IN THE CIRCUIT COURT OF SAINT LOUIS COUNTY
STATE OF MISSOURI

JAMES ADAMS JR., et al.,	)	
	)	
Plaintiffs,	)	
	)	Case No. 17SL-CC02721
v.	)	
	)	
MONSANTO COMPANY,	)	
	)	
Defendant.	)	

PLAINTIFF SHARLEAN GORDON'S RESPONSE TO DEFENDANT MONSANTO COMPANY'S STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT
AND
PLAINTIFF'S STATEMENT OF ADDITIONAL MATERIAL FACTS IN SUPPORT OF ITS OPPOSIITON TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff objects to Defendant's Statement of Undisputed Material Facts ("Statement"), filed in support of its Motion for Summary Judgment, for failure to identify "facts" that are "material" to its motion. See *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986) (explaining that a fact is "material" only if it "might affect the outcome of the suit under the governing law"). Rather than providing only material facts, Defendant offers, instead, factual assertions, including general background information and matters otherwise immaterial to this case.

Subject to that objection, Plaintiff, by and through her undersigned counsel, respectfully submits the following response to Defendant's Statement. This response is designed solely to respond to the Defendant's Statement by identifying which of the factual grounds for Defendant's motion are disputed. These disputes relate only to facts Defendant's proffer.

PLAINTIFF'S RESPONSES TO DEFENDANT'S STATEMENTS OF FACTS

I. About GBHs

1. Glyphosate-based herbicides ("GBHs") were "introduced in 1974" by Monsanto, under the brand name Roundup®, to "control weeds" in "agricultur[e] . . . utility rights-of-way, on roadsides, along railways or in places around the home such as sidewalks and gardens." Ex. 24,[1] Monsanto, *Backgrounder—History of Monsanto's Glyphosate Herbicides* at 1 (June 2005) ("Glyphosate Backgrounder"). GBHs are "among the world's most widely used herbicides." *Id.* GBHs, like "[a]ll pesticides sold or distributed in the United States [,are] registered by the Environmental Protection Agency" ("EPA"). *Id.* at 2. "Glyphosate was initially registered [with the EPA] in 1974." Ex. 6, EPA, Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 12 (Sept. 12, 2016) ("Glyphosate Issue Paper"). It was "re-registered in September 1993." Ex. 24, Glyphosate Backgrounder at 2.

Response: Admit.

II. Ms. Gordon's Alleged Usage of GBHs

2. Ms. Gordon resides at 301 Fourth Street, South Pekin, Illinois, 61564. Ex. 27, Dep. of Sharlean Gordon at 7:9-13, *Adams v. Monsanto Co.*, No. 17SL-CC02721 (Mo. Cir. Ct. St. Louis County, August 21, 2018) ("Gordon Dep."); *see also* Ex. 28, Sharlean Gordon Pl.'s Fact Sheet, Attachment, *Adams v. Monsanto Co*., No. 17SL-CC02721 (Mo. Cir. Ct. St. Louis County May 18, 2018) ("Gordon PFS").

Response: Admit.

3. Ms. Gordon claims to have used GBHs for "personal use" at her residence in South Pekin, Illinois, from 1992 to 2017. Ex. 28, Gordon PFS at 8; *see also* Ex. 27, Gordon Dep. at 121:15-23.

Response: Admit.

4. Ms. Gordon was diagnosed with diffuse large B-cell lymphoma, a subtype of non-Hodgkin's lymphoma ("NHL"), in November 2006, when her primary care provider, Dr. Phil Rossi, gave her the diagnosis via telephone. Ex. 27, Gordon Dep. at 41:12-16, 66:17-20. She treated with Dr. Nguyen Le-Lindqwister in Pekin, Illinois. *Id.* at 67:1-5. She was told her NHL was in remission in 2007. *Id.* at 71:13-17. Subsequently in early 2008, her diffuse large B-cell lymphoma returned. *Id*. at 74:25 – 75:14. She later underwent chemotherapy treatments and received a stem cell transplant at the University of Chicago Medical Center in 2009. *Id*. at 79:13– 80:10. Following the stem cell transplant, she was again told her NHL was in complete remission. Ex. 29, Dep. of Dr. Sonali Smith at 84:1-23, *Adams v. Monsanto Co.*, No. 17SL-CC02721 (Mo. Cir. Ct. St. Louis County, October 25, 2018). Almost a decade later, Ms. Gordon was diagnosed with follicular lymphoma and therapy-related myelodysplastic syndrome in 2017. Ex. 27, Gordon Dep. at 91:6-11. She has continued to receive treatment from Dr. Sonali Smith and Dr. Andrew Artz at the University of Chicago Medical Center, including chemotherapy treatments and a second stem cell transplant. Id. at 92:21 – 93:10. Following her second stem cell transplant, she has no current disease. Id. at 97:4-12.

Response: Admit.

5. Ms. Gordon never read the warning label for any GBH that she used. Id. at 131:6-11 (**Q**: Have you ever read the warning label on a container of Roundup? **A**: I did not.). She read only the name brand, the "type, vegetation and weedkiller," and the directions for use. *Id.* at 185:7-9.

Response: Denied to the extent it mischaracterizes and omits Plaintiff's testimony. Ms. Gordon did not see any warnings on the Roundup container. Ex. 1, Gordon Dep at 131:9-11; See Statement of Additional Material Facts "SAMF", No. 1-3. Furthermore, Ms. Gordon did not see nor read on the Roundup containers that Roundup can contribute to

the development of non-Hodgkin's lymphoma or cancer. *Id*. at 185:10-20. Had she seen or read on the Roundup containers that Roundup could contribute to the development of non-Hodgkins lymphoma or cancer, Ms. Gordon would not have used Roundup. *Id*. at 185:21-186:5.

6. On July 28, 2017, Ms. Gordon filed her products liability action against Monsanto. *See* Petition, *Adams v. Monsanto Co*., No. 17SL-CC02721 (Mo. Cir. Ct. St. Louis County July 28, 2017).

Response: Admit.

III. Regulation of GBHs

7. As part of the pesticide registration process, the EPA "assess[es] a wide variety of potential human health . . . effects associated with use of the product," including "short-term toxicity [and] long-term effects such as cancer and reproductive system disorders." Ex. 1, EPA, *About Pesticide Registration*, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last visited Dec. 6, 2018).

Response: Denied as to the characterization that the EPA independently tested or conducted studies of glyphosate or GBHs. The EPA relies on applicants to perform the tests, assemble the studies, and submit the labeling. See Ex. 2 at ¶ 30-32; 35-42; 53 Fed. Reg. 15952, 15956; 7 USC 136a(c)(1); SAMF No. 4-5. Plaintiff also denies as to the characterization that EPA assesses the health effects of formulated products. The EPA only reviews the toxicity and safety of the active ingredient glyphosate. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

A. EPA Findings on the Non-Carcinogenicity of Glyphosate

8. On June 26, 1991, the EPA "classified glyphosate in Group E (evidence of non-carcinogenicity for humans), based on a lack of convincing evidence of carcinogenicity in adequate studies." Ex. 5, EPA, *Reregistration Eligibility Decision (RED) Glyphosate* at 14 (Sept. 1993). When glyphosate was re-registered in September 1993, the EPA restated in its Reregistration Eligibility Decision ("RED") that glyphosate was classified "as a Group E carcinogen (signifies evidence of non-carcinogenicity in humans)." *Id.* at viii.

Response: Denied as to the characterization that the EPA's classification of glyphosate was based on sufficient data regarding glyphosate's carcinogenic potential. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2, 3, 4, 5; SAMF No. 4 and 5. The EPA has cautioned that any designation should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

9. In 1997, the EPA found that "[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans . . .)." Ex. 12, *Glyphosate; Pesticide Tolerances*, 62 Fed. Reg. 17,723, 17,728 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 180, 185 and 186).

Response: Denied as to the characterization that the EPA conclusively "found" that there was no evidence of carcinogenicity in humans. The EPA initially concluded that glyphosate was oncogenic in male mice in a dose-related manner and classified glyphosate as a Class C possible human carcinogen. Ex. 6, 7; SAMF No. 5. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5; SAMF No. 4-5. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

10. In 2002, in response to a challenge to glyphosate's safety, the EPA found "[n]o evidence of carcinogenicity" of glyphosate. Ex. 13, *Glyphosate; Pesticide Tolerances*, 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).

Response: Denied as to the characterization that the EPA conclusively "found" that there was no evidence of carcinogenicity in humans. The EPA initially concluded that glyphosate was oncogenic in male mice in a dose-related manner and classified glyphosate as a Class C possible human carcinogen. Ex. 6 and 7. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5. Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8 and 9. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

11. In 2004, the EPA found that "[g]lyphosate has no carcinogenic potential." Ex. 14, *Glyphosate; Pesticide Tolerance*, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).

Response: Denied as to the characterization that the EPA conclusively "found" that there was no evidence of carcinogenicity in humans. The EPA initially concluded that glyphosate was oncogenic in male mice in a dose-related manner and classified glyphosate as a Class C possible human carcinogen. Ex. 6 and 7. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5. Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8, and 9. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

12. In 2008, the 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." Ex. 15, *Glyphosate; Pesticide Tolerances*, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).

Response: Denied as to the characterization that the EPA conclusively "found" that glyphosate was not mutagenic, not a carcinogen and not a developmental or reproductive toxicant. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5. Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8 and 9. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

13. In 2013, the "EPA . . . concluded that glyphosate does not pose a cancer risk to humans." Ex. 16, *Glyphosate; Pesticide Tolerances*, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).

Response: Denied as to the characterization that the EPA's conclusion of glyphosate's carcinogenic potential is a substantive rule of law. The EPA's classification is subject to its own 2005 Guidelines for Carcinogen Risk Assessment. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5, 10. Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8 and 9. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

14. In 2015, IARC performed a hazard assessment and concluded that "there is limited evidence in humans for the carcinogenicity of glyphosate." Ex. 3, EPA, Office of

Pesticide Programs, *Cancer Assessment Document—Evaluation of the Carcinogenic Potential of Glyphosate* at 7 (Oct. 1, 2015). Following the IARC hazard assessment, the EPA re-evaluated the carcinogenic potential of glyphosate. *Id.* Upon reevaluation, the EPA classified glyphosate as "[n]ot [l]ikely to be [c]arcinogenic to [h]umans." Id. at 77.

Response: Denied as to the representation of IARC's findings. IARC found that in the epidemiology alone there was "limited evidence" of carcinogenicity. Ex. 2 at ¶ 835. However, IARC concluded that glyphosate was "probably carcinogenic to humans" based on the totality of the evidence, including animal, genotoxicity, and mechanistic data. *Id.* Denied as to the characterization that IARC's review was the sole reason for EPA's re-evaluation of the carcinogenic potential of glyphosate.

15. In September 2016, the 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." Ex. 6, Glyphosate Issue Paper at 137, 141.

Response: Denied as to the characterization that the EPA's classification of glyphosate's carcinogenic potential is a final, agency decision or conclusion. The EPA noted that additional research would need to be performed to determine whether formulation components, including surfactants influenced the toxicity of the product. With respect to non-Hodgkin's lymphoma, the Report found that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." A December 2016 SAP meeting, convened to discuss the methodology used by EPA's Office of Pesticide Programs (OPP) in assessing glyphosate, unanimously concluded "that the EPA evaluation does not appear to follow the EPA (2005) Cancer Guidelines." *See* Ex. 5, 10. Numerous panel members concluded that "the weight-of-evidence conclusion based on EPA's 2005 Guidelines naturally leads to suggestive evidence of potential carcinogenic effects." In evaluation glyphosate, the EPA failed to follow its own carcinogenicity guidelines. Ex. 5, 10. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

16. In December 2017, the EPA concluded that scientific evidence provides "strongest support" for the descriptor "not likely to be carcinogenic to humans." Ex. 7, EPA,

Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 143-44 (Dec. 12, 2017).

Response: Denied as to the characterization that the 2017 Report amounts to final conclusions of the EPA. The EPA noted that additional research would need to be performed to determine whether formulation components, including surfactants influenced the toxicity of the product. With respect to non-Hodgkin's lymphoma, the Report found that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." In evaluation glyphosate, the EPA failed to follow its own carcinogenicity guidelines. Ex. 5, 10. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

17. In December 2017, the EPA published a draft Human Health Risk Assessment in support of the registration review for glyphosate where it concluded that "glyphosate should be classified as 'not likely to be carcinogenic to humans.'" Ex. 4, EPA, *Glyphosate—Health Human Risk Assessment* at 3 (Dec. 12, 2017).

Response: Denied as to the characterization that the EPA's classification of glyphosate's carcinogenic potential is a substantive rule of law. The EPA's classification is subject to its own 2005 Guidelines for Carcinogen Risk Assessment. ¶ 24. See Ex. 10, EPA's Response to the Final Report of the FIFRA SAP. Those Guidelines clearly establish that they are non-binding statements of policy that do not establish any substantive rule of law. See Guidelines at 1-2. In evaluation of glyphosate, the EPA failed to follow its own carcinogenicity guidelines. Ex. 5, 10. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

18. In April 2019, the EPA published a Proposed Interim Registration Review Decision concerning glyphosate. Ex. 8, EPA, *Glyphosate—Proposed Interim Registration Review Decision Case Number 0178* (Apr. 23, 2019). Following a "thorough weight-of-evidence review of all relevant data," the EPA's "independent evaluation of the carcinogenic potential of glyphosate . . . determined that glyphosate is 'not likely to be carcinogenic to humans.'" *Id*. at 7. The EPA's cancer evaluation was "more robust than IARC's evaluation," which included additional studies not considered by IARC, *id*. at 7, and the "evaluation for glyphosate is also more transparent," *id*. at 8. The EPA considered over 2,200 public comments,

many of which cited the IARC's classification of glyphosate, the EPA's weight-of-evidence evaluation, and animal carcinogenicity data. *Id.* at 6-18. The EPA "continues to conclude that exposure to glyphosate when used according to the label does not result in human health risk, including infants and children." Ex. 9, EPA, *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* at 2 (Apr. 23, 2019).

Response: Denied as to the characterization that the EPA's classification of glyphosate's carcinogenic potential is a final, agency decision or conclusion. The EPA's classification is subject to its own 2005 Guidelines for Carcinogen Risk Assessment. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5. Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8 and 9. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

19. The EPA's Proposed Interim Registration Review Decision concerning glyphosate dated April 2019 contains certain proposed labeling changes for glyphosate products. Ex. 8 at 43-47. These proposed labeling changes do not suggest any change to the label related to carcinogenicity.

Response: Denied as to the characterization that the EPA's classification of glyphosate's carcinogenic potential is a final, agency decision or conclusion. The EPA's classification is subject to its own 2005 Guidelines for Carcinogen Risk Assessment. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5, 10. Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8 and 9. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

20. In February 2018, the Science Advisor of the EPA's Office of Pesticide Programs 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.'" Ex. 30, Testimony of Anna B. Lowit, Science

Advisor, Office of Pesticide Programs, EPA, Before the H. Comm. on Sci., Space, and Tech. at 7 (Feb. 6, 2018).

Response: Denied as to the characterization that Anna B. Lowit's testimony represents final conclusions of the EPA. Plaintiff denies that any findings by Anna Lowit and the Office of Pesticide Programs was based on a comprehensive analysis of all available data and reviews. The EPA's regulatory findings were based on insufficient data and was the result of Monsanto's efforts to influence the EPA. See Ex. 2-5 Monsanto failed to conduct recommended studies and also failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. Ex. 2, 8-10. The OPP's review was also influenced by Monsanto. Ex. 13-16. In evaluation of glyphosate, the EPA failed to follow its own carcinogenicity guidelines. Ex. 5, 10. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment.

B. Other Agency Findings on the Non-Carcinogenicity of Glyphosate

21. In October 2015, the European Food Safety Authority ("EFSA") stated that, "[i]n contrast to the IARC evaluation, the EU peer review experts, with only one exception, concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification . . . as carcinogenic . . . ." Ex. 11, EFSA, *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 13 EFSA J. 11:4302, at 2 (2015).

Response: Denied as to the characterization that the EFSA independently tested or conducted studies of glyphosate or GBHs. The EFSA relies on others to perform the tests, assemble the studies, and provide the date to the EFSA. Denied as to the characterization that EFSA's findings were based on a proper evaluation of the scientific evidence. A group of ninety-four scientists published a peer-reviewed article explaining that there were serious flaws in EFSA's scientific evaluation and that IARC's conclusion was correct. See Ex. 11, Portier, et al., Differences in the carcinogenic evaluation of glyphosate between the International Agency for the Research on Cancer (IARC) and the European Food Safety Authority (EFSA), Vol 70. No. 8J Epidemiol. Community Health 741 (2016).

22. In May 2016, the Joint Meeting on Pesticide Residues ("JMPR") of the Food and Agriculture Organization of the United Nations ("FAO") and World Health Organization ("WHO") concluded "glyphosate is unlikely to pose a carcinogenic risk to humans via exposure

from the diet." Ex. 21, JMPR, *Pesticide residues in food – 2016*, Special Session of the Joint FAO/WHO Meeting on Pesticide Residues at 24 (2016).

Response: Denied as to the characterization that the JMPR independently tested or conducted studies of glyphosate or GBHs. Furthermore, Plaintiff denies that this fact is relevant to any issue raised in Defendant's Motion for Summary Judgment as JMPR's evaluation was limited to exposure from the diet alone. It has no bearing on exposure to applicators such as Ms. Gordon.

23. In August 2016, the New Zealand Environmental Protection Authority stated its "overall conclusion . . . that . . . glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification . . . as a carcinogen or mutagen." Ex. 26, N. Z. Envtl. Prot. Auth., *Review of the Evidence Relating to Glyphosate and Carcinogenicity* at 16 (Aug. 2016).

Response: Denied as to the characterization that the New Zealand Environmental Protection Authority independently tested or conducted studies of glyphosate or GBHs. The New Zealand Environmental Protection Authority relies on others to perform the tests, assemble the studies, and provide the date to the New Zealand Environmental Protection Authority. Furthermore, Plaintiff denies that the conclusions of a foreign regulatory agency have any relevance to issues raised in Defendant's Motion for Summary Judgment.

24. In March 2017, the Australian Pesticides and Veterinary Medicines Authority considered the IARC monograph and concluded that "exposure to glyphosate does not pose a carcinogenic risk to humans." Ex. 2, Austl. Pesticides and Veterinary Medicines Auth., *Final regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate* at 38 (Mar. 2017).

Response: Denied as to the characterization that the Australian Pesticides and Veterinary Medicines Authority independently tested or conducted studies of glyphosate or GBHs or that conclusions of a foreign regulatory agency such as the Australian Pesticides and Veterinary Medicines Authority have any relevance to the issues raised in Defendant's Motion for Summary Judgment.

25. In September 2016, the Food Safety Commission for the Government of Japan concluded that "[g]lyphosate had no neurotoxicity, carcinogenicity, reproductive toxicity,

teratogenicity, and genotoxicity." Ex. 20, Japan Food Safety Commission, *Glyphosate Summary*, 4 Food Safety 93, 94 (2016).

Response: Denied as to the characterization that the Food Safety Commission for the Government of Japan independently tested or conducted studies of glyphosate or GBHs. Food Safety Commission for the Government of Japan relies on others to perform the tests, assemble the studies, and provide the date to the Food Safety Commission for the Government of Japan. Furthermore, Plaintiff denies that the conclusions of a foreign regulatory agency have any relevance to issues raised in Defendant's Motion for Summary Judgment.

26. In March 2017, the European Chemicals Agency ("ECHA") "concluded that . . . no hazard classification for carcinogenicity is warranted for glyphosate . . . ." Ex. 10, ECHA, *Opinion Proposing Harmonized Classification and Labelling at EU Level of glyphosate (ISO); N-(phosphonomethyl) glycine* at 31 (Mar. 15, 2017).

Response: Denied as to the characterization that the ECHA independently tested or conducted studies of glyphosate or GBHs. The ECHA relies on others to perform the tests, assemble the studies, and provide the date to the ECHA. Furthermore, Plaintiff denies that the conclusions of a foreign regulatory agency have any relevance to issues raised in Defendant's Motion for Summary Judgment.

27. In January 2019, Health Canada's Pest Management Regulatory Agency ("PMRA") conducted a "thorough scientific review" after receiving several notices of objections following PMRA's final re-evaluation decision on glyphosate in 2017. Ex. 17, Health Canada, *Statement from Health Canada on Glyphosate* at 1 (Jan. 11, 2019). At the conclusion of the "transparent and rigorous science-based regulatory process" by 20 scientists, which included "access to all relevant data and information from federal and provincial governments, international regulatory agencies, published scientific reports and multiple pesticide manufacturers," PMRA concluded that "[n]o pesticide regulatory authority in the world currently considers glyphosate to be a cancer risk to humans at the levels at which humans are currently exposed." *Id*.

Response: Denied as to the characterization that the PMRA independently tested or conducted studies of glyphosate or GBHs. The PMRA relies on others to perform the tests, assemble the studies, and provide the date to the PMRA. Furthermore, Plaintiff denies that the conclusions of a foreign regulatory agency have any relevance to issues raised in Defendant's Motion for Summary Judgment.

PLAINTIFF'S STATEMENT OF ADDITIONAL MATERIAL FACTS IN DISPUTE IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

1. Monsanto's Roundup product never included a warning about non-Hodgkin's lymphoma or cancer.

RESPONSE:

2. Ms. Gordon never saw any warning on the Roundup container regarding non-Hodgkin's lymphoma or cancer. (Exhibit 1, Gordon Depo. p. 131, ln. 9-11; p. 185, ln. 10-20).

RESPONSE:

3. Had Monsanto included a warning about non-Hodgkin's lymphoma or cancer, Ms. Gordon would not have used Roundup. (Ex. 1, p. 185-186, ln. 21-24, 1-5).

RESPONSE:

4. The EPA relies on applicants to perform the tests, assemble the studies, and submit the labeling. (*See* Ex. 2, Report of Charles Benbrook at ¶ 30-32; 35-42; 53 Fed. Reg. 15952, 15956; 7 USC 136a(c)(1)). The EPA does not assess the health effects of formulated products.

RESPONSE:

5. The EPA's findings were based on insufficient data and were the result of Monsanto's efforts to influence the EPA. (*See* Ex. 2, 3, 4, and 5).

RESPONSE:

6. The EPA initially concluded that glyphosate was oncogenic in male mice in a dose-related manner and classified glyphosate as a Class C possible human carcinogen. (*See* Ex. 6 and 7).

RESPONSE:

7. Monsanto failed to conduct recommended studies and failed to submit critical safety information to allow the EPA to make a complete finding as to carcinogenicity. (*See* Ex. 2, 8, 9).

RESPONSE:

8. IARC found that in the epidemiology alone there was "limited evidence" of carcinogenicity. (Ex. 2, at ¶ 835). IARC concluded that glyphosate was "probably carcinogenic to humans" based on the totality of evidence, including animal, genotoxicity, and mechanistic data. *Id.*

RESPONSE:

9. The EPA noted that additional research would need to be performed to determine whether formulation components, including surfactants influenced the toxicity of the product.

With respect to non-Hodgkin's lymphoma, the Report found that "a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available data." (Id.). A December 2016 SAP meeting, convened to discuss the methodology used by EPA's Office of Pesticide Programs (OPP) in assessing glyphosate, unanimously concluded "that the EPA evaluation does not appear to follow the EPA (2005) Cancer Guidelines." (*See* Ex. 10, 5). Numerous panel members concluded that "the weight-of-evidence conclusion based on EPA's 2005 Guidelines naturally leads to suggestive evidence of potential carcinogenic effects." In evaluation glyphosate, the EPA failed to follow its own carcinogenicity guidelines. Id.

RESPONSE:

10. The EPA 2005 Guidelines for Carcinogen Risk Assessment establish that the EPA's classifications are non-binding statements of policy that do not establish any substantive rule of law. (Ex. 10, EPA's Response to the Final Report of the FIFRA SAP).

RESPONSE:

11. Monsanto attempted to improperly influence the Office of Pesticide Programs. (Ex. 13-16).

RESPONSE:

12. A group of ninety-four scientists published a peer-reviewed article explaining that there were serious flaws in EFSA's scientific evaluation and that IARC's conclusion was correct. (*See* Ex. 11, Portier, et al., Differences in the carcinogenic evaluation of glyphosate between the

International Agency for the Research on Cancer (IARC) and the European Food Safety Authority (EFSA), Vol 70. No. 8J Epidemiol. Community Health 741 (2016)).

RESPONSE:

13. Monsanto never provided the EPA with the report it commissioned from Dr. James Parry. (Ex. 12).

RESPOSNE:

14. Monsanto's advertisements for its Roundup never included any warning about cancer. (Ex. 1, Depo., p. 187, ln. 2-9).

RESPONSE:

15. The directions on Roundup containers never directed the user to wear masks, eye protection, or protective clothing. (Ex. 1, Depo., p. 187-88, ln. 25, 1-22).

RESPONSE:

Respectfully submitted,

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Attorneys for Plaintiff Sharlean Gordon

CERTIFICATE OF SERVICE

A copy of the forgoing was filed and served using the Court's electronic filing system this 10th day of June, 2019.

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