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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 ACTIONS	

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF THEIR OPPOSITION TO MONSANTO'S *DAUBERT* AND SUMMARY JUDGMENT MOTION AND IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE MONSANTO'S EXPERTS

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I. INTRODUCTION

The methodology applied by Monsanto's experts turns not on sound science but rather on whether the evidence at issue is favorable or unfavorable to Monsanto's position. Where the evidence is favorable, it receives minimal scrutiny and Monsanto's experts often fail to find *any* flaws or shortcomings. Yet when the evidence shows a positive association between exposure to glyphosate-based formulations (GBFs) and Non-Hodgkin Lymphoma (NHL), Monsanto's experts concoct an inquiry that consistently leads them to disregard the positive evidence in its entirety. Inconsistencies or controverting evidence do not curtail this approach. Rather, when confronted with reliable positive evidence of causation, Monsanto's experts develop novel methods to discount findings, including manufacturing new theories or facts. Such an approach is inherently unreliable and precluded by *Daubert*. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 154 (1999).

Instead of addressing these profound methodological shortcomings, Monsanto's Reply and Opposition brief focuses largely on one study—the now published 2017 AHS study[1]—that it believes is methodologically sound and predominates over all other scientific evidence. In so doing, Monsanto fails to respond in any meaningful way to myriad concerns that render its experts' reliance on and opinions drawn from that study inadmissible. Monsanto further fails to respond to the numerous flaws in its experts' evaluations of toxicological and genotoxic evidence that render those opinions inadmissible.

[1] There are now three interim analyses of the still ongoing AHS study which address the use of glyphosate and the risk of NHL. De Roos (2005) reported the results of NHL cases collected up to 2001 and used the initial questionnaires (1993-1997). There was an unfinished, unpublished manuscript from 2013, which collected NHL cases up to 2009 and used data from follow-up questionnaires completed by only 63% of participants from 1999-2004. The author of that manuscript stated it would be irresponsible to rely on it. The unpublished manuscript was subject to Plaintiffs' Cross-Motions. There is now a recently published manuscript, which uses the same methodology as the unpublished manuscript with the only difference being that NHL cases are collected through 2013. It is unclear when or if the final study results will be analyzed or published as there is now updated exposure data through 2010 that has not yet been included in any study.

II. DR. MUCCI AND DR. RIDER FAILED TO CRITICALLY EVALUATE THE UNPUBLISHED AHS

Monsanto ignores the substantial weight of evidence, which demonstrates a clear, statistically significant, elevated association between glyphosate exposure and NHL, and focuses exclusively on the AHS. In fact, as evaluated by IARC and Plaintiffs' experts, "case-control studies of occupational exposure in the USA, Canada, and Sweden reported increased risks for non-Hodgkin lymphoma that persisted after adjustment for other pesticides,"[2] despite the fact that the AHS did not show an increased risk. These other studies consistently show a positive association between exposure to GBFs and NHL. The AHS, a cohort study, is an outlier for good reason: false negative findings are inherent in its design. And in light of its substantial methodological flaws, which are magnified in the recently published study, the AHS does not erase or otherwise diminish the consistent positive findings in the case-control studies.

Monsanto misconstrues Plaintiffs' motion to exclude the opinions of Dr. Mucci and Dr. Rider regarding the unpublished AHS; indeed, it fails even to address the multiple flaws of the study. Plaintiffs did not argue before, nor do they argue now, that Monsanto's experts' opinions should be excluded solely because the study was not peer-reviewed; rather, their opinions are not reliable because their methodology deviates from established scientific norms in evaluating the updated AHS data. *See e.g.* Pls. Opp. at P. 37, fn. 107. The defects Plaintiffs identified in their motion to exclude Drs. Mucci and Rider's opinions—which were identified before the recent publication of the AHS article—apply equally to the now published 2017 AHS study, which uses the same methodology as the draft manuscript.[3]

Unlike Plaintiffs' experts, who objectively assess the strengths and weaknesses of all studies related to GBFs and cancer, Dr. Rider and Dr. Mucci fail to fairly review all studies and particularly refuse to consider any of the obvious flaws in the unpublished updated AHS

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[2] Guyton, et al., "Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate." The Lancet Oncology, Vol 16 May 2015, p. 460. *Available at*: http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(15)70134-8.pdf

[3] Presumably, Dr. Mucci and Dr. Rider will no longer be relying on the draft AHS manuscript in this litigation now that an updated peer-reviewed version has been published.

analysis.[4] Mucci Rep. at 35 ("[o]ne minor weakness is that the updated analysis on glyphosate and other herbicides has not been published to date."); Rider Rep. at 28-29. Dr. Mucci and Dr. Rider selectively criticize all studies showing a positive association with glyphosate and NHL but accept the methodology of the now published 2017 AHS study without critique. This disparate treatment of positive and null studies "raises an inference of unreliable application of methodology." *In re Zoloft (Sertraline Hydrochloride) Products Liab. Litig*., 858 F.3d 787, 797 (3d Cir. 2017).

Some flaws, of course, are inherent in all epidemiology studies. The Reference Manual instructs that "[i]t is important to emphasize that all studies have 'flaws' in the sense of limitations that add uncertainty about the proper interpretation of the result." Reference Manual at 553; *Cooper v. Takeda Pharm. Am., Inc*., 239 Cal. App. 4th 555, 589, 191 Cal. Rptr. 3d 67, 95 (2015), review denied (Oct. 28, 2015) ("All studies have limitations and flaws... but if most studies consistently reach a similar answer, that gives confidence to an epidemiologist that the answer is correct.").[5] The Monsanto-commissioned 2016 Exponent report agrees: "[i]n epidemiology, there is no universal 'ideal study design.' ...A prospective study design is often preferred, but not for rare outcomes, especially those with a long latency period during which study attrition might be high."[6] But the AHS, in particular, suffers from critical defects that the

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[4] This cherry-picking of studies by Dr. Rider and Dr. Mucci is highlighted by other discrepancies between their litigation methodology and their academic methodology. For example, in this litigation they rely heavily on an incomplete draft manuscript, yet only skim the authoritative IARC monograph. Rider Dep. at 41:3-8 ("I definitely skimmed over the entire thing"); Mucci Dep. at 69:9-11 ("I read the parts specifically related to the epidemiology, and then read through less diligently the other parts.") However, both experts cite to IARC as an authority on cancer etiology in their own publications. *See*, Sigurdardottir, Rider, Mucci, et al. "Sleep Disruption Among Older Men and Risk of Prostate Cancer: Cancer Epidemiol Biomarkers Prev. 2013 May ; 22(5): 872–879; Rider Dep. at 265:16-266:7.

[5] This is not unusual, as Dr. Neugut notes that "the entire epidemiology methodologic system is set up to be conservative, so that null findings are the norm. We don't want to find positive findings. The system is set up not to find positive findings. It's biased, for lack of a better word, to avoid finding positive findings...when you have a positive finding, it's taken more seriously than when you have a null finding." Neugut Dep. at 101.

[6] Exponent "Design of Epidemiologic Studies for Human Health Risk Assessment of Pesticide Exposures" Prepared for CropLifeAmerica, 1/24/2016, MONGLY02314040. Exhibit 53 to Pl. Opp.at 29.

Reference Manual, Exponent and most others who have reviewed the AHS deem fatal to its reliability. Exponent noted that attrition in the AHS was exceptionally high, stating "participation in follow-up questionnaires was also highly incomplete." *Id.* at 19. Experts on both sides agree that NHL is a rare outcome. Rider Dep. 113:10-16; Ritz Rep. at 12-13; Neugut Rep. at. 4-5. Given the extremely low participant follow-up response rate, coupled with the exponential increase in GBF use from the time of the first questionnaire to follow-up, the AHS is not an appropriate study design to answer the question of whether glyphosate causes NHL.

A. <u>False Negative Results Are Inherent in the Design of the AHS Study</u>

The AHS was, due to inherent design flaws, was destined to show false negative results from the outset. Neither Monsanto, nor its experts, address the plethora of flaws in the AHS data analysis, which they themselves openly acknowledged prior to this lawsuit. Instead, Monsanto ignores its pre-litigation critiques of the AHS methodology, now claiming its critiques were not specific to glyphosate but rather to the study in general. Def. Reply at 19. However, *Daubert's* inquiry focuses upon the soundness of methodology. It is neither credible, nor scientifically valid, to criticize a study's methodology *a priori* and then retract those criticisms when the results prove to be favorable to a litigation position.

The biases of a study arise from the original design of the data collection protocol and do not simply disappear once the results arrive.

> Epidemiologists attempt to minimize bias through their study design, including data collection protocols. Study designs are developed before they begin gathering data. However, even the best designed and conducted studies have biases, which may be subtle.. Consequently, after data collection is completed, analytical tools are often used to evaluate potential sources of bias. Sometimes, after bias is identified, the epidemiologist can determine whether the bias would tend to inflate or dilute any association that may exist.

Reference Manual at 574.

With respect to the collection protocol of the AHS, there was universal agreement, including within Monsanto, that the exposure assessment would be ***inaccurate*** and produce ***false negative results*** for the subject pesticides. John Acquavella, Monsanto's epidemiology consultant

and former employee, noted at the outset of the AHS study in 1997 that "[t]he ***exposure assessment in the AHS will be inaccurate***... Inaccurate exposure classification can produce spurious results. The conventional thinking in epidemiology is that exposure misclassification will most often obscure exposure disease relationships." Exhibit 1 (emphasis added).[7] The Monsanto commissioned 2000 Harvard Study noted that exposure "[m]isclassification will reduce the power of the study to detect any genuine cause-effect relationships and will also reduce the validity of findings. Reductions in power are a serious issue because they will undermine the ability of government and industry to regulate harmful exposures and to reassure farmers with 'negative' results."[8] *Id*. at 58.

The lead investigators of the AHS share these concerns. Dr. Aaron Blair published a paper in 2011 describing this bias in the AHS and concluded, "false negative findings might be common."[9]; Neugut Dep. 334:25-337:6. At his deposition, Dr. Blair noted that exposure misclassification "most likely causes false negatives" in cohort studies. Blair Dep. at 88:16-89:2. In a publication using the updated AHS data to analyze the association between non-glyphosate-based pesticides and NHL, the authors caution that "[m]isclassification of pesticide exposures can occur and can have a sizeable impact on estimates of relative risk, which in a prospective cohort design would tend to produce false negative results."[10] With respect to glyphosate, "some misclassification of exposure undoubtedly occurred."[11]

Because of these flaws, scientists do not consider the AHS cohort to be dispositive in evaluating the carcinogenicity of pesticides. Instead, glyphosate is considered a carcinogen

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[7] July 22, 1997 Memo re: "Background Thoughts for the Communications Subcommittee Farmers' health profile," MONGLY00885870.
[8] Gray, et al. The Federal Government's Agricultural Health Study: A Critical Review with Suggested Improvements Human and Ecological Risk Assessment : Vol. 6, No. 1, pp. 47-71 (2000), p. 58; Exhibit 71 to Pls. Opp.
[9] Blair, et al. "Impact of pesticide exposure misclassification on estimates of relative risks in the Agricultural Health Study," Occup Environ Med, published online January 21, 2011. Exhibit 73 to Pls. Opp.
[10] Alavanja, M. et al., "Non-Hodgkin Lymphoma Risk and Insecticide, Fungicide and Fumigant Use in the Agricultural Health Study", 9 PLoS One (2014).. Ex. 76 to Pls. Opp.
[11] Andreotti, et al. (2018) *Glyphosate Use and Cancer Incidence in the Agricultural Health Study* JNCI J Natl Cancer Inst, 110(5).

despite negative findings in the AHS because sound methodology and reputable experts do not consider one study in isolation in determining causality, rather:

> [S]cientific 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. In applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed... "[t]he final overall evaluation is a matter of scientific judgment reflecting the weight of the evidence derived from studies in humans, studies in experimental animals, and mechanistic and other relevant data."

Reference Manual at 19-20.

Despite the universal agreement, *a priori*, that the AHS would produce false negatives, Dr. Mucci and Dr. Rider never bothered to read these criticisms or to consider the AHS's critical flaws. Because they did not consider all of the relevant scientific evidence, their opinions regarding the updated AHS (both the unpublished and published version) demand exclusion. *See McEwen v. Baltimore Washington Med. Ctr. Inc.*, 404 F. App'x 789, 791 (4th Cir. 2010) (excluding expert who "failed to meaningfully account for medical literature at odds with their testimony.").

B. Changing Glyphosate Use Patterns Exacerbate the Flaws In the Updated AHS Analysis

While the methodology of the now published 2017 AHS study tends to produce false negative results for any pesticide, the problem is exacerbated by the dramatically increased use patterns of glyphosate. Dr. Ritz considered changing use patterns; Drs. Rider and Mucci did not. *See, e.g.*, Ritz Dep. 20:15-24:13, 431:1-432; Ritz Rep. 22; Neugut Rep. 13; Ritz Rebuttal Rep. at 2-3. The EPA Scientific Advisory Panel Report even noted this concern:

> The exposure data collected were for the period prior to 1993-1997 when exposures to glyphosate are assumed to have been low. The exposures measured do not adequately capture possibly much higher exposures cohort members likely experienced after the introduction of transgenic crops in 1995. **Failure to update exposure data in follow-up implies that the exposure estimates used in the analysis may be, and are most likely**

significantly underestimated and there would have been misclassification of exposure. SAP report at 32 (emphasis added). The Harvard study likewise noted that "[t]he low and variable response rates to the supplemental questionnaires seriously affect the quality of the AHS" and that "[t]he success of the cohort study also depends upon acceptable response rates to future follow-up surveys of the cohort . . . to determine how exposures and disease states change as the cohort ages." The Harvard Study at 52.

Neither Dr. Rider nor Dr. Mucci even considered the Harvard study or the final EPA SAP report in their analyses. Rider Dep. at 267:17-271:18; Mucci Dep. at 186:7-21 ("I believe I briefly looked at part of it. However, I did not read through the entire document, and it was not part of my evaluation one way or the other of the epidemiology studies."). This alone should render their opinions inadmissible in total but, at a minimum, it renders their opinions regarding the AHS unreliable. *See* PTO 15, at 2 ("Any expert testifying about general causation will, for his opinion to be admissible, almost certainly need to account for the conclusions reached by these agencies."). Even a cursory review of the IARC monograph reveals that glyphosate use has "risen dramatically . . . with the introduction in 1996 of genetically modified glyphosate-tolerant crop varieties." Monograph 112, at 3.

Additionally, Drs. Rider and Mucci do not address the flaws inherent with data imputation, which the now published 2017 AHS study does not cure. There were two follow up questionnaires to the original AHS questionnaire. Among cohort members from the period 1998-2004, ***36% did not respond***. In the second follow-up survey, ***only 46%*** of the study participants responded. Thus, ***over one-third of all cohort subjects never reported*** actual exposures or changes in exposures after initial enrollment in 1993. *Id*. at 34. The now published 2017 AHS study states that for these non-responders, "a data-driven multiple imputation procedure was used to impute pesticide use since enrollment." *Id*. at 2. Given that GBF use increased by 3,900% from 1993 to at least 2014, imputation of glyphosate use data for non-responders yields unreliable results to the instant litigation. The Exponent report acknowledged that "only 44% of enrolled pesticide applicators completed the detailed take-home questionnaire shortly after enrollment, and participation in follow-up questionnaires was also highly incomplete." Pl. Opp. at 32. Both the

published and unpublished versions of the AHS study utilize the exposure data suffering from this high degree of attrition. It necessarily cannot be relied on to determine whether there is an association between GBFs and NHL because there is insufficient data to make that determination.

Dr. Ritz explains the flaw of applying imputation to the AHS due to the low follow-up response rate as follows:

> The AHS researchers attempted to address the loss of active participants with a method called 'imputation' to avoid having large amounts of missing exposure data – for those who did not respond – or generating selection bias (cohort studies may be affected by selection bias due to 'differential' loss to follow-up among the exposed or unexposed cases and controls). . . . This procedure assumes that it is sufficient to use the data in hand to predict/guestimate all future exposures in AHS participants who did not respond; i.e. that the past and current exposures and characteristics of the participants who responded to multiple interviews over time would accurately predict the use of those who did not respond. For glyphosate/ GBFs with a use pattern change as dramatic as described above, it is a flawed approach to predict who would or would not start using Roundup Ready crops after baseline, and otherwise to predict the use of glyphosate/GBFs.

It is this imputation that the AHS researchers describe as an "untestable assumption."[12]

The updated AHS, both the recently published and unpublished versions, do not include the follow-up questionnaire used from 2005-2010; therefore the study is far from complete. Since 36% of the participants in the updated AHS only provided exposure data from 1993-1997, there is a 15-20-year period where it is impossible to know whether the participant used GBFs.[13] Therefore, numerous participants likely started using GBFs after 1997, developed NHL before 2013, and are counted in the study as people unexposed to GBFs. For the remaining 64% who filled out a second questionnaire from 1999-2004, there is a period of 8-14 years where it is impossible to know whether they used GBFs. Thus, even with this partially updated data, some responders could have filled out the follow-up questionnaire in 2000, started using GBFs in 2001, and developed NHL sometime over the next 12 years; yet the AHS would count them as

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[12] S.L. Heltshe, et al. *Using multiple imputation to assign pesticide use for nonresponders in the follow-up questionnaire in the Agricultural Health Study*. 22 J. EXPO. SCI. ENVIRON. EPIDEMIOL.4, 409-416 (2012). Ex. 78 to Pls. Opp.

[13] In the now published 2017 AHS study, NHL cases were collected up to 2012 in North Carolina and 2013 in Iowa.

unexposed.

The second questionnaire is particularly troublesome, too; it only asks for the most recent year of pesticide use. 2017 AHS Study at 2. Therefore, a participant could have filled out the first questionnaire in 1993; started using GBFs in 1995; retired in 2002; filled out the second questionnaire in 2004; and developed NHL over the next eight years. This person with NHL and substantial GBF use would be counted as unexposed to GBFs.

Dr. Mucci and Dr. Rider's opinions regarding the unpublished AHS should be excluded because of their failure to examine the obvious flaws of the study. Plaintiffs maintain that the unpublished, unfinished AHS manuscript itself should be excluded for the reasons articulated in Plaintiffs' Response brief.[14] Thus, it follows that Dr. Rider and Dr. Mucci's opinions regarding the unpublished AHS's methodology, which apply equally to the now published 2017 AHS study, should be excluded for failing to meaningfully consider any of the well-publicized and unavoidable flaws of the study, which tend to cause false-negatives.

III. DR. FOSTER IS UNQUALIFIED, UNRELIABLE, AND MUST BE EXCLUDED

Dr. Foster's expertise is unrelated to the opinion he purports to offer in this case, and he was unable to confirm whether he considers himself an expert in animal toxicology.[15] Dr. Foster's past Health Canada and academic employment, as well as his current employment, relates to reproductive toxicology. Foster Rep. 4. Dr. Foster's academic awards, government recognitions, and other honors are solely for his contributions to reproductive toxicology. Foster Rep. 49-50. Finally, contrary to Monsanto's opposition, less than eight of Dr. Foster's 178

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[14] Both Dr. Ritz and Dr. Neugut acted consistently and appropriately in not relying on unfinished manuscripts. Defendant mischaracterize Dr. Neugut's testimony. Dr. Neugut explained that in another litigation, he had made a mistake in reviewing some unpublished results prior to a deposition; but "did not rely upon it in actual litigation subsequently in any of the testimony that I gave in any of the trials." Neugut Dep. at 191:12-192:5, 254:4-18. Defendants also falsely state that Dr. Ritz relied on the unpublished NAPP manuscript when Dr. Ritz relied only on the published abstract from the NAPP study. Opp. at 27 n.76; Ritz. Dep. at 288:20-289:17.

[15] *See* Foster Dep. 71:11-17 ("Q: I just want to make the record clear that as you sit here today, you are offering an opinion as an animal toxicologist – expert in animal toxicology. A. Okay. To be full in my answer, I am a – have expertise as a toxicologist, and I have been asked to provide my expert opinion on the animal literature – in this litigation.").

publications include assessments of rodents and/or pesticides studies. *Id.* at 119:4-122:15.[16] Rule 702 requires that a witness be qualified "by knowledge, skill, experience, training or education" to render an opinion. FRE 702. Expert testimony is admissible only if the expert is qualified. *See Morton & Bassett, LLC v. Organic Spices, Inc*., 2017 WL 3838097 (N.D. Cal. 2017). The reliability prong envisioned by *Daubert* necessarily questions whether the expert demonstrates "a reliable basis in the knowledge and experience of the relevant discipline." *Kumho*, 526 U.S. at 138. While Dr. Foster's experience at Health Canada and as a professor is impressive, it is not relevant to the instant inquiry and fails the *Daubert* reliability prong.

Monsanto's insistence that Dr. Foster's "clear language" supports the claim that he applied consistent methodology is misdirected. Pl. Opp. at 47-48. Dr. Foster does not list factors he "finds important when examining the rodent toxicology data" (Def. Reply at 48); rather, he lists conclusory statements and assigns weight to each study based on subjective, unsupported and arbitrary facts. Foster Rep. at 6-7. Two of Dr. Foster's methods merely reiterate good laboratory practices, (for instance, he assigns greater weight to studies using three dose groups and with a maximum tolerated dose threshold of 1,000 mg/Kg/day and to studies that use at least 50 animals in each treatment group), while the other two relate to Dr. Foster's belief that tumor progression is necessary in answering whether the tumors seen in this data set are compound-related. Foster Rep. at 7.

Monsanto's defense of his opinions fails to address the methodology Dr. Foster purportedly applied. In fact, Monsanto fails to identify any acceptable methodology to support Dr. Foster's dismissal of tumors merely because he did not observe tumor promotion and progression in the studies. As Plaintiffs explain in their *Daubert* motion, reliance on observances

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[16] Foster Dep. 119:1-122:15 (Dr. Foster was asked, "Have you done any studies that relate to pesticides in association with cancer?" Dr. Foster identified publications: 43 – a study that looked at mammary gland differentiation, but did not involve pesticides; 64 – a study using the chemical Dieldrin to observe mechanistic effects in transgenic mice; 65 – a study that looked at a dietary supplement; 79 – a study with students that observed cancer incidences of Dieldrin with a focus on breast cancer; 99 – a study that dealt with chemicals and looked for cell mutations; 121 & 122 – related studies that dealt with complex chemicals, believed to include pesticides, with the purpose of recording systemic, immune, and reproductive effects; 138 – an *in vitro* study using industrial chemicals.).

of tumor promotion is inappropriate in this instance because the animals in the related carcinogenicity studies are observed only at death, making evidence of tumor progression impossible. (Pl. Opp. at 68-9 & n. 201).[17] Moreover, Dr. Foster primarily relied on the supplemental Greim tables to arrive at his opinion. These tables do not report the presence or non-presence of pre-neoplastic lesions or the tissues surrounding the noted tumor incidences. Dr. Foster simply has no basis to reject tumors based on lack of evidence of tumor progression.

Further, Dr. Foster inconsistently applies his stated methodology. Dr. Foster claims to assign greater weight to those studies with four dose groups and in which the highest dose group achieves or nears the "limit" dose of 1,000 mg/kg/day because this study design allows for assessment of the dose-response relationship. Foster Rep. at 7. Dr. Foster warns, however, that in studies where the high dose group shows adverse health effects or toxicity, such observances "mitigate" the results. *Id.*

For instance, the original study authors of the Knezevich mouse study reported kidney tumors in the male, mid- and high-dose groups, showing a positive, statistically significant trend. Portier Rep. at 36-38; Jameson Rep. at 20-21. Yet, as explained in Plaintiffs' moving brief, Dr. Foster then improperly applies this rationale to the Knezevich and Hogan study and concludes, without support, that an 11% weight loss factored into his conclusion that the four kidney tumors found in the male mice were not compound related. Pl. Opp. at 69; *see also* Foster Rep. 21-22. Conversely, in the Brammer rat study (a study that exceeded the requisite "limit" dose threshold), the authors reported an increased incidence of liver adenomas in the low and high dose groups, noting two and five tumors, respectively. Foster Rep. at 17. Dr. Foster's evaluation of the Brammer study noted no weight loss in the highest dose groups, and, to the contrary, that the highest dose group males "were more robust." Foster Rep. at 17. He noted no other source of adverse toxicity either. Nonetheless, rather than assigning "greater weight" as dictated by his

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[17] Monsanto does not substantively reply to Plaintiffs' argument related to tumor progression. Instead, its defense is slipped into footnote 86 but is unsupported: "Plaintiffs' other objections to Dr. Foster's testimony (opinions regarding tumor progression and loss of body weight) are similarly without merit as Dr. Foster's methodology is based upon established scientific factors. S*ee, e.g.*, Tarazona 2017 at 4 (noting "reduced body weight")."

purported methodology when evaluating the Knezevich study, Dr. Foster concludes here that the tumors in the Brammer study are likely because the animals lived longer, and, thus, the tumors had more time to spontaneously emerge. Foster Rep. at 17. A review of Dr. Foster's expert report and opinions demonstrate that he applies his methodologies on an ad hoc basis and to ensure that they support his objective to dismiss tumor incidences and to declare a study negative.

Lastly, Dr. Foster's failure to cite support for conclusory statements evinces the unreliable nature of his testimony, not that he failed a "memory test" as Monsanto claims. Def. Reply at 49. Dr. Foster's expert report was available to him for the entirety of the deposition; he could not offer (and has not offered) a single citation to support his statement that the high dose group males in the Knezevich and Hogan study showed an 11% weight loss. Further, this is only one such example where Dr. Foster either failed to cite supporting authority or cited to inapplicable authority.[18] Dr. Foster's lack of command over the materials and failure to follow sound methodology in support his conclusions render his opinion inadmissible.

IV. Dr. Corcoran's Basic Misunderstanding of Toxicology Renders His Opinions Inadmissible

Monsanto's defense of Dr. Corcoran based on his experience and/or past federal grants is unavailing. *See* Def. Reply at 49-50. The factual basis for excluding in total Dr. Corcoran's opinions resides in his deposition testimony in which he details his superficial statistical analysis in this case. Dr. Corcoran conceded that he does not know the difference between primary and secondary tumors. Corcoran Dep. 150:12-151:5. Therefore, unlike Dr. Portier, Dr. Corcoran did

[18] *See* Foster Dep. 212:15-214:2 and Foster Rep. at 16 (Dr. Foster's expert report cited two articles to support his use of historical control data ranges in analyzing the studies. The two articles were about dual control groups, not historical controls, and therefore inapplicable.); Foster Dep. 228:6-229:10 and Foster Rep. at 5 (Dr. Foster cites to an article by Elwell to support the statement that hemangiosarcomas are common in CD-1 mice. When questioned about the article at his deposition, Dr. Foster conceded that the Elwell article does not support such a statement.); Foster Rep. at 22 (Dr. Foster explains that the PWG and Dr. Kushner found a tumor in the control group animal in the Knezevich and Hogan study, making the kidney tumors observed in the treatment groups less significant. Yet, Dr. Foster lists an EPA document, *dated after* Kushner's and PWG's report, in his materials consulted list that concludes there is no tumor in the control group animal (*See* EPA Memorandum from D. Stephen Saunders J., Toxicologist, Section V, TOX/HED on Glyphosate Registration Standard Revision to Theodore M. Farber, Chief, Toxicology Branch, Hazard Evaluation Division (March. 1, 1986)).

not even distinguish between primary and secondary tumors in his analysis of the Greim data set unless the tumors were already distinguished as such by the original scientists who conducted the studies. *Id*. at 150:12-156:19. Monsanto cannot deny this deficiency in Dr. Corcoran's analysis.

Further, Dr. Corcoran is not, despite his CV reference, the recipient of $25 million in federal grants. The National Institute of Health grant was for "a large, complex study [that] involve[s] a lot of personnel across different universities. They are very interdisciplinary." *Id*. at 104:11-106:6.[19] And, in any event, these government grants relate to epidemiological studies of Alzheimer disease in the Cache County, Utah. *Id*. at 107:3-107.

V. DR. ROSOL'S OPINIONS MUST BE EXCLUDED

Monsanto does not dispute that Dr. Rosol, a veterinary pathologist, relied upon underlying pathology reports from the glyphosate Reading Room in Brussels, Belgium, nor does Monsanto dispute that the underlying reports are ***presently*** unavailable to Plaintiffs and were at the time that Dr. Rosol issued his report.

At all relevant times, Monsanto knew that these reports, now at issue, were not within its possession, custody, or control and were only available in the Reading Room. However, and as its Reply Brief demonstrates, Monsanto did not inform Plaintiffs that the pathology reports were unavailable until ***after*** the reading room closed at the end of October 2016. Def. Reply at 41. In fact, Monsanto highlights an email from December 30, 2016—approximately two months after the Reading Room closed—to show that Monsanto did not have possession of the underlying pathology reports.[20] Nevertheless, Monsanto attempts to obscure the fact that the underlying pathology reports are not available to Plaintiffs by suggesting that there are other publically available sources of the same information. And while there may be other sources that describe the

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[19] Dr. Corcoran also appears not to have informed both his University and the NIH of his consultancy in this litigation, as he was required to do at the time of seeking and receiving the NIH grants. *See* Corcoran Dep. at 106:15-111:11.

[20] The suggestion that Plaintiffs' decision not to have their experts visit the Reading Room was a litigation ploy is absurd. The Reading Room opened mere weeks after this case was consolidated but well before the first status conference. Plaintiffs had no way of knowing that the pathology reports would not be made available to them at this critical time. Moreover, the Court had not yet held a status conference nor had leadership been appointed.

findings of the pathology reports, Dr. Rosol's testimony is not based upon these secondary sources but rather upon the pathology reports themselves. Dr. Rosol's handwritten notes from his time in the Reading Room do not provide an adequate basis to test his opinions. At his deposition, Dr. Rosol could not articulate what the notes referenced or provide any clarity as to what they concerned. Rosol Dep. at 270:9-271:6; 274:19-25; 276; 14-277:3; 279:13-17; 286:21-287:1; 304:11-15. Without a basis to test the reliability of Dr. Rosol's methodology and opinions stemming from his time in the Reading Room, his resultant opinions must be excluded.

VI. DR. GOODMAN'S OPINIONS ARE INADMISSIBLE

Plaintiffs challenge Dr. Goodman on two grounds: 1) Dr. Goodman's opinions regarding two human *in vivo* studies are so speculative and error ridden that they must be excluded; and 2) Dr. Goodman must be excluded in total because his overarching methodology is a result-oriented selection process and replete with critical errors.

As a preliminary matter, Monsanto does not respond to most of the criticisms that demonstrate Dr. Goodman's opinions are unreliable. Monsanto does not dispute that:

- Dr. Goodman's criticisms of Bolognesi 2009, a human in vivo study, are predicated upon a demonstrably erroneous understanding of the study. *See* Pl. Opp. at 64-65.
- Dr. Goodman's admission that his criticism of Paz-y-Mino 2007—that the test population might have been exposed to other chemicals—is speculative. *See* Pl. Opp. at 63.
- The symptoms reported by the Paz-y-Mino 2007 subjects are consistent with acute glyphosate toxicity. *See* Pl. Opp. at 63.
- Dr. Goodman admits he is unqualified to rule in or rule out acute glyphosate toxicity as the cause of the symptoms reported in Paz-y-Mino 2007. *See* Pl. Opp. at 63.
- Dr. Goodman's criticisms of the Paz-y-Mino 2007 study's use of reviewers is speculative. *See* Pl. Opp. at 64.
- Utilizing multiple reviewers, even if true, would not make Paz-y-Mino 2007 unreliable. *See* Pl. Opp. at 64 n. 184.
- The Paz-y-Mino authors' lack of discussion of heterogeneity (Dr. Goodman's fourth criticism) does not undermine the study results' reliability. *See* Pl. Opp. at 64.

- Dr. Goodman discounted many positive studies due to an erroneous belief that they did not account for cytotoxicity when they did, in fact, account for cytotoxicity using methods Dr. Goodman considers reliable. *See* Pl. Opp. at 66.

- Dr. Goodman discounted many positive studies for not demonstrating dose response even though the studies did account for, and demonstrate, dose response. *See* Pl. Opp. at 65-66.

- Many of the negative studies Dr. Goodman relies upon supposedly contain the same flaws that render positive studies subject to exclusion in Dr. Goodman's opinion; namely failure to account for cytotoxicity or to demonstrate dose response. *See* Pl. Opp. at 65-66 n. 191, n. 192.

- Dr. Goodman discounts positive studies for non-compliance with OECD guidelines but does not discount any negative studies where OECD guidelines are not followed. *See* Pl. Opp. at 66 n. 193.

- Dr. Goodman incorrectly relied upon studies that did not evaluate glyphosate in reaching his opinion that GBFs are non-genotoxic. Def. Reply at 46-47; Pl. Opp. at 66.

A. The Human *In Vivo* Studies are Reliable but Dr. Goodman's Opinions Discounting Them Are Not.

Monsanto attempts to defend Dr. Goodman's opinion discounting the results of Paz-y-Mino 2007 based on his speculative belief that something other than acute glyphosate toxicity caused the myriad ailments in the study subjects, by arguing, "nowhere in Paz-y-Mino 2007 do the study authors attribute these symptoms to glyphosate poisoning." Def. Reply at 35 n. 62. This is false. In fact, the authors *overtly* attribute the reported symptoms to GBF toxicity: "Exposed group individuals manifested symptoms of toxicity ***after several exposures to aerial spraying***." Paz-y-Mino at 457 (emphasis added).[21] [22] Moreover, the authors cite to several articles supporting the symptoms as being consistent with acute GBF toxicity. Additionally, the symptomology reported by those articles is consistent with the symptomology described by sources Dr. Goodman relies upon in his report and testified were reliable and methodologically sound.

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[21] The authors further note that when completing clinical histories for the exposed individuals "a wide-range of reactions were noted," a clear indication that the "reactions" occurred after, and in response to, aerial exposure to GBFs. Paz-y-Mino, C., et al., *Evaluation of DNA Damage in an Ecuadorian Population Exposed to Glyphosate*, 30 Genetics & Molecular Biology 456 (2007) at 457.

[22] Dr. Goodman tacitly acknowledges that the authors attributed these symptoms to GBF exposure. In fact, the authors' attribution of these symptoms to GBF exposure is the foundation of Dr. Goodman's primary criticism of the study. *See* Goodman Rep. at 12.

Goodman Dep. 222:8-10.

Apart from the speculative nature of Dr. Goodman's opinion on symptomology, Monsanto ignores Plaintiffs' argument that Dr. Goodman is not qualified to offer this opinion at all.[23] In order to reliably opine that GBFs did not cause the symptomology in Paz-y-Mino 2007, or to opine that something else may have caused the reported symptoms, Dr. Goodman must be knowledgeable of the symptoms of acute glyphosate toxicity. He is not, and his lack of expertise is fatal to his opinion ruling out GBFs as the cause of the symptoms. *Id.* 220:7-10 ("What I said is I am a Ph.D., not a medical doctor, and I do not know all of the symptoms of glyphosate poisoning").

Next, Monsanto attempts to salvage Dr. Goodman's admittedly speculative opinions for discounting Paz-y-Mino on the basis of purported methodological flaws, by claiming the study requires speculation. This argument misses the point. Dr. Goodman opines that Paz-y-Mino should be afforded no weight due to the possibility that multiple individuals might have been involved in reading slides—a criticism that Monsanto repeats in attacking Plaintiffs' experts' reliance upon the same study. Not only does Dr. Goodman admit that there is no evidence to suggest that multiple individuals actually reviewed the slides and that this criticism is "speculative," but importantly, Dr. Goodman admits that even if multiple individuals reviewed the slides, such a circumstance "would not be problematic." Goodman Dep. 227:1-3. It is this criticism, in conjunction with his speculation about the study symptoms, which lead Dr. Goodman to offer an opinion that Paz-y-Mino 2007 should receive no weight—criticism that, even if proven true, would not rise to the level of being "problematic" or require discounting the study in its entirety or even in part. Accordingly, Dr. Goodman's opinions stating as much are not the product of a reliable methodology and must be excluded.

B. Dr. Goodman Does Not Apply "The Same Rigorous Criteria" to Negative Studies

[23] Dr. Goodman repeatedly acknowledged that he is not qualified to discuss the acute glyphosate toxicity and the resultant symptomology. *See* Goodman Dep 217:17-18; *Id.* 217:8-9; *Id.* 215:19; *Id.* 220:7-10; *Id.* 214:23-24; *see also* Pl. Opp. at 63.

Instead of providing a meaningful explanation for the inconsistencies that define Dr. Goodman's methodology and opinions, Monsanto offers only Dr. Goodman's *ipse dixit* that he applied a consistent and reliable methodology. Goodman Rep. at 46. Such a threadbare assertion is insufficient to meet Monsanto's *Daubert* burden and does not begin to address the gravamen of Plaintiffs' argument that Dr. Goodman's methodology is a conclusion-oriented selection process. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). And despite arguing that "Dr. Goodman applied a rigorous methodology to both positive and negative studies," Monsanto is unable to identify a single example of Dr. Goodman applying a critical methodology to a negative study.[24] Thus, Monsanto does not dispute, nor can it, that Dr. Goodman did not discount *any* negative studies for failing to account for cytotoxicity—even though a number of negative studies, considered and relied upon by Dr. Goodman, *did not* account for cytotoxicity.[25] Conversely, Dr. Goodman discounted every positive study that he *believed* failed to account for cytotoxicity—even when a review of the study results shows his belief to be in error.[26] Nor does Monsanto dispute that Dr. Goodman discounts positive studies for failure to comply with OECD guidelines[27] while accepting negative studies that fail to comply with the same.[28]

The issue before the Court, as explained in *Kumho Tire*, is not simply "the reasonableness in general" of an expert's methodology, but also the expert's "particular method of analyzing the data thereby obtained, to draw a conclusion regarding the particular matter to which the expert testimony was directly relevant.", 526 U.S. at 153-154. Where, as here, "an expert applies certain techniques to a subset of the body of evidence and other techniques to another subset without

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[24] *See, e.g.*, Goodman Dep. 92:23-93:1 ("Q. Did you discount any of the negative studies due to method -- methodological flaws? A. No.").
[25] It is not Dr. Goodman's inability to remember specific details about studies that renders his opinions unworthy of admission as Monsanto claims, but rather, his disparate criteria in weighing positive and negative studies. Plaintiffs highlighted Dr. Goodman's treatment of the Dimitrov, et al. study because this study failed to account for cytotoxicity, a methodological flaw that, in the context of positive studies, universally resulted in Dr. Goodman's rejection.
[26] *See* Opp. at 65-66, n. 191.
[27] *See* Goodman Rep. at 21, 22 (citing to OECD in discounting positive studies).
[28] *See e.g.*, Goodman Dep. 93:3-7 ("Did you discount any of the negative studies due to noncompliance with the OECD guidelines? A. No, but, again, I did not lay down each study and look at it in parallel to the OECD guideline.").

explanation, this raises an inference of unreliable application of methodology." *In re Zoloft*, 858 at 797.[29] *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003) (unpublished) (To establish that an expert's methodology "is truly a methodology, rather than a mere conclusion-oriented selection process that weighs more heavily those studies that supported an outcome, there must be a scientific method of weighting that is used and explained."). Dr. Goodman's approach is methodologically flawed and requires exclusion.

C. Monsanto's Reply Highlights Critical Errors That Render Dr. Goodman's Opinions Unreliable.

Monsanto does not contest the clear errors in Dr. Goodman's opinions that Plaintiffs have identified. Pl. Opp. at 65-66. These errors, which are emblematic of many others, demonstrate an absence of rigor and reliability that requires exclusion. In fact, Monsanto's attempt to paint over Dr. Goodman's result-driven approach underscores the serious methodological flaws that characterize the whole of his testimony. Monsanto uses the example of IP injection studies to argue that Dr. Goodman "critically evaluated the data"; however, inspection of Dr. Goodman's evaluation of these very studies reveals the opposite. Def. Reply at 46.[30] Although Dr. Goodman discounts *every* positive IP study because he does not believe the study to be physiologically relevant to the claims asserted,[31] Dr. Goodman admitted that he has no knowledge whatsoever of the routes of exposure alleged by Plaintiffs. Goodman Dep. 106:15-19. Without knowing the physiological routes of exposure alleged by Plaintiffs, Dr. Goodman cannot reliably assess

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[29] Remarkably, Monsanto takes issue with Plaintiffs' experts' reliance upon a study by Lioi, et al. because it evaluated genotoxicity in bovine blood cells, (*see* Def. Reply at 33 n.57), even though Dr. Goodman relies upon a study similarly utilizing bovine cells to negate glyphosate's genotoxicity. Goodman Rep. at 19; *See* Holeckova, B., *Evaluation of the In Vitro Effect of Glyphosate-based Herbicide on Bovine Lymphocytes Using Chromosome Painting*, 50 Bull. Veterinary Inst. Pulawy 533 (2006). Moreover, the Holeckova study did not comply with OECD guidelines—a factor Dr. Goodman used in order to discount positive genotoxicity studies. *See* Opp. at 66 n. 193.

[30] Monsanto's example mischaracterizes Dr. Goodman's testimony and the relevant evidence. Many IP injection studies demonstrated positive results, as Dr. Goodman readily admitted. And, although Dr. Goodman discounts these studies due to his belief that the routes of exposure were not physiologically relevant, Dr. Goodman testified that glyphosate and GBFs were not genotoxic *regardless* of the route of exposure. Goodman Dep. 244:23-245:5.

[31] Dr. Goodman does not discount a single negative study within this data set.

physiological relevance—especially in light of Monsanto's (incorrect) position that only dermal exposures are physiologically relevant. *See* MSJ at 5 ("plaintiffs' allegations are based only on dermal exposure."). Nor can Dr. Goodman make reliable comparisons between doses in IP injection studies and relevant human doses without this knowledge. *See* Goodman Rep. at 29-30 (arguing that IP injection studies utilize doses thousands of times higher than exposures from glyphosate in food and water).

Despite having no idea what types of exposures Plaintiffs allege, Dr. Goodman bases his assessment of physiological relevance and dose comparison upon EPA's estimate of *residual glyphosate in the food of Children*.[32] *Id* at 29-30. Dr. Goodman selects this figure while blatantly ignoring the preceding line of the same report estimating exposure in occupational workers. Not coincidentally, that estimate, though overly conservative[33] is nearly *fifteen times higher* than the dose Dr. Goodman relies upon. *See* EPA OPP at 96.[34] The exposure of occupational workers reported by the EPA is also over *400 times higher* than the current proposed "no significant risk level" of exposure to glyphosate based on cancer endpoints.[35] Because "the test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology," Dr. Goodman's erroneous determination of physiological relevance is fatal to his opinions. *See Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) (citations and quotations omitted). The unavoidable conclusion of these observations is that either Dr. Goodman's methodology is devoid of scientific rigor or his methodology is a result-oriented approach. Either way, this methodology fails *Daubert* scrutiny.[36]

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[32] Accordingly, even if these opinions were reliable, which they are not, Dr. Goodman's physiological relevance determinations do not "fit" the facts of this case because they are based upon exposures that are irrelevant to this case. *See Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315-16 (9th Cir. 1995).

[33] *See* Opp. at 42

[34] *See, e.g., Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1177 (N.D.Cal. 2007)(excluding expert who reached general causation conclusion by "cherry-picking observational studies that support his conclusion," stating that this "is not 'good science'").

[35] The state of California is currently the only government that is considering what exposure level of glyphosate that is capable of causing cancer in humans. *see* https://oehha.ca.gov/media/downloads/crnr/glyphosate032917isor.pdf.

[36] Similarly, Monsanto attempts, but fails, to deflect Plaintiffs' criticism regarding Dr.

CONCLUSION

For the forgoing reasons, Plaintiffs' motion to exclude Monsanto's expert testimony under *Daubert* must be granted.

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Respectfully Submitted,

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Goodman's erroneous evaluation of the GBF *Ames* test data set. Rather than acknowledge that Dr. Goodman is either unable, or too careless, to discern the substance tested, Monsanto asserts that "plaintiffs' experts failed to consider most of the genotoxicity testing conducted with surfactants." Plaintiffs' allegations, that surfactants render GBFs more toxic than glyphosate alone, are irrelevant to the question of whether Dr. Goodman employed a reliable methodology. Dr. Goodman's report and testimony indicate that his consideration of these four tests resulted from an erroneous belief that the tests involved GBFs, not from a conscious effort to evaluate the genotoxicity of surfactants. Moreover, it is undisputed that Dr. Goodman relies upon four studies—over 10% of the entire data set—that do not involve glyphosate or GBFs at all, to form his opinion that "[a]ll of these studies indicate that GBFs do not cause mutations in bacterial-based test systems." Goodman Rep. at 19. Here, it is impossible to say that Dr. Goodman's opinions are reliable because they are predicated upon blatant mistakes and errors.

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