

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
Case No. 3:16-md-02741-VC

This document relates to:

Tara L. DiVittorio v. Monsanto Co.,
Case No. 3:17-cv-05176-VC

MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Monsanto Company (“Monsanto”), by and through its counsel, respectfully responds by generally denying all allegations contained in plaintiff Tara L. DiVittorio’s Complaint and Jury Demand (“the Complaint”), except as set forth below. As defined in the Complaint and as used in this Answer, Monsanto refers to Monsanto Company, a United States based company incorporated in Delaware, and not to other Monsanto-affiliated companies. Silence as to any allegations shall constitute a denial.

1. Monsanto admits the allegations in the first and second sentences of paragraph 1. Monsanto also admits that glyphosate was one of the world’s most widely used herbicides in 2013, but notes that Monsanto was and is not the only manufacturer of glyphosate-based herbicides. Monsanto lacks information or knowledge sufficient to form a belief as to the

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
9 of seeds that contain the Roundup Ready[®] trait and that use of crops with the Roundup Ready[®]
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.

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
9 glyphosate or Roundup[®]-branded herbicides in any manner different or in addition to such
10 regulatory approval, Monsanto denies such allegations.

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

16 10. Monsanto lacks information or knowledge sufficient to form a belief as to the
17 truth of the allegations in paragraph 10 that plaintiff’s decedent Dan J. DiVittorio, Jr., purchased
18 Roundup[®]-branded products and therefore denies those allegations. The remaining allegations in
19 paragraph 10 set forth conclusions of law for which no response is required.

20 11. The allegations in paragraph 11 set forth conclusions of law for which no
21 response is required.

22 12. Monsanto denies the allegations in the first sentence of paragraph 12. The
23 remaining allegations in paragraph 12 set forth conclusions of law for which no response is
24 required.

25 13. Monsanto denies that exposure to Roundup[®]-branded products did or could have
26 caused plaintiff’s decedent’s alleged non-Hodgkin’s lymphoma (“NHL”). Monsanto lacks
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1 information or knowledge sufficient to form a belief as to the truth of the remaining allegations
2 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[®]-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. Monsanto admits that glyphosate is an herbicide that is used to kill invasive plants
10 and weeds. Monsanto states that the remaining allegations in paragraph 16 are vague and
11 ambiguous and that it lacks information or knowledge sufficient to form a belief as to the truth of
12 the remaining allegations in paragraph 16 and therefore denies those allegations.

13 17. Monsanto admits the allegations in the first sentence of paragraph 17. Monsanto
14 denies the allegations in the second sentence of paragraph 17 because the impact of glyphosate
15 on treated plants varies depending upon the amount of glyphosate applied and the type of plant.
16 Monsanto denies the allegations in the third sentence of paragraph 17 to the extent that they
17 suggest that glyphosate is present in any plants at anything other than *de minimis* amounts well
18 within regulatory safety levels, as determined by EPA.

19 18. In response to the allegations in paragraph 18, Monsanto admits that farmers have
20 safely used Roundup[®]-branded products since the 1970s. Monsanto denies the remaining
21 allegations in paragraph 18.

22 19. Monsanto admits the allegations in the first two sentences of paragraph 19 and
23 admits that it has marketed Roundup[®]-branded products in accord with EPA's regulatory
24 determinations under FIFRA. Monsanto otherwise denies the remaining allegations in paragraph
25 19.

1 20. The allegations in paragraph 20 set forth conclusions of law for which no
2 response is required. To the extent that a response is deemed required, Monsanto admits the
3 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[®]-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”¹; 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.”² 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
 21 shows evidence of non-carcinogenicity for humans—based on the lack of
 22 convincing evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate*:

23 ¹ EPA’s Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic*
 24 *Potential* at 141 (Sept. 12, 2016) (“EPA OPP Report”), [https://www.regulations.gov/](https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094)
 25 [document?D=EPA-HQ-OPP-2016-0385-0094](https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094). The EPA OPP Report was prepared in
 anticipation of an EPA Scientific Advisory Panel meeting on glyphosate’s carcinogenic
 potential.

26 ² Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs,
 27 U.S. Environmental Protection Agency, *Cancer Assessment Document – Evaluation of the*
Carcinogenic Potential of Glyphosate at 10, 77 (Final Report, Oct. 1, 2015) (“EPA CARC Final
 Report”), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

1 *Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993),
2 <http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.

- 3 • “No evidence of carcinogenicity.” Glyphosate; Pesticide Tolerances, 67 Fed.
4 Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- 5 • “Glyphosate has no carcinogenic potential.” Glyphosate; Pesticide Tolerance, 69
6 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- 7 • “There is [an] extensive database available on glyphosate, which indicate[s] that
8 glyphosate is not mutagenic, not a carcinogen, and not a developmental or
9 reproductive toxicant.” Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586,
10 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).
- 11 • “EPA has concluded that glyphosate does not pose a cancer risk to humans.” 78
12 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
- 13 • “In 2014, EPA reviewed over 55 epidemiological studies conducted on the
14 possible cancer and non-cancer effects of [g]lyphosate. Our review concluded
15 that this body of research does not provide evidence to show that [g]lyphosate
16 causes cancer and does not warrant any change in the EPA’s cancer classification
17 for [g]lyphosate.” *Agriculture Biotechnology: A Look at Federal Regulation and
18 Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, &
19 Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director
20 of EPA’s Office of Pesticide Programs),
21 [http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-
22 0e55900753b4](http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4), at time stamp 55:05-56:20.

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[®]-branded product. Monsanto denies that EPA’s regulatory approval of such product is
27 based upon any fraudulent or false IBT studies.

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

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

11 36. In response to the allegations in paragraph 36, Monsanto admits that glyphosate is
12 one of the world's largest herbicides by sales volume, but Monsanto denies any suggestion that it
13 is the only company that sells glyphosate or glyphosate-based herbicides. Monsanto lacks
14 information or knowledge sufficient to form a belief as to the accuracy of the specific numbers
15 cited in paragraph 36 and accordingly denies the same. The remaining allegations in paragraph
16 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[®]-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.

25 38. In response to the allegations in paragraph 38, Monsanto admits it entered into an
26 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.

3 39. Monsanto denies the allegations in paragraph 39.

4 40. In response to the allegations in paragraph 40, Monsanto admits that the French
5 court ruled that Monsanto had falsely advertised its herbicide Roundup[®] as “biodegradable” and
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.

1 45. Monsanto denies the allegations in paragraph 45 to the extent that they suggest
2 that IARC had previously assessed glyphosate. Monsanto admits that IARC classified
3 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.

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

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1 49. In response to the allegations in paragraph 49, to the extent the allegations purport
2 to characterize statements made in the IARC monograph for glyphosate, the statements in that
3 document speak for themselves, but to the extent that this paragraph means that more than *de*
4 *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.

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

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1 55. In response to the allegations in paragraph 55, Monsanto admits that the IARC
2 working group interpreted a selected number of experimental studies as evidence that glyphosate
3 can cause genotoxicity, but Monsanto denies that the working group reliably considered the full
4 body of scientific data on such alleged genotoxic endpoints and denies that the working group
5 reliably interpreted the studies that it selected for consideration. Regulators around the world
6 repeatedly have concluded that glyphosate is not genotoxic. Monsanto denies the remaining
7 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.

11 57. In response to the allegations in paragraph 57, Monsanto admits that the working
12 group reviewed the findings of an Agricultural Health Study (“AHS”) published in 2005, but
13 denies that the working group characterized that study as supporting an association between
14 glyphosate and the specified cancers. The AHS cohort study did not find a positive association
15 between glyphosate and any type of cancer. Monsanto denies all other allegations in paragraph
16 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.

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

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1 60. Monsanto states that the term “toxic” as used in paragraph 60 is vague and
2 ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto
3 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.

8 62. In response to the allegations in the first sentence of paragraph 62, Monsanto
9 admits that Julie Marc published a study titled “Glyphosate-based pesticides affect cell cycle
10 regulation” in 2004. To the extent that the first sentence of paragraph 62 characterizes the
11 meaning of the cited study, Monsanto denies the allegations in the first sentence of paragraph 62.
12 In response to the remaining allegations in paragraph 62, Monsanto states that the document
13 speaks for itself and does not require a response. To the extent that a response is deemed
14 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[®]-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.

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

11 68. In response to the allegations in paragraph 68, Monsanto admits that following the
12 IARC working group classification, in France, all non-professional plant protection products,
13 including but not limited to glyphosate-based products, will be sold behind locked counters (no
14 free sales). Monsanto further admits that the French government has announced that, beginning
15 on January 1, 2019, the sale of non-professional lawn and garden products, including but not
16 limited to non-professional use glyphosate-based products, will be prohibited with certain
17 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.

23 70. In response to the allegations in paragraph 70, Monsanto admits that the IARC
24 monograph appears to be the alleged basis for the Sri Lankan government’s actions, including
25 the allegation that glyphosate can cause kidney disease. Monsanto further states that the
26 allegations regarding kidney disease found in Sri Lanka are unrelated to plaintiff’s allegations
27 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
19 pose a cancer hazard to humans."³ Monsanto contends that OEHHA's decision that it was
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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27 ³ OEHHA, *Public Health Goal for Glyphosate in Drinking Water* (June 2007),
https://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907_0.pdf.

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

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

6 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.”⁶ 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.

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

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

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27 ⁶ EFSA, *EFSA Explains Risk Assessment Glyphosate*, http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf.

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

7 84. In response to the allegations in paragraph 84, Monsanto admits that Dr. Portier
8 sent the letter identified in paragraph 84. Monsanto denies that Dr. Portier or the other
9 signatories to his letter are “renowned international experts in the field.” Monsanto admits that
10 certain members of the IARC working group assigned to glyphosate signed on to the Portier
11 letter, but states that Monsanto lacks information or knowledge sufficient to form a belief as to
12 whether those individuals or the other signatories were aware at the time that Dr. Portier was
13 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
19 carcinogenic hazard to humans.”⁷ To the extent that paragraph 85 characterizes the meaning of
20 the cited document or of EFSA’s evaluation of glyphosate, Monsanto denies the remaining
21 allegations in paragraph 85.

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

26 ⁷ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

27 ⁸ <http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php>.

1 been disclosed as an expert witness retained by plaintiffs’ counsel in the glyphosate cancer
2 litigation against Monsanto – seeks in his letter to challenge the scientific conclusions reached by
3 EFSA in support of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to
4 humans.”⁹ In response to the remaining allegations in paragraph 86, Monsanto states that the
5 cited Portier letter speaks for itself and does not require a response. To the extent that paragraph
6 86 characterizes the meaning of the cited document or of EFSA’s evaluation of glyphosate,
7 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
13 carcinogenic hazard to humans.”¹⁰ To the extent that paragraph 87 characterizes the meaning of
14 the cited document or of EFSA’s and BfR’s evaluation of glyphosate, Monsanto denies the
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
21 carcinogenic hazard to humans.”¹¹ To the extent that paragraph 88 characterizes the meaning of
22 the cited document or of EFSA’s and BfR’s evaluation of glyphosate, Monsanto denies the
23 remaining allegations in paragraph 88.

24 ⁹ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

25 ¹⁰ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

26 ¹¹ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

1 89. Monsanto admits the allegations in paragraph 89.

2 90. In response to the allegations in paragraph 90, Monsanto states that the cited
3 document speaks for itself and does not require a response. Monsanto denies that the self-
4 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
5 extent that paragraph 90 characterizes the scientific evidence regarding the safety of glyphosate-
6 based herbicides, Monsanto denies the remaining allegations in paragraph 90.

7 91. In response to the allegations in paragraph 91, Monsanto states that the cited
8 document speaks for itself and does not require a response. Monsanto denies that the self-
9 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
10 extent that paragraph 91 characterizes the scientific evidence regarding the safety of glyphosate-
11 based herbicides, Monsanto denies the remaining allegations in paragraph 91.

12 92. In response to the allegations in paragraph 92, Monsanto states that the cited
13 document speaks for itself and does not require a response. Monsanto denies that the self-
14 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
15 extent that paragraph 92 characterizes the scientific evidence regarding the safety of glyphosate-
16 based 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 self-
19 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 glyphosate-
21 based herbicides, Monsanto denies the remaining allegations in paragraph 93.

22 94. In response to the allegations in paragraph 94, Monsanto states that the cited
23 document speaks for itself and does not require a response. Monsanto denies that the self-
24 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
25 extent that paragraph 94 characterizes the scientific evidence regarding the safety of glyphosate-
26 based herbicides, Monsanto denies the remaining allegations in paragraph 94.

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1 95. In response to the allegations in paragraph 95, Monsanto states that the cited
2 document speaks for itself and does not require a response. Monsanto denies that the self-
3 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
4 extent that paragraph 95 characterizes the scientific evidence regarding the safety of glyphosate-
5 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 self-
8 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 glyphosate-
10 based herbicides, Monsanto denies the remaining allegations in paragraph 96.

11 97. In response to the allegations in paragraph 97, Monsanto admits that the United
12 States Food and Drug Administration (“FDA”) has authority to enforce pesticide residues and
13 that the FDA announced it would begin testing certain foods for glyphosate residues. In
14 response to the remaining allegations in paragraph 97, Monsanto states that the cited documents
15 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.

23 99. In response to the allegations in paragraph 99, Monsanto admits that the FDA has
24 authority to enforce pesticide residues and that the FDA announced it would begin testing certain
25 foods for glyphosate residues. In response to the remaining allegations in paragraph 99,
26 Monsanto states that the cited documents speak for themselves and do not require a response. To
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1 the extent that paragraph 99 characterizes the meaning of the cited documents, Monsanto denies
2 the remaining allegations in paragraph 99.

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

9 101. 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.

24 106. Monsanto admits the allegations in paragraph 106.

25 107. Monsanto admits the allegations in paragraph 107.

26 108. Monsanto admits the allegations in paragraph 108.

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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 denies the allegations in paragraph 113.

13 114. Monsanto denies that any exposure to Roundup[®]-branded products can cause non-
14 Hodgkin’s lymphoma and other serious illnesses and therefore denies the allegations in
15 paragraph 114. Monsanto states, however, that the scientific studies upon which IARC
16 purported to base its evaluation of glyphosate were all publicly available before March 2015.

17 115. Monsanto denies that any exposure to Roundup[®]-branded products can cause
18 NHL and other serious illnesses and therefore denies the allegations in paragraph 115. Monsanto
19 states, however, that the scientific studies upon which IARC purported to base its evaluation of
20 glyphosate were all publicly available before March 2015.

21 116. In response to the allegations in paragraph 116, Monsanto denies that there is any
22 risk of serious illness associated with the use of and/or exposure to Roundup[®]-branded products
23 and glyphosate and denies that Roundup[®]-branded products or glyphosate are injurious to human
24 health. Monsanto states, however, that the scientific studies upon which IARC purported to base
25 its classification were all publicly available before March 2015. The final sentence of paragraph
26 116 sets forth a conclusion of law for which no response is required.

1 117. In response to the allegations in paragraph 117, Monsanto denies that exposure to
2 Roundup[®]-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.

6 118. In response to the allegations in paragraph 118, Monsanto denies that there is any
7 risk of NHL or other serious illness associated with the use of and/or exposure to Roundup[®]-
8 branded products and glyphosate. Monsanto states, however, that the scientific studies upon
9 which IARC purported to base its cancer classification for glyphosate were all publicly available
10 before March 2015. Monsanto lacks information or knowledge sufficient to form a belief as to
11 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.

20 121. Monsanto denies the allegations in paragraph 121.

21 122. The allegations in paragraph 122 set forth conclusions of law for which no
22 response is required.

23 123. Monsanto denies the allegations in paragraph 123.

24 124. The allegations in paragraph 124 set forth conclusions of law for which no
25 response is required. To the extent that a response is required, Monsanto denies the allegations
26 in paragraph 124. Monsanto states that the scientific studies upon which IARC purported to base
27 its cancer classification for glyphosate were all publicly available before March 2015.

1 125. Monsanto incorporates by reference its responses to paragraphs 1 through 124 in
2 response to paragraph 125 of plaintiff’s Complaint.

3 126. In response to the allegations in paragraph 126, Monsanto admits that plaintiff
4 purports to bring claims for strict liability but denies any liability to plaintiff.

5 127. In response to the allegations in paragraph 127, Monsanto lacks information or
6 knowledge sufficient to form a belief as to the truth of the allegation that plaintiff and/or
7 plaintiff’s decedent used Roundup®-branded products and therefore denies those allegations.
8 Monsanto denies the remaining allegations in paragraph 127.

9 128. In response to the allegations in paragraph 128, Monsanto lacks information or
10 knowledge sufficient to form a belief as to the truth of the allegations that plaintiff and/or
11 plaintiff’s decedent used or was exposed to Roundup®-branded products and therefore denies
12 those allegations. Monsanto denies the remaining allegations in paragraph 128.

13 129. Monsanto denies the allegations in paragraph 129.

14 130. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations in paragraph 130 and therefore denies those allegations.

16 131. Monsanto denies the allegations in paragraph 131.

17 132. Monsanto denies the allegations in paragraph 132.

18 133. Monsanto denies the allegations in paragraph 133 and each of its subparts.

19 134. Monsanto lacks information or knowledge sufficient to form a belief as to the
20 truth of the allegations in paragraph 134 concerning plaintiff and/or plaintiff’s decedent’s
21 claimed use of or exposure to Roundup®-branded products and therefore denies those
22 allegations. Monsanto denies the remaining allegations in paragraph 134, including that
23 Roundup®-branded products have “dangerous characteristics.”

24 135. Monsanto denies the allegations in paragraph 135.

25 136. Monsanto denies the allegations in paragraph 136.

26 137. Monsanto denies the allegations in paragraph 137.

27 138. Monsanto denies the allegations in paragraph 138.

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1 139. Monsanto denies the allegations in paragraph 139.

2 140. Monsanto denies the allegations in paragraph 140.

3 141. Monsanto denies the allegations in paragraph 141.

4 In response to the “WHEREFORE” paragraph following paragraph 141, Monsanto
5 demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be
6 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
7 fees as allowed by law and such further and additional relief as this Court may deem just and
8 proper.

9 142. Monsanto incorporates by reference its responses to paragraphs 1 through 141 in
10 response to paragraph 142 of plaintiff’s Complaint.

11 143. In response to the allegations in paragraph 143, Monsanto admits that plaintiff
12 purports to bring claims for strict liability failure to warn, but denies any liability to plaintiff.

13 144. Monsanto denies the allegations in paragraph 144.

14 145. In response to the allegations in paragraph 145, Monsanto lacks information or
15 knowledge sufficient to form a belief as to the truth of the allegations in paragraph 145 that
16 plaintiff’s decedent or other persons or entities purchased Roundup[®]-branded products and
17 therefore denies those allegations. The allegations in paragraph 145 also set forth conclusions of
18 law for which no response is required. Monsanto denies the remaining allegations in paragraph
19 145.

20 146. The allegations in paragraph 146 set forth conclusions of law for which no
21 response is required.

22 147. Monsanto denies the allegations in paragraph 147. All labeling of Roundup[®]-
23 branded products has been and remains EPA-approved and in compliance with all federal
24 requirements under FIFRA.

25 148. Monsanto denies the allegations in paragraph 148.

26 149. Monsanto denies the allegations in paragraph 149.

27 150. Monsanto denies the allegations in paragraph 150.

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1 162. Monsanto incorporates by reference its responses to paragraphs 1 through 161 in
2 response to paragraph 162 of plaintiff’s Complaint.

3 163. In response to the allegations in paragraph 163, Monsanto states that the phrase
4 “directly or indirectly” is vague and ambiguous and that Monsanto lacks information or
5 knowledge sufficient to form a belief as to the truth of those allegations and therefore Monsanto
6 denies those allegations in paragraph 163.

7 164. Monsanto lacks information or knowledge sufficient to form a belief as to the
8 truth of the allegations in paragraph 164 and therefore denies those allegations.

9 165. The allegations in paragraph 165 set forth conclusions of law for which no
10 response is required.

11 166. The allegations in paragraph 166 set forth conclusions of law for which no
12 response is required.

13 167. Monsanto denies the allegations in paragraph 167.

14 168. Monsanto denies the allegations in paragraph 168.

15 169. Monsanto denies the allegations in paragraph 169.

16 170. Monsanto denies the allegations in paragraph 170.

17 171. Monsanto denies the allegations in paragraph 171. All labeling of Roundup[®]-
18 branded products has been and remains EPA-approved and in compliance with all federal
19 requirements under FIFRA.

20 172. Monsanto denies the allegations in paragraph 172.

21 173. Monsanto denies the allegations in paragraph 173.

22 174. Monsanto denies the allegations in paragraph 174.

23 175. Monsanto denies the allegations in paragraph 175, including each of its subparts.

24 176. Monsanto denies the allegations in paragraph 176.

25 177. Monsanto lacks information or knowledge sufficient to form a belief as to the
26 truth of the allegations in paragraph 177 regarding plaintiff’s decedent’s knowledge and
27 therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 177,
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1 including that intended use of and/or exposure to Roundup[®]-branded products causes any
2 injuries.

3 178. Monsanto denies the allegations in paragraph 178.

4 179. Monsanto denies the allegations in paragraph 179.

5 180. Monsanto denies the allegations in paragraph 180.

6 In response to the “WHEREFORE” paragraph following paragraph 180, 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.

11 181. Monsanto incorporates by reference its responses to paragraphs 1 through 180 in
12 response to paragraph 181 of plaintiff’s Complaint.

13 182. Monsanto denies the allegations in paragraph 182.

14 183. In response to the allegations in paragraph 183, Monsanto admits that it has sold
15 glyphosate-based herbicides in accordance with their EPA-approved labeling. Monsanto further
16 states that paragraph 183 sets forth conclusions of law for which no response is required.

17 Monsanto denies the remaining allegations in paragraph 183.

18 184. Monsanto denies the allegations in the first and second sentences of paragraph
19 184. All labeling of Roundup[®]-branded products has been and remains EPA-approved and in
20 compliance with all federal requirements under FIFRA. Monsanto states that the final sentence
21 of paragraph 184 sets forth conclusions of law for which no response is required.

22 185. Paragraph 185 sets forth conclusions of law for which no response is required.

23 186. Monsanto denies the allegations in paragraph 186.

24 187. Monsanto denies the allegations in paragraph 187 and each of its subparts.

25 188. The allegations in paragraph 188 set forth conclusions of law for which no
26 response is required.

1 189. Monsanto states that the allegation in paragraph 189 that Monsanto made an
2 express warranty sets forth a legal conclusion for which no response is required. Monsanto lacks
3 information or knowledge sufficient to form a belief as to the truth of the remaining allegations
4 in paragraph 189 and therefore denies those allegations.

5 190. Monsanto lacks information or knowledge sufficient to form a belief as to the
6 truth of the allegations in paragraph 190 and therefore denies those allegations.

7 191. Monsanto denies the allegations in paragraph 191.

8 192. Monsanto lacks information or knowledge sufficient to form a belief as to the
9 truth of the allegations in paragraph 192 regarding plaintiff's decedent's knowledge and
10 therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 192.

11 193. Monsanto lacks information or knowledge sufficient to form a belief as to the
12 truth of the allegations in paragraph 193 and therefore denies those allegations.

13 194. Monsanto denies the allegations in paragraph 194.

14 195. Monsanto denies the allegations in paragraph 195.

15 In response to the "WHEREFORE" paragraph following paragraph 195, Monsanto
16 demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be
17 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's
18 fees as allowed by law and such further and additional relief as this Court may deem just and
19 proper.

20 196. Monsanto incorporates by reference its responses to paragraphs 1 through 195 in
21 response to paragraph 196 of plaintiff's Complaint.

22 197. Monsanto denies the allegations in paragraph 197.

23 198. Monsanto denies the allegations in paragraph 198.

24 199. Monsanto lacks information or knowledge sufficient to form a belief as to the
25 truth of the allegations in paragraph 199 concerning plaintiff's decedent's claimed use of and
26 exposure to Roundup[®]-branded products and therefore denies those allegations. The remaining
27 allegations in paragraph 199 set forth conclusions of law for which no response is required.
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1 200. Monsanto denies the allegations in paragraph 200. All labeling of Roundup[®]-
2 branded products has been and remains EPA-approved and in compliance with all federal
3 requirements under FIFRA.

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

8 202. Monsanto lacks information or knowledge sufficient to form a belief as to the
9 truth of the allegations in paragraph 202 and therefore denies those allegations.

10 203. Monsanto lacks information or knowledge sufficient to form a belief as to the
11 truth of the allegations in paragraph 203 concerning plaintiff's decedent's claimed use of or
12 exposure to Roundup[®]-branded products and therefore denies those allegations. The remaining
13 allegations in paragraph 203 set forth conclusions of law for which no response is required.

14 204. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations in paragraph 204 concerning plaintiff's decedent's claimed use of or
16 exposure to Roundup[®]-branded products and therefore denies those allegations. Monsanto denies
17 the remaining allegations in paragraph 204.

18 205. Monsanto lacks information or knowledge sufficient to form a belief as to the
19 truth of the allegations in paragraph 205 concerning the condition of any Roundup[®]-branded
20 product allegedly used by plaintiff's decedent or about plaintiff's decedent's alleged use of such
21 product and therefore denies the allegations in paragraph 205.

22 206. Monsanto denies that there is any risk of serious injury associated with or linked
23 to the as-directed use of and/or exposure to Roundup[®]-branded products and/or glyphosate.
24 Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the
25 allegations in paragraph 206 concerning plaintiff's decedent's knowledge about Roundup[®]-
26 branded products and therefore denies the remaining allegations in paragraph 206.

27 207. Monsanto denies the allegations in paragraph 207.
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1 208. Monsanto denies the allegations in paragraph 208.

2 209. Monsanto denies the allegations in paragraph 209.

3 In response to the “WHEREFORE” paragraph following paragraph 209, Monsanto
4 demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be
5 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
6 fees as allowed by law and such further and additional relief as this Court may deem just and
7 proper.

8 210. Monsanto incorporates by reference its responses to paragraphs 1 through 209 in
9 response to paragraph 210 of plaintiff’s Complaint.

10 211. Monsanto denies the allegation in paragraph 211 that plaintiff’s decedent’s death
11 was “wrongful” and denies that any injuries alleged in the Complaint, including the injury and
12 death of plaintiff’s decedent, were caused by Roundup[®]-branded products. Monsanto admits that
13 plaintiff purports to bring a wrongful death action but denies any liability on that claim. The
14 remaining allegations in paragraph 211 set forth conclusions of law for which no response is
15 required. To the extent a response is deemed required, Monsanto lacks information or
16 knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph
17 211 and therefore denies those allegations.

18 212. Monsanto denies the allegations in paragraph 212.

19 213. Monsanto denies the allegations in paragraph 213.

20 In response to the “WHEREFORE” paragraph following paragraph 213, Monsanto
21 demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be
22 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
23 fees as allowed by law and such further and additional relief as this Court may deem just and
24 proper.

25 214. Monsanto incorporates by reference its responses to paragraphs 1 through 213 in
26 response to paragraph 214 of plaintiff’s Complaint.

27 215. Monsanto admits that plaintiff purports to bring a survival action but denies any
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1 liability to said plaintiff. Monsanto denies the remaining allegations in paragraph 215.

2 216. Monsanto denies the allegations in paragraph 216.

3 217. Monsanto admits that plaintiff purports to bring a survival action but denies any
4 liability for that claim. Monsanto denies the remaining allegations in paragraph 217.

5 In response to the “WHEREFORE” paragraph following paragraph 217, Monsanto
6 demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be
7 dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s
8 fees as allowed by law and such further and additional relief as this Court may deem just and
9 proper.

10 In response to the allegations in the section entitled “PRAYER FOR RELIEF,” Monsanto
11 denies that plaintiff is entitled to the relief sought therein, including any judgment for any
12 damages, interest, costs, or any other relief whatsoever.

13 Every allegation in the Complaint that is not specifically and expressly admitted in this
14 Answer is hereby specifically and expressly denied.

15 **SEPARATE AND AFFIRMATIVE DEFENSES**

16 1. The Complaint, in whole or part, fails to state a claim or cause of action against
17 Monsanto upon which relief can be granted.

18 2. Plaintiff’s claims are barred in whole because plaintiff cannot proffer any
19 scientifically reliable evidence that the products at issue were defective or unreasonably
20 dangerous.

21 3. Any alleged negligent or culpable conduct of Monsanto, none being admitted,
22 was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of
23 plaintiff’s and/or plaintiff’s decedent’s alleged injuries.

24 4. Plaintiff’s claims are barred, in whole or in part, because the products at issue
25 were designed, manufactured, marketed and labeled with proper warnings, information, cautions
26 and instructions, in accordance with the state of the art and the state of scientific and
27 technological knowledge.

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

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

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

10 8. Plaintiff's claims are barred, in whole or in part, by the doctrine of primary
11 jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

12 9. Plaintiff's claims are barred, in whole or in part, because plaintiff's and/or
13 plaintiff's decedent's injuries, if any, were the result of conduct of plaintiff's decedent,
14 independent third parties, and/or events that were extraordinary under the circumstances, not
15 foreseeable in the normal course of events, and/or independent, intervening and superseding
16 causes of the alleged injuries, including but not limited to plaintiff's decedent's pre-existing
17 medical conditions.

18 10. The doctrines contained in Restatement (Second) of Torts § 402A, comments j
19 and k, bar plaintiff's claims against Monsanto in whole or in part.

20 11. Applicable statutes of limitations, prescriptive periods, and/or repose bar
21 plaintiff's claims in whole or in part.

22 12. Plaintiff's decedent's misuse or abnormal use of the product or failure to follow
23 instructions bar plaintiff's claims in whole or in part.

24 13. If plaintiff and/or plaintiff's decedent suffered injury or damages as alleged,
25 which is denied, such injury or damage resulted from: (a) acts or omissions of persons or entities
26 for which Monsanto is neither liable nor responsible or, in the alternative, Monsanto is entitled to
27 an assessment of the relative degree of fault of all such persons and entities; or (b) resulted from
28

1 diseases and/or causes that are not related or connected with any product sold, distributed, or
2 manufactured by Monsanto. Such acts or omissions on the part of others or diseases or causes
3 constitute an independent, intervening and sole proximate cause of plaintiff's and/or plaintiff's
4 decedent's alleged injury or damages.

5 14. Monsanto had no legal relationship or privity with plaintiff and/or plaintiff's
6 decedent and owed no duty to them by which liability could be attributed to it.

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

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

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

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

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

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

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

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

