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1 2 3 4 5 6 7 8 9 10	HOLLINGSWORTH LLP Joe G. Hollingsworth (pro hac vice) Eric G. Lasker (pro hac vice) 1350 I Street, N.W. Washington, DC 20005 Telephone: (202) 898-5800 Facsimile: (202) 682-1639 Email: jhollingsworth@hollingsworthllp.com elasker@hollingsworthllp.com Attorneys for Defendant MONSANTO COMPANY UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION MDL No. 2741 Com No. 246 and 02741 MG
11 12	Case No. 3:16-md-02741-VC       This document relates to:
13 14	Stacy F. Scott v. Monsanto Co., Case No. 3:17-cv-05686-VC
15 16	MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT
17	Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Monsanto
18	Company ("Monsanto"), by and through its counsel, respectfully responds by generally denying
19	all allegations contained in plaintiff Stacy F. Scott's First Amended Complaint and Jury Demand
20	("the Complaint"), except as set forth below. As defined in the Complaint and as used in this
21	Answer, Monsanto refers to Monsanto Company, a United States based company incorporated in
22	Delaware, and not to other Monsanto-affiliated companies. Silence as to any allegations shall
23	constitute a denial.
24	1. Monsanto admits the allegations in the first and second sentences of paragraph 1.
25	Monsanto also admits that glyphosate was one of the world's most widely used herbicides in
26	2013, but notes that Monsanto was and is not the only manufacturer of glyphosate-based
27	herbicides. Monsanto lacks information or knowledge sufficient to form a belief as to the
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1 accuracy of the specific numbers and statistics cited in the remaining sentences of paragraph 1 2 and therefore denies those allegations.

3 2. In response to the allegations in paragraph 2, Monsanto admits that its 4 headquarters are in St. Louis, Missouri, and that it is incorporated in Delaware. Monsanto 5 admits that it and affiliated companies have operations and offices in countries around the world. 6 Monsanto admits that it is a producer of glyphosate-based herbicides but lacks sufficient 7 information regarding the business of other glyphosate producers to admit or deny the allegation 8 as written in the second sentence of paragraph 2. Monsanto admits that it is the leading producer of seeds that contain the Roundup Ready<sup>®</sup> trait and that use of crops with the Roundup Ready<sup>®</sup> 9 10 trait substantially improves a farmer's ability to control weeds. Monsanto lacks information or 11 knowledge sufficient to form a belief as to the accuracy of the specific numbers and statistics 12 provided in the remaining sentences of paragraph 2 and therefore denies those allegations.

- 13 3. In response to the allegations in paragraph 3, Monsanto admits that its glyphosate 14 products are registered in at least 130 countries and approved for use on over 100 different crops. 15 Monsanto admits that certain studies have reported that glyphosate is found at *de minimis* levels 16 significantly below regulatory safety limits in various locations and media. Monsanto denies the 17 remaining allegations in paragraph 3.
- 18 4. Monsanto admits the allegations in the first sentence of paragraph 4. Monsanto 19 denies the allegations in the second sentence of paragraph 4 to the extent they suggest that the 20 International Agency for Research on Cancer ("IARC") based its evaluation on a complete or 21 accurate assessment of the scientific research regarding glyphosate.
- 22 5. Monsanto admits the allegations in the first sentence of paragraph 5. Monsanto 23 denies the allegations in the second sentence of paragraph 5.
- 24 6. In response to the allegations in paragraph 6, Monsanto admits that the IARC 25 working group classified glyphosate under Group 2A. Monsanto denies the remaining 26 allegations in paragraph 6.
- 27
- 7. Monsanto denies the allegations in paragraph 7.
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1 8. In response to the allegations in paragraph 8, Monsanto admits that glyphosate 2 repeatedly has been found to be safe to humans and the environment by regulators in the United 3 States and around the world and further admits that it has labeled glyphosate products as 4 approved by regulatory bodies consistent with those findings. Monsanto also admits that the 5 United States Environmental Protection Agency ("EPA") repeatedly has concluded pursuant to 6 the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") that glyphosate-based 7 herbicides create no unreasonable risk to human health or to the environment when used in 8 accordance with the label. To the extent that paragraph 8 alleges that Monsanto has labeled glyphosate or Roundup<sup>®</sup>-branded herbicides in any manner different or in addition to such 9 10 regulatory approval, Monsanto denies such allegations.

9. Monsanto lacks information or knowledge sufficient to form a belief as to the
 truth of the allegations concerning plaintiff's citizenship. The remaining allegations in paragraph
 9 set forth conclusions of law for which no response is required. To the extent that a response is
 deemed required, Monsanto admits the remaining allegations in paragraph 9.

15 10. Monsanto lacks information or knowledge sufficient to form a belief as to the
16 truth of the allegations in paragraph 10 that plaintiff purchased Roundup<sup>®</sup>-branded products and
17 therefore denies those allegations. The remaining allegations in paragraph 10 set forth
18 conclusions of law for which no response is required.

19 11. The allegations in paragraph 11 set forth conclusions of law for which no20 response is required.

12. In response to the allegations in paragraph 12, Monsanto denies any "omissions"
and certain events giving rise to plaintiff's claim. Monsanto lacks information or knowledge
sufficient to form a belief as to the truth of the allegations in paragraph 12 regarding where
certain other events giving rise to plaintiff's claim occurred and therefore denies those
allegations. The remaining allegations in paragraph 12 set forth conclusions of law for which no
response is required. To the extent that a response is required, Monsanto admits that venue is
proper in the Eastern District of Louisiana.

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- Monsanto lacks information or knowledge sufficient to form a belief as to the
   truth of the allegations asserted in paragraph 13 and therefore denies those allegations.
- 3 14. Monsanto admits that it is a Delaware corporation with its headquarters and
  4 principal place of business in St. Louis, MO.
- 5 15. In response to the allegations in paragraph 15, Monsanto admits that it was the
  6 entity that discovered the herbicidal properties of glyphosate and that Monsanto manufactures
  7 Roundup<sup>®</sup>-branded products that have glyphosate as the active ingredient, but notes that
  8 Monsanto was and is not the only manufacturer of glyphosate-based herbicides.
- 9 16. In response to the allegations in paragraph 16, Monsanto admits that glyphosate is
  10 an herbicide that is used to kill invasive plants and weeds. Monsanto states that the remaining
  11 allegations in paragraph 16 are vague and ambiguous and that it lacks information or knowledge
  12 sufficient to form a belief as to the truth of the remaining allegations in paragraph 16 and
  13 therefore denies those allegations.
- 14 17. Monsanto admits the allegations in the first sentence of paragraph 17. Monsanto
  15 denies the allegations in the second sentence of paragraph 17 because the impact of glyphosate
  16 on treated plants varies depending upon the amount of glyphosate applied and the type of plant.
  17 Monsanto denies the allegations in the third sentence of paragraph 17 to the extent that they
  18 suggest that glyphosate is present in any plants at anything other than *de minimis* amounts well
  19 within regulatory safety levels, as determined by EPA.
- 20 18. In response to the allegations in paragraph 18, Monsanto admits that farmers have
  21 safely used Roundup<sup>®</sup>-branded products since the 1970s. Monsanto denies the remaining
  22 allegations in paragraph 18.
- 19. Monsanto admits the allegations in the first two sentences of paragraph 19 and
  admits that it has marketed Roundup<sup>®</sup>-branded products in accord with EPA's regulatory
  determinations under FIFRA. Monsanto otherwise denies the remaining allegations in paragraph
  19.
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20. The allegations in paragraph 20 set forth conclusions of law for which no
 response is required. To the extent that a response is deemed required, Monsanto admits the
 allegations in paragraph 20.

4 21. In response to the allegations in paragraph 21, Monsanto admits that EPA requires
5 registrants of herbicides to submit extensive data in support of the human health and
6 environmental safety of their products and further admits that EPA will not register or approve
7 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. The remaining
8 allegations in paragraph 21 set forth conclusions of law for which no response is required.

9 22. The allegations in paragraph 22 set forth conclusions of law for which no
10 response is required.

11 23. Monsanto admits that Roundup<sup>®</sup>-branded products are registered by EPA for
12 manufacture, sale and distribution and are registered by the State of Louisiana for sale and
13 distribution.

14 24. In response to the allegations in paragraph 24, Monsanto admits that EPA requires
15 registrants of herbicides to submit extensive data in support of the human health and
16 environmental safety of their products and further admits that EPA will not register or approve
17 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. Monsanto
18 states that the term "the product tests" in the final sentence of paragraph 24 is vague and
19 ambiguous, and Monsanto therefore denies the same. The remaining allegations in paragraph 24
20 set forth conclusions of law for which no answer is required.

21 25. Monsanto denies the allegations in paragraph 25 to the extent that they suggest
22 that EPA only evaluates the safety of pesticide products on the date of their initial registration.
23 Monsanto admits that EPA is in the process of conducting regulatory review of various pesticide
24 products, but Monsanto lacks information or knowledge sufficient to form a belief as to the truth
25 of the allegations in paragraph 25 regarding such pesticide products generally and therefore
26 denies those allegations. The remaining allegations in paragraph 25 set forth conclusions of law
27 for which no response is required.

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1	26. In response to the allegations in paragraph 26, Monsanto admits that EPA has
2	undertaken a review of glyphosate and that EPA has not released its findings. Monsanto states,
3	however, that: (a) in September 2016, EPA's Office of Pesticide Programs ("OPP") issued a 227-
4	page evaluation of glyphosate's carcinogenic potential, concluding that "[t]he strongest support
5	is for [the descriptor] 'not likely to be carcinogenic to humans' at doses relevant to human health
6	risk assessment" <sup>1</sup> ; and (b) at the same time, EPA posted an October 2015 final report by its
7	standing Cancer Assessment Review Committee ("CARC"), in which CARC endorsed EPA's
8	existing classification of glyphosate as "Not Likely to be Carcinogenic to Humans." <sup>2</sup> Monsanto
9	lacks information or knowledge sufficient to form a belief as to the truth of the remaining
10	allegations in paragraph 26 and therefore denies those allegations.
11	27. In response to the allegations in paragraph 27, Monsanto admits that an EPA
12	review committee classified glyphosate as Class C in 1985 based on limited data and that EPA
13	changed its classification of glyphosate to Group E based upon a full evaluation of the scientific
14	evidence, including but not limited to three animal carcinogenicity studies. Monsanto admits
15	that plaintiff has accurately quoted from one passage in an EPA document in 1991 with respect
16	to the designation of an agent as Group E, but states that EPA repeatedly has concluded that
17	glyphosate does not pose any cancer risk to humans. In addition to the conclusions in the EPA
18	OPP Report and the EPA CARC Final Report discussed above, other specific findings of safety
19	include:
20	• "In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows evidence of non-carcinogenicity for humans—based on the lack of
21	convincing evidence of carcinogenicity in adequate studies." EPA, <i>Glyphosate:</i>
22	
23	<sup>1</sup> EPA's Office of Pesticide Programs, <i>Glyphosate Issue Paper: Evaluation of Carcinogenic Potential</i> at 141 (Sept. 12, 2016) ("EPA OPP Report"), <u>https://www.regulations.gov/</u>
24	<u>document?D=EPA-HQ-OPP-2016-0385-0094</u> . The EPA OPP Report was prepared in anticipation of an EPA Scientific Advisory Panel meeting on glyphosate's carcinogenic
25	potential.
26	<sup>2</sup> Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, <i>Cancer Assessment Document – Evaluation of the</i>
27	<i>Carcinogenic Potential of Glyphosate</i> at 10, 77 (Final Report, Oct. 1, 2015) ("EPA CARC Final Report"), <u>https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014</u> .
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1	<i>Reregistration Eligibility Decision (RED) Facts</i> , 2 (Sept. 1993), http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf.
2	<ul> <li>"No evidence of carcinogenicity." Glyphosate; Pesticide Tolerances, 67 Fed.</li> </ul>
3	Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
4	• "Glyphosate has no carcinogenic potential." Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
5	• "There is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or
6 7	reproductive toxicant." Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).
8	• "EPA has concluded that glyphosate does not pose a cancer risk to humans." 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
9	• "In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of [g]lyphosate. Our review concluded
10	that this body of research does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in the EPA's cancer classification
11 12	for [g]lyphosate." Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, &
12	<i>Forestry</i> , 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs), http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-
14	1000000000000000000000000000000000000
15	Monsanto denies the remaining allegations in paragraph 27.
16	28. In response to the allegations in paragraph 28, Monsanto admits that it – along
17	with a large number of other companies and governmental agencies – was defrauded by two
18	chemical testing laboratories, and that Monsanto had hired both of these laboratories to conduct
19	testing on glyphosate. Monsanto states that only one of these laboratories was hired to conduct
20	toxicity tests of glyphosate. Monsanto denies that EPA's registration of glyphosate or any
21	glyphosate-based herbicides is based upon any invalid Industrial Bio-Test ("IBT") Laboratories
22	studies. To the extent that the allegations in paragraph 28 are intended to suggest that Monsanto
23	was anything other than a victim of this fraud, such allegations are denied.
24	29. In response to the allegations in paragraph 29, Monsanto admits that IBT
25	Laboratories was hired to conduct toxicity studies in connection with the registration of a
26	Roundup <sup>®</sup> -branded product. Monsanto denies that EPA's regulatory approval of such product is
27	based upon any fraudulent or false IBT studies.
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1 30. Monsanto denies the allegations in paragraph 30 to the extent they suggest that 2 EPA performed an inspection of IBT Laboratories solely or specifically in connection with 3 studies conducted on glyphosate. Monsanto admits that EPA performed an audit of IBT 4 Laboratories to investigate that laboratory's fraudulent and/or improper testing procedures in 5 connection with services provided to a broad number of private and governmental entities and 6 that this inspection included a review of studies IBT conducted on glyphosate. Monsanto was 7 one of several pesticide manufacturers who had used IBT test results. The audit found some toxicology studies conducted with the original Roundup<sup>®</sup> herbicide to be invalid. As a result, 8 9 Monsanto repeated all required studies in accordance with applicable EPA testing guidelines. 10 Monsanto denies that EPA's registration of glyphosate or any glyphosate-based herbicides is 11 based upon any invalid IBT studies. To the extent that the allegations in paragraph 30 are 12 intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto 13 denies those allegations.

14 31. In response to the allegations in paragraph 31, Monsanto admits that three IBT
15 employees were convicted of the charge of fraud, but Monsanto denies that any of the
16 individuals were convicted based upon studies conducted on glyphosate or glyphosate-based
17 herbicides.

32. In response to the allegations in paragraph 32, Monsanto admits that it – along
with numerous other private companies – hired Craven Laboratories as an independent
laboratory to conduct residue studies for Monsanto agricultural products. Monsanto admits that
it was defrauded by Craven Laboratories and that, as a result, Monsanto repeated the studies
conducted at Craven Laboratories at a substantial cost. To the extent that the allegations in
paragraph 32 are intended to suggest that Monsanto was anything other than a victim of this
fraud, such allegations are denied.

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33. Monsanto denies the allegations in paragraph 33.

34. In response to the allegations in paragraph 34, Monsanto admits that Roundup<sup>®</sup>branded products are highly valued by its customers because of their efficacy and safety.

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Monsanto also admits that the patent for glyphosate expired in the United States in 2000. The
 remaining allegations in paragraph 34 are vague and conclusory and comprise attorney
 characterizations and are accordingly denied.

35. In response to the allegations in paragraph 35, Monsanto admits that following the
development of Roundup<sup>®</sup> Ready seeds, it began to sell them in the 1990s and that such seeds
are now widely used by farmers in the United States and worldwide. Monsanto lacks
information or knowledge sufficient to form a belief as to the accuracy of the specific numbers
cited in paragraph 35 and accordingly denies those allegations. The remaining allegations in
paragraph 35 are vague and conclusory and comprise attorney characterizations and are
accordingly denied.

36. In response to the allegations in paragraph 36, Monsanto admits that glyphosate is
one of the world's largest herbicides by sales volume, but Monsanto denies any suggestion that it
is the only company that sells glyphosate or glyphosate-based herbicides. Monsanto lacks
information or knowledge sufficient to form a belief as to the accuracy of the specific numbers
cited in paragraph 36 and accordingly denies the same. The remaining allegations in paragraph
36 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

17 37. In response to the allegations in paragraph 37, Monsanto admits that the New 18 York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading 19 advertising of Roundup<sup>®</sup>-branded products. This lawsuit was subsequently resolved without any 20 admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney 21 General's allegations related in any way to a purported or alleged risk of cancer. To the extent 22 the subparts purport to quote a document, the document speaks for itself and thus does not 23 require any further answer. The remaining allegations in paragraph 37 are vague and conclusory 24 and comprise attorney characterizations and are accordingly denied.

38. In response to the allegations in paragraph 38, Monsanto admits it entered into an
assurance of discontinuance with the New York Attorney General. The assurance speaks for

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1 itself and thus does not require any further answer. The remaining allegations in paragraph 38 2 are vague and conclusory and comprise attorney characterizations and are accordingly denied. 39.

3

Monsanto denies the allegations in paragraph 39.

4 40. In response to the allegations in paragraph 40, Monsanto admits that the French court ruled that Monsanto had falsely advertised its herbicide Roundup<sup>®</sup> as "biodegradable" and 5 6 that it "left the soil clean," but denies the allegations in paragraph 40 to the extent that they 7 suggest that this ruling was in any way related to plaintiff's claim here that glyphosate can cause 8 cancer. Monsanto denies the remaining allegations in paragraph 40.

9 41. In response to the allegations in paragraph 41, Monsanto denies that IARC 10 follows stringent procedures for the evaluation of a chemical agent. Monsanto lacks information 11 or knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in 12 paragraph 41, which are not limited as of any specified date, and accordingly denies the same.

13 42. In response to the allegations in paragraph 42, Monsanto admits that IARC sets 14 forth in its Preamble the procedures that it claims to follow in its carcinogenicity evaluations. 15 Monsanto denies the remaining allegations in paragraph 42.

16 43. Monsanto denies any suggestion that IARC reviewed the full body of scientific 17 research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies 18 that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to 19 form a belief as to the truth of the remaining allegations in paragraph 43 and therefore denies 20 those allegations.

21 44. Monsanto denies any suggestion that IARC reviewed the full body of scientific 22 research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies 23 that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to 24 form a belief as to the truth of the remaining allegations in paragraph 44 and therefore denies 25 those allegations.

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45. Monsanto denies the allegations in paragraph 45 to the extent that they suggest
 that IARC had previously assessed glyphosate. Monsanto admits that IARC classified
 glyphosate as a Group 2A agent in March 2015.

4 46. In response to the allegations in paragraph 46, Monsanto admits that IARC issued 5 its monograph for glyphosate, Monograph 112, on July 29, 2015, and that a draft of the 6 monograph was prepared by a "working group" of individuals selected by IARC who met over a 7 one-week period in March 2015 to consider glyphosate along with a number of other substances. 8 Monsanto denies the allegation that all members of the working groups are "experts." Monsanto 9 denies that the working group or anyone at IARC conducted a one-year review of the scientific 10 evidence related to glyphosate or that the working group's findings reflected a comprehensive 11 review of the latest available scientific evidence. Monsanto also denies that the working group 12 considered all information available in the scientific literature and all data from government 13 reports that are publicly available. Monsanto denies the remaining allegations in paragraph 46.

14 47. In response to the allegations in paragraph 47, Monsanto denies that the IARC 15 working group considered all of the data in the numerous studies that have been conducted 16 looking at the safety of glyphosate and glyphosate-containing herbicides in human populations or 17 that it reliably considered the studies that it purports to have reviewed, which frequently reach 18 conclusions directly contrary to those espoused by the IARC working group. To the extent the 19 allegations purport to characterize statements made in the IARC monograph for glyphosate, the 20 statements in that document speak for themselves, but Monsanto lacks information or knowledge 21 sufficient to form a belief as to the accuracy of the source of said information and accordingly 22 denies the allegations.

48. The allegations in paragraph 48 are vague and conclusory. To the extent they
purport to characterize statements made in the IARC monograph for glyphosate, the statements
in that document speak for themselves, but Monsanto lacks information or knowledge sufficient
to form a belief as to the accuracy of the source of said information and accordingly denies the
allegations.

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49. In response to the allegations in paragraph 49, to the extent the allegations purport
 to characterize statements made in the IARC monograph for glyphosate, the statements in that
 document speak for themselves, but to the extent that this paragraph means that more than *de minimis* amounts of exposure are present, Monsanto denies the allegations in paragraph 49.

5 50. In response to the allegations in paragraph 50, Monsanto admits that the IARC
6 working group identified a number of case control studies of populations with exposures to
7 glyphosate, but Monsanto denies that any of these studies provide any evidence of a human
8 health concern from such exposures.

9 51. Monsanto denies the allegations in paragraph 51. The IARC working group
10 concluded that there was only limited evidence of carcinogenicity in epidemiologic studies,
11 which, per IARC's guidelines, means that the working group could not rule out chance, bias or
12 confounding so as to reach any conclusion of an increased risk.

- 13 52. In response to the allegations in paragraph 52, Monsanto admits that the working
  14 group cited to a study that it concluded provided evidence of chromosomal damage in
  15 community residents reported to be exposed to glyphosate, but Monsanto denies that the study
  16 supports such a conclusion or that the authors of the study reached such a conclusion.
- 17 53. In response to the allegations in paragraph 53, Monsanto admits that the IARC
  18 working group purported to make these findings, but denies that the animal carcinogenicity
  19 studies of glyphosate in the aggregate provide evidence of a positive trend for or increase in any
  20 of the identified tumors. Monsanto further states that regulatory agencies around the world have
  21 reviewed the same animal studies and concluded that they do not provide evidence that
  22 glyphosate can cause cancer. Monsanto denies the remaining allegations in paragraph 53.

54. In response to the allegations in paragraph 54, Monsanto admits that the IARC
working group purported to make these findings, but denies that the cited studies provide any
reliable basis for a finding that any meaningful levels of glyphosate or AMPA are present or
persists in human blood or urine. Monsanto denies the remaining allegations in paragraph 54.

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55. In response to the allegations in paragraph 55, Monsanto admits that the IARC
 working group interpreted a selected number of experimental studies as evidence that glyphosate
 can cause genotoxicity, but Monsanto denies that the working group reliably considered the full
 body of scientific data on such alleged genotoxic endpoints and denies that the working group
 reliably interpreted the studies that it selected for consideration. Regulators around the world
 repeatedly have concluded that glyphosate is not genotoxic. Monsanto denies the remaining
 allegations in paragraph 55.

8 56. In response to the allegations in paragraph 56, Monsanto admits that the IARC
9 working group purported to find such effects, but denies that there is any reliable scientific basis
10 for such conclusion. Monsanto denies the remaining allegations in paragraph 56.

57. In response to the allegations in paragraph 57, Monsanto admits that the working
group reviewed the findings of an Agricultural Health Study ("AHS") published in 2005, but
denies that the working group characterized that study as supporting an association between
glyphosate and the specified cancers. The AHS cohort study did not find a positive association
between glyphosate and any type of cancer. Monsanto denies all other allegations in paragraph
57.

17 58. In response to the allegations in paragraph 58, Monsanto admits that EPA has a
18 technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water
19 regulations, relating to glyphosate that predates the IARC March 20, 2015 evaluation, which
20 should be read in context of EPA's precautionary regulatory mandate and EPA's consistent
21 finding that glyphosate does not pose any cancer risk to humans.

59. In response to the allegations in paragraph 59, Monsanto admits that the
Northwest Coalition for Alternatives to Pesticides made the identified claims, but denies that the
Coalition provides any reliable basis for any conclusions regarding potential health risks from
glyphosate. Monsanto notes that a federal district court has characterized this same publication
as an "advocacy piece[] published in [a] non-peer-reviewed journal." *See Arias v. DynCorp*, 928
F. Supp. 10, 24 (D.D.C. 2013).

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Monsanto states that the term "toxic" as used in paragraph 60 is vague and
 ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto
 denies the allegations in paragraph 60.

4 61. In response to the allegations in paragraph 61, Monsanto admits that Julie Marc
5 published the cited study in 2002 and states that the document speaks for itself and does not
6 require a response. To the extent that a response is deemed required, Monsanto denies the
7 allegations in paragraph 61.

62. In response to the allegations in the first sentence of paragraph 62, Monsanto
admits that Julie Marc published a study titled "Glyphosate-based pesticides affect cell cycle
regulation" in 2004. To the extent that the first sentence of paragraph 62 characterizes the
meaning of the cited study, Monsanto denies the allegations in the first sentence of paragraph 62.
In response to the remaining allegations in paragraph 62, Monsanto states that the document
speaks for itself and does not require a response. To the extent that a response is deemed
required, Monsanto denies the remaining allegations in paragraph 62.

15 63. In response to the allegations in paragraph 63, Monsanto states that the cited
16 document speaks for itself and does not require a response. To the extent that paragraph 63
17 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
18 paragraph 63.

19 64. In response to the allegations in paragraph 64, Monsanto states that the cited
20 document speaks for itself and does not require a response. To the extent that paragraph 64
21 characterizes the meaning of the cited study, Monsanto denies the allegation that the cited studies
22 support the allegation that glyphosate or Roundup<sup>®</sup>-branded products pose any risk to human
23 health and denies the remaining allegations in paragraph 64.

24 65. In response to the allegations in paragraph 65, Monsanto states that the terms "at
25 all times" and "these studies" are vague and ambiguous, and therefore Monsanto denies those
26 allegations. Monsanto denies the remaining allegations in paragraph 65.

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1 66. In response to the allegations in paragraph 66, Monsanto admits that the IARC
 2 working group's classification of glyphosate as a Class 2A carcinogen has resulted in ongoing
 3 discussions in certain countries regarding the sale of glyphosate-based herbicides, including the
 4 Netherlands. Monsanto denies that any final conclusion has been reached in these countries and
 5 denies that there is any scientific basis for the concerns raised by the improper IARC
 6 classification. Monsanto denies the remaining allegations in paragraph 66.

67. In response to the allegations in paragraph 67, Monsanto admits that the IARC
working group classification led an individual government attorney in Brazil to write a letter to
the Brazilian regulatory authorities requesting a reevaluation of glyphosate. Monsanto denies the
remaining allegations in paragraph 67.

In response to the allegations in paragraph 68, Monsanto admits that following the
IARC working group classification, in France, all non-professional plant protection products,
including but not limited to glyphosate-based products, will be sold behind locked counters (no
free sales). Monsanto further admits that the French government has announced that, beginning
on January 1, 2019, the sale of non-professional lawn and garden products, including but not
limited to non-professional use glyphosate-based products, will be prohibited with certain
exceptions. Monsanto denies the remaining allegations in paragraph 68.

18 69. In response to the allegations in paragraph 69, Monsanto admits that some
19 employees of Bermuda's government announced an intention to suspend the importation of
20 glyphosate-based herbicides, but Monsanto lacks information sufficient to form a belief as to the
21 truth of the allegations about whether this suspension took effect and accordingly denies the
22 same. Monsanto denies the remaining allegations in paragraph 69.

70. In response to the allegations in paragraph 70, Monsanto admits that the IARC
monograph appears to be the alleged basis for the Sri Lankan government's actions, including
the allegation that glyphosate can cause kidney disease. Monsanto further states that the
allegations regarding kidney disease found in Sri Lanka are unrelated to plaintiff's allegations
regarding claimed carcinogenicity. Monsanto denies the remaining allegations in paragraph 70.

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1 71. In response to the allegations in paragraph 71, Monsanto denies the alleged basis 2 for Colombia's suspension of aerial spraying of glyphosate. Colombia's attorney general has 3 explained that the ban on aerial spraying of illicit coca plantations was a concession to the FARC 4 ("Fuerzas Armadas Revolucionarias de Colombia"), and had nothing to do with alleged safety 5 concerns. As of April 2016, the government of Colombia has resumed manual application of 6 glyphosate on illicit coca crops. A federal district court in the United States excluded plaintiffs' 7 expert testimony purporting to link these same aerial eradication operations with cancer as 8 scientifically unreliable. See Arias v. DynCorp, 928 F. Supp. 10 (D.D.C. 2013). Monsanto 9 denies the remaining allegations in paragraph 71.

10 72. In response to the allegations in paragraph 72, Monsanto admits that the 11 California Office of Environmental Health Hazard Assessment ("OEHHA") decided that it was 12 required to add glyphosate to California's Proposition 65 list of chemicals in a process that 13 OEHHA itself considers "ministerial" and "automatic" without any role for consideration of the 14 weight or quality of the evidence considered by IARC. Monsanto further states that this decision 15 was not based upon any independent scientific analysis of glyphosate but instead was in response 16 to a provision of a California ballot proposition triggering such action based solely upon the 17 IARC classification, and indeed was contrary to OEHHA's own conclusion in 2007, based upon 18 its own independent evaluation of the same scientific evidence, that glyphosate is "unlikely to pose a cancer hazard to humans."<sup>3</sup> Monsanto contends that OEHHA's decision that it was 19 20 required to list glyphosate violates the United States Constitution and the California Constitution; 21 Monsanto has sued to block OEHHA's action and is currently engaged in briefing on this issue 22 before the California Court of Appeal. The remaining allegations set forth conclusions of law for 23 which no response is required. To the extent that a response is deemed required, Monsanto 24 denies the allegations in paragraph 72.

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> <sup>3</sup> OEHHA, *Public Health Goal for Glyphosate in Drinking Water* (June 2007), <u>https://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907\_0.pdf</u>.

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73. The allegations in paragraph 73 set forth conclusions of law for which no
 response is required.

74. The allegations in paragraph 74 set forth conclusions of law for which no
response is required. Nevertheless, Monsanto notes that, under Proposition 65, the mere
presence of a listed substance in a consumer product does not require a warning. Instead, a
warning need only be provided if the exposure to the listed substance, for the average user of the
product, exceeds the level at which cancer would be hypothesized to occur, based on
extrapolation from animal studies, in one person in 100,000 persons exposed over a 70-year
lifetime.

10 75. In response to the allegations in paragraph 75, Monsanto admits that it has
11 brought a lawsuit challenging OEHHA's notice of intent to include glyphosate on its Proposition
12 65 list.

13 76. In response to the allegations in paragraph 76, Monsanto admits that plaintiff
14 accurately quotes from Monsanto's complaint in the referenced lawsuit, and states that
15 Monsanto's complaint in that lawsuit speaks for itself. Monsanto further admits that its lawsuit
16 cites to OEHHA's 2007 determination based upon its own independent evaluation of the
17 scientific evidence that glyphosate is "unlikely to pose a cancer hazard to humans."<sup>4</sup> The
18 remaining allegations in paragraph 76 comprise attorney characterizations and are accordingly
19 denied.

20 77. In response to the allegations in paragraph 77, Monsanto admits that, on 21 November 12, 2015, the European Food Safety Authority ("EFSA") issued its Renewal 22 Assessment Report (RAR) on glyphosate, in which it concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans."<sup>5</sup> Monsanto further admits that this conclusion affirmed 23 24 a similar finding by the German Federal Institute for Risk Management (BfR). Monsanto admits 25 OEHHA, Public Health Goal for Glyphosate in Drinking Water (June 2007), https://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907 0.pdf. 26 See EFSA, Glyphosate: EFSA updates toxicological profile, http://www.efsa.europa.eu/en

27 <sup>3</sup> See EFSA, Glyphosate: EFSA updates toxicological profile, <u>http://www.efsa.europa.eu/en</u> /press/news/151112.

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that the European scientists who reached these determinations were acting independently of
 Monsanto and were acting to protect the public.

78. In response to the allegations in paragraph 78, Monsanto denies that "industry
groups" were afforded any ability to review the RAR beyond that afforded to the public
generally. Monsanto otherwise admits the allegations in paragraph 78.

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79. Monsanto admits the allegations in paragraph 79.

7 80. In response to the allegations in paragraph 80, Monsanto states that the cited 8 document speaks for itself and does not require a response. Monsanto denies the allegations in 9 paragraph 80 to the extent that they purport to set forth all of the distinctions identified by EFSA 10 between its evaluation and the evaluation of the IARC working group. Monsanto states that in 11 the same document cited by plaintiff, EFSA states that, in contrast to IARC, "the EU peer review 12 concluded that no significant increase in tumour incidence could be observed in any of the 13 treated groups of animals in the nine long term rat studies considered" and explains that "[a]s 14 well as reviewing a larger number of studies [than IARC], EFSA for example considered that 15 carcinogenic effects observed at high doses were unreliable as they could be related to general 16 toxicity."<sup>6</sup> To the extent that paragraph 80 characterizes the meaning of the cited studies, 17 Monsanto denies the remaining allegations in paragraph 80.

18 81. In response to the allegations in paragraph 81, Monsanto states that the cited
19 document speaks for itself and does not require a response.

82. In response to the allegations in paragraph 82, Monsanto admits that EFSA set
acceptable exposure thresholds for glyphosate that are orders of magnitude higher than those
which occur in the ordinary use of glyphosate-based herbicides. Monsanto denies that these
exposure thresholds are based upon any alleged risk of carcinogenicity.

83. In response to the allegations in paragraph 83, Monsanto admits that certain
individuals, including Dr. Christopher Portier, sent the letter identified in paragraph 83

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<sup>6</sup> EFSA, *EFSA Explains Risk Assessment Glyphosate*, <u>http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/efsaexplainsglyphosate151112en.pdf</u>.

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(hereinafter, "the Portier letter"). Monsanto denies that Dr. Portier or the other signatories to his
 letter are "independent" and "renowned international experts in the field." Monsanto states that
 Dr. Portier has been disclosed as an expert witness retained by plaintiffs' counsel in the
 glyphosate cancer litigation against Monsanto. Monsanto otherwise admits that this letter urged
 the EU Health Commissioner to disregard the scientific findings reached by EFSA and by the
 BfR.

84. In response to the allegations in paragraph 84, Monsanto admits that Dr. Portier
sent the letter identified in paragraph 84. Monsanto denies that Dr. Portier or the other
signatories to his letter are "renowned international experts in the field." Monsanto admits that
certain members of the IARC working group assigned to glyphosate signed on to the Portier
letter, but states that Monsanto lacks information or knowledge sufficient to form a belief as to
whether those individuals or the other signatories were aware at the time that Dr. Portier was
working as a consultant for plaintiffs' counsel.

14 85. In response to the allegations in paragraph 85, Monsanto states that the cited 15 Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr. 16 Portier – who has been disclosed as an expert witness retained by plaintiffs' counsel in the 17 glyphosate cancer litigation against Monsanto - seeks in his letter to challenge the scientific 18 conclusions reached by EFSA in support of its finding that "glyphosate is unlikely to pose a carcinogenic hazard to humans."<sup>7</sup> To the extent that paragraph 85 characterizes the meaning of 19 20 the cited document or of EFSA's evaluation of glyphosate, Monsanto denies the remaining 21 allegations in paragraph 85.

86. In response to the allegations in paragraph 86, Monsanto admits that IARC
concluded that the human epidemiologic data provides only "limited evidence of
carcinogenicity," which IARC defines as meaning that "chance, bias, or confounding could not
be ruled out with reasonable confidence."<sup>8</sup> Monsanto further admits that Dr. Portier – who has

- <sup>7</sup> See EFSA, Glyphosate: EFSA updates toxicological profile, <u>http://www.efsa.europa.eu/en/press/news/151112</u>.
- 27 <sup>8</sup> <u>http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php</u>.
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MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC been disclosed as an expert witness retained by plaintiffs' counsel in the glyphosate cancer
litigation against Monsanto – seeks in his letter to challenge the scientific conclusions reached by
EFSA in support of its finding that "glyphosate is unlikely to pose a carcinogenic hazard to
humans."<sup>9</sup> In response to the remaining allegations in paragraph 86, Monsanto states that the
cited Portier letter speaks for itself and does not require a response. To the extent that paragraph
86 characterizes the meaning of the cited document or of EFSA's evaluation of glyphosate,
Monsanto denies the remaining allegations in paragraph 86.

8 87. In response to the allegations in paragraph 87, Monsanto states that the cited 9 Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr. 10 Portier – who has been disclosed as an expert witness retained by plaintiffs' counsel in the 11 glyphosate cancer litigation against Monsanto – seeks in his letter to challenge the scientific 12 conclusions reached by EFSA in support of its finding that "glyphosate is unlikely to pose a carcinogenic hazard to humans."<sup>10</sup> To the extent that paragraph 87 characterizes the meaning of 13 the cited document or of EFSA's and BfR's evaluation of glyphosate, Monsanto denies the 14 15 remaining allegations in paragraph 87.

16 88. In response to the allegations in paragraph 88, Monsanto states that the cited 17 Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr. 18 Portier – who has been disclosed as an expert witness retained by plaintiffs' counsel in the 19 glyphosate cancer litigation against Monsanto – seeks in his letter to challenge the scientific 20 conclusions reached by EFSA in support of its finding that "glyphosate is unlikely to pose a carcinogenic hazard to humans."<sup>11</sup> To the extent that paragraph 88 characterizes the meaning of 21 22 the cited document or of EFSA's and BfR's evaluation of glyphosate, Monsanto denies the 23 remaining allegations in paragraph 88.

- 27 <sup>11</sup> See EFSA, Glyphosate: EFSA updates toxicological profile, <u>http://www.efsa.europa.eu</u>/<u>en/press/news/151112</u>.
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 <sup>&</sup>lt;sup>24</sup>
 <sup>9</sup> See EFSA, Glyphosate: EFSA updates toxicological profile, <u>http://www.efsa.europa.eu/en/press/news/151112</u>.

 <sup>&</sup>lt;sup>10</sup> See EFSA, Glyphosate: EFSA updates toxicological profile, <u>http://www.efsa.europa.eu</u>
 26 //en/press/news/151112.

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89. Monsanto admits the allegations in paragraph 89.

90. In response to the allegations in paragraph 90, Monsanto states that the cited
document speaks for itself and does not require a response. Monsanto denies that the selflabeled "consensus statement" represents the view of any consensus of scientific opinion. To the
extent that paragraph 90 characterizes the scientific evidence regarding the safety of glyphosatebased herbicides, Monsanto denies the remaining allegations in paragraph 90.

91. In response to the allegations in paragraph 91, Monsanto states that the cited
document speaks for itself and does not require a response. Monsanto denies that the selflabeled "consensus statement" represents the view of any consensus of scientific opinion. To the
extent that paragraph 91 characterizes the scientific evidence regarding the safety of glyphosatebased herbicides, Monsanto denies the remaining allegations in paragraph 91.

92. In response to the allegations in paragraph 92, Monsanto states that the cited
document speaks for itself and does not require a response. Monsanto denies that the selflabeled "consensus statement" represents the view of any consensus of scientific opinion. To the
extent that paragraph 92 characterizes the scientific evidence regarding the safety of glyphosatebased herbicides, Monsanto denies the remaining allegations in paragraph 92.

17 93. In response to the allegations in paragraph 93, Monsanto states that the cited
18 document speaks for itself and does not require a response. Monsanto denies that the self19 labeled "consensus statement" represents the view of any consensus of scientific opinion. To the
20 extent that paragraph 93 characterizes the scientific evidence regarding the safety of glyphosate21 based herbicides, Monsanto denies the remaining allegations in paragraph 93.

94. In response to the allegations in paragraph 94, Monsanto states that the cited
document speaks for itself and does not require a response. Monsanto denies that the selflabeled "consensus statement" represents the view of any consensus of scientific opinion. To the
extent that paragraph 94 characterizes the scientific evidence regarding the safety of glyphosatebased herbicides, Monsanto denies the remaining allegations in paragraph 94.

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95. In response to the allegations in paragraph 95, Monsanto states that the cited
 document speaks for itself and does not require a response. Monsanto denies that the self labeled "consensus statement" represents the view of any consensus of scientific opinion. To the
 extent that paragraph 95 characterizes the scientific evidence regarding the safety of glyphosate based herbicides, Monsanto denies the remaining allegations in paragraph 95.

6 96. In response to the allegations in paragraph 96, Monsanto states that the cited
7 document speaks for itself and does not require a response. Monsanto denies that the self8 labeled "consensus statement" represents the view of any consensus of scientific opinion. To the
9 extent that paragraph 96 characterizes the scientific evidence regarding the safety of glyphosate10 based herbicides, Monsanto denies the remaining allegations in paragraph 96.

97. In response to the allegations in paragraph 97, Monsanto admits that the United
States Food and Drug Administration ("FDA") has authority to enforce pesticide residues and
that the FDA announced it would begin testing certain foods for glyphosate residues. In
response to the remaining allegations in paragraph 97, Monsanto states that the cited documents
speak for themselves and do not require a response.

16 98. In response to the allegations in paragraph 98, Monsanto admits that the U.S.
17 Government Accountability Office ("GAO") issued the cited report regarding pesticide residue
18 monitoring programs, but Monsanto denies that the GAO report was limited to glyphosate. In
19 response to the remaining allegations in paragraph 98, Monsanto states that the cited documents
20 speak for themselves and do not require a response. To the extent that paragraph 98
21 characterizes the meaning of the cited documents, Monsanto denies the remaining allegations in
22 paragraph 98.

- 99. In response to the allegations in paragraph 99, Monsanto admits that the FDA has
  authority to enforce pesticide residues and that the FDA announced it would begin testing certain
  foods for glyphosate residues. In response to the remaining allegations in paragraph 99,
  - Monsanto states that the cited documents speak for themselves and do not require a response. To
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MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC the extent that paragraph 99 characterizes the meaning of the cited documents, Monsanto denies
 the remaining allegations in paragraph 99.

100. In response to the allegations in paragraph 100, Monsanto admits that the FDA
has authority to enforce pesticide residues and that the FDA announced it would begin testing
certain foods for glyphosate residues. In response to the remaining allegations in paragraph 100,
Monsanto states that the cited documents speak for themselves and do not require a response. To
the extent that paragraph 100 characterizes the meaning of the cited documents, Monsanto denies
the remaining allegations in paragraph 100.

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101. Monsanto admits the allegations in paragraph 101.

10 102. In response to the allegations in paragraph 102, Monsanto states that the cited
11 document speaks for itself and does not require a response.

12 103. In response to the allegations in paragraph 103, Monsanto lacks information or
13 knowledge sufficient to form a belief as to whether each of the individuals at the referenced
14 meeting were "experts" and therefore denies that allegation. Monsanto admits the remaining
15 allegations in paragraph 103.

16 104. In response to the allegations in paragraph 104, Monsanto states that the cited
17 document speaks for itself and does not require a response. To the extent that paragraph 104
18 characterizes the meaning of the cited document, Monsanto denies the remaining allegations in
19 paragraph 104.

20 105. In response to the allegations in paragraph 105, Monsanto states that the cited
21 document speaks for itself and does not require a response. To the extent that paragraph 105
22 characterizes the meaning of the cited document, Monsanto denies the remaining allegations in
23 paragraph 105.

Monsanto admits the allegations in paragraph 106.

Monsanto admits the allegations in paragraph 107.

Monsanto admits the allegations in paragraph 108.

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MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC

1 109. Monsanto admits the allegations in paragraph 109. Monsanto notes that, in March 2 2017, the European Chemical Agency ("ECHA") announced that its Committee for Risk 3 Assessment concluded that the available scientific evidence did not meet the criteria to classify 4 glyphosate as a carcinogen. See ECHA, Glyphosate not classified as a carcinogen by ECHA, 5 https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa. 6 110. Monsanto lacks information or knowledge sufficient to form a belief as to the 7 truth of the allegations in paragraph 110 and therefore denies those allegations. 8 111. Monsanto lacks information or knowledge sufficient to form a belief as to the 9 truth of the allegations in paragraph 111 and therefore denies those allegations. 10 112. Monsanto lacks information or knowledge sufficient to form a belief as to the 11 truth of the allegations in paragraph 112 and therefore denies those allegations. 12 113. Monsanto lacks information or knowledge sufficient to form a belief as to the 13 truth of the allegations in paragraph 113 and therefore denies those allegations. Monsanto denies that any exposure to Roundup<sup>®</sup>-branded products can cause non-14 114. 15 Hodgkin's lymphoma ("NHL") and other serious illnesses and therefore denies the allegations in 16 paragraph 114. Monsanto states, however, that the scientific studies upon which IARC 17 purported to base its evaluation of glyphosate were all publicly available before March 2015. Monsanto denies that any exposure to Roundup<sup>®</sup>-branded products can cause 18 115. 19 NHL and other serious illnesses and therefore denies the allegations in paragraph 115. Monsanto 20 states, however, that the scientific studies upon which IARC purported to base its evaluation of 21 glyphosate were all publicly available before March 2015. 22 In response to the allegations in paragraph 116, Monsanto denies that there is any 116. risk of serious illness associated with the use of and/or exposure to Roundup®-branded products 23 and glyphosate and denies that Roundup<sup>®</sup>-branded products or glyphosate are injurious to human 24 25 health. Monsanto states, however, that the scientific studies upon which IARC purported to base 26 its classification were all publicly available before March 2015. The final sentence of paragraph 27 116 sets forth a conclusion of law for which no response is required. 28 - 24 -MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC

1 117. In response to the allegations in paragraph 117, Monsanto denies that exposure to
 2 Roundup<sup>®</sup>-branded products and glyphosate is injurious to human health. Monsanto states,
 3 however, that the scientific studies upon which IARC purported to base its cancer classification
 4 for glyphosate were all publicly available before March 2015. The allegations in paragraph 117
 5 set forth conclusions of law for which no response is required.

118. In response to the allegations in paragraph 118, Monsanto denies that there is any
risk of NHL or other serious illness associated with the use of and/or exposure to Roundup<sup>®</sup>branded products and glyphosate. Monsanto states, however, that the scientific studies upon
which IARC purported to base its cancer classification for glyphosate were all publicly available
before March 2015. Monsanto lacks information or knowledge sufficient to form a belief as to
the truth of the remaining allegations in paragraph 118 and therefore denies those allegations.

12 119. The allegations in paragraph 119 set forth conclusions of law for which no
13 response is required. To the extent that a response is deemed required, Monsanto denies the
14 allegations in paragraph 119. Monsanto states that the scientific studies upon which IARC
15 purported to base its cancer classification for glyphosate were all publicly available before
16 March 2015.

17 120. In response to the allegations in paragraph 120, Monsanto denies that it concealed
18 any facts related to the human health safety of glyphosate. The remaining allegations in
19 paragraph 120 set forth conclusions of law for which no response is required.

121. Monsanto denies the allegations in paragraph 121.

122. Monsanto denies the allegations in paragraph 122.

123. The allegations in paragraph 123 set forth conclusions of law for which noresponse is required.

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124. Monsanto denies the allegations in paragraph 124.

25 125. The allegations in paragraph 125 set forth conclusions of law for which no
26 response is required. To the extent that a response is required, Monsanto denies the allegations

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MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC

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1	in paragraph 125. Monsanto states that the scientific studies upon which IARC purported to base	
2	its cancer classification for glyphosate were all publicly available before March 2015.	
3	126. Monsanto incorporates by reference its responses to paragraphs 1 through 125 in	
4	response to paragraph 126 of plaintiff's Complaint.	
5	127. In response to the allegations in paragraph 126, Monsanto admits that plaintiff	
6	purports to bring claims for strict liability but denies any liability to plaintiff.	
7	128. In response to the allegations in paragraph 127, Monsanto lacks information or	
8	knowledge sufficient to form a belief as to the truth of the allegation that plaintiff used	
9	Roundup®-branded products and therefore denies that allegation. Monsanto denies the	
10	remaining allegations in paragraph 127.	
11	129. In response to the allegations in paragraph 128, Monsanto lacks information or	
12	knowledge sufficient to form a belief as to the truth of the allegations that plaintiff used or was	
13	exposed to Roundup <sup>®</sup> -branded products and therefore denies those allegations. Monsanto denies	
14	the remaining allegations in paragraph 128.	
15	130. Monsanto denies the allegations in paragraph 130.	
16	131. Monsanto lacks information or knowledge sufficient to form a belief as to the	
17	truth of the allegations in paragraph 131 and therefore denies those allegations.	
18	132. Monsanto denies the allegations in paragraph 132.	
19	133. Monsanto denies the allegations in paragraph 133.	
20	134. Monsanto denies the allegations in paragraph 134 and each of its subparts.	
21	135. Monsanto lacks information or knowledge sufficient to form a belief as to the	
22	truth of the allegations in paragraph 135 concerning plaintiff's claimed use of or exposure to	
23	Roundup <sup>®</sup> -branded products and therefore denies those allegations. Monsanto denies the	
24	remaining allegations in paragraph 135, including that Roundup <sup>®</sup> -branded products have	
25	"dangerous characteristics."	
26	136. Monsanto denies the allegations in paragraph 136.	
27	137. Monsanto denies the allegations in paragraph 137.	
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	MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC	

1	138. Monsanto denies the allegations in paragraph 138.	
2	139. Monsanto denies the allegations in paragraph 139.	
3	140. Monsanto denies the allegations in paragraph 140.	
4	141. Monsanto denies the allegations in paragraph 141.	
5	142. Monsanto denies the allegations in paragraph 142.	
6	In response to the "WHEREFORE" paragraph following paragraph 142, Monsanto	
7	demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be	
8	dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's	
9	fees as allowed by law and such further and additional relief as this Court may deem just and	
10	proper.	
11	143. Monsanto incorporates by reference its responses to paragraphs 1 through 142 in	
12	response to paragraph 143 of plaintiff's Complaint.	
13	144. In response to the allegations in paragraph 144, Monsanto admits that plaintiff	
14	purports to bring claims for strict liability failure to warn, but denies any liability to plaintiff.	
15	145. Monsanto denies the allegations in paragraph 145.	
16	146. In response to the allegations in paragraph 146, Monsanto lacks information or	
17	knowledge sufficient to form a belief as to the truth of the allegations that plaintiff or other	
18	persons or entities purchased Roundup <sup>®</sup> -branded products and therefore denies those allegations.	
19	The allegations in paragraph 146 also set forth conclusions of law for which no response is	
20	required. Monsanto denies the remaining allegations in paragraph 146.	
21	147. The allegations in paragraph 147 set forth conclusions of law for which no	
22	response is required.	
23	148. Monsanto denies the allegations in paragraph 148. All labeling of Roundup <sup>®</sup> -	
24	branded products has been and remains EPA-approved and in compliance with all federal	
25	requirements under FIFRA.	
26	149. Monsanto denies the allegations in paragraph 149.	
27	150. Monsanto denies the allegations in paragraph 150.	
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	MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC	

- 1 151. Monsanto denies the allegations in paragraph 151. 2 152. Monsanto lacks information or knowledge sufficient to form a belief as to the 3 truth of the allegations in paragraph 152 and therefore denies those allegations. 4 153. Monsanto lacks information or knowledge sufficient to form a belief as to the 5 truth of the allegations in paragraph 153 concerning plaintiff's claimed use of and exposure to Roundup<sup>®</sup>-branded products and therefore denies those allegations. Monsanto denies the 6 remaining allegations in paragraph 153, including that Roundup<sup>®</sup>-branded products have 7 8 "dangerous characteristics." 9 154. Monsanto lacks information or knowledge sufficient to form a belief as to the 10 truth of the allegations in the final sentence of paragraph 154 and therefore denies those 11 allegations. Monsanto denies the remaining allegations in paragraph 154. Monsanto states, 12 however, that the scientific studies upon which IARC purported to base its evaluation of 13 glyphosate were all publicly available before March 2015. 14 155. Monsanto denies the allegations in paragraph 155. 15 156. Monsanto denies the allegations in paragraph 156. 16 157. Monsanto denies the allegations in paragraph 157. 17 158. Monsanto denies the allegations in paragraph 158. 18 159. Monsanto denies the allegations in paragraph 159. 19 160. Monsanto denies the allegations in paragraph 160. 20 Monsanto denies the allegations in paragraph 161. All labeling of Roundup<sup>®</sup>-161. 21 branded products has been and remains EPA-approved and in compliance with all federal 22 requirements under FIFRA. 23 162. Monsanto denies the allegations in paragraph 162. 24 In response to the "WHEREFORE" paragraph following paragraph 162, Monsanto 25 demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be 26 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's 27 28 - 28 -MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT
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1	fees as allowed	d by law and such further and additional relief as this Court may deem just and
2	proper.	
3	163.	Monsanto incorporates by reference its responses to paragraphs 1 through 162 in
4	response to pa	ragraph 163 of plaintiff's Complaint.
5	164.	In response to the allegations in paragraph 164, Monsanto states that the phrase
6	"directly or ine	directly" is vague and ambiguous and that Monsanto lacks information or
7	knowledge sufficient to form a belief as to the truth of those allegations and therefore Monsanto	
8	denies those al	llegations.
9	165.	Monsanto lacks information or knowledge sufficient to form a belief as to the
10	truth of the all	egations in paragraph 165 and therefore denies those allegations.
11	166.	The allegations in paragraph 166 set forth conclusions of law for which no
12	response is rec	quired.
13	167.	The allegations in paragraph 167 set forth conclusions of law for which no
14	response is rec	quired.
15	168.	Monsanto denies the allegations in paragraph 168.
16	169.	Monsanto denies the allegations in paragraph 169.
17	170.	Monsanto denies the allegations in paragraph 170.
18	171.	Monsanto denies the allegations in paragraph 171.
19	172.	Monsanto denies the allegations in paragraph 172. All labeling of Roundup <sup>®</sup> -
20	branded produ	cts has been and remains EPA-approved and in compliance with all federal
21	requirements u	under FIFRA.
22	173.	Monsanto denies the allegations in paragraph 174.
23	174.	Monsanto denies the allegations in paragraph 174.
24	175.	Monsanto denies the allegations in paragraph 175.
25	176.	Monsanto denies the allegations in paragraph 176, including each of its subparts.
26	177.	Monsanto denies the allegations in paragraph 177.
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	MONSANTO	COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC

1	178. Monsanto lacks information or knowledge sufficient to form a belief as to the	
2	truth of the allegations in paragraph 178 regarding plaintiff's knowledge and therefore denies	
3	those allegations. Monsanto denies the remaining allegations in paragraph 178, including that	
4	intended use of and/or exposure to Roundup <sup>®</sup> -branded products causes any injuries.	
5	179. Monsanto denies the allegations in paragraph 179.	
6	180. Monsanto denies the allegations in paragraph 180.	
7	181. Monsanto denies the allegations in paragraph 181.	
8	In response to the "WHEREFORE" paragraph following paragraph 181, Monsanto	
9	demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be	
10	dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's	
11	fees as allowed by law and such further and additional relief as this Court may deem just and	
12	proper.	
13	182. Monsanto incorporates by reference its responses to paragraphs 1 through 182 in	
14	response to paragraph 181 of plaintiff's Complaint.	
15	183. Monsanto denies the allegations in paragraph 183.	
16	184. In response to the allegations in paragraph 184, Monsanto admits that it has sold	
17	glyphosate-based herbicides in accordance with their EPA-approved labeling. Monsanto further	
18	states that paragraph 183 sets forth conclusions of law for which no response is required.	
19	Monsanto denies the remaining allegations in paragraph 183.	
20	185. Monsanto denies the allegations in the first and second sentences of paragraph	
21	185. All labeling of Roundup <sup>®</sup> -branded products has been and remains EPA-approved and in	
22	compliance with all federal requirements under FIFRA. Monsanto states that the final sentence	
23	of paragraph 185 sets forth conclusions of law for which no response is required.	
24	186. Paragraph 186 sets forth conclusions of law for which no response is required.	
25	187. Monsanto denies the allegations in paragraph 187.	
26	188. Monsanto denies the allegations in paragraph 188 and each of its subparts.	
27		
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	MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT	
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1	189. The allegations in paragraph 189 set forth conclusions of law for which no	
2	response is required.	
3	190. Monsanto states that the allegation in paragraph 190 that Monsanto made an	
4	express warranty sets forth a legal conclusion for which no response is required. Monsanto lacks	
5	information or knowledge sufficient to form a belief as to the truth of the remaining allegations	
6	in paragraph 190 and therefore denies those allegations.	
7	191. Monsanto lacks information or knowledge sufficient to form a belief as to the	
8	truth of the allegations in paragraph 191 and therefore denies those allegations.	
9	192. Monsanto denies the allegations in paragraph 192.	
10	193. Monsanto lacks information or knowledge sufficient to form a belief as to the	
11	truth of the allegations in paragraph 193 regarding plaintiff's knowledge and therefore denies	
12	those allegations. Monsanto denies the remaining allegations in paragraph 193.	
13	194. Monsanto lacks information or knowledge sufficient to form a belief as to the	
14	truth of the allegations in paragraph 194 and therefore denies those allegations.	
15	195. Monsanto denies the allegations in paragraph 195.	
16	196. Monsanto denies the allegations in paragraph 196.	
17	In response to the "WHEREFORE" paragraph following paragraph 196, Monsanto	
18	demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be	
19	dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's	
20	fees as allowed by law and such further and additional relief as this Court may deem just and	
21	proper.	
22	197. Monsanto incorporates by reference its responses to paragraphs 1 through 196 in	
23	response to paragraph 197 of plaintiff's Complaint.	
24	198. Monsanto denies the allegations in paragraph 198.	
25	199. Monsanto denies the allegations in paragraph 199.	
26	200. Monsanto lacks information or knowledge sufficient to form a belief as to the	
27	truth of the allegations in paragraph 200 concerning plaintiff's claimed use of and exposure to	
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	MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC	

Roundup<sup>®</sup>-branded products and therefore denies those allegations. The remaining allegations in
 paragraph 200 set forth conclusions of law for which no response is required.

3 201. Monsanto denies the allegations in paragraph 201. All labeling of Roundup<sup>®</sup>4 branded products has been and remains EPA-approved and in compliance with all federal
5 requirements under FIFRA.

6 202. Monsanto lacks information or knowledge sufficient to form a belief as to the
7 truth of the allegations in paragraph 202 regarding plaintiff's and plaintiff's employers' reliance
8 and therefore denies those allegations. The remaining allegations in paragraph 201 set forth
9 conclusions of law for which no response is required.

203. Monsanto lacks information or knowledge sufficient to form a belief as to the
truth of the allegations in paragraph 203 and therefore denies those allegations.

204. Monsanto lacks information or knowledge sufficient to form a belief as to the
truth of the allegations in paragraph 204 concerning plaintiff's claimed use of or exposure to
Roundup<sup>®</sup>-branded products and therefore denies those allegations. The remaining allegations in
paragraph 204 set forth conclusions of law for which no response is required.

16 205. Monsanto lacks information or knowledge sufficient to form a belief as to the
17 truth of the allegations in paragraph 205 concerning plaintiff's claimed use of or exposure to
18 Roundup<sup>®</sup>-branded products and therefore denies those allegations. Monsanto denies the
19 remaining allegations in paragraph 205.

20 206. Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the allegations in paragraph 206 concerning the condition of any Roundup<sup>®</sup>-branded
22 product allegedly used by plaintiff or about plaintiff's alleged use of such product and therefore
23 denies the allegations in paragraph 206.

24 207. Monsanto denies that there is any risk of serious injury associated with or linked
25 to the as-directed use of and/or exposure to Roundup<sup>®</sup>-branded products and/or glyphosate.
26 Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the

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1	allegations in paragraph 207 concerning plaintiff's knowledge about Roundup <sup>®</sup> -branded
2	products and therefore denies the remaining allegations in paragraph 206.
3	208. Monsanto denies the allegations in paragraph 208.
4	209. Monsanto denies the allegations in paragraph 209.
5	210. Monsanto denies the allegations in paragraph 210.
6	In response to the "WHEREFORE" paragraph following paragraph 210, Monsanto
7	demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be
8	dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's
9	fees as allowed by law and such further and additional relief as this Court may deem just and
10	proper.
11	In response to the allegations in the section entitled "PRAYER FOR RELIEF," Monsanto
12	denies that plaintiff is entitled to the relief sought therein, including any judgment for any
13	damages, interest, costs, or any other relief whatsoever.
14	Every allegation in the Complaint that is not specifically and expressly admitted in this
15	Answer is hereby specifically and expressly denied.
16	SEPARATE AND AFFIRMATIVE DEFENSES
17	1. The Complaint, in whole or part, fails to state a claim or cause of action against
18	Monsanto upon which relief can be granted.
19	2. Plaintiff's claims are barred in whole because plaintiff cannot proffer any
20	scientifically reliable evidence that the products at issue were defective or unreasonably
21	dangerous.
22	3. Any alleged negligent or culpable conduct of Monsanto, none being admitted,
23	was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of
24	plaintiff's alleged injuries.
25	4. Plaintiff's claims are barred, in whole or in part, because the products at issue
26	were designed, manufactured, marketed and labeled with proper warnings, information, cautions
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	MONSANTO COMPANY'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT 3:16-md-02741-VC & 3:17-cv-05686-VC

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and instructions, in accordance with the state of the art and the state of scientific and
 technological knowledge.

5. Plaintiff's claims are barred, in whole or in part, because the products at issue
were not defective or unreasonably dangerous in that they complied with, at all relevant times,
all applicable government safety standards.

6 6. Plaintiff's claims are preempted, in whole or in part, by applicable federal law
7 relating to the design, testing, producing, manufacturing, labeling, distributing, modeling,
8 processing, and supply of Roundup<sup>®</sup>-branded products and/or glyphosate-containing products.

9 7. Plaintiff's claims are preempted, in whole or in part, because of U.S. EPA
10 findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved
11 product labeling.

- 12 8. Plaintiff's claims are barred, in whole or in part, by the doctrine of primary
  13 jurisdiction, including by the authority delegated by Congress to the U.S. EPA.
- 9. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if
  any, were the result of conduct of plaintiff, independent third parties, and/or events that were
  extraordinary under the circumstances, not foreseeable in the normal course of events, and/or
  independent, intervening and superseding causes of the alleged injuries, including but not limited
  to plaintiff's pre-existing medical conditions.
- 19 10. The doctrines contained in Restatement (Second) of Torts § 402A, comments j
  20 and k, bar plaintiff's claims against Monsanto in whole or in part.
- 21 11. Applicable statutes of limitations, prescriptive periods, and/or repose bar
  22 plaintiff's claims in whole or in part.
- 23 12. Plaintiff's misuse or abnormal use of the product or failure to follow instructions
  24 bar plaintiff's claims in whole or in part.
- 13. If plaintiff suffered injury or damages as alleged, which is denied, such injury or
  damage resulted from: (a) acts or omissions of persons or entities for which Monsanto is neither
  liable nor responsible or, in the alternative, Monsanto is entitled to an assessment of the relative
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degree of fault of all such persons and entities; or (b) resulted from diseases and/or causes that
 are not related or connected with any product sold, distributed, or manufactured by Monsanto.
 Such acts or omissions on the part of others or diseases or causes constitute an independent,
 intervening and sole proximate cause of plaintiff's alleged injury or damages.
 14. Monsanto had no legal relationship or privity with plaintiff and owed no duty to

6 her by which liability could be attributed to it.

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7 15. Monsanto made no warranties of any kind or any representations of any nature
8 whatsoever to plaintiff. If any such warranties were made, which Monsanto specifically denies,
9 then plaintiff failed to give notice of any breach thereof.

10 16. Plaintiff's claims are preempted in whole or part by the Freedom of Speech
11 Clause of the First Amendment of the U.S. Constitution.

12 17. Plaintiff's claims for punitive and/or exemplary damages are barred because such
13 an award would violate Monsanto's due process, equal protection and other rights under the
14 United States Constitution, the Louisiana Constitution, and/or other applicable state
15 constitutions.

16 18. Plaintiff's claims for punitive and/or exemplary damages are barred because
17 plaintiff has failed to allege conduct warranting imposition of such damages under Louisiana law
18 and/or other applicable state laws.

19 19. Plaintiff's claims for punitive and/or exemplary damages are barred and/or limited
20 by operation of state and/or federal law, including La. R.S. 9:2800.52, *et seq*.

21 20. Plaintiff's claims are barred in whole or in part by plaintiff's own
22 contributory/comparative negligence.

23 21. Plaintiff's claims are barred in whole or in part by plaintiff's own failure to
24 mitigate damages.

22. Plaintiff's claims are barred in whole or in part by the sophisticated user doctrine.

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1	23. To the extent that plaintiff recovered payments for her alleged injuries from any		
2	collateral source(s) or other source(s), plaintiff's recovery in this lawsuit, if any, shall be reduced		
3	to the extent allowed by applicable law.		
4	24. If plaintiff has been injured or damaged, no injury or damages being admitted,		
5	such injuries were not caused by a Monsanto product.		
6	25. Plaintiff's claims are barred or limited to the extent that plaintiff asserts claims		
7	that are governed by the laws of a state that does not recognize or limit such claims.		
8	26. Plaintiff's common law claims are barred, in whole or in part, under the Louisiana		
9	Products Liability Act ("LPLA"), La. Rev. Stat. Ann § 9:2800.51 et seq.		
10	27. Monsanto hereby gives notice that it intends to rely upon such other defenses as		
11	may become available or apparent during the course of discovery and thus reserves its right to		
12	amend this Answer to assert such defenses.		
13	WHEREFORE, Defendant Monsanto demands judgment in its favor and against		
14	plaintiff, dismissing plaintiff's Complaint with prejudice, together with the costs of suit and such		
15	other relief as the Court deems equitable and just.		
16	JURY TRIAL DEMAND		
17	Monsanto demands a jury trial on all issues so triable.		
18			
19	DATED: November 6, 2017 Respectfully submitted,		
20	/s/ Joe G. Hollingsworth		
21	Joe G. Hollingsworth ( <i>pro hac vice</i> ) (jhollingsworth@hollingsworthllp.com)		
22	Eric G. Lasker ( <i>pro hac vice</i> ) (elasker@hollingsworthllp.com)		
23	HOLLINGSWORTH LLP 1350 I Street, N.W.		
24	Washington, DC 20005 Telephone: (202) 898-5800		
25	Facsimile: (202) 682-1639		
26	Attorneys for Defendant MONSANTO COMPANY		
27			
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