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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC
This document relates to all cases	Hearing: February 27, 2017, 9:30 a.m. Courtroom 4, 17h Floor, N.D. Cal. San Francisco, CA

PLAINTIFFS' SUBMISSION IN RESPONSE TO PRETRIAL ORDER NO. 8

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

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

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

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

I. IARC IS RELEVANT TO GENERAL CAUSATION

A. IARC: The Gold Standard for Scientific Cancer Assessments

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

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

[2] The United Nations World Health Organization founded IARC in 1965 "to promote international collaboration in cancer research." IARC's Statute, Rules, and Regulations, Fourteenth Edition (IARC Statute), Art. I, at 5-6, (Ex. 1, excerpts from IARC statute.) The United States was a founding member of IARC and, as of the date of this memorandum, remains a member. *Id.* at 5, 27 (Ex. 1). Each IARC member state nominates scientific experts to 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/.

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

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

> IARC, a well-regarded international public health agency, evaluates the human carcinogenicity of various agents. In doing so, IARC obtains all of the relevant evidence, including animal studies as well as any human studies. On the basis of a synthesis and evaluation of that evidence, IARC publishes a monograph containing that evidence and its analysis of the evidence and provides a categorical assessment of the likelihood the agent is 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.***

[4] Monograph, at 350 (citing meta-analysis showing a statistically significant increase in NHL).

[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.

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

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

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

[7] https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-14-503.html#_Part_2._Full

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

[9] California's Carcinogen Identification Committee deems IARC an authoritative body 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.

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

B. IARC's Assessment Process

Each IARC assessment is published in the form of a "Monograph," which comprises a Preamble (*see IARC Monographs on the Evaluation of Carcinogenic Risks to Humans,* Preamble, 2006, Ex. 2) (hereinafter "Preamble") and "critical reviews and evaluations of evidence of the carcinogenicity of a wide range of human exposures." *Id.* at 2. Monographs are "used by national and international authorities to make risk assessments, formulate decisions concerning preventive measures, provide effective cancer control programmes and decide among alternate options for public health decisions." *Id.* at 3.[12] IARC's assessment process is a year-long endeavor, described in detail in the Preamble, which involves a review of peer-reviewed scientific literature and data from publicly-available government agency reports. *Id.* at 4.

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

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

[11] http://oehha.ca.gov/proposition-65/crnr/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.

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

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

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

[13] http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-F03.pdf.

[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.

agency that "promote[s] international collaboration in cancer research" and "[i]dentifies agents that increase risk of human cancer." *Id*. at Slide 2. Monsanto understood that because of IARC's reputation, a finding of carcinogenicity would "disrupt our narrative," and "call into question the safety of glyphosate/Roundup, putting industry on the defensive." *Id.* at Slide 6.[15] In reaction to IARC's determination that glyphosate is a probable carcinogen, Monsanto has engaged in an aggressive media and political attack on IARC generally and the Monograph 112 members specifically, an unprecedented reaction in the cancer agency's 40-year history of reviewing carcinogens.

C. Judicial and Industry Reliance on IARC

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

[15] Monsanto has spoken favorably about IARC's methodology in court filings in other cases as well. In *Town of Lexington v. Pharmacia, et al*., C.A. No. 12-CV-11645, Rec. Doc. 263, for example, a case involving harm caused by polychlorinated biphenyls (PCBs), Monsanto 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.

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

II. EPA'S ACTIONS ARE FLAWED, BIASED, AND IRRELEVANT TO GENERAL CAUSATION

A. EPA Does Not Review The Carcinogenicity of Roundup®

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

EPA's minimal standards do not require human health data submissions related to the formulated product—here, Roundup®. Instead, EPA regulations require only studies and data

[16] Although not directly on point and based on facts different than those here, the Fifth Circuit Court of Appeals mentioned IARC's "weight of the evidence" standard in the context of assessing reliability required for admission of expert opinions in two cases, expressing 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).

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

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

Potentially in an effort to correct the flaws in its pesticide registration analysis, following IARC's classification of glyphosate as a 2A carcinogen, the EPA delayed re-registration of

[17] In 1992, the Health Effects Division (HED) within EPA's OPP determined that regulation of metabolites in glyphosate need not be regulated based on toxicological considerations regardless of levels observed in food or feeds. *See*, MONGLY02811704-2811785 at 2, dated June 2, 2009, (hereinafter, "Scoping Document") (attached as Ex. 8).

[18] One of the ingredients in the formulated product is polyethozylated tallow amine (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.

glyphosate (the process began in 2009) and asked Monsanto to submit additional studies.[20] These EPA requests included materials Monsanto did not previously submit to the agency. Most notably, the EPA specifically requested European cancer data that Monsanto previously submitted to the German Federal Institute for Risk Assessment (BfR) but not to the EPA.[21] The EPA has not yet issued a final decision related to the review of these newly obtained materials.

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

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

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

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

[23] The OPP assessment is not yet final. The issue paper and proposed conclusion was supposed to be submitted for peer review in October 2016, but that assessment was then 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.

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

In stark contrast, IARC's review of glyphosate included data relating to the manner in which it is used in the real world—as one of the ingredients of the Roundup® formulation—and furthermore, necessarily included "high dose" and "injected" studies because these are studies that can determine the carcinogenic potential of both glyphosate and Roundup®.

C. EPAs "Cancer Risk Assessment" for Glyphosate Is Flawed

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

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

[26] *Id.* at 70.

[27] EPA, Glyphosate: Evaluation of Carcinogenic Potential, Charge to the FIFRA SAP for 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).

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

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

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

[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.

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

[30] Greim, et al. (2015), Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies, *available at* http://www.tandfonline.com/doi/full/10.3109/10408444.2014.1003423; Kier & Kirkland (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 (2000), Safety Evaluation and Risk Assessment of the Herbicide Roundup1 and Its Active Ingredient, Glyphosate, for Humans, *available at* http://www.msal.gob.ar/agroquimicos/pdf/Williams-et-al-2000.pdf.

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

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

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

[31] See attached Ex. 11, MONGLY02145917, (Saltmiras removed as author in part and non-Monsanto employee David Kirkland added because "manuscript turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of 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.").

There is no clear consensus on the glyphosate analysis even within the EPA. Recently published internal documents obtained in a Freedom of Information (FOIA) request filed by The Free Market Environmental Law Clinic[32] reveal that when the EPA's Office of Research and Development (ORD) scientists reviewed and commented on OPP's glyphosate cancer analysis, ORD scientists ***agreed*** with IARC that "'a positive association has been observed' for which a causal association is Credible, but chance, bias, or confounding could not be ruled out with reasonable confidence." *See* Office of Research and Development, Summary of Comments on OPP's glyphosate cancer assessment (December 14, 2015), attached here as Exhibit 14.

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

> scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention. It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine, the National Research Council, and the National 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.

Id. at 20.

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

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

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

CONCLUSION

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

DATED: February 8, 2017

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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