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PLAINTIFF ALVA AND ALBERTA PILLIOD'S RESPONSE TO MONSANTO'S MOTION TO EXCLUDE DR. WEISENBURGER AND DR. NABHAN

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PLAINTIFF ALVA AND ALBERTA PILLIOD'S RESPONSE TO MONSANTO'S MOTION TO EXCLUDE DR. WEISENBURGER AND DR. NABHAN

### MEMORANDUM OF POINTS AND AUTHORITIES

Dr. Dennis Weisenburger ("Weisenburger") and Dr. Chadi Nabhan ("Nabhan") are being offered as general causation experts and specific causation experts in this case. Nabhan is a board-certified clinical medical oncologist; past Assistant Professor of Medicine at the University of Chicago; and currently Executive Vice President & Chief Medical Officer at Aptitude Health. His clinical practice and academic research for the past 17 years has focused on lymphomas, treating approximately 30 lymphoma patients per week. Nabhan has published over 300 original manuscripts, review articles, and abstracts; the majority focusing on NHL. Weisenburger is Chair of the Pathology Department of the City of Hope Medical Center. He specializes in the studies of the hematopoietic and immune systems, with a specialty in NHL that has spanned nearly 40 years. The Ninth Circuit stated of Weisenburger, "[w]here, 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." *Wendell v. GlaxoSmithKline LLC*, (9th Cir. 2017) 858 F.3d 1227, 1237.

Because both of these eminently qualified experts have spent hundreds of hours reviewing the relevant materials and have conducted exhaustive differential diagnoses of the Plaintiffs it is not surprising that Monsanto has lost this identical "Sargon/Cooper" motion in its previous attempts. The Honorable Curtis E.A. Karnow rejected the identical Sargon/Cooper motion and allowed Dr. Nabhan to testify on general causation and case specific causation in the *Johnson v. Monsanto* trial with precisely the same methodology. Hoke Decl. Ex. 5 (5/17/2018 Sargon Order at 25). The Honorable Suzanne Bolanos after hearing the trial testimony of Dr. Nabhan denied Monsanto's Motion for a directed verdict on these same worn out arguments. Judge Bolanos again rejected these arguments in Monsanto's Motion for JNOV and Motion for New Trial. Hoke Decl. Ex. 6 (10/22/2018 Order Denying JNOV).

Dr. Weisenburger has similarly used his 40 years of experience in this issue and combined his extensive review of the literature with an extensive differential diagnosis. Dr. Weisenburger has been deposed four times and has submitted to extensive cross-examination in the federal court proceedings in the Roundup MDL Daubert challenge for both general causation and specific causation. Monsanto's

Daubert motion to exclude Weisenburger's general causation testimony has been denied.<sup>1</sup>

Plaintiffs' experts' opinions have been bolstered by a February 6, 2019 peer-reviewed metaanalysis conducted by three of the scientists who evaluated glyphosate at the EPA FIFRA Scientific
Advisory Panel (SAP) Meeting in December 2016. Ex. 1 to Declaration of Curtis Hoke ("Hoke Decl.")
Zhang, Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A MetaAnalysis and Supporting Evidence, Mutation Research-Reviews in Mutation Research (2019). The journal
is also run by an EPA toxicologist.<sup>2</sup> The SAP "serves as the primary scientific peer review mechanism"
of the EPA.<sup>3</sup> These independent scientists conducted an exhaustive independent review of the evidence,
including the reviews by EFSA and the EPA, as well as the updated AHS study. Hoke Decl. Ex. 1. They
concluded that "Overall, in accordance with evidence from experimental animal and mechanistic studies,
our current meta-analysis of human epidemiological studies suggests a compelling link between
exposures to GBHs and increased risk for NHL." *Id.* These opinions are in complete accord with the
opinions previously expressed by Weisenburger and Nabhan.

Such a conclusion naturally arises when scientists follow good scientific principles that the "body of studies be considered as a whole." *Cooper v. Takeda Pharm. Am., Inc.*, (2015) 239 Cal. App. 4th 555, 589–90. The Federal Judicial Center's Reference Manual on Scientific Evidence (3rd. Ed.) instructs:

... It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), ... consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence. ... "summing, or synthesizing, data addressing different linkages [between kinds of data] forms a more complete causal evidence model and can provide the biological plausibility needed to establish the association" being advocated or opposed. P. 53.

The link becomes more compelling with the Pilliods because they are married and therefore have a shared exposure to Roundup® after spraying it together for over one thousand days over a time period of thirty years when they both contracted diffuse large B-cell lymphomas. Hoke Decl. Ex. 2 (Nabhan Rep. at 31)

Ignoring good science, Monsanto claims that Plaintiffs' experts have no basis to even rule in Roundup® as a cause of NHL despite the "compelling link" found by the EPA SAP scientists, the

<sup>&</sup>lt;sup>1</sup> Monsanto's Motions to Exclude Weisenburger's and Nabhan's case-specific testimony in the Roundup MDL has been tentatively denied and the parties are awaiting a written order.

<sup>&</sup>lt;sup>2</sup> https://www.journals.elsevier.com/mutation-research-reviews-in-mutation-research/editorial-board/david-m-demarini

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conclusions by IARC the most prestigious scientific body; and the findings of the California EPA that glyphosate is a carcinogen. Monsanto asks this Court to reject controlling California law embodied in *Cooper v. Takeda*; reject the rulings of three judges in the Roundup litigation; and instead impose draconian expert admissibility standards that have no place in the American jury system. As described by Judge Chhabria, Monsanto's proposed standards are untenable because, under Monsanto's view "nobody could ever get past specific causation even if they were [] showering in Roundup every day for 20 years..." Hoke Decl. Ex. 3 at (MDL Hearing Tr. at 47:9-16).

Monsanto fails to heed *Cooper's* admonition that it is Monsanto's burden to point to "**substantial evidence** to indicate that another cause" other than Roundup® was "ignored" by Plaintiffs' experts. Tellingly, Monsanto fails to cite any expert testimony that any of the various "causes" conjured up by Monsanto's attorneys constitute substantial evidence of a cause of the Pilliods' NHL. The arguments of Monsanto's attorneys are wholly contradicted by Monsanto's own expert on case specific causation, Dr. Bello, will not give an opinion of an alternative cause for Mrs. Pilliod's NHL because in her view "[t]he cause of Ms. Pilliod's CNS NHL is unknown." Hoke Decl. Ex. 16 (Bello Rep. at 16). Arguments and assertions by Monsanto's attorneys do not constitute evidence, and do not trump the opinions of actual scientists at the top of their field such as Weisenburger and Nabhan whose opinions are developed after decades of scientific training, research and experience.

#### I. LEGAL STANDARD

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

expert to rule out smoking as contributing cause to Plaintiff's injury).

In conducting a differential diagnosis one "[a]ssumes the pertinence of all potential causes, then rules out the ones as to which there is no plausible evidence of causation, and then determines the most likely cause among those that cannot be excluded." *Id.* It is unnecessary that "an expert be able to identify the sole cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a substantial causative factor." *Messick v. Novartis Pharm. Corp.*, (9th Cir. 2014) 747 F.3d 1193, 1199. "This is true in patients with multiple risk factors, and analogously, in cases where there is a high rate of idiopathy... when an expert establishes causation based on a differential diagnosis, the expert may rely on his or her extensive clinical experience as a basis for ruling out a potential cause of the disease." *Wendell*, 858 F.3d at 1198

"The court does not resolve scientific controversies. Rather, it conducts a 'circumscribed inquiry' to 'determine as a matter of logic the studies and other information cited by experts adequately support the conclusion that the experts general theory or technique is valid." Sargon Enterprises, Inc. v. Univ. of S. Cal., (2012) 55 Cal. 4th 747, 776. In the Court's gatekeeping role "[t]he gate tended is not a partisan checkpoint. It bars expert opinion only if it fails to meet the minimum qualifications for admission. If the opinion is based on materials on which the expert may reasonably rely in forming the opinion, and flows in a reasoned chain of logic from those materials rather than from speculation or conjecture, the opinion may pass, even though the trial court or other experts disagree with its conclusion or the methods and materials used to reach it." Davis v. Honeywell Int'l Inc., (2016) 245 Cal. App. 4th 477, 492.

#### II. ARGUMENT

## A. Nabhan and Weisenburger Conducted Proper Differential Diagnoses

Both Nabhan and Weisenburger followed the proper methodology for conducting differential diagnoses. Nabhan explained his methodology as follows:

In order to reach a sound and clear conclusion on the causes of Mrs. Pilliod's NHL, I considered all of the potential causative and risk factors for NHL and then determined whether such factors were relevant to Mrs. Pilliod's case. This process, termed "differential etiology" is a customary method that is taught to medical students, residents, and fellows. In fact approaching the question of "etiology" is the essence of why history and physical are performed the way they are. Standard of care dictates that oncologists (and all physicians for that matter) conduct a careful comprehensive history and focused detailed examination... Being aware of risk factors that can cause cancers, allows oncologists to provide proper counseling and implement strategies that ultimately help patients and relatives. This same principle is applied here in my methodology to determine why Mrs. Pilliod developed NHL.

Hoke Decl. Ex. 2 (Nabhan Rep. at 12-13). Weisenburger likewise explained:

Well, you know, in the review of his medical records and in my interviews and the other documents that I reviewed, you know, I did a – an exhaustive evaluation of the causes that — things that cause non-Hodgkin's lymphoma and the kinds of diseases and exposures that Mr. Pilliod had. In other words, I did what's called a differential diagnosis, or better called a differential etiology. So I tried to understand what — based on all of these documents and my interviews, what was the most likely cause of his non-Hodgkin's lymphoma. And, you know, I concluded that Roundup was the most likely, most substantial cause of his non-Hodgkin's lymphoma.

Hoke Decl. Ex. 4 (Weisenburger Dep. at 37:14-38:1). Weisenburger stated that he also utilized his "general knowledge, [] my knowledge of general causation and specification causation for NHL, and I weighed all of the information all the evidence" in conducting his differential diagnosis. *Id.* at 217:18-25. This type of differential diagnosis is admissible under *Cooper*. 239 Cal. App.4<sup>th</sup> at 566-568. Weisenburger and Nabhan went further than the expert in *Cooper* and personally interviewed the Pilliods to inquire about their medical history (Weisenburger via phone, and Nabhan via personal examination). Judge Karnow in the *Johnson v. Monsanto* case found this precise methodology admissible noting:

With respect to specific causation, Nabhan incorporated his entire general causation analysis and highlighted the following factors: (1) Plaintiffs exposure history (i.e., the number of times Plaintiff sprayed glyphosate-based herbicides, the amount of time spent on each occurrence, the protective gear worn, and the occurrence of spilling events); (2) The fact that Plaintiffs exposure was greater than the exposure in two epidemiological studies that reported relative risk of greater than 2.0; (3) Plaintiffs mycosis fungoides diagnosis, including its timing; and (4) The absence of other known causal factors of NHL to which Plaintiff was exposed (i.e., immunosuppressive therapy; although there are some associations - such as Plaintiffs sex –that may indicate he is more susceptible to the disease than other members of the population). Id., Ex. 20. Nabhan admitted that he could not rule out other contributing factors; but he is not required to do so. Cooper, 239 Cal.App.4th at 585-86; Wendell, 858 F.3d at 1237.

Hoke Decl. Ex. 5 (5/17/2018 Sargon Order at 25). Judge Karnow's Johnson ruling noted that in *Cooper*, the Appeals Court "chastis[ed]--and revers[ed]-the trial judge" because he "engage[d] in settling a scientific controversy" in excluding the case-specific expert. *Id.* at 4. Judge Bolanos in denying Monsanto's motion for a new trial and JNOV stated that Nabhan utilized the proper methodology in conducting a differential diagnosis stating that "Nabhan's methodology in this case is similar to the differential diagnosis accepted by the Court of Appeal in Cooper." Hoke Decl. Ex. 6 (10/22/2018 Order Denying JNOV)

# 1. Alva and Alberta Pilliod Had Extensive Exposure to Roundup.

As explained in the general causation brief on *Sargon*, Weisenburger and Nabhan each extensively reviewed the literature in coming to an opinion the Roundup® can and does cause Roundup® in people. Based on the "compelling link" between Roundup® and NHL it was necessary that the Pilliods' shared

history of Roundup® use be "ruled in" as a potential cause of their NHL.

Weisenburger and Nabhan do not utilize an "always Roundup®" methodology. Judge Chhabria rejected this claim by Monsanto stating "[t]hat's not what they [Nabhan and Weisenburger] said. All right. They didn't say they would never rule it out." Hoke Decl. Ex. 3 (MDL Hrg. at 41:11-12). In considering whether Roundup® as a cause, these experts considered the Pilliods' exposure history. Weisenburger noted that "when I interviewed them, we talked about the number of times they used it per year, how many years they used it, we talked about how much they used each time in terms of gallons. We talked about the clothes they wore, did they get it on their skin, you know, when did they wash, when did they shower, when did they change their clothes, whether they wore protective equipment or not." Hoke Decl. Ex. 4 (Weisenburger Dep. At 40:5-12). Weisenburger stated that "if it was greater than twice a year for 28 years, I would say, yeah, that's pretty significant. If it was twice a year for one year, I would say, well, gee, that's probably not significant. Okay? So you'd have -- you have to take it in the context of the whole body of information." *Id.* at 143:1-7. Nabhan stated:

I would ask, for example, about the exposure, and they would say "a lot of exposure." I'm, like, "Well, I get that. But what is a lot? A lot to you might be different than a lot to me." So I try to get a little bit more detail, so I could have more accurate information... [T]he easiest way for me to do this is based on these properties because as I was talking to them, they were mentioning several properties they had. I said, "Okay. Let's just go through each property because this way at least in my mind I can understand it better." Hoke Decl. Ex. 7 (Nabhan Dep. at 95:19-98:16).

The Pilliod have been married and shared the same residences for over 40 years in Alameda County. Hoke Decl. Ex. 2 (Nabhan Rep. at 31). Studies have shown that married couples are at an increased risk of NHL likely due to shared environmental exposures such as pesticides. *Id.* Both Weisenburger and Nabhan conducted thorough exposure analyses based on intereviews with the Pilliods and in reviewing their depositions. *Id.* at 10-12. Hoke Decl. Exs. 8-10 (Weisenburger Dep. Exs. 2-4). Mr. and Mrs. Pilliod were extensive users of Roundup®. They sprayed Roundup together at four different properties over the course of thirty years and 1500 total days. Hoke Decl. Ex. 2 (Nabhan Rep. at 8-10). During this time they did not wear protective gear such as gloves or impermeable clothing based on representations by Monsanto that such gear was unnecessary. *Id.* at 10, 26.

Based on this extensive exposure history, Nabhan ruled in Roundup as a potential cause of Mrs. Pilliod's NHL because she "had extensive exposure to RoundUp over 3 decades using it in her residences."

Her exposure is above the threshold that had been described in the epidemiologic studies and scientific literature." *Id.* at p. 22. He likewise ruled in Roundup as a potential cause for Mr. Pilliod, because he used it even more than Mrs. Pilliod. *Id.* at p. 26. Weisenburger he ruled in Roundup® because "He used it for many years, I think 28 years, prior to developing his non-Hodgkin's lymphoma. He used it frequently. He used it in large quantities." Hoke Decl. Ex. 4 (Weisenburger Dep at 38:9-38:11). Weisenburger stated that both Mr. and Mrs. Pilliod are within the "high-risk category of exposure" to Roundup®. *Id.* at 229:12-20. A summary of the Plaintiffs' exposure and medical history is attached at Hoke Decl. Exs. 19, 20.

In stark contrast to Nabhan and Weisenburger, Monsanto's experts ignore in litigation what they preach in the real world of medicine. Both Monsanto's case-specific experts medical institutions list pesticides as a cause of NHL, yet neither expert listed the number one used pesticide, used for years by the Pilliods, as a potential cause for the Pilliods' NHL. <sup>4</sup>

# 2. Plaintiffs' Experts Considered the Totality of the Evidence in Arriving at Their Opinions

Plaintiffs' experts properly considered the totality of the evidence in opining that Roundup® can cause NHL in humans and in concluding that the evidence supports specific causation. To the extent Defendants' attorneys disagree, they can cross-examine these experts and let the jury decide. *Cooper* 239 Cal. App. 4th at 592–93 ("The courts' evidentiary gatekeeping function is ... not a warrant for judicial intervention in genuine scientific debates over substantive principles... The flaws in the study methodologies were explored in detail through cross-examination and with the defense expert witnesses") *Milward v. Acuity Specialty Products Group, Inc.*, (1st Cir. 2011) 639 F.3d 11, 22 (the Court should not "[take] sides on questions that are currently the focus of extensive scientific research and debate—and on which reasonable scientists can clearly disagree."); *Schultz v. Akzo Nobel Paints, LLC*, (7th Cir. 2013) 721 F.3d 426, 433 ("Rule 702 did not require, or even permit, the district court to choose between those two studies at the gatekeeping stage. Both experts were entitled to present their views, and the merits and demerits of each study can be explored at trial.").

In stark contrast to Monsanto's assertion that Plaintiffs' experts "cherry picked" the epidemiological literature they relied upon, each of Plaintiffs' experts considered all relevant evidence in

<sup>&</sup>lt;sup>4</sup>Dr. Levine: <a href="https://www.cityofhope.org/clinical-program/lymphoma">https://www.cityofhope.org/clinical-program/lymphoma</a>; Dr. Bello <a href="https://moffitt.org/cancers/lymphomas-hodgkin-and-non-hodgkin/risk-factors/">https://moffitt.org/cancers/lymphomas-hodgkin-and-non-hodgkin/risk-factors/</a>

forming their opinions. For example, Weisenburger testified that he considered the AHS study, but did not give it much weight due to extensive flaws. Hoke Decl. Ex. (Weisenburger Dep. at 59:17-60:11); see also Nabhan Rep. at 15-20 (evaluating both positive and negative studies on Roundup® and NHL, including the AHS study). Plaintiffs have briefed the Court as to why an expert may reliably discount the AHS study in its general causation brief. Both Weisenburger and Nabhan served expert reports specifically and only discussing the AHS study, and sat through depositions relating only to the AHS study. For Monsanto to claim that Plaintiffs' experts did not consider the AHS study is nonsensical and disingenuous.

Plaintiffs' experts explained that the De Roos (2003), Eriksson (2008), Shinasi (2014) and McDuffie (2001) studies, all of which demonstrate statistically significant doubling of the risk of NHL, support their opinion that the Pilliods NHL was caused by Roundup®. Nabhan Rep. 15-20. The evidence is strengthened by data showing a dose response in McDuffie (2.1. O.R. for greater than 2 days/year) and Eriksson (2.36 O.R. for greater than 10 lifetime days of use). *Id.* Weisenburger also considered the data form the upcoming North American Pooled Project (NAPP) study<sup>5</sup> of which he is an author. Weisenburger Dep. at 225:8-228:9. Weisenburger explained that in NAPP "the risk was about two-and-a-half-fold increased for diffuse large B-cell lymphoma with greater than two days exposure per year exposure to glyphosate. And both of these were statistically significant, and they did a trend analysis here and the trend analysis is also significant." *Id.* Weisenburger explained that NAPP adjusted for other pesticides, proxy respondents, age and a family history of NHL, among other things.

## 3. The Pilliods' Roundup® Use Far Exceeds the Exposure in the Epidemiological Literature

It is well-recognized that "[w]hile 'precise information concerning the exposure necessary to cause specific harm [is] beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic...and need not invariably provide the basis for an expert's opinion on causation." Clausen v. M/V NEW CARISSA, (9th Cir. 2003) 339 F.3d 1049, 1060.

Neither Plaintiffs' residential use of Roundup® nor the formulations used cast doubt upon the reliability of Plaintiffs' experts' opinions. The McDuffie (2001), Eriksson (2008), De Roos (2003), and NAPP studies—which Plaintiff's experts rely upon—each pulled cases from cancer registries that included both commercial and residential users. For example, the authors of McDuffie note the study

<sup>&</sup>lt;sup>5</sup> Dr. Nabhan did not consider the NAPP because it is not published yet, and he is not involved in the study.

"included individuals in many different occupations as well as home and garden users." Each Plaintiff mixed and used Roundup® in a method and manner consistent with the epidemiological literature where increased risk of NHL was associated with Roundup® exposure. Indeed, Monsanto fails to cite any case-control epidemiological study indicating that Plaintiffs' exposures fall below levels otherwise correlated with an increased risk of NHL following exposure to GBFs. In fact, the Pilliods' exposure greatly exceed the exposure of the participants in the epidemiology studies. For example, in Andreotti (2018), the median exposure to glyphosate was only 48 lifetime days, or eight years. Hoke Decl. Ex. 11. In the NAPP study (pooling De Roos (2003) and McDuffie (2008)), the participants used GBFs for an "average of 5 years and handled for an average of 5 days/year." Hoke Decl. Ex. 12 (NAPP manuscript at 12).

It is not true that occupational users have more intense exposure than residential users. Monsanto's own study shows that the single most important factor in reducing glyphosate exposure is wearing "rubber gloves when handling the pesticide formulation." Hoke Decl. Ex. 13 (Acquavella (2004) at 324). Alberta Pilliod never wore gloves, and Alva Pilliod only sometimes wore gloves due to Monsanto's failure to warn. It is entirely appropriate to rule in Roundup® as a possible cause of any individual's NHL where use and exposure conform to the epidemiological literature evincing increased risk. As noted above, ruling in Roundup® as a possible or potential cause of NHL is simply a step in any reliable differential diagnosis. Clausen, 339 F.3d at 1057 ("The first step [of a differential diagnosis] is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.").

# 4. A Doubling of the Risk is Not Required to Prove Specific Causation

First, even though Plaintiffs' experts *did* rely upon five epidemiological studies with statistically significant odds ratios above 2.0, California law is clear that the admissibility of a specific causation opinion under *Daubert* does not require such evidence. *Davis*, 245 Cal. App. 4<sup>th</sup> at 493 ("[t]here is no such requirement [for a relative risk of 2.0] in California."). Defendant's argument rests on a misreading of *Cooper*, and was rejected by both Judge Karnow and Judge Bolanos in the *Johnson v. Monsanto* trial. In *Cooper*, the issue was not whether epidemiology studies showing a doubling of the risk were required to prove specific causation, but rather whether those studies could be used to prove specific causation in the absence of a thorough differential diagnosis; a plausible mechanism of action; and animal carcinogenicity

<sup>&</sup>lt;sup>6</sup>McDuffie et al., Non-Hodgkin's Lymphoma and Specific Pesticide Exposures in Men: Cross-Canada Study of Pesticides and Health, 10 CANCER EPIDEMIOL, BIOMARKERS & PREVENTION 1155 (2001) at 1161; 8.

studies. The Court determined that a study reporting an odds ratio of 2.0 *could be* used as evidence of specific causation even in the *absence* of other evidence, not that it was required to be used. *Cooper* 239 Cal. App. 4<sup>th</sup> at 593. Under this correct interpretation of *Cooper*, Judge Karnow ruled that "[i]n the present case" where the experts rely on more than just epidemiology<sup>7</sup> "Johnson's experts may, if this case proceeds to trial, rely on relative risk ratios of lower than 2.0 and other considerations in support of their conclusion that Johnson's mycosis fungoides was caused by occupational exposure to Monsanto's products. Nothing in *Cooper* forecloses such an approach." Hoke Decl. Ex. 14 (5/17/18 Order re: Jury Instructions, p. 11).

As stated above, five studies show a statistically significant doubling of the risk of NHL or B-Cell Lymphoma. Confronted with the inconvenient fact that Plaintiffs' experts rely on two studies demonstrating an odds ratio above 2.0 *after* adjusting for other pesticides (De Roos 2003 and NAPP), Monsanto spends considerable effort attacking reliance upon the McDuffie and Eriksson studies. Under *Cooper*, an epidemiology study showing an odds ratio over 2.0 is admissible for specific causation even absent adjustment for other risk factors. In *Cooper*, the main study (Azoulay) showing a relative risk over 2.0 was admissible and relevant to causation even though it "lacked data on other occupational exposures, race, and family history of bladder cancer... and did not control for smoking based on the number of years the subject smoked, when they smoked, or how much they smoked." 239 Cal. App. at 588, n. 18.

Furthermore, while the McDuffie and Eriksson studies buttress the experts' opinions, they do not provide the sole basis for ruling in Roundup<sup>®</sup> as a cause for each Plaintiff's NHL. Weisenburger and Nabhan also rely on the other epidemiology studies, the mechanistic and animal studies, and a differential diagnosis in concluding that Roundup was a substantial factor in causing the Pilliods' NHL.

### 5. Plaintiffs' Experts Can Rely on Studies Looking at NHL as One Disease.

An expert may rely upon epidemiology looking at NHL as one disease to support a causation opinion on any NHL subtype. Judge Karnow ruled: "I reject Monsanto's argument that there is no scientific basis for Nabhan to rely on studies that apply to NHL generally in the context of mycosis fungoides. There is a scientific basis for Nabhan's opinion – mycosis fungoides is a subtype of NHL." Hoke Decl. Ex. 5 at

<sup>&</sup>lt;sup>7</sup>A relative risk of 2.0 is unnecessary where "Evidence of a pathological mechanism may be available for the plaintiff that is relevant to the cause of the plaintiff's disease" or if the agent is a tumor-promoter then the "relative risk from a study will understate the probability that exposure accelerated the occurrence of the disease." Reference Manual at 614-618. A "threshold increase in risk or a doubling in incidence in a group study in order to satisfy the burden of proof of specific causation is usually inappropriate." Restatement (3rd) of Torts: Liability for Physical and Emotional Harm, § 28 cmt. c (4).

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23; see also Ruff v. Ensign Bickford Industries, Inc., (D. Utah 2001) 168 F. Supp. 2d 1271 at 1285 (Holding Weisenburger's testimony admissible and stating "[T]hat plaintiffs' expert opinion need not include data showing studies of the exact subtype of plaintiffs' NHL to satisfy their general causation burden."). In Milward, 639 F.3d 11, the court held that it was error to exclude an expert opinion that was based on epidemiology of benzene and AML, where the injury was a rare subtype of AML, APL stating "the rarity of APL and difficulties of data collection in the United States make it very difficult to perform an epidemiological study of the causes of APL that would yield statistically significant results." Id. at 24.

Monsanto's assertion that Plaintiffs' experts failed to consider specific subtypes within the epidemiological studies is wrong. For example, Nabhan specifically stated:

Not all epidemiologic studies were able to look at subtypes of NHL when assessing epidemiologic causation. Some did but not all. This is understandable as the classification of NHL has evolved over the years and there are many new subtypes that have been recognized that were not known in the late 1990s or early 2000s. .. This shows that epidemiologic studies would rarely be able to investigate association between any occupational hazard and types of NHL. Add to this the rarity of PCNSL (1% of all NHLs), and we can conclude that studying epidemiologic evidence can be done for the entire disease category; in this instance NHL, analogous to studying epidemiology of other diseases where studying epidemiology is done as a whole as opposed to subtypes because smaller numbers might limit the ability to doing so...

Hoke Decl. Ex. 2 (Nabhan Rep. at 20-21). Weisenburger explained, "often there aren't enough cases of specific subtypes to really – to really do meaningful analyses. So they did it in the Eriksson study, but they – they didn't have a lot of cases of the various different subtypes then. So although you see elevated odds ratios, they – they generally aren't statistically significant..." Hoke Decl. Ex. 19 (Weisenburger Stevick Dep at 142:18-143:3). Weisenburger did explain that "if you have the data [on subtypes] you should look at it that way" which was why the NAPP study showing a doubling of the risk diffuse large b-cell lymphoma was important for him. Hoke Decl. Ex. 4 (Weisenburger Dep. at 201; 226-227). He also stated that the NAPP study showed elevated risks caused by Roundup® for all subtypes of NHL. Id.

#### 6. **Biological Markers Are Not Required to Demonstrate Specific Causation**

Ignoring Cooper, Monsanto argues that Plaintiffs' experts need to be excluded because they "have not pointed 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 causes." Def.'s Mot. at 10; *Id.* at 1. In *Cooper*, the Appeals Court rejected this exact argument that the experts should be excluded because there were "no physiological or biological markers to distinguish Mr. Cooper's bladder cancer from the myriad of bladder cancer patients

he treats with no known causes." 239 Cal. App. 4th at 576. It is this argument that Judge Chhabria found would prevent even a person showering in Roundup for twenty years from proving his/her case. *See supra*. The absence of a marker showing a cause of cancer is "neither unexpected nor unusual. If there were one such test, in all likelihood, our inquiry would be quite different. In and of itself, this point is not determinative, rather, reflects the medical and scientific dispute at hand." *In re Actos (Pioglitazone)Prods. Liab. Litig.*, 2013 U.S. Dist. LEXIS 179670 at \*39.

# 7. Weisenburger and Nabhan Properly Considered and Ruled Out Other Potential Causes of the Pilliods' NHL

Mrs. Pilliod: Weisenburger and Nabhan both conducted a thorough review of the Pilliods' medical and social history to determine if there were other plausible causes of their NHL. Nabhan personally examined Alberta Pilliod and noted the following factors in her medical history: a superficial bladder cancer diagnosed in 2010 with no chemotherapy or radiation; hypertension; hyperlipidemia; type II diabetes mellitus; history of hepatitis A (she believes sometime in the 1970s); genital and oral herpes; obesity; she takes synthroid (a medication for hypothyroidism); a father with prostate cancer; a sister with ovarian cancer; and she quit smoking in 1981. Hoke Decl. Ex. 2 (Nabhan Rep. at 8-11). She was diagnosed with diffuse large-B cell lymphoma of the central nervous system in April, 2015 at the age of 70. Id. at 6.

Nabhan discussed the potential causes of NHL considering idiopathic cause and age noting that these factors "do not preclude us, as clinicians, from investigating potential causative factors." *Id.* at 13. Nabhan stated that "PCNSL is an aggressive and rare form of NHL that is generally developed in immunocompromised patients. It is less likely diagnosed in immunocompetent individuals, such as Mrs. Pilliod. This highlights a further importance in attempting to find out why this patient probably developed this disease." *Id.* at 12-14. Nabhan, noted that Mrs. Pilliod was not on any immunotherapy drugs thought to cause NHL; had no "risk of potential viral pathogens" that are known to be causative factors for NHL; "There is nothing in Mrs. Pilliod's history to suggest a familial predisposition to her developing NHL." *Id.* at 12-14. Nabhan did note that he "was unable to completely rule out obesity as a possible contributing factor" however "such causative risk to Mrs. Pilliod would be negligible." *Id* at 21. Nabhan, found the evidence between obesity and NHL to be inconclusive, but nonetheless considered it as a potential factor. *Id.* at 15. Therefore, after ruling in and ruling out the relevant risk factors, Nabhan concluded that "that

RoundUp/Glyphosate was a substantial contributing factor to Mrs. Pilliod's development of NHL."

Weisenburger also went through all of the potential causative factors with Mrs. Pilliod through a review of her records and a telephone interview stating:

Mrs. Pilliod, we asked -- talked to her about her hypothyroidism, her diabetes. So we explored the -- some of the diseases that may be related to non-Hodgkin's lymphoma. I asked about other diseases that -- that they -- other diseases that are risk factors for non-Hodgkin's lymphoma which they didn't have, things like, you know, immunodeficiency, HIV infection. We talked about autoimmune diseases, family history, et cetera. So I tried to go through the sort of laundry list of - first of all, I dealt with the things that had already been identified in the medical record and then I went through a laundry list of other potential causes of non-Hodgkin's lymphoma

Hoke Decl. Ex. 4 (Weisenburger Dep. at 46:12-50:21) (also discussing bladder cancer, viruses, and obesity); Hoke Decl. Ex. 10 (Weisenburger Dep. Ex. 4). Like Nabhan, Weisenburger excluded other risk factors concluding that "Roundup was a substantial risk factor; whereas, obesity was a less substantial risk factor or a minor risk factor." Hoke Decl. Ex. 4 (Weisenburger Dep. at 136:10-12).

*Mr. Pilliod:* Mr. Pilliod was diagnosed with diffuse large B-cell lymphoma in June 2011 at the age of 69. Hoke Decl. Ex. 2 (Nabhan Rep. at 23). In Nabhan's personal examination of Mr. Pilliod and his review of the medical records, he noted a history of hemochromatosis; skin cancer, diverticulitis, meningitis, encephalitis, hepatitis A; other potential exposures to chemicals. *Id.* at 26. There was no family history of NHL, and he quit smoking in 1977. *Id.* at 26-27. Weisenburger also noted the same history and potential risk factors as Nabhan. Hoke Decl. Ex. 4 (Weisenburger Dep. at 46:12-53:10); Hoke Decl. Ex. 9 (Weisenburger Dep. Ex. 3). After ruling in and ruling out plausible causative factors, Nabhan concluded:

Although, I was unable to completely rule out ulcerative colitis and obesity as possible contributing factors, any causative risk to Mr. Pilliod would be minimal, especially as he never received any of the potent immunosuppressive therapies used to treat ulcerative colitis, and the major causative risk factor that Mr. Pilliod has and that was likely a substantial contributing factor to his developing NHL was her three decades of exposure to RoundUp/Glyphosate. Accordingly, It is my opinion that Mr. Pilliod's Roundup/Glyphosate exposure was the major and substantial cause of his NHL

Hoke Decl. Ex. 2 (Nabhan Rep. at 30). Weisenburger similarly concluded that "Some patients with ulcerative colitis do get non-Hodgkin's lymphoma, but it's probably related to the drugs they're treated with. So before the time that these drugs were used, there were studies that showed that people with ulcerative colitis don't have an increased risk of non-Hodgkin's lymphoma. So even if he had it, it wouldn't really affect in any way my opinion." Hoke Decl. Ex. 4 (Weisenburger Dep. at 114:21-115:4) Weisenburger, like Nabhan, concluded that Roundup and obesity were risk factors for Mr. Pilliod, stating

"we know that their [the Pilliods'] risk [from Roundup] was at least twofold, over a twofold increase. Okay? Whereas, with obesity, it was really about a 30 percent increase. So, you know, my judgment was that Roundup was a substantial risk factor; whereas, obesity<sup>8</sup> was a less substantial risk factor or a minor risk factor." *Id.* at 128:5-129:4; 136:6-12.

The opinions of Weisenburger and Nabhan go well beyond the requirements in *Cooper* and therefore their opinions are admissible under well settled California law.

# B. Defendants Fail to Point to Substantial Evidence of an Alternative Explanation for the Pilliods' NHL Ignored by Plaintiffs' Experts

Defendants' simply ignore the holding in *Cooper* that they need to provide substantial evidence of an alternative cause not considered by Plaintiffs' experts that would defeat Plaintiffs' claim in order to challenge the admissibility of their opinions. Defendants have wholly failed to carry that burden. Defendants can't simply proffer alternative causes based on their attorneys' say-so without citing expert testimony to back up those claims. This tactic was expressly rejected in *Cooper*. 239 Cal. App. 4th at 585–86. The possible causes floated by Monsanto mirror those floated by the Defendant in *Cooper*. *Id*. at 569, 574, 586 (Defendant claimed that expert failed to consider renal insufficiency; power lines; possible exposures in the Army or at work; skin cancer; diabetes; age; race; gender; second-hand smoke; and idiopathic causes): *Id*. at 596 ("Dr. Smith says that he has a lot of patients in this age group who have bladder cancer, and he can find no cause."). In *Cooper*, the expert considered hypotheses proffered by Defendants at deposition and trial and properly rejected them. *Id*. at 568. (Expert disagree with theory that renal insufficiency "directly contribute to the incidence of bladder cancer"); *Id*. (Disagreeing that diabetes caused cancer although "there were some papers indicating a slight risk associated with diabetes.")

In reversing the trial court's exclusion of Plaintiff's expert in *Cooper for* not considering remote suggestions made by the Defendants the Appellate Court stated:

Takeda introduced no substantial evidence to indicate that he had [been exposed to other risk factors]; it only raised the speculation that he might have...That is the critical point: Takeda cannot point to any substantial evidence to indicate that another cause of bladder cancer, other than Actos®, was ignored by Dr. Smith, such that his opinion was unreliable....Bare conceivability of another possible cause does not defeat a claim; the relevant question is whether there is "substantial evidence" of an alternative explanation for the disease. *Cooper*, 239 Cal. App. 4th at 585–86.

<sup>&</sup>lt;sup>8</sup> Defendant claims that Nabhan and Weisenburger ruled out obesity as contributing to the Pilliods' NHL. That is incorrect.

Defendants seek to conflate association with causation based on isolated data points. However, an increased odds ratio between an exposure and outcome in one or two studies does not demonstrate causality. Bradford-hill mandates consideration of the totality of the data including biological plausibility and coherence. As Nabhan explained to Defense Counsel:

if something is associated with a particular event, it doesn't always mean that it's causing that event. When you talk about 2,4-D or Roundup or glyphosate, these are occupational or residential hazards that are known to cause, you know, problems or genotoxicity, and they have shown to have – to cause the development of particular tumors in animal studies... this type of association, given the other body of evidence that has demonstrated on the cellular level, animal level, as well as in epidemiologic human studies is very strong....Family history or age and other things, these are certain things that are association but not causation. Hoke Decl. Ex. 7 (Nabhan Dep. at 237-238)

Prior History of Cancer: Neither of Plaintiffs' experts ignored the Pilliods' history of prior cancer. Both experts noted their prior histories of cancer during their interviews. However, neither expert believes that the Pilliods' history of cancer caused their NHL. Defendants offer no evidence that Mrs. Pilliod's history of bladder cancer caused her NHL. Defendants point to one odds ratio where a history of cancer in general was associated with increased NHL. As Weisenburger notes, chemotherapy is a cause of NHL, so it makes sense that a history of cancer would be associated with NHL, but not because the cancer caused the NHL, but rather because the chemotherapy caused the NHL. Hoke Decl. at Ex. 4 (Weisenburger Dep. at 147:5-9). Mrs. Pilliod never received chemotherapy for her bladder cancer and that it why Nabhan placed emphasis on the fact that the bladder cancer was superficial. Defendants' expert makes no claim that Mrs. Pilliod's bladder cancer contributed to her NHL; only Monsanto's attorneys do.

Plaintiffs' experts with decades of scientific training disagree with Monsanto's attorneys that a prior history of cancer contributed to the Pilliods' NHL. Nabhan explained "[w]hen you talk about the totality of evidence, in my opinion, would be inconclusive and is not supported because we just agreed we have to look at the totality of evidence, not at one paper or another." Hoke Decl. Ex. 7 (Nabhan Dep. at 349:1-5). As Nabhan notes, "[a]n association between non-melanoma skin cancer and a second primary could be the result of many factors, including adverse toxic effects of treatment, shared etiologic factors, random effect, false associations." *Id.* 334:21-335:4. Nabhan states the shared etiologic factors include outdoor work where people are exposed to other causative factors for NHL such as pesticides. *Id.* at 334:8-13; 342:13-21. Nabhan concludes that "to me, it doesn't really suggest that the non-melanoma skin cancer, such as basal cell skin cancer or squamous cause non-Hodgkin lymphoma." *Id.* at 335:17-21.

Weisenburger explained that he does not believe it is a cause of NHL because "[T]here's no biological plausibility to how a skin cancer, which is due to ultraviolet light from sun -- from sun, would be a cause of a non-Hodgkin's lymphoma." Hoke Decl. Ex. 4 (Weisenburger Dep. at 189:13-16). He further stated we "really don't know what it is about people who spend a lot of time in the sunlight... what other practices they have that might increase their risk for non-Hodgkin's lymphoma." *Id.* at 190:1-4.

Family History of Cancer: Again Defendant points to no evidence and have no expert that suggests that the history of prostate cancer and ovarian cancer in Mrs. Pilliod's family has anything to do with her NHL. All Defendant can point to is an elevated association between family history of cancer in general and NHL in one study. That is not substantial evidence. Hoke Decl. at Ex. 7 (Nabhan Dep. at 381:12-382:20). Weisenburger stated that "you have to understand more about the data than just one data point...You can't generalize from one study[] and make a conclusion...it's dangerous to do that" Hoke Decl. Ex. 4 (Weisenburger Dep. at 144-145). He explained that:

So most studies look at hematopoietic cancer, which is lymphoma, leukemia, myeloma. If you have a family history in a first-degree relative of one of those related hematologic malignancies, the risk is about twofold increase. If you separate that — other cancers out, usually there isn't much of an increase. So this [the one data point] is probably driven, although we don't know, it's probably driven by hematologic malignancies and not breast cancer or lung cancers or other cancers...

*Id.* at 145:7-17. For the same reason Nabhan found no risk for the Pilliods from family history because no family members had NHL. Hoke Decl. Ex. 2 (Nabhan Rep. at 13, 26).

Hashimoto's Disease: There is no confirmation that Mrs. Pilliod has Hashimoto's disease (a cause of a deficiency in thyroid hormones); and in any event it would not affect either Nabhan or Weisenburger's opinion. Hoke Decl. Ex. 7 (Nabhan Dep. at 201:1-203:24). Nabhan noted that Mrs. Pilliod was taking Synthroid as a supplement for hypothyroidism, but noted that Hashimoto's is not the only cause of hypothyroidism. *Id.* Defendant again points to only on data point on Hashimoto's and NHL showing an odds ratio of 1.4. Dr. Bello, Monsanto's expert, does not consider Hashimoto's to be a risk factor for Mrs. Pilliod's NHL. Nabhan likewise did not consider Mrs. Pilliods' thyroid problems (that might be caused by Hashimoto's) to be a causative or risk factor of NHL. 153:6-154:9. Weisenburger explained that the literature on Hashimoto's and NHL was "scant." Hoke Decl. Ex. 4 (Weisenburger Dep. at 120:17). Weisenburger explained why Hashimoto's is not a risk factor for Mrs. Pilliod's NHL:

when you look into that literature carefully, the increased risk is for NHL involving the thyroid

gland. It's not for NHL overall. So the autoimmune disease attacks the thyroid gland, you get inflammation in the thyroid gland, and then you get lymphoma of the thyroid gland. And so the risk of lymphoma in Hashimoto's is primarily for lymphoma of the thyroid...*Id.* at 118:23-119:8.

HPV: Neither Weisenburger nor Nabhan consider HPV to be a cause of NHL. The Nordenvall and Blomberg studies are outliers as Nordenvall specifically states that previously, "Neither Hodgkin, nor non-Hodgkin lymphoma, has been associated with HPV." Hoke Decl. Ex. 15. Nabhan did not recoil when seeing the outlier study, instead he reasonably questioned whether the study adjusted for HIV status stating, "I don't agree with that data. It could be a surrogate to these people having HIV. If you have genital warts, maybe you have higher risk behavior that might lead to having HIV." Hoke Decl. Ex. 7 at 326:4-25 (HIV is a known cause of NHL). In fact, upon closer look at the paper, Nabhan's concern was confirmed as the authors state that "[t]he observing of higher risks of HPV-related cancers among men than among women may be confounded by male homosexual behavior. This possibility is supported by the sex-specific period prevalences of HIV infection in the cohort between (1% among men vs. 0.2% among women)." *Id.* at 399:5-19. This explanation proved Nabhan's point that:

it's not really a direct correlation. It's not a direct causation that HPV causes the cancer, which is different than anal cancer and different than head and neck cancer where we actual have evidence that HPV causes these cancers. In this situation, you have to think of other aspects of the person's behavior that might lead to immunocompromised state or might lead to HIV, et cetera, none of which Mr. and Mrs. Pilliod had." *Id.* at 400:6-15.

Weisenburger like, Nabhan, explained that you have to look at the data stating:

So, again, you know, it's an association where you'd like to say, now, how does that -- how do I explain that? How does that make sense?...And so you wonder whether this increase in males, but not in females, is mainly driven by homosexual men. Okay? And they do discuss that, actually, and raise that as an issue in the discussion. And homosexuals, as you know, are at increased -- at increased risk for non-Hodgkin's lymphoma. Weisenburger Dep. At 182:13-183:16.

He concluded "do we think genital warts causes non-Hodgkin's lymphoma? I would say no." 185:11-16.

**Smoking:** Nabhan doesn't rule out smoking based on subjective belief. He is an oncologist specializing in NHL who has studied the causes of NHL for decades. Smoking and its relation to all cancer has been extensively studied and smoking simply does not cause NHL. Defendants' experts make no claim that smoking causes NHL. Dr. Gupta, the Pilliods' treating physician and oncologist states that smoking does not cause NHL. 377:17-378:12. Weisenburger states that "[t]here's no general acceptance" that smoking causes NHL, and points out that only one subtype of NHL in women (that Mrs. Pilliod does not have) has been shown to be associated with smoking. 200:18-24. Nabhan is correct that no expert would

conclude that smoking played a role in the Pilliods' NHL. Defendant certainly provides no substantial evidence that it could have played a role.

**Teaching:** Defendants' own expert disavows that teaching is a cause of Mrs. Pilliod's NHL stating that some studies "showed an association, but I wouldn't say it was like a cause" explaining that "being exposed to kids and having certain infections" might be a factor or "that maybe these people had something going on with their immune system and being a schoolteacher played a role in that, but I have -- I have no idea." Hoke Decl. Ex. 17 (Bello Dep. at 56:12-57:5).

Likewise, Nabhan does not agree that being a teacher is a causal risk factor stating:

whenever you suggest that teachers are going to simply -- just by being a teacher you are going to have an increased risk of a particular cancer, ... the authors acknowledge the limitation I stated earlier in my testimony, which is that, you know, the job itself, the title of the job is not necessarily the issue here, but maybe there are other problems that we need to investigate. Hoke Decl. Ex. 7 (Nabhan Dep. at 404:23-405:13).

Nabhan did investigate whether Mrs. Pilliod had any of the viruses or infections that could have caused her NHL and she did not. Weisenburger testified that "there are a few papers that show that teachers have an increased risk, but there are lots of papers that show that lots of occupations have increased risk. So there's no generally accepted idea that teachers are at increased risk for non-Hodgkin's lymphoma." Hoke Decl. Ex. 4 (Weisenburger Dep at 196:3-80). He further explained that if "you read their conclusions" in the study on teachers the authors "dismiss" the association as a causative factor and "give some other reasons why it might be increased." 197:22-198:5. Defendants fail to provide any evidence of an exposure Mrs. Pilliod might have experienced during her tenure as a school teacher that may have been a cause of her NHL. *Cooper* 239 Cal App. 4<sup>th</sup> at 582 (rejecting Defendants' speculation that plaintiff "may have had any exposures at his work associated with bladder cancer, and whether he may have had exposure to anything during his Army service.").

**Age:** Like occupational exposure, Defendants pulls a tactic out of the Takeda playbook, which was rejected in *Cooper*, by arguing age was the cause of the Pilliods' NHL. It is Nabhan's opinion that "Age doesn't cause cancer. Age is a surrogate. The older we live, the more likely we would be exposed to carcinogens. The more likely we would be exposed to materials that, if we are younger, we are not exposed to. So we can't really say age is causing cancer." Hoke Decl. Ex. 7 (Nabhan Dep. at 238:10-19). Nabhan thus took a detailed history from the Pilliods to determine what potential carcinogens the Pilliods were

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exposed to during their lifetime. Id. at 238:14-19. Weisenburger likewise does not considers age a causative risk factor. Hoke Decl. Ex. 4 (Weisenburger Dep. at 186:1-25). All of the epidemiology studies involving Roundup® and NHL adjust for age, so the increased risks apply regardless of a persons' age. Hoke Decl. Ex. 2 (Nabhan Rep. 17-19); Weisenburger Dep. at 227:17-229:1 (NAPP study).

In the Stevick case, Nabhan was consistent in his opinion in opining that Roundup was a substantial factor in another woman in her 60s who developed PCNSL stating that "in her situation because she has other risk factors as we are going to go through, I presume, in terms of exposure to Roundup, but in her particular situation, you can't state or assume that age by itself was the reason for why she developed this disease." Hoke Decl. Ex. 18 (Nabhan Stevick Dep. 18:1-9). This exact issue arose in *Cooper* where the expert did not consider age to be a causative risk factor, but rather a demographic risk factor. The Court held "we find adequate Dr. Smith's explanation that describing these things as risk factors or demographics is a matter of semantics. Importantly, however, Dr. Smith stated that all of the epidemiological studies upon which he relied had adjusted for age, sex, and race." Cooper 239 Cal. App. 4<sup>th</sup> at 587.

**Idiopathic Causes:** Monsanto claims that no expert could ever conclude that Roundup is a cause of anyone's NHL because the causes of most people's NHL is unknown. This circular reasoning was rejected in Cooper. The trial court in Cooper excluded plaintiff's expert based on the acknowledgments that "he has a lot of patients in this age group who have bladder cancer, and he can find no cause" and "there are so many possible causes and so much still unknown about the causation of bladder cancer." .]239 Cal. App. 4th at 585, 593. The Appeals court reversed, holding that "[b]are conceivability of another possible cause does not defeat a claim." Id. at 586. Judge Karnow, in denying Monsanto's motion to exclude the opinion of Nabhan, noted that "[i]diopathy need not be entirely ruled out, but there needs to be an explanation as to why an identified cause is considered likely... Nabhan admitted that he could not rule out other contributing factors; but he is not required to do so." Hoke Decl. Ex. 5 at 25. Wendell is also instructive on this point. In Wendell, held that the trial court abused its discretion when "it excluded Plaintiffs' experts' opinion testimony because of the high rate of idiopathic [unknown] HSTCL and the alleged inability of the experts to rule out an idiopathic origin or IBD itself." 858 F. 3d at 1237. Holding that "[i]t is enough that the proposed cause 'be a substantial causative factor.' This is true in patients with multiple risk factors, and analogously, in cases where there is a high rate of idiopathy..." Id.

Plaintiffs' experts do not dispute that they are unable to identify a cause of NHL in many patients. However, that doesn't invalidate their opinions that Plaintiffs' NHL was not idiopathic. Nabhan explained:

The majority of NHL cases have no known identifiable cause. This however does not mean that all cases of NHL have no cause. ...In reaching my opinions in this case, I specifically considered whether this was a case of idiopathic NHL, however, I was able to rule out idiopathy as there is evidence that Mrs. Pilliod had substantial exposure to a known causative risk factor for NHL.

Nabhan Rep. 12, 21. In *Wendell*, Weisenburger stated "[W]hen you have a patient with obvious and known risk factors, you tend to assume that those risk factors were the cause." 858 F. 3d at 1235. This is particularly true where five studies show a doubling of the risk of NHL for Roundup® users.

#### C. Plaintiffs' Experts Faithfully Applied their Methodology

In sum, Nabhan, and Weisenburger have impeccable qualifications and did not engage in outcome driven methodologies in reaching their conclusions here. Where there was an association, these experts considered whether the association was biologically plausible or confounded as is required under Bradford-Hill. Plaintiffs' experts do consider the evidence that Roundup causes NHL to be strong. Plaintiffs' opinions are supported by the authoritative scientific body IARC, the unanimous jury in the Johnson trial, the State of California, the three members of the EPA SAP panel that just published a meta-analysis finding a compelling link between Roundup® and NHL.

#### III. CONCLUSION

For the aforementioned reasons, Monsanto's motion should be denied.

DATED: February 21, 2019 Respectfully submitted,

#### THE MILLER FIRM, LLC

By: /s/ Curtis G. Hoke

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