R. Brent Wisner, Esq. (SBN: 276023)
rbwisner@baumhedlundlaw.com
Michael L. Baum, Esq. (SBN: 119511)
mbaum@baumhedlundlaw.com
BAUM, HEDLUND, ARISTEI, & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Telephone: (310) 207-3233
Facsimile: (310) 820-7444

Attorneys for Plaintiffs
(Additional attorneys on signature page)

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	MDL No. 2741 HON. VINCE CHHABRIA **PLAINTIFFS' SUPPLEMENTAL MEMORANDUM IN RESPONSE TO MONSANTO'S CONTENTION THAT PLAINTIFFS' EXPERTS OFFERED NEW OPINIONS**

TABLE OF CONTENTS

INTRODUCTION

On March 19, 2018, the Court issued PTO 43, in which the Court ordered the Plaintiffs to bring back certain experts for additional days of testimony because, *inter alia*, that there was insufficient time during the *Daubert* hearing, held during the week of March 5, 2018, to address the epidemiology opinions of Drs. Ritz and Portier. The Court further provided that it intended to ask follow up questions at the second *Daubert* hearing, which the Court scheduled for April 4 and 6, 2018. See PTO No. 43. In addition to PTO No. 43, at the oral argument on March 14th, the Court identified many of the epidemiology issues the Court wanted answered. The Plaintiffs came prepared on April 4th and 6th to answer the issues that the Court identified. None of that testimony is "new"; to the extent that it was presented in a different format or with hypotheticals or examples, it remains squarely within the scope of the experts' opinions as set forth in their reports. To rule otherwise would be to penalize the Plaintiffs for doing exactly what the Court asked: to address the questions that the Court posed during the Daubert hearing of March 5 - 9, 2018 at the oral argument on March 14th.

In its supplemental brief, Monsanto incorrectly argues that Plaintiffs' experts Dr. Beate Ritz and Dr. Christopher Portier offered "new" opinions during their *Daubert* testimonies and that, because these opinions were not previously disclosed, they should be excluded from this Court's consideration. In other words, Monsanto asks this Court to ignore relevant testimony—testimony that was subjected to rigorous cross-examination and is based on sound scientific methodology. Further, as stated above, it is evidence that is encompassed in both experts' opinions. Monsanto's argument has no merit.

First, the supposedly "new" opinions that Monsanto seeks to exclude are not new at all. As explained below, each of these opinions were disclosed in Dr. Ritz's and Dr. Portier's expert reports and were discussed during their depositions. Thus, the *Daubert* testimony of Drs. Ritz and Portier only served to further explicate or elaborate upon existing opinions. Second, even if these opinions were deemed "new," the unique posture of this case would militate against excluding the testimony. The Court is engaged in a highly complex *Daubert* proceeding, far removed from any jury. The risk of "sandbagging" before a jury is not at issue. Plus, the opinions that Monsanto now

challenges were all proffered in response to questions raised by the Court, and Monsanto has been afforded a complete opportunity to cross-examine and challenge those opinions during the proceeding. In the absence of any prejudice and considering the purpose of these *Daubert* proceedings, the Court is fully within its discretion to consider them.

ARGUMENT

I. Dr. Ritz and Dr. Portier Did Not Offer Any "New" Opinions During either *Daubert* Hearing

At the heart of Monsanto's supplemental brief is the assertion that Dr. Ritz and Dr. Portier offered "new" opinions during the *Daubert* hearings. This is simply untrue. As discussed below, every "new" opinion challenged by Monsanto was either clearly disclosed in their expert reports and/or in their various depositions.

A. Dr. Ritz's Opinions Regarding Confounding and Latency at the Daubert Hearings Were Described in Her Reports and Discussed in her Depositions

1. Dr. Ritz Did Not Offer Any "New" Opinions about Confounding, and Monsanto's Claim that She Never Considered Adjusted Odd Ratios Is a Complete Fabrication

At oral argument, Monsanto told this Court:

> Dr. Ritz does not present and did not present, in this hearing or in her Expert Reports, an opinion that was predicated on the adjusted Odds Ratios. She repeatedly went to the unadjusted Odds Ratios as providing a basis for her opinions. So we don't have an opinion from her that is based upon the properly adjusted Odds Ratios.

Tr. of Proceedings on March 14, 2018 ("Daubert Argument") at 8:13-18. This is plainly false. Not only did Dr. Ritz discuss her consideration of adjusting for other pesticides, but she specifically *invited* Monsanto's counsel to discuss how she considered this issue for each study during her deposition.

In Dr. Ritz's initial report, she specifically defines confounding, *see* Exh. 1[1] at 7, and then explains that she considered confounders in arriving at her opinion:

> ***The most highly adjusted estimates (also known as "fully adjusted" models) are the estimates that adjust for as many confounding variables as possible, such as adjusting for age, sex, race, and also sometimes other pesticide exposures. This is relevant because it gives the reader confidence that the findings are most likely due***

[1] All exhibits cited are from the official *Daubert* record.

> ***to glyphosate/Roundup exposure, instead of another potential cause that acts as a confounder.*** As such IARC's Working Group conducted their own meta-analysis using solely the most highly adjusted estimates from the same studies, and reported a meta risk-ratio of 1.3 (95% CI, 1.03–1.65), with consistent findings across studies (low heterogeneity). I concur with the IARC conclusions after ***conducting my own independent analysis of the studies***[.]

Id. at 16 (emphasis added). Throughout her report, Dr. Ritz discusses various odds ratios ("ORs") from the published literature, many of which did adjust for exposures to other pesticides. Specifically, Dr. Ritz discusses De Roos 2003, which adjusted for 47 other pesticides, and she explained that "the OR for glyphosate was among the highest of 47 pesticides tested, which suggests that glyphosate may indeed be the pesticide most strongly related to NHL in these farmers among all pesticides they used." *Id.* at 19. Dr. Ritz also reported ORs from Cantor 1992, Hardell 1999, Hohenadel 2011, Schinasi 2014, and Chang 2016, which also adjusted for exposures to other pesticides. *Id.* at 14. She also discussed the effects of co-exposures of glyphosate and other pesticides in the McDuffie 2001 study. *Id.* at 18. And, while Dr. Ritz did not specifically report the multivariate ORs for Hardell 2002 and Eriksson 2008, she reviewed those studies and considered the ORs of the multivariate analyses. *See* Ritz Sept. Depo. at 154:19-158:5. Regarding the North American Pooled Project ("NAPP"), Dr. Ritz did not have the fully-adjusted ORs when she prepared her initial report, but she did review them later and concluded "[t]he only way it changed my opinion is that it solidified the opinion that there is, in fact, carcinogenicity to go after." *Id.* at 429:21-23.

Dr. Ritz also discussed the confounding issue in her rebuttal report, responding to criticism from Monsanto's experts that she did not properly consider confounding by exposures to other pesticides. Exh. 2 at 7, 9-10. She explained that throwing everything into a model can generate its own bias and that epidemiologists are very careful in deciding what, if anything, to adjust for:

> This generates the necessity to distinguish between true confounding co-exposures (pesticides that truly cause NHL and are also associated with glyphosate exposures) and co-exposures that solely act as 'proxy measures' for glyphosate/GBFs but do not cause NHL. ***For the latter, one should not adjust since this would lead to over-adjustment and introduce major bias.***[2]

[2] During the first day of *Daubert* testimony, after Dr. Ritz had left the stand, the Court queried "unless we are confident that there's not a link, I don't understand why we would ever think it is not a good idea to adjust." Daubert Tr. 211:7-9. This is the reason—over adjustment can, itself, inject

…

> [T]he issue of confounding control as raised by both defense experts is clearly out of step with the current thinking in epidemiology. This methodology, used by both Drs. Rider and Mucci, is not the methodology that is currently accepted by epidemiologists, especially those who study and analyze complex exposures. For example, multiple exposures have to be cautiously addressed in terms of ***what is or isn't a risk factor for the outcome or should be considered a confounder. We have to consider prior knowledge, and just claiming that something is a confounder is not enough. Rather, the question would be how strong a confounder we would need to change the results we observe and in what direction this change would be*** [not all confounding changes the estimates away from the null]; and ***what variables would qualify as confounders***[.]

Exh. 2 at 7, 9-10 (emphasis added). Dr. Ritz's critical evaluation about whether there is true confounding is proper science. *See, e.g.*, Ref. Man. at 591 ("Often the mere possibility of uncontrolled confounding is used to call into question the results of a study. This was certainly the strategy of some seeking … to undermine … studies … linking cigarette smoking to lung cancer. The critical question is whether it is plausible that the findings of a given study could indeed be due to unrecognized confounders."); *see also In re Abilify (Aripiprazole) Prod. Liab. Litig.*, No. 3:16-MD-2734, 2018 WL 1357914, at *19 (N.D. Fla. Mar. 15, 2018) (rejecting defendant's attempt to discredit an epidemiology study during general causation phase because of potential confounders: "[C]onfounding is a 'reality' inherent in all epidemiological research… It cannot be said that an epidemiological analysis … is unreliable evidence … simply because it did not account for all possible confounders. Only when a methodology' is so incomplete as to be inadmissible as irrelevant' should it be excluded[.]"). Indeed, Monsanto's own epidemiologist, Jennifer Rider, agrees:

> Well, I think this is why epidemiologists need to know, you know, something about the relationship between the exposure and the outcome to determine what those potential confounders might be. ***The wrong approach is just simply, you know, throwing everything in a model.*** You have to think that that could actually be a common cause potentially of the exposure and the outcome.

---

major bias into a study, rendering the results meaningless. When the Court asked this question, Plaintiffs offered to put Dr. Ritz back on the stand to answer it, but the Court declined. That said, it is stated in her report and she discussed this issue during her second *Daubert* testimony. Ritz Second Daubert at 18:1-14.

Rider Depo. at 46:12-21 (emphasis added).[3] And, in the epidemiological studies that looked at confounding from other pesticides, there was *no* indication other pesticides had any impact:

> **Cantor 1992:** "There was minimal evidence for confounding of results for any single pesticide by exposure to pesticides belonging to other chemical families." Exh. 222, pg. 2461.
>
> **McDuffie 2001:** "Among individual pesticides, carbaryl, lindane, DDT, and malathion insecticides, and captan fungicide user/nonuser were included in the initial multivariate model and found not to contribute significantly to the risk of NHL." Exh. 21, pg. 1160.
>
> **De Roos 2003:** "Adjustment for multiple pesticides suggested that there were few instances of substantial confounding of pesticide effects by other pesticides." Exh. 15, pg. 7.
>
> **Andreotti 2018:** "In our study, controlling for other pesticides did not change the risk estimates." Exh. 17, pg. 7.[4]

During her original deposition, Monsanto's attorney Eric Lasker spent considerable time asking Dr. Ritz about her opinions related to confounding and Dr. Ritz made it abundantly clear that she considered the issue. Even Mr. Lasker pointed out that Dr. Ritz offered the opinion in her report, prompting Dr. Ritz to invite Mr. Lasker to go through each study and discuss confounding:

> Q. Dr. Ritz, we were talking about confounding, and I think ***one of the points you made in your report***, I think elsewhere, is in analyzing or conducting a study, you'd want to identify as best you can other risk factors for disease that you're studying to be able to see whether or not those are confounders; correct?
>
> A. It is correct that you're always very worried about confounding no matter what and that you're identifying strong risk factors for the disease that also is associated with exposure. …

[3] Indeed, Dr. Rider's definition and methodological approach to potential confounders is strikingly similar to Dr. Ritz's. Rider Depo at 45:21-48:11. Dr. Rider testified that the propriety of adjusting for potential confounders depends upon one's "biological knowledge" and the relationship between the potential confounder and the disease. *Id* at 45:21-46:6. And Dr. Rider agrees with Dr. Ritz that reflexive adjustment for *any* potential confounder is the "wrong approach." *Id.* at 46:17.

[4] Monsanto's concerns about confounding from other pesticides finds little support in the epidemiolocal data for glyphosate. Indeed, as Dr. Aaron Blair noted in a publication devoted expressly to the issue of confounding in occupation epidemiology: "It is rare to find substantial confounding in occupational studies (or in other epidemiologic studies for that matter), even by risk factors that are strongly related to the outcome of interest." Exh. 31 at 205. The reason for this is that it is rare for an agent to be both associated with NHL *and* differentially associated with just glyphosate use. In the epidemiological studies, other pesticides are either not strongly associated with NHL or they are similarly distributed among glyphosate and non-glyphosate users.

…

And so what that means is we have to convince ourselves that a variable is a confounder, meaning, there's an underlying true association between that variable and the outcome as well as that variable and the exposure of interest and that that variable is not just a proxy measure of the exposure that I'm actually trying to evaluate.

…

So confounding is always a possibility especially with highly correlated exposures. So the intellectual challenge here is to decide how to treat these variables. ***Are they truly confounders in the sense that we are assuming that glyphosate has no effect and all the effect comes from the other pesticide, or are there one or two or three carcinogens, all of them contributing to the risk of NHL, and how do we put those together in a model*** if we -- if they're highly correlated, we put them all three in the model, then they will just split variance, and none of them will show anything.

…

Q. Has there been, in fact, an epidemiological study conducted that you've reviewed that would allow you to tease out that fact between the different pesticide exposures?

[Objection omitted]

[A]. That depends on which study we are talking about because ***confounding is a study-specific issue.*** So in some studies, one of these pesticides may be a confounder. In another study, it might not be, and that would depend on the timing of exposure.

…

[Q]. Is there an epidemiological study that you've identified in the literature that allows you to distinguish between glyphosate and other pesticides that are potentially being used by that population to determine whether all of them are risk factors, one of them is a risk factor, or distinguish between them?

[objection omitted]

[A]. Well, I think the De Roos 2003 study is actually a very good example where even after we adjust for 40-some pesticides, the effect of glyphosate is still apparent.

…

Q. Other than De Roos 2003, is there a study that you believe allows you to tease out the effects of glyphosate versus another pesticide to determine which of those are risk factors and which of those are just correlated?

A. I believe that the Eriksson study also made multiple adjustments and glyphosate survived those, but it is real [sic] study to study. ***We could go through all of them.***

Ritz Sept. Depo. at 144:24-145:11, 167:12-20, 330:18-331:8, 333:4-333:16, 334:13-335:22

(emphasis added). Mr. Lasker, however, did *not* take Dr. Ritz up on her offer to go through each study.[5]

This issue came up, again, during her original *Daubert* testimony. There, Dr. Ritz once again defined confounders and discussed why it was important to be cautious in making adjustments for other pesticides. *See* Daubert Tr. 14:24-16:22, 23:1-26:15. During that discussion, the Court asked a clarifying question:

> THE COURT: So your opinion is that if we don't know a pesticide is a risk factor for NHL, we should not adjust for it in a study?
>
> THE WITNESS: That's not -- sorry if it came across wrong. No. I'm not saying we should not adjust for it, but when we adjust for it, we should really be careful about how we interpret what's happening to the effect estimates. Most likely is that the confidence intervals widen when you do this, and that the effect estimates -- if that pesticide is highly correlated with the one under investigation, it is you who has to decide whether it means as a confounder it's a true risk factor and I should adjust for it, or it's a proxy, like the breath mint. Right? And nobody will take that away from us. We just have to do that.

Daubert Tr. at 26:5-15. Clearly, nothing about this testimony was new. It was, in fact, nearly identical to the discussion in her rebuttal report and deposition testimony.

Finally, at the April 4, 2018, hearing, the Court asked Dr. Ritz some specific questions about her consideration of confounders. And, once again, her testimony was the same:

> THE COURT: In the opinions that you provide in your reports and in your testimony, you -- you place very heavy emphasis on numbers that are not adjusted for other pesticide use. And I wanted to ask you sort of a methodological question, I guess, which is: Is it okay in, you know, forming an opinion like this to place such heavy emphasis on numbers that are not adjusted for other pesticide use when you have numbers that are adjusted for other pesticide use that you could be emphasizing instead?
>
> THE [WITNESS]: I'm actually a little shocked that you say that because I didn't feel that I did that. And I feel very misunderstood if that's what you read. ***Definitely, I want to look at adjusted estimates. I looked at adjusted estimates.*** But for the early studies, as I said, ***I would be just as worried about that sparse data bias which you throw everything in to the model.*** And sometimes ***with the multiply adjusted estimates, I'm a little worried about them putting things in there that they shouldn't be putting in there.*** …[W]hat I tried to convey is that even though we are generally having a knee-jerk reaction of, oh, just put everything into the model, that is probably the wrong approach. ***You have to think about which of the pesticides are risk factors, are associated with glyphosate.*** The number issue. ***Can I adjust without***

[5] Although, for the Eriksson 2008 study, Mr. Lasker did discuss the fully-adjusted estimate and how, if at all, it affected Dr. Ritz's opinions. *See* Ritz Sept. Depo. at 308:2-312:19.

> ***introducing bias? And all of that goes into my evaluation. And, yes, if I'm able to adjust for as much as I want to, I definitely want to see those numbers, and I think that the De Roos paper did a really good job in that. So if it came across like I didn't look at those, that's not what I intended.***

Tr. of Proceedings on April 4, 2018 ("Daubert II Tr.") at 36:24-38:5 (emphasis added). Again, there was nothing new in her testimony. Rather, she continued to take the position that she did, in fact, review the fully adjusted ORs and they supported her opinion—although, she was cautious of mindlessly adjusting for all possible confounders.

Later in the hearing, the Court delved further into Dr. Ritz's opinions, and asked whether Dr. Ritz's opinion would change if she exclusively relied on fully-adjusted data, and she explained that it would not. *See id.* at 38:6-39:2. Again, testifying that her opinion does not change when she ignores certain data does not qualify as a new opinion—it is just clarification about her already-expressed opinion.

The entire premise of Monsanto's argument is that Dr. Ritz offered new opinions at the *Daubert* hearing and that Monsanto was deprived of its ability to properly cross-examine her. As shown above, this is not true. Monsanto was fully apprised of Dr. Ritz's opinions concerning adjustment for other pesticides and that opinion did not change from day one. Moreover, not only did Monsanto have an opportunity to explore this topic during her deposition, but Dr. Ritz specifically invited Monsanto's counsel to do so. Any attempt to exclude this testimony because it is supposedly "new" and unfair is wholly without merit.

2. Dr. Ritz Offered No "New" Opinion Concerning Latency

At the *Daubert* argument, Mr. Lasker attempted to discredit Dr. Ritz's opinions about latency, suggesting her opinion about the issue shifts depending on whether it supports her opinion. He told the Court:

> The issue for Dr. Ritz with the Cantor Study is that it recorded a 1.1 Odds Ratio. It was not statistically significant. And you can look at the study to see how they analyzed that and came to that conclusion, but it was not an Odds Ratio that was helpful to the plaintiffs' case. And Dr. Ritz, in her Expert Report, says, Well, true, but this is not informative, because of the latency. There's only 6 to 10 years of possible time that could have elapsed in this study. And the issue, of course, is: Why would that same analysis not apply, then, to De Roos?

Daubert Argument at 18:25-19:9. This argument was also reasserted in Monsanto's supplemental brief. *See* Suppl. Br. at 5:14-21. The argument, however, is dishonest. Dr. Ritz explained in her

report that the Cantor study was incorporated into the Lee study, which was then pooled into De Roos 2003. *See* Exh. 1 at 18-19. She also explained that "[t]he Lee study utilized Cantor's cohort to build upon by including subjects from Nebraska who were diagnosed July 1983 to June 1986, thus this study includes cases with a longer latency period, which improves confidence in results." Exh. 1 at 19. Then, at her deposition, Mr. Lasker asked about whether the latency concern in Cantor applied to De Roos 2003, and Dr. Ritz agreed that it did, but explained that De Roos 2003 was slightly better because it contained longer latency data from Nebraska:

> Q. Am I correct, though, in my understanding that the -- your concern -- while you're concerned about the latency period in the Cantor study as making that study less informative, you do not have that same concern for the De Roos 2003 study?
>
> A. … ***With respect to latency, the same rules apply.*** However, she added some studies that actually had longer latency. Again, the latency issue is an issue because I'm missing cases that are truly caused by the exposure, if I believe exposure causes disease, and so it has to do with early studies where I'm catching these early cases and not yet the later ones.
>
> ...
>
> Again, the latency period in Cantor cannot be different from what the latency period of the part of the data that is Cantor data in this pooled analysis is. So it is what it is. However, adding additional states and additional data improves what this study can do over the Cantor study. Plus it overall increases the latency because we have the Nebraska study as well.
>
> …
>
> Q. … In the Cantor 1992 study, you raised concerns about a median latency period of less than ten years as making that study which had a 1.1 adjusted odds ratio, in your mind, less informative. And I'm just trying to understand if that same concern about the median latency period of less than ten years makes the De Roos 2003 study which has that hierarchy ratio that you cite less informative.
>
> …
>
> [A]. Cantor is part of the study; however, the beauty of pooled studies is that they ***pool across different studies with different strengths and different weaknesses***. It helps for the sample size. It helps for the statistical power. ***In this case, it helps even to adjust for more variables that you would be happy to adjust for***, and overall, it's more powerful because of all of these reasons.
>
> …

> I think De Roos is a really excellent study that did everything we can do in terms of pooling data in terms of relating the exposures that she had access to to the outcomes ***in adjusting and trying different methods*** and in actually lengthening the overall latency by including Nebraska.
>
> …
>
> Q. My question is: Do you believe that the De Roos study is less informative because it has a median latency period of less than ten years?
>
> ...
>
> [A]. So the De Roos study generally is a better study than the Cantor study because it pools data. So it's not less informative. It's actually more informative, ***that it cannot go beyond the latency period of one of the studies included for that data is a no-brainer.***
>
> However, she added data with a longer latency; so she is actually now covering all sorts of latency periods that we can look at. ***And the longer, of course, we would have a latency period, the more powerful.*** If she had another study to add, it would become more powerful, but it is an incremental step going from one study that may be less informative to two studies that are more informative to three studies that are even more informative.

Ritz Sept. Depo. at 214:13-223:1 (emphasis added).

This latency issue in De Roos 2003 did not arise during Dr. Ritz's first day of testimony, but it did arise during her second. And, her testimony on April 4, 2018 was the same as her testimony during her deposition. She stated that the latency issue was not as much of a problem in De Roos 2003 because it included data from a longer study and it was able to adjust for other pesticides. Daubert II Tr. at 15:19-18:14. Nothing in her testimony changed.

Monsanto, however, argues that Dr. Ritz offered three new opinions during her second *Daubert* testimony. These assertions are meritless.

First, Monsanto claims that "Dr. Ritz opined that latency would only be an issue for solid tumors and apologized if she hadn't qualified that for blood-related tumors." Suppl. Br. at 6:5-6. However, Dr. Ritz did not say that latency is only an issue for solid tumors. She testified, in reference to a quote from her expert report on page 18-19, that "I'm phrasing here very carefully what usually would be expected in cancer studies. And I apologize if I didn't qualify that for blood-related cancers. ***I thought I did***, but I guess I didn't." Daubert II at 14:16-19 (emphasis added). It turns out, however, that Dr. Ritz was right—earlier in her report, at page 17, she qualified blood-related cancers with a shorter latency period: "typically we would generally expect a ***5-10 year***

minimum latency between exposure and disease onset for ***blood system related cancers***. (However, in an individual case the latency period could be as short as 1 year, and as long as 50+ years.)[.]" Exh. 1 at 17 (emphasis added).

Second, Monsanto claims that "Dr. Ritz claimed for the first time at the April 4, 2018 *Daubert* hearing that the latency problem in the Cantor study was 'fixed' in De Roos (2003) by the study authors' methodology adjusting for all other pesticides[.]" Suppl. Br. at 6. However, the word "fixed" appears nowhere in the transcript. Instead, Dr. Ritz was answering the Court's question about other causes of the increased NHL in the US studies: "How do we know that it wasn't something else that was causing the NHL that the people in these groups were being exposed to before they started being exposed to glyphosate given particularly that we know that farmers have always had elevated cases of NHL?" Daubert II Tr. at 16:2-6. And, in response, Dr. Ritz explained that this "hidden" confounder was not an issue in De Roos 2003 because the study was able to adjust for all other possible pesticides and still observe a statistically-significant doubling of the risk. This point was expressly noted in her expert report, where she explained that the De Roos 2003 data "suggests that glyphosate may indeed be the pesticide most strongly related to NHL in these farmers among all pesticides they used." Exh. 1 at 19. And, during her deposition, Dr. Ritz explained that "I think the De Roos 2003 study is actually a very good example where even after we adjust for 40-some pesticides, the effect of glyphosate is still apparent." Ritz Sept. Depo. at 334:23-335:2. There was nothing "new" in her *Daubert* testimony.

Finally, Monsanto argues that "Dr. Ritz presented a new theory regarding latency, speculating that individuals who are exposed later in life would be more susceptible to cancer due to age or weakened immune systems[.]" Suppl. Br. at 6:15-17. But, this opinion was *not* new. In Dr. Ritz's deposition, she clearly explained that age and susceptibility relate to latency:

> I'm using this in terms of epidemiologic latency time which we are estimating was in groups. … ***That's why I also refer to age.*** For example, ***somebody who is already age 60 and is more susceptible to exposures***, that cancer might just happen earlier after exposure than in somebody where the cancer cell is dormant and ***kept in check by the immune system and other factors for 20 more years.*** So the latency period is really an average or minimum dependent on what population I'm looking at and ***whether I allow for that population to age into the time when the cancers would occur.*** So mostly I would imagine ***I have higher power in my study when the people are aged into that age when they actually have cancer.***

Ritz Sept. Depo. at 188:16-189:15 (emphasis added). Once again, Monsanto misrepresents the facts.

Like Monsanto's assertions regarding confounding, these claims about new opinions related to latency are completely unfounded. Dr. Ritz's opinions concerning latency have been consistent and were not only explored during her deposition, but were described in her expert reports.

B. Dr. Portier Did Not Offer Any "New" Opinions During *Daubert*

Monsanto claims that Dr. Portier offered two new opinions during his Daubert testimony on April 6, 2018. This is not correct.

First, Monsanto argues that "Dr. Portier presented a series of complicated, hypothetical calculations regarding what he opined were possible biases created by the imputation methodology used in the 2018 Andreotti study." Suppl. Br. at 7. This imputation methodology, as reflected in the slides discussing his opinion, comes from the Heltshe 2012 publication, which describes, in detail, how the Agricultural Health Study ("AHS") imputed missing data in the cohort. Dr. Portier's supplemental AHS expert report discusses this publication, noting that there was considerable bias for the glyphosate imputation which "suggests either a systematic bias towards imputing no exposure or there is some aspect of non-response that is correlated with cohort members having less exposure during this period." Exh. 164 at 3. In his supplemental report, Dr. Portier explains that "[i]f the bias is systematic, this would lead to a differential exposure misclassification potentially assigning cohort members to the unexposed group when they are really exposed." *Id.* What is more, Mr. Lasker questioned Dr. Portier about the Heltshe publication extensively at his Supplemental deposition. During his testimony on April 6, 2018, Dr. Portier explained what this means using a graphical display designed to explain the best and worst-case scenarios. His overall opinion, however, was that "you still have differential exposure misclassification and you could have a lot of non-differential exposure misclassification error" using the imputation methodology. Tr. of Proceedings on April 6, 2018 ("Daubert III Tr.") at 56:9-13. This is not a new opinion—it is reflected in his report and was also discussed, at length, in his AHS deposition. *See* Portier AHS Depo. at 78:6-104:18.

Second, Monsanto asserts that Dr. Portier offered "new, undisclosed opinions seeking to

distinguish between latency concerns in cohort and case control studies." Suppl. Br. at 7 20-22. Remarkably, Monsanto chose ***not*** to depose Dr. Portier about his epidemiological opinions for any length of time (other than the AHS). However, Dr. Portier explained in his expert report that "[b]ecause the latency period for cancers can be long (years), evaluation of studies should consider whether the exposure occurred sufficiently long ago to be associated with cancer development[.]" Exh. 162 at 5. And, in discussing the epidemiological data, Dr. Portier discussed what the data showed regarding latency. When the Court asked Dr. Portier to apply his understanding of latency to a particular study, he responded, consistent with the opinion in his report, that De Roos 2003 "is the strongest study with sufficient power[.]" *Id.* at 9:

> Because De Roos adjusted for every other pesticide she could possibly adjust for, unless there is a phantom pesticide out there or a phantom exposure causing the NHL, then seeing NHL should worry you. If you hadn't seen NHL in that study you might argue: Okay, the latency wasn't long enough. But having seen it and having adjusted for everything, I would have to conclude that that's a real NHL finding.

Daubert III Tr. at 150:12-19. This opinion, too, is not new—it is merely foundational to his overall discussion of De Roos 2003 and the weight Dr. Portier placed on the study.

Thus, as with Dr. Ritz, Monsanto's attempt to characterize Dr. Portier's testimony as a "new" opinion is unpersuasive and unsupported. Dr. Portier did not offer any new opinions—his testimony simply consisted of deeper explication of already-disclosed opinions.

II. Even If New Opinions Were Disclosed, It Would Not Preclude Their Consideration by the Court

Setting aside whether Drs. Ritz and Portier offered any "new" opinions at the *Daubert* hearing, there is an issue of whether that even matters in this procedural context. In expert discovery, "the party's duty to supplement extends both to information included in the report and to information given during the expert's deposition[.]" Fed. R. Civ. P. 26(e)(2). "Any additions or changes to this information must be disclosed by the time the party's pretrial disclosures under Rule 26(a)(3) are due." *Id.* And, under Rule 26(a)(3), supplementation must be done at least 30 days before trial." In the context of expert discovery, the obligation to supplement is tethered to a trial date. And this makes sense—new facts emerge or developments occur and the disclosure deadlines are designed to prevent undue surprise to opposing party when presenting to a trier of fact, where

"surprise" opinions can cause unfair prejudice.

Here, there is no trial date. For now, the Parties and Court are exclusively concerned with general causation, defined by the Ninth Circuit as "whether the substance at issue had the capacity to cause the harm alleged[.]" *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002). This is a circumscribed inquiry. For example, in *Hanford*, the Ninth Circuit reversed a district court for requiring plaintiffs, at the general causation phase, to prove causation at "specific threshold dose levels of exposure." *Id.* Thus, the purpose of this initial *Daubert* hearing is to allow the Court, acting as a gatekeeper, to explore and understand the nuances and bases of Plaintiffs' experts' opinions relating to general causation only. And, as part of that process, the Court is empowered to ask questions seeking clarification and even challenge Plaintiffs' expert opinions. It would make little sense to prevent Plaintiffs' experts from responding to those questions because, in preparing their expert reports, the expert did not foresee the Court's specific question. This is especially true when Monsanto is permitted to cross-examine any "new" response or opinion long before the case ever gets submitted to a jury.

As the Court noted, *In re Seroquel Prod. Liab. Litig.*, No. 6:06-MD-1769-ORL-22D, 2009 WL 3806435, at *13 (M.D. Fla. June 23, 2009), is particularly applicable here. In *Seroquel*, the plaintiffs' expert decided to proffer an entirely new opinion concerning the potential dose-response of a drug on a disease. *Id.*, at *13. That opinion was offered only a few weeks before the *Daubert* hearing. The *Seroquel* court held that "[i]n the ordinary toxic tort case, in which the parties often have only a few months to evaluate the expert testimony proffered by the opposing side prior to trial,… failure to promptly form and voice an opinion on dose-response … would likely result in exclusion of her testimony." *Id.* But, "[t]he circumstances of th[e] MDL counsel against such a result" because "the parties have had many months to develop and examine the testimony of Plaintiffs' general causation experts" and the defendant "was able to test these opinions at the *Daubert* hearing … and will have ample time to prepare a response to the opinions before her trial testimony is taken." *Id.* Thus, according to the court, the defendant "suffered no apparent prejudice, as counsel for the company had ample opportunity to question … these new opinions at the *Daubert* hearing." *Id.*

Here, unlike the expert in *Seroquel*, there is absolutely no evidence that Dr. Ritz or Portier offered a substantially new opinion—at worst, Dr. Ritz and Dr. Portier merely explained in greater detail the bases of their already-disclosed opinions. That said, the reasoning in *Seroquel* applies with equal force. Like the defendant in *Seroquel*, Monsanto has not suffered and will not suffer any prejudice in this case. Neither Dr. Ritz nor Dr. Portier are expected to be testifying to a jury in the case any time soon—the parties still have to work up general liability and any potential trial picks. Moreover, Monsanto was given ample time and opportunity to cross-examine both Dr. Ritz and Dr. Portier about these allegedly "new" opinions, and, in fact, Monsanto took that opportunity. Like the court in *Seroquel*, this Court should not exclude otherwise relevant and important testimony.

Ultimately, this Court has broad discretion to consider or restrict new opinions offered during a *Daubert* hearing. And, considering many of these "new" opinions were offered in response to the Court's inquiry, it would only make sense for the Court to exercise its discretion and consider these important and relevant opinions in the context of the overall *Daubert* analysis.

CONCLUSION

For the foregoing reasons, the Court should reject Monsanto's effort to exclude any testimony from the *Daubert* hearings, and it should consider the entire record before it.

DATED: April 11, 2018

Respectfully submitted,

By: /s/ R. Brent Wisner
R. Brent Wisner, Esq. (SBN: 276023)
rbwisner@baumhedlundlaw.com
Michael L. Baum, Esq. (SBN: 119511)
mbaum@baumhedlundlaw.com
BAUM, HEDLUND, ARISTEI, & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Telephone: (310) 207-3233
Facsimile: (310) 820-7444

Aimee Wagstaff
aimee.wagstaff@andruswagstaff.com
ANDRUS WAGSTAFF, P.C.
7171 West Alaska Drive
Lakewood CO 80226
Ph 303-376-6360
F 303-376-6361

Robin Greenwald
rgreenwald@weitzlux.com
WEITZ & LUXENBERG, P.C.
700 Broadway
New York NY 10003
Telephone: (212) 558-5500
Facsimile: (212) 344-5461

Michael Miller
mmiller@millerfirmllc.com
THE MILLER FIRM, LLC
108 Railroad Ave
Orange VA 22960
Telephone: (540) 672 4224
Facsimile: (540) 672-3055

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, R. Brent Wisner, hereby certify that, on April 11, 2018, I electronically filed the foregoing with the Clerk for the United States District Court for the Northern District of California using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ R. Brent Wisner
R. Brent Wisner