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21 UNITED STATES DISTRICT COURT
22 NORTHERN DISTRICT OF CALIFORNIA

23 IN RE: ROUNDUP PRODUCTS
24 LIABILITY LITIGATION

25 MDL No. 2741
26 Case No. 16-md-02741-VC
27 Hearing: February 27, 2017, 9:30 a.m.
28 Courtroom 4, 17h Floor, N.D. Cal.
San Francisco, CA

29 This document relates to all cases

30 **PLAINTIFFS' SUBMISSION IN RESPONSE TO PRETRIAL ORDER NO. 8**

1 As a preliminary matter, it is important for the Court to understand that the IARC and the
2 EPA are analyzing different issues. Aside from issues of methodology, the fundamental
3 difference between their assessments is that IARC performs a “hazard assessment”—can
4 glyphosate and/or Roundup[®] cause NHL—while EPA makes a “risk assessment”—at what level
5 is there a risk of cancer and is that an acceptable risk. In addition, IARC considers studies of
6 both glyphosate and the formulated product while the EPA considers only glyphosate. In a legal
7 sense, IARC performs a general causation assessment.

9 IARC is the “gold standard” for scientific cancer assessments and followed generally
10 accepted and sound methodology in reaching its conclusion that glyphosate is a probable human
11 carcinogen;¹ thus, its conclusions are reliable and relevant to a general causation analysis. The
12 President’s Cancer Panel, Reducing Environmental Cancer Risk, at 13 (Apr. 2010), *available at*
13 http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf.
14 There is no evidence of IARC bias. The Federal Judicial Center lists IARC as one “of the most
15 well-respected and prestigious scientific bodies” and states that when IARC Monographs are
16 available, they are “generally recognized as authoritative.” *See Reference Manual On Scientific*
17 *Evidence*, 3rd Edition (2011) (Reference Manual), pp. 20, 564.

20 On the other hand, because the EPA does not actually review the carcinogenicity of the
21 Roundup[®] formulation and because there are substantial flaws and biases in its procedures and
22 methods to determine whether glyphosate can cause non-Hodgkin lymphoma (“NHL”), EPA’s
23 *ad hoc* conclusions are neither reliable nor relevant to support issues of general causation.
24

26 ¹ World Health Org., IARC Monographs on the Evaluation of Carcinogenic Risks to
27 Humans: Some Organophosphate Insecticides and Herbicides (Volume 112) (hereinafter
28 “Monograph”), *available at* <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf>.

1 **I. IARC IS RELEVANT TO GENERAL CAUSATION**

2 **A. IARC: The Gold Standard for Scientific Cancer Assessments**

3 The International Agency for Research on Cancer (IARC) is the most preeminent cancer-
4 assessment authority in the world.² As such, the IARC monographs should be reviewed,
5 considered, and relied upon by all causation experts in this litigation, whether for Plaintiffs or
6 Monsanto. *See Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014)
7 (considering whether “theory or technique enjoys general acceptance within the relevant
8 scientific community” in addressing *Daubert*’s reliability prong). “The IARC Monographs are ...
9 relevant to a determination of general causation and [are] the type of scientific data relied on by
10 experts in the field of study.” *Lewis v. Airco, Inc.*, No. A-3509-08T3, 2011 WL 2731880, at *18
11 (N.J. Super. Ct. App. Div. July 15, 2011).
12
13

14 In assessing cancer etiology, scientists utilize a hierarchy of evidence to review the
15 scientific literature. *See Oxford Centre for Evidence Based Medicine – Levels of Evidence.*³ At
16 the top of that hierarchy are systematic reviews, which “focus on peer-reviewed publications
17 about a specific health problem and use rigorous, standardized methods for selecting and
18 assessing articles.” *Id.* (glossary); *see also Federal Judicial Center, Reference Manual on*
19 *Scientific Evidence* 723-24 (“When ordered from strongest to weakest, systematic review of
20 randomized trials (meta-analysis) is at the top, followed by single randomized trials, systematic
21

22
23 ² The United Nations World Health Organization founded IARC in 1965 “to promote
24 international collaboration in cancer research.” IARC’s Statute, Rules, and Regulations,
25 Fourteenth Edition (IARC Statute), Art. I, at 5-6, (Ex. 1, excerpts from IARC statute.) The
26 United States was a founding member of IARC and, as of the date of this memorandum, remains
27 a member. *Id.* at 5, 27 (Ex. 1). Each IARC member state nominates scientific experts to
28 comprise IARC’s Scientific Council, the body that reviews IARC’s cancer research program. *Id.*
at 8. Further, members elect representatives to serve on the Governing Council, which is
responsible for, *inter alia*, setting general policy for IARC. *Id.* at 7.

³ <http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>.

1 reviews of observational studies, single observational studies, physiological studies, and
2 unsystematic clinical observations.”).⁴ As the Court has noted, the experts will review the
3 underlying studies that IARC relied on as part of its assessment. Nonetheless, independent
4 systematic reviews such as those conducted by IARC are strong evidence upon which experts in
5 the field rely, and thus, experts in this litigation may also appropriately rely in part on IARC.
6
7 Fed. R. Evid. 703.

8 In assessing whether Roundup[®] can cause NHL, evidence-based science dictates that
9 experts review the most reliable systematic review of cancer etiology, the IARC Monograph. In
10 making cancer assessments, IARC considers all relevant, publicly available scientific evidence to
11 determine whether a particular chemical or agent causes cancer.⁵ *See* Reference Manual on
12 Scientific Evidence, 3rd Edition (2011) (Reference Manual) at 20. Indeed, the Reference Manual
13 describes IARC’s cancer assessments as follows:
14

15 IARC, a well-regarded international public health agency,
16 evaluates the human carcinogenicity of various agents. In doing so,
17 IARC obtains all of the relevant evidence, including animal studies
18 as well as any human studies. On the basis of a synthesis and
19 evaluation of that evidence, IARC publishes a monograph
20 containing that evidence and its analysis of the evidence and
21 provides a categorical assessment of the likelihood the agent is
22 carcinogenic. . . . ***When IARC monographs are available, they are
generally recognized as authoritative. Unfortunately, IARC has
conducted evaluations of only a fraction of potentially
carcinogenic agents, and many suspected toxic agents cause
effects other than cancer.***

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24
25
26 ⁴ Monograph, at 350 (citing meta-analysis showing a statistically significant increase in
27 NHL).

28 ⁵ In contrast, in its registration analysis of glyphosate, the EPA mostly considered private,
non-peer-reviewed studies and literature funded and/or conducted by Monsanto.

1 Reference Manual at n. 46 (emphasis added). The American Cancer Society also relies
 2 on IARC for its list of substances that are known or suspected to cause cancer.⁶ The U.S.,
 3 Department of Health and Human Services considers IARC monographs to be “critical
 4 references that inform health policy and cancer research worldwide about carcinogenic risks to
 5 reduce cancer globally.” Limited Competition, IARC Monographs Program (2014).⁷
 6

7 Because of its exacting standards and neutrality, federal laws incorporate IARC
 8 classifications into regulatory standards.⁸ Similarly, many California state laws⁹ and other
 9 states’ laws¹⁰ specifically rely on IARC’s cancer assessments. Importantly, when the State of
 10

11 ⁶ [https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-](https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html)
 12 [carcinogens.html](https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html).

13 ⁷ [https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-14-503.html# Part 2. Full](https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-14-503.html#_Part_2_Full)

14 ⁸ For example, under the Toxic Substances Control Act of 1976 (TSCA), as interpreted
 15 by the EPA, “[a] chemical is considered to be a known or potential human carcinogen, for
 16 purposes of TSCA section 12(b) export notification, if that chemical is . . . classified as . . .
 17 ‘probably carcinogenic to humans’ (Group 2A) . . . by the World Health Organization
 18 International Agency for Research on Cancer (IARC)[.]” 40 C.F.R. § 707.60(2)(c). Similarly,
 19 the U.S. Consumer Product Safety Commission (CPSC) and the Occupational Safety and Health
 20 Administration (OSHA) both recognize and accept the authority of IARC in assessing the
 21 potential cancer hazard of an agent. *See* 16 C.F.R. § 1500.135(a)(1)-(3) (relying on the IARC
 22 classifications for known, probable and possible human carcinogen assessments); 29 C.F.R. §
 23 1910.1450(b) (defining carcinogen as any substance identified as such by IARC). The U.S.
 24 Centers for Disease Control and Prevention lists IARC Monographs as one of the “Other
 25 Government Agency Resources” for identifying chronic health effects of exposure to hazardous
 26 chemicals. *See* <http://www.cdc.gov/niosh/topics/chemical-safety4other>.

27 ⁹ California’s Carcinogen Identification Committee deems IARC an authoritative body
 28 for purposes of Proposition 65’s listing mechanism. *See* 27CCR, § 25306, subd. (m)(1).
 California’s Labor Code, which provides workers information about hazardous chemicals in the
 workplace, requires OEHHA to list “substances identified by reference in Labor Code Section
 6382(b)(1)”, which, in turn, identifies “[s]ubstances listed as human or animal carcinogens by the
 [IARC].” 27CCR, § 25249.8, subd. (a) and (b)(1).

¹⁰ Other states also rely on IARC’s carcinogenicity evaluations. Pennsylvania’s
 hazardous substance list must include all substances listed by IARC as having “sufficient
 evidence of carcinogenicity in animals.” (Penn. Statutes, tit. 35, § 7303, subd. (a)(6); Penn.
 Admin. Code, tit. 34, § 323.5, subd. (20)(6)). New Jersey’s “Right to Know Hazardous
 Substance List” must be updated based on the IARC Monograph Supplements. (N.J. Admin.
 Code, tit. 8:59-93, subd. (b)(7)). Rhode Island is required by statute to maintain a hazardous
 and/or toxic chemical list that includes chemicals listed as carcinogens by IARC (R.I. Gen.

1 California noticed its intent to list glyphosate as a chemical “known to cause cancer,” which
 2 requires Monsanto to warn Californians about the dangers of glyphosate,¹¹ Monsanto sued
 3 California in Fresno Superior Court to avoid providing cancer risk warnings. At present, the
 4 Court has issued a tentative ruling only.

5
 6 **B. IARC’s Assessment Process**

7 Each IARC assessment is published in the form of a “Monograph,” which comprises a
 8 Preamble (*see IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*,
 9 Preamble, 2006, Ex. 2) (hereinafter “Preamble”) and “critical reviews and evaluations of
 10 evidence of the carcinogenicity of a wide range of human exposures.” *Id.* at 2. Monographs are
 11 “used by national and international authorities to make risk assessments, formulate decisions
 12 concerning preventive measures, provide effective cancer control programmes and decide among
 13 alternate options for public health decisions.” *Id.* at 3.¹² IARC’s assessment process is a year-
 14 long endeavor, described in detail in the Preamble, which involves a review of peer-reviewed
 15 scientific literature and data from publicly-available government agency reports. *Id.* at 4.

16
 17
 18 The Working Group evaluating glyphosate included 17 experts from around the world,
 19 who volunteered their time to undertake this important public health assessment. These experts
 20

21
 22 Laws, tit. 28, § 28-21-2(13)). Massachusetts’ list of toxic or hazardous substances includes
 23 substances found to have sufficient evidence of carcinogenicity in animals as indicated in the
 24 IARC Monographs. (Mass. Reg. tit. 105, § 670.010, subd. (B)(1); Mass. Gen. Laws Ann. 111F §
 25 4, subd. (b)(2).) These and other states, including Alaska, Connecticut, Illinois, Indiana,
 26 Louisiana, Missouri, Nevada, New Hampshire, Oregon, Tennessee, Texas, Vermont, Virginia,
 27 and Washington, rely on IARC’s evaluations to help them identify carcinogens for public health
 28 purposes. A list of these state statutes is attached as Exhibit 3.

¹¹ <http://oehha.ca.gov/proposition-65/crn/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate>

¹² While the Preamble uses the term “risk,” IARC Monographs evaluated cancer
 “hazards,” not risk. Preamble, at 2-3.

1 included scientists from the U.S. EPA, California EPA, and the National Cancer Institute.¹³
2 IARC also permits representatives from government agencies and even observers from affected
3 industries to observe the meeting. *Id.* For example, Monsanto retained Thomas Sorahan to
4 attend the meeting for Monograph 112 on Monsanto's behalf; he reported that the Chair, sub-
5 chairs, and invited experts for the glyphosate Working Group were "very friendly" and "prepared
6 to respond to all comments I made." He continued, "[i]n my opinion the meeting followed the
7 IARC guidelines." Ex. 4, MONGLY00977035-36.

8
9 The product of this process is the IARC Monograph, which includes exposure data,
10 studies of cancer in humans, studies of cancer in experimental animals, mechanistic and other
11 relevant data, a summary of the contents, and an evaluation and rationale for the chemical's
12 categorization. As detailed in the Preamble, IARC's classification process is rigorous and
13 includes numerous procedures and safeguards designed to promote the scientific integrity of its
14 decisions. *See AFL-CIO v. Deukmejian*, 212 Cal.App.3d 425, 433 (1989). Scholars agree that
15 the IARC review process follows well-accepted and sound methodology, including interpreting
16 data according to the generally accepted Bradford Hill criteria for cancer assessments. *See IARC*
17 *Monographs: 40 Years of Evaluating Carcinogenic Hazards to Humans*, Pearce, *et al.*,
18 *Environmental Perspectives*, Vol. 123, No. 6, at 513 (June 2015), at 6.

19
20
21 Monsanto is well aware of the significance of a finding of carcinogenicity by IARC.
22 After learning that IARC planned to assess glyphosate, it launched a campaign to discredit an
23 IARC finding, even before the Working Group meeting began.¹⁴ In a PowerPoint designed to
24 confront IARC's anticipated assessment of carcinogenicity, Monsanto describes IARC as an
25

26
27 ¹³ <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-F03.pdf>.

28 ¹⁴ *See* Ex. 5, in which Monsanto laid out in a Power Point presentation the respect the scientific community and governments around the globe have for IARC assessments.

1 agency that “promote[s] international collaboration in cancer research” and “[i]dentifies agents
2 that increase risk of human cancer.” *Id.* at Slide 2. Monsanto understood that because of
3 IARC’s reputation, a finding of carcinogenicity would “disrupt our narrative,” and “call into
4 question the safety of glyphosate/Roundup, putting industry on the defensive.” *Id.* at Slide 6.¹⁵
5
6 In reaction to IARC’s determination that glyphosate is a probable carcinogen, Monsanto has
7 engaged in an aggressive media and political attack on IARC generally and the Monograph 112
8 members specifically, an unprecedented reaction in the cancer agency’s 40-year history of
9 reviewing carcinogens.

10 **C. Judicial and Industry Reliance on IARC**

11 Federal courts, which have relied on its methodology and classifications, routinely
12 acknowledge IARC’s status as an expert scientific agency. *See, e.g., Adams v. Cooper Industries*
13 (E.D. Ky. Apr. 4, 2007, No. 03-476-JBC) 2007 WL 1075647, at *14 (holding that IARC
14 classifications were admissible, as they were probative, not unduly prejudicial, and “result from
15 an in-depth analysis by experts in their fields”); *Current v. Atochem* (W.D. Tex. Nov. 30, 2001,
16 No. W-00-CA-332) 2001 WL 36101283, at *4 (using IARC’s findings as a benchmark for
17 evaluating expert testimony for link between rectal cancer and arsenic); *Burst v. Shell Oil Co.*,
18 No. CIV.A. 14-109, 2015 WL 3620111, at *8 (E.D. La. May 9, 2015), *aff’d*, 650 F. App’x 170
19 (5th Cir. 2016), *cert. denied*, 137 S. Ct. 312, 196 L. Ed. 2d 219 (2016); *Baldonado v. Wyeth*
20 (N.D. Ill. Aug. 31, 2012, No. 04 C 4312), 2012 WL 3779100, at *4-6). Even Monsanto has relied
21 on IARC’s published monographs to argue that certain chemicals should not be considered
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24

25 ¹⁵ Monsanto has spoken favorably about IARC’s methodology in court filings in other
26 cases as well. In *Town of Lexington v. Pharmacia, et al.*, C.A. No. 12-CV-11645, Rec. Doc.
27 263, for example, a case involving harm caused by polychlorinated biphenyls (PCBs), Monsanto
28 took the position that IARC’s methodology was sound and that its expert followed a similar
methodology, albeit reaching a different conclusion. *See Ex. 6 at 6-8.*

1 carcinogens. *See, e.g., Williams v. Monsanto Co.* (E.D. La. Feb. 20, 1997, No. 93-4237) 1997
2 WL 73565, *2 (granting summary judgment for defendant in part because, as defendant argued,
3 the chemical had not been classified as a human carcinogen by IARC).¹⁶ In short, IARC is a key
4 piece of the general causation analysis.

6 **II. EPA’S ACTIONS ARE FLAWED, BIASED, AND IRRELEVANT TO 7 GENERAL CAUSATION**

8 **A. EPA Does Not Review The Carcinogenicity of Roundup[®]**

9 The EPA’s role is not to assess the carcinogenicity of Roundup[®]; rather, it is to “register”
10 glyphosate for sale as a pesticide. Pesticide registration is an administrative procedure that
11 includes examination of the ingredients of a pesticide, geographic use, frequency of use, and
12 storage and disposal practices for a pesticide pre-and-post use. 40 C.F.R §§150-189. FFDCA
13 and FIFRA were amended in 1996 by the Food Quality Protection Act of 1996 (FQPA), 21
14 U.S.C. § 301 *et seq.*, which vests power in the EPA’s Office of Pesticide Protection (OPP) to
15 evaluate the risks associated with the use of pesticides to make safety determinations. Unlike
16 IARC, the scientific data and studies that EPA considers pursuant to FIFRA are provided by the
17 companies seeking registration. *See* 40 C.F.R. §160. There is no requirement that reports and
18 studies be subject to peer review or free from bias or influence, and often (as the case here) they
19 are not.
20
21

22 EPA’s minimal standards do not require human health data submissions related to the
23 formulated product—here, Roundup[®]. Instead, EPA regulations require only studies and data
24

25 ¹⁶ Although not directly on point and based on facts different than those here, the Fifth
26 Circuit Court of Appeals mentioned IARC’s “weight of the evidence” standard in the context of
27 assessing reliability required for admission of expert opinions in two cases, expressing
28 disapproval of an expert’s *sole* reliance upon others’ research. *See, e.g., Johnson v. Arkema, Inc.*, 685 F.3d 452, 464 (5th Cir. 2012); *Allen v. Pennsylvania Eng’g Corp.*, 102 F.3d 194, 198 (5h Cir. 1996).

1 that relate to the active ingredient, which in the case of Roundup[®] is glyphosate.¹⁷ As a result,
2 the body of scientific literature EPA has reviewed is not only primarily provided by the industry,
3 but it also only considers *one part* of the chemical ingredients that make up Roundup[®]. In fact,
4 Monsanto's lead toxicologist, Dr. Donna Farmer, recognized that Monsanto "cannot say that
5 Roundup[®] does not cause cancer" because, "[w]e [Monsanto] have not done the carcinogenicity
6 studies with Roundup[®]." Deposition of Donna Farmer at 49:21-50:8, quoting Ex. 1-8 (Ex. 7
7 (Donna Farmer deposition excerpts)).¹⁸ Further, as Dr. Farmer explained, in the 35 years that
8 Roundup[®] has been on the market, Monsanto has conducted no chronic carcinogenicity studies
9 on the formulated Roundup[®] product because such a study was not required by the EPA for
10 registration of glyphosate. *Id.* at 51:22-52:12. Simply put, the EPA does not require, and thus
11 does not consider, chronic effects data resulting from continuous exposure to Roundup[®]—the
12 root of all Plaintiffs' allegations in this case.¹⁹ For this fact alone, the EPA's conclusions related
13 to glyphosate should be excluded as irrelevant.

14
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16 **B. EPA's Self-Corrective Attempts Highlight Its Process Gaps**

17 Potentially in an effort to correct the flaws in its pesticide registration analysis, following
18 IARC's classification of glyphosate as a 2A carcinogen, the EPA delayed re-registration of
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23 ¹⁷ In 1992, the Health Effects Division (HED) within EPA's OPP determined that
24 regulation of metabolites in glyphosate need not be regulated based on toxicological
25 considerations regardless of levels observed in food or feeds. *See*, MONGLY02811704-
26 2811785 at 2, dated June 2, 2009, (hereinafter, "Scoping Document") (attached as Ex. 8).

27 ¹⁸ One of the ingredients in the formulated product is polyethoxylated tallow amine
28 (POEA). Monsanto is being forced to remove POEA from Roundup in the European Union
(Farmer Dep. at 79:24-82:13).

¹⁹ Furthermore, Monsanto admits that the additives have biological action and are not
inert in the biological sense; they are only inert in that they have no herbicidal effect. Farmer
Dep. at 417:19-23.

1 glyphosate (the process began in 2009) and asked Monsanto to submit additional studies.²⁰

2 These EPA requests included materials Monsanto did not previously submit to the agency. Most
3 notably, the EPA specifically requested European cancer data that Monsanto previously
4 submitted to the German Federal Institute for Risk Assessment (BfR) but not to the EPA.²¹ The
5 EPA has not yet issued a final decision related to the review of these newly obtained materials.
6

7 On September 12, 2016, OPP submitted an issue paper on the carcinogenic potential of
8 glyphosate, wherein it issued a “proposed conclusion”: glyphosate is “not likely to be
9 carcinogenic to humans *at doses relevant to human health risk assessment.*” (emphasis
10 added).²² There are no authors listed on this issue paper.²³ This draft report reiterates and
11 adopts the conclusions of an October 2015 assessment by Jess Rowland of the OPP’s Cancer
12 Assessment Review Committee (“CARC”).²⁴ In arriving at this not yet peer-reviewed decision,
13 the OPP explicitly noted that its review “focused on studies on the active ingredient glyphosate”
14 and “additional research could also be performed to determine whether formulation components,
15 such as surfactants, influence the toxicity of glyphosate formulations.”²⁵ The OPP noted that it
16
17

18 ²⁰ See attached Ex. 9. MONGLY02054538-40, email between Monsanto and EPA,
19 3/31/2016 (initial study request); *also see*, MONGLY03416927, email between Monsanto and
20 EPA, 5/17/2016 (request for second list of studies).

21 ²¹ See attached Ex. 10. MONGLY03410604 at 3410607, email between Monsanto and
22 EPA, 5/23/2016 (following up on an oral conversation related to the EPA’s request for European
23 cancer data for glyphosate).

24 ²² This statement shows that EPA is not considering whether glyphosate causes NHL;
25 rather, it addresses the dosage required to develop NHL.

26 ²³ The OPP assessment is not yet final. The issue paper and proposed conclusion was
27 supposed to be submitted for peer review in October 2016, but that assessment was then
28 postponed to December 2016. From December 13 to 16, 2016, the EPA held FIFRA Scientific
Advisor Panel (“SAP”) meetings to consider issues raised by the OPP’s evaluation of glyphosate
but no final report has yet issued.

²⁴ CARC also limits its conclusion to the amount of pesticide required to cause NHL; it
also does not address the “general causation” question of whether Roundup[®] can cause NHL at
any level.

²⁵ OPP draft assessment, at 141.

1 rejected all studies that considered Roundup[®]—the formulated product—instead of studies that
2 isolated glyphosate because “[g]lyphosate formulations contain various components other than
3 glyphosate and it has been hypothesized these components are more toxic than glyphosate
4 alone.”²⁶ In its charge to the FIFRA Scientific Advisory Panel (“SAP”), established to perform a
5 peer review of the OPP draft assessment, the OPP notes that “[a]lthough there are studies
6 available on glyphosate-based pesticide formulations, the agency is soliciting advice from the
7 SAP on this evaluation of human carcinogenic potential for the active ingredient glyphosate only
8 at this time.”²⁷ The SAP is still considering the evidence on glyphosate and has not issued any
9 findings to date. Because Plaintiffs here allege exposure to Roundup[®], the OPP review (even if
10 it were free of irregularities identified below) is not relevant to this litigation.
11
12

13 In stark contrast, IARC’s review of glyphosate included data relating to the manner in
14 which it is used in the real world—as one of the ingredients of the Roundup[®] formulation—and
15 furthermore, necessarily included “high dose” and “injected” studies because these are studies
16 that can determine the carcinogenic potential of both glyphosate and Roundup[®].
17

18 **C. EPAs “Cancer Risk Assessment” for Glyphosate Is Flawed**

19 The EPA’s own cancer risk guidelines describe the meta-analysis technique used by
20 IARC and acknowledge that:

21 Meta-analysis is a means of integrating the results of multiple
22 studies of similar health effects and risk factors. This technique is
23 particularly useful when various studies yield varying degrees of
24 risk or even conflicting associations (negative and positive). It is
25 intended to introduce consistency and comprehensiveness into
what otherwise might be a more subjective review of the literature.

26 ²⁶ *Id.* at 70.

27 ²⁷ EPA, Glyphosate: Evaluation of Carcinogenic Potential, Charge to the FIFRA SAP for
28 October 18-21, 2016 Meeting https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_sap_charge_questions_-final.pdf (last accessed February 3, 2017).

1 The value of such an analysis is dependent upon a systematic
2 review of the literature that uses transparent criteria of inclusion
and exclusion.²⁸

3 IARC “conducted an objective statistical analysis of the results of all of the available
4 studies on glyphosate and non-Hodgkin lymphoma, which included the AHS and all of the case-
5 control studies. The data from all of the studies combined show a statistically significant
6 association between non-Hodgkin lymphoma and exposure to glyphosate.”²⁹ The EPA provides
7 no criticism of the meta-analysis itself or its application by IARC. There is no demonstrated bias
8 or demonstrated confounding factor—only the potential that these exist. Despite IARC’s
9 systematic review ranking at the top of the hierarchy of evidence relied upon by experts in the
10 field and in the EPA’s own guidelines, Jess Rowland of the OPP simply ignored it. Still, the
11 CARC did not look at the primary literature related to glyphosate. True to history, CARC based
12 its review upon industry-sponsored articles and studies. CARC compounded this error by
13 ignoring relevant studies so as to only examine risk analysis, not hazard analysis, i.e., the general
14 causation issue.
15
16
17

18 EPA’s carcinogenicity review of glyphosate relied heavily on Greim, et al. (2015),
19 Williams (2000) and Kier & Kirkland (2013).³⁰ EPA Memorandum, GLYPHOSATE: Report of
20 the Cancer Assessment Review Committee, October 1, 2015 at 8; EPA Issue Paper, September
21

22 ²⁸ U.S. EPA, Guidelines for Carcinogen Risk Assessment, available at,
https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

23 ²⁹ https://www.iarc.fr/en/media-centre/iarcnews/pdf/Q&A_Glyphosate.pdf.

24 ³⁰ Greim, et al. (2015), Evaluation of carcinogenic potential of the herbicide glyphosate,
25 drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies, *available*
26 *at* <http://www.tandfonline.com/doi/full/10.3109/10408444.2014.1003423>; Kier & Kirkland
27 (2013), Review of genotoxicity studies of glyphosate and glyphosate-based formulations,
available at <http://www.tandfonline.com/doi/full/10.3109/10408444.2013.770820>; Williams
28 (2000), Safety Evaluation and Risk Assessment of the Herbicide Roundup1 and Its Active
Ingredient, Glyphosate, for Humans, *available at*
<http://www.msaf.gob.ar/agroquimicos/pdf/Williams-et-al-2000.pdf>.

1 2016, at 22. The Greim article, co-authored by a Monsanto employee, offers Monsanto's
2 opinions related to thirteen industry animal studies that have not been subjected to the peer-
3 review process, and was newly submitted to the Agency as part of OPP's current review of
4 glyphosate. Importantly, the Greim article does not include sufficient underlying data to support
5 the conclusion; as a result, the article was not, and could not have been, considered by IARC.
6 IARC evaluates review articles to determine whether the authors provide sufficient information
7 about the data reviewed in order to arrive at their conclusion; if they do not, then IARC does not
8 consider it because it cannot perform an independent analysis. Preamble at 18.
9

10 The importance of IARC's review, and alternatively EPA's flawed review, is highlighted
11 by the fact that Monsanto's Toxicology Manager, David Saltmiras, was a ghost-writer on the
12 Kier & Kirkland publication and Bill Heydens, Saltmiras's boss, was a ghostwriter on the
13 Williams (2000) article.³¹ The EPA may be unaware of Monsanto's deceptive authorship
14 practice and therefore accepted representations about 17 genotox studies reported in the Kier &
15 Kirkland article without having looked at the original reports. See EPA Position Paper,
16 September 2016, page 8. In the Greim paper, at least one study was omitted from the manuscript
17 (and thus omitted from the EPA review) because "the original mouse data suggested some
18 carcinogenic potential." Ex. 13, MONGLY01009950. Therefore, Monsanto's corporate
19 practices have long controlled the literature.
20
21

22 **D. There is Disagreement within EPA Whether the OPP Assessment is Valid**
23

24
25 ³¹ See attached Ex. 11, MONGLY02145917, (Saltmiras removed as author in part and
26 non-Monsanto employee David Kirkland added because "manuscript turned into such a large
27 mess of studies reporting genotoxic effects, that the story as written stretched the limits of
28 credibility among less sophisticated audiences."); Ex. 12, MONGLY00977264 ("we would be
keeping the cost down by us doing the writing and they would just edit & sign their names so to
speak. Recall that is how we handled Williams Kroes & Munro, 2000.").

1 There is no clear consensus on the glyphosate analysis even within the EPA. Recently
2 published internal documents obtained in a Freedom of Information (FOIA) request filed by The
3 Free Market Environmental Law Clinic³² reveal that when the EPA's Office of Research and
4 Development (ORD) scientists reviewed and commented on OPP's glyphosate cancer analysis,
5 ORD scientists *agreed* with IARC that "'a positive association has been observed' for which a
6 causal association is Credible, but chance, bias, or confounding could not be ruled out with
7 reasonable confidence." *See* Office of Research and Development, Summary of Comments on
8 OPP's glyphosate cancer assessment (December 14, 2015), attached here as Exhibit 14.
9

10 The ORD reviewers also noted that "the analysis of the cancer data in the [OPP]
11 assessment was basically conducted on a study-by-study basis instead of using a more inclusive,
12 systematic approach to provide an integrated analysis of the data." The authors of the Reference
13 Manual of Scientific Evidence call this technique "atomization," and in disapproving this
14 "slicing and dicing" approach state that:
15

16 scientific inference typically requires consideration of numerous
17 findings, which, when considered alone, may not individually
18 prove the contention. It appears that many of the most well-
19 respected and prestigious scientific bodies (such as the
20 International Agency for Research on Cancer (IARC), the Institute
21 of Medicine, the National Research Council, and the National
22 Institute for Environmental Health Sciences) consider all the
relevant available scientific evidence, taken as a whole, to
determine which conclusion or hypothesis regarding a causal claim
is best supported by the body of evidence.

23 *Id.* at 20.

24 It is vitally important that all conflicts of interest and bias be eliminated where possible.
25 "[M]ethodology that is 'biased toward a particular conclusion' ... does not 'comport[] with the
26

27 ³² These documents are available on the FOIA website:
28 <https://foiaonline.regulations.gov/foia/action/public/view/request?objectId=090004d280e576c0>.

1 dictates of good science.” *Perez v. State Farm Mut. Auto. Ins. Co.*, No. C 06-01962 JW, 2012
2 WL 3116355, at *6 (N.D. Cal. July 31, 2012) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43
3 F.3d 1311, 1320 (9th Cir.1995). EPA is plagued with bias. As Plaintiffs have already briefed in
4 the motion to compel the deposition of Jess Rowland, EPA employees are unduly influenced by
5 Monsanto. Plaintiffs herein incorporate that brief by reference, as well as the opposition to seal
6 the documents to that brief.³³ Specifically, Plaintiffs seek the deposition of Jessie Rowland as
7 the former head of the CARC as the core piece of discovery to evaluate the EPA’s inherent flaws
8 and biases. Similarly, the parties have agreed to, and are in the process of scheduling, the
9 deposition of Dr. Aaron Blair (Overall Chair of the IARC Working Group assessing Glyphosate
10 and Scientist Emeritus at the National Cancer Institute) where the parties will be free to explore
11 the scientific process that resulted in the IARC monograph on glyphosate.
12

14 **CONCLUSION**

15 For the reasons stated above, Plaintiffs respectfully submit that IARC’s methods, studies,
16 reports and conclusions are relevant to general causation, but methods, studies, reports and
17 conclusions of the EPA are not relevant to general causation.
18

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Respectfully submitted,

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³³ However, if the Court allows Monsanto’s experts to rely in whole or in part on EPA conclusions, Plaintiffs should be allowed to conduct discovery on these flawed assessments.

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