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: *Engilis v. Monsanto Company*, No. 3:19-cv-07859-VC	**PRETRIAL ORDER NO. 288: ORDER GRANTING MOTIONS TO EXCLUDE EXPERTS CHARLES AND SCHNEIDER** Re: Dkt. Nos. 15887, 15888

The expert testimony of Dr. Ambrose Charles and Dr. Andrew Schneider is excluded. Regarding general causation, both experts are excluded for the same essential reason: they did not personally engage with and evaluate the scientific literature they rely on. Regarding specific causation, the reasons diverge. Charles admitted that, due to the method he used, his specific causation opinion was inextricably intertwined with his general causation opinion. Additionally, in his deposition and at the *Daubert* hearing, Charles showed his opinion to be unreliable in many other ways, including making error-riddled calculations, offering results-oriented analysis, and demonstrating an inability to explain basic points without reading verbatim from papers or being led by counsel. On the other hand, the admissibility of Schneider's specific causation opinion is a close call. He performed a differential diagnosis similar in many respects to those deemed admissible earlier in this case, and he has the requisite experience to perform that assessment. Ultimately, however, his treatment of obesity as a risk factor was unreliable, and that made his differential diagnosis unreliable.[1] This ruling assumes that the reader is familiar with

[1] The motion to exclude Schneider's testimony was initially granted on the papers on June 1,

the experts' testimony, the Court's prior orders on general and specific causation, and the Ninth Circuit opinion on appeal. *See generally In re Roundup Products Liability Litigation*, 390 F. Supp. 3d 1102 (N.D. Cal. 2018) (Pretrial Order No. 45, Dkt. No. 1596); *In re Roundup Products Liability Litigation*, 358 F. Supp. 3d 956 (N.D. Cal. 2019) (Pretrial Order No. 85, Dkt. No. 2799); *Hardeman v. Monsanto Company*, 997 F.3d 941 (9th Cir. 2021).

I

Neither Charles nor Schneider took the key step necessary for a reliable general causation opinion in this case: "offering independent and relatively comprehensive opinions that the epidemiological and other evidence demonstrates glyphosate causes NHL in some people who are exposed to it." Pretrial Order No. 45, Dkt. No. 1596 at 3. Consider the discussion of Dr. Portier as compared to Dr. Nabhan in this Court's prior order. In ruling Portier's general causation opinion admissible, the Court noted that he "considered the possible roles that chance, confounding, small sample sizes, and recall bias might have played in explaining the observed results" of the studies he took into account. *Id.* at 37; *see also id.* at 37–39. Meanwhile, Nabhan merely "summarized many relevant studies"—he "offered little in the way of critical analysis of these studies" and said "little about how or whether they addressed possible bias or confounding, for instance." *Id.* at 62–63. "Instead, he deferred to the opinions of other experts, and to IARC in particular, in arriving at his conclusions." *Id.* at 62. Ultimately, because Nabhan "did not demonstrate that he engaged in his own objective analysis of the epidemiologic literature," his general causation opinion was excluded. *Id.*

Charles admitted that he too did not engage in that kind of objective analysis. Multiple times, Charles stated that he did not assess the quality or limitations of the various studies that he considered. *See* Dkt. No. 17275, Sept. 11, 2023, Hearing Transcript at 69:12–70:9 (admitting that he "did not assess" the "limitations," "quality," or "methodology" of the studies he relied on to

2023. Dkt. No. 16763. Engilis then filed a motion to reconsider, which demonstrated that the Court's initial review of Schneider's opinion was too cursory. So the motion to reconsider was granted, and a *Daubert* hearing on the specific causation portion of the opinion was held. This ruling now supersedes the Court's prior ruling regarding Schneider's opinion.

form his opinions and instead relied on the fact that the studies were peer reviewed); *id.* at 70:24–25 ("I do not examine methodology of any other studies, you know. That comes before the paper is published."); Dkt. No. 15888-3, Aug. 17, 2022, Deposition Transcript at 112:20–113:2 ("I am not here in my report or my opinions – you know, I was not weighing in who is right and who is wrong. I never made that kind of comparison. I was only making the statements of presentation to the data by EPA. This is what EPA did and this is how they came out with these kinds of conclusions."); Dkt. No. 15888-5, June 28, 2022, Deposition Transcript at 340:4–11 (deposition in *Ferro v. Monsanto Co.*, No. 20SL-CC03678) (responding to a question about whether a study was well conducted with "I did not analyze and see, my point there, if you are asking me those questions about epidemiological studies and a deep analysis of all those studies, you know, I – I have not done because my training is not to look at the limitations or how they conduct – that study was designed. Those things are not my expertise. I was only looking at the data and their supportive or dissenting opinions, the papers").

Charles's general causation analysis had many other problems. First, he admitted that the table in his expert report describing the findings of the epidemiology studies was riddled with errors. Dkt. No. 15888-5 at 286:15–20; 325:16–327:14; 336:23–24; 364:8–15; 365:19–20; Dkt. No. 17275 at 67:13–68:9. Second, Charles cherry-picked the findings of the epidemiology studies, reporting only certain odds ratios—those most favorable to his ultimate opinion. At the hearing, he was unable to explain why he selected certain data points and not others, or why the contrary data points didn't sway him. Third, Charles said at the hearing that the findings reported by the McDuffie and Eriksson studies (the studies on which his opinion rests) were adjusted for other pesticide exposures. Dkt. No. 17275 at 71:11–72:9. But that is not true—and the lack of adjustment is an important drawback of those studies that experts must consider. *See* Pretrial Order No. 45, Dkt. No. 1596 at 24, 50; *Hardeman*, 997 F.3d at 965. Fourth, Charles reported and relied on the results of animal studies and genotoxicity studies without reading the studies or the published papers describing those studies. He read only the summaries generated by other organizations for their reports about glyphosate. Dkt. No. 17275 at 93–95. Yet, despite relying

entirely on their summaries of the studies, Charles reached different conclusions about what the studies mean for causation, and without ever explaining where he thinks those organizations went wrong in their reasoning. Dkt. No. 15888 at 12–13. Fifth, at the hearing, Charles was not able to discuss his report, the literature, or his opinion without reading directly from his notes or being supplied the answers by counsel through leading questions or displayed exhibits. Qualified experts sometimes make mistakes, but the many flaws in Charles's presentation disqualify him from testifying. *See* Pretrial Order No. 45, Dkt. No. 1596 at 58–59.

Schneider asserts that he did engage with the scientific literature and came to his own independent conclusions, but his expert report and his deposition answers demonstrate otherwise. The general causation section of Schneider's report spans only about two pages. Dkt. No. 15887-3 at 8–9. It summarizes the IARC report and identifies the citations for and results of six studies the IARC report relies upon. A couple of other articles are mentioned. The only reference to the strengths and weaknesses of the underlying studies is very limited. *Id.* at 9 ("The study by Orsi had limited statistical power. The Agricultural Health Study (AHS) had 37% applicators failing to complete follow up survey, leading to misclassification bias."). Moreover, in his deposition in this case, Schneider said that he "reviewed all of the available pertinent literature." Dkt. No. 15887-6, Aug. 9, 2022, Deposition Transcript at 24:16–17. Shortly thereafter, however, he said that he "reviewed, first, animal data, and then epidemiologic data," including "six or seven main studies" and "multiple meta-analysis or pool studies." *Id.* at 25:18–26:1. When Schneider was asked about studies that he did not cite on his reliance list, he could not explain their omission—he claimed to be familiar with these studies, but he did not articulate any reason why he discarded them or how they factored into his analysis. *Id.* at 36:24–38:8. As counsel for Monsanto pointed out, the studies missing from Schneider's reliance list were also not included on the reliance lists of the general causation experts whose work Schneider reviewed. *Id*. That undermines Schneider's claim that the expert reports were not the basis of his opinion but merely "additive" to his own literature review. *Id.* at 33:15. Moreover, despite consulting the other expert reports, Schneider could not, from memory, identify any portions of those expert reports

that he did not agree with. *Id.* at 31:8–32:3.

As the Court has noted, the admissibility of any general causation opinion that Roundup causes NHL is a "very close question." Pretrial Order No. 45, Dkt. No. 1596 at 1. It is not enough to simply read the conflicting studies in the literature and describe their findings. And it's certainly not enough to read and report on the summaries of the studies performed by other bodies or experts. For an expert to express an opinion that Roundup causes NHL, that expert must have engaged with the relevant literature enough to assess whether a study is credible, to explain why they relied on one study more than another, and to articulate how they reached their conclusion in the face of conflicting evidence. Like Charles, Schneider did not do that, so his general causation opinion is excluded.[2]

II

A specific causation expert may rely on the general causation opinions of others admitted at trial to "rule in" glyphosate as a potential cause of the plaintiff's NHL. Pretrial Order No. 85, Dkt. No. 2799 at 3; *Hardeman*, 997 F.3d at 966. They may also "rely on the general causation opinions to testify that the risk of NHL increases as exposure increases." Pretrial Order No. 85, Dkt. No. 2799 at 8. But the expert must separately conduct a reliable specific causation analysis, and Charles did not come close to doing so.

Indeed, there was essentially no difference between Charles's inadmissible general

[2] The unreliability of Charles's and Schneider's methods justifies the exclusion of their general causation opinions without turning to the question of qualifications. Presumably it is sometimes appropriate for an expert to offer an opinion regarding the epidemiology literature even without a PhD in epidemiology. But an expert must be capable, whether based on formal training or professional experience, of conducting an independent analysis of the literature. Charles's and Schneider's own qualifications are relevant here in that they both cited their inexperience in epidemiology, biostatistics, etc., as a reason for limitations on their engagement with the literature. *Compare* Pretrial Order No. 45, Dkt. No. 1596 at 62 (describing Nabhan's deference to other experts and discussion of his own lack of qualification to interrogate the studies), *with* Dkt. No. 15887-6, Aug. 9, 2022, Deposition Transcript at 83:25–84:6 (Schneider declining to discuss the dose of glyphosate that creates a risk of NHL by pointing to his own training as a "medical oncologist," and not a "epidemiologist, statistician, or pathologist"). Had Charles and Schneider engaged with the literature similar to how Portier, or other general causation experts, did, then the Court would have had to reach the question of whether either of them was qualified by training or experience to do so.

causation opinion and his specific causation analysis. At some points during the hearing, he seemed to say that as long as someone was exposed to glyphosate for over two lifetime days, the probability that the glyphosate exposure had caused their cancer was high given the odds ratios in the epidemiology studies. Dkt. No. 17275 at 145:16–146:1. That approach, even if consistently maintained by Charles, would still have been problematic. *Compare* Pretrial Order No. 85, Dkt. No. 2799 at 8 (rejecting as unreliable specific causation opinions that use the underlying studies showing a relationship between glyphosate and NHL to attempt to "quantify that risk and assign it to a particular plaintiff"), *with* Dkt. No. 15888-4 at 11–12, 29–31 (calculating Engilis's lifetime exposure to Roundup and concluding, using the numbers in the epidemiology studies as a baseline, that glyphosate was a substantial cause of Engilis's cancer). But at other points he went even farther, saying that when a person experiences that amount of Roundup exposure, the conclusion that the exposure caused their NHL is automatic. *See, e.g.*, Dkt. No. 17275 at 151:24–152:3 ("If this particular chemical that this particular person has used, if there is a positive association somewhere, they can – I can relate this exposure to the positive association. There is no need of bringing in negative association with this person's positive finding and positive diagnosis."); *id.* at 37–38 (stating that in his prior work he could tell Superfund site proximity was the cause of a person's sickness "because they went to the hospital" and "they were sick").[3] At still another point in the hearing, Charles recounted his "methodology in determining the cause of Mr. Engilis's cancer" as follows: "I follow a weight of evidence pattern. Okay? Weight of evidence of the different data I evaluate. Epidemiological studies support data or positive association is only one of those that tells me probably yes, this is associated." *Id.* at 154:8–13. Counsel for Monsanto followed up, asking whether that approach was what Charles used to determine that Roundup caused Engilis's cancer. And Charles said merely "I rely on the human data available, yes." *Id.* at 154:14–17. As discussed in more detail

[3] That's consistent with the fact that much of his experience was with human exposure cases where the symptoms occurred shortly after a documented exposure to a toxic chemical, but the question presented in this case is very different—something Charles did not seem to understand.

below, it is somewhat difficult to determine how Charles reached his proffered opinions. But what's clear is that the flaws in his general causation analysis extend to his specific causation analysis, such that they are both inadmissible.

Charles's specific causation opinion had other problems. One exchange exemplifies several of them. There was a significant error in his calculation of Engilis's exposure to Roundup. His report stated that Engilis had used Roundup for 53 years, and his total exposure calculation was based on that number. Dkt. No. 15888-4 at 12. But at the hearing, Charles said that "53 was a wrong number." Dkt. No. 17275 at 132:7. He then presented new calculations, for the first time, based on 43 years. *See, e.g.*, *id.* at 132:11–24. The Court asked Charles how he made this mistake. *Id.* at 132:25. Charles replied that the 53 years number was based on assuming the "worst case" from Engilis's self-reporting his Roundup use. *Id*. at 133:22. But that does not make sense—a "worst case" assessment would tend to affect the number of hours per year, not the number of years of use. Beyond that, the Court followed up by asking Charles why he reduced the number (either moving away from the "worst case" approach or recalculating the number of years). The Court asked Charles that question—why the change—repeatedly. *Id.* at 133:23–135:12. Ultimately, Charles said merely that he changed the calculations because he "was told at [his] deposition that [he] was exaggerating," so he "said, well, let me go look at what exactly exaggerated." *Id.* at 135:5–8. In addition to all of that, Engilis used Roundup for 26 years, not 53, and not 43. Charles said that he reached the 43 number by adding up the years from Roundup use at each property to reach a kind of aggregate number, which is obviously not an appropriate way to calculate the number of years someone used Roundup. Moreover, even using that approach, the number was still incorrect: walking through the years of use at each property, and adding them up again with Monsanto's counsel, Charles agreed that the number was actually 39 years. *Id.* at 137:24–139:8. In the end, Charles acknowledged that he had presented the Court with three different calculations (one in his report, one in his notes, and one that he did orally on direct examination), all of which were based on different methodologies than the ones used by the epidemiology studies for which the calculation was meant to be a

comparator. *Id.* at 140:8–13; 142:5–23. At no point in the hearing did Charles tell a coherent story to explain or justify his methodology.

Finally, as with his general causation testimony, at several points during the hearing Charles was simply reading word-for-word from his expert report, or reading items that were highlighted on documents presented to him by counsel, or reading from the notes in front of him. *See, e.g., id.* at 112:14–19 (The Court: "I mean you're asking him a very basic question, and then you show him the answer on the screen, and then he answers the question. I mean that's basically been the entirety of the direct so far. Not just on specific causation, but on general causation, too."). Charles was simply unable to describe his opinion on his own, much less explain it or answer any questions about it in his own words. *Cf.* Pretrial Order No. 45, Dkt. No. 1596 at 56–57, 58–59.

III

The admissibility of Schneider's specific causation opinion is a closer call. Schneider performed a "differential diagnosis," which is a proper method for a doctor to generate a specific causation opinion. Pretrial Order No. 85, Dkt. No. 2799 at 1–2. And Schneider properly relied on others' general causation opinions that will be admitted at trial to "rule in" glyphosate as a potential cause for Engilis's cancer. *Id.* at 2–3. However, Schneider did not reliably "rule out" obesity, which is widely discussed as a possible risk factor for NHL. The problem with Schneider's treatment of obesity was twofold. First, Schneider asserted in his report that Engilis was not obese, and the opinion expressed in the report that Roundup caused Engilis's NHL appears based partly on that assertion. But Schneider was never able to justify that assertion, and the only objective measures available to him suggested that Engilis was indeed obese. Second, when Schneider pivoted and attempted to argue that obesity is not actually a risk factor for NHL, he failed to reliably justify that position as well.

The report describes Engilis as "negative" for a series of "medical conditions," one of which is "Obesity." Dkt. No. 15887-3 at 11. Thus, the report says, those medical conditions "are not suggested as related to or as causative factors to the onset of different types of cancers." *Id.*

But the report makes no mention of Engilis's body mass index or weight. At the hearing, Schneider was asked whether he looked at Engilis's medical records to confirm his conclusion that Engilis was "negative" for obesity, and he asserted that he did. Dkt. No. 17306, Sept. 20, 2023, Hearing Transcript at 60:17–24. But counsel then showed Schneider several years of medical records that showed that Engilis had a BMI that would be classified as obese. *Id.* at 61:3–64:6. Schneider responded that BMI is not the whole story: "really what matters is how [the weight is] distributed on a person." *Id*. at 62:9–10. But Schneider admitted that he didn't have that information either: "I don't know how his weight was distributed. I know he rode his bike. Maybe he had very thick muscular legs. I have not seen a picture." *Id.* at 62:2–4. Instead, Schneider simply intoned that none of the records used the word "obese." *See, e.g., id.* at 60:23–24; 62:16–17, 20–21; 63:15–16. Schneider was asked whether he "consider[ed] the fact that Mr. Engilis had a BMI of greater than 30 for the 14 years prior to . . . his diagnosis." *Id.* at 62:22–24. In response, Schneider said "I did consider it, but rejected it." *Id.* at 62:25. In short, Schneider declared Engilis "negative" for obesity without truly examining the issue.

Although Schneider's report seemed to acknowledge obesity as a risk factor for NHL, at the hearing, Schneider pivoted to the position that obesity is not actually a risk factor. Schneider repeatedly uttered the "magic words" from the *Daubert* caselaw, saying that he formed the opinion based on his "training," his years of clinical "experience," and the "fund of knowledge" he had built up from reading articles as he came across them over that time. *Id.* at 18:1–18; 65:1–24. But he conceded that he did not rely on any particular studies or articles to form his opinion that obesity was not a risk factor for NHL. *Id.* at 64:17–65:24.[4] Moreover, Schneider's description of how his clinical experience informed his opinion that obesity is not a risk factor was fairly unscientific: "In my opinion, having practiced oncology for 34 years, I see no association between weight and CLL. I see fat people get CLL; I see skinny people get CLL." *Id.*

[4] Schneider did note that, the night before the Daubert hearing, after being sent an article about an association between obesity and NHL, he researched the question to find a study that supported his opinion. Dkt. No. 17306 at 65:11–66:17. Obviously, this is insufficient from the standpoint of both timing and substance.

at 17:12–14. Moreover, immediately after that observation, he said, "In my mind, the medical databases does not [sic] really have a strong opinion that weight is a risk factor for NHL." *Id.* at 17:14–16. That discussion suggests that the basis for his conclusion that obesity is not a risk factor was not, in fact, his clinical experience, but rather the medical literature that he did not describe, cite, or review in preparation of the report.

Schneider's approach to obesity can be differentiated from that of earlier experts whose specific causation opinions were admissible, such as Dr. Shustov. *Contra* Dkt. No. 17343 at 4. Shustov expressed the opinion that obesity was not a strong risk factor. As Engilis points out, Shustov testified that he "did not find compelling evidence linked to it" and explained that "obesity is a reflection of most likely other factors that come with it that can cause heart disease and other disease . . . [s]o not having a very defined mechanistic explanation [of] how obesity can cause lymphomas, it is a wrong factor to interrogate in the first place." *Id.* To be sure, there is some similarity between what Shustov and Schneider said at their *Daubert* hearings. But there are also important differences between the two experts' overall treatments of obesity. First, a whole paragraph of Shustov's report was dedicated to the link between obesity and NHL. Dkt. No. 2478-10 at 8.[5] Shustov cited and described the results of a pooled analysis of case control studies. *Id.* Based on his description of that study and the literature, Shustov stated that despite the plaintiff's having "moderate obesity," it was "highly unlikely that his obesity had significant

[5] "Mr. Hardeman has moderate obesity. Obesity has been interrogated for its association with NHL risk. To date, no published studies have provided definitive link between obesity and heightened risk of developing lymphomas or solid proof of specific mechanism to further investigate in the experimental setting. In a pooled analysis of 18 case-control studies (overall, including 10,000 NHL subjects and 16,000 controls) from InterLymph Consortium, *E. Willet and colleagues* analyzed association between various degrees of obesity and a risk of non-Hodgkin lymphomas. No association was found overall (pooled OR=1.00, 95% CI (CI) 0.70-1.41). While excess was observed for DLBCL (pooled OR=1.8, 95% CI 1.24-2.62), not all study specific ORs were raised. It was the conclusion of the investigators, that no evidence was found to support hypothesis that obesity increases risk of HNL. The study also could not definitively prove obesity impact on development of DLBCL and suggested that more studies would need to be performed. Additional weaknesses of the study were inability to control for numerous other confounding environmental, household, lifestyle factors and self-reporting manner of study parameters with inherent biases and inaccuracies. It is my conclusion, that in Mr. Hardeman's case, it is highly unlikely that his obesity had a significant impact on the risk of lymphoma development." Dkt. No. 2470-10 at 8.

impact on the risk of lymphoma development." *Id.* Contrast that with Schneider's report, which made no mention of a conclusion that obesity was not a serious risk factor nor of any literature that he might have relied on to reach such a conclusion. Moreover, unlike Shustov, Schneider affirmatively stated that the plaintiff was "negative" for obesity despite indications to the contrary in the plaintiff's medical records, and despite not doing any follow up to confirm whether those indications were a miscue (due to weight distribution, for example). In all, Shustov's treatment of obesity was meaningfully more reliable than Schneider's.

"Under Ninth Circuit caselaw, doctors enjoy wide latitude in how they practice their art when offering causation opinions." Pretrial Order No. 85, Dkt. No. 2799 at 5 (citing *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1237 (9th Cir. 2017). Moreover, there is no requirement that "experts [ ] eliminate all other possible causes of a condition," and a doctor "may rely on his or her extensive clinical experience as a basis for ruling out a potential cause of the disease." *Wendell*, 858 F.3d at 1237. But even with the tremendous deference due to doctors performing differential diagnoses, Schneider's treatment of obesity in this case renders his opinion unreliable. The caselaw does not suggest that a court should simply abdicate its gatekeeping function when presented with a clinician's differential diagnosis—a court must still assess whether the expert can "provide reasons for rejecting alternative hypotheses using scientific methods . . . founded on more than subjective beliefs or unsupported speculation." *Messick v. Novartis Pharmaceuticals Corp*, 747 F.3d 1193, 1198 (9th Cir. 2014). And as the Ninth Circuit has previously acknowledged in a Roundup case, reliable review of the scientific literature can be an important part of conducting a reliable "rule out" process. *Hardeman*, 997 F.3d at 967.[6]

Finally, Schneider's opinions about the NHL causing Engilis's melanoma and bladder

[6] The task at hand is really "differential etiology"—identifying the cause of the disease—rather than "differential diagnosis"—identifying the disease itself. Pretrial Order No. 85, Dkt. No. 2799 at 2 n.2. Given that, it's not clear why a practicing doctor offering an opinion of this sort should get more deference than a non-clinician. In their day-to-day jobs, clinicians diagnose and treat patients. They are rarely called upon to identify what caused a patient's disease within a reasonable degree of scientific certainty. In any event, here the Court has extended the highest possible level of deference to Schneider (as well as Charles), based on its understanding of the caselaw.

cancer are inadmissible. The report does not contain any rule out process. It does not even mention alternative causes for either disease. Dkt. Rpt. 15887-3 at 12–13. Schneider's attempts to conduct a rule out process at the hearing—identifying risk factors that were never mentioned in his report—are insufficient to remedy the problem. *See* Dkt. No. 17306 at 24:2–9.

IV

It appears a sentiment may have developed in this MDL that because some general and specific causation opinions have now been admitted, additional experts can get through the *Daubert* gate with a casual wave of the hand. That is wrong. The opinions of Dr. Charles and Dr. Schneider are excluded. And because they are the only two specific causation experts offered in Engilis's case, there will be no evidence from which a reasonable jury could conclude that Roundup caused his NHL, so summary judgment will be granted to Monsanto.

IT IS SO ORDERED.

Dated: November 15, 2023

VINCE CHHABRIA
United States District Judge