Sandra A. Edwards (State Bar No. 154578)
Joshua W. Malone (State Bar No. 301836)
Farella Braun + Martel LLP
235 Montgomery Street, 17th Floor
San Francisco, CA 94104
Telephone: (415) 954-4400
Fax: (415) 954-4480
sedwards@fbm.com
jmalone@fbm.com

Joe G. Hollingsworth (appearance *pro hac vice*)
Eric G. Lasker (appearance *pro hac vice*)
Kirby T. Griffis (appearance *pro hac vice*)
Hollingsworth LLP
1350 I Street, N.W.
Washington, DC 20005
Telephone: (202) 898-5800
Fax: (202) 682-1639
jhollingsworth@hollingsworthllp.com
elasker@hollingsworthllp.com
kgriffis@hollingsworthllp.com

Attorneys for Defendant
MONSANTO COMPANY

K. Lee Marshall (State Bar No. 277092)
Bryan Cave Leighton Paisner LLP
Three Embarcadero Center, 7th Floor
San Francisco, California 94111-4070
Telephone: 415-675-3400
Fax: 415-675-3434
klmarshall@bclplaw.com

George C. Lombardi (appearance *pro hac vice*)
James M. Hilmert (appearance *pro hac vice*)
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601
Telephone: (312) 558-5969
Fax: (312) 558-5700
glombard@winston.com
jhilmert@winston.com

Attorneys for Defendant
MONSANTO COMPANY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY,

Defendant.

Case No. CGC-16-550128

[PROPOSED] ORDER GRANTING MONSANTO COMPANY'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

Hon. Judge Suzanne R. Bolanos

Hearing Date:	October 10, 2018
Time:	2:00 p.m.
Department:	504
Trial Date:	June 18, 2018

BACKGROUND

I. BRIEF OVERVIEW OF CASE

This case involves the trial of design defect and failure to warn claims asserted by Dewayne Johnson ("Plaintiff") alleging that his exposure to glyphosate and glyphosate-based herbicides ("GBHs") developed by Monsanto Company ("Monsanto") caused him to develop mycosis fungoides ("MF"), a subtype of non-Hodgkin's lymphoma ("NHL").

Plaintiff testified he first began using GBHs, at the earliest, in June 2012. In October 2014, Plaintiff was diagnosed with MF. Plaintiff stopped using GBHs in approximately January 2016. The parties stipulated to a trial date of June 18, 2018, and trial commenced on that date.

Among other things, this case required the jury to resolve the complex scientific question of whether Plaintiff's exposure to GBHs caused his MF. Both sides presented expert testimony about the science underlying GBHs. The evidence introduced by Plaintiff's experts focused largely on epidemiology studies and an IARC Monograph published in March 2015, along with various animal and genotoxicity studies. Plaintiff proffered Dr. Portier, a biostatistician; Dr. Neugut, an epidemiologist; Dr. Nabhan, an oncologist; and Dr. Sawyer, a toxicologist, to testify about various aspects of the science underlying GBHs. As discussed below, Dr. Nabhan, who proffered a differential diagnosis opinion, formed the linchpin of Plaintiff's case that his exposure to GBHs caused his cancer.

Monsanto proffered Dr. Mucci, an epidemiologist; Dr. Foster, a toxicologist; Dr. Kuzel, an oncologist; and Dr. al-Khatib, a weed scientist.

Both parties designated the deposition testimony of several factual witness, including scientists involved with the evaluation of GBHs' safety and regulatory approval. The evidence showed that Monsanto has produced GBHs in the United States and much of the rest of the world for decades, and that glyphosate has developed one of the largest bodies of scientific data of any substance in the world. Before and after IARC's classification of glyphosate as a "probable" human carcinogen, regulatory and public health agencies worldwide have reviewed and rejected claims about the carcinogenicity of GBHs.

During trial, Monsanto timely moved for nonsuit and a directed verdict, both of which

were denied. The jury was instructed, among other things, on CACI 1203 (Strict Liability-Design Defect-Consumer Expectation Test-Essential Factual Elements), CACI 1205 (Strict Liability-Failure to Warn-Essential Factual Elements), and CACI 1222 (Negligence-Manufacturer or Supplier-Duty to Warn-Essential Factual Elements). The jury was also given CACI 430 (Causation: Substantial Factor). The jury concluded its deliberations on August 10, 2018, and found in favor of Plaintiff, awarding economic loss in the amount of $2,253,209.35; noneconomic loss in the amount of $37,000,000.00; and punitive damages in the amount of $250,000,000.00.

Notice of this Motion for JNOV was timely filed, and the Motion was argued concurrently with Monsanto's Motion for New Trial.

ANALYSIS

II. LEGAL STANDARD FOR JNOV

"The court … shall render judgment in favor of the aggrieved party notwithstanding the verdict whenever a motion for a directed verdict for the aggrieved party should have been granted had a previous motion been made." Cal. Civ. Proc. Code § 629(a). The power to grant judgment notwithstanding the verdict is the same as the power to grant a nonsuit or directed verdict, all of which are based on the legal sufficiency of the evidence. *Beavers v. Allstate Ins. Co.*, 225 Cal. App. 3d 310, 327-28 (1990). A party is entitled to JNOV when "giving to the plaintiff's evidence all the value to which it is legally entitled and indulging in every legitimate inference which may be drawn from that evidence, the result is a determination there is no evidence of sufficient substantiality to support" the jury's verdict. *Dell'Oca v. Bank of New York Tr. Co.*, 159 Cal. App. 4th 531, 548 (2008). "Substantial evidence is not synonymous with 'any' evidence. To constitute sufficient substantiality to support the verdict, the evidence must be reasonable in nature, credible, and of solid value; it must actually be substantial proof of the essentials which the law requires in a particular case." *Osborn v. Irwin Mem'l Blood Bank*, 5 Cal. App. 4th 234, 284 (1992) (internal citation and quotations omitted). The plaintiff must "produce evidence which supports a logical inference in his favor and which does more than merely permit speculation or conjecture." *Jones v. Ortho Corp.*, 163 Cal. App. 3d 396, 402 (1985).

III. THE EVIDENCE OF CAUSATION WAS NOT LEGALLY SUFFICIENT.

All of Plaintiff's claims require him to prove by a preponderance of the evidence that his use of GBHs was a "substantial factor" in causing his harm. *E.g. Lockheed Litig. Cases*, 23 Cal. Rptr. 3d 762, 773–74 (Cal. App. 2005), *review dismissed*, 192 P.3d 403 (Cal. 2005). California law recognizes that such proof is "especially troublesome" in cases alleging cancer as the injury, because "it is frequently difficult to determine the nature and cause of a particular cancerous growth." *Jones*, 163 Cal. App. 3d at 403. The law thus applies guiderails that prohibit finding liability where causation is merely medically "possible" but does not rise to the level of "reasonable medical probability." *Id.* "A possible cause only becomes 'probable' when, in the absence of other reasonable causal explanations, it becomes more likely than not that the injury was the result of its action. This is the outer limit of inference upon which an issue may be submitted to the jury." *Id.* Under this standard, "[a] less than 50-50 possibility that defendants' omission caused the harm does not meet the requisite reasonable medical probability test of proximate cause." *Simmons v. W. Covina Med. Clinic*, 212 Cal. App. 3d 696, 702–03 (1989). If the probabilities "are at best evenly balanced, *it becomes the duty of the court to direct a verdict for the defendant*." *Jennings v. Palomar Pomerado Health Sys., Inc.*, 114 Cal. App. 4th 1108, 1118 (2003) (citation omitted).

Plaintiff's evidence that his NHL was caused by his exposure to GBHs was based on the testimony of Dr. Nabhan, a former practicing oncologist.[1] Dr. Nabhan elected to conduct a type of causation analysis known as a differential diagnosis, or differential etiology, in reaching the opinion that GBHs caused Plaintiff's NHL. "In performing a differential diagnosis, a physician begins by 'ruling in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains. The final result of a differential diagnosis is the expert's conclusion that a defendant's product caused (or did not cause) the plaintiff's injury." *Glastetter v. Novartis Pharms. Corp.* 252 F.3d 986, 989 (8th Cir.

[1] Plaintiff also presented Dr. Sawyer to discuss Plaintiff's use of GBHs. Dr. Sawyer did not provide an exposure dose, but testified that Plaintiff's days of exposure "puts him approximately in the middle of the human epidemiology studies that show human cancer. He falls in the middle of the exposure categories…." Tr. at 3674:25-3675:13.

Farella Braun + Martel LLP
235 Montgomery Street, 17th Floor
San Francisco, California 94104
(415) 954-4400

2001); *see also Cooper v. Takeda Pharms. Am., Inc.*, 239 Cal. App. 4th 555, 593-594 (2015). To be legally sufficient under the differential-diagnosis framework, there must be proof (1) that GBHs can be validly "ruled in," and (2) that every substantial cause supported by evidence can be "ruled out." *Id.* at 585-86, 593-94.

A. Dr. Nabhan Did Not Have a Basis to "Rule In" GBHs.

In conducting a differential diagnosis, Dr. Nabhan was required first to establish that GBHs are a probable cause of NHL. Without establishing that fact, he could not "rule in" GBHs as a probable cause of Plaintiff's cancer. *Cooper,* 239 Cal. App. 4th at 585-86, 593-54. However, the evidence presented at trial was insufficient to rule in GBHs as a cause.

1. The Epidemiology Did Not Provide a Basis to "Rule In" GBHs.

The principal basis that Dr. Nabhan articulated for "ruling in" GBHs involved epidemiology studies. As Dr. Nabhan and other experts explained, epidemiology investigates whether individuals' real-world exposures to a product (here GBHs) are associated with an outcome (here NHL). Epidemiology is "the best evidence of general causation in a toxic tort case." *Norris v. Baxter Healthcare Corp*., 397 F.3d 878, 882 (10th Cir. 2005). "While the presence of epidemiology does not necessarily end the inquiry, where epidemiology is available, it cannot be ignored. As the best evidence of general causation, it must be addressed." *Id*.

Cooper explained the significance of epidemiology in the context of a differential diagnosis. The Court of Appeals observed: "When statistical analyses or probabilistic results of epidemiological studies are offered to prove specific causation ... under California law those analyses must show a relative risk greater than 2.0 to be 'useful' to the jury." 239 Cal. App. 4th at 593 (citing *Daubert v. Merrell Dow Pharms. Inc.* 43 F.3d 1311 (9th Cir. 1995)). "This is so, because a relative risk greater than 2.0 is needed to extrapolate from generic population-based studies to conclusions about what caused a specific person's disease." *Id.* "When the relative risk is 2.0, the alleged cause is responsible for an equal number of cases of the disease as all other background causes present in the control group. Thus, a relative risk of 2.0 implies a 50% probability that the agent at issue was responsible for a particular individual's disease." *Id.* The

court concluded that the studies warranted "ruling in" the drug Actos where they "resulted in hazard ratios for developing bladder cancer ranging from 2.54 to 6.97." *Id.* at 593.

In this case, the epidemiology evidence was insufficient to rule in GBHs. Most significantly, Plaintiff conceded that the epidemiology was insufficient. Summarizing the testimony of his expert witnesses during closing argument, Plaintiff's counsel admitted: "Nobody is saying it gets you there. Nobody. Dr. Portier, Dr. Neugut, nobody says it gets you there, and IARC themselves concluded it was limited." Tr. at 5072:16-20. Dr. Portier testified: "I can't conclude it's causal". Tr. at 1964:13. "[T]he effects are small," ,"I can't really rule out chance," "I can't rule out that there aren't confounders," Tr. at 1965:1-7, and "you can't make a firm statement about glyphosate from the epidemiology data alone." Tr. at 1964:2-3. Dr. Neugut, Plaintiff's principal epidemiology expert, agreed that "the epidemiology alone is not sufficient to show a causal link." Tr. at 2679:1-5; 2736:25-2737:3.

By Plaintiff's admission, the epidemiology studies did not show a statistically significant risk exceeding the 2.0 level. It was undisputed that the largest and most recent study (the 2018 NCI cohort study) found no association between GBH use and NHL overall or any of its subtypes. Dr. Neugut presented a Forest plot showing the results of several other studies; however, he admitted that none of the results that he presented on this plot identified a statistically significant association between GBHs and NHL. *See e.g., Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 681 (M.D.N.C. 2003) ("Statistically insignificant results do not constitute proof that Parlodel causes stroke."). Dr. Neugut also testified that a meta-analysis of multiple studies identified a statistically significant result at a 1.3 to "possibly" 1.5 level, which he stated was "modest." Tr. at 2612:22-2613:12; 2645:18. During oral arguments on post-trial motions, Plaintiff's counsel agreed that the overall risk level was 1.5 or a "50% increased risk." JNOV Hrg. Tr. at 56:15-17. Even if the Court were to find that substantial evidence supported a 1.5 risk level, that level is significantly less than the required 2.0. *Cooper*, 239 Cal. App. 4th at 593-94 ("[*A] relative risk that is greater than 2.0 permits the conclusion that the agent was more likely than not responsible for a particular individual's disease*"); *Daubert*, 43 F.3d at 1321 (explaining "[a] relative risk of

less than two may suggest teratogenicity, but it actually tends to *dis*prove legal causation") (emphasis added).

Dr. Nabhan also discussed epidemiology as the basis for "ruling in" GBHs. However, Dr. Nabhan, who is not an epidemiologist, discussed only a few epidemiology studies. One of the studies he did not discuss was the 2018 NCI study. Although Dr. Nabhan cited three studies he contended showed a doubling of the risk, every study Dr. Nabhan considered was also considered by Dr. Portier and Dr. Neugut, and was therefore part of their conclusions that the epidemiology is insufficient to establish causation. Furthermore, Dr. Nabhan admitted that two of the three studies he presented were not adjusted for other pesticides, making them legally incapable of showing any specific risk for GBHs. *See, e.g., In re Lockheed Litig. Cases*, 23 Cal. Rptr. 3d at 774 ("We conclude that the multiple-solvent studies provide no reasonable basis for an opinion that any of the solvents here at issue can cause disease."). In the third study, De Roos (2003), the authors published two alternative analyses for GBHs, one of which showed a non-statistically significant risk ratio of 1.6. In light of the admissions of Plaintiff's counsel and the conclusion of Plaintiff's expert epidemiologist about a 1.3-1.5 risk, and the totality of the evidence, the single analysis in De Roos (2003) cited by Dr. Nabhan is not substantial evidence of a statistically significant doubling of the risk.[2] *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986*), aff'd sub nom. Wheelahan v. G D Searle & Co.*, 814 F.2d 655 (4th Cir. 1987) ("Neither of these risk figures indicate a two-fold risk, and the 1.3 figure is well below the two-fold risk level.").

Plaintiff relies on the Ninth Circuit's *Daubert* ruling in *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017), for the proposition that an expert can validly rule in a chemical as a potential cause in the absence of supporting epidemiology. However, *Wendell* involved a different situation where no epidemiology existed for an extremely rare disease. *Id.* at 1236. In the absence of epidemiology, the court allowed experts to "rule in" a drug by calculating risk ratios from specific case reports linking the disease with the drug, where the drug was a well-known carcinogen, there was a tiny probability of getting the disease without the exposure, and the

[2] De Roos (2003) was one part of the data set involved in the largest meta-analysis Dr. Neugut relied upon for his bottom-line conclusion about a 1.3 to 1.5 risk ratio.

Farella Braun + Martel LLP
235 Montgomery Street, 17th Floor
San Francisco, California 94104
(415) 954-4400

manufacturer's FDA-approved label acknowledged the cancer risk. *Id.* at 1230, 1234-36. Here, by contrast, epidemiology literature *does* exist, and it was the primary basis for Plaintiff's causation arguments. To argue that epidemiological studies are not required to establish causation is unpersuasive given they were utilized for such a purpose, and where they failed to show a legally significant risk level.

Finally, even assuming it would be appropriate to consider a risk level of below 2.0 for assessing specific causation, Plaintiff did not present evidence that distinguished Plaintiff from the individuals in the epidemiology studies. On the contrary, Plaintiff's expert Dr. Sawyer concluded that Plaintiff fell within the "middle" of the epidemiology studies. Because the epidemiology studies show at most a legally insufficient 1.5 risk, and Plaintiff failed to distinguish himself from the average person in those studies, he cannot demonstrate a greater individual risk than shown in the admittedly insufficient epidemiology literature. Thus, as a whole, the epidemiology refutes, rather than proves, specific causation, and does not provide substantial evidence of causation to support the verdict.

2. The Animal and Mechanism Studies Provided No Basis to "Rule In" GBHs.

Plaintiff argues that the combination of epidemiology data with animal studies and mechanism (genotoxicity) studies was sufficient to rule in GBHs. The Court disagrees that the animal or mechanism studies constitute legally sufficient evidence of causation.

In order for animal studies to be probative of specific causation, there must be a showing justifying the extrapolation between the species, dosage, and diseases in question to humans, and thus, to Plaintiff's cancer. In *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-45 (1997), for example, the Supreme Court affirmed the exclusion of animal data where an expert failed to adequately extrapolate disease from rodent to humans. In *Lockheed Litig. Cases*, 23 Cal. Rptr. 3d at 779-80, the Court of Appeals ruled that animal data was legally insufficient where the expert did not account for the differences in dosage or species. Likewise, there must be an evidentiary basis to link the results of genotoxicity or mechanism studies to human cancers. *In re Accutane Prod. Liab.*, 511 F. Supp. 2d 1288, 1294–95 (M.D. Fla. 2007) ("The problem with this approach is also

extrapolation-whether one can generalize the findings from the artificial setting of tissues in laboratories to whole human beings." (citation omitted)).

Here there was not substantial evidence to support extrapolation. Plaintiff's experts did not offer testimony accounting for the differences between those studies and Plaintiff's cancer, including the differences in biology, dosage, route of exposure, or in the diseases they suffered. Consequently, Plaintiff did not present a substantial basis for linking these studies to human cancer generally or Plaintiff's MF specifically. *Lockheed Litig. Cases*, 23 Cal. Rptr. 3d at 779-80.

3. IARC Did Not Provide a Basis to "Rule In" GBHs.

Finally, Dr. Nabhan testified that IARC's classification of glyphosate as a probable human carcinogen was a basis for ruling GBHs into his differential diagnosis. The Court disagrees. IARC conducted a generic *hazard* assessment. IARC inquired whether glyphosate had a capacity to cause NHL "at any hypothetical dose," rather than assess a human *risk* at relevant exposures. *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2018 WL 3368534, at *5 (N.D. Cal. July 10, 2018). As Judge Chhabria has observed, "IARC conducts its inquiry at a higher level of generality than what the Court must do"—even for the purpose of assessing general causation. *Id.* at *7. Here, Plaintiff bears the burden to prove that *his* cancer was more likely than not caused by *his* exposure to GBHs. IARC's classification of glyphosate does not speak to that issue. Furthermore, as Plaintiff's counsel conceded in closing arguments, Tr. at 5072:16-20, IARC found the epidemiology evidence "limited" and it could not rule out chance, confounding, or bias. Tr. at 2676:25-2677:10; 2678:16-25.[3]

In sum, Plaintiff's scientific evidence was legally insufficient at each level. The epidemiology failed to demonstrate causation. Plaintiff did not present a basis to extrapolate from animal or cell testing. Nor did Plaintiff explain how any of the evidence he presented was relevant to Plaintiff himself, other than Dr. Sawyer's statement placing Plaintiff into the "middle" of the epidemiology studies that did not show causation. Tr. at 3674:25-3675:16. And, IARC's

[3] IARC reached this conclusion of "limited" evidence without considering the North American Pooled Project that combined various North American case control studies and the NCI 2018 study.

assessment that glyphosate can be a "probable" cancer *hazard* under some hypothetical circumstances does not address the issue of whether it was a substantial factor causing Plaintiff's MF. On this record, there was no legal basis to "rule in" GBHs as a potential cause.

4. <u>There Was No Basis To "Rule Out" Idiopathic Causes.</u>

In conducting a differential diagnosis, Dr. Nabhan was also required to rule out all other explanations for the NHL that were supported by substantial evidence. *Cooper*, 239 Cal. App. 4th at 585-586. However, Dr. Nabhan did not address the fact that NHL is a predominantly idiopathic disease. Because there was "substantial evidence" that idiopathy was an "alternative explanation for the disease," and Dr. Nabhan did not address it, his differential diagnosis was legally insufficient to support causation. *Id.* at 585-586.

The evidence at trial showed that NHL generally, and MF specifically, is an idiopathic cancer. Dr. Nabhan testified that the vast majority of NHL cases are idiopathic. Tr. at 2990:6-14; 2812:8-10; 2997:17-23; 2998:16-21. There was undisputed testimony that the causes of MF specifically are entirely idiopathic. Dr. Nabhan acknowledged that Dr. Kim, Plaintiff's physician and a world renowned expert in MF, had testified: "But right now, the scientific fact –not my opinion, the scientific fact is that so far there is no established cause for this particular rare disease." Nabhan Tr. at 2995:12-23. Dr. Kuzel testified likewise. Tr. at 4790:3-4 ("I would say every case of mycosis fungoides is of unknown etiology."). Thus, there was substantial evidence of an alternative explanation for Plaintiff's MF that needed to be ruled out.

Precedent holds that when an overwhelming percentage of cases of disease are idiopathic, a differential diagnosis is unhelpful in showing causation. In *Hall v. Conoco Inc.*, for example, the Tenth Circuit found that "because the evidence had pointed to idiopathic causes in most cases of acute myeloid leukemia," "the district court could reasonably view the failure to rule out idiopathic causes as a fatal error tainting the differential diagnosis." 886 F.3d 1308, 1314 (10th Cir. 2018); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir. 2010) (reversing admission of "differential diagnosis" testimony where idiopathic causation "currently accounts for the vast majority of Parkinson's Disease cases, making it impossible to ignore and difficult to rule out."); *Bland v. Verizon Wireless*, 538 F.3d 893, 897 (8th Cir. 2008) (holding "[w]here the cause

of the condition is unknown in the majority of cases, [an expert] cannot properly conclude, based upon a differential diagnosis," the plaintiff's "exposure to freon was 'the most probable cause' of [his]exercise-induced asthma.").

Even if a differential diagnosis theoretically could be used to prove causation in this case, at a minimum, Dr. Nabhan would need logically to rule out idiopathic causes. However, Dr. Nabhan did not attempt to do so. When he presented his differential diagnosis to the jury, Dr. Nabhan wrote all of the possible causes he considered on a white board. As Plaintiff conceded in post-trial briefing, besides GBHs, Dr. Nabhan ruled in "age, race, immunosuppressant therapies, autoimmune diseases, skin conditions, occupation, occupational exposures and viruses," while explaining that tobacco and alcohol use should not be considered. JNOV Opp. at 11. Dr. Nabhan did not "rule in" idiopathy as a potential cause of Plaintiff's disease, and because he did not, he also did not rule it out. On cross-examination, Dr. Nabhan stated that idiopathy was "implied" in his differential diagnosis, Tr. at 2996:20-21, but did not provide any articulated reasoning for why Plaintiff's cancer was not one of the overwhelming majority of NHL cases that have no known cause.[4]

During oral argument on Monsanto's Motion for JNOV, Plaintiff's counsel appeared to concede that Dr. Nabhan did not rule out idiopathic causes, arguing "it's not our job" to "find those." JNOV Hrg. Tr. at 50:5-24. That is incorrect as applied to the facts of this case. California law requires an expert rule out "an alternative explanation for the disease" that is supported by "substantial evidence." *Cooper*, 239 Cal. App. 4th at 585-586. In *Cooper*, the Court of Appeals held that an expert did not need to account for each and every hypothetical cause of a disease, where there was no substantial evidence that the alternative causes the expert allegedly ignored were potential causes. This case presents the opposite situation. The overwhelmingly idiopathic

[4] Plaintiff argues that Dr. Nabhan adequately accounted for idiopathic causes. Plaintiff points to testimony where Dr. Nabhan asserted that, because Plaintiff was far younger than the typical MF patient, that would constitute a "red flag" suggesting to him that there was something behind the NHL. JNOV Opp. at 11. But all that testimony accomplished was ruling out age as a risk factor. Dr. Nabhan did not list idiopathy, did not explain whether the rates for this idiopathic disease are any different in younger patients, and made no attempt to explain why it could not be ruled out in Plaintiff's case.

nature of NHL and MF was supported by substantial evidence, and admitted by Dr. Nabhan. Plaintiff suggests that Monsanto had a burden to identify a specific alternative cause, but Plaintiff bore the burden of showing why Plaintiff's case was more probably than not caused by GBHs as opposed to idiopathic causes that constitute the vast majority of NHL cases. Plaintiff did not meet his burden.

In this respect, the Court observes that the evidence showed the latency period following environmental exposures and the development of NHL is typically several years, if not decades. The evidence also established that Plaintiff's cancer developed, at most, approximately 2.25 years after his first use of GBHs, an atypically short period of time. Plaintiff introduced evidence to the effect that it is possible that he could have developed NHL within 2.25 years after his exposure (the time to his diagnosis), but did not establish that it was more likely than not that he would have developed NHL in that atypically short period of time. Even if it had been appropriate for Dr. Nabhan to "rule in" GBHs, this unusual chronology underscores the importance of an explanation why Plaintiff's NHL was more likely caused by GBHs as opposed to idiopathic causes. Plaintiff provided no such explanation.

Plaintiff relies on *Wendell* as support for the argument that a physician undertaking a differential diagnosis need not address the fact that a disease is of overwhelmingly idiopathic origin. Plaintiff's argument is incorrect. In *Wendell*, the expert witness, unlike Dr. Nabhan, "ruled in" idiopathic causes, but then proceeded to conclude, based on substantial clinical experience, that the drug in question more likely than not caused the extraordinarily rare disease. 858 F.3d at 1235-36. *Wendell* confirms that an expert must articulate reasoning that shows the chemical in question is a more likely cause than an idiopathic cause, which did not occur here.

In light of the foregoing, Dr. Nabhan's opinion was legally insubstantial to support the verdict. Thus, the Court grants Monsanto's Motion for JNOV on all Counts.

B. <u>Failure to Warn Was Not Established.</u>

There was not substantial evidence that the probable risks of NHL and MF were known or reasonably knowable at the time of distribution in light of the "generally recognized and prevailing best scientific and medical knowledge" as required to establish Plaintiff's failure to warn claim.

See Carlin v. Super. Ct., 13 Cal. 4th 1104, 1112, 1116 (1996); *Valentine v. Baxter Healthcare Corp*., 68 Cal. App. 4th 1467, 1483-84 (1999). The mere possibility of risk does not trigger a duty to warn. *See Carlin*, 13 Cal. 4th at 1115-16 (failure-to-warn claim requires evaluating "whether available evidence established a causal link").

There was not substantial evidence that the probable risks of NHL were generally recognized or prevailing in the scientific community at the time when the GBHs were distributed, which had to have been prior to Plaintiff's diagnosis in 2014. As is true today, the scientific and regulatory communities were virtually uniform in the belief that GBHs do not cause NHL. Until the 2015 publication of the IARC Monograph, every scientific and regulatory agency that had examined the issue concluded that glyphosate was unlikely to cause cancer and that no warning was necessary. *See also* CACI 1205 Directions for Use (risk must be "generally recognized," "as prevailing in the relevant scientific community," and "represents the best scholarship available," not a minority viewpoint); *Ramirez v. Plough, Inc*., 6 Cal. 4th 539, 556 (1993) (regulatory findings "deserve[] serious consideration").

The IARC Monograph is not evidence that any risk about NHL was known or reasonably knowable. The IARC Monograph was not published until 2015—three years after Plaintiff's first exposure in 2012, one year after Plaintiff's MF diagnosis in 2014, and, thus, well after the distribution of the product. Putting the timing aside, as Dr. Neugut testified IARC's classification does not mean that IARC is recommending a warning. The IARC Monograph is not evidence to establish knowledge of a risk of NHL or that a warning was required because it is a hazard assessment and not a risk assessment. It thus does not support that cancer is a probable risk from exposure to GBHs, particularly in light of the far more substantial and thorough epidemiology studies showing no causal association between GBHs and cancer. Plaintiff presented no evidence that any risk was known or reasonably knowable to the scientific community during the relevant time period, and JNOV is granted on Plaintiff's failure to warn claim.

There was also no evidence that Monsanto's conduct fell below the applicable standard of care to support his claim for negligent failure to warn. Plaintiff was required to prove what a "reasonable" manufacturer would have warned. *See Trejo*, 13 Cal. App. 5th at 137 ("Negligence

law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care ….”). Plaintiff did not present any evidence regarding standard of care, and thus failed to satisfy a necessary element of his negligent failure to warn claim.

C. Design-Defect Was Not Established

The consumer-expectation test was not appropriate here as a matter of law. “A bedrock principle in strict liability law requires that the plaintiff’s injury must have been caused by a ‘defect’ in the [defendant’s] product.” *O’Neil v. Crane Co.*, 53 Cal. 4th 335, 347 (2012). “A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective.” *Trejo*, 13 Cal. App. 5th at 142 (citation omitted).

Plaintiff here elected to pursue his claim only under the consumer-expectation test for design defect. The consumer-expectation test is “reserved for cases in which the *everyday experience* of the product’s users permits a conclusion that the product’s design violated *minimum* safety assumptions ….” *Trejo*, 13 Cal. App. 5th at 156 (citation omitted). “[W]hen the ultimate issue of design defect calls for a careful assessment of feasibility, practicality, risk, and benefit, the case should not be resolved simply on the basis of ordinary consumer expectations ….” (citation omitted). *Id.* In a jury case, “the trial court must initially determine as a question of foundation, within the context of the facts and circumstances of the particular case, whether the product is one about which the ordinary consumer can form reasonable minimum safety expectations.” *Saller v. Crown Cork & Seal Co., Inc.*, 187 Cal. App. 4th 1220, 1233 (2010). The consumer-expectation test is *not* helpful when “the alleged circumstances of the product’s failure involve technical and mechanical details about the operation of the manufacturing process, and then the effect of the product upon an individual’s health.” *Morson v. Super. Ct.*, 90 Cal. App. 4th 775, 792 (2001).

Plaintiff’s claims turn on complex scientific details about how GBHs work *and* expert testimony about the “effect of the product upon [Plaintiff’s] health.” The consumer expectation test does not apply simply because Plaintiff did not expect GBHs to give him cancer. That would create an exception to swallow the rule, and the applicability of the consumer expectation test would be unbounded. Plaintiff’s own evidence that GBHs can be used safely reinforces that the

Farella Braun + Martel LLP
235 Montgomery Street, 17th Floor
San Francisco, California 94104
(415) 954-4400

test does not apply. Dr. Sawyer testified that GBHs are safe to use and he has safely used them for decades. The ultimate issue of design defect in this case "calls for a careful assessment of feasibility, practicality, risk, and benefit," not for an assessment of consumer expectations, *Trejo*, 13 Cal. App. 5th at 159 (citation omitted), such that the ordinary consumer could not reasonably appreciate the complex scientific issues of safety and risk at play here.

For the jury's verdict to stand under "the consumer expectation" test, there must be substantial evidence that (1) GBHs are products about which an ordinary consumer can form reasonable expectations, (2) GBHs did not perform as safely as an ordinary consumer would have expected, (3) causation, and (4) harm. Pl.'s Proposed Substantive Jury Instrs. at 1 (May 8, 2018). The lack of evidence on causation is dispositive of the second and third elements of the consumer-expectation test. Because the evidence does not support that GBHs caused Plaintiff's cancer, it likewise does not support the jury's conclusion that the product did not perform as safely as an ordinary consumer would have expected. Additionally, Plaintiff presented no evidence that the *design of the product*, i.e. GBHs as opposed to pure glyphosate, caused Plaintiff's MF. To the contrary, Dr. Nabhan testified that glyphosate and GBHs are "interchangeable." The evidence also did not "support a finding that the ordinary consumer can form reasonable minimum safety expectations" about GBHs. *See Saller*, 187 Cal. App. 4th at 1234. There was no evidence GBHs or its effects are part of the "everyday" experience of the ordinary consumer or that minimum safety standards for GBHs are common knowledge of the ordinary consumer. Plaintiff himself was not an ordinary consumer: he was certified as a qualified applicator, purchased the product from a special distributor, not a retail store, and had specialized training on how to mix and apply the product safely. In light of the complex expert evidence on the critical issues in this case, the consideration of safety expectations for GBHs are simply beyond the purview of ordinary consumers. JNOV is granted on the design-defect claim.

D. <u>JNOV as to Punitive Damages is Warranted.</u>

As to his punitive damages claim, Plaintiff was required to prove by clear and convincing evidence that an officer, director, or managing agent of Monsanto acted with malice or oppression in the conduct that gave rise to liability. Cal. Civ. Code § 3294(a) (b). Malice is defined as

"despicable conduct . . . carried on by the defendant with a willful and conscious disregard of the rights and safety of others." Cal. Civ. Code § 3294(c)(1). Oppression is defined similarly to mean "despicable conduct that subjects a person to cruel and unjust hardship in conscious disregard of that person's rights." Cal. Civ. Code § 3294(c)(2). "Despicable" means "circumstances that are 'base,' 'vile,' or 'contemptible.'" *Coll. Hosp. Inc. v. Super. Ct.*, 8 Cal. 4th 704, 725 (1994) (citation omitted). A "managing agent" includes "only those corporate employees who exercise substantial independent authority and judgment in their corporate decision-making so that their decisions ultimately determine corporate policy." *Wilson v. Southern Cal. Edison Co.*, 234 Cal. App. 4th 123, 164 (2015). The conduct giving rise to punitive liability must be causally tied to Plaintiff's harm. *See Holdgrafer v. Unocal Corp.*, 160 Cal. App. 4th 907, 928 (2008); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-423 (2003).

Plaintiff failed to meet his burden of producing clear and convincing evidence for any of the elements of his punitive damages claim. When the evidence is viewed most favorably to Plaintiff, there is not legally sufficient evidence that Monsanto acted with "conscious disregard" of safety risks posed by GBHs, nor is there legally sufficient evidence that Monsanto's conduct was "despicable," both of which are requirements to prove "malice" or "oppression." There is also not legally sufficient evidence of conduct by an officer, director, or managing agent of Monsanto. Finally, for much of the evidence that Plaintiff points to as evidence supporting punitive liability—such as "ghostwriting" articles and Monsanto's response to IARC's 2015 hazard assessment—there is not legally sufficient evidence establishing that conduct had any causal relationship to Plaintiff's MF.

1. <u>No Legally Sufficient Evidence of a Conscious Disregard of Safety</u>

Plaintiff failed to produce legally sufficient evidence that Monsanto "conscious[ly] disregard[ed]" that GBHs could cause NHL. Both Plaintiff's and Monsanto's experts testified that glyphosate has developed one of the largest bodies of scientific data of any substance in the world. Plaintiff points to evidence showing that Monsanto was aware of a few epidemiological studies and genotoxicity papers in the late 1990s and 2000s suggesting a potential association between glyphosate and NHL as evidence Monsanto knew and disregarded a cancer risk. But there was no

evidence suggesting that any Monsanto employee believed the voluminous scientific data, taken as a whole, showed that exposure to glyphosate or GBHs causes NHL.

Monsanto scientists Dr. Farmer and Dr. Goldstein both testified that they believed there was no causal link between GBHs and NHL. The two exhibits upon which Plaintiff primarily relied do not establish that anyone at Monsanto believed there was such a causal link. In Dr. Farmer's email (PX305), she agreed that "Roundup did not cause cancer, birth defects, or adverse reproductive changes at dose levels far in excess of likely exposure." The 2002 internal Monsanto memorandum (PX282, which was not admitted into evidence), stated: "Glyphosate has very favorable toxicologic properties. It is not carcinogenic, mutagenic or neurotoxic and it is not a reproductive or developmental toxin." These exhibits do not demonstrate that Monsanto consciously disregarded a risk allegedly posed by GBHs and cannot be the basis for punitive damages.

It is also undisputed that worldwide regulators have found, and continue to find, that glyphosate is not a human carcinogen and is safe based on the extensive available data. These worldwide regulators and scientific bodies include U.S. EPA, Canadian EPA, ECHA, EFSA, German BfR, the Australian, New Zealand and Japanese regulatory authorities, and the WHO's JMPR. IARC, which assessed whether glyphosate could cause NHL at any hypothetical dose and not real world doses, is the only scientific body that has issued a contrary assessment. The uniform scientific view of worldwide regulatory bodies, both before and after IARC issued its Monograph, has been consistent with Monsanto's view of the science.

Even when viewed in isolation, the IARC Monograph cannot support punitive damages. It is a hazard assessment, not a risk assessment. In addition, the Monograph was issued after Plaintiff was diagnosed with MF, and thus cannot inform Monsanto's state of mind at any relevant time. Finally, all of the Monsanto scientists who testified explained that they disagreed with IARC's classification after it was released.

The evidence is legally insufficient to support a finding that Monsanto consciously disregarded the risk that glyphosate or GBHs causes NHL. A "bona fide disagreement" about a scientific dispute does not demonstrate clear and convincing evidence of malice as a matter of law.

Cf. Kendall Yacht Corp. v. United Cal. Bank, 50 Cal. App. 3d 949, 959 (1975) (reversing punitive damages award because it "remains purely speculative as to whether the Bank acted with such malice rather than out of a bona fide disagreement over" plaintiff's claims); *Berroyer v. Hertz*, 672 F.2d 334, 342 (3d Cir. 1982) ("difference of medical opinion on the degree of cancer risk" among experts is "insufficient support" for punitive damages). After reviewing all the evidence in the light most favorable to Plaintiff, the most that can be said is that the IARC Monograph spurred a discussion in the scientific and medical community about whether glyphosate or GBHs causes NHL, which to this day has been resolved by regulators in favor of the safety of GBHs.

For this first independent reason, JNOV on punitive damages is granted.

2. No Legally Sufficient Evidence of Despicable Conduct

Plaintiff also failed to produce legally sufficient evidence that Monsanto's conduct was "despicable." Plaintiff argued that Monsanto's response to Dr. Parry's recommendation that it conduct certain genotoxicity studies in the late 1990s and early 2000s was despicable. However, the evidence shows that Monsanto conducted tests in an accredited laboratory in response to Dr. Parry's recommendations. The evidence shows that those results were provided to the regulators and were publicly released. And the evidence shows that upon review of those results, Dr. Parry agreed that GBHs were not genotoxic. Furthermore, while Plaintiff's counsel argued at the JNOV hearing that Monsanto never conducted studies on the formulated products, rather than glyphosate alone, the evidence presented at trial was that the studies Monsanto performed in response to Dr. Parry's suggestions involved the formulated products. The undisputed evidence is inconsistent with any conclusion that Monsanto's conduct with respect to Dr. Parry was despicable.

The evidence pertaining to Monsanto's relationship with the authors of Williams (2000) and Kier & Kirkland (2013) does not support Plaintiff's claims that Monsanto acted "despicably." Monsanto's employees are listed as contributors to those articles and there is no evidence those articles contain material scientific misstatements. There was no evidence that these articles contain scientific misrepresentations, or that the authors did not have editorial control. There was no evidence that Plaintiff's allegations of ghostwriting are related to the conduct that gave rise to liability—Plaintiff did not introduce any evidence that related these allegations, or Monsanto's

responses to the IARC classification, to Plaintiff's harm. There was no evidence that Monsanto's participation in the scientific debate was despicable.

In addition, Plaintiff asserts Dr. Goldstein intentionally failed to return Plaintiff's phone call made after Plaintiff had been diagnosed with MF. Even if true, failure to return a phone call does not rise to the level of despicable conduct. The evidence was that Plaintiff was able to obtain information about the product both times he called Monsanto. There was no evidence that Dr. Goldstein's failure to return the phone call was intentional, and the contemporaneous evidence reflected in Dr. Goldstein's email reflected that Dr. Goldstein intended to return Plaintiff's telephone call. In other words, the evidence is that the failure to return the phone call was inadvertent, and there was no evidence to the contrary. Further, Dr. Goldstein testified that he did not believe that GBHs were the cause of Plaintiff's illness and would have told the Plaintiff the same over the phone. There is no nexus between Dr. Goldstein's conduct and Plaintiff's illness, and Plaintiff already had been diagnosed with MF at the time of Plaintiff's call.

The evidence presented in this case falls well short of the type of conduct that has been deemed "despicable" by California courts. *Cf. Boeken v. Philip Morris Inc.*, 127 Cal. App. 4th 1640, 1692 (2005) (the evidence showed that Philip Morris "manufactured a dangerous product, knowing that it was a dangerous product," "added chemicals to the product to make it more addictive and easier to draw into the lungs," and then through "misleading advertising specifically targeted" youth); *Pfeifer v. John Crane, Inc.*, 220 Cal. App. 4th 1270, 1301-02 (2013) (the evidence showed that "JCI knew that its customers used the products in ways capable of generating dangerous levels of asbestos dust" and that "it was widely accepted that asbestos dust was carcinogenic" in the medical community). There is no evidence here that could legally support a finding of "despicable" conduct by Monsanto.

For this second independent reason, JNOV on punitive damages is granted.

3. <u>No Legally Sufficient Evidence of Managing Agent Conduct</u>

Plaintiff additionally failed to produce legally sufficient evidence that the Monsanto employees whose conduct was at issue in this trial were officers, directors, or managing agents of the company. Section 3294 of the California Civil Code expressly provides that with regard to a

corporate defendant, the malice or oppression required for an award of punitive damages must be on the part of an officer, director, or managing agent. The evidence showed that Dr. Farmer was a toxicologist and spokesperson for Monsanto's GBHs. Likewise, Dr. Heydens was a regulatory toxicologist. Dr. Goldstein served as a "director" in medical toxicology" and a "lead" in "medical sciences and outreach.", who reviews "complaints of human health" made to Monsanto. There is no evidence that they had independent authority to determine corporate decision-making with respect to GBHs. *See Wilson*, 234 Cal. App. 4th at 164 ("managing agent" includes "only those corporate employees who exercise substantial independent authority and judgment in their corporate decisionmaking so that their decisions ultimately determine corporate policy.") (citation omitted). The same is true of the other Monsanto scientists whose testimony and conduct was introduced at trial. The evidence showed that Kirk Azevedo and Steven Gould, whose testimony was irrelevant to any alleged harm to Plaintiff, were salespeople, not managing agents. Although Plaintiff deposed Monsanto employees and played the videotapes of those depositions during trial, Plaintiff failed to introduce evidence to satisfy the requirements of Section 3294.

For this third independent reason, JNOV on punitive damages is granted.

IV. ORDER

For the reasons stated above, Monsanto's Motion for JNOV is GRANTED.

IT IS SO ORDERED.

Date: _____

_____
Honorable Suzanne R. Bolanos

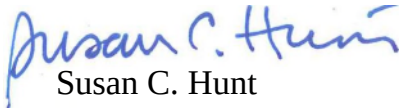
CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of October, 2018, I electronically filed the foregoing

- **[PROPOSED] ORDER GRANTING MONSANTO COMPANYS MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT**

with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Curtis G. Hoke, Esq.
The Miller Firm, LLC
108 Railroad Avenue
Orange, VA 22960



Susan C. Hunt