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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS  
LIABILITY LITIGATION

MDL No. 2741

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

This document relates to:

ALL ACTIONS

**Hearing Date: March 5, 2018**  
**Time: 9:00 a.m.**

**MONSANTO COMPANY’S SUPPLEMENTAL MEMORANDUM  
OF POINTS AND AUTHORITIES REGARDING ANDREOTTI, ET AL.,  
GLYPHOSATE USE AND CANCER INCIDENCE IN THE AGRICULTURAL HEALTH  
STUDY, JOURNAL OF THE NATIONAL CANCER INSTITUTE (2018)  
IN SUPPORT OF ITS DAUBERT AND SUMMARY JUDGMENT MOTION**

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**INTRODUCTION**

“In order to qualify as ‘scientific knowledge’ [as required by Rule 702], an inference must be derived by the scientific method. Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method.” *Claar v. Burlington N. R. Co.*, 29 F.3d 499, 502-03 (9th Cir. 1994) (citations omitted). This unscientific approach, however, describes the methodology used by plaintiffs’ experts in discounting powerful new epidemiologic evidence directly contrary to their general causation opinion that glyphosate-based herbicides (“GBHs”) cause non-Hodgkin’s lymphoma (“NHL”). *See* G. Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 J. Nat’l Cancer Inst. 1, 1 (2018) (“2018 NCI study”) (“In this large, prospective cohort study, no association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL and its subtypes.”).<sup>1</sup>

Plaintiffs’ experts’ results-oriented arguments against the 2018 NCI study cannot avoid what plaintiffs have acknowledged and *Daubert* case law makes clear: “[u]nquestionably, epidemiological studies provide the best proof of the general association of a particular substance with particular effects.”<sup>2</sup> Thus, a plaintiff seeking to prove general causation absent unbiased, statistically-significant associations proven through epidemiology faces “a high bar ... with respect to the [*Daubert*] reliability requirement.” *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1358 (N.D. Ga. 2001), *aff’d* 295 F.3d 1194 (11th Cir. 2002).<sup>3</sup> Plaintiffs’ experts seek to clear this high bar by lobbing various criticisms at the 2018 NCI study, but “[m]ere criticism of epidemiology cannot establish causation.” *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886

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<sup>1</sup> *Id.* at 1-2. (This study was identified in earlier filings as the 2017 AHS study. We refer to the study herein as the 2018 NCI study to avoid confusion with other AHS studies and to reflect the fact that the study first published online in November 2017 will be published in hard copy in the next issue of the NCI journal in 2018.).

<sup>2</sup> Pls.’ (1) Resp. in Opp’n to Monsanto Co.’s *Daubert* & Summ. J. Mot. Based on Failure of Gen. Causation Proof & (2) *Daubert* Mot. to Strike Certain Op. of Monsanto Co.’s Expert Witnesses at 19, 20, ECF No. 647 (“Opp’n Br.”).

<sup>3</sup> *See also Pritchard v. Dow Agro Scis.*, 705 F. Supp. 2d 471, 485 (W.D. Pa. 2010) (“while an expert’s conclusions reached on the basis of other studies could be sufficiently reliable where no epidemiological studies have been conducted, *no reliable scientific approach can simply ignore the epidemiology that exists*”), *aff’d* 430 Fed. App’x 102 (3d Cir. 2011) (emphasis added).

1 (10th Cir. 2005). “Plaintiffs’ burden is an affirmative one, not served by such attacks.” *Caraker v.*  
 2 *Sandoz Pharm. Corp.*, 188 F. Supp. 2d 1026, 1034 (S.D. Ill. 2001). Moreover, plaintiffs’ experts’  
 3 criticisms are a complete “about face” of their pre-2018 NCI study opinions. Such unabashed  
 4 willingness to fully abandon or otherwise qualify prior opinions to reach desired results renders  
 5 their opinions unreliable under *Daubert*.<sup>4</sup>

6 **I. The 2018 NCI Study is the Most Powerful Epidemiologic Evidence Regarding GBHs**  
 7 **and NHL and Answers Plaintiffs’ Experts’ Previous Criticisms of the 2005 AHS**  
 8 **Study.**

9 In order to satisfy their affirmative burden under *Daubert*, plaintiffs’ experts must explain  
 10 how they can reliably opine that GBHs cause NHL in the face of the 2018 NCI study’s powerful  
 11 findings of no such association. *See In re Nexium Eesomeprazole*, 662 Fed. App’x 528, 530 (9th  
 12 Cir. 2016) (affirming exclusion of plaintiffs’ general causation expert who “did not adequately  
 13 explain how he inferred a causal relationship from epidemiological studies that did not come to  
 14 such a conclusion themselves”); *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, MDL  
 15 No. 2342, No. 12-md-2342, 2015 WL 7776911, at \*9 (E.D. Pa. Dec. 2, 2015) (excluding testimony  
 16 of expert who failed to account for more recent epidemiologic findings contrary to his causation  
 17 opinion), *aff’d* 858 F.3d 787 (3d Cir. 2017). They fail to satisfy their burden.

18 As plaintiffs’ experts concede, the 2018 NCI study is by far the largest epidemiologic study  
 19 of GBHs and NHL, with data on more exposed NHL cases than all of the other glyphosate  
 20 epidemiologic studies combined.<sup>5</sup> The 2018 NCI study includes significantly more years of  
 21 follow-up after exposure (to allow for latency of NHL development) than any other epidemiology  
 22 study, extending nearly 40 years after the introduction of glyphosate onto the market.<sup>6</sup> Further,  
 23 aside from earlier studies of the AHS cohort, the 2018 NCI study is the only epidemiologic study

24 <sup>4</sup> *See In re Bausch & Lomb, Inc. Contact Lens Solution Prod. Liab. Litig.*, MDL No. 1785, Civil  
 25 Action No. 2:06-MN-77777-DCN, 2009 WL 2750462, \*13 (D.S.C. Aug. 26, 2009) (excluding  
 26 general causation expert whose “changing opinions, and willingness to abandon or qualify her  
 27 opinions when faced with further facts, undermines the reliability of her opinions”).

28 <sup>5</sup> Dep. of Christopher Portier 20:9-13 (Jan. 12, 2018) (Hollingsworth Decl., Ex. 1) (“Portier Supp.  
 Dep.”).

<sup>6</sup> Dep. of Alfred Neugut 14:21-15:1 (Jan. 3, 2018) (Hollingsworth Decl., Ex. 2) (“Neugut Supp.  
 Dep.”); Portier Supp. Dep. 16:23-17:2.

1 involving a dose-response analysis of GBH exposure and NHL that accounts for exposure-  
 2 influencing variables such as applicator use of personal protective equipment.<sup>7</sup> The 2018 NCI  
 3 study was funded by the National Cancer Institute (“NCI”) and National Institute of Environmental  
 4 Health Sciences (“NIEHS”), which means that “high standards and best practices are used to  
 5 ensure that the data is accurate.”<sup>8</sup> It was authored by NCI, NIEHS and independent academician  
 6 scientists, and was published in one of the most highly respected, peer-reviewed cancer journals in  
 7 the world.<sup>9</sup> And the 2018 NCI study is part of a broader AHS cohort investigation that has  
 8 resulted to date in over 250 studies and publications in peer-reviewed scientific journals, without  
 9 the broadside criticisms leveled by plaintiffs’ litigation experts here.<sup>10</sup>

10 The 2018 NCI study’s conclusions are unequivocal: “In our study, we observed *no*  
 11 *associations* between glyphosate use and NHL overall or any of its subtypes.” 2018 NCI study at  
 12 7 (emphasis added). The lack of association held true regardless of how one looked at the data:  
 13 “This lack of association was consistent for both exposure metrics, unlagged and lagged analyses,  
 14 after further adjustments for pesticides linked to NHL in previous AHS analyses, and when we  
 15 excluded multiple myeloma from the NHL grouping.” *Id.* “These findings were unchanged in  
 16 sensitivity analyses [investigating the possibility of biases], including further adjustments for  
 17 additional potential confounders, or by exclusion of women and non-whites.” *Id.* at 3. Plaintiffs’  
 18 experts concede further that the 2018 NCI study found no association between GBHs and NHL  
 19 when it looked at exposures dating back prior to the introduction of Roundup<sup>®</sup> Ready (glyphosate  
 20

21 <sup>7</sup> Neugut Supp. Dep. 29:18-30:21; Dep. of Alfred Neugut 132:23-133:3 (Aug. 7, 2017), ECF No.  
 22 546-3 (“Neugut Init. Dep.”); Dep. of Dennis Weisenburger 91:25-92:6 (Jan. 22, 2018)  
 23 (Hollingsworth Decl., Ex. 3). As plaintiffs’ expert Dr. Portier acknowledged, “[f]or most  
 24 epidemiologists, they would argue [this] intensity measure is probably a better measure” of  
 25 exposure. Portier Supp. Dep. 71:22-23. While criticizing the intensity measure here as a litigation  
 26 expert, plaintiffs’ expert Dr. Ritz has used the same intensity measure in her own published  
 27 epidemiological studies looking at pesticide exposure and Parkinson’s disease. Dep. of Beate Ritz  
 28 108:24-109:18, 109:25-110:13 (Jan. 19, 2018) (Hollingsworth Decl., Ex. 4) (“Ritz Supp. Dep.”).

<sup>8</sup> Dep. of Chadi Nabhan 25:12-17 (Jan. 15, 2018) (Hollingsworth Decl., Ex. 5) (“Nabhan Supp.  
 Dep.”).

<sup>9</sup> Neugut Supp. Dep. 12:17-14:4; Portier Supp. Dep. 7:4-24; Dep. of Charles Jameson 6:5-12, 73:3-  
 74:24, 76:5-24 (Jan. 10, 2018) (Hollingsworth Decl., Ex. 6) (“Jameson Supp. Dep.”).

<sup>10</sup> See *Publications, Agricultural Health Study*, <https://aghealth.nih.gov/news/publications.html>.

1 tolerant) crops or after the introduction of Roundup® Ready crops and the corresponding increase  
 2 in glyphosate use.<sup>11</sup> The study's primary analyses of NHL show uniformly null results at every  
 3 level (quartile) of GBH exposure.<sup>12</sup>

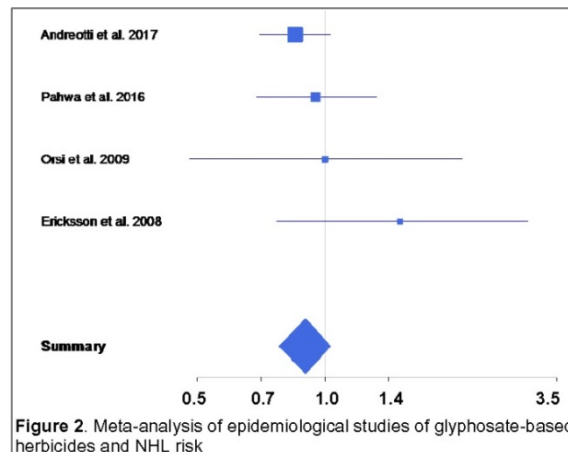
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5 **Table 1.** Relative risk (and 95% confidence intervals) for association between GBH exposure based on intensity-weighted lifetime days and NHL risk in the Agricultural Health Study (Andreotti et al, 2017)

	Overall risk NHL	5-year lag	20-year lag	Sensitivity analyses		
				Exposure at enrollment	Responded to both QQs	Truncated follow-up to 2005
Never	1.0 (reference)	1.0 (reference)	1.0 (reference)	1.0 (reference)	1.0 (reference)	1.0 (reference)
Quartile 1	0.83 (0.59-1.18)	0.92 (0.66-1.28)	1.22 (0.91-1.64)	NR	NR	NR
Quartile 2	0.83 (0.61-1.12)	0.79 (0.59-1.06)	1.15 (0.86-1.55)	NR	NR	NR
Quartile 3	0.88 (0.65-1.19)	1.03 (0.75-1.41)	0.98 (0.71-1.36)	NR	NR	NR
Quartile 4	0.87 (0.64-1.20)	0.87 (0.64-1.17)	1.12 (0.83-1.51)	0.82 (0.62-1.80)	0.90 (0.63-1.27)	1.04 (0.70-1.57)

6  
7  
8

9 Moreover, taking into account these updated study results, the full body of glyphosate  
 10 epidemiologic literature unambiguously fails to provide any support for a causal association  
 11 between GBHs and NHL. To the contrary, the full body of literature shows non-significant  
 12 adjusted odds ratios and risk ratios in the individual epidemiology studies above and below 1.0,  
 13 which plaintiffs' experts acknowledge is the expected pattern where there is no association  
 14 between an exposure and a disease.<sup>13</sup>



22 The 2018 NCI study also directly refutes plaintiffs' experts' prior criticisms of earlier AHS

23

24 <sup>11</sup> Neugut Supp. Dep. 35:9-36:13.

25 <sup>12</sup> Supplemental Expert Report of Lorelei Mucci at 6 (Hollingsworth Decl., Ex. 7) ("Mucci Supp. Rep.") (Table 1); Supplemental Expert Report of Jennifer Rider at 3 (Hollingsworth Decl., Ex. 8) (Figure 1).

26 <sup>13</sup> Expert Report of Alfred Neugut, ECF No. 546-11. Figure 2 taken from Mucci Supp. Rep. at 8. The studies identified in Figure 2 encompass the most comprehensive and updated epidemiologic analyses of the four populations that have been studied to date with respect to GBHs and NHL, along with a summary meta-analysis of the GBH-NHL epidemiology as a whole.



1 analyses. Plaintiffs' experts reached their earlier general causation opinions by seeking to dismiss  
 2 prior AHS epidemiologic studies in 2005 and 2013 as flawed. While plaintiffs' experts' criticisms  
 3 lacked merit for the reasons we have explained,<sup>14</sup> the 2018 NCI study negates the very criticisms  
 4 they had levied in their initial expert reports. For example, plaintiffs' experts criticized De Roos  
 5 2005 as involving too short of a period of time to take account for the long latency period for  
 6 potential development of NHL following glyphosate exposure.<sup>15</sup> The 2018 NCI study, however,  
 7 includes an additional 12 to 13 years of follow up for NHL outcomes.<sup>16</sup> Plaintiffs' experts also  
 8 criticized De Roos 2005 as being too small (notwithstanding the fact that even this earlier AHS  
 9 analysis provided the most powerful adjusted analysis of GBHs and NHL).<sup>17</sup> But the 2018 NCI  
 10 study is six times larger than De Roos 2005 and, as noted above, is larger than all of the other  
 11 glyphosate AHS studies combined.<sup>18</sup> Plaintiffs' experts criticized De Roos 2005 for failing to look  
 12 at different dates of exposure to assess NHL latency.<sup>19</sup> But the 2018 NCI study looks at different  
 13 lag periods of exposure to assess NHL latency, finding no associations in any period.<sup>20</sup> Plaintiffs'  
 14 experts criticized Alavanja 2013 because it was unpublished, and Dr. Ritz contended that its  
 15 analysis could not withstand peer review.<sup>21</sup> But plaintiffs' experts acknowledge that the 2018 NCI  
 16 study was published after rigorous peer review in a leading oncology journal.<sup>22</sup>

17 **II. Plaintiffs' Experts Fail to Apply Proper Scientific Methodology in Their Attempts to**  
 18 **Discredit the 2018 NCI Study.**

19 Now that the 2018 NCI study negates their previous criticisms, plaintiffs' experts try to  
 20 manufacture other criticisms against the 2018 NCI study to salvage their causation opinions.

21 <sup>14</sup> Monsanto Co.'s Notice of Mot. & *Daubert* & Summ. J. Mot. Based on Failure of Gen. Causation  
 22 Proof, ECF No. 545 ("Monsanto *Daubert* Br."); Monsanto Co.'s Reply Mem. of P. & A. in Supp.  
 23 of Its *Daubert* & Summ. J. Mot. Based on Failure of Gen. Causation Proof & Opp'n to Pls.'  
*Daubert* Mot. to Strike Certain Ops. of Monsanto Co.'s Expert Witnesses, ECF No. 681  
 ("Monsanto *Daubert* Reply Br.).

24 <sup>15</sup> Neugut Supp. Dep. 48:15-23; Portier Supp. Dep. 9:8-12.

25 <sup>16</sup> Neugut Supp. Dep. 48:24-49:2; Portier Supp. Dep. 16:23-17:2.

26 <sup>17</sup> Portier Supp. Dep. 17:3-13.

27 <sup>18</sup> Neugut Supp. Dep. 17:25-18:5; Portier Supp. Dep. 20:9-13.

28 <sup>19</sup> Neugut Supp. Dep. 49:3-9.

<sup>20</sup> Neugut Supp. Dep. 49:9-17; Portier Supp. Dep. 39:17-41:24.

<sup>21</sup> Rebuttal Expert Report of Beate Ritz at 8, ECF No. 653-2 ("Ritz Rebuttal Rep.").

<sup>22</sup> Neugut Supp. Dep. 11:25-14:4; Jameson Supp. Dep. 77:17-23.

1 Plaintiffs’ experts’ criticisms of the epidemiologic evidence cannot satisfy their affirmative burden  
 2 under *Daubert*. See *Norris*, 397 F.3d at 886. But equally importantly, their criticisms demonstrate  
 3 glaring flaws in their expert methodology because they rely on speculation in the face of contrary  
 4 data and published analyses. See *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1169-  
 5 70 (E.D. Wash. 2009) (expert opinions “must be based on facts which enable [the expert] to  
 6 express a reasonably accurate conclusion as opposed to conjecture or speculation”); *In re Bextra &*  
 7 *Celebrex Mktg. Sales Prac. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1171 (N.D. Cal. 2007)  
 8 (“[T]he trial judge in all cases of proffered expert testimony must find that it is properly grounded,  
 9 well-reasoned, and not speculative before it can be admitted.”) (citations omitted).

10 In her initial deposition, plaintiffs’ lead epidemiology expert, Dr. Ritz, explained the  
 11 methodology that epidemiologists follow outside the courtroom before concluding that a study  
 12 signals a positive association between an exposure and a disease:

13 So the short form is that you start with the study design, that you  
 14 start with the exposure assessment validity, that you start with the  
 15 outcome assessment validity, that you then go into a sample size,  
 16 exposure prevalence, any kind of bias you can think of, and once  
 17 you have wrapped it all together, that’s when you’re doing a lot of  
 sensitivity analyses in your data to convince yourself that no way -  
 - ***no matter how you look at your data, there is a signal.***

18 Dep. of Beate Ritz 48:12-49:12 (Sept. 18, 2017), ECF No. 546-13 (“Ritz Init. Dep.”). In response  
 19 to the 2018 NCI study, however, Dr. Ritz and all other plaintiffs’ experts abandoned this  
 20 methodology and concluded that a positive association exists despite independent validation studies  
 21 and sensitivity analyses showing that ***no matter how you look at the data there is no signal.***<sup>23</sup>

22 Plaintiffs’ experts pursue two primary strategies to advance this argument. First,  
 23 astonishingly, they adopt as their own recommendations for improvements to the AHS study design  
 24 recommendations first made by others in the late 1990s and early 2000s, while failing to  
 25 acknowledge that those recommendations were ***in fact implemented*** by the AHS investigators years

26 \_\_\_\_\_  
 27 <sup>23</sup> See *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 n.11 (9th Cir. 1995) (plaintiffs  
 28 must “demonstrate in some objectively verifiable way that the expert has both chosen a reliable  
 scientific method *and followed it faithfully*”) (emphasis added).

1 prior to the 2018 NCI study. Second, they speculate about potential biases in the 2018 NCI study *in*  
2 *the face of actual data* demonstrating that those speculated biases had no impact on the 2018 NCI  
3 study's findings of no association.

4 **A. Plaintiffs' Experts Cannot Reliably Discredit the 2018 NCI Study By Citing**  
5 **Early Recommendations for Improvements to AHS Study Designs That Were**  
6 **Adopted Years Prior to the 2018 NCI Study.**

7 In support of their claim that the 2018 NCI study is unreliable, plaintiffs' experts rely  
8 heavily on a 1997 memorandum by Monsanto's then in-house epidemiologist, John Acquavella,  
9 and a 2000 publication by Dr. Gray at the Harvard School of Public Health.<sup>24</sup> At her deposition,  
10 however, Dr. Ritz conceded that these documents were prepared during the initial design stage of  
11 the AHS cohort and that the recommendations made by Drs. Acquavella and Gray *in fact were*  
12 *adopted* years prior to the 2018 NCI study.<sup>25</sup> While Dr. Ritz in her supplemental report points to  
13 Dr. Acquavella's 1997 concern about exposure analyses that do not consider application methods  
14 and the use of personal protective equipment, she later admitted at her deposition that the AHS  
15 investigators in fact incorporated these factors in all of their epidemiologic analyses, including the  
16 2018 NCI study.<sup>26</sup> Likewise, Dr. Ritz in her supplemental report points to recommendations made  
17 by Dr. Gray in 2000 that the AHS investigators conduct validation and biomonitoring studies to test  
18 the reliability of the cohort members' questionnaire responses regarding pesticides exposures, but  
19 she failed to acknowledge until confronted at her deposition that the AHS investigators actually  
20 conducted those studies thereafter and had them published in the peer reviewed literature.<sup>27</sup>

21 <sup>24</sup> See Supplemental Expert Report of Beate Ritz at 4 (Hollingsworth Decl., Ex. 9). Plaintiffs'  
22 experts also cite to a 2016 report by the consulting group Exponent, which in fact was repeatedly  
23 laudatory in its discussion of the AHS methodology. See Monsanto Daubert Reply Br. at 19 n.34.

24 <sup>25</sup> Ritz Supp. Dep. 104:7-105:4, 105:5-106:9, 108:8-23, 133:24-134:14, 136:20-138:8, 143:21-  
145:19, 145:22-147:11, 147:14-150:4.

25 <sup>26</sup> *Id.* By sharp contrast, the glyphosate case-control studies upon which plaintiffs' experts so  
26 heavily rely ignore these exposure factors. See *supra* at 11 n.44.

27 <sup>27</sup> Ritz Supp. Dep. 137:13-139:6, 141:3-15, 142:25-143:13, 143:21-145:19. Indeed, in sharp  
28 contrast to plaintiffs' experts, even IARC acknowledges the strengths of the AHS study design  
(albeit without knowledge of either the 2013 or 2018 updated analyses showing no association  
between GBHs and NHL, which would have altered its meta-analysis). See Nabhan Supp. Dep.  
92:25-97-8, 100:5-101:4; Jameson Supp. Dep. 104:13-105:24; Monsanto's Daubert Br. at 14 n.21.

1           **B. Plaintiffs' Experts Offer Only Speculation in the Face of Contradictory Data in**  
 2           **Validation Studies and Sensitivity Analyses.**

3           Even more fatal to their methodology, plaintiffs' experts raise nothing more than rank  
 4 speculations about potential biases that "could have" impacted the results in the 2018 NCI study.  
 5 Plaintiffs' experts ignore that their claimed biases could not and would not conceal a positive  
 6 association between GBHs and NHL if one actually existed; they also impermissibly disregard  
 7 validation studies and sensitivity analyses demonstrating that their speculated biases are not born  
 8 out in the actual study data, in violation of *Daubert*. See *In re Zoloft (Setraline Hydrochloride)*  
 9 *Prod. Liab. Litig.*, 858 F.3d 787, 798 (3d Cir. 2017) (excluding general causation expert who relied  
 10 upon speculative criticisms of epidemiologic study not born out in sensitivity analysis).

11           Plaintiffs' experts inexplicably focus on the possibility of "nondifferential exposure  
 12 misclassification" (i.e., errors in identifying glyphosate exposures that are equally likely in cases  
 13 and controls).<sup>28</sup> Yet plaintiffs' experts acknowledge that this type of error generally moves a risk  
 14 ratio *closer to the null* value of 1.0 (i.e., no association).<sup>29</sup> It would not flip a reported GBH-NHL  
 15 risk ratio below 1.0 (as reported in the 2018 NCI study) to a statistically significant risk ratio above  
 16 1.0 (as plaintiffs' experts need for their causation opinion).<sup>30</sup> Undeterred by their acknowledgement  
 17 that "most of the time you're not going to have that," they offer the following hopeful calculus:  
 18 with "random error" you "sometimes might" see such a switch.<sup>31</sup> It is upon this "sometimes might"  
 19 speculation of a "random error" that their entire argument of bias impermissibly relies.<sup>32</sup>

20           Remarkably, the very foundation of even this speculative foundation does not exist; the  
 21 AHS investigators themselves ruled out substantial non-differential exposure misclassification in  
 22 the 2018 NCI study, as confirmed by independent, peer-reviewed analyses. Thus, although

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 24 <sup>28</sup> Portier Supp. Dep. 55:12-19; Ritz Supp. Dep. 99:2-100:6.

25 <sup>29</sup> Ritz Supp. Dep. 127:18-128:17.

26 <sup>30</sup> Mucci Supp. Rep. at 3, 7; see also Ritz Supp. Dep. 127:18-128:17; Dep. of Lorelei Mucci 42:13-  
 42:4 (Jan. 23, 2018) (Hollingsworth Decl., Ex. 10); Dep. of Jennifer Rider 25:21-27:7 (Jan. 23,  
 2018) (Hollingsworth Decl., Ex. 11).

27 <sup>31</sup> Ritz Supp. Dep. 129:2-19, 132:6-24.

28 <sup>32</sup> See also Neugut Supp. Dep. 124:16-125:3 (cannot point to any data showing that opined biases  
 concealed a positive association between GBH exposure and NHL in 2018 NCI study).

1 plaintiffs' experts hypothesize that the AHS cohort members provided faulty glyphosate exposure  
2 information in their questionnaires,<sup>33</sup> plaintiffs' experts admitted at deposition that the investigators  
3 demonstrated the reliability of those questionnaire responses through published validation studies  
4 showing close agreement in AHS questionnaire responses for glyphosate exposures provided in  
5 different surveys conducted a year apart.<sup>34</sup> Plaintiffs' experts also admitted at deposition that  
6 investigators conducted biomonitoring studies that demonstrated that AHS calculations of intensity-  
7 based exposure (taking into account, e.g., whether subjects wore personal protective equipment)  
8 tracked levels of pesticide absorbed through skin, as measured through urine tests.<sup>35</sup>

9 In hunting for other purported bias, plaintiffs' experts criticize the AHS investigators' use of  
10 a well-accepted imputation methodology to calculate certain exposure data for a portion of the AHS  
11 cohort who provided historical exposure data at baseline but who did not complete a second phase  
12 questionnaire.<sup>36</sup> Plaintiffs' experts acknowledge that this imputation methodology is generally  
13 accepted in epidemiology and has been used in eight other peer-reviewed studies of the AHS cohort  
14 published between 2013 and 2017, three of which presented data specific to glyphosate.<sup>37</sup> They  
15 further acknowledge that the imputation methodology has not been criticized by them or anyone  
16 else outside of this litigation.<sup>38</sup> They maintain, however, that the imputation methodology is  
17 somehow uniquely unreliable for glyphosate because it cannot capture the increased use of  
18 glyphosate between the first phase and second phase questionnaires.

19 Again, plaintiffs' experts' criticisms do not match the factual record and fail in the face of  
20 validation studies conducted by the AHS investigators that confirm the reliability of the imputation  
21 methodology. First, the AHS investigators examined whether there were any meaningful  
22 differences between responders and non-responders to the second phase questionnaire that could  
23 impact the use of the imputation methodology. As set forth in their peer-reviewed, published

24 <sup>33</sup> *Id.* 65:24-66:5.

25 <sup>34</sup> *Id.* 67:4-69:3, 76:8-77:4, 78:7-13, 79:6-11, 80:13-19.

26 <sup>35</sup> Portier Supp. Dep. 69:2-18.

27 <sup>36</sup> Ritz Supp. Dep. 68:2-74:14; Ritz Supp. Dep., Ex. 30-10 (Hollingsworth Decl., Ex. 12)  
(explaining how imputation is conducted); Neugut Supp. Dep. 106:12-109:11 (same).

28 <sup>37</sup> Neugut Supp. Dep. 122:7-21; Ritz Supp. Dep. 11:16-24:2, 37:4-23.

<sup>38</sup> Neugut Supp. Dep. 122:23-123:12; Ritz Supp. Dep. 25:17-27:11.

1 analysis, the investigators found that “[d]ifferences between non-participants and participants in the  
2 follow-up interview were generally small, and we did not find significant evidence of selection  
3 bias.”<sup>39</sup> Second, the AHS investigators tested their imputation methodology by using it on a  
4 random subset of cohort members who **had** responded to the second questionnaire and comparing  
5 their actual responses with data derived through imputation. The investigators concluded that their  
6 imputation method reliably identified second phase pesticide exposures, both generally and for  
7 glyphosate.<sup>40</sup> Despite scientific validation of the results, plaintiffs’ experts speculate that the  
8 increase in GBH use starting in the late 1990s introduced too many variables in the imputation  
9 methodology. But Dr. Ritz conceded at her deposition that this increase was driven almost entirely  
10 by the development of just three Roundup<sup>®</sup> Ready crops (soybeans, corn and cotton), which allows  
11 for a simple imputation of future glyphosate use.<sup>41</sup>

12 Moreover, plaintiffs’ experts uniformly ignore the sensitivity analyses conducted in the  
13 2018 NCI study which demonstrate that there is no association between GBH exposure and NHL  
14 **with or without use** of the imputed data. The study investigators first studied the glyphosate  
15 exposure data of all 54,000-plus cohort members from the phase 1 questionnaire and found no  
16 association with NHL, with a rate ratio for the highest exposure group of 0.82 (0.62-1.80).<sup>42</sup>

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18 <sup>39</sup> M. Montgomery et al., *Effects of Self-Reported Health Conditions and Pesticide Exposures on*  
19 *Probability of Follow-up in a Prospective Cohort Study*, 53 Am. J. Indus. Med. 486, 486 (2010);  
Neugut Supp. Dep. 97:9-21.

20 <sup>40</sup> Neugut Supp. Dep. 119:12-22; Portier Supp. Dep. 108:7-109:1; *see also* S. Heltshe et al., *Using*  
21 *Multiple Imputation to Assign Pesticide Use for Non-responders in the Follow-up Questionnaire in*  
22 *the Agricultural Health Study*, 22 J. Exposure Sci. & Envtl. Epidemiology 409, 409 (2012) (“The  
23 observed and imputed prevalence of any pesticide use in the holdout dataset were 85.7% and  
24 85.3%, respectively. The distribution of prevalence and days/year of use for specific pesticides  
25 were similar across observed and imputed in the holdout sample.”). Dr. Portier points to an  
intermediate measure in the Heltshe analysis called the “Brier score” which was used in a further  
26 calculation of a “Brier skill score” showing the merits of the imputation. He admits, however, that  
he had never heard the term Brier score before reviewing the paper, that Brier scores cannot  
27 compare accuracy of predictions between pesticides with different use prevalence, and that there  
can be – and in the Heltshe analysis was – a complete mismatch between the Brier score and  
28 concordance between actual and imputed exposure information. Portier Supp. Dep. 91:24-92:8,  
100:23-101:8, 104:25-105:8, 108:7-25.

<sup>41</sup> Ritz Supp. Dep. 43:3-18, 49:12-23, 53:4-15, 55:21-56:20, 57:1-16, 60:25-61:11.

<sup>42</sup> Ritz Supp. Dep. 76:20-77:21; Ritz Supp. Dep., Ex. 30-12 (Hollingsworth Decl., Ex. 13).

1 Second, the investigators looked at all exposure data from the nearly 35,000 cohort members who  
 2 responded to both the first and second phase questionnaires. This sub-analysis – which alone is  
 3 larger and more powerful than that of any prior glyphosate epidemiology study – likewise found no  
 4 association, with a rate ratio for the highest exposure group of 0.90 (0.63 – 1.27).<sup>43</sup> Thus, plaintiffs’  
 5 experts’ speculation that the imputation method concealed an actual association between GBHs and  
 6 NHL is contrary to the 2018 NCI study’s reported findings.<sup>44</sup>

7 **III. Plaintiffs’ Experts’ Lack of Any Reliable Methodology is Demonstrated By Their**  
 8 **Shifting Positions in Response to the 2018 NCI Study.**

9 In seeking to avoid the 2018 NCI study findings, plaintiffs’ experts also readily discard  
 10 previously-expressed opinions that no longer support their conclusion, which is the antithesis of the  
 11 scientific method. *See In re Bausch & Lomb, Inc. Contact Lens Solution Prod Liab. Litig.*, MDL  
 12 No. 1785, Civil Action No. 2:06-MN-77777-DCN, 2009 WL 2750462, \*13 (D.S.C. Aug. 26, 2009)  
 13 (excluding general causation expert whose “changing opinions, and willingness to abandon or  
 14 qualify her opinions when faced with further facts, undermines the reliability of her opinions”).<sup>45</sup>

15 Plaintiffs’ experts’ moving-target approach is most clearly illustrated in their discussion of  
 16 meta-analyses, on which plaintiffs’ experts heavily relied prior to the 2018 NCI study but now  
 17 abandon because an updated meta-analysis including the 2018 NCI study finds no association.<sup>46</sup>

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 19 <sup>43</sup> Neugut Supp. Dep. 86:22-88:7; Ritz Supp. Dep. 82:3-83:15; Ritz Supp. Dep., Ex. 30-13  
 (Hollingsworth Decl., Ex. 14).

20 <sup>44</sup> Plaintiffs’ experts’ disregard of the AHS validation studies and sensitivity analyses serves as the  
 21 flip side of the coin from their faulty methodology in assessing the glyphosate case control studies.  
 22 In those studies, when investigators conducted sensitivity analyses adjusting for the impact of other  
 23 confounding pesticide exposures or the use of less reliable proxy data, the odds ratios upon which  
 24 plaintiffs’ experts seek to rely disappeared, confirming in the case control studies the same finding  
 of no association between GBHs and NHL. *See* Expert Report of Lorelei Mucci at 45-47, ECF No.  
 546-18 (explaining how adjustments to data in North American case control studies reduced odds  
 ratios below 1.0, showing no association); *id.* at 52-53 (adjusting for confounders in Eriksson case  
 control study reduced odds ratio to non-significant null finding).

25 <sup>45</sup> *See also Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271, 1296-97 (M.D. Fla. 2009)  
 26 (excluding expert witness whose “veritable moving target” opinion “smacks of post-hoc  
 27 rationalization and is devoid of the intellectual rigor that *Daubert* demands”); *In re Rezulin Prod.*  
*Liab. Litig.*, 309 F. Supp. 2d 531, 563-64 (S.D.N.Y. 2004) (excluding expert who shifted prior  
 position when confronted with epidemiologic studies inconsistent with his prior opinion).

28 <sup>46</sup> Mucci Supp. Rep. at 8; Neugut Supp. Dep. 45:1-11.

1 Notwithstanding the methodological concerns in relying on meta-associations (acknowledged by  
 2 one of their own epidemiology experts in his initial deposition),<sup>47</sup> plaintiffs in their *Daubert*  
 3 Opposition, argued that “meta-analysis is considered the strongest of medical evidence types.”  
 4 Opp’n Br. at 28. Plaintiffs’ expert Dr. Ritz was one of the chief proponents of the strength of the  
 5 meta-analysis method, citing repeatedly to the meta-relative risks in her initial expert report and  
 6 first round of deposition testimony, and arguing that any biases in the underlying studies included in  
 7 the meta-analyses likely cancelled out so that the reported summary associations were reliable.<sup>48</sup>  
 8 With the 2018 NCI study clearly changing the meta-analysis output to “no association,” however,  
 9 Dr. Ritz has reversed course. Dr. Ritz now disavows reliance on meta-relative risks, stating that  
 10 “[a]s a scientist, I never rely on any summaries” and that meta-relative risks are “least informative  
 11 ... because that just gives you a summary estimate that might be highly biased.”<sup>49</sup>

12 To avoid the plain import of the 2018 NCI study, Dr. Ritz abandoned other sworn positions  
 13 as well. For example, in her critique of De Roos 2005, Dr. Ritz argued that the adjustment for  
 14 confounders in the AHS cohort “would lead to over-adjustment and introduce major bias.”<sup>50</sup> Dr.  
 15 Ritz argued that “just claiming that something is a confounder is not enough,”<sup>51</sup> and in their  
 16 *Daubert* Opposition, plaintiffs criticized using “the mere *possibility* of uncontrolled confounding ...  
 17 to call into question the results of a study.” Opp’n Br. at 40. Faced now though with the daunting  
 18 task of turning the null findings in the 2018 NCI study into a statistically significant positive  
 19 association, Dr. Ritz unabashedly relies on the mere possibility of uncontrolled confounding.<sup>52</sup>  
 20 Likewise, Dr. Ritz initially criticized De Roos 2005 for what she (mistakenly) believed was a short  
 21 latency period, arguing that for “biological plausibility ... we would generally expect a 5-10 year  
 22  
 23

24 <sup>47</sup> See Monsanto *Daubert* Br. at 19-21.

25 <sup>48</sup> Expert Report of Beate Ritz at 16, 23, 25, ECF No. 546-9 (“Ritz Init. Rep.”); Ritz Rebuttal Rep.  
 at 10; Ritz Init. Dep. 321:11-322:3.

26 <sup>49</sup> Ritz Supp. Dep. 112:18-114:19.

27 <sup>50</sup> Ritz Rebuttal Rep. at 7.

28 <sup>51</sup> *Id.* at 9.

<sup>52</sup> Ritz Supp. Dep. 94:4-18; 167:14-22.



1 minimum latency between exposure and disease onset for blood system related cancers.”<sup>53</sup> With  
 2 the emergence of the updated AHS analyses unambiguously negating that criticism – and Dr. Ritz’s  
 3 recognition that this opinion undercuts her attempted reliance on case-control studies that required  
 4 significantly shorter latency periods – Dr. Ritz again reversed course, contending now that the  
 5 latency period for NHL development might be as short as 1-2 years.<sup>54</sup> Before the 2018 NCI study,  
 6 Dr. Ritz also criticized De Roos 2005 for conducting a dose response analysis that compared the  
 7 most highly exposed glyphosate users with lower exposed glyphosate users rather than individuals  
 8 with no exposure, contending that this approach “reduces any remaining exposure contrasts even  
 9 further and thus reduces the ability to estimate risk increases with exposure.”<sup>55</sup> But with the 2018  
 10 NCI study following her preferred approach of comparing highly exposed glyphosate users to those  
 11 with no exposure (and finding no increase in NHL), Dr. Ritz reversed course yet again and now  
 12 argues in favor of the high-to-low exposure dose response approach she previously attacked.<sup>56</sup>

13 “Put bluntly, this is not how good science is done.” *Haller*, 598 F. Supp. 2d at 1297.

14 **IV. Plaintiffs’ Experts’ “Opinion First, Analysis Later” Approach to the 2018 NCI Study**  
 15 **is Illustrative of Their Flawed Methodology in All of Their General Causation**  
 16 **Opinions.**

17 In relying on speculation and disproven hypotheses to dismiss the 2018 NCI study’s finding  
 18 of no association between GBHs and NHL, plaintiffs’ experts “turn[] scientific analysis on its head.  
 19 Instead of reasoning from known facts to reach a conclusion, the experts here reasoned from an end  
 20 result in order to hypothesize what needed to be known but what was not.” *Sorenen v. Shaklee*  
 21 *Corp.*, 31 F.3d 638, 649 (8th Cir. 1994).

22 Plaintiffs’ experts’ “opinion first, analysis later” methodology has infected their general

23 <sup>53</sup> Ritz Init. Rep. at 17. Dr. Ritz argued that De Roos 2005 did not allow sufficient time for NHL to  
 24 develop because the study only followed the cohort for 4-8 years. *Id.* at 20. In fact, the study had  
 25 collected exposure information dating back some 20 years prior to enrollment, allowing far longer  
 26 latency than the case control studies on which she relies. *See* Neugut Init. Dep. 145:18-146:8.

27 <sup>54</sup> Ritz Init. Dep. 196:15-198:14. The impact of Dr. Ritz’s earlier latency argument in undermining  
 28 her reliance on the U.S.-based case control studies was acknowledged in an earlier deposition by  
 plaintiffs’ other epidemiologist, Dr. Neugut. *See* Neugut Init. Dep. 196:9-198:17, 229:11-233:17.

<sup>55</sup> Ritz. Init. Rep. at 23.

<sup>56</sup> Ritz Supp. Dep. 82:18-83:23, 166:10-167:22.

1 causation opinions in this litigation from its inception. Many of their experts readily acknowledge  
 2 reaching their causation opinion upfront based solely on IARC’s outlier 2015 classification of  
 3 glyphosate as a probable human carcinogen.<sup>57</sup> The 2015 IARC analysis does not withstand  
 4 *Daubert* scrutiny on its face because it (1) conceded the limited nature of the then-existing  
 5 epidemiologic literature for which “chance, bias, and confounding” could not be excluded<sup>58</sup> and (2)  
 6 followed a hazard assessment approach that disregards dose such that “the Monographs identify  
 7 cancer hazards even when risks are very low at current exposure levels.”<sup>59</sup> But an objective expert  
 8 in any event would not have continued blindly relying on IARC after discovery revealed that the  
 9 IARC Working Group: (1) based its classification on only “a day or two” of review of the  
 10 glyphosate science,<sup>60</sup> (2) was not told about updated epidemiologic analyses – including an earlier  
 11 update of the AHS cohort in the possession of the Working Group Chair, Aaron Blair – that  
 12 contradicted any suggestion of association between GBHs and NHL,<sup>61</sup> (3) did not – unlike EPA and  
 13 international regulatory agencies which reached contrary conclusions – review any of the actual  
 14 glyphosate rodent cancer studies,<sup>62</sup> (4) failed to consider publicly available data on tumor findings  
 15 in 12 glyphosate rodent cancer studies because “the amount of data in the tables was

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 18 <sup>57</sup> Neugut Init. Dep. 11:8-16, 16:19-23, 18:6-18; Dep. of Christopher Portier 39:24-40:9, 71:8-17,  
 152:19-153:14, ECF No. 546-2 (“Portier Init. Dep.”); Dep. of Chadi Nabhan 64:19-65:6, 68:5-20,  
 ECF No. 546-4; Dep. of Charles Jameson 246:16-247:5, ECF No. 546-14 (“Jameson Fact Dep.”).

19 <sup>58</sup> *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) (“Before any inferences are  
 20 drawn about causation, the possibility of other reasons for the association must be examined,  
 including chance, biases ... and confounding causes.”).

21 <sup>59</sup> IARC, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Preamble, 2 (Jan.  
 22 2006), <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>; *In re Hanford Nuclear*  
 23 *Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002) (“the appropriate understanding of [general]  
 causation is ... whether exposure to a substance for which a defendant is responsible, such as  
 radiation at the level of exposure alleged by the plaintiffs, is capable of causing a particular injury  
 or condition in the general population”).

24 <sup>60</sup> Dep. of Aaron Blair 115:12-15, ECF No. 546-17.

25 <sup>61</sup> *Id.* 176:5-178:7 (updated AHS analysis); *id.* 148:7-22, 149:22-150:11 (updated pooled analysis of  
 26 North American case-control studies (“NAPP”)); *id.* 183:5-18, 188:24-189:3, 192:23-193:3 (Dr.  
 Blair acknowledgment that if updated AHS analysis and NAPP study had been considered, it would  
 27 have lowered and rendered insignificant IARC-calculated meta-analysis relative risk of GBHs and  
 NHL upon which plaintiffs’ experts previously relied).

28 <sup>62</sup> Jameson Fact Dep. 279:6-24, 284:8-17.

1 overwhelming,”<sup>63</sup> and (5) relied upon incorrect statistical analyses (that differed from the analyses  
 2 used by original study investigators and the EPA or other regulatory bodies) in concluding that  
 3 there was a statistically significant trend in renal tumors in one rodent study.<sup>64</sup>

4 Clearly, from day one, plaintiffs’ experts have been fixed in their causation opinions without  
 5 waiver, even in the face of new or additional data that is directly contrary to those opinions. As  
 6 plaintiffs’ expert oncologist Dr. Nabhan frankly concedes, “at this point, nothing would shake my  
 7 conviction” that glyphosate causes NHL.<sup>65</sup> Such preconceived intransigence now has led them to  
 8 opine that the 2018 NCI study “provides [no] evidence at all,”<sup>66</sup> has “no impact on my evaluation of  
 9 the epidemiology data,”<sup>67</sup> “contributes nothing,”<sup>68</sup> and “[does not have] any weight in the  
 10 evaluation of whether glyphosate-based herbicides cause[] non-Hodgkin’s lymphoma.”<sup>69</sup>  
 11 Plaintiffs’ experts’ methodological contortions in support of their “pay no attention to the science”  
 12 opinions underscore their failure to meet the *Daubert* standards of scientific reliability and  
 13 relevance.

#### CONCLUSION

14  
 15 Monsanto’s *Daubert* Motion and Summary Judgment Motion Based on Failure of General  
 16 Causation Proof should be granted.

17 DATED: February 16, 2018

Respectfully submitted,

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 19 <sup>63</sup> *Id.* 191:25-192:6. Another IARC working group member, Dr. Ross, who served on the subgroup  
 20 that assessed glyphosate for genotoxicity, conceded at deposition that he had not even read the key  
 21 genotoxicology study cited by IARC in support of its carcinogenicity classification until after the  
 22 working group had announced its decision. Dep. of Matthew Ross 202:20-203:1 (May 3, 2017)  
 23 (describing 2009 study as “strong piece[] of evidence”); *id.* 203:22-204:2 (admitting he did not read  
 24 that study until after conclusions were reached).

25 <sup>64</sup> Portier Init. Dep. 257:24-259:8; *see also* Expert Report of Christopher Portier, Ex. 7, ECF No.  
 26 546-19 (acknowledging error in IARC’s failure to use exact trend test, which “overstat[ed] the  
 27 significance of the observed trend”); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. &*  
 28 *Prod. Liab. Litig.*, 145 F. Supp. 3d 573, 582-584 (D.S.C. 2015) (excluding plaintiff’s causation  
 expert for similar “results driven” statistical manipulations).

<sup>65</sup> Nabhan Supp. Dep. 17:23-18:8.

<sup>66</sup> Neugut Supp. Dep. 47:4-17.

<sup>67</sup> Portier Supp. Dep. 53:23-54:10.

<sup>68</sup> Jameson Supp. Dep. 86:19-87:16; *see also id.* 95:12-23 (arguing that 2018 NCI study “should not  
 be included in any consideration of the cancer hazard of glyphosate or glyphosate formulations”).

<sup>69</sup> Ritz Supp. Dep. 112:13-17.

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