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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS)	MDL No. 2741
LIABILITY LITIGATION)	
_____)	Case No. 3:16-md-02741-VC
<i>Hardeman v. Monsanto Co., et al.,</i>)	MONSANTO COMPANY’S REPLY
3:16-cv-0525-VC)	BRIEF IN SUPPORT OF MOTION TO
<i>Stevick v. Monsanto Co., et al.,</i>)	EXCLUDE TESTIMONY OF DR.
3:16-cv-2341-VC)	CHADI NABHAN, DR. ANDREI
<i>Gebeyehou v. Monsanto Co., et al.,</i>)	SHUSTOV, AND DR. DENNIS
3:16-cv-5813-VC)	WEISENBURGER ON DAUBERT
)	GROUND
)	Hearing dates: January 28, February 4
)	and 11, 2019
)	Time: 9:30AM
_____)	

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INTRODUCTION

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2 The task that Plaintiffs have set for themselves is hardly “daunting.” They argue not only that
3 their experts have reliably ruled in Roundup as a cause of their particular NHL, but that it would
4 actually be an error for an expert to reach any other conclusion, simply because this Court found that
5 Plaintiffs “barely” surmounted the broader question of whether Roundup could conceivably cause
6 cancer at the highest doses to which humans might be exposed. Plaintiffs’ position excuses them
7 from answering the question that the first prong of a valid specific causation differential diagnosis
8 poses: What is it about a particular Plaintiff that allows the expert to reliably rule in Roundup as a
9 cause of his or her NHL? In their experts’ collective view, as long as a minimal exposure threshold
10 is reached, Roundup automatically becomes a substantial factor in causing a Plaintiff’s NHL.
11 Plaintiffs then treat the ruling out prong as a largely illusory exercise. Their experts have offered
12 nothing more than say-so in dismissing other, well-recognized risk factors for Plaintiffs’ NHL, and
13 in fact violate basic tenets of logic and scientific consistency in dismissing other causes based on
14 reasoning that if faithfully employed would apply equally to Roundup. Recognizing that this method
15 is indefensible, Plaintiffs seek to eviscerate the ruling-out requirement, claiming that as a matter of
16 law, other causes, including unknown causes, need not really be excluded, or at least not definitively
17 so. Even if such other causes might exist, they argue, that does not excuse Roundup as an equal
18 contributing cause.

19 Plaintiffs are wrong. The upshot of their argument is that everyone with a minimal level of
20 Roundup exposure who later develops NHL has established causation, regardless of other risk factors
21 or the fact that the vast majority of NHL cases have no known cause. That’s a tautology, not a
22 differential diagnosis. But *Daubert* requires more. Here, it requires a daunting, Plaintiff-specific
23 exercise grounded in scientific methodology that Plaintiffs’ experts have not even attempted to
24 provide. Because Plaintiffs’ experts have failed to apply the proper rigorous analysis at both stages
25 of their differential diagnosis, Plaintiffs have not met their burden of establishing the reliability of
26 their experts under Rule 702.

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ARGUMENT**I. The Three Experts Fail to Reliably Rule in Roundup as a Cause of Each Plaintiff's NHL.****A. The Subset of Cherry-Picked Epidemiological Studies Provides an Insufficient Basis to Rule in Glyphosate as a Cause of Each Specific Plaintiff's NHL.**

Plaintiffs' approach fundamentally conflates the general and specific causation inquiries. The question at the general cause phase was whether Roundup can cause NHL at the highest dose humans could possibly experience. *See In re Roundup Prods. Liab. Litig.*, 2018 WL 3368534, at *5 (N.D. Cal. July 10, 2018). ("Picture, for instance, a professional gardener who has applied Roundup without using protective equipment several times per week, many hours per day, for decades."). Here, that inquiry is materially different, and focuses on individual Plaintiff-specific facts and circumstances. Plaintiffs' experts cannot mechanically rule in Roundup for particular Plaintiffs simply because the Court concluded that Plaintiffs' proffered studies provided a (barely) sufficient basis to create a jury question for the conceivably most at-risk person. *See, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prod. Liab. Litig.*, 892 F.3d 624, 644 (4th Cir. 2018) ("That Lipitor may cause an increased risk of diabetes notwithstanding certain other risk factors is insufficient to conclude that the drug was a substantial contributing factor in an individual patient. To hold otherwise would obviate the need for any specific causation evidence at all."). Yet Plaintiffs have conceded that all their experts offer to rule in Roundup is a subset of cherry-picked studies used at the general causation phase—without regard to the individual facts of a given Plaintiff and without recognition of the different epidemiological burden at the specific causation stage.

Where, as here, experts rely solely on epidemiological studies to meet their specific causation ruling in burden, those studies must meet certain reliability standards. But the two main studies all of Plaintiffs' experts rely upon—McDuffie 2001 and Eriksson 2008—do not provide a reliable basis for a specific causation opinion because they fail to control for other pesticides or other "statistically significant medical variables." *Compare* Ex. 1, Helen H. McDuffie et al., *Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health*, 10 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 1155, 1158 (2001), *with id.* at 1161. This Court has explained that this failure to control for confounding variables "can skew the results," rendering the

1 studies unreliable. *In re Roundup*, 2018 WL 3368534, at *8. To be sure, courts have admitted studies
2 that did not control for all confounding variables. *See Cooper v. Takeda Pharm. Am., Inc.*, 191 Cal.
3 Rptr. 3d 67, 94 (Cal. Ct. App. 2015). But in *Cooper*, the Azoulay study authors acknowledged the
4 unaccounted-for variables and concluded the failure to control for them would not have “*affected the*
5 *internal validity of the study*” because it was “unlikely that these variables were differentially
6 distributed between ever users of [the at-issue product] and ever users of other [substitute goods].”
7 *Id.* *Cooper* also noted the Azoulay study’s other remarkable strengths. *Id.* The authors of McDuffie
8 2001 and Eriksson 2008 came to no such conclusion regarding the failure to control for other
9 pesticides. This omission is fatal.

10 Plaintiffs now highlight De Roos 2003, even though the experts themselves place little
11 emphasis on that study because it does not show a dose-response and make no effort to account for
12 the disparate odds ratios in the different analyses. Ex. 2, A.J. De Roos et al., *Integrative Assessment*
13 *of Multiple Pesticides as Risk Factors for Non-Hodgkin’s Lymphoma Among Men*, 60 OCCUP &
14 ENVIRON MEDI 1, 5 (2003) (hierarchical regression analysis yielded an odds ratio for glyphosate, after
15 controlling for other pesticides, of 1.6 that was not statistically significant); *see also In re Roundup*,
16 2018 WL 3368534, at *30 (excluding Dr. Neugut as unreliable after he failed to explain the difference
17 between De Roos’s two regressions). Plaintiffs also ignore that the De Roos data was ultimately
18 pooled into NAPP, and when properly adjusted, showed no increased risk. *See* Ex. 3, Manisha Pahwa
19 et al., *An Evaluation of Glyphosate Use and the Risks of Non-Hodgkin Lymphoma Major Histological*
20 *Sub-Types in the North American Pooled Project* (Aug. 31, 2015); *In re Roundup*, 2018 WL 3368534,
21 at *10 (NAPP “overall odds ratio for glyphosate use of 1.13 (0.84, 1.51), when adjusted for use of
22 three other pesticides and several other potential confounders. . . . When proxy respondents were
23 removed from the data, the odds ratio dropped to 0.95 (0.69, 1.32).”). Plaintiffs’ selective reliance
24 on what they perceive to be the favorable component of De Roos only reinforces the outcome-
25 determinative nature of their experts’ methodology, simply picking and choosing results that support
26 their position while ignoring the larger scientific landscape.

27 That Plaintiffs go to such lengths in this cherry-picking exercise only reinforces their implicit
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1 recognition of the problem they have meeting the threshold California requirement: for an expert to
2 rule in a cause at the specific causation stage through a differential diagnosis based on epidemiology,
3 which is what all three experts do here, that epidemiology must show at least a doubling of the risk
4 to provide a proper foundation for that opinion. *In re Bextra & Celebrex Mktg. Sales Practices &*
5 *Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1172 (N.D. Cal. 2007). This heightened standard highlights
6 the difference between the general and specific causation phases: only when “a relative risk that is
7 greater than 2.0” can a jury conclude “that the agent was more likely than not responsible for a
8 particular individual’s disease.” *In re Silicone Gel Breast Implants Prod. Liab Litig.*, 318 F. Supp.
9 2d 879, 893 (C.D. Cal. 2004) (citing *Reference Manual on Scientific Evidence*, 384 n.140 (Federal
10 Judicial Center 2d ed. 2000)). That standard has not been met here.

11 In the face of their experts’ unequivocal testimony that they are relying solely on the
12 insufficient epidemiology to rule in Roundup for specific Plaintiffs based on exposure days, Plaintiffs’
13 counsel attempts (at 7) to bolster their methodology by asserting that the experts also rely on “a
14 thorough differential diagnosis; a plausible mechanism of action; and animal carcinogenicity studies.”
15 But lawyer argument boasting that each expert performed a “thorough differential diagnosis” does
16 nothing to change the methodology the experts actually used. And in fact, none of these experts
17 themselves adopt this lawyer argument: Dr. Weisenburger never mentions these factors at any point
18 in his brief specific causation reports, and Dr. Nabhan’s and Dr. Shustov’s reports only mention
19 “mechanisms of action” and “animal studies” when discussing the background of the IARC
20 monograph. The record is undisputed that these experts did not consider these factors when ruling in
21 Roundup, nor could their ancillary reference to them in the context of IARC’s monograph cleanse
22 their methodology given the Court’s previous pronouncements that the IARC monograph is
23 insufficient to support either specific or general causation. *In re Roundup*, 2018 WL 3368534, at *7.

24 The experts’ failure to consider the totality of the relevant scientific literature as it may apply
25 to a given Plaintiff is also disqualifying. As the seventh most common cancer, NHL has been
26 extensively studied—there is no dearth of scientific literature examining this issue. But the face of
27 the experts’ reports belie Plaintiffs’ blanket statement (at 9) that their experts “considered the totality
28

1 of the evidence . . . in concluding that the epidemiology supports specific causation.” Experts cannot
2 claim to have considered all the literature on an entire subject “without informing the Court what . . .
3 works [they actually considered] or what conclusion the original authors reached.” *Lust By &*
4 *Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596 (9th Cir. 1996). It is “hardly scientific”
5 for experts to highlight the few studies that are most supportive of their conclusion and present them
6 to the court as a valid, final result without an assessment of the remainder of the body of literature on
7 the subject. *Id.* Yet that is exactly what Plaintiffs’ experts did here. For example, after being
8 excluded at the general causation phase for mishandling the epidemiology, Dr. Nabhan limits his
9 reports to discuss only the IARC monograph and the three carefully curated studies. *See, e.g.*, Nabhan
10 *Hardeman Rep.* at 6–7, ECF No. 2420-3. He briefly addressed the AHS, but dismissed it as flawed
11 without applying the same critical eye to the other three studies he selected. *Id.* at 7. Even worse,
12 Dr. Shustov openly admits that he simply cut-and-pasted Dr. Nabhan’s flawed analysis, began his
13 analysis with the assumption that there was a link between glyphosate and NHL, and ignored studies,
14 like the AHS, that did not support this pre-conceived assumption. Shustov *Hardeman Dep.* at 279:22–
15 280:8, ECF No. 2420-11. “[I]t is essential that the results of other studies conducted by other
16 scientists on the same subject, that aim to correct for the limitations and flaws in prior studies, be
17 taken into account, and the body of studies be considered as a whole.” *Cooper*, 191 Cal. Rptr. 3d at
18 95. Plaintiffs’ experts have skipped this essential methodological step. They rely solely on
19 epidemiology, and an unhelpful, cherry-picked subset of it, at that. They must be excluded as a result.

20 **B. The Failure of These Experts to Do Anything Beyond Pointing to Their**
21 **Preferred Studies Demonstrates the Unreliability of Their Approach.**

22 Plaintiffs all but concede that their experts have failed to offer *anything more* as justification
23 for ruling in glyphosate beyond their preferred epidemiology studies. Plaintiffs acknowledge (at 34–
24 35) there is no test or marker that would identify Roundup, as opposed to anything else, as the cause
25 of any Plaintiff’s NHL. Plaintiffs also recognize (at 11–12) their experts failed to specifically take
26 into account that each of the Plaintiffs used glyphosate formulations for residential home and garden
27 use. Plaintiffs offer no response to the first defect, and try to gloss over the second by arguing that
28 their experts’ favored studies included *some* home and garden users. In reality, only McDuffie 2001

1 mentions the inclusion of home and garden users, and this study does not identify how many study
2 participants were home and garden users. But more fundamentally, lawyer argument cannot change
3 the fact that their experts consider these studies to be “farmer studies.” *See* Def’s Mot. at 8. The
4 experts fail to grapple with the critical fact that these studies do not control for type of use, and their
5 counsel’s urging to excuse this flaw because the studies included *some* home users cannot substitute
6 for a scientific justification—voiced by the experts themselves—on how these studies can still be
7 relevant to these specific Plaintiffs, all of whom are casual home users.

8 In essence, Plaintiffs seek to flip the burden of proof. Contrary to Plaintiffs’ argument,
9 Monsanto is not required to show that the studies it has cited, like the AHS, controlled for the type of
10 use or the particular formulation used. Rather, Plaintiffs must establish the scientific literature on
11 which their experts rely is sufficiently reliable in methodology and sufficiently specific in application
12 to be helpful to the jury. *Allen v. Penn. Eng’g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996) (explaining
13 that in toxic tort cases, “[s]cientific knowledge of the harmful level of exposure to a chemical plus
14 knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the
15 plaintiff’s burden”); *see also In re Bextra.*, 524 F. Supp. 2d at 1181 (“Plaintiffs cite no case, however,
16 that suggests that they can satisfy their burden of proof based on a lack of evidence.”). Plaintiffs’
17 experts have not come forward with any reliable analysis on how the level of exposure experienced
18 by agricultural workers in the farmer studies translates to exposure by consumers in casual home and
19 garden use. As noted above, Plaintiffs hope to skip that step altogether. But that is a leap unwarranted
20 by the available science. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (expert must be excluded
21 when “there is simply too great an analytical gap between the data and the opinion proffered”).

22 Ultimately, Plaintiffs experts’ cookie-cutter, days-per-year-approach does not provide a
23 reliable method for ruling in Roundup for all Plaintiffs. First, this approach is derived directly from
24 McDuffie 2001 and Eriksson 2008—the two studies Plaintiffs’ experts principally relied on but
25 Plaintiffs’ brief now downplays given the critical flaw with those studies’ failure to adjust for the use
26 of other pesticides and for different types of use. Second, the line derived from these studies is
27 arbitrary, and chosen only to support the experts’ inappropriate “always Roundup” mantra. Third,
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1 Plaintiffs' assertion (at 14) that their experts performed nuanced, "relative risk" assessments on each
2 Plaintiff is simply wrong. Dr. Weisenburger's threshold for placing the Plaintiffs in the "high risk
3 category for the development of NHL" is actually just the lower thresholds announced in McDuffie
4 and Eriksson. See Weisenburger *Hardeman* Rep. at 4, ECF No. 2420-9 ("This would place him in
5 the high-risk category for the development of NHL (>10 days of use, or>2 days/year)[.]"). Plaintiffs
6 concede this days-per-year-approach was created for litigation, is not used in clinical practice, has not
7 been validated, and has not been peer reviewed. See Def's Mot. at 20. And it is based on studies that
8 failed to control for other pesticides or particular conditions of use. Accordingly, this approach cannot
9 be reliably applied to Plaintiffs' individual circumstances at the ruling in stage.

10 **II. Plaintiffs Fail To Rule-Out Other Potential Causes of Plaintiffs' NHL.**

11 Plaintiffs do not dispute that Ninth Circuit law requires that an expert "*provide reasons for*
12 *rejecting alternative hypotheses 'using scientific methods and procedures'*" and "the elimination of
13 those hypotheses" must be based on more than "subjective beliefs or unsupported speculation." Pls.'
14 Resp. at 17 (quoting *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994)) (emphasis
15 added). That is the principal question this Court must address: have these experts faithfully applied
16 a logically consistent, science-driven rationale for ruling out other potential causes for these particular
17 Plaintiffs' NHL. It is not an answer, as Plaintiffs summarily proclaim (at 26), that their experts "have
18 impeccable qualifications and did not engage in outcome driven methodologies in reaching their
19 conclusions here." Rather, the Court must dig below the veneer of conclusions and labels and test
20 the scientific reliability of their explanations, for any expert can offer a set of talking points to obscure
21 what amounts only to "subjective beliefs or unsupported speculation."

22 Such an inquiry here demonstrates that these experts cannot meet *Daubert's* strictures.
23 Perhaps most telling is Plaintiffs' unwillingness to come to terms with the inherent inconsistency in
24 how their experts handled the evidence in these cases: they muster arguments for discounting other
25 potential causes of Plaintiffs' NHL that, if faithfully applied, would equally rule out Roundup.
26 Plaintiffs' opposition makes no meaningful attempt to confront this irreconcilable inconsistency.
27 Likewise, Plaintiffs cannot justify their experts' inability to rule out (or even attempt to rule out)
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1 idiopathic causes. The law is not so malleable as to excuse them from doing so in these circumstances,
2 and Plaintiffs’ effort to avoid such an obligation through legal argument only verifies that their experts
3 cannot reliably rule out such unknown causes. Plaintiffs cannot skate past *Daubert* by claiming their
4 experts performed a differential diagnosis when that differential diagnosis cannot stand up to
5 legitimate scrutiny by the Court. See *In re Lipitor*, 892 F.3d at 643 (“A rose by another name may
6 smell as sweet—but simply calling an analysis a differential diagnosis doesn’t make it so.”).

7 **A. Plaintiffs’ Experts Cannot Explain Why They Rule Out Non-Roundup Risk**
8 **Factors With Arguments They Fail To Apply to Roundup.**

9 Plaintiffs’ opposition sidesteps their experts’ biggest vulnerability: they rule out non-Roundup
10 risk factors with arguments they fail to apply equally to Roundup. This fundamental inconsistency
11 highlights the unreliability of their methodology. As this Court bluntly stated, the epidemiology
12 connecting Roundup and NHL is “rather weak.” *In re Roundup*, 2018 WL 3368534, at *1. But
13 according to Plaintiffs’ experts, they can rule out other potential alternative causes because (in their
14 cursory review) the epidemiology connecting those risks is weak. For Roundup, weak epidemiology
15 is no obstacle; for other risk factors, it is determinative. Such inconsistency cannot be squared with
16 *Daubert*. See *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 561 (W.D. Pa. 2003)
17 (“[C]onsistency is a hallmark of the scientific method[.]”).

18 Neither the experts in their reports and testimony, nor the Plaintiffs in their response brief, try
19 to reconcile this disparity. [REDACTED]

20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED]

B. Plaintiffs' Experts Did Not Reliably Rule Out Idiopathic Causes.

1 Plaintiffs fully admit (at 20) that their “experts do not dispute that they are unable to identify
2 a cause of NHL in many patients.” But in their view, once the experts rule in Roundup, as they do
3 with every Roundup user, then the need to rule out unknown causes vanishes, because that case (at
4 least to them) is no longer “idiopathic.” See Pls.’ Resp. at 20 (“Plaintiffs’ NHL here was not
5 idiopathic and that there was substantial evidence that each Plaintiffs’ NHL was caused by exposure
6 to the Roundup® each Plaintiff used.”) Such self-validating argument lacks logical or legal sense. If
7 ruling in Roundup alone sufficed to rule out idiopathic causes, it would obliterate the core legal
8 requirement to rule out “an alternative explanation for the disease” with “substantial evidence,” as
9 California law requires. *Cooper*, 191 Cal. Rptr. at 91–92; see also *Henrickson ConocoPhillips Co.*,
10 605 F. Supp. 2d 1142, 1162–63 (E.D. Wash. 2009) (rejecting differential diagnosis where it was
11 un rebutted that 80–90% of all cases of AML were idiopathic, but expert did not address idiopathy);
12 *Hall v Baxter*, 947 F. Supp. 1387, 1398, 1414 (D. Or. 1996) (rejecting differential diagnosis where
13 expert “has not testified as to how he eliminated other causes of Ms. Hall’s disease”).

14 Plaintiffs’ experts do not attempt to rule out idiopathic causes here because there is no
15 scientifically justifiable way to do so in the context of these particular cases. It is true that they do
16 not have “to eliminate all other possible causes of a condition for the expert’s testimony to be
17 reliable.” *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1237 (9th Cir. 2017) (citing *Messick v.*
18 *Novartis Pharm. Corp.*, 747 F.3d at 1193, 1199 (9th Cir. 2014)). But “the proposed cause [must] ‘be
19 a substantial causative factor.’” *Id.* (quoting *Messick*, 747 F.3d at 1199). And while Plaintiffs cite
20 part of California’s jury instructions defining substantial cause, they omit the crucial sentence relevant
21 in these circumstances: “Conduct is not a substantial factor in causing harm *if the same harm would*
22 *have occurred without that conduct.*” CACI No. 430 (emphasis added). This aspect of the causation
23 burden is embodied within the differential diagnosis methodology itself: the expert must be able to
24 opine that other factors were *not* the cause of the NHL (that is, rule them out) irrespective of whether
25 the Plaintiff also used Roundup.
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1 Here, Plaintiffs’ experts have not ruled out that the harm could have occurred without
2 Roundup exposure, including through gene mutations that happen as a result of idiopathic causes.
3 Plaintiffs admit that the cause of NHL is unknown in approximately 70% of cases. *See* Weisenburger
4 *Adams* Dep. at 56:18–24, 212:7–14, ECF No. 2420-14. They concede that when the cause of a
5 patient’s NHL is idiopathic, genetic mutations occur without explanation. *See, e.g., id.* at 164:3–16.
6 And they further agree that those genetic mutations can occur in people exposed to Roundup,
7 independent of their Roundup exposure. *See id.* at 164:20–25. Most importantly, they admit that the
8 three Plaintiffs could have gotten NHL even if they had not been exposed to Roundup. *See*
9 Weisenburger *Hardeman* Dep. at 93:1–96:25, ECF No. 2420-17; Weisenburger *Gebeyehou* Dep. at
10 86:2–5, ECF No. 2420-27; Weisenburger *Stevick* Dep. at 102:14–18, ECF No. 2420-12; Shustov
11 *Hardeman* Dep. at 209:6–11, ECF No. 2420-11; *id.* at 212:11–15; Nabhan *Hardeman* Dep. at 67:14–
12 18, ECF No. 2420-15; Nabhan *Gebeyehou* Dep. at 25:23–26:5, ECF No. 2420-16. In this sense, this
13 case differs from *Messick*, where the expert “equated [plaintiff’s] use of bisphosphonates leading to
14 BRONJ with the oxygen necessary to start a fire,” and thus reasoned that the injury would not have
15 happened on its own without the use of the medicine. 747 F.3d at 1197. If the same harm would
16 have occurred without Roundup exposure, then Roundup exposure cannot by definition be a
17 substantial causative factor.

18 Likewise, *Wendell* does not hold that a physician undertaking a differential diagnosis can
19 simply ignore that a disease is overwhelmingly idiopathic in origin. In *Wendell*, the expert witnesses
20 ruled out idiopathic causes based on substantial clinical experience—observing that two out of seven
21 patients of the extremely rare illness had taken the drug in question. 858 F.3d at 1233–34. Plaintiffs
22 here differ in two important aspects. First, NHL is a far more common type of cancer than the “one
23 in six million” form of cancer at issue in *Wendell*. *See* 858 F.3d at 1234; Shustov *Hardeman* Dep. at
24 265:5–12, ECF No. 2420-15; Weisenburger *Stevick* Dep. at 131:4–15, ECF No. 2420-12. And
25 second, Plaintiffs’ experts here do not observe, or even ask, their patients with NHL whether they
26 were exposed to Roundup, thus making it impossible to rely on the same clinical observations the
27 experts made in *Wendell*. *See* Def’s Mot. at 18; Nabhan *Hardeman* Dep. at 21:17–20; *id.* at 25:2–7,
28

1 ECF No. 2420-15; Shustov *Hardeman* Dep. at 85:21–22, ECF No. 2420-11; Weisenburger *Adams*
2 Dep. at 54:3–15; 76:19–22, ECF No. 2420-14. Plaintiffs also cite (at 21) *Hall v. Conoco* for the
3 unremarkable proposition that an expert need not eliminate every “conceivable” cause. 886 F.3d
4 1308, 1314 (10th Cir. 2018). But they ignore the core holding affirming the exclusion of the expert’s
5 differential diagnosis because the expert failed to reliably rule out idiopathic causes: “Because
6 idiopathy accounts for more than half of the cases of acute myeloid leukemia, a differential diagnosis
7 could be considered inherently unreliable here.” *Id.* at 1315.¹

8 **C. Plaintiffs’ Experts Failed to Reliably Rule Out These Plaintiffs’ Specific Risk**
9 **Factors.**

10 Plaintiffs’ specific defense of their experts’ ruling out of the risk factors present for these
11 Plaintiffs (at 21–26) betrays the central outcome-driven nature of their experts’ methodology. Resort
12 to vacuous generalities like “clinical judgment and extensive knowledge” (at 21) in purportedly ruling
13 out other risk factors does not serve as some magic wand to bless an otherwise unscientific exercise.
14 *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prod. Liab. Litig.*, 185 F. Supp.
15 3d 786, 805–06 (D.S.C. 2016) (excluding expert who noted that the plaintiff’s age put her at an
16 increased risk of diabetes, but summarily concluded it was “not clinically significant”: “clinical
17 judgment is nothing more than unacceptable ipse dixit testimony”), *aff’d*, 892 F.3d at 644 (“Dr.
18 Murphy did consider (and purportedly ruled out) several other risk factors, including Ms.
19 Hempstead’s family history, race, body mass index (‘BMI’), and age. But her analysis of those
20 factors—and, more importantly, her reasons for rejecting them as the likely cause of Ms. Hempstead’s
21 disease—fell short.”). At bottom, Plaintiffs all but concede this issue, instead arguing (at 21–22) that
22 ruling out the other risk factors does not really matter in the end: even if the other causes cannot be
23 ruled out, as long as Roundup is one of those factors, that should be enough under *Daubert*. That
24 simply cannot be the law, for taken to its logical conclusion, there would be no need for specific
25 causation evidence at all. *See, e.g., In re Lipitor*, 185 F. Supp. 3d at 799 (expert “cannot simply opine

26 _____
27 ¹ Plaintiffs’ citation to dicta in *In re Diet Drugs*, 890 F. Supp. 2d 552, 557 (E.D. Pa. 2012) hardly
28 helps them because the court in that case was simply interpreting the terms of a settlement agreement
and concluded that “evidence excluding idiopathic or unknown causes of PPH is not required under
the plain meaning of the Settlement Agreement.” *Id.* at 558.

1 that all present risk factors are ‘substantial contributing factors’”); *Guinn v. AstraZeneca Pharm. LP*,
2 602 F.3d 1245, 1255 (11th Cir. 2010) (“An expert, however, cannot merely conclude that all risk
3 factors for a disease are substantial contributing factors in its development.”).

4 1. [REDACTED]

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III. Plaintiffs’ Motion to Exclude Monsanto’s Expert Witnesses Is Meritless.

To help the jury address whether Roundup caused Plaintiffs’ NHL in particular, Monsanto retained leading clinicians with experience and specialized training in treating patients with cancer.

1 These experts span a variety of fields: hematology/oncology (Dr. Levine, at City of Hope, and Celeste
2 Bello, at the Moffitt Cancer Center); oncology (Dr. Michael Grossbard, at New York University);
3 pathology (Lawrence Zuckerberg, at Massachusetts General Hospital, and Christian Steidl, at the
4 University of British Columbia); and neuroradiology (Juan Pablo Villablanca, at UCLA). They each
5 brought their clinical perspective to bear in conducting a differential diagnosis of one or several
6 Plaintiffs to determine if there is an identifiable cause for their NHL (recognizing that NHL is
7 idiopathic in the vast majority of cases), including potentially Roundup.

8 Without bothering to depose any of these experts, Plaintiffs launch a series of broadsides that
9 are both devoid of supporting authority and seemingly calculated only to shift attention away from
10 their own experts. Plaintiffs' attacks seek to blur the task of Plaintiffs' experts—to come forward
11 with reliable, admissible evidence supporting specific causation in the face of a dubious scientific
12 connection—with the role of a defense expert, whose proper focus can be critiquing the Plaintiffs'
13 experts unscientific efforts and explaining why the available science is inadequate to demonstrate
14 causation. *See, e.g., In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 418–19 (S.D.N.Y.
15 2016), *aff'd*, 2017 WL 4785947 (2d Cir. Oct. 24, 2017) (“pointing to the absence of convincing
16 studies or the weaknesses of studies on which Plaintiffs rely, and evaluating them in light of their
17 clinical experience, training and research, is . . . a logical and valid approach.”).

18 **A. Plaintiffs' Challenge to Monsanto's Specific Causation Experts Misrepresents**
19 **the Experts' Methodology and Mischaracterizes the Specific Causation Inquiry.**

20 There is nothing improper about the way Monsanto's experts conducted their differential
21 diagnoses here. To take just one example, Dr. Grossbard conducted an extensive review of Mr.
22 Hardeman's medical records, *see* Grossbard *Hardeman* Rep. at 3–4, ECF No. 2481-1; explained the
23 nature of NHL, the relevant recognized risk factors for it, and the literature supporting those risk
24 factors, *id.* at 5–7; and then analyzed and considered several epidemiological studies in assessing
25 whether Roundup could be “ruled in” as an additional risk factor that somehow rises to an identifiable
26 cause of Mr. Hardeman's cancer, *id.* at 7–8; *see Clausen*, 339 F.3d at 1057 (first step of diagnosis is
27 “to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings
28 under consideration”). In that last step, Dr. Grossbard considered not just the studies Plaintiffs'

1 experts highlight (or the odds ratios unadjusted for other pesticides in those studies), but the 2018
2 NCI study, which is the largest epidemiological analysis of whether there is any connection between
3 glyphosate and NHL. Ultimately, relying on his clinical judgment and assessment of the medical
4 records and the literature, and after considering all the possible risk factors, [REDACTED]

5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 Those are the elements of a valid differential diagnosis. Defendants’ experts addressed in
16 depth the specific other risk factors present for the individual Plaintiffs, as well as the established
17 medical literature surrounding those risk factors. That is the critical distinction between the
18 excludable, results-oriented methodology Plaintiffs’ experts apply and the reliable methods
19 Defendants’ experts have employed.²

20 Plaintiffs (at 28) complain that Monsanto’s experts are offering improper general causation
21 opinions. Not so. As even a cursory review of the experts’ reports reveals, Defendants’ specific
22 causation experts focus on the individual circumstances of the Plaintiffs, not previously-discussed
23

24 _____
25 ² Indeed, the authorities Plaintiffs cite all demonstrate that *Plaintiff’s* experts should be excluded.
26 *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 887 (10th Cir. 2005) (specific causation opinions
27 based purely on say-so about clinical experience excluded and have “not gained acceptance in the
28 relevant scientific community.”); *In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, 218 F. Supp.
3d 700, 714 (N.D. Ill. 2016) (excluding an opinion that consisted of nothing more than a “bottom
line”); *In re Mirena IUD Products Liability Litigation*, 169 F. Supp. 3d 396, 436 (S.D.N.Y. 2016)
(excluding the specific causation testimony of an expert who like Dr. Nabhan here had no reliable
opinions on general causation).

1 studies of Roundup. *See, e.g.*, Grossbard *Hardeman* Rep. at 3–7, ECF No. 2481-1; Levine *Hardeman*
2 Rep. at 12–19, ECF No. 2479-18. To be sure, Defendants’ experts did provide some analysis of the
3 epidemiological studies regarding Roundup—but they did so in order to fairly consider the
4 circumstances of each Plaintiff and to put into perspective why they do not believe Roundup or
5 glyphosate are established risk factors that must be ruled out. *See, e.g.*, Ex. 4, Case Management
6 Conference Tr. at 28:20–29:7, Dec. 5, 2018 (“And I was assuming that it would be impossible to have
7 a strict delineation between the concept of general causation and the concept of specific causation.);
8 *see also* Pretrial Order No. 7 at 8, ECF No. 103 (“This Order shall not preclude the parties from
9 designating additional experts who may offer opinions relating to general or specific causation if this
10 MDL proceeds beyond the general-causation phase.”).

11 Plaintiffs next accuse Monsanto’s experts (at 30) of conducting only a “superficial review” of
12 the existing epidemiology. But it is Plaintiffs’ experts who limit their analysis to a “superficial
13 review” of the cherry-picked subset of epidemiological studies that support their pre-ordained
14 conclusions, whereas Defendants’ experts by contrast surveyed more of the epidemiology, including
15 both the studies Plaintiffs’ experts favor as well as other relevant papers, including broad-ranging
16 2018 NCI study.

17 Plaintiffs’ final suggestion (at 34)—that Defendants’ experts should actually be excluded
18 because they do not consider Roundup to be a risk factor for any of these Plaintiffs—would stand
19 *Daubert* on its head. Plaintiffs effectively argue that Roundup must be deemed to be a substantial
20 factor in every case, with the burden on Defendants to disprove that point based on the medical
21 records of a specific Plaintiff. But the Court’s prior *Daubert* ruling concluded only that there is a jury
22 question as to whether Roundup could conceivably cause cancer in some people. It did not ordain,
23 as an undisputed point of scientific fact, that Roundup *is actually* a risk factor for any particular
24 Plaintiff’s NHL—and indeed, the Court rejected Plaintiffs’ *Daubert* challenges essentially seeking to
25 advance that point. Ultimately, Defendants’ experts carefully considered the Plaintiffs’ medical
26 records, the nature of NHL, the recognized risk factors for NHL and the literature surrounding them,
27 and the best available scientific evidence regarding the possibility that Roundup may also be a risk
28

1 factor. They then applied their real-world experience to that evidence and concluded that Roundup
2 did not constitute a substantial factor in the Plaintiffs' NHL.

3 **B. Plaintiffs' Challenges to Dr. Sullivan and Dr. Al-Khatib Go To Weight, Not**
4 **Admissibility.**

5 Plaintiffs' challenge to Dr. Sullivan and Dr. Al-Khatib is not a *Daubert* challenge at all. The
6 *Daubert* inquiry fundamentally is about the methods an expert employs, not their results. *See Belisle*
7 *v. BNSF Ry. Co.*, 697 F. Supp. 2d 1233, 1244 (D. Kan. 2010). But Plaintiffs do not challenge these
8 experts' methodology at all. Their objection is instead to the facts the experts plugged into their
9 analysis. For example, they complain that Dr. Al-Khatib may not have examined the entire property,
10 and speculate that the condition of the property to which the experts applied their exposure
11 methodology may have changed since the time the Hardemans vacated it. Pls.' Resp. at 38–39. That
12 is a quintessential challenge to weight, not admissibility. Plaintiffs cite no authority supporting their
13 arguments for exclusion. On the contrary, both experts explain that they interviewed the current
14 owner of the property and concluded that there were not material changes. And Plaintiffs themselves
15 cite authority confirming that experts can “rely on hearsay evidence in coming to their conclusions,
16 so long as an expert in the field would reasonably rely on that information”—and when experts do
17 so, “[i]t is for a jury to decide” whether the expert's reliance was reasonable. *Interwoven, Inc. v.*
18 *Vertical Computer Sys.*, No. CV 10-04645 RS, 2013 WL 3786633, at *7 (N.D. Cal. July 18, 2013).

19 **C. Plaintiffs' Challenge to Dr. Welch Would At Minimum Require Exclusion Of**
20 **Their Own Regulatory Expert, Dr. Benbrook.**

21 Plaintiffs' complaints about Dr. Welch underscore why the testimony she seeks to offer is
22 within the proper purview of a regulatory expert—unlike the testimony of Plaintiffs' expert, Dr.
23 Benbrook. For example, Plaintiffs highlight that Dr. Welch did not apply “the weight of the evidence
24 methodology while at EPA.” Pls.' Resp. at 40. But the relevant point is that Dr. Welch actually
25 worked at EPA, unlike Dr. Benbrook—who purports to comment not only on EPA's process but also
26 its motives despite never working at any regulatory body or any company subject to EPA regulations.
27 *See* Def.'s Mot. to Exclude Testimony of Dr. Charles Benbrook at 10, ECF No. 2417. Likewise,
28 Plaintiffs complain that Dr. Welch offers “a historical narrative of EPA's treatment of glyphosate”

1 without any further opinions, Pls.' Resp. at. 39, but the types of opinions Dr. Benbrook offers, about
2 the motives and interests of third parties, is improper. *See* Def.'s Mot. to Exclude Testimony of Dr.
3 Charles Benbrook at 11, ECF No. 2417. In short, Dr. Welch's properly limited, experience-based
4 assessment of EPA's actions regarding glyphosate is the only regulatory testimony that should be
5 admitted in this case.

1 DATED: January 18, 2019

Respectfully submitted,

2 /s/ Brian L. Stekloff

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of January 2019, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system which sent notice of the filing to all appearing parties of record.

/s/ Brian L. Stekloff