Office of Pesticide Programs, <i>Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate</i> at 10, 77 (Oct. 1, 2015) (“CARC”)).		
6	18.	In September 2016, EPA concluded that “the available data and weight-of-evidence clearly do not support the descriptors ‘carcinogenic to humans,’ ‘likely to be carcinogenic to humans,’ or ‘inadequate information to assess carcinogenic potential’” and that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	18.	
7		RJN Exh. 9 (Glyphosate Issue Paper at 137, 141).		
8	19.	In December 2017, EPA concluded that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	19.	
9		RJN Exh. 10 (EPA, Office of Pesticide Programs, <i>Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 143-44 (Dec. 12, 2017)).		

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20.	EPA thus concluded in that report that glyphosate is “not likely to be carcinogenic to humans.” <i>Id.</i>	20.	
21.	In February 2018, the Science Advisor of EPA’s OPP testified before the House Committee on Science, Space, and Technology that “[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is ‘not likely to be carcinogenic to humans.’” RJN Exh. 11 (Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)).	21.	
22.	Regulatory agencies like EPA, the European Food Safety Authority (“EFSA”), and the European Chemicals Agency (“ECHA”) have evaluated the safety of glyphosate numerous times and continually found it to be safe. RJN Exh 17 (December 21, 2018 U.S. EPA letter to the Australian Senate).	22.	
23.	Prior to Plaintiffs’ NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans. <i>Id.</i>	23.	
24.	In July 2015, the International Agency for Research on Cancer (“IARC”) issued a monograph that classified glyphosate as Group 2A (probably	24.	

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	carcinogenic to humans). Brown Decl. Exh. 9 (IARC Monograph); <i>see also</i> FAC ¶¶ 5-6.		
25.	IARC found “limited evidence” that glyphosate causes cancer in humans. Brown Decl. Exh. 9 (IARC Monograph).	25.	
26.	“Limited evidence” means that IARC found a positive association between glyphosate and cancer that could have resulted from “chance, bias, or confounding.” <i>Id.</i>	26.	
27.	Since IARC came out with its classification of glyphosate, EPA re-reviewed the data and again determined that glyphosate is “not likely to be carcinogenic to humans.” RJN Exhs. 8, 9, 10, 14, 15, 16, 17.	27.	
28.	EPA again reiterated that “it is confident” that “glyphosate is not likely to be carcinogenic” and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators. RJN Exh. 17.	28.	
29.	IARC’s assessment prompted EPA’s Cancer Assessment Review Committee (“CARC”) to begin its own reassessment of glyphosate’s safety. Based on its assessment of all available epidemiological data, 11 animal studies, and 54 mutagenicity and genotoxicity studies, CARC concluded that glyphosate should continue to be classified as “not likely to be carcinogenic to humans.”	29.	

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	RJN Exh. 8 (CARC).		
30.	EFSA likewise reevaluated glyphosate and concluded that it was not carcinogenic to humans. RJN Exh. 17.	30.	
31.	The European Chemicals Agency concluded in 2017 that “[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted.” Brown Decl. Exh. 10 (European Chemical Agency’s glyphosate report dated March 15, 2017).	31.	
32.	The New Zealand Environmental Protection Authority, weighing all the available evidence, found: “glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen.” Brown Decl. Exh. 11, at p. 16 (New Zealand Environmental Protection Authority’s glyphosate report dated August 2016).	32.	
33.	In 2016, the Joint Meeting on Pesticides Residues Report concluded “glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.” Brown Decl. Exh. 12, at p. 13 (2016 Joint FAO/WHO Meeting on Pesticides Residues Report).	33.	
34.	In 1994, the International Programme on Chemical Safety (“IPCS”) conducted an Environmental Health Criteria and concluded that “no adverse effects were found” in workers using GBFs, and in	34.	

1		2005, the WHO Guidelines for Drinking-Water Quality concluded in		
2		2005 that “the presence of glyphosate . .		
3		. in drinking-water does not represent a hazard to human health.”		
4		Brown Decl. Exh. 13, 14 (International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); Ex. 20 World Health Organization (WHO), <i>Glyphosate and AMPA in Drinking-water: Background Document for Development of WHO Guidelines for Drinking-water Quality</i> , WHO/SDE/WSH/03.04/97 (June 2005)).		
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12	35.	The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study (“AHS”), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer risk in farmers and pesticide applicators.	35.	
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16		Brown Decl. Exh. 15 (Andreotti, G. et al., <i>Glyphosate Use and Cancer Incidence in the Agricultural Health Study</i> , 110 J. Nat’l Cancer Inst (2017) (“AHS Study”)).		
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19	36.	AHS followed more than 54,000 professional pesticide applicators and continued to track their progress for more than 20 years.	36.	
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22		<i>Id.</i>		
23	37.	It represents the largest population of glyphosate users ever studied and the largest study in which researchers controlled for other pesticide use in order to isolate the effects of glyphosate on the study population.	37.	
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27		<i>Id.</i>		
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1	38.	The paper grouped participants into four tiers based on exposure levels. Each tier showed a risk ratio less than 1.0 and there was no dose-response trend to suggest that cancer was associated with greater glyphosate exposure.	38.	
2		<i>Id.</i>		
3	39.	When researchers first published results from this population in 2005, they concluded that “[t]here was no association between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes we evaluated, including NHL.”	39.	
4		<i>Id.</i>		
5	40.	Based on the AHS study, the prestigious <i>Journal of the National Cancer Institute</i> in 2018 (“JNCI 2018”) published data showing “no associations between glyphosate use and NHL risk overall or any of its subtypes.”	40.	
6		<i>Id.</i>		
7	41.	The North American Pooled Project (“NAPP”) is a project also funded by the National Institute of Health specifically addressing the hypothesis of glyphosate and NHL risk.	41.	
8		Brown Decl. Exh. 5 (Expert Report and Supplemental Expert Report of Dr. Lorelei Mucci), Exh. 16 (Manisha Pahwa et al., <i>An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin’s Lymphoma Major Histological Sub-types in the North American Pooled Project</i>).		
9	42.	NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis.	42.	
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	<i>Id.</i>		
43.	Like JNCI 2018, the results of NAPP showed “no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL.” <i>Id.</i>	43.	
44.	When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL. Brown Decl. Exh. 5 (Supplemental Expert Report of Dr. Lorelei Mucci).	44.	
45.	The acknowledgements section of Williams (2000) thanks “the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions.” It then names the specific toxicologists who had assisted the authors and gives credit to the company for giving the authors “complete access” to a large volume of valuable data. Brown Decl. Ex. 17 (Gary Williams, Robert Kroes, and Ian Munro, <i>Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans</i> , Regulatory Toxicology and Pharmacology (2000)).	45.	
46.	The Williams (2012) publication also acknowledges Monsanto for “funding and for providing its unpublished glyphosate and surfactant toxicity study	46.	

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	reports.” Brown Decl. Exh. 18 (Amy Lavin Williams, Rebecca E. Watson, John M. DeSesso, <i>Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis</i> , Journal of Toxicology and Enviro. Health, Part B (2012)).		
47.	The acknowledgement section for Kier and Kirkland (2013) references the contributions of “David Saltmiras (Monsanto Company)” for “his invaluable service in providing coordination with individual companies and the Glyphosate Task Force.” Brown Decl. Exh. 19 (Larry D. Kier and David J. Kirkland, <i>Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations</i> , Critical Reviews in Toxicology (2013)).	47.	
48.	In response to Dr. Parry’s recommendations, Monsanto completed tests in an accredited laboratory and either submitted them to the EPA or, in some instances, published the results in peer-reviewed journals. Brown Decl. Exh. 6 (Martens Dep. 128:23-129:4; 216:16-217:21; 218:18-25); <i>see also</i> Brown Decl. Exh. 20 (Heydens, W. et al., <i>Genotoxic Potential of Glyphosate Formulations: Mode-of-Action Investigations</i> , 56 J. Agric. Food Chem. 1517 (2008); Hotz, K., <i>A Study of the Short-Term Effects of Mon 3050 in Male CD-1 Mice</i> , Monsanto Study MSL-16949, Monsanto Co. (July 26, 2002) (unpublished study on file with Monsanto)).	48.	
49.	The evidence shows that upon review of the results of those tests, Dr. Parry agreed that GBHs were not genotoxic. Brown Decl. Exh. 6 (Martens Dep. 224-28).	49.	

1	50.	NHL is a cancer that consists of over 60 different subtypes, each of which can have different risk factors.	50.	
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4		Brown Decl. Exh. 3 (Nabhan Dep. 27:6-8; 28:14-18).		
5	51.	The majority of NHL cases are idiopathic, meaning there is no known cause.	51.	
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8		<i>Id.</i> (Nabhan Dep. 313:23-25); <i>see also</i> Brown Decl. Exh. 4 (Expert Report of Chadi Nabhan); Brown Decl. Exh. 7 (Gupta Dep. 114:18-20).		
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10	52.	The risk of getting NHL, like most cancers, dramatically increases as people age. A man in his 70's is six times more likely to be diagnosed with diffuse large B-cell lymphoma ("DLBCL"), the most common subtype of NHL, than a man in his 50's.	52.	
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15		Brown Decl. Exh. 3 (Nabhan Dep. 21:16-17; 28:3-5; 35:13-16).		
16	53.	Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012.	53.	
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19		Brown Decl. Exh. 4, p. 22-23 (Expert Report of Dr. Chadi Nabhan); Exh. 1 (Alva Pilliod Dep. 100:14-18).		
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21	54.	He was [REDACTED]	54.	
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23		<i>Id.</i> ; <i>see also</i> Brown Decl. Exh. 3 (Nabhan Dep. 43:12-14).		
24	55.	Mrs. Pilliod was diagnosed with primary CNS lymphoma ("PCNSL"), a rare subtype of lymphoma, in April 2015, though her symptoms started a few months earlier.	55.	
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27		Brown Decl. Exh. 4, p. 4-5 (Expert Report of Dr. Chadi Nabhan); Brown		
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	Decl. Exh. 3 (Nabhan Dep. 37:8-10); Exh. 2 (Alberta Pilliod Dep. 156:17-19).		
56.	She was [REDACTED] <i>Id.</i>	56.	
57.	None of Plaintiffs' treating doctors told them that their NHL was caused by Roundup. Brown Decl. Exh. 1, 2 (Alva Pilliod Dep. 107:14-18, 107:24-108:2; Alberta Pilliod Dep. 159:1-4).	57.	

ISSUE THREE

The third cause of action for negligence on the grounds that it is preempted by federal law and there are no disputed issues of material fact.

	<u>Moving Party's Undisputed Material Facts and Supporting Evidence:</u>		<u>Opposing Party's Response and Supporting Evidence</u>
1.	Roundup® is an herbicide manufactured and sold by Monsanto. First Amended Complaint ("FAC") ¶¶ 1, 2.	1	
2.	Roundup's active ingredient is glyphosate. <i>Id.</i>	2.	
3.	The U.S. Environmental Protection Agency ("EPA") first approved glyphosate-based herbicides for sale in 1974. Request for Judicial Notice ("RJN") Exhibit 9 at p. 12; <i>see also</i> FAC ¶ 1.	3.	

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4.	<p>EPA provides express regulatory limitations as to what types of label changes can be made without prior approval.</p> <p>RJN Exh. 1(EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998)).</p>	4.	
5.	<p>Pesticide Registration Notice (“PRN”) 98-10 prohibits a “change in the ingredients statement, signal word, use classification, <i>precautionary statements</i>, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.”</p> <p><i>Id.</i> at p. 8.</p>	5.	
6.	<p>Warnings about health hazards, like cancer, are required to appear in the “Precautionary Statements” section of the label.</p> <p>40 C.F.R. § 156.70(a).</p>	6.	
7.	<p>PRN 98-10 does not list health warnings as label changes that can occur without EPA approval.</p> <p>RJN Exh. 1; <i>see also</i> Declaration of Eugene Brown (“Brown Decl.”) Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 248:8-13 (agreeing that “in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve”); 249:10-16 (agreeing that a “registrant can’t make a unilateral label change except for minor adjustments to the label”)).</p>	7.	
8.	<p>Changes to EPA-approved product formulations are governed by the same</p>	8.	

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	<p>1 criterion as label changes.</p> <p>2 40 C.F.R. §§ 152.44, 152.46; RJN Exh.</p> <p>3 1; <i>see also</i> Brown Decl. Exh. 8</p> <p>4 (Benbrook <i>Hardeman</i> Dep. at 242:17-21</p> <p>5 (agreeing that “[e]very time that</p> <p>6 Monsanto changes a glyphosate-based</p> <p>7 formulation, it has to submit an</p> <p>8 application to EPA to get approval of</p> <p>9 that new formulation”)).</p>		
9.	<p>7 EPA classified glyphosate as non-</p> <p>8 carcinogenic for humans “based on a</p> <p>9 lack of convincing evidence of</p> <p>10 carcinogenicity in adequate studies.”</p> <p>11 RJN Exh. 2, at p. 8, 39 (EPA,</p> <p>12 <i>Reregistration Eligibility Decision</i></p> <p>13 (<i>RED</i>) <i>Glyphosate</i> at 14 (Sept. 1993)).</p>	9.	
10.	<p>12 On June 26, 1991, EPA classified</p> <p>13 glyphosate as non-carcinogenic for</p> <p>14 humans “based on a lack of convincing</p> <p>15 evidence of carcinogenicity in adequate</p> <p>16 studies.”</p> <p>17 RJN Exh. 2, at 7, 38.</p>	10.	
11.	<p>16 In 1993, glyphosate was registered</p> <p>17 again, and EPA again concluded in its</p> <p>18 Reregistration Eligibility Decision</p> <p>19 (“RED”) that there was “evidence of</p> <p>20 non-carcinogenicity in humans.”</p> <p>21 <i>Id.</i> at 21.</p>	11.	
12.	<p>21 In 1997, EPA again found that “[d]ata</p> <p>22 indicate that glyphosate is a group E</p> <p>23 carcinogen (evidence of</p> <p>24 noncarcinogenicity for studies in</p> <p>25 humans . . .).”</p> <p>26 RJN Exh. 3 (<i>Glyphosate; Pesticide</i></p> <p>27 <i>Tolerances</i>, 62 Fed. Reg. 17,723, 17,728</p> <p>28 (Apr. 11, 1997) (to be codified at 40</p> <p>C.F.R. pts. 180, 185 and 186)).</p>	12.	

1	13.	In 2002, in response to a challenge to glyphosate’s safety, the EPA found “[n]o evidence of carcinogenicity” of glyphosate.	13.	
2		RJN Exh. 4 (<i>Glyphosate; Pesticide Tolerances</i> , 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180)).		
3				
4	14.	In 2004, the EPA found that “[g]lyphosate has no carcinogenic potential.”	14.	
5		RJN Exh. 5 (<i>Glyphosate; Pesticide Tolerance</i> , 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180)).		
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7	15.	In 2008, EPA found that “[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.”	15.	
8		RJN Exh. 6 (<i>Glyphosate; Pesticide Tolerances</i> , 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).		
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10	16.	In 2013, “EPA . . . concluded that glyphosate does not pose a cancer risk to humans.”	16.	
11		RJN Exh. 7 (<i>Glyphosate; Pesticide Tolerances</i> , 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180)).		
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13	17.	In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA’s Office of Pesticide Programs re-evaluated the chemical and again classified it as “[n]ot [l]ikely to be [c]arcinogenic to [h]umans.”	17.	
14		RJN Exh. 8 (EPA, Office of Pesticide Programs, <i>Cancer Assessment</i>		
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1		<i>Document—Evaluation of the Carcinogenic Potential of Glyphosate at 10, 77 (Oct. 1, 2015) (“CARC”)</i> .		
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3	18.	In September 2016, EPA concluded that “the available data and weight-of-evidence clearly do not support the descriptors ‘carcinogenic to humans,’ ‘likely to be carcinogenic to humans,’ or ‘inadequate information to assess carcinogenic potential’” and that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	18.	
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11	19.	In December 2017, EPA concluded that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	19.	
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14		RJN Exh. 10 (EPA, Office of Pesticide Programs, <i>Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 143-44 (Dec. 12, 2017)).		
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17	20.	EPA thus concluded in that report that glyphosate is “not likely to be carcinogenic to humans.”	20.	
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19		<i>Id.</i>		
20	21.	In February 2018, the Science Advisor of EPA’s OPP testified before the House Committee on Science, Space, and Technology that “[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is ‘not likely to be carcinogenic to humans.’”	21.	
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25		RJN Exh. 11 (Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)).		
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1	22.	Regulatory agencies like EPA, the European Food Safety Authority (“EFSA”), and the European Chemicals Agency (“ECHA”) have evaluated the safety of glyphosate numerous times and continually found it to be safe. RJN Exh 17 (December 21, 2018 U.S. EPA letter to the Australian Senate).	22.	
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7	23.	Prior to Plaintiffs’ NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans. <i>Id.</i>	23.	
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12	24.	In July 2015, the International Agency for Research on Cancer (“IARC”) issued a monograph that classified glyphosate as Group 2A (probably carcinogenic to humans). Brown Decl. Exh. 9 (IARC Monograph); <i>see also</i> FAC ¶¶ 5-6.	24.	
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18	25.	IARC found “limited evidence” that glyphosate causes cancer in humans. Brown Decl. Exh. 9 (IARC Monograph).	25.	
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22	26.	“Limited evidence” means that IARC found a positive association between glyphosate and cancer that could have resulted from “chance, bias, or confounding.” <i>Id.</i>	26.	
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26	27.	Since IARC came out with its classification of glyphosate, EPA re-reviewed the data and again determined	27.	
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1		that glyphosate is “not likely to be carcinogenic to humans.”		
2		RJN Exhs. 8, 9, 10, 14, 15, 16, 17.		
3				
4	28.	EPA again reiterated that “it is confident” that “glyphosate is not likely to be carcinogenic” and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators.	28.	
5		RJN Exh. 17.		
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19	31.	The European Chemicals Agency concluded in 2017 that “[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted.”	31.	
20		Brown Decl. Exh. 10 (European Chemical Agency’s glyphosate report dated March 15, 2017).		
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26	32.	The New Zealand Environmental Protection Authority, weighing all the available evidence, found: “glyphosate	32.	
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1		is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen.”		
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4		Brown Decl. Exh. 11, at p. 16 (New Zealand Environmental Protection Authority’s glyphosate report dated August 2016).		
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6	33.	In 2016, the Joint Meeting on Pesticides Residues Report concluded “glyphosate in unlikely to pose a carcinogenic risk to humans via exposure from diet.”	33.	
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9		Brown Decl. Exh. 12, at p. 13 (2016 Joint FAO/WHO Meeting on Pesticides Residues Report).		
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11	34.	In 1994, the International Programme on Chemical Safety (“IPCS”) conducted an Environmental Health Criteria and concluded that “no adverse effects were found” in workers using GBFs, and in 2005, the WHO Guidelines for Drinking-Water Quality concluded in 2005 that “the presence of glyphosate . . . in drinking-water does not represent a hazard to human health.”	34.	
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17		Brown Decl. Exh. 13, 14 (International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); Ex. 20 World Health Organization (WHO), <i>Glyphosate and AMPA in Drinking-water: Background Document for Development of WHO Guidelines for Drinking-water Quality</i> , WHO/SDE/WSH/03.04/97 (June 2005)).		
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25	35.	The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study (“AHS”), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer	35.	
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1		risk in farmers and pesticide applicators.		
2		Brown Decl. Exh. 15 (Andreotti, G. et.		
3		al., <i>Glyphosate Use and Cancer</i>		
4		<i>Incididence in the Agricultural Health</i>		
		<i>Study</i> , 110 J. Nat’l Cancer Inst (2017)		
		(“AHS Study”).		
5	36.	AHS followed more than 54,000	36.	
6		professional pesticide applicators and		
7		continued to track their progress for		
8		more than 20 years.		
		<i>Id.</i>		
9	37.	It represents the largest population of	37.	
10		glyphosate users ever studied and the		
11		largest study in which researchers		
12		controlled for other pesticide use in		
13		order to isolate the effects of glyphosate		
		on the study population.		
		<i>Id.</i>		
14	38.	The paper grouped participants into four	38.	
15		tiers based on exposure levels. Each tier		
16		showed a risk ratio less than 1.0 and		
17		there was no dose-response trend to		
18		suggest that cancer was associated with		
		greater glyphosate exposure.		
		<i>Id.</i>		
19	39.	When researchers first published results	39.	
20		from this population in 2005, they		
21		concluded that “[t]here was no		
22		association between glyphosate		
23		exposure and all cancer incidence or		
		most of the specific cancer subtypes we		
		evaluated, including NHL.”		
		<i>Id.</i>		
25	40.	Based on the AHS study, the prestigious	40.	
26		<i>Journal of the National Cancer Institute</i>		
27		in 2018 (“JNCI 2018”) published data		
28		showing “no associations between		
		glyphosate use and NHL risk overall or		
		any of its subtypes.”		

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	<i>Id.</i>		
41.	<p>The North American Pooled Project (“NAPP”) is a project also funded by the National Institute of Health specifically addressing the hypothesis of glyphosate and NHL risk.</p> <p>Brown Decl. Exh. 5 (Expert Report and Supplemental Expert Report of Dr. Lorelei Mucci), Exh. 16 (Manisha Pahwa et al., <i>An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin’s Lymphoma Major Histological Sub-types in the North American Pooled Project</i>).</p>	41.	
42.	<p>NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis.</p> <p><i>Id.</i></p>	42.	
43.	<p>Like JNCI 2018, the results of NAPP showed “no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL.”</p> <p><i>Id.</i></p>	43.	
44.	<p>When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL.</p> <p>Brown Decl. Exh. 5 (Supplemental Expert Report of Dr. Lorelei Mucci).</p>	44.	

1 2 3 4 5 6 7 8 9 10 11	45.	<p>The acknowledgements section of Williams (2000) thanks “the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions.” It then names the specific toxicologists who had assisted the authors and gives credit to the company for giving the authors “complete access” to a large volume of valuable data.</p> <p>Brown Decl. Ex. 17 (Gary Williams, Robert Kroes, and Ian Munro, <i>Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans</i>, Regulatory Toxicology and Pharmacology (2000)).</p>	45.	
12 13 14 15 16 17 18 19	46.	<p>The Williams (2012) publication also acknowledges Monsanto for “funding and for providing its unpublished glyphosate and surfactant toxicity study reports.”</p> <p>Brown Decl. Exh. 18 (Amy Lavin Williams, Rebecca E. Watson, John M. DeSesso, <i>Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis</i>, Journal of Toxicology and Enviro. Health, Part B (2012)).</p>	46.	
20 21 22 23 24 25 26 27	47.	<p>The acknowledgement section for Kier and Kirkland (2013) references the contributions of “David Saltmiras (Monsanto Company)” for “his invaluable service in providing coordination with individual companies and the Glyphosate Task Force.”</p> <p>Brown Decl. Exh. 19 (Larry D. Kier and David J. Kirkland, <i>Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations</i>, Critical Reviews in Toxicology (2013)).</p>	47.	

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1	48.	In response to Dr. Parry's	48.
2		recommendations, Monsanto completed	
3		tests in an accredited laboratory and	
4		either submitted them to the EPA or, in	
5		some instances, published the results in	
6		peer-reviewed journals.	
7		Brown Decl. Exh. 6 (Martens Dep.	
8		128:23-129:4; 216:16-217:21; 218:18-	
9		25); <i>see also</i> Brown Decl. Exh. 20	
10		(Heydens, W. et al., <i>Genotoxic Potential</i>	
11		<i>of Glyphosate Formulations: Mode-of-</i>	
		<i>Action Investigations</i> , 56 J. Agric. Food	
		Chem. 1517 (2008); Hotz, K., <i>A Study</i>	
		<i>of the Short-Term Effects of Mon 3050</i>	
		<i>in Male CD-1 Mice</i> , Monsanto Study	
		MSL-16949, Monsanto Co. (July 26,	
		2002) (unpublished study on file with	
		Monsanto)).	
12	49.	The evidence shows that upon review of	49.
13		the results of those tests, Dr. Parry	
14		agreed that GBHs were not genotoxic.	
15		Brown Decl. Exh. 6 (Martens Dep. 224-	
16		28).	
17	50.	NHL is a cancer that consists of over 60	50.
18		different subtypes, each of which can	
19		have different risk factors.	
20		Brown Decl. Exh. 3 (Nabhan Dep. 27:6-	
21		8; 28:14-18).	
22	51.	The majority of NHL cases are	51.
23		idiopathic, meaning there is no known	
24		cause.	
25		<i>Id.</i> (Nabhan Dep. 313:23-25); <i>see also</i>	
26		Brown Decl. Exh. 4 (Expert Report of	
27		Chadi Nabhan); Brown Decl. Exh. 7	
28		(Gupta Dep. 114:18-20).	
	52.	The risk of getting NHL, like most	52.
		cancers, dramatically increases as	
		people age. A man in his 70's is six	
		times more likely to be diagnosed with	
		diffuse large B-cell lymphoma	
		("DLBCL"), the most common subtype	

1		of NHL, than a man in his 50's.		
2		Brown Decl. Exh. 3 (Nabhan Dep. 21:16-17; 28:3-5; 35:13-16).		
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4	53.	Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012.	53.	
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6		Brown Decl. Exh. 4, p. 22-23 (Expert Report of Dr. Chadi Nabhan); Exh. 1 (Alva Pilliod Dep. 100:14-18).		
7				
8	54.	He was [REDACTED]	54.	
9				
10		<i>Id.</i> ; see also Brown Decl. Exh. 3 (Nabhan Dep. 43:12-14).		
11	55.	Mrs. Pilliod was diagnosed with primary CNS lymphoma ("PCNSL"), a rare subtype of lymphoma, in April 2015, though her symptoms started a few months earlier.	55.	
12				
13		Brown Decl. Exh. 4, p. 4-5 (Expert Report of Dr. Chadi Nabhan); Brown Decl. Exh. 3 (Nabhan Dep. 37:8-10); Exh. 2 (Alberta Pilliod Dep. 156:17-19).		
14				
15	56.	She was [REDACTED]	56.	
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17		<i>Id.</i>		
18	57.	None of Plaintiffs' treating doctors told them that their NHL was caused by Roundup.	57.	
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20		Brown Decl. Exh. 1, 2 (Alva Pilliod Dep. 107:14-18, 107:24-108:2; Alberta Pilliod Dep. 159:1-4).		
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ISSUE FOUR

The fourth cause of action for breach of implied warranty on the grounds that it is preempted by federal law and there are no disputed issues of material fact.

	<u>Moving Party’s Undisputed Material Facts and Supporting Evidence:</u>		<u>Opposing Party’s Response and Supporting Evidence</u>
1.	<p>Roundup® is an herbicide manufactured and sold by Monsanto.</p> <p>First Amended Complaint (“FAC”) ¶¶ 1, 2.</p>	1	
2.	<p>Roundup’s active ingredient is glyphosate.</p> <p><i>Id.</i></p>	2.	
3.	<p>The U.S. Environmental Protection Agency (“EPA”) first approved glyphosate-based herbicides for sale in 1974.</p> <p>Request for Judicial Notice (“RJN”) Exhibit 9 at p. 12; <i>see also</i> FAC ¶ 1.</p>	3.	
4.	<p>EPA provides express regulatory limitations as to what types of label changes can be made without prior approval.</p> <p>RJN Exh. 1(EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998)).</p>	4.	
5.	<p>Pesticide Registration Notice (“PRN”) 98-10 prohibits a “change in the ingredients statement, signal word, use classification, <i>precautionary statements</i>, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.”</p> <p><i>Id.</i> at p. 8.</p>	5.	

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6.	Warnings about health hazards, like cancer, are required to appear in the “Precautionary Statements” section of the label. 40 C.F.R. § 156.70(a)).	6.	
7.	PRN 98-10 does not list health warnings as label changes that can occur without EPA approval. RJN Exh. 1; <i>see also</i> Declaration of Eugene Brown (“Brown Decl.”) Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 248:8-13 (agreeing that “in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve”); 249:10-16 (agreeing that a “registrant can’t make a unilateral label change except for minor adjustments to the label”)).	7.	
8.	Changes to EPA-approved product formulations are governed by the same criterion as label changes. 40 C.F.R. §§ 152.44, 152.46; RJN Exh. 1; <i>see also</i> Brown Decl. Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 242:17-21 (agreeing that “[e]very time that Monsanto changes a glyphosate-based formulation, it has to submit an application to EPA to get approval of that new formulation”)).	8.	
9.	EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.” RJN Exh. 2, at p. 8, 39 (EPA, <i>Reregistration Eligibility Decision (RED) Glyphosate</i> at 14 (Sept. 1993)).	9.	

1	10.	On June 26, 1991, EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.”	10.	
2		RJN Exh. 2, at 7, 38.		
3	11.	In 1993, glyphosate was registered again, and EPA again concluded in its Reregistration Eligibility Decision (“RED”) that there was “evidence of non-carcinogenicity in humans.”	11.	
4		<i>Id.</i> at 21.		
5	12.	In 1997, EPA again found that “[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans . . .).”	12.	
6		RJN Exh. 3 (<i>Glyphosate; Pesticide Tolerances</i> , 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 180, 185 and 186)).		
7	13.	In 2002, in response to a challenge to glyphosate’s safety, the EPA found “[n]o evidence of carcinogenicity” of glyphosate.	13.	
8		RJN Exh. 4 (<i>Glyphosate; Pesticide Tolerances</i> , 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180)).		
9	14.	In 2004, the EPA found that “[g]lyphosate has no carcinogenic potential.”	14.	
10		RJN Exh. 5 (<i>Glyphosate; Pesticide Tolerance</i> , 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180)).		

1 2 3 4 5 6 7	15. In 2008, EPA found that “[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.” RJN Exh. 6 (<i>Glyphosate; Pesticide Tolerances</i> , 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).	15.	
8 9 10 11 12	16. In 2013, “EPA . . . concluded that glyphosate does not pose a cancer risk to humans.” RJN Exh. 7 (<i>Glyphosate; Pesticide Tolerances</i> , 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180)).	16.	
13 14 15 16 17 18 19	17. In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA’s Office of Pesticide Programs re-evaluated the chemical and again classified it as “[n]ot [l]ikely to be [c]arcinogenic to [h]umans.” RJN Exh. 8 (EPA, Office of Pesticide Programs, <i>Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate</i> at 10, 77 (Oct. 1, 2015) (“CARC”)).	17.	
20 21 22 23 24 25 26	18. In September 2016, EPA concluded that “the available data and weight-of-evidence clearly do not support the descriptors ‘carcinogenic to humans,’ ‘likely to be carcinogenic to humans,’ or ‘inadequate information to assess carcinogenic potential’” and that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.” RJN Exh. 9 (Glyphosate Issue Paper at 137, 141).	18.	

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1	19.	In December 2017, EPA concluded that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	19.	
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4		RJN Exh. 10 (EPA, Office of Pesticide Programs, <i>Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 143-44 (Dec. 12, 2017)).		
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7	20.	EPA thus concluded in that report that glyphosate is “not likely to be carcinogenic to humans.”	20.	
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9		<i>Id.</i>		
10				
11	21.	In February 2018, the Science Advisor of EPA’s OPP testified before the House Committee on Science, Space, and Technology that “[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is ‘not likely to be carcinogenic to humans.’”	21.	
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16		RJN Exh. 11 (Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)).		
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19	22.	Regulatory agencies like EPA, the European Food Safety Authority (“EFSA”), and the European Chemicals Agency (“ECHA”) have evaluated the safety of glyphosate numerous times and continually found it to be safe.	22.	
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23		RJN Exh 17 (December 21, 2018 U.S. EPA letter to the Australian Senate).		
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25	23.	Prior to Plaintiffs’ NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans.	23.	
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	<i>Id.</i>		
24.	In July 2015, the International Agency for Research on Cancer (“IARC”) issued a monograph that classified glyphosate as Group 2A (probably carcinogenic to humans). Brown Decl. Exh. 9 (IARC Monograph); <i>see also</i> FAC ¶¶ 5-6.	24.	
25.	IARC found “limited evidence” that glyphosate causes cancer in humans. Brown Decl. Exh. 9 (IARC Monograph).	25.	
26.	“Limited evidence” means that IARC found a positive association between glyphosate and cancer that could have resulted from “chance, bias, or confounding.” <i>Id.</i>	26.	
27.	Since IARC came out with its classification of glyphosate, EPA re-reviewed the data and again determined that glyphosate is “not likely to be carcinogenic to humans.” RJN Exhs. 8, 9, 10, 14, 15, 16, 17.	27.	
28.	EPA again reiterated that “it is confident” that “glyphosate is not likely to be carcinogenic” and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators. RJN Exh. 17.	28.	
29.	IARC’s assessment prompted EPA’s Cancer Assessment Review Committee	29.	

1		(“CARC”) to begin its own reassessment of glyphosate’s safety. Based on its assessment of all available epidemiological data, 11 animal studies, and 54 mutagenicity and genotoxicity studies, CARC concluded that glyphosate should continue to be classified as “not likely to be carcinogenic to humans.”		
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6		RJN Exh. 8 (CARC).		
7	30.	EFSA likewise reevaluated glyphosate and concluded that it was not carcinogenic to humans.	30.	
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10		RJN Exh. 17.		
11	31.	The European Chemicals Agency concluded in 2017 that “[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted.”	31.	
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15		Brown Decl. Exh. 10 (European Chemical Agency’s glyphosate report dated March 15, 2017).		
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17	32.	The New Zealand Environmental Protection Authority, weighing all the available evidence, found: “glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen.”	32.	
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22		Brown Decl. Exh. 11, at p. 16 (New Zealand Environmental Protection Authority’s glyphosate report dated August 2016).		
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24	33.	In 2016, the Joint Meeting on Pesticides Residues Report concluded “glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.”	33.	
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27		Brown Decl. Exh. 12, at p. 13 (2016 Joint FAO/WHO Meeting on Pesticides		
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1		Residues Report).		
2				
3	34.	In 1994, the International Programme on Chemical Safety (“IPCS”) conducted an Environmental Health Criteria and concluded that “no adverse effects were found” in workers using GBFs, and in 2005, the WHO Guidelines for Drinking-Water Quality concluded in 2005 that “the presence of glyphosate . . . in drinking-water does not represent a hazard to human health.”	34.	
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16	35.	The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study (“AHS”), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer risk in farmers and pesticide applicators.	35.	
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24	36.	AHS followed more than 54,000 professional pesticide applicators and continued to track their progress for more than 20 years.	36.	
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27		<i>Id.</i>		

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1	37.	It represents the largest population of glyphosate users ever studied and the largest study in which researchers controlled for other pesticide use in order to isolate the effects of glyphosate on the study population.	37.	
2				
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5		<i>Id.</i>		
6	38.	The paper grouped participants into four tiers based on exposure levels. Each tier showed a risk ratio less than 1.0 and there was no dose-response trend to suggest that cancer was associated with greater glyphosate exposure.	38.	
7				
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10		<i>Id.</i>		
11	39.	When researchers first published results from this population in 2005, they concluded that “[t]here was no association between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes we evaluated, including NHL.”	39.	
12				
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16		<i>Id.</i>		
17	40.	Based on the AHS study, the prestigious <i>Journal of the National Cancer Institute</i> in 2018 (“JNCI 2018”) published data showing “no associations between glyphosate use and NHL risk overall or any of its subtypes.”	40.	
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21		<i>Id.</i>		
22	41.	The North American Pooled Project (“NAPP”) is a project also funded by the National Institute of Health specifically addressing the hypothesis of glyphosate and NHL risk.	41.	
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25		Brown Decl. Exh. 5 (Expert Report and Supplemental Expert Report of Dr. Lorelei Mucci), Exh. 16 (Manisha Pahwa et al., <i>An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin’s Lymphoma Major</i>		
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	<i>Histological Sub-types in the North American Pooled Project).</i>		
42.	NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis. <i>Id.</i>	42.	
43.	Like JNCI 2018, the results of NAPP showed “no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL.” <i>Id.</i>	43.	
44.	When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL. Brown Decl. Exh. 5 (Supplemental Expert Report of Dr. Lorelei Mucci).	44.	
45.	The acknowledgements section of Williams (2000) thanks “the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions.” It then names the specific toxicologists who had assisted the authors and gives credit to the company for giving the authors “complete access” to a large volume of valuable data. Brown Decl. Ex. 17 (Gary Williams, Robert Kroes, and Ian Munro, <i>Safety Evaluation and Risk Assessment of the</i>	45.	

1		<i>Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans, Regulatory Toxicology and Pharmacology</i> (2000)).	
2			
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4	46.	The Williams (2012) publication also acknowledges Monsanto for “funding and for providing its unpublished glyphosate and surfactant toxicity study reports.”	46.
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7		Brown Decl. Exh. 18 (Amy Lavin Williams, Rebecca E. Watson, John M. DeSesso, <i>Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis</i> , <i>Journal of Toxicology and Enviro. Health, Part B</i> (2012)).	
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11	47.	The acknowledgement section for Kier and Kirkland (2013) references the contributions of “David Saltmiras (Monsanto Company)” for “his invaluable service in providing coordination with individual companies and the Glyphosate Task Force.”	47.
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16		Brown Decl. Exh. 19 (Larry D. Kier and David J. Kirkland, <i>Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations</i> , <i>Critical Reviews in Toxicology</i> (2013)).	
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19	48.	In response to Dr. Parry’s recommendations, Monsanto completed tests in an accredited laboratory and either submitted them to the EPA or, in some instances, published the results in peer-reviewed journals.	48.
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23		Brown Decl. Exh. 6 (Martens Dep. 128:23-129:4; 216:16-217:21; 218:18-25); <i>see also</i> Brown Decl. Exh. 20 (Heydens, W. et al., <i>Genotoxic Potential of Glyphosate Formulations: Mode-of-Action Investigations</i> , 56 <i>J. Agric. Food Chem.</i> 1517 (2008); Hotz, K., <i>A Study of the Short-Term Effects of Mon 3050 in Male CD-1 Mice</i> , Monsanto Study MSL-16949, Monsanto Co. (July 26,	
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1		2002) (unpublished study on file with Monsanto)).		
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4	49.	The evidence shows that upon review of the results of those tests, Dr. Parry agreed that GBHs were not genotoxic.	49.	
5				
6		Brown Decl. Exh. 6 (Martens Dep. 224-28).		
7				
8	50.	NHL is a cancer that consists of over 60 different subtypes, each of which can have different risk factors.	50.	
9				
10		Brown Decl. Exh. 3 (Nabhan Dep. 27:6-8; 28:14-18).		
11				
12	51.	The majority of NHL cases are idiopathic, meaning there is no known cause.	51.	
13				
14		<i>Id.</i> (Nabhan Dep. 313:23-25); <i>see also</i> Brown Decl. Exh. 4 (Expert Report of Chadi Nabhan); Brown Decl. Exh. 7 (Gupta Dep. 114:18-20).		
15				
16				
17	52.	The risk of getting NHL, like most cancers, dramatically increases as people age. A man in his 70's is six times more likely to be diagnosed with diffuse large B-cell lymphoma ("DLBCL"), the most common subtype of NHL, than a man in his 50's.	52.	
18				
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21		Brown Decl. Exh. 3 (Nabhan Dep. 21:16-17; 28:3-5; 35:13-16).		
22				
23	53.	Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012.	53.	
24				
25		Brown Decl. Exh. 4, p. 22-23 (Expert Report of Dr. Chadi Nabhan); Exh. 1 (Alva Pilliod Dep. 100:14-18).		
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1	54.	He was [REDACTED]	54.	
2		<i>Id.</i> ; <i>see also</i> Brown Decl. Exh. 3		
3		(Nabhan Dep. 43:12-14).		
4	55.	Mrs. Pilliod was diagnosed with	55.	
5		primary CNS lymphoma (“PCNSL”), a		
6		rare subtype of lymphoma, in April		
7		2015, though her symptoms started a		
8		few months earlier.		
9		Brown Decl. Exh. 4, p. 4-5 (Expert		
10		Report of Dr. Chadi Nabhan); Brown		
11		Decl. Exh. 3 (Nabhan Dep. 37:8-10);		
12		Exh. 2 (Alberta Pilliod Dep. 156:17-19).		
13	56.	She was [REDACTED]	56.	
14		<i>Id.</i>		
15	57.	None of Plaintiffs’ treating doctors told	57.	
16		them that their NHL was caused by		
17		Roundup.		
18		Brown Decl. Exh. 1, 2 (Alva Pilliod		
19		Dep. 107:14-18, 107:24-108:2; Alberta		
20		Pilliod Dep. 159:1-4).		

ISSUE FIVE

The fifth cause of action for punitive damage on the ground that there are no disputed issues of material fact.

	<u>Moving Party’s Undisputed Material Facts and Supporting Evidence:</u>		<u>Opposing Party’s Response and Supporting Evidence</u>
23			
24	1.	Roundup® is an herbicide manufactured and sold by Monsanto.	1
25		First Amended Complaint (“FAC”) ¶¶	
26		1, 2.	
27			

1	2.	Roundup's active ingredient is glyphosate.	2.	
2				
3		<i>Id.</i>		
4	3.	The U.S. Environmental Protection Agency ("EPA") first approved glyphosate-based herbicides for sale in 1974.	3.	
5				
6				
7		Request for Judicial Notice ("RJN") Exhibit 9 at p. 12; <i>see also</i> FAC ¶ 1.		
8				
9	4.	EPA provides express regulatory limitations as to what types of label changes can be made without prior approval.	4.	
10				
11				
12		RJN Exh. 1(EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998)).		
13				
14	5.	Pesticide Registration Notice ("PRN") 98-10 prohibits a "change in the ingredients statement, signal word, use classification, <i>precautionary statements</i> , statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use."	5.	
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19		<i>Id.</i> at p. 8.		
20	6.	Warnings about health hazards, like cancer, are required to appear in the "Precautionary Statements" section of the label.	6.	
21				
22				
23		40 C.F.R. § 156.70(a).		
24				
25	7.	PRN 98-10 does not list health warnings as label changes that can occur without EPA approval.	7.	
26				
27		RJN Exh. 1; <i>see also</i> Declaration of Eugene Brown ("Brown Decl.") Exh. 8		
28				

1		(Benbrook <i>Hardeman</i> Dep. at 248:8-13 (agreeing that “in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve”); 249:10-16 (agreeing that a “registrant can’t make a unilateral label change except for minor adjustments to the label”)).		
2	8.	Changes to EPA-approved product formulations are governed by the same criterion as label changes.	8.	
3		40 C.F.R. §§ 152.44, 152.46; RJN Exh. 1; <i>see also</i> Brown Decl. Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 242:17-21 (agreeing that “[e]very time that Monsanto changes a glyphosate-based formulation, it has to submit an application to EPA to get approval of that new formulation”)).		
4	9.	EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.”	9.	
5		RJN Exh. 2, at p. 8, 39 (EPA, <i>Reregistration Eligibility Decision (RED) Glyphosate</i> at 14 (Sept. 1993)).		
6	10.	On June 26, 1991, EPA classified glyphosate as non-carcinogenic for humans “based on a lack of convincing evidence of carcinogenicity in adequate studies.”	10.	
7		RJN Exh. 2, at 7, 38.		
8	11.	In 1993, glyphosate was registered again, and EPA again concluded in its Reregistration Eligibility Decision (“RED”) that there was “evidence of non-carcinogenicity in humans.”	11.	
9		<i>Id.</i> at 21.		

1	12.	In 1997, EPA again found that “[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans . . .).”	12.	
2		RJN Exh. 3 (<i>Glyphosate; Pesticide Tolerances</i> , 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 180, 185 and 186)).		
3	13.	In 2002, in response to a challenge to glyphosate’s safety, the EPA found “[n]o evidence of carcinogenicity” of glyphosate.	13.	
4		RJN Exh. 4 (<i>Glyphosate; Pesticide Tolerances</i> , 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180)).		
5	14.	In 2004, the EPA found that “[g]lyphosate has no carcinogenic potential.”	14.	
6		RJN Exh. 5 (<i>Glyphosate; Pesticide Tolerance</i> , 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180)).		
7	15.	In 2008, EPA found that “[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.”	15.	
8		RJN Exh. 6 (<i>Glyphosate; Pesticide Tolerances</i> , 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).		
9	16.	In 2013, “EPA . . . concluded that glyphosate does not pose a cancer risk to humans.”	16.	
10		RJN Exh. 7 (<i>Glyphosate; Pesticide Tolerances</i> , 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40		

1		C.F.R. pt. 180)).		
2				
3	17.	In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA’s Office of Pesticide Programs re-evaluated the chemical and again classified it as “[n]ot [l]ikely to be [c]arcinogenic to [h]umans.”	17.	
4		RJN Exh. 8 (EPA, Office of Pesticide Programs, <i>Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate</i> at 10, 77 (Oct. 1, 2015) (“CARC”)).		
5				
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10	18.	In September 2016, EPA concluded that “the available data and weight-of-evidence clearly do not support the descriptors ‘carcinogenic to humans,’ ‘likely to be carcinogenic to humans,’ or ‘inadequate information to assess carcinogenic potential’” and that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	18.	
11		RJN Exh. 9 (Glyphosate Issue Paper at 137, 141).		
12				
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16				
17	19.	In December 2017, EPA concluded that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	19.	
18		RJN Exh. 10 (EPA, Office of Pesticide Programs, <i>Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 143-44 (Dec. 12, 2017)).		
19				
20				
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23	20.	EPA thus concluded in that report that glyphosate is “not likely to be carcinogenic to humans.”	20.	
24		<i>Id.</i>		
25				
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1	21.	In February 2018, the Science Advisor of EPA’s OPP testified before the House Committee on Science, Space, and Technology that “[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is ‘not likely to be carcinogenic to humans.’”	21.	
2		RJN Exh. 11 (Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)).		
3	22.	Regulatory agencies like EPA, the European Food Safety Authority (“EFSA”), and the European Chemicals Agency (“ECHA”) have evaluated the safety of glyphosate numerous times and continually found it to be safe.	22.	
4		RJN Exh 17 (December 21, 2018 U.S. EPA letter to the Australian Senate).		
5	23.	Prior to Plaintiffs’ NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans.	23.	
6		<i>Id.</i>		
7	24.	In July 2015, the International Agency for Research on Cancer (“IARC”) issued a monograph that classified glyphosate as Group 2A (probably carcinogenic to humans).	24.	
8		Brown Decl. Exh. 9 (IARC Monograph); <i>see also</i> FAC ¶¶ 5-6.		
9	25.	IARC found “limited evidence” that glyphosate causes cancer in humans.	25.	

1		Brown Decl. Exh. 9 (IARC Monograph).		
2				
3	26.	“Limited evidence” means that IARC found a positive association between glyphosate and cancer that could have resulted from “chance, bias, or confounding.”	26.	
4				
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6		<i>Id.</i>		
7				
8	27.	Since IARC came out with its classification of glyphosate, EPA re-reviewed the data and again determined that glyphosate is “not likely to be carcinogenic to humans.”	27.	
9				
10				
11		RJN Exhs. 8, 9, 10, 14, 15, 16, 17.		
12	28.	EPA again reiterated that “it is confident” that “glyphosate is not likely to be carcinogenic” and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators.	28.	
13				
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16		RJN Exh. 17.		
17	29.	IARC’s assessment prompted EPA’s Cancer Assessment Review Committee (“CARC”) to begin its own reassessment of glyphosate’s safety. Based on its assessment of all available epidemiological data, 11 animal studies, and 54 mutagenicity and genotoxicity studies, CARC concluded that glyphosate should continue to be classified as “not likely to be carcinogenic to humans.”	29.	
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23		RJN Exh. 8 (CARC).		
24	30.	EFSA likewise reevaluated glyphosate and concluded that it was not carcinogenic to humans.	30.	
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27		RJN Exh. 17.		

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1 2 3 4 5 6 7	31.	<p>The European Chemicals Agency concluded in 2017 that “[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted.”</p> <p>Brown Decl. Exh. 10 (European Chemical Agency’s glyphosate report dated March 15, 2017).</p>	31.	
8 9 10 11 12 13 14	32.	<p>The New Zealand Environmental Protection Authority, weighing all the available evidence, found: “glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen.”</p> <p>Brown Decl. Exh. 11, at p. 16 (New Zealand Environmental Protection Authority’s glyphosate report dated August 2016).</p>	32.	
15 16 17 18 19	33.	<p>In 2016, the Joint Meeting on Pesticides Residues Report concluded “glyphosate in unlikely to pose a carcinogenic risk to humans via exposure from diet.”</p> <p>Brown Decl. Exh. 12, at p. 13 (2016 Joint FAO/WHO Meeting on Pesticides Residues Report).</p>	33.	
20 21 22 23 24 25 26 27 28	34.	<p>In 1994, the International Programme on Chemical Safety (“IPCS”) conducted an Environmental Health Criteria and concluded that “no adverse effects were found” in workers using GBFs, and in 2005, the WHO Guidelines for Drinking-Water Quality concluded in 2005 that “the presence . . . in drinking-water does not represent a hazard to human health.”</p> <p>Brown Decl. Exh. 13, 14 (International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); International Programme on Chemical Safety</p>	34.	

1		(“IPCS”), Environmental Health Criteria 159 (1994); Ex. 20 World Health Organization (WHO), <i>Glyphosate and AMPA in Drinking-water: Background Document for Development of WHO Guidelines for Drinking-water Quality</i> , WHO/SDE/WSH/03.04/97 (June 2005)).		
2	35.	The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study (“AHS”), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer risk in farmers and pesticide applicators.	35.	
3		Brown Decl. Exh. 15 (Andreotti, G. et al., <i>Glyphosate Use and Cancer Incidence in the Agricultural Health Study</i> , 110 J. Nat’l Cancer Inst (2017) (“AHS Study”)).		
4	36.	AHS followed more than 54,000 professional pesticide applicators and continued to track their progress for more than 20 years.	36.	
5		<i>Id.</i>		
6	37.	It represents the largest population of glyphosate users ever studied and the largest study in which researchers controlled for other pesticide use in order to isolate the effects of glyphosate on the study population.	37.	
7		<i>Id.</i>		
8	38.	The paper grouped participants into four tiers based on exposure levels. Each tier showed a risk ratio less than 1.0 and there was no dose-response trend to suggest that cancer was associated with greater glyphosate exposure.	38.	
9		<i>Id.</i>		

1	39.	When researchers first published results from this population in 2005, they concluded that “[t]here was no association between glyphosate exposure and all cancer incidence or most of the specific cancer subtypes we evaluated, including NHL.”	39.	
2		<i>Id.</i>		
3	40.	Based on the AHS study, the prestigious <i>Journal of the National Cancer Institute</i> in 2018 (“JNCI 2018”) published data showing “no associations between glyphosate use and NHL risk overall or any of its subtypes.”	40.	
4		<i>Id.</i>		
5	41.	The North American Pooled Project (“NAPP”) is a project also funded by the National Institute of Health specifically addressing the hypothesis of glyphosate and NHL risk.	41.	
6		Brown Decl. Exh. 5 (Expert Report and Supplemental Expert Report of Dr. Lorelei Mucci), Exh. 16 (Manisha Pahwa et al., <i>An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin’s Lymphoma Major Histological Sub-types in the North American Pooled Project</i>).		
7	42.	NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis.	42.	
8		<i>Id.</i>		
9	43.	Like JNCI 2018, the results of NAPP showed “no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL.”	43.	
10		<i>Id.</i>		

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44.	<p>When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL.</p> <p>Brown Decl. Exh. 5 (Supplemental Expert Report of Dr. Lorelei Mucci).</p>	44.	
45.	<p>The acknowledgements section of Williams (2000) thanks “the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions.” It then names the specific toxicologists who had assisted the authors and gives credit to the company for giving the authors “complete access” to a large volume of valuable data.</p> <p>Brown Decl. Ex. 17 (Gary Williams, Robert Kroes, and Ian Munro, <i>Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans</i>, Regulatory Toxicology and Pharmacology (2000)).</p>	45.	
46.	<p>The Williams (2012) publication also acknowledges Monsanto for “funding and for providing its unpublished glyphosate and surfactant toxicity study reports.”</p> <p>Brown Decl. Exh. 18 (Amy Lavin Williams, Rebecca E. Watson, John M. DeSesso, <i>Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis</i>, Journal of Toxicology and Enviro. Health, Part B (2012)).</p>	46.	

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47.	<p>The acknowledgement section for Kier and Kirkland (2013) references the contributions of “David Saltmiras (Monsanto Company)” for “his invaluable service in providing coordination with individual companies and the Glyphosate Task Force.”</p> <p>Brown Decl. Exh. 19 (Larry D. Kier and David J. Kirkland, <i>Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations</i>, Critical Reviews in Toxicology (2013)).</p>	47.	
48.	<p>In response to Dr. Parry’s recommendations, Monsanto completed tests in an accredited laboratory and either submitted them to the EPA or, in some instances, published the results in peer-reviewed journals.</p> <p>Brown Decl. Exh. 6 (Martens Dep. 128:23-129:4; 216:16-217:21; 218:18-25); <i>see also</i> Brown Decl. Exh. 20 (Heydens, W. et al., <i>Genotoxic Potential of Glyphosate Formulations: Mode-of-Action Investigations</i>, 56 J. Agric. Food Chem. 1517 (2008); Hotz, K., <i>A Study of the Short-Term Effects of Mon 3050 in Male CD-1 Mice</i>, Monsanto Study MSL-16949, Monsanto Co. (July 26, 2002) (unpublished study on file with Monsanto)).</p>	48.	
49.	<p>The evidence shows that upon review of the results of those tests, Dr. Parry agreed that GBHs were not genotoxic.</p> <p>Brown Decl. Exh. 6 (Martens Dep. 224-28).</p>	49.	

1	50.	NHL is a cancer that consists of over 60 different subtypes, each of which can have different risk factors.	50.	
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4		Brown Decl. Exh. 3 (Nabhan Dep. 27:6-8; 28:14-18).		
5	51.	The majority of NHL cases are idiopathic, meaning there is no known cause.	51.	
6				
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8		<i>Id.</i> (Nabhan Dep. 313:23-25); <i>see also</i> Brown Decl. Exh. 4 (Expert Report of Chadi Nabhan); Brown Decl. Exh. 7 (Gupta Dep. 114:18-20).		
9				
10	52.	The risk of getting NHL, like most cancers, dramatically increases as people age. A man in his 70's is six times more likely to be diagnosed with diffuse large B-cell lymphoma ("DLBCL"), the most common subtype of NHL, than a man in his 50's.	52.	
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14				
15		Brown Decl. Exh. 3 (Nabhan Dep. 21:16-17; 28:3-5; 35:13-16).		
16	53.	Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012.	53.	
17				
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19		Brown Decl. Exh. 4, p. 22-23 (Expert Report of Dr. Chadi Nabhan); Exh. 1 (Alva Pilliod Dep. 100:14-18).		
20				
21	54.	He was [REDACTED]	54.	
22				
23		<i>Id.</i> ; <i>see also</i> Brown Decl. Exh. 3 (Nabhan Dep. 43:12-14).		
24	55.	Mrs. Pilliod was diagnosed with primary CNS lymphoma ("PCNSL"), a rare subtype of lymphoma, in April 2015, though her symptoms started a few months earlier.	55.	
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27		Brown Decl. Exh. 4, p. 4-5 (Expert Report of Dr. Chadi Nabhan); Brown		
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	Decl. Exh. 3 (Nabhan Dep. 37:8-10); Exh. 2 (Alberta Pilliod Dep. 156:17-19).		
56.	She was [REDACTED] <i>Id.</i>	56.	
57.	None of Plaintiffs’ treating doctors told them that their NHL was caused by Roundup. Brown Decl. Exh. 1, 2 (Alva Pilliod Dep. 107:14-18, 107:24-108:2; Alberta Pilliod Dep. 159:1-4).	57.	

ISSUE SIX

The sixth cause of action for loss of consortium on the ground that there are no disputed issues of material fact.

	<u>Moving Party’s Undisputed Material Facts and Supporting Evidence:</u>		<u>Opposing Party’s Response and Supporting Evidence</u>
1.	Roundup® is an herbicide manufactured and sold by Monsanto. First Amended Complaint (“FAC”) ¶¶ 1, 2.	1	
2.	Roundup’s active ingredient is glyphosate. <i>Id.</i>	2.	
3.	The U.S. Environmental Protection Agency (“EPA”) first approved glyphosate-based herbicides for sale in 1974. Request for Judicial Notice (“RJN”) Exhibit 9 at p. 12; <i>see also</i> FAC ¶ 1.	3.	

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4.	EPA provides express regulatory limitations as to what types of label changes can be made without prior approval. RJN Exh. 1(EPA Pesticide Registration Notice 98-10, Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998)).	4.	
5.	Pesticide Registration Notice (“PRN”) 98-10 prohibits a “change in the ingredients statement, signal word, use classification, <i>precautionary statements</i> , statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.” <i>Id.</i> at p. 8.	5.	
6.	Warnings about health hazards, like cancer, are required to appear in the “Precautionary Statements” section of the label. 40 C.F.R. § 156.70(a).	6.	
7.	PRN 98-10 does not list health warnings as label changes that can occur without EPA approval. RJN Exh. 1; <i>see also</i> Declaration of Eugene Brown (“Brown Decl.”) Exh. 8 (Benbrook <i>Hardeman</i> Dep. at 248:8-13 (agreeing that “in order to change the labeling for a registered pesticide, the registrant must submit it to EPA to review and approve”); 249:10-16 (agreeing that a “registrant can’t make a unilateral label change except for minor adjustments to the label”)).	7.	
8.	Changes to EPA-approved product formulations are governed by the same	8.	

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	<p>1 criterion as label changes.</p> <p>2 40 C.F.R. §§ 152.44, 152.46; RJN Exh.</p> <p>3 1; <i>see also</i> Brown Decl. Exh. 8</p> <p>4 (Benbrook <i>Hardeman</i> Dep. at 242:17-21</p> <p>5 (agreeing that “[e]very time that</p> <p>6 Monsanto changes a glyphosate-based</p> <p>7 formulation, it has to submit an</p> <p>8 application to EPA to get approval of</p> <p>9 that new formulation”)).</p>		
9.	<p>10 EPA classified glyphosate as non-</p> <p>11 carcinogenic for humans “based on a</p> <p>12 lack of convincing evidence of</p> <p>13 carcinogenicity in adequate studies.”</p> <p>14</p> <p>15 RJN Exh. 2, at p. 8, 39 (EPA,</p> <p>16 <i>Reregistration Eligibility Decision</i></p> <p>17 (<i>RED</i>) <i>Glyphosate</i> at 14 (Sept. 1993)).</p>	9.	
10.	<p>18 On June 26, 1991, EPA classified</p> <p>19 glyphosate as non-carcinogenic for</p> <p>20 humans “based on a lack of convincing</p> <p>21 evidence of carcinogenicity in adequate</p> <p>22 studies.”</p> <p>23</p> <p>24 RJN Exh. 2, at 7, 38.</p>	10.	
11.	<p>25 In 1993, glyphosate was registered</p> <p>26 again, and EPA again concluded in its</p> <p>27 Reregistration Eligibility Decision</p> <p>28 (“RED”) that there was “evidence of</p> <p>non-carcinogenicity in humans.”</p> <p><i>Id.</i> at 21.</p>	11.	
12.	<p>29 In 1997, EPA again found that “[d]ata</p> <p>30 indicate that glyphosate is a group E</p> <p>31 carcinogen (evidence of</p> <p>32 noncarcinogenicity for studies in</p> <p>33 humans . . .).”</p> <p>34</p> <p>35 RJN Exh. 3 (<i>Glyphosate; Pesticide</i></p> <p>36 <i>Tolerances</i>, 62 Fed. Reg. 17,723, 17,728</p> <p>(Apr. 11, 1997) (to be codified at 40</p> <p>C.F.R. pts. 180, 185 and 186)).</p>	12.	

1	13.	In 2002, in response to a challenge to glyphosate’s safety, the EPA found “[n]o evidence of carcinogenicity” of glyphosate.	13.	
2		RJN Exh. 4 (<i>Glyphosate; Pesticide Tolerances</i> , 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180)).		
3				
4	14.	In 2004, the EPA found that “[g]lyphosate has no carcinogenic potential.”	14.	
5		RJN Exh. 5 (<i>Glyphosate; Pesticide Tolerance</i> , 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180)).		
6				
7	15.	In 2008, EPA found that “[t]here is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.”	15.	
8		RJN Exh. 6 (<i>Glyphosate; Pesticide Tolerances</i> , 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180)).		
9				
10	16.	In 2013, “EPA . . . concluded that glyphosate does not pose a cancer risk to humans.”	16.	
11		RJN Exh. 7 (<i>Glyphosate; Pesticide Tolerances</i> , 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180)).		
12				
13	17.	In 2015, after IARC released its classification of glyphosate as a likely carcinogen, EPA’s Office of Pesticide Programs re-evaluated the chemical and again classified it as “[n]ot [l]ikely to be [c]arcinogenic to [h]umans.”	17.	
14		RJN Exh. 8 (EPA, Office of Pesticide Programs, <i>Cancer Assessment</i>		
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1		<i>Document—Evaluation of the Carcinogenic Potential of Glyphosate at 10, 77 (Oct. 1, 2015) (“CARC”)</i> .		
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3	18.	In September 2016, EPA concluded that “the available data and weight-of-evidence clearly do not support the descriptors ‘carcinogenic to humans,’ ‘likely to be carcinogenic to humans,’ or ‘inadequate information to assess carcinogenic potential’” and that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	18.	
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9		RJN Exh. 9 (Glyphosate Issue Paper at 137, 141).		
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11	19.	In December 2017, EPA concluded that scientific evidence provides “strongest support” for the descriptor “not likely to be carcinogenic to humans.”	19.	
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14		RJN Exh. 10 (EPA, Office of Pesticide Programs, <i>Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 143-44 (Dec. 12, 2017)).		
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17	20.	EPA thus concluded in that report that glyphosate is “not likely to be carcinogenic to humans.”	20.	
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19		<i>Id.</i>		
20	21.	In February 2018, the Science Advisor of EPA’s OPP testified before the House Committee on Science, Space, and Technology that “[b]ased on the comprehensive analysis of all available data and reviews, the EPA concludes that glyphosate is ‘not likely to be carcinogenic to humans.’”	21.	
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25		RJN Exh. 11 (Testimony of Anna B. Lowit, Science Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, & Tech. at 7 (Feb. 6, 2018)).		
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1	22.	Regulatory agencies like EPA, the European Food Safety Authority (“EFSA”), and the European Chemicals Agency (“ECHA”) have evaluated the safety of glyphosate numerous times and continually found it to be safe.	22.	
2		RJN Exh 17 (December 21, 2018 U.S. EPA letter to the Australian Senate).		
3	23.	Prior to Plaintiffs’ NHL onset, those agencies had uniformly determined that glyphosate is not likely to cause cancer in humans.	23.	
4		<i>Id.</i>		
5	24.	In July 2015, the International Agency for Research on Cancer (“IARC”) issued a monograph that classified glyphosate as Group 2A (probably carcinogenic to humans).	24.	
6		Brown Decl. Exh. 9 (IARC Monograph); <i>see also</i> FAC ¶¶ 5-6.		
7	25.	IARC found “limited evidence” that glyphosate causes cancer in humans.	25.	
8		Brown Decl. Exh. 9 (IARC Monograph).		
9	26.	“Limited evidence” means that IARC found a positive association between glyphosate and cancer that could have resulted from “chance, bias, or confounding.”	26.	
10		<i>Id.</i>		
11	27.	Since IARC came out with its classification of glyphosate, EPA re-reviewed the data and again determined	27.	

1		that glyphosate is “not likely to be carcinogenic to humans.”		
2		RJN Exhs. 8, 9, 10, 14, 15, 16, 17.		
3				
4	28.	EPA again reiterated that “it is confident” that “glyphosate is not likely to be carcinogenic” and that its conclusion is consistent with Canadian, EU, German, and Japanese regulators.	28.	
5		RJN Exh. 17.		
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8	29.	IARC’s assessment prompted EPA’s Cancer Assessment Review Committee (“CARC”) to begin its own reassessment of glyphosate’s safety. Based on its assessment of all available epidemiological data, 11 animal studies, and 54 mutagenicity and genotoxicity studies, CARC concluded that glyphosate should continue to be classified as “not likely to be carcinogenic to humans.”	29.	
9		RJN Exh. 8 (CARC).		
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16	30.	EFSA likewise reevaluated glyphosate and concluded that it was not carcinogenic to humans.	30.	
17		RJN Exh. 17.		
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19	31.	The European Chemicals Agency concluded in 2017 that “[b]ased on the epidemiological data as well as the data from long-term studies in rats and mice, taking a weight of the evidence approach, no classification for carcinogenicity is warranted.”	31.	
20		Brown Decl. Exh. 10 (European Chemical Agency’s glyphosate report dated March 15, 2017).		
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26	32.	The New Zealand Environmental Protection Authority, weighing all the available evidence, found: “glyphosate	32.	
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1		is unlikely to be genotoxic or carcinogenic to humans and does not require classification as a carcinogen or mutagen.”		
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4		Brown Decl. Exh. 11, at p. 16 (New Zealand Environmental Protection Authority’s glyphosate report dated August 2016).		
5				
6	33.	In 2016, the Joint Meeting on Pesticides Residues Report concluded “glyphosate in unlikely to pose a carcinogenic risk to humans via exposure from diet.”	33.	
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9		Brown Decl. Exh. 12, at p. 13 (2016 Joint FAO/WHO Meeting on Pesticides Residues Report).		
10				
11	34.	In 1994, the International Programme on Chemical Safety (“IPCS”) conducted an Environmental Health Criteria and concluded that “no adverse effects were found” in workers using GBFs, and in 2005, the WHO Guidelines for Drinking-Water Quality concluded in 2005 that “the presence of glyphosate . . . in drinking-water does not represent a hazard to human health.”	34.	
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17		Brown Decl. Exh. 13, 14 (International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); International Programme on Chemical Safety (“IPCS”), Environmental Health Criteria 159 (1994); Ex. 20 World Health Organization (WHO), <i>Glyphosate and AMPA in Drinking-water: Background Document for Development of WHO Guidelines for Drinking-water Quality</i> , WHO/SDE/WSH/03.04/97 (June 2005)).		
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25	35.	The largest epidemiology study of glyphosate-based herbicides to date, the Agricultural Health Study (“AHS”), is a cohort study funded by the National Institutes of Health and EPA designed to analyze if pesticides increase cancer	35.	
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1		risk in farmers and pesticide applicators.		
2		Brown Decl. Exh. 15 (Andreotti, G. et.		
3		al., <i>Glyphosate Use and Cancer</i>		
4		<i>Incididence in the Agricultural Health</i>		
		<i>Study</i> , 110 J. Nat’l Cancer Inst (2017)		
		(“AHS Study”).		
5	36.	AHS followed more than 54,000	36.	
6		professional pesticide applicators and		
7		continued to track their progress for		
8		more than 20 years.		
		<i>Id.</i>		
9	37.	It represents the largest population of	37.	
10		glyphosate users ever studied and the		
11		largest study in which researchers		
12		controlled for other pesticide use in		
13		order to isolate the effects of glyphosate		
		on the study population.		
		<i>Id.</i>		
14	38.	The paper grouped participants into four	38.	
15		tiers based on exposure levels. Each tier		
16		showed a risk ratio less than 1.0 and		
17		there was no dose-response trend to		
18		suggest that cancer was associated with		
		greater glyphosate exposure.		
		<i>Id.</i>		
19	39.	When researchers first published results	39.	
20		from this population in 2005, they		
21		concluded that “[t]here was no		
22		association between glyphosate		
23		exposure and all cancer incidence or		
24		most of the specific cancer subtypes we		
		evaluated, including NHL.”		
		<i>Id.</i>		
25	40.	Based on the AHS study, the prestigious	40.	
26		<i>Journal of the National Cancer Institute</i>		
27		in 2018 (“JNCI 2018”) published data		
28		showing “no associations between		
		glyphosate use and NHL risk overall or		
		any of its subtypes.”		

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	<i>Id.</i>		
41.	<p>The North American Pooled Project (“NAPP”) is a project also funded by the National Institute of Health specifically addressing the hypothesis of glyphosate and NHL risk.</p> <p>Brown Decl. Exh. 5 (Expert Report and Supplemental Expert Report of Dr. Lorelei Mucci), Exh. 16 (Manisha Pahwa et al., <i>An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin’s Lymphoma Major Histological Sub-types in the North American Pooled Project</i>).</p>	41.	
42.	<p>NAPP combines case-control data reported in two earlier epidemiology papers McDuffie (2001) and De Roos (2003) and then adjusts the data for other pesticides to improve the validity of the analysis.</p> <p><i>Id.</i></p>	42.	
43.	<p>Like JNCI 2018, the results of NAPP showed “no evidence of a positive association between glyphosate, including higher levels of glyphosate exposure, and the risk of NHL.”</p> <p><i>Id.</i></p>	43.	
44.	<p>When the currently available epidemiological evidence is analyzed together in an epidemiological study design called a meta-analysis, the result is that no association is found between Roundup and NHL.</p> <p>Brown Decl. Exh. 5 (Supplemental Expert Report of Dr. Lorelei Mucci).</p>	44.	

1 2 3 4 5 6 7 8 9 10 11	45.	<p>The acknowledgements section of Williams (2000) thanks “the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions.” It then names the specific toxicologists who had assisted the authors and gives credit to the company for giving the authors “complete access” to a large volume of valuable data.</p> <p>Brown Decl. Ex. 17 (Gary Williams, Robert Kroes, and Ian Munro, <i>Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans, Regulatory Toxicology and Pharmacology</i> (2000)).</p>	45.	
12 13 14 15 16 17 18 19	46.	<p>The Williams (2012) publication also acknowledges Monsanto for “funding and for providing its unpublished glyphosate and surfactant toxicity study reports.”</p> <p>Brown Decl. Exh. 18 (Amy Lavin Williams, Rebecca E. Watson, John M. DeSesso, <i>Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis</i>, <i>Journal of Toxicology and Enviro. Health, Part B</i> (2012)).</p>	46.	
20 21 22 23 24 25 26 27	47.	<p>The acknowledgement section for Kier and Kirkland (2013) references the contributions of “David Saltmiras (Monsanto Company)” for “his invaluable service in providing coordination with individual companies and the Glyphosate Task Force.”</p> <p>Brown Decl. Exh. 19 (Larry D. Kier and David J. Kirkland, <i>Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations</i>, <i>Critical Reviews in Toxicology</i> (2013)).</p>	47.	

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1	48.	In response to Dr. Parry's	48.
2		recommendations, Monsanto completed	
3		tests in an accredited laboratory and	
4		either submitted them to the EPA or, in	
5		some instances, published the results in	
6		peer-reviewed journals.	
7		Brown Decl. Exh. 6 (Martens Dep.	
8		128:23-129:4; 216:16-217:21; 218:18-	
9		25); <i>see also</i> Brown Decl. Exh. 20	
10		(Heydens, W. et al., <i>Genotoxic Potential</i>	
11		<i>of Glyphosate Formulations: Mode-of-</i>	
		<i>Action Investigations</i> , 56 J. Agric. Food	
		Chem. 1517 (2008); Hotz, K., <i>A Study</i>	
		<i>of the Short-Term Effects of Mon 3050</i>	
		<i>in Male CD-1 Mice</i> , Monsanto Study	
		MSL-16949, Monsanto Co. (July 26,	
		2002) (unpublished study on file with	
		Monsanto)).	
12	49.	The evidence shows that upon review of	49.
13		the results of those tests, Dr. Parry	
14		agreed that GBHs were not genotoxic.	
15		Brown Decl. Exh. 6 (Martens Dep. 224-	
16		28).	
17	50.	NHL is a cancer that consists of over 60	50.
18		different subtypes, each of which can	
19		have different risk factors.	
20		Brown Decl. Exh. 3 (Nabhan Dep. 27:6-	
21		8; 28:14-18).	
22	51.	The majority of NHL cases are	51.
23		idiopathic, meaning there is no known	
24		cause.	
25		<i>Id.</i> (Nabhan Dep. 313:23-25); <i>see also</i>	
26		Brown Decl. Exh. 4 (Expert Report of	
27		Chadi Nabhan); Brown Decl. Exh. 7	
28		(Gupta Dep. 114:18-20).	
	52.	The risk of getting NHL, like most	52.
		cancers, dramatically increases as	
		people age. A man in his 70's is six	
		times more likely to be diagnosed with	
		diffuse large B-cell lymphoma	
		("DLBCL"), the most common subtype	

1		of NHL, than a man in his 50's.		
2		Brown Decl. Exh. 3 (Nabhan Dep. 21:16-17; 28:3-5; 35:13-16).		
3				
4	53.	Mr. Pilliod was diagnosed with DLBCL, the most common subtype of NHL, in 2012.	53.	
5				
6		Brown Decl. Exh. 4, p. 22-23 (Expert Report of Dr. Chadi Nabhan); Exh. 1 (Alva Pilliod Dep. 100:14-18).		
7				
8	54.	He was [REDACTED]	54.	
9				
10		<i>Id.</i> ; see also Brown Decl. Exh. 3 (Nabhan Dep. 43:12-14).		
11	55.	Mrs. Pilliod was diagnosed with primary CNS lymphoma ("PCNSL"), a rare subtype of lymphoma, in April 2015, though her symptoms started a few months earlier.	55.	
12				
13		Brown Decl. Exh. 4, p. 4-5 (Expert Report of Dr. Chadi Nabhan); Brown Decl. Exh. 3 (Nabhan Dep. 37:8-10); Exh. 2 (Alberta Pilliod Dep. 156:17-19).		
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17	56.	She was [REDACTED]	56.	
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19		<i>Id.</i>		
20	57.	None of Plaintiffs' treating doctors told them that their NHL was caused by Roundup.	57.	
21				
22		Brown Decl. Exh. 1, 2 (Alva Pilliod Dep. 107:14-18, 107:24-108:2; Alberta Pilliod Dep. 159:1-4).		
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Respectfully submitted,

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