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 11 **MONSANTO COMPANY**

12 UNITED STATES DISTRICT COURT
 13 NORTHERN DISTRICT OF CALIFORNIA

14 IN RE: ROUNDUP PRODUCTS
 15 LIABILITY LITIGATION

16 MDL No. 2741
 17 Case No. 3:16-md-02741-VC

18 This document relates to:
 19 *Bennierita Smith, et al. v. Monsanto Co.*,
 20 Case No. 3:17-cv-01129-VC

21 **MONSANTO COMPANY’S ANSWER TO PLAINTIFFS’ COMPLAINT**

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

1. Monsanto admits the allegations in the first sentence of paragraph 1. In response
 to the allegations in the second sentence of paragraph 1, Monsanto admits that glyphosate, the
 active ingredient in Roundup®-branded herbicides, is a non-selective herbicide and that certain
 Roundup®-branded herbicides are used to kill weeds that commonly compete with growing
 crops. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of

1 the specific numbers and statistics cited in the remaining sentences of paragraph 1 and therefore
2 denies those allegations.

3 2. Monsanto lacks information or knowledge sufficient to form a belief as to the
4 truth of the allegations asserted in the first sentence of paragraph 2 and therefore denies those
5 allegations. In response to the allegations in second sentence of paragraph 2, Monsanto admits
6 that Roundup[®]-branded products are safe when used in accordance with the products' labeling;
7 that glyphosate repeatedly has been found to be safe to humans and the environment by
8 regulators in the United States and around the world; and that Monsanto has labeled glyphosate
9 products as approved by regulatory bodies consistent with those findings. To the extent that the
10 second sentence of paragraph 2 alleges that Monsanto has labeled glyphosate or Roundup[®]-
11 branded herbicides in any manner different or in addition to such regulatory approval, Monsanto
12 denies such allegations. Monsanto denies the remaining allegations in paragraph 2.

13 3. Monsanto lacks information or knowledge sufficient to form a belief as to the
14 truth of the allegations asserted in paragraph 3 and therefore denies those allegations.

15 4. In response to the allegations in paragraph 4, Monsanto admits that the World
16 Health Organization's International Agency for Research on Cancer ("IARC") issued a
17 monograph relating to glyphosate in 2015 and that an IARC working group classified glyphosate
18 under Group 2A, but denies that the IARC Monograph is the authoritative standard for cancer
19 hazard assessment around the world or that IARC based its evaluation on a complete or accurate
20 assessment of the scientific research regarding glyphosate. Monsanto further denies that the
21 members of the panel were "renowned scientists" or that they were free from conflicts of
22 interest. Monsanto denies the remaining allegations in paragraph 4.

23 5. In response to the allegations in the first sentence of paragraph 5, Monsanto
24 admits that it has stated, and continues to state, that Roundup[®]-branded products are safe when
25 used in accordance with the products' labeling. Monsanto denies that any exposure to
26 glyphosate-based herbicides or Roundup[®]-branded products can cause cancer or other serious
27 illnesses. Monsanto denies the remaining allegations in paragraph 5.

28 6. Monsanto lacks information or knowledge sufficient to form a belief as to the

1 truth of the allegations asserted in paragraph 6 and therefore denies those allegations.

2 7. Monsanto admits the allegations in the first and second sentences of paragraph 7.
3 In response to the allegations in the final sentence of paragraph 7, Monsanto admits that it
4 discovered the herbicidal properties of glyphosate. Monsanto lacks information or knowledge
5 sufficient to form a belief as to the truth of the remaining allegations in the final sentence of
6 paragraph 7 and therefore denies those allegations.

7 8. The allegations in paragraph 8 set forth conclusions of law for which no response
8 is required. To the extent that a response is deemed required, Monsanto admits the allegations in
9 paragraph 8.

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

12 10. Monsanto denies the allegations in paragraph 10.

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

15 12. Monsanto admits that glyphosate is a non-selective herbicide and is the active
16 ingredient in various herbicides, including Roundup[®]-branded products.

17 13. Monsanto admits the allegations in the first sentence of paragraph 13. Monsanto
18 denies the allegations in the second sentence of paragraph 13 because the impact of glyphosate
19 on treated plants varies depending upon the amount of glyphosate applied and the type of plant.
20 Monsanto denies the allegations in the final sentence of paragraph 13 to the extent that they
21 suggest that glyphosate is present in any plants at anything other than *de minimis* amounts well
22 within regulatory safety levels, as determined by the United States Environmental Protection
23 Agency (“EPA”).

24 14. Monsanto admits the allegations in paragraph 14.

25 15. Monsanto denies the allegations in paragraph 15.

26 16. Monsanto denies the allegations in paragraph 16.

27 17. The allegations in paragraph 17 set forth conclusions of law for which no
28 response is required. To the extent that a response is deemed required, Monsanto admits the

1 allegations in paragraph 17.

2 18. In response to the allegations in paragraph 18, Monsanto admits that EPA requires
3 registrants of herbicides to submit extensive data in support of the human health and
4 environmental safety of their products and further admits that EPA will not register or approve
5 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. The remaining
6 allegations in paragraph 18 set forth conclusions of law for which no response is required.

7 19. The allegations in paragraph 19 set forth conclusions of law for which no
8 response is required.

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

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

23 22. In response to the allegations in paragraph 22, Monsanto admits that EPA has
24 undertaken a regulatory review of glyphosate and further admits that that EPA has not released
25 its findings. Monsanto states, however, that: (a) in September 2016, EPA’s Office of Pesticide
26 Programs (“OPP”) issued a 227-page evaluation of glyphosate’s carcinogenic potential,
27 concluding that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to
28

1 humans’ at doses relevant to human health risk assessment”¹; and (b) at the same time, EPA
 2 posted an October 2015 final report by its standing Cancer Assessment Review Committee
 3 (“CARC”), in which CARC endorsed EPA’s existing classification of glyphosate as “Not Likely
 4 to be Carcinogenic to Humans.”² In addition to the conclusions in the EPA OPP Report and the
 5 EPA CARC final Report, other specific findings of safety include:

- 6 • “In June 1991, EPA classified glyphosate as a Group E [carcinogen] — one that
 7 shows evidence of non-carcinogenicity for humans — based on the lack of
 8 convincing evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate:
 Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993),
<http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.
- 9 • “No evidence of carcinogenicity.” *Glyphosate; Pesticide Tolerances*, 67 Fed. Reg.
 10 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- 11 • “Glyphosate has no carcinogenic potential.” *Glyphosate; Pesticide Tolerance*, 69
 12 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- 13 • “There is [an] extensive database available on glyphosate, which indicate[s] that
 14 glyphosate is not mutagenic, not a carcinogen, and not a developmental or
 15 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).
- 16 • “EPA has concluded that glyphosate does not pose a cancer risk to humans.”
 17 *Glyphosate; Pesticide Tolerances*, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be
 codified at 40 C.F.R. pt. 180).
- 18 • “In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible
 19 cancer and non-cancer effects of [g]lyphosate. Our review concluded that this body
 20 of research does not provide evidence to show that [g]lyphosate causes cancer and
 21 does not warrant any change in EPA’s cancer classification for [g]lyphosate.”
*Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder
 22 Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, & Forestry*, 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->

23
 24 ¹ EPA’s Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (Sept.
 25 12, 2016) (“EPA OPP Report”), <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, U.S.
 27 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”),
 28 <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

1 [5056-a055-64af-0e55900753b4](#), at time stamp 55:05 – 56:20 (“EPA 2015 Desk
2 Statement”).

3 Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the
4 remaining allegations in paragraph 22 and therefore denies those allegations.

5 23. In response to the allegations in paragraph 23, Monsanto admits that EPA posted
6 the EPA CARC Final Report on EPA’s website in late April 2016 and took the report off the
7 website in early May 2016. Monsanto further states that, in September 2016, EPA posted the
8 EPA CARC Final Report that endorsed EPA’s existing classification of glyphosate as “Not
9 Likely to be Carcinogenic to Humans.” Monsanto lacks information or knowledge sufficient to
10 form a belief as to the truth of the remaining allegations in paragraph 23 and therefore denies
11 those allegations.

12 24. In response to the allegations in paragraph 24, Monsanto admits that an EPA
13 review committee classified glyphosate as Class C in 1985 based on limited data and that EPA
14 changed its classification of glyphosate to Group E based upon a full evaluation of the scientific
15 evidence, including but not limited to three animal carcinogenicity studies. Monsanto admits
16 that plaintiffs have accurately quoted from one passage in an EPA document in 1991 with
17 respect to the designation of an agent as Group E, but states that EPA repeatedly has concluded
18 that glyphosate does not pose any cancer risk to humans. Monsanto denies the remaining
19 allegations in paragraph 24.

20 25. In response to the allegations in paragraph 25, Monsanto admits that it – along
21 with a large number of other companies and governmental agencies – was defrauded by two
22 chemical testing laboratories, and that Monsanto had hired both of these laboratories to conduct
23 testing on glyphosate. Monsanto states that only one of these laboratories was hired to conduct
24 toxicity tests of glyphosate. Monsanto denies that EPA’s registration of glyphosate or any
25 glyphosate-based herbicides is based upon any invalid Industrial Bio-Test (“IBT”) Laboratories
26 studies. To the extent that the allegations in paragraph 25 are intended to suggest that Monsanto
27 was anything other than a victim of this fraud, such allegations are denied.

28

1 26. In response to the allegations in paragraph 26, Monsanto admits that IBT
2 Laboratories was hired to conduct toxicity studies in connection with the registration of a
3 Roundup[®]-branded product, but Monsanto denies the allegations to the extent they suggest that
4 EPA performed an inspection of IBT Laboratories solely or specifically in connection with
5 studies conducted on glyphosate. Monsanto admits that EPA performed an audit of IBT
6 Laboratories to investigate that laboratory's fraudulent and/or improper testing procedures in
7 connection with services provided to a broad number of private and governmental entities and
8 that this inspection included a review of studies IBT conducted on glyphosate. Monsanto was
9 one of several pesticide manufacturers who had used IBT test results. The audit found some
10 toxicology studies conducted with the original Roundup[®] herbicide to be invalid. As a result,
11 Monsanto repeated all required studies in accordance with applicable EPA testing guidelines.
12 Monsanto denies that EPA's registration of glyphosate or any glyphosate-based herbicides is
13 based upon any invalid IBT studies. To the extent that the allegations in paragraph 26 are
14 intended to suggest that Monsanto was anything other than a victim of this fraud, such
15 allegations also are denied.

16 27. In response to the allegations in paragraph 27, Monsanto admits that three IBT
17 employees were convicted of the charge of fraud, but Monsanto denies that any of the
18 individuals were convicted based upon studies conducted on glyphosate or glyphosate-based
19 herbicides.

20 28. In response to the allegations in paragraph 28, Monsanto admits that it – along
21 with numerous other private companies – hired Craven Laboratories as an independent
22 laboratory to conduct residue studies for Monsanto agricultural products. Monsanto further
23 admits that it was defrauded by Craven Laboratories and that, as a result, Monsanto repeated the
24 studies conducted at Craven Laboratories at a substantial cost. To the extent that the allegations
25 in paragraph 28 are intended to suggest that Monsanto was anything other than a victim of this
26 fraud, Monsanto denies those allegations.

27 29. In response to the allegations in paragraph 29, Monsanto admits that the New
28 York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading

1 advertising of Roundup[®]-branded products. This lawsuit was subsequently resolved without any
2 admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney
3 General's allegations related in any way to a purported or alleged risk of cancer. To the extent
4 the subparts purport to quote a document, the document speaks for itself and thus does not
5 require any further answer. The remaining allegations in paragraph 29 are vague and conclusory
6 and comprise attorney characterizations, and are accordingly denied.

7 30. In response to the allegations in paragraph 30, Monsanto admits it entered into an
8 assurance of discontinuance with the New York Attorney General. The assurance speaks for
9 itself and thus does not require any further answer. The remaining allegations in paragraph 30
10 are vague and conclusory and comprise attorney characterizations, and are accordingly denied.

11 31. Monsanto denies the allegations in paragraph 31.

12 32. Monsanto admits that IARC was created in 1965. The remaining allegations in
13 paragraph 32 are vague and conclusory and comprise attorney characterizations, and are
14 accordingly denied.

15 33. Monsanto denies the allegations in the first and second sentences of paragraph 33.
16 Monsanto admits the allegations in the final sentence of paragraph 33.

17 34. In response to the allegations in paragraph 34, Monsanto denies that IARC
18 follows stringent procedures for the evaluation of a chemical agent. Monsanto lacks information
19 or knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in
20 paragraph 34, which are not limited as of any specified date, and accordingly denies the same.

21 35. In response to the allegations in paragraph 35, Monsanto admits that IARC sets
22 forth in its Preamble the procedures that it claims to follow in its carcinogenicity evaluations.
23 Monsanto denies the remaining allegations in paragraph 35.

24 36. Monsanto denies any suggestion that IARC reviewed the full body of scientific
25 research in conducting its evaluation of glyphosate or that it reliably reviewed the studies that it
26 cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to form
27 a belief as to the truth of the remaining allegations in paragraph 36 and therefore denies those
28 allegations.

1 37. Monsanto denies any suggestion that IARC reviewed the full body of scientific
2 research in conducting its evaluation of glyphosate or that it reliably reviewed the studies that it
3 cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to form
4 a belief as to the truth of the remaining allegations in paragraph 37 and therefore denies those
5 allegations.

6 38. Monsanto denies the allegations in paragraph 38 to the extent that they suggest
7 that IARC had previously assessed glyphosate. Monsanto admits that IARC classified
8 glyphosate as a Group 2A agent in March 2015.

9 39. In response to the allegations in paragraph 39, Monsanto admits that IARC issued
10 its monograph for glyphosate, Monograph 112, on July 29, 2015 and that a draft of the
11 monograph was prepared by a “working group” of individuals selected by IARC who met over a
12 one week period in March 2015 to consider glyphosate along with a number of other substances.
13 Monsanto denies the allegation that all members of the working group are “experts.”

14 40. In response to the allegations in paragraph 40, Monsanto denies that the working
15 group or anyone at IARC conducted a one-year review of the scientific evidence related to
16 glyphosate or that the working group’s findings reflected a comprehensive review of the latest
17 available scientific evidence. Monsanto also denies that the working group considered all
18 information available in the scientific literature and all data from government reports that are
19 publicly available. Monsanto denies the remaining allegations in paragraph 40.

20 41. In response to the allegations in paragraph 41, Monsanto denies that the IARC
21 working group considered all of the data in the numerous studies that have been conducted
22 looking at the safety of glyphosate and glyphosate-containing herbicides in human populations or
23 that it reliably considered the studies that it purports to have reviewed, which frequently reach
24 conclusions directly contrary to those espoused by the IARC working group. To the extent the
25 allegations purport to characterize statements made in the IARC monograph for glyphosate, the
26 statements in that document speak for themselves, but Monsanto lacks information or knowledge
27 sufficient to form a belief as to the accuracy of the source of said information and accordingly
28 denies the allegations.

1 42. The allegations in paragraph 42 are vague and conclusory. To the extent they
2 purport to characterize statements made in the IARC monograph for glyphosate, the statements
3 in that document speak for themselves, but Monsanto lacks information or knowledge sufficient
4 to form a belief as to the accuracy of the source of said information and accordingly denies the
5 allegations.

6 43. In response to the allegations in paragraph 43, to the extent the allegations purport
7 to characterize statements made in the IARC monograph for glyphosate, the statements in that
8 document speak for themselves, but to the extent that this paragraph means that more than *de*
9 *minimis* amounts of exposure are present, the allegations in paragraph 43 are denied.

10 44. In response to the allegations in paragraph 44, Monsanto admits that the IARC
11 working group identified a number of case control studies of populations with exposures to
12 glyphosate, but Monsanto denies that any of these studies provide any evidence of a human
13 health concern from such exposures.

14 45. In response to the allegations in paragraph 45, 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 that
19 the allegations in paragraph 45 purport to characterize statements made in the IARC monograph
20 for glyphosate, the statements in that document speak for themselves.

21 46. In response to the allegations in paragraph 46, Monsanto admits that the IARC
22 working group identified a number of case control studies of populations with exposures to
23 glyphosate, but Monsanto denies that any of these studies provide any evidence of a human
24 health concern from such exposures. Monsanto denies the remaining allegations in paragraph
25 46. The IARC working group concluded that there was only limited evidence of carcinogenicity
26 in epidemiologic studies, which, per IARC's guidelines, means that the working group could not
27 rule out chance, bias or confounding so as to reach any conclusion of an increased risk.

28

1 47. In response to the allegations in paragraph 47, Monsanto admits that the IARC
2 working group purported to make these findings, but denies that the animal carcinogenicity
3 studies of glyphosate in the aggregate provide evidence of a positive trend for or increase in any
4 of the identified tumors. Monsanto further states that regulatory agencies around the world have
5 reviewed the same animal studies and concluded that they do not provide evidence that
6 glyphosate can cause cancer. Monsanto denies the remaining allegations in paragraph 47.

7 48. In response to the allegations in paragraph 48, Monsanto admits that the working
8 group cited to a study that it concluded provided evidence of chromosomal damage in
9 community residents reported to be exposed to glyphosate, but Monsanto denies that the study
10 supports such a conclusion or that the authors of the study reached such a conclusion.

11 49. In response to the allegations in the first sentence of paragraph 49, Monsanto
12 admits that certain studies have reported that glyphosate and glyphosate-based formulations
13 induced oxidative stress under artificial experimental conditions. Monsanto denies that these
14 studies provide any reliable evidence that glyphosate or glyphosate-based formulations induce
15 oxidative stress in humans or animals under real-world exposure conditions. In response to the
16 allegations in the second sentence of paragraph 49, Monsanto states that the cited document
17 speaks for itself and does not require a response. In response to the allegations in the final
18 sentence of paragraph 49 and in footnote 1, Monsanto denies that any exposure to glyphosate-
19 based herbicides or Roundup[®]-branded products can cause cancer or other serious illnesses.
20 Monsanto denies the remaining allegations in paragraph 49.

21 50. In response to the allegations in paragraph 50, Monsanto admits that the IARC
22 working group purported to make these findings, but denies that the cited studies provide any
23 reliable basis for a finding that any meaningful levels of glyphosate or AMPA are present or
24 persist in human blood or urine. Monsanto denies the remaining allegations in paragraph 50.

25 51. In response to the allegations in paragraph 51, Monsanto admits that the working
26 group reviewed the findings of an Agricultural Health Study (“AHS”) published in 2005, but
27 denies that the working group characterized that study as supporting an association between
28 glyphosate and the specified cancers. The AHS cohort study did not find a positive association

1 between glyphosate and any type of cancer. Monsanto denies all other allegations in paragraph
2 51.

3 52. In response to the allegations in paragraph 52, Monsanto admits that the
4 referenced studies were published, but denies that the studies show any scientifically reliable
5 findings.

6 53. In response to the allegations in paragraph 53, Monsanto denies that the cited
7 study provides any reliable basis for a finding that any meaningful levels of glyphosate are
8 present or persist in human blood or urine. Monsanto denies the remaining allegations in
9 paragraph 53.

10 54. In response to the allegations in paragraph 54, Monsanto denies that any exposure
11 to Roundup[®]-branded products can cause cancer and other serious illnesses and therefore denies
12 the allegations in the first and fourth sentences of paragraph 54. Monsanto admits that certain
13 Roundup[®]-branded herbicides contain adjuvants and that EPA has classified such adjuvants as
14 inert. Monsanto notes that EPA has determined that the surfactants used in Roundup[®]-branded
15 herbicides do not pose an unreasonable risk to human health. The remaining allegations in
16 paragraph 54 are vague and conclusory and comprise attorney characterizations, and are
17 accordingly denied.

18 55. In response to the allegations in paragraph 55, Monsanto admits that the IARC
19 working group's classification of glyphosate as a Class 2A carcinogen has resulted in ongoing
20 discussions in certain countries regarding the sale of glyphosate-based herbicides. Monsanto
21 denies that any final conclusion has been reached in these countries and denies that there is any
22 scientific basis for the concerns raised by the improper IARC classification. Monsanto denies
23 the remaining allegations in paragraph 55.

24 56. In response to the allegations in paragraph 56, Monsanto admits that the IARC
25 working group's classification of glyphosate as a Class 2A carcinogen has resulted in ongoing
26 discussions in certain countries regarding the sale of glyphosate-based herbicides, including the
27 Netherlands. Monsanto denies that any final conclusion has been reached in these countries and
28 denies that there is any scientific basis for the concerns raised by the improper IARC

1 classification. Monsanto denies the remaining allegations in paragraph 56.

2 57. In response to the allegations in paragraph 57, Monsanto admits that the IARC
3 working group classification led an individual government attorney in Brazil to write a letter to
4 the Brazilian regulatory authorities requesting a reevaluation of glyphosate. Monsanto denies the
5 remaining allegations in paragraph 57.

6 58. In response to the allegations in paragraph 58, Monsanto admits that following the
7 IARC working group classification, in France, all non-professional plant protection products,
8 including but not limited to glyphosate-based products, will be sold behind locked counters (no
9 free sales). Monsanto further admits that the French government has announced that beginning
10 on January 1, 2019, the sale of non-professional lawn and garden products, including but not
11 limited to non-professional use glyphosate-based products, is prohibited with certain exceptions.
12 Monsanto denies the remaining allegations in paragraph 58.

13 59. In response to the allegations in paragraph 59, Monsanto admits that some
14 employees of Bermuda's government announced an intention to suspend the importation of
15 glyphosate-based herbicides, but lacks information sufficient to form a belief as to the truth of
16 the allegations about whether this suspension took effect and accordingly denies the same.
17 Monsanto denies the remaining allegations in paragraph 59.

18 60. In response to the allegations in paragraph 60, Monsanto admits that the IARC
19 monograph appears to be the alleged basis for the Sri Lankan government's actions, including
20 the allegation that glyphosate can cause kidney disease. Monsanto further states that the
21 allegations regarding kidney disease found in Sri Lanka are unrelated to plaintiffs' allegations
22 regarding claimed carcinogenicity. Monsanto denies the remaining allegations in paragraph 60.

23 61. In response to the allegations in paragraph 61, Monsanto denies the alleged basis
24 for Colombia's suspension of aerial spraying of glyphosate. Colombia's attorney general has
25 explained that the ban on aerial spraying of illicit coca plantations was a concession to the FARC
26 ("Fuerzas Armadas Revolucionarias de Colombia"), and had nothing to do with alleged safety
27 concerns. As of April 2016, the government of Colombia has resumed manual application of
28 glyphosate on illicit coca crops. A federal district court in the United States excluded plaintiffs'

1 expert testimony purporting to link these same aerial eradication operations with cancer as
2 scientifically unreliable. *See Arias v. DynCorp*, 928 F. Supp. 2d 10 (D.D.C. 2013). Monsanto
3 denies the remaining allegations in paragraph 61.

4 62. In response to the allegations in paragraph 62, Monsanto admits that 96
5 individuals signed a letter sent by Dr. Christopher Portier to the EU Health Commissioner
6 (hereinafter “the Portier letter”). Monsanto states that Dr. Portier has subsequently admitted that
7 he is working as a consultant for plaintiffs’ counsel in the glyphosate cancer litigation against
8 Monsanto. Monsanto denies that Dr. Portier or the other signatories to his letter are “prominent
9 experts.” Monsanto admits that certain members of the IARC working group assigned to
10 glyphosate signed on to the Portier letter but states that Monsanto lacks information or
11 knowledge sufficient to form a belief as to whether those individuals or the other signatories
12 were aware at the time that Dr. Portier was working as a consultant for plaintiffs’ counsel.
13 Monsanto admits that, in this letter, Dr. Portier urged the EU Health Commissioner to disregard
14 the conclusion that glyphosate is not carcinogenic found by EFSA and by the BfR.

15 63. In response to the allegations in paragraph 63, Monsanto denies that the self-
16 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
17 extent that paragraph 63 characterizes the scientific evidence regarding the safety of glyphosate-
18 based herbicides, Monsanto denies the remaining allegations in paragraph 63.

19 64. Monsanto admits that, as of June 2016, the European Union continued to consider
20 the reregistration of glyphosate. Monsanto notes that, in March 2017, the European Chemical
21 Agency (“ECHA”) announced that its Committee for Risk Assessment concluded that the
22 available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen. *See*
23 *ECHA, Glyphosate not classified as a carcinogen by ECHA*, [https://echa.europa.eu/-/glyphosate-](https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa)
24 [not-classified-as-a-carcinogen-by-echa](https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa). Monsanto lacks information or knowledge sufficient to
25 form a belief as to the truth of the allegations in paragraph 64 regarding predictions of possible
26 future events and therefore denies those allegations. The remaining allegations in paragraph 64
27 are vague and conclusory and comprise attorney characterizations, and are accordingly denied.

28

1 65. Monsanto lacks information or knowledge sufficient to form a belief as to the
2 truth of the allegations asserted in paragraph 65 and therefore denies those allegations.

3 66. Monsanto denies that any exposure to Roundup[®]-branded products can cause
4 NHL and other serious illnesses. Monsanto lacks information or knowledge sufficient to form a
5 belief as to the truth of the remaining allegations asserted in paragraph 66 and therefore denies
6 those allegations.

7 67. Monsanto lacks information or knowledge sufficient to form a belief as to the
8 truth of the allegations asserted in paragraph 67 and therefore denies those allegations.

9 68. Monsanto lacks information or knowledge sufficient to form a belief as to the
10 truth of the allegations asserted in paragraph 68 and therefore denies those allegations.

11 69. Monsanto lacks information or knowledge sufficient to form a belief as to the
12 truth of the allegations asserted in paragraph 69 and therefore denies those allegations.

13 70. Monsanto denies that any exposure to Roundup[®]-branded products can cause
14 NHL and other serious illnesses and therefore denies the allegations in paragraph 70. Monsanto
15 states, however, that the scientific studies upon which IARC purported to base its evaluation of
16 glyphosate were all publicly available before March 2015.

17 71. Monsanto incorporates by reference its responses to paragraphs 1 through 70 in
18 response to paragraph 71 of plaintiffs' Complaint.

19 72. Paragraph 72 sets forth conclusions of law for which no response is required. To
20 the extent that the allegations in paragraph 72 assert that Monsanto violated state or federal laws,
21 Monsanto denies such allegations.

22 73. Monsanto denies the allegations in paragraph 73. All labeling of Roundup[®]-
23 branded products has been and remains EPA-approved and in compliance with all federal
24 requirements under FIFRA.

25 74. Monsanto incorporates by reference its responses to paragraphs 1 through 73, in
26 response to paragraph 74 of plaintiffs' Complaint.

27 75. In response to the allegations in paragraph 75, Monsanto admits that plaintiffs
28 purport to bring a claim for defective design, but Monsanto denies any liability to plaintiffs as to

1 that claim.

2 76. In response to the allegations in paragraph 76, Monsanto lacks information or
3 knowledge sufficient to form a belief as to the truth of the allegation that plaintiffs used
4 Roundup[®]-branded products and therefore denies that allegation. Monsanto denies the
5 remaining allegations in paragraph 76.

6 77. Monsanto denies the allegations in paragraph 77.

7 78. Monsanto denies the allegations in paragraph 78.

8 79. Monsanto denies the allegations in paragraph 79.

9 80. Monsanto denies the allegations in paragraph 80.

10 81. In response to the allegations in paragraph 81, Monsanto lacks information or
11 knowledge sufficient to form a belief as to the truth of the allegation that plaintiffs used
12 Roundup[®]-branded products and therefore denies that allegation. Monsanto denies the
13 remaining allegations in paragraph 81.

14 82. Monsanto denies the allegations in paragraph 82.

15 83. Monsanto denies the allegations in paragraph 83.

16 84. Monsanto lacks information or knowledge sufficient to form a belief as to the
17 truth of the allegations in paragraph 84 concerning plaintiff's claimed use of Roundup[®]-branded
18 products and therefore denies those allegations. Monsanto denies the remaining allegations in
19 paragraph 84, including that Roundup[®]-branded products have "dangerous characteristics."

20 85. Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the allegations in paragraph 85 concerning plaintiffs' claimed use of Roundup[®]-branded
22 products and therefore denies those allegations. Monsanto denies the remaining allegations in
23 paragraph 85, including that Roundup[®]-branded products have "dangerous characteristics."

24 86. Monsanto denies the allegations in paragraph 86.

25 87. Monsanto denies the allegations in paragraph 87.

26 88. Monsanto denies the allegations in paragraph 88.

27 89. Monsanto denies the allegations in paragraph 89.

28 90. Monsanto denies the allegations in paragraph 90.

1 91. In response to the allegations in paragraph 91, Monsanto demands that judgment
2 be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed, with
3 prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed
4 by law and such further and additional relief as this Court may deem just and proper.

5 92. Monsanto incorporates by references its responses to paragraphs 1 through 91 in
6 response to paragraph 92 of plaintiffs' Complaint.

7 93. In response to the allegations in paragraph 93, Monsanto admits that plaintiffs
8 purport to bring a claim for strict liability failure to warn, but denies any liability to plaintiffs.

9 94. Monsanto denies the allegations in paragraph 94.

10 95. In response to the allegations in paragraph 95, Monsanto lacks information or
11 knowledge sufficient to form a belief as to the truth of the allegation that plaintiffs or other
12 individuals purchased or used Roundup[®]-branded products and therefore denies that allegation.
13 Paragraph 95 also sets forth conclusions of law for which no response is required. Monsanto
14 denies the remaining allegations in paragraph 95.

15 96. Paragraph 96 sets forth conclusions of law for which no response is required.

16 97. Monsanto denies the allegations in paragraph 97. All labeling of Roundup[®]-
17 branded products has been and remains EPA-approved and in compliance with all federal
18 requirements under FIFRA.

19 98. Monsanto denies the allegations in paragraph 98.

20 99. Monsanto denies the allegations in paragraph 99.

21 100. Monsanto denies the allegations in paragraph 100.

22 101. Monsanto lacks information or knowledge sufficient to form a belief as to the
23 truth of the allegations in paragraph 101 and therefore denies those allegations.

24 102. Monsanto lacks information or knowledge sufficient to form a belief as to the
25 truth of the allegations in paragraph 102 concerning plaintiff's alleged use and exposure to
26 Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the
27 remaining allegations in paragraph 102, including that Roundup[®]-branded products have
28 "dangerous characteristics."

1 103. Monsanto lacks information or knowledge sufficient to form a belief as to the
2 truth of the allegations in paragraph 103 concerning plaintiff's alleged use and exposure to
3 Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the
4 remaining allegations in paragraph 103, including that Roundup[®]-branded products have
5 "dangerous characteristics."

6 104. Monsanto denies the allegation in paragraph 104.

7 105. Monsanto denies the allegations in paragraph 105.

8 106. In response to the allegations in paragraph 106, Monsanto denies that there is any
9 risk of NHL or any other serious illnesses associated with the intended use of and/or exposure to
10 Roundup[®]-branded products and glyphosate. The allegations in the second sentence of
11 paragraph 106 set forth conclusions of law for which not response is required. Monsanto denies
12 the remaining allegations in paragraph 106. All labeling of Roundup[®]-branded products has
13 been and remains EPA-approved and in compliance with all applicable laws and regulations.

14 107. Monsanto denies the allegations in paragraph 107.

15 108. Monsanto lacks information or knowledge sufficient to form a belief as to the
16 truth of the allegations in paragraph 108 concerning plaintiffs' alleged use of Roundup[®]-branded
17 products and therefore denies those allegations. Monsanto denies the remaining allegations in
18 paragraph 108.

19 109. Monsanto denies the allegations in paragraph 109.

20 110. Monsanto denies the allegations in paragraph 110. All labeling of Roundup[®]-
21 branded products has been and remains EPA-approved and in compliance with all federal
22 requirements under FIFRA.

23 111. Monsanto denies the allegations in paragraph 111.

24 112. In response to the allegations in paragraph 112, Monsanto demands that judgment
25 be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed, with
26 prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed
27 by law and such further and additional relief as this Court may deem just and proper.

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1 113. Monsanto incorporates by references its responses to paragraphs 1 through 112 in
2 response to paragraph 113 of plaintiffs' Complaint.

3 114. Paragraph 114 sets forth conclusions of law for which no response is required.

4 115. Monsanto denies the allegations in paragraph 115.

5 116. Monsanto denies the allegations in paragraph 116.

6 117. Monsanto lacks information or knowledge sufficient to form a belief as to the
7 truth of the allegations in paragraph 117 regarding plaintiff's reliance and therefore denies those
8 allegations. Monsanto denies the remaining allegations in paragraph 117.

9 118. The allegations in paragraph 118 set forth conclusions of law for which no
10 response is required.

11 119. The allegations in paragraph 119 set forth conclusions of law for which no
12 response is required.

13 120. Monsanto denies the allegations in paragraph 120.

14 121. Monsanto denies the allegations in paragraph 121.

15 122. Monsanto incorporates by references its responses to paragraphs 1 through 121 in
16 response to paragraph 122 of plaintiffs' Complaint.

17 123. Monsanto denies the allegations in paragraph 123.

18 124. The allegations in the first sentence of paragraph 124 set forth conclusions of law
19 for which no response is required. Monsanto denies the remaining allegations in paragraph 124.

20 125. Monsanto denies the allegations in paragraph 125.

21 126. The allegations in paragraph 126 set forth conclusions of law for which no
22 response is required.

23 127. Monsanto lacks information or knowledge sufficient to form a belief as to the
24 truth of the allegations in the first sentence of paragraph 127 regarding plaintiffs' purchase of
25 Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the
26 allegation that Roundup[®]-branded products contain "defects." Monsanto denies the allegations
27 in the second sentence of paragraph 127.

28 128. Monsanto denies the allegations in paragraph 128.

1 129. Monsanto denies the allegations in paragraph 129.

2 130. Monsanto denies the allegations in paragraph 130 and each of its subparts.

3 131. In response to the allegations in paragraph 131, Monsanto demands that
4 judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed,
5 with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as
6 allowed by law and such further and additional relief as this Court may deem just and proper.

7 132. Monsanto incorporates by references its responses to paragraphs 1 through 131 in
8 response to paragraph 132 of plaintiffs' Complaint.

9 133. Monsanto lacks information or knowledge sufficient to form a belief as to the
10 truth of the allegations in paragraph 133 regarding the specific products allegedly used by
11 plaintiffs or any advertising or marketing allegedly seen or considered by plaintiffs and therefore
12 denies the allegations in paragraph 133.

13 134. Paragraph 134 sets forth conclusions of law for which no response is required.

14 135. Paragraph 135 sets forth conclusions of law for which no response is required.

15 136. Monsanto denies the allegations in paragraph 136.

16 137. Monsanto denies the allegations in paragraph 137.

17 138. Monsanto denies the allegations in paragraph 138. All labeling of Roundup[®]-
18 branded products has been and remains EPA-approved and in compliance with all federal
19 requirements under FIFRA.

20 139. Monsanto denies the allegations in paragraph 139.

21 140. Monsanto denies the allegations in the first sentence of paragraph 140. In
22 response to the allegations in the second sentence of paragraph 140, Monsanto denies that
23 Monsanto's promotional activities were not honest. The remaining allegations in the second
24 sentence of paragraph 140 set forth conclusions of law for which no response is required.

25 141. Monsanto denies the allegations in paragraph 141.

26 142. Monsanto denies the allegations in paragraph 142, including each of its subparts.

27 143. Monsanto denies the allegations in paragraph 143.

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1 144. Monsanto lacks information or knowledge sufficient to form a belief as to the
2 truth of the allegations in paragraph 144 regarding plaintiffs' knowledge and therefore Monsanto
3 denies those allegations. Monsanto denies the remaining allegations in paragraph 144, including
4 that intended use and/or exposure to Roundup[®]-branded products causes any injuries.

5 145. Monsanto denies the allegations in paragraph 145.

6 146. Monsanto denies the allegations in paragraph 146.

7 147. In response to the allegations in paragraph 147, Monsanto demands that
8 judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed,
9 with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as
10 allowed by law and such further and additional relief as this Court may deem just and proper.

11 148. Monsanto incorporates by references its responses to paragraphs 1 through 147 in
12 response to paragraph 148 of plaintiffs' Complaint.

13 149. Monsanto denies the allegations in paragraph 149.

14 150. Monsanto denies the allegations in paragraph 150. All labeling of Roundup[®]-
15 branded products has been and remains EPA-approved and in compliance with all federal
16 requirements under FIFRA.

17 151. Monsanto denies the allegations in paragraph 151. All labeling of Roundup[®]-
18 branded products has been and remains EPA-approved and in compliance with all federal
19 requirements under FIFRA.

20 152. Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the allegations in paragraph 152 regarding plaintiff's claimed purchase and use of
22 Roundup[®]-branded products and plaintiff's knowledge or reliance and therefore denies those
23 allegations. Monsanto denies that any exposure to glyphosate-based herbicides or Roundup[®]-
24 branded products can cause cancer or other serious illnesses. All labeling of Roundup[®]-branded
25 products has been and remains EPA-approved and in compliance with all federal requirements
26 under FIFRA. Monsanto denies the remaining allegations in paragraph 152.

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1 dangerous.

2 3. Any alleged negligent or culpable conduct of Monsanto, none being admitted,
3 was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of
4 plaintiffs' alleged injuries.

5 4. Plaintiffs' claims are barred, in whole or in part, because the products at issue
6 were designed, manufactured, marketed and labeled with proper warnings, information, cautions
7 and instructions, in accordance with the state of the art and the state of scientific and
8 technological knowledge.

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

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

15 7. Plaintiffs' claims are preempted, in whole or in part, because of U.S. EPA
16 findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved
17 product labeling.

18 8. Plaintiffs' claims are barred, in whole or in part, by the doctrine of primary
19 jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

20 9. Plaintiffs' claims are barred, in whole or in part, because plaintiff's injuries, if
21 any, were the result of conduct of plaintiff, independent third parties, and/or events that were
22 extraordinary under the circumstances, not foreseeable in the normal course of events, and/or
23 independent, intervening and superseding causes of the alleged injuries, including but not limited
24 to plaintiff's pre-existing medical conditions.

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

27 11. Applicable statutes of limitations, prescriptive periods, and/or statutes of repose
28 bar plaintiffs' claims in whole or in part.

1 12. Plaintiff's misuse or abnormal use of the product or failure to follow instructions
2 bar plaintiffs' claims in whole or in part.

3 13. If plaintiffs suffered injury or damages as alleged, which is denied, such injury or
4 damage resulted from: (a) acts or omissions of persons or entities for which Monsanto is neither
5 liable nor responsible or, in the alternative, Monsanto is entitled to an assessment of the relative
6 degree of fault of all such persons and entities; or (b) resulted from diseases and/or causes that
7 are not related or connected with any product sold, distributed, or manufactured by Monsanto.
8 Such acts or omissions on the part of others or diseases or causes constitute an independent,
9 intervening and sole proximate cause of plaintiffs' alleged injury or damages.

10 14. Monsanto had no legal relationship or privity with plaintiffs and owed no duty to
11 them by which liability could be attributed to it.

12 15. Monsanto made no warranties of any kind or any representations of any nature
13 whatsoever to plaintiffs. If any such warranties were made, which Monsanto specifically denies,
14 then plaintiffs failed to give notice of any breach thereof.

15 16. Plaintiffs' claims are preempted in whole or part by the Freedom of Speech
16 Clause of the First Amendment of the U.S. Constitution.

17 17. Plaintiffs' claims for exemplary and/or punitive damages are barred because such
18 an award would violate Monsanto's due process, equal protection and other rights under the
19 United States Constitution, the Louisiana Constitution, and/or other applicable state constitutions
20 – and would be improper under the common law and public policies of the United States, the
21 laws of Louisiana and/or other state laws.

22 18. Plaintiffs' claims for exemplary and/ or punitive damages are barred because
23 plaintiffs have failed to allege conduct warranting imposition of punitive damages under
24 Louisiana law and/or other applicable state laws.

25 19. Plaintiffs' claims for punitive and/or exemplary damages are barred and/or limited
26 by operation of state and/or federal law, including La. R.S. 9:2800.52.

27 20. Plaintiffs' claims are barred in whole or in part by plaintiff's own
28 contributory/comparative negligence.

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Respectfully submitted,

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