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UNITED ST	ATES DISTRICT COURT
NORTHERN I	DISTRICT OF CALIFORNIA
IN RE: ROUNDUP PRODUCTS)) MDL No. 2741
LIABILITY LITIGATION)) Case No. 3:16-md-02741-VC
) Case No. 5.10-IIId-02741-VC
Hardeman v. Monsanto Co., et al.,) MONSANTO COMPANY'S NOTICE OI
3:16-cv-0525-VC Stevick v. Monsanto Co., et al.,	 MOTION AND MOTION TO EXCLUDE TESTIMONY OF DR. CHADI NABHAN
3:16-cv-2341-VC) DR. ANDREI SHUSTOV, AND DR.
Gebeyehou v. Monsanto Co., et al.,) DENNIS WEISENBURGER ON
3:16-cv-5813-VC) DAUBERT GROUNDS
) Hearing dates: February 4, 6, and 11, 2019
) Time: 9:30AM
)
TO THE COURT, ALL PARTIES, AN	D THEIR ATTORNEYS OF RECORD:
	nning on February 4, 2019, in Courtroom 4 of the U

MONSANTO'S MOTION TO EXCLUDE TESTIMONY OF DRS. NABHAN, SHUSTOV AND WEISENBURGER 3:16-md-02741-VC & 3:16-cv-0525-VC, 3:16-cv-2341-VC, 3:16-cv-5813-VC

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Francisco, CA 94102, or as ordered by the Court, Defendant Monsanto Company ("Monsanto") will present its *Daubert* Motion to Exclude the Testimony of Dr. Chadi Nabhan, Dr. Andrei Shustov, and Dr. Dennis Weisenburger. Monsanto seeks an order excluding the specific cause opinions of these three experts under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

DATED: January 3, 2019

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6	Respectfully submitted,	
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INTRODUCTION

Having barely cleared the general causation hurdle, Plaintiffs now face the "daunting challenge" of presenting reliable expert evidence that Roundup specifically caused each of their non-Hodgkin's lymphoma (NHL). *See In re Roundup Prods. Liab. Litig.*, 2018 WL 3368534, at *2 (N.D. Cal. July 10, 2018). Plaintiffs offer three experts to attempt to meet that challenge— Dr. Chadi Nabhan, Dr. Andrei Shustov, and Dr. Dennis Weisenburger. In nearly uniform fashion, each purports to employ the device of a "differential diagnosis"—a methodology whereby they purport to "rule in" all of the possible causes of the Plaintiffs' disease, including (they claim) Roundup, and then profess to "rule out" all of the causes except Roundup. But mere invocation of the phrase "differential diagnosis" does not sanitize what is otherwise an outcome-driven litigation conclusion. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010) ("[S]imply claiming that an expert used the 'differential diagnosis' method is not some incantation that opens the *Daubert* gate." (citation and quotations omitted)).

In this case, Plaintiffs' three experts fail to meet *Daubert*'s reliability requirements as to both steps of the differential diagnosis analysis.

First, in a largely identical manner, they all claim to "rule in" Roundup as a cause of each Plaintiffs' NHL, a common cancer that they agree has no known cause (is "idiopathic") in the vast majority of cases. They do so not through a detailed analysis (or any analysis at all) of each Plaintiff's individual characteristics or medical condition, but through a cherry-picked subset of primarily unadjusted epidemiological data about glyphosate exposure. The Court considered this data at the general causation phase, and stated both that reliance on only unadjusted data would be "disqualifying," and that the specific causation inquiry is even more demanding. *See In re Roundup*, 2018 WL 3368534, at *26. Plaintiffs' experts, however, add nothing more to this data, let alone offer any explanation for how Roundup operated to cause cancer in any particular Plaintiff, or in what dose. Indeed, even though the experts rely exclusively on epidemiological evidence to rule in Roundup, they can point to no peer-reviewed, published data that demonstrates an odds ratio, or relative risk, for Roundup of over 2.0. Under Ninth Circuit precedent, reliance upon epidemiological data with a relative risk of less than 2.0 is insufficient to establish specific

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causation as a matter of law. *See Daubert v. Merrell Dow Pharms. Inc.*, 43 F.3d 1311, 1321 (9th Cir. 1995) ("For an epidemiological study to show causation under a preponderance standard, the relative risk . . . will, at a minimum, have to exceed 2." (citation and quotations omitted)).

Second, in similar unison the experts purport to "rule out" all other potential causes including unknown causes—of each Plaintiff's NHL. But the record makes clear that the experts paid little if any attention to each Plaintiff's individual risk factors. The experts offer no explanation for ruling out some risk factors beyond their own say-so, and they admit that they cannot rule out other risk factors. What is even more damning under *Daubert* is that they rule out non-Roundup causes based on reasoning that, if applied faithfully and consistently, would require them to rule out Roundup as well.

The bottom line for these experts is that as long as a Plaintiff was exposed to Roundup for what they declare to be a "sufficient" amount of time according to a handful of cherry-picked epidemiological studies, then Roundup must be the cause of his or her NHL—regardless of when or how a Plaintiff used Roundup, regardless of when a Plaintiff contracted NHL, regardless of the Plaintiff's individual medical history and risk factors, and regardless of the fact that the causes of NHL are unknown in the vast majority of cases. These experts' "always Roundup" opinions are just the type courts have justifiably rejected as pure *ipse dixit* conclusions. *See, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prod. Liab. Litig.*, 892 F.3d at 644–45 (4th Cir. 2018) (affirming exclusion of specific causation expert who "appeared to simply conclude that 'so long as the patient took Lipitor and developed diabetes, then Lipitor was a substantial contributing factor" (citation omitted)).

Permitting Plaintiffs to go to a jury based on such conclusory analysis would also effectively nullify the Court's decision to bifurcate pretrial proceedings—and the issue of specific causation generally—by allowing Plaintiffs to argue that Roundup *did* cause a particular Plaintiffs' cancer simply because it *allegedly can* cause cancer at certain doses. Defendant respectfully submits that the cursory, outcome-driven analyses of these experts do not come close to satisfying the type of "daunting" specific causation inquiry that the Court's prior ruling envisioned, nor does it move past the general causation analysis in any meaningful way. As such, the Court should exclude Plaintiffs'

specific causation experts under Rule 702.

BACKGROUND

NHL Is a Common Cancer with No Known Cause in the Majority of Cases.

Non-Hodgkin's lymphoma is an umbrella term used to describe more than 60 different subtypes of cancer involving the lymphocytes, a type of white blood cell. *See* Ex. 10, Shustov *Hardeman* Dep. at 61:7–13; Ex. 11, Weisenburger *Stevick* Dep. at 32:20–22, 125:22–126:4, 130:22–131:10. NHL is a "heterogeneous disease," meaning the various sub-types have different clinical and prognostic characteristics. Ex. 10, Shustov *Hardeman* Dep. at 56:4–9. Different subtypes of NHL may also have different risk factors and different causes. *Id.* at 56:10–22; Ex. 11, Weisenburger *Stevick* Dep. at 32:20–33:4.

Notwithstanding the differences among the various types of NHL, there are some common features. NHL is frequent—it is one of the most common cancers in the United States, accounting for 4% of all cancers, and the average American's risk of developing NHL during his or her lifetime is about 1 in 47. Ex. 10, Shustov *Hardeman* Dep. at 265:5–12; *see also* Ex. 11, Weisenburger *Stevick* Dep. at 131:4–15. And as a general matter, its causes are unknown: In the "vast" majority of NHL cases, doctors do not know the cause of the patients' NHL. Ex. 12, Nabhan *Adams* Dep. at 68:22–69:2; Ex. 10, Shustov *Hardeman* Dep. at 58:10–11; Ex. 13, Weisenburger *Adams* Dep. at 56:18–24. Dr. Weisenburger estimates that the cause of NHL is unknown in 70 percent of cases. Ex. 13, Weisenburger *Adams* Dep. at 56:18–24, 212:7–14.

While the cause of NHL usually cannot be determined, doctors and scientists have identified certain risk factors for the disease. These risk factors may increase a person's chances of developing NHL, though they are not necessarily the cause. *See, e.g.*, Ex. 14, Nabhan *Hardeman* Dep. at 61:13–24. One well-known risk factor for NHL is age. Both NHL and DLBCL (diffuse large B-cell lymphoma—the subtype of NHL at issue in all three cases at issue here) "[are] more common in patients over the age of 60 years." *See* Ex. 5, Shustov *Hardeman* Rep. at 4; *see also* Ex. 15, Nabhan *Gebeyehou* Dep. at 19:25–20:23; Ex. 16, Weisenburger *Hardeman* Dep. at 90:7–22. Like many cancers, the risk of developing NHL increases throughout life, and more than half of NHL patients are 65 or older at the time of diagnosis. Ex. 10, Shustov *Hardeman* Dep. at 265:17–

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21; *see also* Ex. 11, Weisenburger *Stevick* Dep. at 100:2–24. Other risk factors include autoimmune disease, certain infections, and use of immunosuppressants. *See, e.g.*, Ex. 2, Nabhan *Hardeman* Rep. at 3. Viral hepatitis C and hepatitis B are also risk factors. *Id.* at 3–4. Indeed, both hepatitis C and hepatitis B are also risk factors. *Id.* at 3–4. Indeed, both hepatitis C and hepatitis B are well-established causes of cancer, and are classified by IARC as Group I carcinogens, *i.e.*, as "carcinogenic to humans." *See, e.g.*, Ex. 16, Weisenburger *Hardeman* Dep. at 54:2–55:13; Ex. 10, Shustov *Hardeman* Dep. at 100:13–101:12. Finally, and as relevant here, exposure to radiation and obesity are also risk factors. *See, e.g.*, Ex. 11, Weisenburger *Stevick* Dep. at 106:20–107:25 (conceding that radiation may be a risk factor in certain doses); Ex. 2, Nabhan *Hardeman* Rep. at 5.

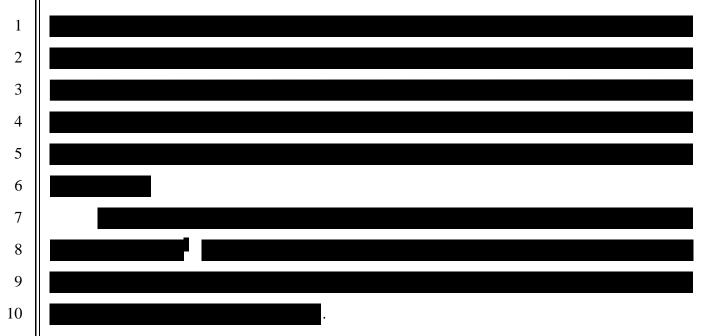
Relying on nothing more than the exact epidemiology and other studies they and other experts relied upon at the general causation stage, including IARC's classification of glyphosate as a Group 2A probable carcinogen to humans, the specific causation experts also identify pesticides as a risk factor, including specifically Roundup, even though no physician who ever treated any of these Plaintiffs has attributed their NHL to Roundup.

II. Plaintiffs All Had Several Risk Factors Associated with NHL.

which "represents the most common lymphoma in adults." Ex. 5, Shustov *Hardeman* Rep. at 4 ("annual incidence" of DLBCL is "approximately 5.5 new diagnoses per 100,000 men/women"); *see also* Ex. 15, Nabhan *Gebeyehou* Dep. at 18:23–19:9; Ex. 16, Weisenburger *Hardeman* Dep. at 33:16–34:2. As with NHL generally, for the "vast majority of DLBCL patients, the cause is unknown." Ex. 10, Shustov *Hardeman* Dep. at 58:10–11; *see also* Ex. 2, Nabhan *Hardeman* Rep. at 3.

DLBCL patients, the cause is unknown." Ex. 10, Shustov *Hardeman* Dep. at 58:10–11; *see also* Ex. 2, Nabhan *Hardeman* Rep. at 3. See, e.g., Ex. 6, Shustov Stevick Rep. at 2; Ex. 11, Weisenburger Stevick Dep. at 36:3–37:9.

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III. Plaintiffs' Experts' Exposure-Based Methodology.

Plaintiffs have retained three experts, each of whom provided a report regarding each Plaintiff. Each of those experts purports to reach his specific causation opinion through what he asserts to be a differential diagnosis. In medical practice, "[d]ifferential diagnosis is 'the determination of which of two or more *diseases* with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings." *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003) (quoting Stedman's Medical Dictionary 474 (26th ed. 1995)) (emphasis added). Courts, however, have often used the term to describe the "scientific technique of identifying the *cause* of a medical problem by eliminating the likely causes until the most probable one is isolated." *Id.* (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)) (emphasis added). This process requires an expert to first "rule in" potential causes—*i.e.*, "to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration." *Id.* The expert must then "rule out" the possible causes using a scientific method until only the most likely cause remains. *Id.*

Although these three experts have each filed separate case-specific reports for

¹ Ex. 17, Ye *Hardeman* Dep. at 122:13–22 (Mr. Hardeman's treating oncologist); Ex. 18, Pai *Gebeyehou* Dep. at 21:3–10 (Mr. Gebeyehou's treating oncologist); Ex. 19, Kim *Stevick* Dep. at 72:8–11 (Ms. Stevick's treating oncologist).

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Mr. Hardeman, Mr. Gebeyehou, and Ms. Stevick, all nine reports follow a strikingly similar (and cursory) format.

They then each

proceed in the same two-step process:

First, the reports all "rule in" Roundup as a possible cause of NHL in the same manner—by relying on a small subset of epidemiological studies that the Court previously considered at the general causation phase:

Dr. Nabhan relies primarily on two such studies: (1) McDuffie 2001, for the proposition that "[t]he risk of NHL was statistically significantly increased among glyphosate exposed individuals more than two days per year with an [odds ratio] of 2.12 (95% CI: 1.20–3.73)"; and (2) Eriksson 2008, which he asserts "showed an [odds ratio] of 2.36 (95% CI: 1.04–5.37) for developing NHL in individuals exposed to glyphosate more than 10 days in their lifetime." Ex. 2, Nabhan *Hardeman* Rep. at 6–7. Based on those two studies—which involve data that is not adjusted for other pesticides to which the participants were exposed—

In other words, Dr. Nabhan will always rule in Roundup for a Plaintiff that has exposure for more than 2 days per year or more than 10 days in their lifetime. *See* Ex. 14, Nabhan *Hardeman* Dep. at 93:5–94:2.

Dr. Shustov rules in Roundup for each Plaintiff using the exact same epidemiology studies (and often the exact same language) as Dr. Nabhan. This symmetry was not accidental, as it turns out Dr. Shustov simply copied his "lymphoma causation" section from a draft report from Dr. Nabhan that the Plaintiffs' lawyers gave him. Ex. 10, Shustov *Hardeman* Dep. at 143:5–146:25. Neither expert can explain why he chose those two epidemiology studies over the others, beyond the unstated reality that the vast majority of other epidemiological studies that use adjusted data (including NCI 2018) do not support the exposure thresholds the experts have set forth, let alone contain an odds ratio above 2.0 tying exposure to Roundup to NHL. To the extent Dr. Shustov's (and thus Dr. Nabhan's) "ruling in" discussion highlights anything else, it is IARC's

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classification of glyphosate, which, as this Court has already ruled, involves "a higher level of generality than what the Court must do" in assessing whether Roundup can even cause cancer generally, as opposed to in any particular plaintiff. See In re Roundup, 2018 WL 3368534, at *7. In the end, Dr. Shustov acknowledged (just like Dr. Hardeman) that he will always rule in Roundup for a plaintiff that has exposure for more than 2 days per year or more than 10 days in his or her lifetime. Ex. 10, Shustov Hardeman Dep. at 215:11-24, 217:8-218:23.

Dr. Weisenburger takes only three sentences to "rule in" Roundup. Relying on the same two epidemiology studies as Dr. Nabhan and Dr. Shustov,

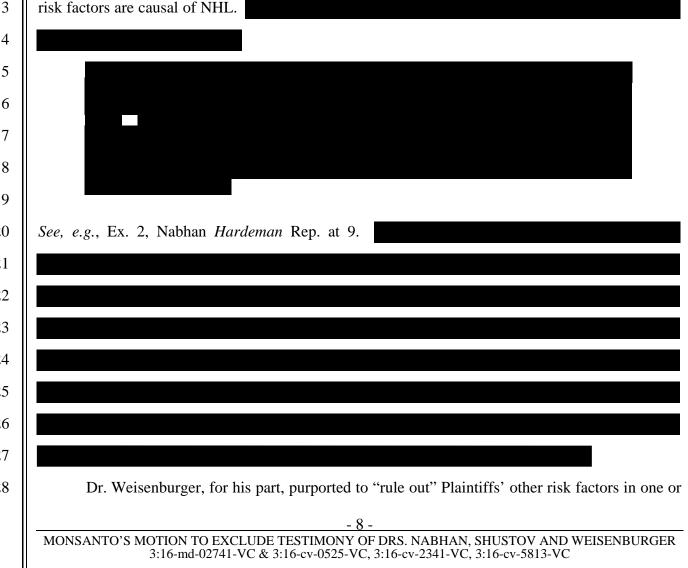
See Ex. 8, Weisenburger Hardeman Rep. at 4. He also cites to an isolated data point from still-unpublished (and apparently still shifting) data from the North American Pooled Project (NAPP), which he claims shows an increased risk for more than 2 days per year. Id. As with Dr. Nabhan and Dr. Shustov, Dr. Weisenburger will always rule in Roundup for any plaintiff who was exposed for more than 2 days per year or more than 10 days in their lifetime. Ex. 13, Weisenburger Adams Dep. at 112:16-25.

Collectively, none of the experts move past the general causation evidence in any material way. None offer an explanation for how Roundup would have caused any particular Plaintiff's NHL. Indeed, each admits that the mechanism of action for how Roundup causes NHL is still unknown and subject to hypotheses. In addition, none of the experts make any effort to take into account the type of exposures alleged by these plaintiffs—each of whom used glyphosate formulations for residential home and garden use—or explain how those residential exposures can be shoehorned to fit the experts' cherry-picked epidemiological studies that primarily evaluate farmers with more intense use of differently formulated agricultural glyphosate-based products. Indeed, even IARC conceded that its analysis of glyphosate did not suggest any increased risk of NHL for residential users of glyphosate like the plaintiffs here. See Ex. 20, Maria Cheng, "Roundup Weed Killer Has Probable Carcinogen, U.N. Says," U.S. News & World Report (Mar. 20, 2015, 2:25 PM), https://bit.ly/2F2Vo9c (quoting Kate Guyton of IARC as saying, "I don't think home use is the issue. It's agricultural use that will have the biggest impact."); Ex. 21, 3/5/18 Hr'g

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Tr. at 95:7–23 ("THE COURT: And your opinion that Roundup® causes NHL -- is it -- is it that Roundup® is currently causing NHL in the exposure levels that human beings are experiencing today, or is it that Roundup® is carcinogenic, and therefore it's capable of causing NHL in the abstract, or somewhere in between? [DR. RITZ]: It's probably the second, because I base my opinion on the farmer studies. And we know that farmers are really at the front line. Right? They're the ones who have the highest exposure. And that's what I'm basing my opinion on, because that's the studies we have at hand; the human studies that we have. THE COURT: Okay. So is that to say, then, that your opinion is not that it is currently causing NHL? It's that it's capable of causing NHL? [DR. RITZ]: Currently, it's -- yeah. It's capable of causing NHL.").

Second, the experts then purport to "rule out" the other risk factors for each plaintiff. But they offer no explanation of why any individual risk factor should be ruled out. Ultimately, the experts simply assert, without further explanation, that the literature does not establish that the other



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two sentences, only to later concede that he could not actually rule those factors out. Indeed,

Ex. 8, Weisenburger Hardeman Rep.; Ex.

7, Weisenburger *Gebeyehou* Rep.; Ex. 9, Weisenburger *Stevick* Rep. For the reasons explained below, all of these opinions should be excluded.

LEGAL STANDARD

Under *Daubert* and Federal Rule of Evidence 702, an expert may give opinion testimony only if (a) the expert's "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (b) "the testimony is based on sufficient facts or data"; (c) "the testimony is the product of reliable principles and methods"; and (d) the expert "has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. In other words, an expert must be qualified and must offer testimony that is both relevant and reliable. *Id.; see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Here, the experts' opinions should be excluded because they are not reliable.

Daubert created "exacting standards of reliability," *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000), which require far "more than subjective belief or unsupported speculation," *Daubert*, 509 U.S. at 590. *Daubert*'s objective "is to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Thus, "in determining whether proposed expert testimony amounts to good science, [the court] may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Daubert*, 43 F.3d at 1317.

In the specific causation context, *Daubert* requires experts purporting to use a differential diagnosis to carry out both aspects of that methodology—"ruling in" all possible causes and then "ruling out" all but the subject exposure—in a reliable fashion. To reach an admissible causation opinion through a reliable differential diagnosis, an expert must "accurately diagnose the nature of the disease, reliably rule in the possible causes of it, and reliably rule out the rejected causes." *In re*

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Aredia & Zometa Prod. Liab. Litig., 483 F. App'x 182, 188 (6th Cir. 2012); *see also Poust v. Huntleigh Healthcare*, 998 F. Supp. 478, 496 (D.N.J. 1998); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) ("[a]n expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient."); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 551 (W.D. Pa. 2003) ("the mere statement by an expert that he or she applied differential diagnosis in determining causation does not *ipso facto* make that application scientifically reliable or admissible."). Because the inherent malleability of this methodology can shroud what may be little more than subjective guesswork, the district court must "delve into the particular witness's method of performing a differential diagnosis to determine if his or her ultimate conclusions are reliable." *Poust*, 998 F. Supp. at 496. Courts have consistently held that expert opinions that pay lip service to this methodology but do not reliably apply it should be excluded. *See, e.g., Lipitor*, 892 F.3d at 642–45.²

ARGUMENT

All three experts purport to "rule in" Roundup as a cause of a particular Plaintiff's NHL based solely on a cherry-picked subset of epidemiological studies, and then "rule out" all other causes based purely on their say-so. The experts effectively concede that they will opine that *any plaintiff*'s NHL was caused by Roundup so long as the plaintiff was exposed to Roundup for more than 2 days per year or more than 10 days in his or her lifetime, regardless of what other risk factors the Plaintiff had and regardless of the fact that they make no attempt to rule out unknown causes. This type of jerry-rigged, results-driven approach does not satisfy the strictures of *Daubert*.

I. The Three Experts Fail to Reliably Rule in Roundup as a Cause of Each Plaintiff's NHL.

All three experts employ the virtually identical rationale for "ruling in" glyphosate as a cause for Plaintiffs' cancer: (1) they pluck out exposure data from a small subset of epidemiological

 ² See also, e.g., Sims v. Kia Motors of Am., Inc., 839 F.3d 393, 401–02 (5th Cir. 2016); Chapman v. Proctor & Gamble Distrib., LLC, 766 F.3d 1296, 1309 (11th Cir. 2014); Guinn, 602 F.3d at 1253; Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1342–43 (11th Cir. 2010); Cooper v. Smith & Nephew, 259 F.3d 194, 200 (4th Cir. 2001); Brown v. Burlington N. Santa Fe Ry. Co., 765 F.3d 765, 773–74 (7th Cir. 1996).

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studies primarily evaluating farmers' use of glyphosate, (2) they catalog the number of days they believe each Plaintiff used Roundup, and (3) they then deduce that each Plaintiff's residential use of Roundup was sufficient to fall within the agricultural exposure parameters set forth in their cherry-picked studies. On that basis alone, they conclude that Roundup caused each of the Plaintiffs' NHL. Under their approach, the only salient variable is a given Plaintiffs' purported exposure to Roundup—if a Plaintiff used Roundup for more days than set forth in the farmer studies, then Roundup will be ruled in as a cause of his or her NHL. This approach cannot satisfy *Daubert*, especially because none of the experts cite any peer-reviewed data establishing a relative risk greater than 2.0 based on data adjusted for other pesticides—evidence that is *required* by both California and Ninth Circuit precedent to rule in a potential cause at the specific causation stage.

A. The Subset of Cherry-Picked Epidemiological Studies Provides an Insufficient Basis to Rule in Glyphosate as a Cause of Each Plaintiff's NHL.

Simply relying on a subset of previously-considered studies misses the critical distinction between general and specific causation. In the first phase of the litigation, the Court assessed whether Roundup "can cause [NHL] at exposure levels people realistically may have experienced." *In re Roundup*, 2018 WL 3368534, at *1. The Court concluded that the Plaintiffs' proffered studies provided a (barely) sufficient basis to create a jury question on that issue of general causation. But the inquiry at this second stage is fundamentally different: Plaintiffs must adduce sufficient additional evidence to meet the "daunting challenge" of showing that "glyphosate caused the NHL *they developed*." *Id.* at *2 (emphasis added). Evidence that supported general causation cannot alone establish specific causation—were it otherwise, there would be little need for a second phase of the litigation. But that is in fact all the evidence Plaintiffs have. Making matters worse, Plaintiffs' experts have chosen an inapplicable subset of those studies for no apparent reason other than to engineer a conclusion they would like to reach in the broadest possible set of cases.

In strikingly similar fashion, both Dr. Nabhan and Dr. Weisenburger highlight the same basic evidence to rule in Roundup. Each devote considerable space to the IARC monograph, notwithstanding this Court's previous pronouncements that the IARC monograph is insufficient to establish either specific or general causation. Both experts then discuss two studies primarily

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evaluating the agricultural use of glyphosate by farmers: McDuffie 2001, which they assert showed an increased risk of NHL among individuals exposed "more than two days a year," and Eriksson 2009, which allegedly showed the same for individuals exposed "more than 10 days in their lifetime." Ex. 2, Nabhan *Hardeman* Rep. at 6–7; *see also* Ex. 8, Weisenburger *Hardeman* Rep. at 4. They claim that the exposure information gleaned from those studies provides a sufficient basis to rule in Roundup as a potential cause for each of the residential-use Plaintiffs here because they were "exposed to glyphosate in a manner that fits within the published epidemiologic literature and the studies where causation and an association between NHL and glyphosate have been demonstrated." Ex. 2, Nabhan *Hardeman* Rep. at 8; *see also* Ex. 8, Weisenburger *Hardeman* Rep. at 4 (claiming that each Plaintiff had "extensive and significant exposure to Roundup"). Dr. Weisenburger goes a little further, citing unadjusted data from an unpublished presentation of data from the North American Pooled Project (NAPP), which reported a "risk estimate for diffuse large B-cell NHL [of] 2.49 (95% CI 1.23-5.04) for > 2 days per year." Ex. 8, Weisenburger *Hardeman* Rep. at 4.³ The Court considered all of these studies at the general causation phase. *See In re Roundup*, 2018 WL 3368534, at *9–13.

Dr. Shustov's approach is particularly unsound. As noted above, his report for all three Plaintiffs contains a two-page section purporting to discuss "causation" for each Plaintiff, which consists of thirteen bullet points on IARC and other epidemiology studies. *See, e.g.*, Ex. 5, Shustov *Hardeman* Rep. at 7–8. Although he initially testified that he authored this central part of his report, *see* Ex. 10, Shustov *Hardeman* Dep. at 107:7–10 ("Q. And did you write this section of your report? A. Of course I did. Q. You didn't copy it? A. I typed the section of my report."), Dr. Shustov eventually had to acknowledge that he simply copied this section largely verbatim from an earlier draft report of Dr. Nabhan that the lawyers had given him. *Id.* at 143:5–9 (finally admitting, after discussion with his counsel, that it "just occurred" to him that one of the Plaintiffs'

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³ The NAPP data has yet to be published, and Dr. Weisenburger has since admitted that results remain in flux, with the odds ratio reported in that presentation apparently continuing to move toward the null as the authors adjust for other pesticides in response to peer-review comments from an unidentified medical journal. *See* Ex. 14, Weisenburger *Adams* Dep. at 44:15-25.

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lawyers "provided me with Dr. Nabhan's report from another case"). Dr. Shustov ultimately sought to rationalize his use of Dr. Nabhan's report as a template because "I don't know how to speak in the proper legal terms." *Id.* at 139:21–24.

Aside from the facial impropriety of plagiarizing another expert's report, Dr. Shustov made no apparent effort to independently verify any of Dr. Nabhan's conclusions. For example, both Dr. Nabhan's report and Dr. Shustov's report erroneously state that the Schinasi and Leon Meta-Analysis "found an association between glyphosate and development of B-cell lymphoma with an [odds ratio of] 2.0 (95% CI: 1.1-3.6) and there was the same OR for DLBCL subtype." Ex. 5, Shustov *Hardeman* Rep. at 7; *see also* Ex. 2, Nabhan *Hardeman* Rep. at 5. When asked to identify where in the Schinasi and Leon study he found an odds ratio for DLBCL, Dr. Shustov eventually admitted that he had made a "mistake" because there was no such odds ratio in the analysis. Ex. 10, Shustov *Hardeman* Dep. at 133:11–134:7. "[E]xpert testimony based solely or primarily on the opinions of other experts is inherently unreliable." *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014) (excluding testimony where expert "copied verbatim from the reports of other experts [which he] did not independently verify"). That maxim especially holds here, where the pinched report from the "other expert]" got the basic facts wrong. *Id*.

More fundamentally, Dr. Shustov's cut-and-paste starkly illustrates the central flaw infecting the opinions of all three experts: Even assuming general causation studies could be sufficient to rule in glyphosate, the experts have no valid methodological basis for relying on these limited studies while ignoring the much broader scientific landscape. *See Lust v. Merrell Dow Pharm., Inc.,* 89 F.3d 594, 598 (9th Cir. 1996) (affirming district court's exclusion of expert testimony, explaining that experts cannot "pick and choose" from the scientific landscape). For instance, they cannot explain why they chose to rely on the results of the studies that were confounded by the use of other pesticides—a flaw the Court has described as "disqualifying." *See In re Roundup,* 2018 WL 3368534, at *26. As Dr. Shustov ultimately conceded in deposition, the data points that he, Dr. Nabhan, and Dr. Weisenburger rely on from McDuffie 2001 and Eriksson 2009 are both confounded because they do not control for the use of other pesticides. *See* Ex. 10, Shustov *Hardeman* Dep. at 226:24–232:24, 241:20–248:3 (admitting that he chose to cite the

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finding that was not adjusted for other pesticides, rather than the finding that was); see also Ex. 11, Weisenburger Stevick Dep. at 47:15–51:1, 54:4–55:14 (admitting that the data he cited from McDuffie 2001 and Eriksson 2009 is not adjusted for other pesticides).⁴ If this confounded data was too flawed to establish general causation, the same data surely cannot meet the still more demanding requirement of showing that a particular Plaintiff's cancer was caused by Roundup.

Nor can these experts explain why they ignored the broader array of studies that describe non-confounded data—apart from the naked fact that they did not like the conclusions. As Dr. Shustov remarkably admitted, he chose to disregard the data from the Agricultural Health Study (which evaluated glyphosate-based herbicides and NHL based on days of exposure, including a wider range of subjects with different levels of exposure, and found no association) because that study did not support his pre-determined assumption that Roundup causes NHL. Ex. 10, Shustov Hardeman Dep. at 279:22-280:8 ("Mr. Hardeman was exposed to glyphosate, and I already assumed from epidemiologic studies that it is a causative factor in non-Hodgkin lymphoma. So the [AHS] study shows that it's not a factor. It—it doesn't help me."); see also Ex. 11, Weisenburger Stevick Dep. at 61:5–69:23 (conceding that the AHS did control for other pesticides, considered cumulative lifetime days of use, and found no exposure-response relationship).

Plaintiffs' experts further cannot explain their failure to consider studies that looked specifically at the subtype of NHL that each Plaintiff developed. The experts agree that NHL is a "heterogeneous disease," and that the different sub-types can have different risk factors and different causes. Ex. 10, Shustov Hardeman Dep. at 56:4-19; id. at 61:11-17; see also Ex. 11, Weisenburger Stevick Dep. at 32:20–33:4. But neither of the data points cited from McDuffie 2001 nor Eriksson 2009 apply to DLBCL specifically. See Ex. 10, Shustov Hardeman Dep. at 243:23-244:4. And although Dr. Weisenburger cites a data point about DLBCL from the unpublished

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Although Dr. Weisenburger also cites an odds ratio from the unpublished NAPP data, even that citation suffers from the same measure of cherry-picking. The NAPP authors evaluated exposure response in three ways: two showed no exposure response, and one did. Dr. Weisenburger has relied only on the data point that supports his opinion, while ignoring others. He also conceded that another presentation of the NAPP data on cumulative exposure did *not* show any exposure-response relationship. See Ex. 11, Weisenburger Stevick Dep. at 146:5-150:8.

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NAPP presentation, he also agreed that other published studies do not find a statistically significant association between glyphosate-based herbicides and DLBCL. For example, he conceded that Eriksson 2009 evaluated sub-types but found no statistically significant associations, as did the Agricultural Health Study. Ex. 11, Weisenburger *Stevick* Dep. at 54:4–56:8, 61:5–66:3. Moreover, he conceded that there is *no literature* (published or otherwise) on PCNSL

Id. at 46:4–10. In the end, these experts do not (and cannot) offer any scientific rationale for why they limit their review to such a results-driven slice of the general causation evidence.

The experts' slipshod assessment of the epidemiological evidence not only confirms that their methods should be excluded under *Daubert*, but it also provides an independent basis for granting summary judgment to defendants. The experts in this case all purport to rule in Roundup based solely on epidemiological evidence. But both the California state courts and the Ninth Circuit have made clear that at the specific causation phase, experts relying on epidemiological evidence can rule in a potential cause only if it has a relative risk, or risk ratio, above 2.0. See Cooper v. Takeda Pharms. Am., Inc., 239 Cal. App. 4th 555, 593-594 (2015) ("When statistical analyses or probabilistic results of epidemiological studies are offered to prove specific causation ... under California law those analyses must show a relative risk greater than 2.0 to be 'useful' to the jury."); Daubert, 43 F.3d at 1321 ("For an epidemiological study to show causation under a preponderance standard, 'the relative risk . . . will, at a minimum, have to exceed '2'") (quoting DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 958 (3d Cir. 1990)); id. ("A relative risk of less than two may suggest teratogenicity, but it actually tends to *dis*prove legal causation); In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 524 F. Supp. 2d 1166, 1172 (N.D. Cal. 2007) (epidemiological studies are probative of specific causation "only if the relative risk is greater than 2.0"). Plaintiffs' experts implicitly acknowledge this standard in citing only studies with a risk ratio above 2.0. But none of the peer-reviewed and published studies involve data adjusted for other pesticides, which is what would be necessary to make the risk ratios relevant. See In re Roundup, 2018 WL 3368534, at *26 (calling use of unadjusted data "disqualifying"); In re Lockheed Litig. Cases, 23 Cal. Rptr. 3d 762, 774 (2005) ("We conclude that the multiple-solvent studies provide no reasonable basis for an opinion that any of the solvents here at issue can cause disease."). Plaintiffs'

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experts cite no other peer-reviewed study that uses adjusted data and finds a risk ratio above 2.0. That flaw might not be disqualifying if the experts moved past the epidemiological evidence in some way, but as described in the next section, they do not do so.

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

The hand-picked epidemiological studies Plaintiffs' experts cite are not just the starting point for their analysis—they are also the end point. Plaintiffs' experts do not offer *anything more* as justification for ruling in glyphosate. They make no effort to explain how Roundup operates to cause any particular Plaintiff's cancer—they cannot point to any marker or test that would identify Roundup as the cause of any Plaintiff's NHL, as opposed to the myriad of other potential known or unknown causes. *See, e.g.*, Ex. 22, Shustov *Stevick* Dep. at 32:20–22 ("Q: So, for example, you can't test a tumor and see if it was caused by a pesticide or a particular herbicide? A: That is

correct."); *id.* at 33:2–6

Ex. 13, Weisenburger Adams Dep.

at 55:8–18 ("Q. And when you look at their tumors, you can't tell whether they ever used glyphosate or Roundup; is that right? A. Yes. Q. There is no biomarker for glyphosate or Roundup; correct? A. Correct. Q. There is nothing you can see as a pathologist on a slide that tells you whether that NHL was a glyphosate NHL or a nonglyphosate NHL? A. That's correct."); Ex. 12, Nabhan *Adams* Dep. at 192:9–17 ("Q. There is no pathology test, examination, or other medical test that can be done on a lymphoma to determine whether Roundup caused a patient's cancer, correct? A. Correct, there is no phenotype.").

To these experts, the specific facts and medical history of the individual plaintiff bear no particular relevance; they make no effort even to analyze them. Take their approach to exposure. While the experts all note that the Plaintiffs used Roundup, they offer no analysis as to the type used or the nature and quantity of exposure. In fact, each of the Plaintiffs used glyphosate formulations for residential home and garden use, while the epidemiological studies on which the experts base their conclusions primarily involved farmers with more intense use of differently formulated agricultural glyphosate-based products. The experts do not account for this distinction in any way,

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even though Plaintiffs' other evidence, as well as case law and common sense, suggest they should. See Ex. 20, Maria Cheng, "Roundup Weed Killer Has Probable Carcinogen, U.N. Says," U.S. News & World Report (Mar. 20, 2015, 2:25 PM), https://bit.ly/2F2Vo9c (quoting Kate Guyton of IARC as saying, "I don't think home use is the issue. It's agricultural use that will have the biggest impact."); Ex. 21, 3/5/18 Hr'g Tr. at 95:7–23 (testimony of plaintiffs' expert Dr. Ritz that her opinion that Roundup is "capable" of causing NHL is based on the exposure data in the "farmers studies"); Bextra, 524 F. Supp. 2d at 1174 ("The Court finds that dose matters"; declining to find general causation where dose was insufficient); In re Accutane Prods. Liab., 511 F. Supp. 2d 1288, 1293 (M.D. Fla. 2005) ("An expert who ignores the dose-response relationship casts suspicion on the reliability of his methodology."), aff'd sub nom. Rand v. Hoffman-LaRoche Inc., 291 Fed. Appx. 249 (11th Cir. 2008). For these experts, as long as a Plaintiff used Roundup for more than 2 days per year or more than 10 lifetime days, that ends their inquiry. The occasional spring gardener gets lumped in with professional farmer; the spray-bottle user is the same as the agricultural worker hand-mixing industrial batches of glyphosate.

This reality was laid bare in another case pending in Missouri, where Dr. Nabhan reached his same "always Roundup" conclusion for a different Plaintiff before ever reviewing that Plaintiff's medical records or even learning the facts of his case. See Ex. 23, Nabhan Hall Dep. at 28:7–29:7, 22:1–3. When asked to explain how he could have formed an opinion about causation before looking at even a single medical record, Dr. Nabhan stated that his initial opinion was "really based on the communication that I've had with the counsel and the firms," who told him that the plaintiff had "significant exposure" to Roundup. Id. at 28:12–29:7.

Dr. Nabhan's testimony in the Hall case confirms that he would rule in Roundup as a cause-and rule out every other cause-whenever a Plaintiff reaches his self-identified exposure threshold. Dr. Shustov and Dr. Weisenburger follow a virtually identical process and reach the same conclusion: "sufficient" exposure means that Roundup caused an individual Plaintiff's NHL. See, e.g., Ex. 10, Shustov Hardeman Dep. at 66:15–67:17; Ex. 13, Weisenburger Adams Dep. at 69:6–20. But exposure to a dose of an allegedly toxic substance is just the beginning of the causation inquiry, not the end of it. "The fact that exposure to a substance may be a risk factor for a

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disease does not make it an actual cause simply because the disease developed." *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1255 (11th Cir. 2010) (quotation marks and alterations omitted) (citing *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 846 (W.D. Tex. 2005)); *see also Lipitor*, 892 F.3d at 644–45 (affirming exclusion of specific causation testimony of expert who "appeared to simply conclude that 'so long as the patient took Lipitor and developed diabetes, then Lipitor was a substantial contributing factor").

Further, and unlike in prior cases approving use of a differential diagnosis methodology, the experts cannot buttress their decision to rule in Roundup by relying on their clinical practice. *Compare Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017). On the contrary, each expert has made clear that he does not apply this methodology in his clinical practice, or even mention Roundup to his Lymphoma patients. *See* Ex. 14, Nabhan *Hardeman* Dep. at 21:17–20 ("Q. But to answer my question, you've never told a patient that his or her non-Hodgkin lymphoma was caused by Roundup or glyphosate; correct? A. I did not."); *id.* at 25:2–7 ("Q. And when you say 'pesticides in general,' you never spoke even to any of your farming patients, agriculture patients— patients that were involved in agriculture specifically about Roundup or glyphosate; correct? A. Not specifically, no."); Ex. 10, Shustov *Hardeman* Dep. at 85:21–22 ("I would not ask specifically every patient were [you] exposed to Roundup. . . . I would ask them in general were they exposed to agricultural chemicals or radiation or military carcinogens, et cetera."); Ex. 13, Weisenburger *Adams* Dep. at 54:3–15 ("Q. Did you ever tell a patient at University of Nebraska that his or her NHL was caused by glyphosate or Roundup? A. No."); *id.* at 76:19–22 ("Q. Now to be clear, you, in your clinical practice, you've never used this methodology." A. No ...").

Drs. Nabhan and Weisenburger further admitted that they have never asked a patient about his or her Roundup exposure, have never determined that Roundup caused a patient's NHL, and have never even used a differential diagnosis to assess the cause of a patient's NHL. *See, e.g.*, Ex. 14, Nabhan *Hardeman* Dep. at 21:17–20 (when asked whether he ever "told a patient that his or her non-Hodgkin's lymphoma was caused by Roundup or glyphosate": "I did not."); Ex. 10, Shustov *Hardeman* Dep. at 85:21–22 (does not ask patients about Roundup exposure specifically); *id.* at 85:7–9 (never told any patient that Roundup caused his or her NHL); Ex. 13, Weisenburger *Adams*

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Dep. at 54:3–15 (has never told any patient that Roundup or glyphosate caused his or her NHL); Ex. 16, Weisenburger Hardeman Dep. at 103:17–21 (has never written in a pathology report that a patient's NHL was caused by Roundup).

The Wendell case, which affirmed the use of a differential diagnosis by Dr. Shustov and Dr. Weisenburger, stands in stark contrast as a result of these facts. There, Dr. Shustov stated that of the 7 patients he had treated for the type of lymphoma at issue in that case, 2 had taken the medication that the plaintiff claimed had caused his cancer. 858 F.3d at 1233. Here, by contrast, none of the experts have any idea how many of their patients have ever used Roundup, because they never ask. In fact, Dr. Shustov conceded that any knowledge he has about any alleged association between Roundup (as opposed to pesticides generally) and NHL came from research he did exclusively for this litigation. Ex. 10, Shustov Hardeman Dep. at 34:12-37:11.⁵ These experts should not be allowed to invoke their "clinical experience" as a license to engage in a causation analysis that they admit they have never done in practice for a product about which they have never asked a patient. Braun v. Lorillard Inc., 84 F.3d 230, 235 (7th Cir. 1996) ("[O]ne of the abuses at which *Daubert* and its sequelae are aimed... is the hiring of reputable scientists, impressively credentialed to testify for a fee to propositions that they have not arrived at through the methods that they use when they are doing their regular professional work rather than being paid to give an opinion helpful to one side in a lawsuit.").

Nor have Plaintiffs' experts shared their litigation-driven conclusions in any capacity outside of the courtroom, whether through submitting their opinions for formal peer review or even by

⁵ Nor have any of these experts engaged in the sort of detailed analysis that supported the specific cause opinions allowed in Wendell. For example, in Wendell, Dr. Shustov conducted a literature review, and concluded that there was an "increased risk of [Hepatosplenic T-cell lymphoma] in patients taking [the medication at issue] over the general population. 858 F.3d at 1234. After conducting that literature review, he "compiled the numbers about frequency of diseases . . . and looked at the biological causation of lymphoma pertaining to this case." Id. Specifically, he calculated that there was a one in six million chance that the plaintiff there would have developed Hepatosplenic T-cell lymphoma without being exposed to the medication at issue. Id. Moreover, in that case, Dr. Weisenburger at least relied on published literature addressing the specific type of lymphoma at issue in that case. Id. at 1235. Here, all of the Plaintiffs' experts have failed to put forward the same sort of detailed analysis. Instead, they all summarily rule in Roundup for any Plaintiff that exceeds an exposure threshold that they've plucked out of cherry-picked epidemiology data.

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sharing them with their colleagues. *See, e.g.*, Ex. 14, Nabhan *Hardeman* Dep. at 21:22–22:18 (has never told anyone—neither his colleagues nor any medical students, residents, or fellows—that he believes Roundup or glyphosate can cause any person's NHL, even though some of those colleagues are actively treating patients with NHL); *id.* at 24:1–17 (admitting that he has not published or otherwise presented his opinion that there is an association between glyphosate and NHL); Ex. 10, Shustov *Hardeman* Dep. at 23:16–25:10 (has never done any research, presented any publications, or authored any articles about Roundup, glyphosate, or pesticides); *id.* at 273:16–20. (when asked whether he has ever told any other clinicians that they should assess their patients for Roundup use, he responded, "[t]hat would be ... nonsensical."). Indeed, the first and only time Dr. Shustov *ever* opined that glyphosate was a possible carcinogen was in this litigation. Ex. 24, Shustov *Gebeyehou* Dep. at 15:25–16:5.

It is thus no surprise that these experts have conceded that their specific causation methodologies fail each of the *Daubert* factors: (1) they were created entirely for litigation, *see e.g.*, Ex. 24, Shustov *Gebeyehou* Dep. at 15:25–16:5; (2) they have not been validated, *see, e.g.*, Ex. 12, Nabhan *Adams* Dep. at 67:7–68:20; Ex. 10, Shustov *Hardeman* Dep. at 69:6–10; (3) they have no known error rate, Ex. 12, Nabhan *Adams* Dep. at 74:4–12; Ex. 24, Shustov *Gebeyehou* Dep. at 91:23–92:4; Ex. 13, Weisenburger *Adams* Dep. at 93:17–94:4; and (4) they have not been peerreviewed or published in medical literature as a method for assessing causes of disease, Ex. 12, Nabhan *Adams* Dep. at 64:9–65:4; Ex. 10, Shustov *Hardeman* Dep. at 69:1–5; Ex. 13, Weisenburger *Adams* Dep. at 64:9–65:4; Ex. 10, Shustov *Hardeman* Dep. at 69:1–5; Ex. 13, Weisenburger *Adams* Dep. at 64:9–65:4; Ex. 10, Shustov *Hardeman* Dep. at 69:1–5; Ex. 13, Weisenburger *Adams* Dep. at 64:9–65:4; Ex. 10, Shustov *Hardeman* Dep. at 69:1–5; Ex. 13, Weisenburger *Adams* Dep. at 64:9–65:4; Ex. 10, Shustov *Hardeman* Dep. at 69:1–5; Ex. 13, Weisenburger *Adams* Dep. at 64:9–65:4; Ex. 10, Shustov *Hardeman* Dep. at 69:1–5; Ex. 13, Weisenburger *Adams* Dep. at 63:11–64:5.

In sum, none of these experts have provided a reliable methodology to rule in Roundup as a cause of these three Plaintiffs' NHL. Their "always Roundup" approach cannot survive *Daubert* scrutiny and should not be presented to a jury.

II. The Experts Provide No Reliable Basis for Ruling Out Other Potential Causes of Plaintiffs' NHL.

The experts' methodology also fails at the second differential diagnosis step because they offer no principled basis for ruling out alternative potential causes of each Plaintiff's NHL. An expert conducting a differential diagnosis "must provide reasons for rejecting alternative hypotheses

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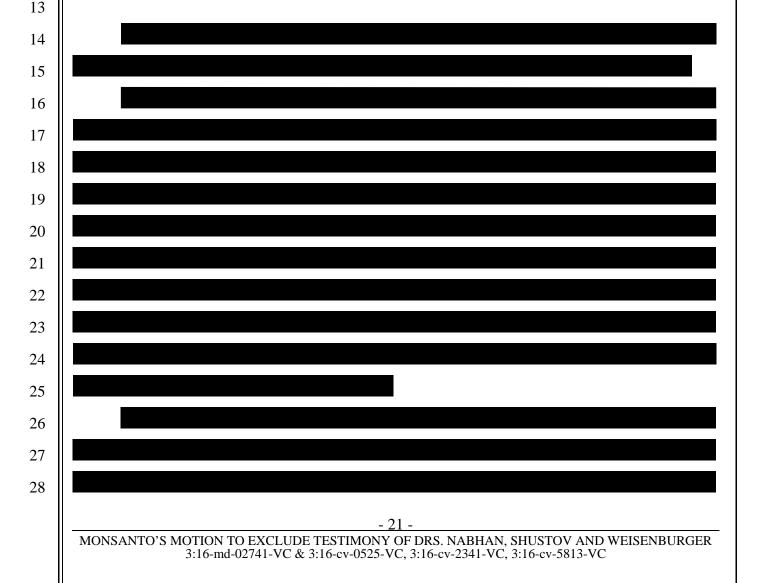
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A.

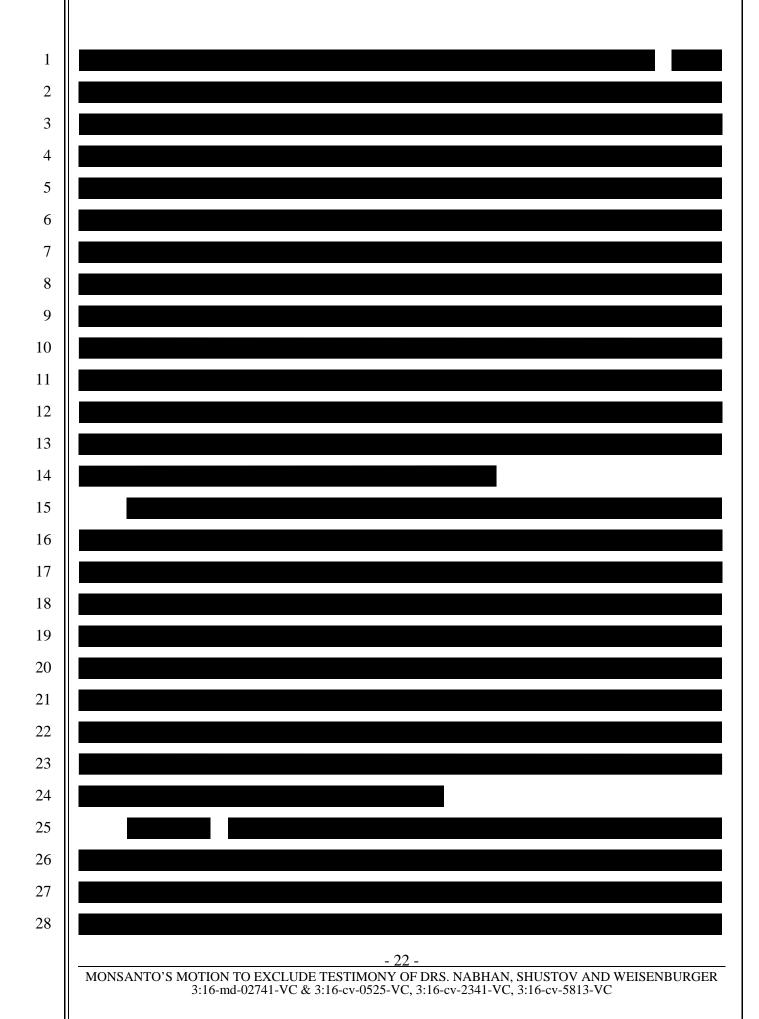
'using scientific methods and procedures' and the elimination of those hypotheses must be founded on more than 'subjective beliefs or unsupported speculation.'" *Clausen*, 339 F.3d at 1058 (quoting *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994)). Here, each of the Plaintiffs has a unique medical history and range of different recognized risk factors. Yet Plaintiffs' experts paint all of the Plaintiffs with the same brush, cursorily dismissing their individual risk factors based on pure say-so. The experts ultimately admitted that they cannot rule out some of the risk factors, and for others, they can offer no logical explanation for why their same reasoning for ruling out a non-Roundup factor would not equally apply to Roundup. Here too, this results-driven, "always Roundup" methodology is precisely the type of unreliable approach that *Daubert* prohibits.

Plaintiffs' Experts Do Not Meaningfully Address the Plaintiffs' Individual Risk Factors.

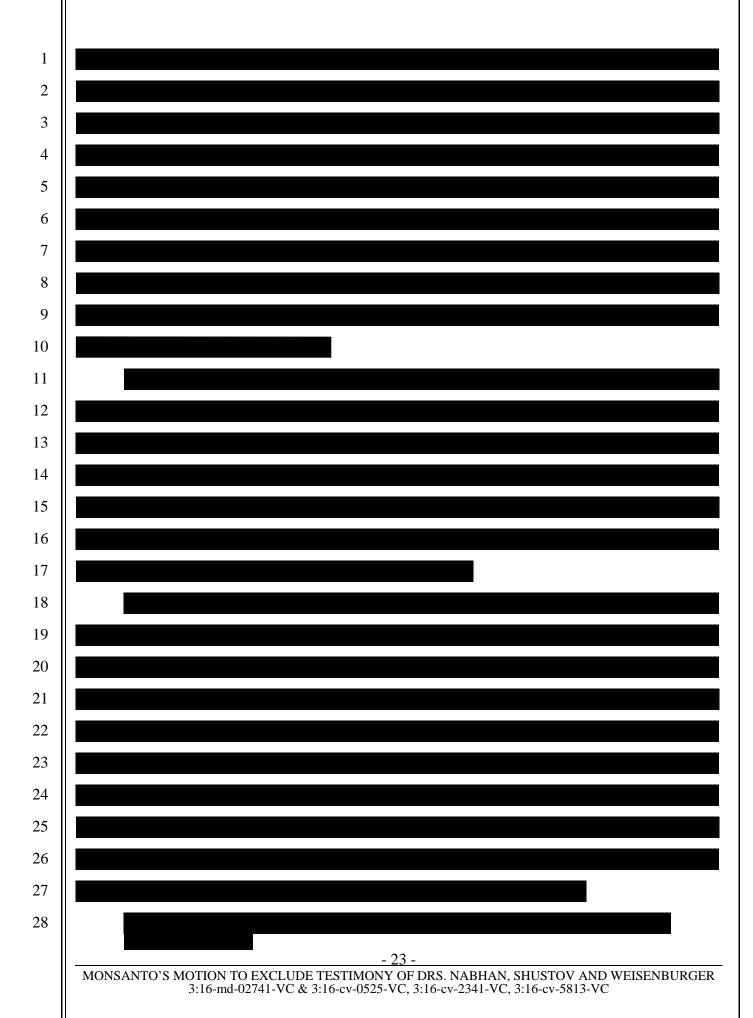
1. Plaintiffs' experts do not have a reliable basis for ruling out Mr. Hardeman's various risk factors.

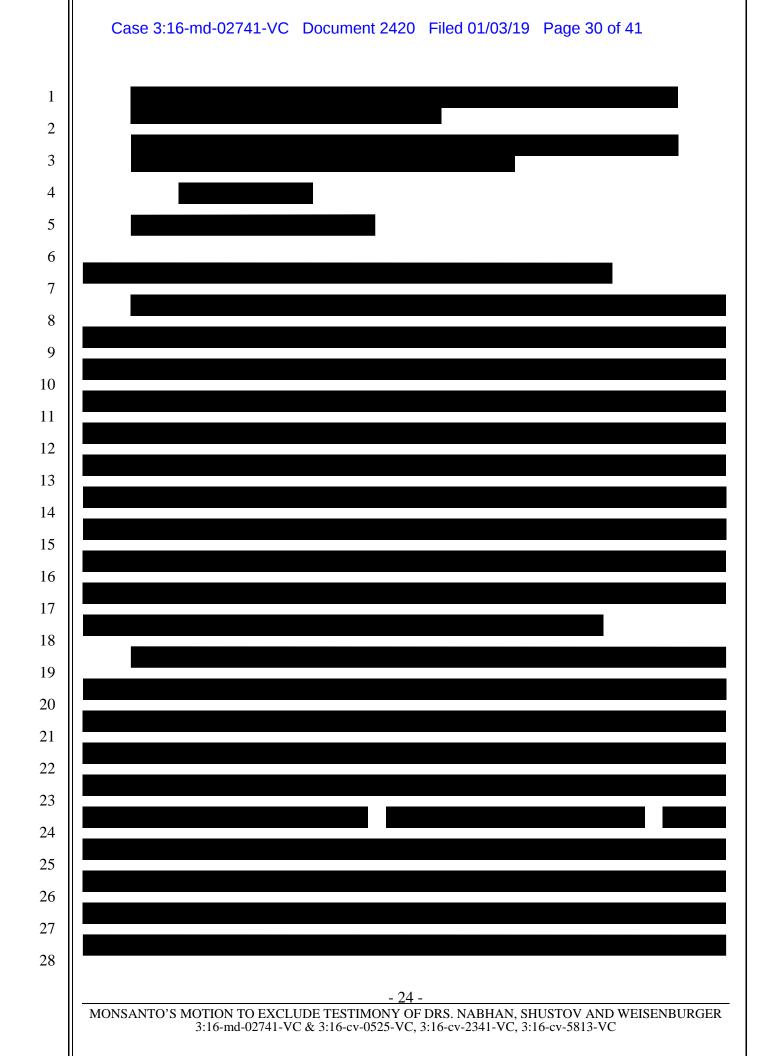


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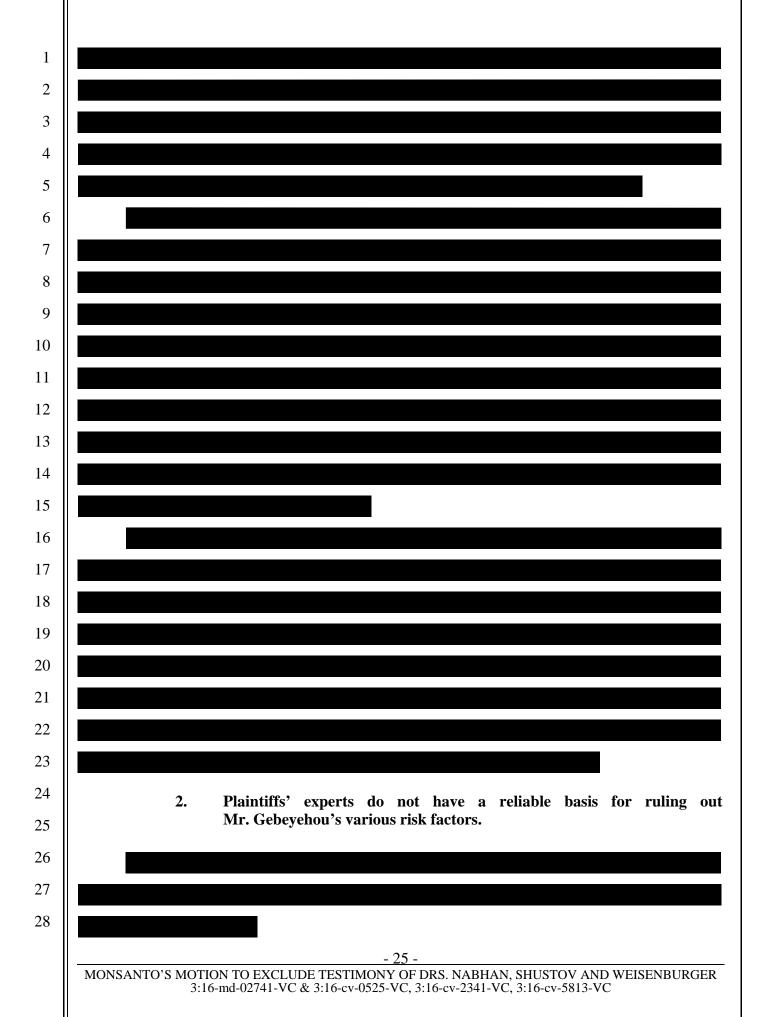




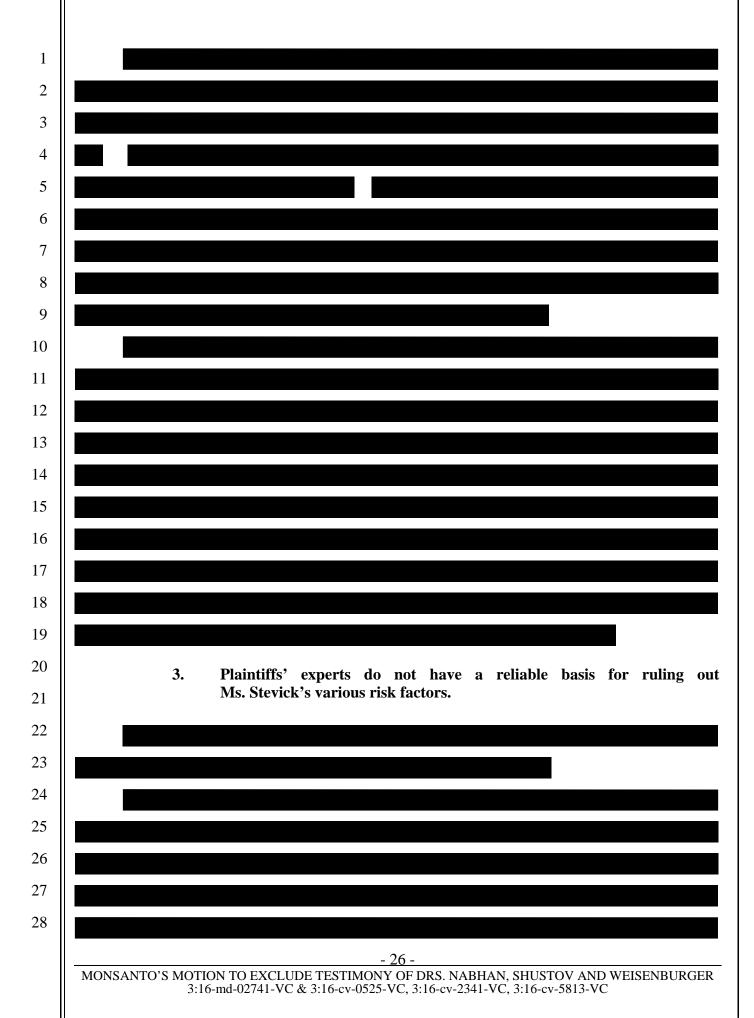




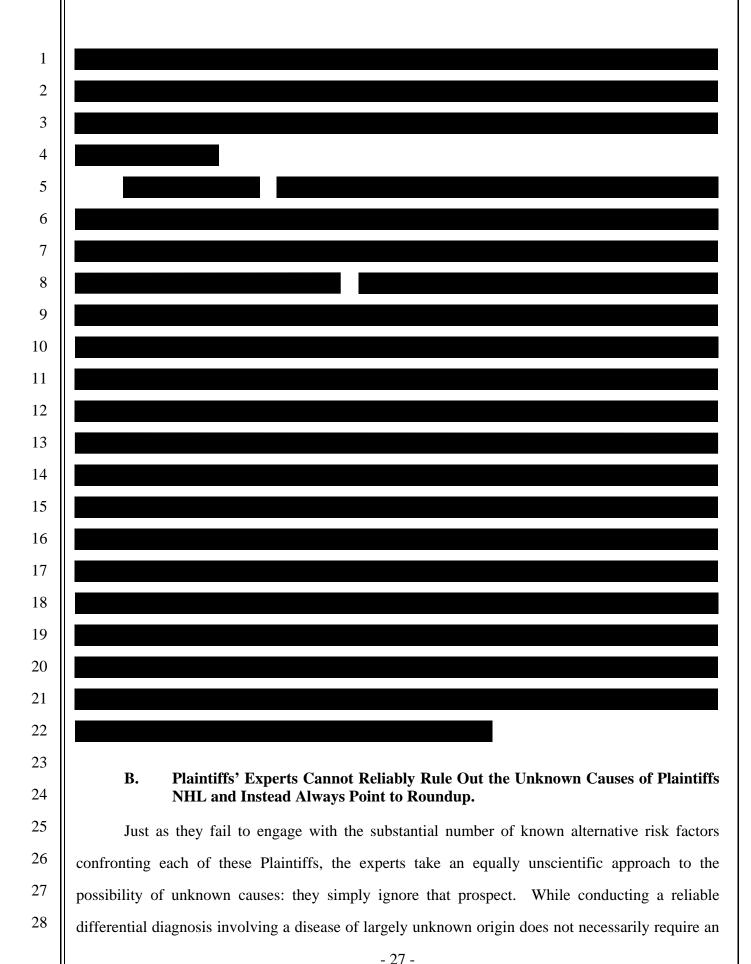












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expert "to eliminate all other possible causes of a condition," Wendell, 858 F.3d at 1237, the leeway the law provides does not give license to summarily dismiss potential unknown causes without any measure of scientific rigor and coherence. Id. at 1232 (confirming that "principles and methodology used by an expert [must be] grounded in the methods of science") (citing *Clausen*, 339 F.3d at 1056). In a case such at this, where Plaintiffs have experienced an unfortunately fairly common disease and for which some 70% of cases have no identifiable cause, these experts' summary disregard of such unknown causes deserves special scrutiny. See, e.g., Perry v. Novartis Pharm. Corp., 564 F. Supp. 2d 452, 470 (E.D. Pa. 2008) (where a condition has mostly unknown causes, an "analysis beyond a differential diagnosis will likely be required" to render a reliable specific causation opinion); Tamraz, 620 F.3d at 675 ("Not every opinion that is reached via a differential-diagnosis method will meet the standard of reliability required by Daubert") (internal quotation marks omitted) (quoting Best v. Lowe's Home Centers, Inc., 536 F.3d 171, 179 (6th Cir. 2009); Doe v. Ortho-Clinical Diagnostics, Inc., 440 F. Supp. 2d 465, 478 (M.D.N.C. 2006) ("[The expert] did not properly perform the differential diagnosis given his failure to consider within his analysis the high probability that an unknown genetic cause cannot be ruled out as the specific cause of Minor Child Doe's autism"); Carlson v. Okerstrom, 675 N.W.2d 397, 267 Neb. 397, 399 (Neb. 2004) ("If the expert completely fails to consider a cause that could explain the patient's symptoms, the differential diagnosis is not reliable.").

These experts cannot survive that scrutiny. They concede that in cases where the cause of a patient's NHL is idiopathic, genetic mutations occur without explanation. *See, e.g.*, Ex. 13, Weisenburger *Adams* Dep. at 164:3–16. And they further concede that those same genetic mutations can occur in people exposed to Roundup, independent of their Roundup exposure. *See id.* at 20–25. As such, Roundup cannot automatically be deemed the cause of an individual Plaintiff's NHL. Rather, in light of the largely idiopathic nature of NHL, Plaintiffs' experts must provide some basis for saying that Plaintiffs' cancer would not have occurred absent exposure to Roundup. And yet they cannot do so, admitting that Plaintiffs could just as possibly have gotten NHL even if they had not been exposed to Roundup. *See* Ex. 16, Weisenburger *Hardeman* Dep. at 93:1–96:25; Ex. 26, Weisenburger *Gebeyehou* Dep. at 86:2–5; Ex. 11, Weisenburger *Stevick* Dep. at

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102:14–18; Ex. 10, Shustov *Hardeman* Dep. at 209:6–11; *id.* at 212:11–15; Ex. 14, Nabhan *Hardeman* Dep. at 67:14–18; Ex. 15, Nabhan *Gebeyehou* Dep. at 25:23–26:5. Pretending unknown causes do not exist is hardly the equivalent of reliably ruling them out.

For instance, Dr. Weisenburger-who estimates that the cause of NHL is unknown in approximately 70% of cases, Ex. 13, Weisenburger Adams Dep. at 56:18–24, 212:7–14—stated that he would not even consider the possibility of an unknown cause in any case where the Plaintiff used Roundup for a sufficient amount of time and then developed NHL. Dr. Weisenburger provides a list of "causative factors" he considered: autoimmune diseases, certain infections, chronic inflammatory conditions; breast implants; immunosuppression drugs; chemotherapy; solvents; and immunodeficiencies. Ex. 13, Weisenburger Adams Dep. at 70:18-72:17. Unless one of his "causative factors" is present, he will blame Roundup "in every instance" as long as there was (in his view) sufficient exposure. Id. at 69:6–17, 69:21–70:17, 130:2–11; 82:2–12; see also id. at 84:9– 19 (same opinion even for a plaintiff with a first-degree relative with a history of NHL as long as "there was significant exposure."). He gives zero consequence to the possibility that the actual cause might be an unknown reason beyond Roundup and his list of causative factors. Thus, when asked whether it is even possible that a person could be sufficiently exposed to Roundup, develop NHL, and not have Roundup be the cause, he answered, "probably not." Id. at 93:10–16; see also id. at 226:15–25 ("Q.... In any case, absent extreme examples of very minimal use or super Tyvek suits ... if you have a patient who was exposed to Roundup and developed NHL, in every one of those cases, you are going to say that Roundup was... more likely than not, a substantial contributing factor to that patient's NHL, correct? A. More likely than not."). Even the most generous reading of Wendell could not sanction such an approach.

Dr. Shustov and Dr. Nabhan engage in the same exercise. Dr. Shustov has admitted that "*[f]or anybody* who had sufficient exposure to Roundup, based on the published literature . . . [Roundup] will be [a] substantial contributing factor." Ex. 10, Shustov *Hardeman* Dep. at 218:20–23 (emphasis added). So long as the Plaintiff used Roundup for a sufficient amount of time and developed NHL, without further analysis Dr. Shustov will conclude causation without even factoring in the possibility that there might be an unknown, non-Roundup cause. Dr. Nabhan's

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testimony makes equally clear that he will find causation whenever a Plaintiff has what he deems to be a "sufficient" exposure, regardless of a potential unknown, idiopathic cause. See Ex. 23, Nabhan Hall Dep. at 28:7-29:7; see also Ex. 14, Nabhan Hardeman Dep. at 60:1-7 (explaining that "idiopathic" is just his "default" when he can't point to a cause).

These experts' "always Roundup" methodology cannot be reconciled with science. It simply cannot be the case that mere exposure in tandem with subsequent disease development automatically provides the basis for a legally admissible expert opinion, especially when dealing with a comparatively common disease which all agree is largely idiopathic. In that respect, the experts' methodology here presents a markedly different situation than in *Wendell*, which involved a much rarer disease and a decidedly broader assessment of the individual patient's unique characteristics. Compare Wendell, 858 F.3d at 1234 ("Dr. Shustov stated that there was a one in six million chance that [plaintiff] would have developed HSTCL without being exposed to 6-MP."). In Wendell, the expert expressly considered the possibility of an idiopathic cause, but the court noted that the expert explained that two of the seven patients he had treated for the extremely rare type of lymphoma at issue had taken the medication that the plaintiff claimed had caused his cancer. 858 F.3d at 1233. In that setting, the Court agreed that an expert "may rely on his or her extensive clinical experience as a basis for ruling out a potential cause of the disease." Id.

But here the situation could not be more different. Unlike the "exceedingly rare" HSTCL cancer at issue in Wendell, NHL is remarkably common. See Ex. 10, Shustov Hardeman Dep. at 265:5–12 (average American's lifetime risk of developing NHL is about 1 in 47). It is one thing to permit a physician to draw on his clinical experience treating a rare form of cancer to rule out potential unknown causes when he personally observed in his specialized practice a striking concurrence of two of his seven patients having used the same medicine-which even Wendell still called a "close question." Wendell, 858 F.3d at 1233. Here, however, none of these experts purport to rely on any similar clinical experience with a signature disease to rule out unknown causes, nor could they given the far more common occurrence of NHL and fact that they all acknowledge that the vast majority of NHL cases have no known cause.

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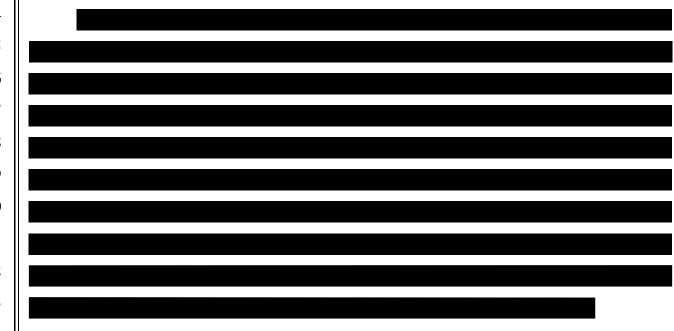
Rather, the experts' reasoning more closely tracks that of the expert excluded in Lipitor,

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whose conclusions "focused almost exclusively on the fact that [the plaintiff] took the drug and later developed the disease, rather than explaining what led her to believe that it was a substantial contributing factor as compared to other possible causes." 892 F.3d at 645. Here, as in *Lipitor*, the experts' reports simply "dismiss other possible causes in favor of [Roundup] in a cursory fashion that appeared closer to an ipse dixit than a reasoned scientific analysis." *Id.* The Court should exclude each experts' opinion on that basis.

C. Plaintiffs' Experts Rule Out Non-Roundup Risk Factors with Arguments They Fail to Faithfully Apply to Roundup.

Perhaps most fatal to the experts' methodology is the unscientific manner in which they generate arguments to rule out other potential causes of Plaintiffs' NHL, but abandon those very same arguments when it comes to Roundup. The reason is clear: had they faithfully applied those arguments to Roundup, they would have ruled out Roundup as well. *Daubert* means nothing if it permits such outcome-driven, inconsistent application of an expert's stated methodology.



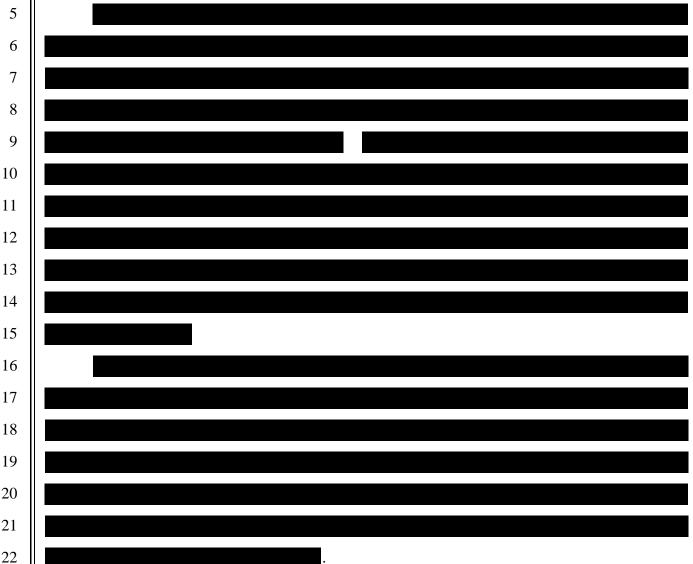
But as this Court meticulously documented in its general causation *Daubert* ruling, the epidemiology connecting Roundup and NHL is "rather weak." *See In re Roundup*, 2018 WL 3368534, at *1. Evenhandedly applying the "clear," "conclusive," or "definitive" standard these experts adopt to exclude the other risk factors would necessarily mean that they would have to rule out Roundup as well. Their failure to objectively carry out their methodology in both directions

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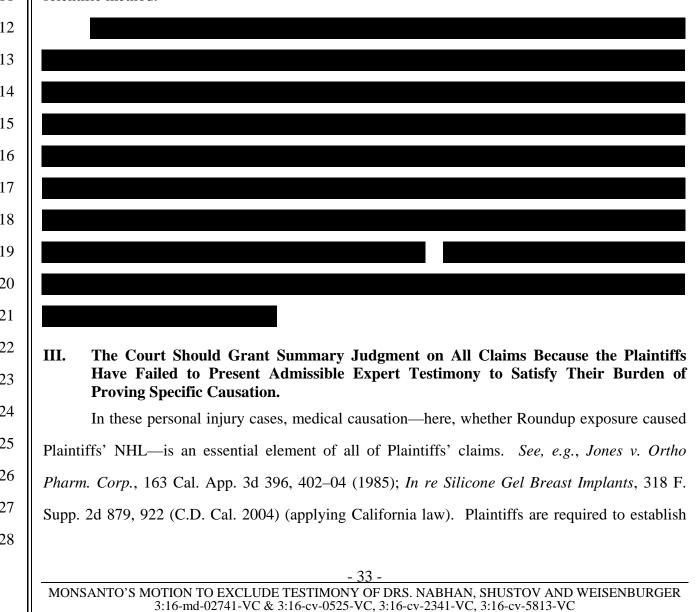
signals a hallmark of unreliability under Daubert. See, e.g., Soldo, 244 F. Supp. 2d at 561 (excluding experts for failing to apply their own scientific standards "[b]ecause consistency is a hallmark of the scientific method [and] plaintiff's experts must be required to satisfy their own standards of reliability").



In the same vein, the experts cite IARC when its findings support them, and ignore IARC when its findings do not. The experts all rule in Roundup in part based on IARC's classification of glyphosate as a Group 2A "probabl[e] human carcinogen," which draws on IARC's findings of "sufficient" evidence of carcinogenicity in experimental animals but only "limited" evidence of carcinogenicity in humans. See, e.g., Ex. 2, Nabhan Hardeman Rep. at 6; Ex. 5, Shustov Hardeman Rep. at 7; Ex. 27, IARC Monograph on Glyphosate at 78. But IARC found Hepatitis B and

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Hepatitis C to be Group 1 "carcinogenic to humans," based on "sufficient evidence in humans for . . carcinogenicity." See Ex. 28, IARC Monograph on Hepatitis В 123. at https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100B-7.pdf (emphases omitted); Ex. 29. С 158, IARC Monograph Hepatitis at https://monographs.iarc.fr/wpon content/uploads/2018/06/mono100B-8.pdf (emphases omitted). As Plaintiffs' experts have admitted, IARC's findings about Hepatitis B and C present "a stronger conclusion than IARC has put forth regarding glyphosate and carcinogenicity findings in humans." Ex. 16, Weisenburger Hardeman Dep. at 56:17-20; accord Ex. 10, Shustov Hardeman Dep. at 98:24-99:20; Ex. 14, Nabhan Hardeman Dep. at 37:7–12. Picking out the IARC conclusion they like but ignoring the (objectively stronger) IARC conclusion that undercuts their desired result hardly evinces the scientific method.



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two aspects of medical causation in this case—general causation (*i.e.*, that the substance at issue is capable of causing the injury alleged) and specific causation (*i.e.*, that the substance actually caused a specific plaintiff's injury). *See Avlia v. Willis Envir. Remediation Tr.*, 633 F.3d 828, 836 (9th Cir. 2011) (applying California law). Whether a chemical can cause NHL is beyond the experience and common knowledge of lay jurors, so Plaintiff's must prove it through expert testimony. *See Jones*, 163 Cal. App. 3d at 403; *Avlia*, 633 F.3d at 836.

Plaintiffs cannot satisfy their burden of proving medical causation because the opinions of their experts regarding specific causation are inadmissible for the reasons set forth above. Plaintiffs also cannot establish specific causation because their experts rely on epidemiological evidence to rule in Roundup, and have cited no peer-reviewed study involving unadjusted data showing a relative risk above 2.0. Therefore, Monsanto is entitled to summary judgment on all claims. *See, e.g., In re Lockheed Litig. Cases*, 115 Cal. App. 4th 558, 561–65 (2004) (affirming summary judgment based on exclusion of plaintiffs' expert's causation opinion); *Daubert*, 43 F.3d at 1321 ("For an epidemiological study to show causation under a preponderance standard, the relative risk ... will, at a minimum, have to exceed '2.' (quotations omitted)).

CONCLUSION

For the reasons stated above, the Court should exclude the specific cause opinions of Dr. Nabhan, Dr. Shustov, and Dr. Weisenburger for all three Plaintiffs.

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24	4 CERTIFICATE OF S	CERTIFICATE OF SERVICE		
25	5 I HEREBY CERTIFY that on this 3rd day of .	I HEREBY CERTIFY that on this 3rd day of January 2019, a copy of the foregoing was		
26	5 filed with the Clerk of the Court through the CM/ECF	system which sent notice of the filing to all		
27	7 appearing parties of record.			
28	3 / <u>/s/ Brian L</u> .	Stekloff		
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