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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: *Hardeman v. Monsanto Co., et al.*, *3:16-cv-0525-VC* *Stevick v. Monsanto Co., et al.*, 3:16-cv-2341-VC *Gebeyehou v. Monsanto Co., et al.*,	**PLAINTIFFS' (1) RESPONSE IN OPPOSITION TO MONSANTO COMPANY'S SPECIFIC CAUSATION *DAUBERT* AND SUMMARY JUDGMENT MOTION AND (2) *DAUBERT* MOTION TO STRIKE CERTAIN OPINIONS OF MONSANTO COMPANY'S EXPERT WITNESSES**

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

Please take notice that Plaintiffs will and hereby do oppose Defendant Monsanto Company's Specific Causation *Daubert* and Summary Judgment Motion and move to strike certain opinions of Defendant Monsanto Company's expert witnesses. This motion is supported by the following memorandum of points and authorities, attached exhibits, all other filings and evidence in this case, and any such arguments or evidence considered by this Court.

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INTRODUCTION

"Nothing in *Daubert*, or its progeny, properly understood, suggests that the most experienced and credentialed doctors in a given field should be barred from testifying based on a differential diagnosis," but nevertheless, this is exactly what Defendant Monsanto Company ("Monsanto") asks the Court to do here. *See Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235 (9th Cir. 2017). Because differential diagnosis has repeatedly been found to be a reliable methodology, the only question before the Court is whether "[each] expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The Parties and this Court spent over 2 years "ruling in" exposure to Roundup® as a potential cause of non-Hodgkin's lymphoma ("NHL"). *See In re Roundup Prods. Liab. Litig.*, No. 16-md-02741-VC, 2018 WL 3368534 (N.D. Cal. July 10, 2018). And, because the Court held that the evidence supports that Roundup® is, at a minimum, *potentially* capable of causing NHL, any reliable differential diagnosis *must* "rule in" Roundup® as a potential cause of NHL. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057–58 (9th Cir. 2003) as amended on denial of reh'g (Sept. 25, 2003) (a differential diagnosis "is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.") (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)).

Of course, a differential diagnosis may be unreliable where it "rules in a potential cause that is *not* so capable [of causing the disease]," *Clausen*, 339 F.3d at 1058 (emphasis original), but whether a potential cause is capable of causing a disease is a general causation question. *See In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002) (general causation means "whether the substance at issue had the capacity to cause the harm alleged.") (internal citations omitted). Ignoring the last 2 years, and the Court's warning that re-litigating general causation to exclude specific causation experts at the *Daubert* stage will be "a waste of time,"[1] Monsanto spends a significant portion of its brief on whether Roundup® was properly "ruled in."[2] Moreover,

[1] *See* December 5, 2018 CMC Transcript, 16: 19-17:9.
[2] Amazingly, Monsanto even argues that Dr. Weisenburger did not properly "rule in" Roundup,

during Phase 1, this Court ruled Dr. Weisenburger could testify regarding general causation; yet, Monsanto now seeks to exclude him for failing to "rule in" Roundup®. Monsanto's argument is illogical. For the reasons articulated at the December 5, 2018 hearing (CMC Transcript, pages 16-18), the Court should reject that argument in short order. The only question before the Court is a simple one: did each expert reliably rule out other causes and risk factors in determining that Roundup® was a, but not necessarily the *only*, substantial contributing factor in each Plaintiff's NHL?

Here, each expert evaluated the relevant medical and scientific literature surrounding glyphosate exposure as well as each Plaintiff's salient risk factors. The experts carefully considered Plaintiffs' risk factors and even concluded, where appropriate, that certain risk factors could not be ruled out entirely. However, as explained below, California law does not require that experts rule out every risk factor or that the experts determine Roundup® exposure was the *only* cause of each Plaintiff's NHL. Rather, each expert must only opine that Roundup® exposure constitutes a substantial contributing factor and, importantly, the law holds Monsanto responsible even if there is more than one substantial contributing factor. *See Wendell*, 858 F.3d at 1237; *see also* Judicial Council of California Civil Jury Instructions 430 & 431. Curiously, Monsanto did not—and cannot—identify a single risk factor that Plaintiffs' experts did not explicitly consider. Rather, Monsanto argues the weight of the evidence and asks the Court to strike Plaintiffs' experts on the basis that it disagrees with their conclusions. However, and as this Court is aware, "[t]he district court is not tasked with deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." *City of Pomona v. SQM N.A. Corp*., 750 F.3d 1036, 1044 (9th Cir. 2014) (internal citation omitted).

For these reasons, there is no basis to exclude Plaintiffs' specific causation experts' opinions or to grant summary judgment in Monsanto's favor. By contrast, Monsanto's submission of unreliable expert testimony fails to meet even the modest *Daubert* standard.

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even though the Court already found Dr. Weisenburger applied reliable methods to testify that exposure to Roundup causes NHL.

STANDARD

The 9th Circuit has mandated that "Rule 702 should be applied with a 'liberal thrust' favoring admission." *Wendell*, 858 F.3d at 1232 (quoting *Messick v. Novartis Pharm. Corp*., 747 F.3d 1193, 1196 (9th Cir. 2014)). Expert testimony is admissible under Rule 702 when based on a reliable differential diagnosis. *See id.* at 1235 ("Nothing in *Daubert*, or its progeny, properly understood, suggests that the most experienced and credentialed doctors [specifically referencing Dr. Weisenburger and Dr. Shustov] in a given field should be barred from testifying based on a differential diagnosis."). In conducting a differential diagnosis,[3] an expert considers the "pertinence of all potential causes, then rules out the ones as to which there is no plausible evidence of causation, and then determines the most likely cause among those that cannot be excluded." *Id.* at 1234 (approving Dr. Shustov's methodology). The Ninth Circuit also "consistently recognize[s] the difficulties in establishing certainty in the medical sciences." *Messick v. Novartis Pharm. Corp*., 747 F.3d 1193, 1197-98 (9th Cir. 2014) (citing *Primiano v. Cook,* 598 F.3d 558, 565 (9th Cir.2010)). Therefore, it is not necessary that "an expert be able to identify the sole cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a substantial causative factor." *Id.* at 1199*; see also Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 434 (7th Cir. 2013) ("[A] reliable expert should consider alternative causes, they do not require an expert to rule out every alternative cause."); *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 563 (8th Cir. 2014) ("However, we have consistently ruled that experts are not required to rule out all possible causes when performing the differential etiology analysis.") (internal citations omitted).

The relevancy of an expert opinion is governed by California law. *Messick* 747 F.3d at 1196–97. Under California law, "[t]he plaintiff must offer an expert opinion that contains a

[3] *See Wendell*, 858 F.3d at 1234 ("When performing a differential diagnosis, [Dr. Shustov] first assumes the pertinence of all potential causes, then rules out the ones as to which there is no plausible evidence of causation, and then determines the most likely cause among those that cannot be excluded. We have recognized that this method of conducting a differential diagnosis is scientifically sound.") (citing *Clausen*, 339 F.3d at 1057-58).

reasoned explanation illuminating why the facts have convinced the expert, and therefore convince the jury, that it is more probable than not the negligent act was a cause-in-fact of the plaintiff's injury." *Cooper v. Takeda Pharm. Am., Inc.*, 239 Cal. App. 4th 555, 578 (2015) (quoting *Jennings v. Palomar Pomerado Health Sys., Inc.*, 114 Cal.App.4th 1108, 1118 (2003)). "Under the applicable substantial factor test, it is not necessary for a plaintiff to establish the negligence of the defendant as the proximate cause of injury with absolute certainty so as to exclude every other possible cause of a plaintiff's illness, even if the expert's opinion was reached by performance of a differential diagnosis." *Id.* "A substantial factor in causing harm is a factor that a reasonable person would consider to have contributed to the harm. It must be more than a remote or trivial factor. It does not have to be the only cause of the harm." *Id.* at 595 (quoting CACI 430) (holding that it was unnecessary for expert to rule out smoking as contributing cause to Plaintiff's injury).

Argument

I. Plaintiffs' Experts Reliably Ruled in Roundup® As a Cause of Each Plaintiff's NHL.

The Parties and the Court spent over 2 years "ruling in" Roundup® as a potential cause and the Court warned Monsanto that re-litigating this issue would be a "waste of time" at the *Daubert* stage. *See* Ex. 1, December 5, 2018 CMC Transcript, 16:19 – 17:9. Even so, Monsanto spends a considerable amount of time re-litigating whether Drs. Shustov, Weisenburger,[4] and Nabhan considered evidence that properly "ruled in" Roundup®. For that reason alone, this argument should be rejected in total. However, even if the Court entertains Monsanto's re-litigation of general causation, the argument fails.

As the Ninth Circuit explained, "[t]he first step [of a properly conducted differential diagnosis] is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. The issue at this point in the process is which of the competing causes are *generally* capable of causing the patient's symptoms or mortality." *Clausen*, 339 F.3d at 1057–58 (emphasis in original) (internal citation omitted). Here, the Court previously

[4] Monsanto's claim that Dr. Weisenburger didn't properly "rule in" Roundup is particularly incredible as this Court already held Dr. Weisenberger's applied reliable methods and could testify that exposure to Roundup can cause NHL.

determined that Roundup® can be reliably ruled in as a potential cause of NHL. *In re Roundup*, 2018 WL 3368534. The Court later conclusively established there will not be "any relitigation of whether glyphosate is capable of causing NHL in human relevant doses" at this specific causation phase of the litigation. See Ex. 1 December 5, 2018 CMC Transcript, 16:20-22; *see also id.* at 16:24-17:4 ("Monsanto's experts need to adopt for the purposes of the testimony that they're giving at the *Daubert* hearings[. . .]they need to buy into the assumption that glyphosate is capable of causing non-Hodgkin's lymphoma at human relevant doses."). Accordingly, and because the question at this phase is whether Roundup® caused each Plaintiff's disease, Plaintiffs' experts ruling in Roundup® as a *potential* cause of each Plaintiff's NHL is not only reliable—it is required. *See Clausen*, 339 F.3d at 1058; *see also Westberry*, 178 F.3d at 265 ("A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.") (internal citation omitted). Conversely, any opinion that fails to rule Roundup® into a differential diagnosis is at best a general causation opinion disguised as an opinion on specific causation; such opinions by definition fail to accept that Roundup® is *generally*—and at minimum *potentially*—capable of causing NHL in human relevant doses.

A. Plaintiffs' Experts' Conducted a Proper Differential Diagnosis in Concluding that Roundup® Was a Substantial Factor in Causing Plaintiffs' NHL.

"[D]ifferential diagnosis is not a method that lends itself to establishing a 'direct link' between an activity and an injury," but rather "a method by which a physician 'considers all relevant potential causes of the symptoms and then eliminates alternative causes....' In other words, it is a process of elimination." *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 262 (6th Cir. 2001) (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* 214 (1994)). An expert may properly form case specific opinions by "perform[ing] a differential diagnosis to 'rule in' and 'rule out' other possible causes of a disease..." *Cooper*, 239 Cal. App. 4th at 581. Indeed, a differential diagnosis is a "standard" and well accepted medical technique. *Baker v. Dalkon Shield Claimants Tr.*, 156 F.3d 248, 253 (1st Cir. 1998).

The Ninth Circuit's decision in *Wendell v. GlaxoSmithKline* is controlling because it

involved a rare disease[5] and expert testimony from two of the same experts Plaintiffs proffer in this case (Drs. Weisenberger and Shustov). *See* 858 F.3d 1227, 1230, 1236 (9th Cir. 2017). The *Wendell* court explained that, in conducting a differential diagnosis, one "[a]ssumes the pertinence of all potential causes, then rules out the ones as to which there is no plausible evidence of causation, and then determines the most likely cause among those that cannot be excluded." *Id.* at 1234. Further, it is not necessary for an expert to "rely on animal or epidemiological studies" for a differential diagnosis to be "found reliable and admissible." *Id*. at 1235 This is particularly true in the case of rare cancers, the low occurrence of which makes it difficult to conduct studies powerful enough to create statistically significant results. *See, id.*

i. Epidemiological Evidence with 2.0 Odds Ratio, Although Present Here, Is Not Required to Prove Specific Causation.

First, even though Plaintiffs' experts *did* rely upon epidemiological studies with odds ratios above 2.0 as explained herein, Ninth Circuit law is clear that the admissibility of a specific causation opinion under *Daubert* does not even require reliance upon epidemiological studies, regardless of the odds ratios. *See Wendell*, 858 F.3d at 1236-1237 ("The district court also wrongfully required that the experts' opinions rely on animal or epidemiological studies. Neither is necessary for an expert's testimony to be found reliable and admissible.") (citing *Kennedy v. Collagen Corp*., 161 F.3d 1226, 1229 (9th Cir. 1998)). And, although this holding in *Wendell* is especially applicable to "rare" diseases, the applicability of the rule does not extend to *only* rare diseases.[6]

[5] Despite Monsanto's repeated proclamations, NHL is actually a "rare" disease, its own expert testified as much. Dr. Mucci testified as follows: "Do you consider non-Hodgkin's lymphoma a rare or common disease? A. In -- I -- in the -- in general, it is, on an annual basis, a -- it's more rare than it would be considered common." Daubert Hr'g at 981:8-11. The National Cancer Institute's ("NCI") SEER database estimates that there are only 19.4 new cases of NHL per 100,000 men and women per year. *See* National Cancer Institute, *Cancer Stat Facts: Non-Hodgkin Lymphoma*, https://seer.cancer.gov/statfacts/html/nhl.html.

[6] As explained herein, Monsanto's criticisms that Plaintiffs' experts should have only considered epidemiological data pertaining to the precise subtype of Plaintiffs' NHL is inconsistent with its pronouncements that NHL—in general—is not rare. *See* footnote 5, supra.

The relevancy of epidemiology is governed by California law, and controlling California law explicitly states "[t]here is no such requirement [for a relative risk of 2.0] in California." *Davis v. Honeywell Int'l Inc.*, 245 Cal. App. 4th 477, 493 (2016). Defendant's argument rests on a misreading of *Cooper*, and was rejected by both Judge Karnow and Judge Bolanos in the *Johnson v. Monsanto* trial. In *Cooper*[7], the issue was not whether epidemiology studies showing a doubling of the risk were required to prove specific causation, but rather whether those studies could be used to prove specific causation in the absence of a thorough differential diagnosis; a plausible mechanism of action; and animal carcinogenicity studies. Unlike *Cooper*, we have all three here. The Court determined that a study reporting an odds ratio of 2.0 could be used as evidence of specific causation in the *absence* of other evidence. *Cooper*, 239 Cal. App. 4th at 593.[8] Under this correct interpretation of *Cooper*, Judge Karnow in *Johnson* ruled that "[i]n the present case" where the experts rely on more than just epidemiology, "Johnson's experts may, if this case proceeds to trial, rely on relative risk ratios of lower than 2.0 and other considerations in support of their conclusion that Johnson's mycosis fungoides was caused by occupational exposure to Monsanto's products. Nothing in *Cooper* forecloses such an approach." May 17, 2018 Order re: Jury Instructions, at 11, Ex. 2.

Nonetheless, here, Plaintiffs' experts rely upon multiple studies with odds ratios greater than 2.0, which are probative of specific causation. *See In re Bextra & Celebrex Marketing Sales Practices & Prod. Liab. Lit.*, 524 F. Supp. 2d 1166, 1172-73 (N.D. Cal. 2007) (explaining that a relative risk of greater 2.0 can be *probative* of specific causation). McDuffie (2002) showed a

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[7] The Miller Firm were the trial attorneys in *Cooper* and drafted the appellate briefs.

[8] *See also In re Hanford Nuclear Reservation Litig.*, 292 F.3d at 1136 (Relative risk of 2.0 only applicable where "there was no scientific evidence of capacity to cause the plaintiffs' injuries."). Other factors also make a relative risk of 2.0 unnecessary such as "Evidence of a pathological mechanism may be available for the plaintiff that is relevant to the cause of the plaintiff's disease" or if the agent is a tumor-promoter then the "relative risk from a study will understate the probability that exposure accelerated the occurrence of the disease." Reference Manual on Sci. Evid. 549, 2011 WL 7724261, at 614-618. For these reasons, a requirement that a "....threshold increase in risk or a doubling in incidence in a group study in order to satisfy the burden of proof of specific causation is usually inappropriate." Restatement (Third) of Torts: Liability for Physical and Emotional Harm, § 28 cmt. c (4), Specific Causation.

statistically significant 2.12 odds ratio for glyphosate-based formulation (GBF) use greater than 2 days per year. Eriksson (2008) likewise showed a 2.36 odds ratio for GBF use greater than 10 days and 2.26 odds ratio for greater than 10 years of use. *See In re Roundup*, 2018 WL 3368534 at *10. Additionally, De Roos (2003) showed a statistically significant doubling of the risk (2.1) after adjusting for over forty pesticides using a logistical regression model. *Id.*[9] Importantly, all three of these studies show a statistically significant doubling of the risk as exposure to Roundup® increases. Accordingly, all of these studies—which Plaintiffs' experts each cited and relied upon—are probative of specific causation, and any opinions derived from these studies are properly reliable.

Confronted with the inconvenient fact that Plaintiffs' experts all relied upon a study demonstrating an odds ratio above 2.0 *after* adjusting for other pesticides (De Roos 2003), Monsanto expends considerable effort attacking Plaintiffs' experts' reliance upon the McDuffie and Eriksson studies. However, under *Cooper*, an epidemiology study showing an odds ratio over 2.0 is admissible for specific causation even if it does not adjust for other risk factors. In *Cooper*, the main study (Azoulay) showing a relative risk over 2.0 was found admissible and relevant to causation even though it "lacked data on other occupational exposures, race, and family history of bladder cancer... and did not control for smoking based on the number of years the subject smoked, when they smoked, or how much they smoked." 239 Cal. App. at 588. Another study that was found relevant and admissible was a meta-analysis of clinical studies showing a relative risk over 2.0 with a maximum latency periods of three years and no dose-duration analysis. *Id.* at fn. 18.

Furthermore, contrary to Monsanto's assertion, while the McDuffie and Eriksson studies buttress the experts' opinions, they do not provide the sole basis for ruling in Roundup® as a cause for each Plaintiff's NHL. Plaintiffs will use Phase 1 testimony and Dr. Weisenburger will rely on his own general causation opinion, which was admitted during the Phase 1 proceedings.

[9] Importantly, the 2.1 odds ratio occurred in subjects with greater than 20 days of use, a number far lower than any Plaintiffs' use of Roundup. *See* Ex. 29 (De Roos 2003 at 5, Table 3).

ii. Plaintiffs' Experts Considered All the Evidence When Ruling In Roundup®.

Plaintiffs' experts properly considered the totality of the evidence in opining that GBFs can cause NHL in humans and in concluding that the epidemiology supports specific causation. In stark contrast to Monsanto's assertion that Plaintiffs' experts "cherry picked" the epidemiological literature they relied upon, each of Plaintiffs' experts considered all relevant evidence in forming their opinions. For example, Dr. Weisenburger (who the Court already determined could testify as to general causation) testified that he considered every relevant epidemiological study, including the AHS study:

> Q: Did you consider any scientific literature that is contrary to your opinion that greater than two days of use per year or greater than 10 time – 10 days of lifetime exposure puts someone at a risk for non-Hodgkin's lymphomas?
>
> A: Well, I looked at all the – all the epidemiological literature on the subject of glyphosate and non-Hodgkin's lymphoma.
>
> Q: And was any of it contrary to your opinion that greater than two days of use per year or greater than 10 days of lifetime – lifetime days of exposure puts someone like Ms. Stevick at a risk for non-Hodgkin's lymphoma?
>
> A: Well the agricultural health study is a negative study so that would contradict –
>
> Q: Okay
>
> A: -- the conclusion.

Weisenburger *Stevick* Dep. at 59:17-60:11;[10] *see also* Nabhan *Hardeman* Rep. at 6 ("I have personally evaluated epidemiologic studies published on the topic and how they correlate clinically on patients diagnosed with lymphoma.").

Here, with regard to each of Plaintiffs' experts' consideration of the relevant evidence (and particularly each experts' explanation for placing less weight on the AHS study), the Court must not "[take] sides on questions that are currently the focus of extensive scientific research and

[10] During Phase 1 of this MDL, Monsanto made similar critiques of Dr. Weisenburger, which the Court rejected. Importantly, Dr. Weisenburger is also disclosed as a general causation expert pursuant to the Court's Phase 1 *Daubert* Order. *See*, PTO 45.

debate—and on which reasonable scientists can clearly disagree." *Milward*, 639 F.3d at 22. Plaintiffs provided extensive briefing to the Court as to why an expert may reliably discount the AHS study, and it would be improper to relitigate that issue here. Moreover, last year, pursuant to PTO 34, both Dr. Weisenburger and Dr. Nabhan served expert reports specifically and only discussing the AHS study, and sat through depositions relating exclusively to the AHS. Both Monsanto and the Court cross-examined them during the March 2018 *Daubert* proceedings about the AHS study. For Monsanto to now claim that Plaintiffs' experts did not consider the AHS study is nonsensical and disingenuous. Plaintiffs' experts focus on the De Roos (2003), Eriksson (2008), and McDuffie (2001) studies, all of which demonstrate statistically significant doubling of the risk of NHL at certain intensity of exposure or duration intervals. Dr. Weisenburger also considered an unpublished version of the upcoming North American Pooled Project (NAPP) study of which he is an author. Weisenburger *Stevick* Dep. at 143:4-9 ("[T]he NAPP study is nice because it – it pools together studies that are very similar in their design and it is able to actually report – it's actually able to – to adjust for the use of other pesticides as well as look at some of the major histologic subtypes."). At this stage, it is impermissible for the Court to pick and choose among the studies upon which Plaintiffs' experts rely.

The Seventh Circuit's holding in *Schultz* is particularly informative here. In *Schultz*, the trial court excluded an expert's testimony based on a finding that his opinion was unreliable because his "conclusion diverged from a different study in the record." 721 F.3d at 432-33. The 7th Circuit reversed, holding that:

> In finding Dr. Gore's testimony unreliable, the district court also emphasized that Dr. Gore's conclusion diverged from a different study in the record in which the authors found that benzene has carcinogenic effects only at exposures greater than 40 ppm-years. But the competing study appears to rely on the identical methodology—observing AML rates in populations exposed to benzene over time—as the studies that Dr. Gore cited in support of his opinion that greater than 10 ppm-years exposure increases the risk of AML, even after 15 years. Indeed, as we noted earlier, Dr. Gore explained that the study finding a 40 ppm-year threshold was conducted with an extremely small sample size (only six cases of AML), unlike (for example) the Chinese study he submitted, which found that more than 10 ppm-years' exposure was a significant risk factor based on observations of more than 30 cases of AML. Rule 702 did not require, or even permit, the district court to choose between those two studies at the gatekeeping stage. Both experts were entitled to

> present their views, and the merits and demerits of each study can be explored at trial.

Id. at 432-433.

Naturally, Plaintiffs' experts relied upon studies that examine intensity and duration of use and exposure in reaching their case specific opinions. Accordingly, the existence of epidemiological studies—and particularly the AHS—showing a different result than the studies that Plaintiffs' experts rely upon most heavily is no bar to admission under *Daubert*.

iii. Plaintiff's Experts Considered Each Plaintiff's Exposure and Formulation.

It is well-recognized that "[w]hile 'precise information concerning the exposure necessary to cause specific harm [is] beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic...and need not invariably provide the basis for an expert's opinion on causation.'" *Clausen*, 339 F.3d at 1060 (quoting *Westberry*, 178 F.3d at 264; *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996)) ("We do not require a mathematically precise table equating levels of exposure with levels of harm, but there must be evidence from which a reasonable person could conclude that a defendant's emission has probably caused a particular plaintiff the kind of harm of which he or she complains.[. . .]"); *Heller v. Shaw Indus., Inc*., 167 F.3d 146, 157 (3d Cir. 1999) ("[E]ven absent hard evidence of the level of exposure to the chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff's illness.").

Neither Plaintiffs' residential use of Roundup® nor the formulations used cast doubt upon the reliability of Plaintiffs' experts' opinions. Monsanto's assertion that different Roundup® products present specific factual and causation inquiries ignores not only the common regulatory treatment of all glyphosate-containing products, but also Monsanto's own representations to EPA and the public about the safety of its formulated products. Of the thirty-two (32) currently registered Roundup® formulations, twenty-six (26) are conditionally registered under the Federal Insecticide and Rodenticide Act ("FIFRA").[11] This means that for these twenty-six (26) products,

[11] EPA Pesticide Product Label System, available at: https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:5:::NO:::

Monsanto has represented and the EPA determined that "(i) the pesticide and proposed use are *identical or substantially similar* to any currently registered pesticide and use thereof, or differ *only in ways that would not significantly increase the risk of unreasonably adverse effects on the environment.*"[12] 7 U.S.C. § 136a(c)(7)(A) (emphasis added). As Monsanto's representations to the EPA reveal as a logical necessity, the uses and risks that accompany the various Roundup® products are so substantially similar as to negate any minor differences.

Here, Plaintiffs' residential use of Roundup® products is inconsequential for at least two reasons. First, the McDuffie (2001), Eriksson (2008), and De Roos (2003) studies—which Plaintiff's experts rely upon—each pulled cases from cancer registries that included both commercial and residential users. For example, the authors of McDuffie note the study "included individuals in many different occupations as well as *home and garden users*." Helen H. McDuffie et al., *Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health*, 10 CANCER EPIDEMIOL, BIOMARKERS & PREVENTION 1155 (2001) at 1161; *see also* A.J. De Roos et al., *Integrative Assessment of Multiple Pesticides as Risk Factors for Non-Hodgkin's Lymphoma Among Men*, 60 OCCUP & ENVIRON MEDI 1 (2003) at 1-2, 4; Mikael Eriksson et al., *Pesticide Exposure as Risk Factor for Non-Hodgkin Lymphoma Including Histopathological Subgroup Analysis*, 123 INTERNATIONAL JOURNAL OF CANCER 1657 (2008) at 1658.

Second, each Plaintiff was exposed to the same type of highly concentrated glyphosate that farmers in the agricultural studies used. Monsanto's own formulation information confirms this, and shows that each Plaintiff used and was exposed to concentrated Roundup®. *See* Ex. 20 Formulation Information Records. Further, each Plaintiff mixed and used Roundup® in a method and manner consistent with the epidemiological literature where increased risk of NHL was

[12] The term ''unreasonable adverse effects on the environment'' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 346a). 7. U.S.C. § 136(bb).

associated with Roundup® exposure[13].

Moreover, Monsanto's criticism that the epidemiological literature can only be extrapolated to those individuals who used the exact same formulations and engaged in the exact same type of use is not only misguided—it effectively asks the Court to create a rule precluding *any* reliance upon epidemiological studies. None of the epidemiological studies provide detailed analysis of the exact formulation used by the cases and controls. And, for example, common sense dictates that it is exceedingly unlikely that all study subjects for the AHS, Monsanto's favored study, used identical formulations. By Monsanto's logic, any inference drawn from the AHS study would *only* be applicable to licensed, commercial sprayers, a notion rejected by Monsanto's own specific cause experts. *See, e.g.*, Bello Hardeman Rep. at 20. Thus, if Monsanto's attempt to highlight differences in formulations were correct, then the AHS is hardly evidence that GBFs are not associated with NHL because no opinions about a single glyphosate based formulation's effects can be inferred from the study with such a broad array of formulations. In any case, each of the epidemiology studies relied upon by plaintiffs' experts provide supportive evidence of their specific cause opinions regarding which Monsanto can cross-examine the specific formulation issue; however, the failure to analyze exactly the same formulations is not a basis for excluding that epidemiology evidence or the opinions relying on that evidence.

iv. Days Per Year Approach.

After reading the relevant medical records and literature, and prior to completing their specific causation opinions, Drs. Weisenburger, Nabhan, and Shustov individually met with each Plaintiff. [14] During their in-person examinations, each doctor conducted a thorough physical

[13] For example, Mr. Hardeman "used Roundup concentrate and did the mixing himself before application," which would sometimes result in dermal exposure and "occasional spills while mixing." Weisenburger Hardeman Rep. at 2. Similarly, Mr. Gebeyehou "sprayed [his] property... with Roundup herbicide three times every month from 1987-2016," where he "used a hand pump" and "used Roundup concentrate and did the mixing himself." Weisenburger Gebeyehou Rep. at 1-2. Further, Ms. Stevick also used concentrated Roundup® which she often mixed and sprayed herself. Weisenburger *Stevick* Dep. 94:9-96:20.

[14] Dr. Weisenburger interviewed the plaintiffs by telephone and Dr. Nabhan interviewed Mr. Gebeyehou on the telephone rather than in person because travel to Chicago was difficult for Mr. Gebeyehou. Monsanto's experts did not conduct examinations of the Plaintiffs.

examination and interviewed each Plaintiff regarding their particular Roundup® exposure and other risk factors. The doctors used that information to compare individual Plaintiffs' Roundup® exposure and circumstances to the cases in the epidemiological literature. Plaintiffs' experts' approach of using the results of epidemiological studies, which show increased risk at specified intervals of exposure, is reliable to infer specific causation. Just as Plaintiffs' experts do here, an expert may satisfy the specific causation burden by "present[ing] evidence that the specific level of [toxic] exposure actually experienced caused plaintiff's illness." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 969 F. Supp. 2d 101, 111 (D. Mass. 2013), *aff'd sub nom. Milward v. Rust-Oleum Corp.*, 820 F.3d 469 (1st Cir. 2016).

Here, all of Plaintiffs' experts did exactly that by comparing Plaintiffs' reported exposures with the quantities of exposure that, according to peer-reviewed epidemiological studies, significantly increase the risk of developing NHL. For example, Dr. Shustov determined that "Mr. Hardeman has been exposed to glyphosate in a manner and with magnitude that fits within the published epidemiological literature and studies where causation and an association between NHL and glyphosate have been demonstrated." Shustov Hardeman Rep at 9. Similarly, Dr. Weisenburger determined that Mr. Hardeman's use and exposure to Roundup® "would place him in the high-risk category for the development of NHL..." Weisenburger Hardeman Pep at 4. This type of analysis of "relative risk" is an appropriate means of establishing specific causation. *Schultz*, 721 F.3d at 432–33; *see generally* Reference Manual on Sci. Evid. 549, 2011 WL 772426, at 611–612 (discussing propriety of using magnitude of relative risk to establish specific causation); *Restatement (Third) of Torts: Phys. & Emot. Harm* § 28, cmt. c(4) rprts. note (2010).

Plaintiffs' use of and exposure to Roundup® is consistent with the epidemiological literature. Indeed, Monsanto fails to cite any case control epidemiological study indicating that Plaintiffs' exposures fall below levels otherwise correlated with an increased risk of NHL following exposure to GBFs. In fact, exposures for all three Plaintiffs greatly exceed the exposure of the participants in the epidemiology studies. For example, in Andreotti (2018), the median exposure to glyphosate was only 48 lifetime days, or eight years. In the NAPP study (pooling De Roos (2003) and McDuffie (2008)), the participants used GBFs for an "average of 5 years and

handled for an average of 5 days/year." NAPP manuscript at 12. Conversely, Ms. Stevick used GBFs for approximately 241 lifetime days, 24 years; Mr. Hardeman used GBFs for approximately 378 lifetime days, 26 years; and Mr. Gebeyehou used GBFs for approximately 442 lifetime days, 25 years. Furthermore, it is simply not true that occupational users have more intense exposure than residential users. Monsanto's own study shows that the single most important factor in reducing glyphosate exposure is wearing "rubber gloves when handling the pesticide formulation." FFES study at 324. Plaintiffs unfortunately did not wear gloves or any protective gear because there was no warning on the label.

In fact, Monsanto's own internal analyses using exposure modeling demonstrate that residential users have a much higher rate of exposure per hour than professional users. MONGLY01075506, Ex. 21; *compare* Appendix 8 (showing dose for tractor mounted sprayer after six hours without gloves to be 0.67 mg/kg/day) *with* Appendix 10 (dose for tractor mounted sprayer after six hours with gloves to be 0.066 mg/kg/day) *and* Appendix 14 (dose for home and garden user sprayer after only 30 minutes is 0.13 mg/kg/day). Under the UK POEM methodology, the highest dose for a professional user is therefore only 0.11 mg/kg/hr compared to a dose of 0.26 mg/kg/hr for residential users. *Id.*

It is entirely appropriate to rule in Roundup® as a possible cause of any individual's NHL where use and exposure conform to the epidemiological literature evincing increased risk. As noted above, ruling in Roundup® as a possible or potential cause of NHL under these circumstances is simply a step in any reliable differential diagnosis. *See Clausen* 339 F.3d at 1057 ("The first step [of a properly conducted differential diagnosis] is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.").

v. NHL Subtypes

An expert may rely upon epidemiology looking at NHL as one disease to support a causation opinion on any NHL subtype. Judge Karnow ruled: "I reject Monsanto's argument that there is no scientific basis for Dr. Nabhan to rely on studies that apply to NHL generally in the context of mycosis fungoides. There is a scientific basis for Dr. Nabhan's opinion - mycosis fungoides is a subtype of NHL." Johnson *Sargon* Order at 23, Ex. 22; *see also Ruff v. Ensign-*

Bickford Industries, Inc., 168 F. Supp. 2d 1271 (D. Utah 2001) at 1285 ("[T]hat plaintiffs' expert opinion need not include data showing studies of the exact subtype of plaintiffs' NHL to satisfy their general causation burden."). In *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011), the court held that it was error to exclude an expert opinion that was based on epidemiology of benzene and AML, where the injury was a rare subtype of AML, APL. The court stated "the rarity of APL and difficulties of data collection in the United States make it very difficult to perform an epidemiological study of the causes of APL that would yield statistically significant results." *Id*. at 24.

Monsanto's assertion that Plaintiffs' experts failed to consider specific subtypes within the epidemiological studies in ruling in Roundup® as a probable cause of each Plaintiff's NHL is wrong. For example, Dr. Shustov explained why, based upon his extensive clinical experience, a carcinogen is unlikely to discriminately affect certain types of lymphoid cells resulting in particular malignancies. Shustov *Hardeman* Dep. 225:5-10 ("When I look at the studies by those authors and groups, for me as a clinician, it didn't really matter whether it was DLBCL or other lymphoma because I believe that exposure to chemical carcinogens do not discriminate the type of lymphoid cells that they affect and can give rise to any type of lymphoma."). Similarly, in evaluating Ms. Stevick's CNS lymphoma, Dr. Weisenburger explained that "Diffuse large B-cell lymphoma not otherwise specified has different subtypes. One of them is called the activated B-cell type, okay? And it just so happens that the primary CNS lymphomas are mainly of the activated B-cell type. So they have the same mutation patterns." Weisenburger *Stevick* Dep 40:18-24. This is especially true here, where the precise lymphoid cells—here B-Cells—are affected.

The reasons why Plaintiffs' experts' were unable to draw definitive conclusions from studies pertaining to only specific subtypes is clear: as data are further divided by subtype, the number of cases become smaller and smaller and the power of the study to detect a statistically significant result diminishes. This is precisely because NHL is rare and becomes significantly rarer when atomized into subtypes. As Dr. Weisenburger explained:

> Q: And with regard to subtypes, how is it that you're not always able to determine odds ratios for particular subtypes in some of the epidemiological studies?

> A: Well, often there aren't enough cases of specific subtypes to really – to really do meaningful analyses. So they did it in the Eriksson study, but they – they didn't have a lot of cases of the various different subtypes then. So although you see elevated odds ratios, they – they generally aren't statistically significant..."

Weienburger *Stevick* Dep at 142:18-143:3.

Similarly, Dr. Nabhan explains that "[the number of subtypes] shows that epidemiologic studies would rarely be able to investigate association between any occupational hazard and types of NHL." Hardeman Rep. at 8.

This illustrates why Monsanto's assertion that "NHL is remarkably common" in its attempts to distinguish *Wendell* cannot be squared with its criticism that experts must only draw inferences from statistically significant associations related to individual subtypes within the epidemiological literature. *Compare* Mot. at 14 ("Plaintiffs' experts further cannot explain their failure to consider studies that looked specifically at the subtype of NHL that each Plaintiff developed") *with* Mot. at 30 ("Unlike the 'exceedingly rare' HSTCL cancer at issue in Wendell, NHL is remarkably common."). Indeed, if the relevant inquiry only pertains to the specific subtype of NHL at issue, then whether or not NHL as a whole is a rare disease is immaterial. Rather, the relevant question would necessarily become whether the Plaintiff's specific subtype is rare. *See e.g., Milward*, 639 F.3d at 24 (recognizing that the "rarity" of a particular form of leukemia was one reason that it would be "very difficult to perform an epidemiological study of the causes of [the disease] that would yield statistically significant results.").

II. Plaintiffs' Experts Reliably Ruled Out Other Causes.

Importantly, in its bid to disqualify Plaintiffs' experts, Monsanto does not identify a single risk factor that Plaintiffs' experts did not consider (*i.e.*, both "rule in" and "rule out") in their reports. A district court is justified in excluding evidence only if an expert "utterly fails [...] to offer an explanation for why the proffered alternative cause" was ruled out. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001). The expert must provide reasons for rejecting alternative hypotheses "using scientific methods and procedures" and the expert must base the elimination of those hypotheses on more than "subjective beliefs or unsupported speculation." *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir.1994). However, Plaintiffs' experts are

not required to show, nor do they purport to offer the opinion, that exposure to Roundup® is the sole cause of each Plaintiff's NHL. *See Schultz*, 721 F.3d at 433 ("In order to show that a toxin is '*a* cause' or '*a substantial factor*,' [plaintiff] was not required to demonstrate that [toxin] exposure was the *sole* cause of his disease, so long as he showed that [the toxin] contributed substantially to the disease's development or significantly increased his risk of developing [the disease].") (emphasis in original). In fact, the CACI Jury Instruction does not require Plaintiffs to prove that Roundup® was the sole cause of Plaintiffs' disease. *See* Judicial Council of California Civil Jury Instruction 430 ("A substantial factor in causing harm is a factor that a reasonable person would consider to have contributed to the harm... *It does not have to be the only cause of the harm*.") (emphasis added); *see also* Judicial Council of California Civil Jury Instruction 431 *(*"A person's negligence may combine with another factor to cause harm. If you find that [Monsanto]'s negligence was a substantial factor in causing [Plaintiffs'] harm, then [Monsanto] is responsible for the harm. [Monsanto] cannot avoid responsibility just because some other person, condition, or event was also a substantial factor in causing [Plaintiffs'] harm.").

Monsanto misstates this standard by implying that a differential diagnosis can only be reliable if all other potential causes are eliminated to an absolute certainty. *See. e.g.,* Mot at 21 ("The experts ultimately admitted that they cannot rule out some of the risk factors…"). But this is contrary to medicine and science, and it is not what the law requires. As the Ninth Circuit explained in *Wendell*, "[w]e do not require experts to eliminate all other possible causes of a condition for the expert's testimony to be reliable." 858 F.3d at 1237; *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1238 n.6 (10th Cir. 2005) (A reliable differential diagnosis does not require that an expert consider and rule out every *conceivable* cause to be reliable); *Schultz* 721 F.3d at 434 ("[T]he Committee Notes [to Fed. R. Evid. 702] suggest that a reliable expert should consider alternative causes, *they do not require an expert to rule out every alternative cause.*") (emphasis added). And, where, as here, "a properly qualified medical expert performs a reliable differential diagnosis through which, to a reasonable degree of medical certainty, all other possible causes of the victims' condition can be eliminated, leaving only the toxic substance as the cause, a causation opinion based on that differential diagnosis should be admitted." *Turner v. Iowa Fire Equip. Co.*,

229 F.3d 1202, 1209 (8th Cir. 2000).

A. Plaintiffs' Experts Reliably Ruled Out Idiopathic Causes.

Monsanto contends that the testimony of Drs. Nabhan, Shustov, and Weisenburger is unreliable and inadmissible because these experts allegedly did not adequately consider and definitively rule out idiopathic[15] causes of Plaintiffs' NHL. Mot. at 27. *Wendell v. GlaxoSmithKline LLC* is instructive on this point. In *Wendell*, the trial court excluded plaintiff's causation experts on the basis that "they could not completely rule out the possibility that [plaintiff's cancer] was idiopathic." 858 F. 3d at 1237. The Ninth Circuit held that the trial court abused its discretion by excluding case-specific causation opinions on the basis of a high rate of idiopathic cancer and the inability to rule out an idiopathic origin. *Id.* More importantly, definitively ruling out all unknown causes of a disease is not a bar to testimony under *Daubert*. *See id.* As the Ninth Circuit explained in *Wendell*:

> [T]he district court erred when it excluded Plaintiffs' experts' opinion testimony because of the high rate of idiopathic [unknown] HSTCL and the alleged inability of the experts to rule out an idiopathic origin or IBD itself. We do not require experts to eliminate all other possible causes of a condition for the expert's testimony to be reliable. *Messick*, 747 F.3d at 1199. It is enough that the proposed cause "be a substantial causative factor." *Id*. This is true in patients with multiple risk factors, and analogously, in cases where there is a high rate of idiopathy... Moreover, when an expert establishes causation based on a differential diagnosis, the expert may rely on his or her extensive clinical experience as a basis for ruling out a potential cause of the disease. See *Id*. at 1198

Id. at 1237.[16] Similarly, other federal courts have noted that definitively ruling out unknown causes does not preclude an expert's ability to provide a reliable opinion. *See, e.g., In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 890 F. Supp. 2d 552, 557 (E.D. Pa. 2012) ("While an expert can surely opine that the cause of any injury is unknown, it is at least questionable whether an expert can ever really exclude an unknown cause since by definition it is

[15] A disease that is idiopathic is one that does not have a known cause. *See Wendell*, 858 F. 3d at 1233, f. 3.

[16] *See Wendell*, 858 F. 3d at 1235 ("[W]hen you have a patient with obvious and known risk factors, you tend to assume that those risk factors were the cause.").

unknown.").

Plaintiffs' experts do not dispute that they are unable to identify a cause of NHL in many patients. However, that does not invalidate their opinions before the Court that Plaintiffs' NHL here was not idiopathic and that there was substantial evidence that each Plaintiffs' NHL was caused by exposure to the Roundup® each Plaintiff used. Dr. Nabhan explained:

> [. . .] [W]hat is important any time you are dealing with a disease such as non-Hodgkin lymphoma and you are looking at causation is to look at all of the factors and be very inclusive in investigating all potential contributing factors to this disease, and then you really have to weigh these factors and apply them in every specific case and make a determination whether one of these factors contributed – more than one of these factors contributed or none of these factors contributed, and when none of the factors contribute, that's what we call 'idiopathic.'"

Nabhan Hardeman Dep at 59:14-25.[17]

Plaintiffs' experts' methodology in this case is nearly identical to the differential diagnosis accepted by the courts in *Wendell* and in *Cooper v. Takeda Pharmaceuticals.* Indeed, the trial court in *Cooper* excluded plaintiff's expert oncologist, in part, on the expert's acknowledgment that "he has a lot of patients in this age group who have bladder cancer, and he can find no cause." 239 Cal. App. 4th at 593. The *Cooper* expert further acknowledged that "there are so many possible causes and so much still unknown about the causation of bladder cancer[. . .]." *Id.* at 585. However, the court held that "[b]are conceivability of another possible cause does not defeat a claim: the relevant question is whether there is 'substantial evidence' of an alternative explanation for the disease." *Id*. at 586. Indeed, Judge Karnow, in denying Monsanto's summary judgment motion to exclude the specific-causation opinion of Dr. Nabhan, noted that "[i]diopathy need not be entirely ruled out, but there needs to be an explanation as to why an identified cause is considered likely… Dr. Nabhan admitted that he could not rule out other contributing factors; but he is not required to do so." Johnson *Sargon* Order at 25.

[17] In its post-trial motions related to the *Johnson* case, Monsanto made the same argument—that Dr. Nabhan's differential diagnosis was improper because he did not consider idiopathic causes. Judge Bolanos rejected that argument. *Johnson v. Monsanto Co.*, Case No. CGC-16-550128, (Cal. Super. C., S.F. City Oct. 22, 2018), attached as Ex. 23.

Here, Plaintiffs' experts' testimony, and the inferences drawn therefrom, is sufficient for admissibility under the applicable substantial factor test for causation because it is not necessary for Plaintiffs' experts to definitively "eliminate all other possible causes of a condition for the expert's testimony to be reliable." *Wendell,* 858 F.3d at 1237; *Hall v. Conoco Inc*., 886 F.3d 1308, 1314 (10th Cir. 2018) ("An expert need not consider and rule out every *conceivable* cause.") (emphasis original); *Schultz*, 721 F.3d 426 at 434 ("[T]he Committee Notes [to Fed. R. Evid. 702] suggest that a reliable expert should consider alternative causes, *they do not require an expert to rule out every alternative cause*.) (emphasis added). This is especially true here, where the most relevant epidemiological studies reveal an odds ratio over 2.0 following exposure to GBFs in the same quantities and duration as each Plaintiffs' exposures. Accordingly, it can be deduced that Roundup exposure is more likely than any unknown factor to have caused each Plaintiff's NHL.

B. Plaintiffs' Experts Reliably Ruled Out Plaintiff Specific Risk Factors.

Plaintiffs' experts *actually ruled in* and considered all of the risk factors Monsanto cites. As meticulously documented in the Court's *Daubert* ruling, Plaintiffs' experts did not rely solely on epidemiology in ruling in GBFs[18] Furthermore, Plaintiffs' experts did not rule out other risk factors simply because there was no conclusive link in the epidemiology. Rather, Plaintiffs' experts used their clinical judgment and extensive knowledge about the risk factors for NHL to make decisions on what risk factors to rule out after an extensive review of the plaintiffs' medical history and physical examination of the Plaintiffs. The experts then gave a reasoned explanation as to why some risk factors were more or less important for each particular plaintiff.

Monsanto's argument on this point attempts to blur the relevant standard by suggesting that Roundup® must be ruled in as the *only* cause of each Plaintiff's NHL when, in fact, the relevant question is whether Plaintiffs' Roundup® exposure constituted a substantial contributing factor to

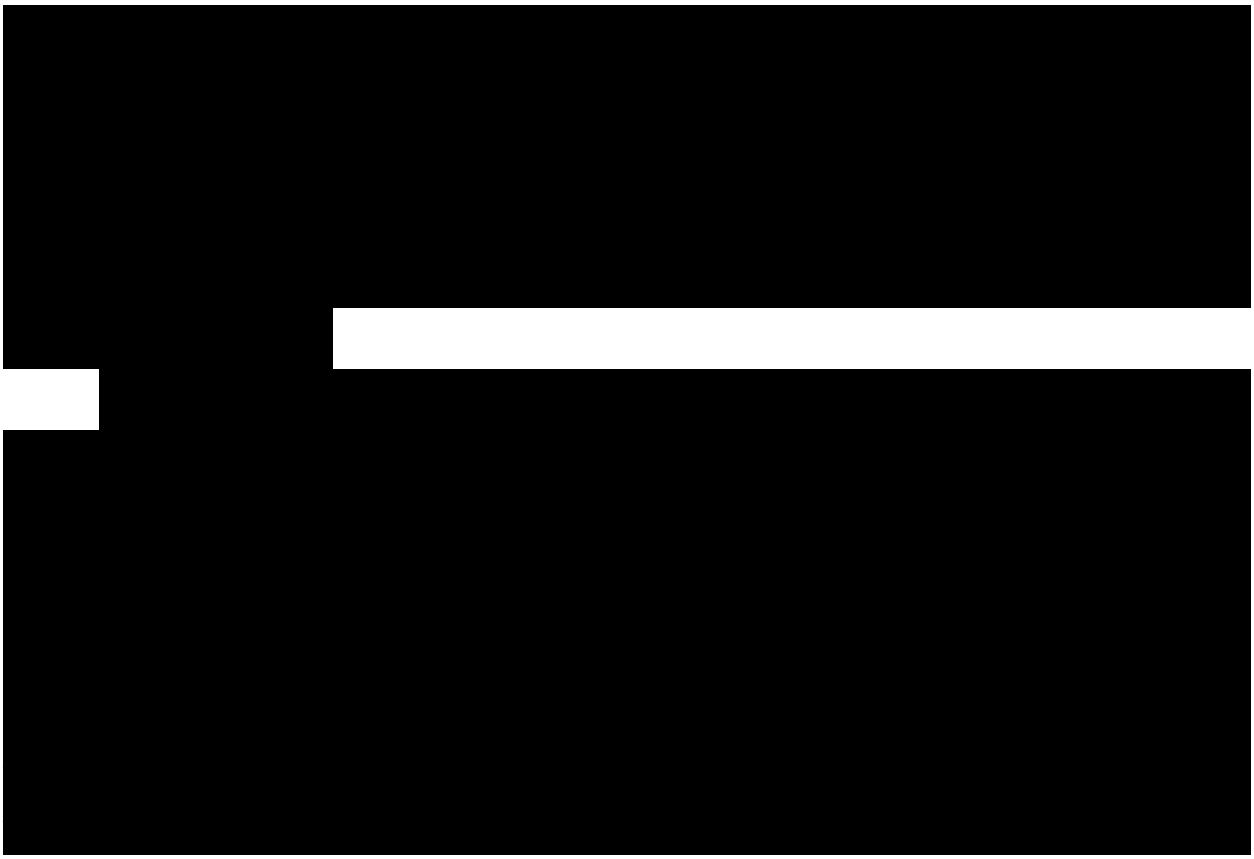
[18] As a practical matter, however, application of these criteria requires an expert to consider more than the epidemiology literature. In particular, by inquiring about biological plausibility and coherence with other knowledge, the Bradford Hill framework asks experts to survey all the available evidence that might support or disprove causation.
In re Roundup Prod. Liab. Litig., No. 16-MD-02741-VC, 2018 WL 3368534, at *18 (N.D. Cal. July 10, 2018)

their risk of developing NHL. *See Schultz*, 721 F.3d at 433 ("In order to show that a toxin is '*a* cause' or '*a substantial factor,*' [plaintiff] was not required to demonstrate that [toxin] exposure was the *sole* cause of his disease, so long as he showed that [the toxin] contributed substantially to the disease's development or significantly increased his risk of developing [the disease].") (emphasis in original); *see also* Judicial Council Of California Civil Jury Instruction 431; *see Ex. 3, e.g.*, Shustov Stevick Dep. 19:7-11 ("Q: Did you conclude that the – the sole known risk factor Ms. Stevick had was her use of glyphosate to kill weeds in her garden? A: That was my conclusion, that exposure to glyphosate was the main substantial contributing factor."). In reaching their opinions, each expert considered and evaluated each of the alleged risk factors described below.

[redacted]

[redacted]

[redacted]



iii. Age (all Plaintiffs)

Dr. Shustov explained, based largely on his training and experience, that he does "not consider age as a causative factor for any lymphoma, but a reflection of other factors that are more prevalent in older populations." Ex. 3 Shustov *Stevick* Dep. 33:8-11. Dr. Shustov explained: "aging itself does not cause problems. Aging is a reflection of factors and exposures that people accumulate through lifetime. The longer you live, the more exposures or more damages you accumulate. And it's a reflection of that. I think it's a silly factor to interrogate because it doesn't have any mechanistic underpinning." Shustov *Hardeman* Dep. 205:6-12; *Ex. 8* Shustov *Gebeyehou* Dep. 55:5-10 ("I do not think, as a lymphoma scientist and expert, age causes lymphomas. We see lymphomas more commonly with older people. But with all the knowledge and experience in lymphomas that I have, to me it means it's a reflection that older people have longer time of exposure or chance to be exposed."). Dr. Nabhan provided a similar explanation, noting "age doesn't cause cancer, but the older we get, we are more likely to get all diseases, including cancer. So again, unfortunately, as we age, we could get cancer, heart disease, anything.

But you are correct, so more older patients get diagnosed with cancer than younger patients." Nabhan *Gebeyehou* Dep. 19:15-23; Weisenburger *Hardeman* Dep. 91:2-10 ("[A]s I said before, I don't think that age is a causative risk factor. At least we don't understand it. So it is a risk factor, but I wouldn't consider it a causative risk factor in the sense that age doesn't cause the lymphoma. There are probably some things about age that may cause lymphoma."). *See also* Shustov *Gebeyehou* Dep. 52:6, 53:5-9, 55:3-17; Nabhan *Gebeyehou* Dep. 19:17-23.

[redacted]

v. Ms. Stevick's Radiation

Although Ms. Stevick had some ionizing radiation exposure, her exposure "was not high

enough or impressive enough to suggest that it is related" to her NHL. Ex. 14 Nabhan *Stevick* Dep. 37:1-2. Dr. Nabhan confirms that "speech pathologists don't get exposed [to] enough to radiation to suggest even radiation remotely involved in the pathogenesis of any particular type of brain cancer or brain lymphoma." Nabhan *Stevick* Dep. 39:6-9. Ms. Stevick only took about 14 to 15 x-rays in her job as a speech pathologist. *Id.* at 58:13-59:8. Dr. Shustov is familiar with the doses of radiation necessary to cause NHL because using radiation is "close to home in my field." Shustov *Stevick* Dep. 82:13-84:3. Dr. Shustov regularly treats patients (as does Dr. Nabhan) with radiation therapy with doses of up to 50 rays; Ms. Stevick would need to take thousands of x-rays before even getting to a dose of 1 ray. *Id.* Dr. Weisenburger conducted a literature search to determine whether Ms. Stevick's radiation exposure could be possible linked to her NHL. He found that "the level of exposure that she had would not increase her risk of non-Hodgkin's lymphoma... radiation is not a risk factor for non-Hodgkin's lymphoma unless it's very high doses of radiation, like an atomic bomb or some other kind of exposure that's a very large exposure." Ex. 15 Weisenburger *Stevick* Dep. 107:3-8.

vi. Plaintiffs' Experts Faithfully Applied their Methodology

In sum, Dr. Nabhan, Dr. Shustov, and Dr. Weisenburger have impeccable qualifications and did not engage in outcome driven methodologies in reaching their conclusions here. Nor are Plaintiffs' experts inconsistent with their reliance on IARC. No expert disputes IARC's finding that [redacted]

[20] [redacted]

III. CONCLUSION REGARDING PLAINTIFFS' CASE SPECIFIC EXPERTS

Monsanto moves for summary judgment solely on the basis of its motion to exclude Plaintiffs' specific causation experts. On a motion for summary judgment, the Court must consider all facts in the light most favorable to the non-movant. *See Messick*, 747 F.3d, at 1199 (reversing summary judgment because plaintiff's admissible expert testimony created issues of fact). As set forth above, Plaintiffs have submitted relevant and reliable specific causation expert testimony, which raises genuine issues of material fact as to whether glyphosate and GBFs can cause NHL. *See id.*; *see* also Fed. R. Civ. P. 56(a). Monsanto is not entitled to summary judgment and the Court should deny the instant motion in its entirety.

IV. Plaintiffs' Affirmative *Daubert* Challenges

There are two aspects to Plaintiffs' *Daubert* challenges. First, Monsanto should not be allowed to offer new general causation experts or new general causation opinions. Monsanto's new "specific causation" experts offer sweeping general causation opinions; consistent with this Court's prior rulings, Monsanto should not be permitted to offer these new opinions. That said, even if the Court were to entertain these new opinions, none of Monsanto's new experts conducted a valid general causation analysis sufficient to survive *Daubert*. Their analyses are, at best, superficial. They fail to explain or justify why they give more or less weight to various studies and they all fail to consider, in any meaningful way, the animal toxicology or genotoxicity data.

Second, none of Monsanto's new specific causation experts should be permitted to opine about whether Roundup® caused any Plaintiffs' NHL because none of them applied a valid differential methodology. As discussed below, each of Monsanto's new experts "ruled out" Roundup® exposure as a possible cause of each Plaintiff's NHL by concluding that Roundup®, *generally*, cannot cause NHL. None offered an opinion that, even if Roundup® was a risk factor, it did not cause an individual Plaintiff's cancer. Thus, each of Monsanto's experts' "specific causation" testimony amounts to little more than a thinly veiled general causation opinion imitating, but not actually conducting, a specific causation analysis. This is not a valid differential assessment and, thus, is not helpful or relevant.

A. Monsanto's New Experts Should Not Be Allowed to Offer General Causation Opinions

i. Only Monsanto's General Causation Experts Should Be Allowed to Offer General Causation Opinions

Over Plaintiffs' objection, and at considerable expense, the Parties and this Court spent over two years discovering and testing the testimony, evidence, and opinions of the Parties' general causation experts. After each side presented their experts, the Court issued a 68-page *Daubert* Order setting forth the admissible general causation testimony for this MDL. *See generally* Pretrial Order No. 45

During the October 29, 2018 hearing, it became clear that Monsanto intended to use its "specific causation" experts to proffer general causation opinions—even going so far as not calling a single general causation expert from the general causation phase to trial. The Court rejected this proposal:

> [T]he answer to that question is basically no. You cannot add general causation experts. If there is an emergency-type situation, if Loralei Mucci has a medical emergency or, you know, something like that, and you want to seek permission to sub somebody in to provide, you know, substantially the same testimony, I will entertain it. I'm not saying I will grant it, but I will entertain it. But the basic answer is, no, I don't think it's appropriate, given everything we've been through already as a team, to be adding general causation experts.

Ex. 16 Tr. Of Proceedings at 41:8-18 (Oct. 29, 2018). Plaintiffs agree with the Court's guidance. If Monsanto wants to mount a challenge to general causation, then it must do so using its general causation experts.

Notwithstanding the Court's clear direction, Monsanto's new specific-causation experts offer a wide-range of new general causation opinions. And, as discussed below, these general causation opinions regarding Roundup® form, in their entirety, the basis of their specific causation opinions. This is improper and violates this Court's express ruling. It also undermines the last two years of work in this MDL. All of Monsanto's new "specific causation" experts should be prohibited from offering any general causation opinion.

B. Monsanto Should Not Be Allowed to Offer Any *New* General Causation Opinions Using Specific Cause Experts

Separate and apart from Monsanto proffering new general causation *experts*, it also offers new general causation *opinions* that were not proffered during the general causation phase. These new general opinions should be excluded as well.

During the general causation phase, each of Plaintiffs' general causation experts examined all three pillars of cancer science—epidemiology, animal toxicology, and mechanism—and performed a comprehensive Bradford Hill analysis. Monsanto, having seen this approach, took a different one, electing to have its carefully-selected general causation experts focus on only one of the three pillars—epidemiology (Drs. Mucci & Ryder), animal toxicology (Drs. Foster & Rossol), and mechanism (Dr. Goodman). None of Monsanto's general causation experts considered all three areas of science and none performed—or was even willing to perform—a Bradford Hill analysis. Monsanto's experts, therefore, did not offer the ultimate conclusion that Roundup® does not cause NHL. Instead, they offered siloed opinions about each discipline—Drs. Mucci and Rider opined that that epidemiology did not support causation; Drs. Foster and Rossol opined that the animal toxicology did not support causation; and Dr. Goodman opined that Roundup® is neither genotoxic nor capable of inducing oxidative stress.

However, one of Monsanto's new "specific causation" experts, Dr. Steidl, seeks to offer opinions on all three of the pillars of science. In his Hardeman Report, Dr. Steidl offers an opinion that the epidemiological, toxicological, and mechanistic evidence considered together does not support a causal relationship between exposure to GBFs and NHL. Ex. 17 Steidl Rpt. at 2, 13. He also attempts to conduct, albeit superficially, a Bradford Hill / weight of evidence analysis. *Id.* at 13. This is an entirely new general causation opinion, not just a new general causation expert. It is improper and violates the phased discovery process. To the extent this Court permits Dr. Steidl to offer any general causation opinion, he should not be allowed to testify about any Bradford Hill or weight of evidence opinion because such an opinion has never been offered by any Monsanto expert until now.

i. Even If Monsanto's Specific Causation Experts Did Not Violate the General Causation Phase Process, Their General Causation Opinions Are Otherwise Insufficient under *Daubert*

The Court conducted a rigorous analysis of Plaintiffs and Monsanto's general causation experts' opinions under *Daubert*. And, through that process, this Court barred and/or limited a significant number of expert opinions. When that same rigor is applied to Monsanto's new "specific causation" expert's general causation opinions, none are admissible.

a. Dr. Alexandra Levine

Dr. Levine is a "hematologist/oncologist" who rules out exposure to GBFs as a potential cause of Mr. Hardeman's disease based exclusively on a brief summary of the strengths of the AHS and a passing comment that she "reviewed" four of the epidemiology studies considered by IARC. Levine Rep at 2, 10-11. Dr. Levine, however, fails to discuss the strengths and weaknesses of the four case-control studies, the flaws of the AHS, or why she chose to afford substantial weight to the AHS despite the study's shortcomings. *See, e.g.*, *In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 495 (E.D. Pa. 2016), *aff'd sub nom. In re Zoloft* (*Sertraline Hydrochloride*) *Prod. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017) (excluding expert's opinion which stated, without more, that "he 'analyzed the relevant, publicly available scientific literature on the causes and risk factors…'"). Despite such omissions, Dr. Levine claims that she reached her conclusion "[b]ased upon the full extent of available epidemiologic data…" See Ex. 18 Levine Rpt at 12. But, even a cursory reading of Dr. Levine's report belies this assertion. Moreover, Dr. Levine did not examine, consider, or discuss any animal toxicology or mechanistic data. Her general causation opinion is based exclusively on a superficial review of epidemiology. That is simply not a sufficient basis to conclude, categorically, that Roundup® does not cause NHL.

b. Dr. Christian Steidl

Dr. Steidl purports to have adopted an "evidence-based" approach that considered the "weight of the evidence" for the carcinogenicity of GBFs in the fields of epidemiology, toxicology, and genotoxicity. Steidl Rep. at 2. Nevertheless, Dr. Steidl did not consider any weaknesses of the only epidemiology study he deems worthwhile—the AHS—and pays lip-service to only four case-control studies. *See Id.* at 2-4, 5-6. Indeed, Dr. Steidl incorrectly claims, contrary to the

holding of this Court, that no case-control epidemiological study found an increased risk of NHL after adjustment for exposure to other pesticides, thereby ignoring the results of De Roos (2003) and Pahwa (2015). *Id*. at 13. Importantly, Dr. Steidl does not even claim to have read the IARC monograph, considered the conclusions of the working group in any meaningful detail or explained why, if at all, he disagrees with the IARC classification. Instead, he provides a cursory discussion of two mouse studies and quotes at length from ECHA's conclusion regarding the animal bioassay data without explaining the basis for his reliance on the agency's evaluation.[21] Parroting a regulatory agency's analysis without conducting any independent analysis is, on its face, inadmissible.

Indeed, out of the many available genotoxicity studies on GBFs and NHL, Dr. Steidl provides a brief review of only two—compared to the hundreds analyzed by Dr. Portier—and quickly follows with the conclusion that the "weight of the evidence" does not support GBFs causing gene mutation or chromosomal damage. Steidl Rep. at 11. Dr. Steidl, however, fails to incorporate a substantive discussion of genotoxicity, such as why he considers *in-vitro* bacterial reversion assays to be among the "most important for assessing potential carcinogenicity" when Monsanto's own general causation genotoxicity experts do not profess such beliefs, rendering his mechanistic opinions unreliable. *Compare Id*. at 10, Ex. 24 Goodman Dep. at 60:22-61:1 ("Q: So do you believe it's possible that a substance can be genotoxic in humans and not promote a mutation in bacteria in the Ames test? A: Yes."); *see also In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 436 (S.D.N.Y. 2016) (excluding specific causation opinions based on unreliable general causation opinions).

c. Dr. Michael Grossbard

Dr. Grossbard devotes just over a page of his report to discussing the reasons for ruling out exposure to GBFs as a potential cause of Mr. Hardeman's NHL. *See Ex. 19* Grossbard Rep. at 7-8. Although Dr. Grossbard states that IARC's epidemiology conclusion does not establish

[21] Dr. Steidl also fails to consider the importance of animal models in the context of the biological plausibility prong of Bradford Hill, even though he claims to have applied a Bradford Hill methodology. *See* Steidl Rep at 2.

causation in clinical terms, he fails to discuss whether any other body of evidence considered by IARC satisfies his vague "clinical" definition of causation, such as the genotoxicity evidence. *Id.* at 7. This casts doubt on whether Dr. Grossbard applied a consistent, objective differential methodology for his opinion. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 887 (10th Cir. 2005) ("We cannot allow the jury to speculate based on an expert's opinion which relies only on clinical experience…" when expert's general causation opinion is invalid.). Dr. Grossbard proceeds to "summarize" in cursory fashion four case control studies and the AHS and appears to prioritize statistically significant results without addressing the consistency of elevated risks across studies. Grossbard Rep. at 7-8*; see In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2018 WL 3368534, at *8, 15 (N.D. Cal. July 10, 2018) ("…there may be a causal association even in the absence of statistically significant results…the potential flaws in the data from the case-control studies and meta-analyses are not overwhelmingly greater than the potential flaws in the data from the AHS study."). Indeed, Dr. Grossbard reckons that it is "impossible" to conclude that exposure to "even high degrees of glyphosate" is associated with NHL because the hierarchical model in De Roos (2003) was not statistically significant. *Id.* at 8.[22] Dr. Grossbard does not explain why he relies so heavily on statistical significance in a handful of studies or why the AHS is the "most scientifically rigorous study." *Id.* at 8. Dr. Grossbard's general causation opinion should be excluded as unreliable.[23]

d. Dr. Lawrence Zukerberg

The only bases for Dr. Zukerberg's opinion that exposure to GBFs cannot be a potential cause of NHL are the results of the AHS, which Dr. Zukerberg discusses in two sentences without

[22] Dr. Grossbard's inaccurate, selective reading of the data is further illustrated by his discussion of De Roos (2003), which Dr. Grossbard asserts only adjusted for exposure to other pesticides in the hierarchical analysis. Grossbard Rep. at 8. However, it is undisputed, as acknowledged by Monsanto's epidemiologist, Dr. Mucci that the study adjusted in both the logistic and hierarchical models. Johnson Trns. at 4379:4-4383:21. And, Dr. Grossbard's conclusion that "the preponderance" of the literature shows no significant increase in NHL incidence following exposure to Roundup" does not follow from his brief consideration of only five epidemiological studies." Grossbard Rep. at 8.

[23] Dr. Grossbard employs the same unreliable methodology for his specific-causation opinions with regards to Mr. Gebeyehou's NHL and these should also be excluded for the same reasons.

mentioning any of the case-control studies, other data indicating the association between exposure to GBFs and NHL, or why Dr. Zukerberg does not believe that the published literature on GBFs and NHL indicate causation. *See* Ex. 25 Zukerberg Rep. at 4. Without more, this is an unreliable opinion, as it does not even come close to the rigor expected of a general causation expert.

e. Dr. Celeste Bello

Dr. Bello concludes that GBFs "did not cause or substantially contribute to Ms. Stevick's CNS Lymphoma because there is no prospective epidemiologic data that show a statistically significant association between glyphosate based formulations and the development of NHL." Ex. 26 Bello Rep. at 15-16. Dr. Bello does not explain why she only considered epidemiological studies to the exclusion of *in vivo* genotoxicity data or animal toxicology. Instead, Dr. Bello speculates that the case-control studies were subject to recall bias, does not explain her reliance on statistical significance over consistent elevated risks in the studies, and does not cite or discuss her understanding of a single odds ratio or relative risk in *any* of the epidemiological studies. Also, Dr. Bello relies on the EPA's review of the data without justifying the greater weight she placed on the EPA's analysis over IARC, even though she notes that several of EPA's observations were shared by IARC. Bello Rep. at 11. In short, Dr. Bello's general causation opinion is not supported by any rigorous analysis.

f. Dr. J. Pablo Villablanca

Dr. Villablanca's opinion on GBFs is limited to the conclusions of the EPA and European regulators regarding the carcinogenicity of GBFs, and vague references to genotoxicity studies and the AHS, all summarized in four cursory paragraphs. Ex. 27 Villablanca Rep. at 16, 15. Dr. Villablanca does not explain the basis for his reliance on the agencies, or why he prioritized genotoxicity and the AHS, nor why he dismissed *in-vivo* genotoxicity studies which indicate an association between exposure to GBFs and genetic damage. Dr. Villablanca's general causation opinion is wholly unreliable.

ii. Monsanto's Case-Specific Experts Failed to Employ a Proper Differential Methodology and Should be Precluded from Offering a Specific Causation Opinion

Here, all of Monsanto's experts reached specific causation conclusions based on inadmissible general causation opinions, i.e., ruled out Roundup as a possible risk factor because, in their opinion, Roundup® is not a risk factor. And, although "courts frequently have pointed to an expert's reliance on the reports of others as an indication that their testimony is reliable," none of Monsanto's specific causation experts relied on the opinions of Monsanto's general causation experts admitted by the Court. Walker v. Soo Line R. Co., 208 F.3d 581, 588 (7th Cir. 2000); see Jones v. Novartis Pharm. Corp., 235 F. Supp. 3d 1244, 1277 (N.D. Ala. 2017), aff'd in part sub nom. Jones v. Novartis Pharm. Co., 720 F. App'x 1006 (11th Cir. 2018) ("[I]f no expert has been offered who can provide an admissible general causation opinion, then an expert may not rely on a differential diagnosis to prove specific causation."); In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 605 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013) (because "[expert's] general causation opinions are not based on reliable methodology and principles, her specific causation opinions—based on her general causation opinions—should also be excluded."). In other words, none of Monsanto's experts performed a valid differential analysis because none of them ever considered the possibility that Roundup® was a substantial factor in causing any Plaintiff's NHL. Without making that assumption, their opinion is nothing more than a general causation opinion. See In re Hanford, 292 F.3d at 1133 (general causation means "whether the substance at issue had the capacity to cause the harm alleged.")

a. Dr. Alexandra Levine

Dr. Levine fails to explain why GBFs did not cause Mr. Hardeman's cancer beyond denying that Roundup® can cause NHL. Dr. Levine does not consider the extent, duration, or concentration of Mr. Hardeman's exposure to GBFs. Instead, Dr. Levine concludes that "there is no test, biomarker, or genetic signature associated with Mr. Hardeman's exposure" which would be indicative of Roundup® causing his cancer. Levine Rpt. at 15. But that is a meaningless statement. [redacted]

[redacted] Her observation is a red herring and not helpful or even relevant. Other than this statement concerning biomarkers, Dr. Levine's entire approach is little more than a thinly-veiled general causation opinion. Dr. Levine did not conduct a real differential analysis, and her opinion, therefore, should be excluded.

b. Dr. Christian Steidl

Dr. Steidl's specific causation opinion that exposure to GBFs did not cause Mr. Hardeman's NHL is, like Dr. Levine's, a disguised general causation opinion. Dr. Steidl makes only a passing comment regarding the extent and duration of Mr. Hardeman's GBF exposure, but then fails to take the next step of explaining why he believes that Mr. Hardeman's exposure to GBFs did not substantially contribute to Mr. Hardeman's NHL. Instead, he merely concludes that GBFs do not cause cancer and, thus, did not cause Mr. Hardeman's cancer. *See* Steidl Rep. at 12.

c. Dr. Michael Grossbard

Dr. Grossbard's specific causation opinion rises and falls with his general causation opinion; he does not proffer any case-specific, differential analysis of Mr. Hardeman's exposure to GBFs or explain how he ruled out exposure to GBFs after considering Mr. Hardeman's clinical history, despite that fact he includes such an analysis of [redacted] *See* Ex. 19 Grossbard Rep. at 5-6. Dr. Grossbard did not apply a proper differential methodology.[24]

d. Dr. Daniel A. Arber

Dr. Arber has no opinion as to whether or not GBHs are a cause of NHL and concedes "I don't consider myself an expert" on that topic. Ex. 28 Arber Dep. at 8:8-11.Dr. Arber's differential methodology boils down to the statement that "there is nothing unusual or unique about Mr. [redacted]

[24] Dr. Grossbard employs the same unreliable methodology for his specific-causation opinions with regards to Mr. Gebeyehou's NHL and these should also be excluded for the reasons stated above.

[redacted] *Id.* Dr. Arber's failure to meaningfully discuss exposure to GBFs beyond a general statement, which is equally applicable to other risk factors, renders his specific causation inadmissible. *See, e.g., In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.,* 218 F. Supp. 3d 700, 714 (N.D. Ill. 2016), *aff'd sub nom. In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.,* 884 F.3d 746 (7th Cir. 2018) ("An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.").[25]

e. Dr. Lawrence Zukerberg

Dr. Zukerberg rules out exposure to GBFs as a potential cause of Mr. Gebeyehou's NHL stating "[t]here is nothing in the morphology, the immunological characteristics, or the genomic analysis… pathology, medical history, or clinical course that points to Roundup as the etiology." Zukerberg Rpt. at 4. Dr. Zukerberg provides no basis or explanation for this conclusion. *See United States v. Frazier*, 387 F.3d 1244, 1296 (11th Cir. 2004) ("expert must explain how the conclusion is so grounded.") (internal quotations omitted). Given that Dr. Zukerberg's consideration of GBFs does not venture beyond a brief discussion of the AHS—which is an unreliable attempt to reopen general causation—his specific causation opinion fails to perform a proper differential analysis and must be excluded.

f. Dr. William H. Fleming

Similar to Dr. Arber's analysis, Dr. Fleming concludes that Mr. Gebeyehou's clinical and pathological history is "indistinguishable" from other cases of DLBCL not involving exposure to GBFs. Ex. 30 Fleming Suppl. Rep. at 5. But Dr. Fleming does not explain why he ruled out exposure to GBFs as a potential cause, particularly since an analysis of Mr. Gebeyehou's tumors cannot demonstrate that his disease was caused by any other risk factors. In short, Dr. Fleming has not utilized a reliable differential methodology, nor does he explain how a proper differential diagnosis is to be conducted, despite criticizing Plaintiff's experts by asserting "this is not how clinicians use differential diagnosis in practice." *Id.*

[25] Dr. Arber employs the same unreliable methodology for his specific-causation opinions with regard to Ms. Stevick's NHL and these should also be excluded for the reasons stated above.

g. Dr. Celeste Bello

Dr. Bello's presents her differential methodology in a series of bullet points where she fails to discuss exposure to GBFs relative to Ms. Stevick's case. *See* Bello Rep. at 15-16. The bullet points summarize a general causation opinion, and Dr. Bello's plaintiff-specific conclusion is that the cause of Ms. Stevick's NHL is unknown, which, Dr. Bello asserts, resembles what Dr. Bello encounters in her practice. *Id*. at 15. However, merely likening Ms. Stevick's case to what Dr. Bello observes in practice, without more, cannot withstand *Daubert* scrutiny. *See Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1201 (11th Cir. 2010) ("'If the witness is relying…primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. ") (quoting Advisory Note on Rule 702). Dr. Bello failed to apply a differential methodology and actually consider GBFs as a risk factor. Thus, her opinion that the cause is unknown is unreliable and largely irrelevant.

h. Dr. J. Pablo Villablanca

Dr. Villablanca, a neuroradiologist with no expertise in epidemiology, toxicology or genotoxicity, bases his specific causation opinion primarily on "imaging studies" of Ms. Stevick's brain. Villablanca Rep. at 2. This opinion is particularly useless as he simply relies on "clinical experience" to conclude that Ms. Stevick' primary cerebral lymphoma was "typical" for such patients, that patients with and without environmental exposures have "comparable imaging findings" and that "there are no medical imaging findings" implicating exposures to GBFs as a potential cause of Ms. Stevick's NHL. Villablanca Rep. at 16. In lieu of performing each step of a proper differential analysis, Dr. Villablanca posits, in general terms, [redacted] Such unsound, conclusory opinions have no place at trial and should be excluded.

C. This Court Should Exclude the Opinions of Dr. Al-Khatib and Dr. Sullivan as they are Based upon a Site Inspection that Occurred Six Years After the Fact and Was Limited in Scope.

The opinions of Monsanto's experts, Dr. Kassim Al-Khatib and Dr. Michael Sullivan, should be excluded because they are based upon speculation, the prejudice substantially outweighs the probative value, and they do not assist the trier of fact. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993) ("Rule 702 further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.'") (quoting Fed. R. Evid. 702); Fed. R. Evid. 403, 702. Both Dr. Al-Khatib and Dr. Sullivan state in their reports that they relied upon their own recent inspections of the Hardemans' former property in forming their opinions in this case. *See* Al-Khatib Rep. at 2; Sullivan Rep. at 2. The Hardemans, however, sold this property six years prior to Drs. Al-Khatib and Sullivan's inspection. Neither expert addresses the fact that the property, which encompasses 56 acres, has changed over the intervening six-year period. Moreover, both Drs. Al-Khatib and Sullivan failed to inspect the entire property; nonetheless, they form opinions as if they had. Such opinions are based upon mere speculation and will mislead and confuse the jury. Fed. R. Evid. 403.

An expert witness' testimony must be based upon sufficient facts in order to be admissible. Fed. R. Evid. 702. Here, neither expert gathered sufficient facts from their inspections to form reliable opinions. First, the inspections took place six years after the Hardemans sold the property and thus, after six years of different growth patterns, weather changes, and use by other people. Second, the inspections did not even cover the entire area where Mr. Hardeman sprayed. Specifically, on November 19, 2018, Dr. Al-Khatib conducted an inspection of the property, but limited his inspection to only certain areas of the 56-acre property. Ex. 31 Al-Khatib Rep. at 42. In fact, he admits he only inspected 1600 feet and the "plants and landscaping around the house" of the 56-acre property. *Id.* One acre equals 43,560 square feet. Clearly, Dr. Al-Khatib selected a small portion of the property to form his opinion that Mr. Hardeman did not need to spray much. There is absolutely no basis in fact for such an opinion. Likewise, Dr. Sullivan admitted that he spent about an hour on the 56-acre property on the same day as Dr. Al-Khatib and also limited his

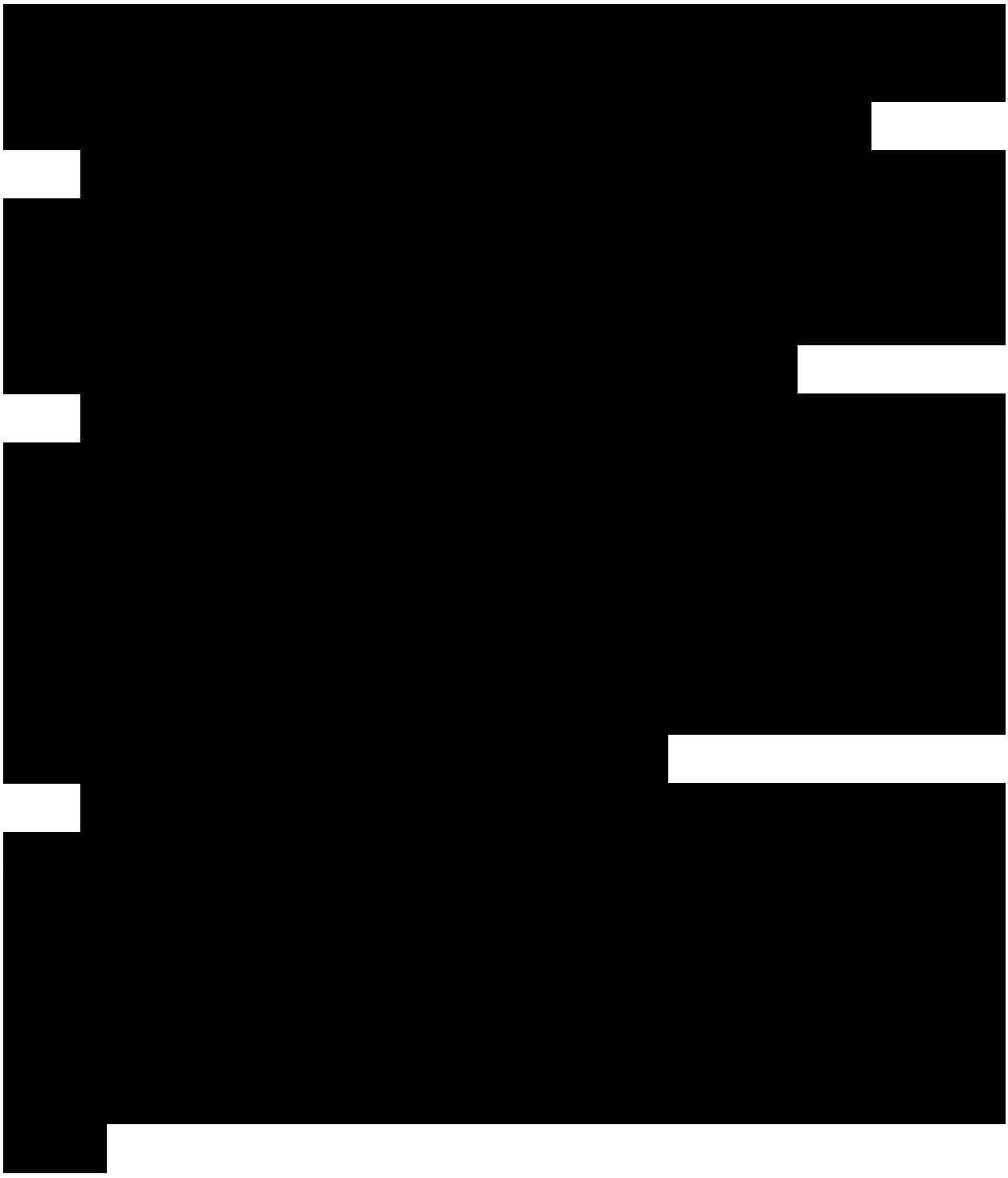
inspection to a few select areas.[26] Ex. 32 Sullivan Dep. 13:1-4; 15:12-17:12 and Exhibit 9.

Neither expert offers (or can offer) any evidence that the property remained in the same condition over the six years since the Hardemans sold it and moved. Given the remoteness in time and the changes to property that occur over a six-year period, their site inspections do not assist the trier of fact and are based upon speculation as to the condition of the property six years earlier. FRE 702; *see Nationwide Transport Finance v. Cass Info. Sys., Inc.*, 523 F.3d 1051 (9th Cir. 2008) (evidence that merely tells the jury what result to reach is not sufficiently helpful to the trier of fact to be admissible). It is virtually impossible, given the small area they inspected and the limited amount of time Dr. Sullivan admits to having spent on the property, for either expert to have acquired reliable scientific data to use to form their opinions. Reliance on heresy statements from the current owner should also be struck. *See Interwoven, Inc. v. Vertical Computer Sys.*, 2013 U.S. Dist. LEXIS 3786633, at *7 (N.D. Cal. July 18, 2013) (experts are permitted to rely on hearsay, only if an expert in the field would reasonably rely upon that information); *see also* FRE 703. Plaintiffs respectfully request this Court exclude the opinions of Drs. Al-Khatib and Sullivan as unreliable.

D. Dr. Welch's Opinions are Inadmissible

[redacted]

[26] Dr. Sullivan conceded there were necessary limits to his site inspection: "[the current owner] answered [questions] to the extent that he understood the property. Obviously he probably didn't understand spray activities because he's not Mr. Hardeman." Sullivan Dep. 18:16:23.



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Respectfully submitted,

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