

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS
LIABILITY LITIGATION

MDL No. 2741

Case No. 16-md-02741-VC

This document relates to:
ALL ACTIONS

**PRETRIAL ORDER NO. 85:
DENYING MONSANTO'S MOTION FOR
SUMMARY JUDGMENT ON SPECIFIC
CAUSATION**

The Court previously denied Monsanto's motion for summary judgment on general causation, concluding that the opinions of the plaintiffs' experts were shaky but admissible. The question now is whether the plaintiffs have cleared the specific causation hurdle – that is, whether they have presented evidence from which a reasonable jury could conclude that exposure to glyphosate caused the non-Hodgkin's lymphoma of the three bellwether plaintiffs: Edwin Hardeman, Sioum Gebeyehou, and Elaine Stevick. To defeat Monsanto's motion for summary judgment on this issue, the plaintiffs must present at least one admissible expert opinion to support their specific causation argument. It is again a close question, but the plaintiffs have barely inched over the line. All three of the plaintiffs' specific causation experts may testify at trial, although, as discussed below, some aspects of their opinions will not be admitted.¹

I.

The plaintiffs' specific causation experts use a "differential diagnosis" as the basis for their opinion that exposure to glyphosate caused these plaintiffs' NHL. A differential diagnosis is simply

¹ This ruling presumes the reader is familiar with the experts' testimony and the Court's general causation ruling. *See In re Roundup Products Liability Litigation*, No. 16-md-02741-VC, 2018 WL 3368534 (N.D. Cal. July 10, 2018).

a framework for identifying the most probable cause of a disease.² See *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1234 (9th Cir. 2017). To conduct a differential diagnosis, a physician “rules in” all potential causes of a disease, “rules out” those for “which there is no plausible evidence of causation, and then determines the most likely cause among those that cannot be excluded.” *Id.* The Ninth Circuit has repeatedly approved the use of a differential diagnosis under *Daubert*, provided, of course, that it is applied reliably. See *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003). Monsanto does not dispute that the plaintiffs’ experts may use a differential diagnosis as the basis for their opinions, but instead argues that both their “ruling in” and “ruling out” were unreliable.

A.

At the ruling-in stage, the question is “which of the competing causes are *generally* capable of causing the” disease. *Clausen*, 339 F.3d at 1057-58. And here, the Court already determined that the plaintiffs offered admissible expert opinions that glyphosate is capable of causing NHL. Thus, Monsanto’s primary criticism of the ruling-in process – namely, that the specific causation experts improperly ruled in glyphosate exposure by cherry-picking favorable epidemiological studies – is off point. As this Court has previously ruled, the specific causation experts are permitted to build from the plaintiffs’ admissible general causation opinions. And the admissible general causation opinions grappled with the full body of evidence. Thus, it does not matter that the specific

² It appears that courts have used the term “differential diagnosis” to describe two separate tasks: identifying a plaintiff’s disease and identifying the cause of that disease. While differential diagnosis accurately describes the first task, differential etiology more accurately describes the latter. See *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). Here, there is no dispute that all three plaintiffs have been accurately diagnosed with NHL. Because the operative question is what *caused* their NHL, the relevant analysis is a differential etiology, rather than a differential diagnosis. Nevertheless, in this ruling the Court will follow the parties and experts in this case (not to mention the terminology typically used in Ninth Circuit opinions) and stick with “differential diagnosis.”

causation experts mentioned only a subset of the epidemiological studies in their reports; at trial, their basis for ruling in glyphosate will be the general causation opinions. This result is the byproduct of the decision to bifurcate pretrial proceedings between general and specific causation – a decision that Monsanto urged.³

On a related note, Monsanto complains that the specific causation experts ruled in glyphosate exposure as a risk factor without presenting epidemiological evidence that it has an adjusted odds ratio above 2.0. But the inquiry for this step of the differential diagnosis is whether a risk factor is a *potential* cause, not whether it is in fact the cause. *See Wendell*, 858 F.3d at 1234. Indeed, as discussed further in Section II of this ruling, there is not even a categorical requirement that an expert present a study identifying an adjusted odds ratio above 2.0 to justify a decision not to rule out a risk factor. And in any event, the general causation opinions on which the specific causation experts may build are based significantly on De Roos (2003), which reported an adjusted odds ratio of 2.1 with a 95% confidence interval of 1.1 to 4.0. *See generally In re Roundup Products Liability Litigation*, No. 16-md-02741-VC, 2018 WL 3368534, at *9 (N.D. Cal. July 10, 2018). The specific causation experts cite De Roos as well, but, again, the important point is that these experts will not be repeating the analysis of the general causation experts, but rather relying on them to rule in glyphosate.

³ The plaintiffs' three specific causation experts are testifying from different postures. Dr. Andrei Shustov was not involved in the general causation proceedings, and his specific causation opinion is therefore the only one he has offered in this case. Dr. Chadhi Nabhan did offer a general causation opinion, but it was excluded on the basis that he failed to offer his own analysis of the relevant studies, instead relying excessively on IARC's conclusions. *See In re Roundup Products Liability Litigation*, 2018 WL 3368534, at *32-33. Dr. Dennis Weisenburger offered a general causation opinion that was admitted. *Id.* at *27-29.

B.

The next question is whether the experts adequately assessed all of the potential causes of the plaintiffs' NHL, and properly ruled out factors other than glyphosate, while at the same time declining to rule out glyphosate itself.

The biggest concern, which affects all three plaintiffs, is how the experts account for idiopathy – that is, the possibility that a plaintiff's NHL is attributable to an unknown cause. Imagine 100 people who develop NHL after using Roundup. Imagine further that they had no other significant risk factors for NHL. Assuming for argument's sake that the plaintiffs' general causation opinions are correct, glyphosate was a substantial factor in causing NHL for *some* of those 100 people. But the experts cannot automatically assume that glyphosate caused all 100 people's NHL. For some, the cause of their NHL may not be determinable with the degree of certainty necessary to prevail in court (perhaps because their exposure to glyphosate was just too low, or perhaps for some other reason). The question for any particular plaintiff, then, is whether there is evidence from which a jury could conclude by a preponderance of the evidence that the plaintiff falls into the category of people whose NHL was caused by glyphosate. To assist the jury in making this assessment, an expert must have a way to differentiate Roundup users who developed NHL because they used the product from Roundup users who would have developed NHL regardless.

One way for an expert to do this is to point to a biomarker or genetic signature associated with a particular risk factor. *See, e.g., Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1162 (E.D. Wash. 2009). But as the plaintiffs themselves note, that is not possible here, nor is there any evidence suggesting that NHL presents differently when caused by exposure to glyphosate. Under a strict interpretation of *Daubert*, perhaps that would be the end of the line for the plaintiffs and their experts (at least without much stronger epidemiological evidence). But in the Ninth

Circuit, that is clearly not the case. *See Wendell*, 858 F.3d at 1233-37; *see also Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1198-99 (9th Cir. 2014). Recognizing that “[m]edicine partakes of art as well as science,” the Ninth Circuit’s recent decisions reflect a view that district courts should typically admit specific causation opinions that lean strongly toward the “art” side of the spectrum. *Messick*, 747 F.3d at 1198; *see also Wendell*, 858 F.3d at 1237 (“The first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims’ condition and the toxic substance, has not yet been completed.” (quoting *Clausen*, 339 F.3d at 1060)). While the specific holdings of *Wendell* and *Messick* are in some ways distinguishable, particularly with respect to the rarity and specificity of the involved conditions, the opinions are impossible to read without concluding that district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits. *Compare In re Lipitor Mktg., Sales Practices and Prods. Liab. Litig.*, 892 F.3d 624, 644-45 (4th Cir. 2018); *Tamraz*, 620 F.3d at 677-78. Of course, district judges still must exercise their discretion, but in doing so they must account for the fact that a wider range of expert opinions (arguably much wider) will be admissible in this circuit.

Under Ninth Circuit caselaw, doctors enjoy wide latitude in how they practice their art when offering causation opinions. *See Wendell*, 858 F.3d at 1237 (“Where, as here, two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease or class of disease at issue, are prepared to give expert opinions supporting causation, we conclude that *Daubert* poses no bar based on their principles and methodology.”). It is sufficient for a qualified expert, in reliance on his clinical experience, review of a plaintiffs’ medical records, and evaluation of the general causation evidence, to conclude that an “obvious and known risk factor[.]” is the cause of that plaintiff’s disease. *See Wendell*, 858 F.3d at 1235. Here, the specific causation experts did that. Relying on the plaintiffs’ admissible general causation opinions – which

assert a robust connection between glyphosate and NHL – the experts concluded that glyphosate was a substantial factor in causing the plaintiffs’ NHL.

Moreover, the experts relied heavily on the plaintiffs’ exposure levels in drawing their conclusions. All three experts noted the plaintiffs’ extensive Roundup usage, and further explained – as did the plaintiffs’ general causation opinions – that both the McDuffie (2001) and Eriksson (2008) studies showed a dose-response relationship between glyphosate and NHL. *See generally In re Roundup Products Liability Litigation*, 2018 WL 3368534, at *9-10. Thus, consistent with Ninth Circuit caselaw, the experts provided a basis for their conclusion that these plaintiffs fall into the category of Roundup users who developed NHL. The Court may be skeptical of their conclusions, and in particular of the assumption built into their opinions from the general causation phase about the strength of the epidemiological evidence. But their core opinions – that the plaintiffs had no other significant risk factors and were exposed to enough glyphosate to conclude that it was a substantial factor in causing their NHL – are admissible.⁴

II.

During cross-examination at the *Daubert* hearings, Monsanto asked the plaintiffs’ specific causation experts several hypothetical questions. These questions typically did not go directly to whether there was a sound basis for concluding that one of the plaintiffs’ NHL was caused by glyphosate, but rather to whether the expert would maintain his conclusion if the plaintiffs’

⁴ There is another significant risk factor for Mr. Hardeman: hepatitis C. The experts explained that while active hepatitis C is a known risk factor for NHL, it was highly unlikely that Mr. Hardeman’s development of NHL was attributable to his past hepatitis C infection almost a decade after he had a sustained virologic response – meaning the hepatitis C virus was no longer detected in his blood. While the experts could certainly have explored the hepatitis C issue with more rigor, including by providing a more comprehensive discussion of the possible mechanisms by which hepatitis C causes cancer and how it differs from pesticides in that respect, they had significant support in the scientific literature for their conclusion. Monsanto can certainly challenge their interpretation of the literature, but their underlying methodology was sound.

exposure was far less severe. In other words, returning to the previously-mentioned scenario of 100 NHL patients with glyphosate exposure but no other risk factors, how, precisely, would they draw the line between those whose NHL was caused by glyphosate and those whose NHL is idiopathic? The primary response of the plaintiffs' experts – which, as discussed above, falls within the range of admissible expert testimony – was that, however they draw the line, the exposure for these three plaintiffs was so significant that their NHL should not be considered idiopathic. When further pressed, however, these experts sometimes crossed into the realm of junk science. These aspects of their opinions will be excluded, unless of course Monsanto chooses to use them as impeachment material. *See Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 825-26 (7th Cir. 2010) (holding that it was not an abuse of discretion for the district court to exclude a portion of expert testimony that it deemed unreliable); *Smith v. Ford Motor Co.*, 215 F.3d 713, 721 n.3 (7th Cir. 2000); *cf. Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Mgmt., Inc.*, 618 F.3d 1025, 1040-41 (9th Cir. 2010). To the extent the other witnesses intend to offer the same opinions, they are precluded from doing so as well.

First, Dr. Nabhan may not testify that the McDuffie and Eriksson studies stand for the proposition that if someone uses Roundup more than two days per year or more than ten days in their lifetime, their risk of developing NHL doubles. *See* Feb. 4, 2018 Tr. [Nabhan] 251:06-20 [Dkt. No. 2672]. Because those studies did not adjust for the use of other pesticides, that statement is inaccurate, misleading, and untethered to any sound scientific method. *See In re Roundup Products Liability Litigation*, 2018 WL 3368534, at *26.⁵ Relatedly, Drs. Nabhan and Shustov may

⁵ A doubling of the risk is significant under California law because it shows a 50% chance that a specific factor was the cause of an individual's disease. *See Cooper v. Takeda Pharm. Am., Inc.*, 239 Cal. App. 4th 555, 593-94 (2015); *see also Daubert v. Merrell Dow Pharm., Inc.* (“*Daubert II*”), 43 F.3d 1311, 1321-22 (9th Cir. 1995). Accordingly, when a study shows a relative risk greater than 2.0, it can be used, on its own, “to prove that the product at issue was more likely than not responsible for causing a particular person's disease.” *Cooper*, 239 Cal. App. 4th at 593.

not testify that glyphosate is a substantial causative factor for anyone who exceeds two days per year or ten lifetime days of Roundup use, because that conclusion is again based on unadjusted data. *See* Feb. 4, 2018 Tr. [Nabhan] 253:13-254:05; 260:03 – 261:10 [Dkt. No. 2672]; Jan. 28, 2018 Tr. [Shustov] 213:21 – 214:02 [Dkt. No. 2635]. While they may rely on the general causation opinions to testify that the risk of NHL increases as exposure increases, it is not scientifically sound to quantify that risk and assign it to a particular plaintiff using the unadjusted numbers from McDuffie and Eriksson.

Nor may Dr. Weisenburger testify that Mr. Hardeman’s risk of developing NHL more than doubled because he used Roundup far more than the threshold of ten lifetime days set by the Eriksson and McDuffie studies. Even putting aside the problems with unadjusted data, those studies simply do not support Dr. Weisenburger’s assertion. Eriksson found an unadjusted odds ratio of 2.36 for those exposed to glyphosate for *more than* 10 lifetime days; McDuffie found an unadjusted odds ratio of 2.12 for those exposed to glyphosate for *more than* 2 days per year.

Because neither study further delineated the subjects’ level of exposure, those results do not show

But California law does not categorically require a study showing a doubling of the risk before an expert can opine, based on the totality of the evidence, that a risk factor caused a plaintiff’s disease. *Cf. Daubert II*, 43 F.3d at 1322 (noting that an expert can testify “*either* that [a product] actually caused plaintiffs’ injuries” *or* that the product “more than doubled the likelihood of” those injuries) (emphasis added).

Although the parties speak of this issue in terms of *Daubert*, it is perhaps better understood as a question of the sufficiency of the evidence. As in any case, a plaintiff might be able to prove their case using one strong piece of evidence. Or they might be able to prove their case using multiple pieces of evidence, none of which could, on its own, satisfy the burden of proof. While a study showing a risk factor greater than 2.0 might itself be enough to submit a case to the jury (assuming the study is scientifically sound), there is no bright-line rule in California law requiring such evidence for a case involving medical causation to survive summary judgment. *Cf. Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(4) (2010) (“[A]ny judicial requirement that plaintiffs must show a threshold increase in risk or a doubling in incidence in a group study in order to satisfy the burden of proof of specific causation is usually inappropriate. So long as there is adequate evidence of general causation, courts should permit the parties to attempt to show,” using different types of evidence, “whether the plaintiff’s disease was more likely than not caused by the agent.”).

that someone who well exceeds the exposure threshold would necessarily have a higher odds ratio – as Dr. Weisenburger eventually acknowledged at the *Daubert* hearing in response to questions from the Court.

Finally, Dr. Nabhan may not suggest that the risks posed by glyphosate are similar to those posed by smoking, nor may he invoke the uncertainty from decades ago on the dangers of smoking to argue that it will eventually become obvious that glyphosate causes NHL. *See* Feb. 4, 2018 Tr. [Nabhan] 261:17-262:12 [Dkt. No. 2672]. This comparison is highly speculative, and, given its limited probative value, inadmissible under both Rules 403 and 702. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993); Pretrial Order No. 81, Ruling on Monsanto’s Motion in Limine No. 4.1 [Dkt. No. 2275].

III.

There are several other *Daubert* motions pending before the Court. The plaintiffs’ motion to exclude portions of the opinions offered by Monsanto’s specific causation experts is largely granted in accordance with the Court’s motions in limine order. *See* Pretrial Order No. 81, Ruling on Plaintiffs’ Motion in Limine 2 [Dkt. No. 2275]. At the summary judgment hearing, the parties jointly concluded that neither Dr. Sullivan, Monsanto’s exposure expert, nor Dr. Sawyer, Mr. Hardeman’s exposure expert, would testify during Phase 1 of Mr. Hardeman’s trial. The Court will address challenges to the Phase 2 experts, including any challenges to Drs. Sawyer and Sullivan, prior to the start of Phase 2.

IT IS SO ORDERED.

Date: February 24, 2019



Honorable Vince Chhabria
United States District Court