Sandra A. Edwards (State Bar No. 154578)
Joshua W. Malone (State Bar No. 301836)
Farella Braun + MartelLLP
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

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF 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

TABLE OF CONTENTS

Page

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

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

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

STATE CASES

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

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

STATE STATUTES

STATE RULES AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

Monsanto Company ("Monsanto") has produced glyphosate-based herbicides (the "Formulation") in the United States and much of the rest of the world for more than 40 years. These herbicides have a safety record supported by a body of studies more extensive than almost any other chemical in regular use anywhere. The studies include rigorous registration studies—done by multiple registrants including Monsanto—required by U.S. EPA and European regulators to demonstrate the safety of the Formulation, as well as many studies by independent scientists, ranging from small laboratories to the National Cancer Institute. Based on these studies, regulators across the world have concluded on multiple occasions, after multi-year evaluations, that glyphosate is *not* a human carcinogen.

Under these circumstances, a jury verdict proclaiming that the Formulation caused Plaintiff's cancer and that Monsanto's behavior in relying on the science and the regulators was so egregious as to warrant a $250 million punitive damages award requires exceptional scrutiny. That extraordinary verdict cannot be sustained for multiple reasons.

First, the evidence Plaintiff presented on causation was insufficient as a matter of law to establish the Formulation was a "substantial factor" in causing his cancer. To prove causation, Plaintiff relied on epidemiological studies, animal and mechanistic studies, and a differential diagnosis from a single physician. But Plaintiff and his experts repeatedly admitted that the epidemiology—the most important type of evidence—was "not causal" and that it showed a risk well below the threshold required under California law to establish causation. Plaintiff's reliance on animal or mechanistic studies was similarly flawed because he presented no evidence that linked the outcomes of any of those studies to human forms of cancer much less that linked the Formulation with his specific form of Non-Hodgkin's Lymphoma ("NHL"), mycosis fungoides ("MF"). And because it did not account for the extent and timing of exposure to the Formulation, and due to multiple other methodological flaws, the differential diagnosis is legally incapable of supporting causation.

Second, the individual legal theories Plaintiff presented fail for various independent reasons. Plaintiff presented his design defect claim to the jury based exclusively on the consumer

expectation test, but it does not fit this case as a matter of law. *See Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 158-59 (2017). For the failure-to-warn claims, the evidence was insufficient to prove that the "generally recognized and prevailing best scientific and medical knowledge" had established the Formulation had a risk of cancer. *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1112, 1116 (1996). Rather, the undisputed evidence disproved the claim: the state of the art reflected in the domestic and foreign regulatory opinions and the scientific literature before and after IARC's classification is that glyphosate is *not* carcinogenic.

Third, the punitive damages award cannot stand. There was no evidence, much less clear and convincing evidence, that Monsanto's executives or managing agents acted with "malice or oppression" in marketing a product repeatedly certified by competent regulatory authorities as not carcinogenic. Further, there was no evidence that any alleged "despicable" conduct resulted in harm to Plaintiff. For all of these reasons, the Court should grant JNOV in Monsanto's favor.

ARGUMENT

I. STANDARD FOR JUDGMENT NOTWITHSTANDING THE VERDICT

A party is entitled to JNOV when "there is no evidence of sufficient substantiality to support" the jury's verdict. *See Magic Kitchen LLC v. Good Things Int'l, Ltd.*, 153 Cal. App. 4th 1144, 1154 (2007); *see also* Cal. Code Civ. Proc. § 629(a). 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 Pharm. Corp.*, 163 Cal. App. 3d 396, 402 (1985) (affirming nonsuit where plaintiff failed to demonstrate medication caused cancer). "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). Such evidence was wholly lacking here.

II. THERE WAS NO SUBSTANTIAL EVIDENCE THAT THE FORMULATION CAUSED PLAINTIFF'S MYCOSIS FUNGOIDES.

The Court should grant Monsanto JNOV on all of Plaintiff's claims because there was not

substantial evidence to support an essential, common element—that the Formulation was, to a reasonable medical probability, a "substantial factor," or proximate cause, of his injury. *Trejo*, 13 Cal. App. 5th at 110. California law recognizes that causation is "especially troublesome" with cancer because "it is frequently difficult to determine the nature and cause of a particular cancerous growth." *Jones*, 163 Cal. App. 3d at 403. Given these uncertainties, California law uses special 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.* (emphasis added). Under this standard, a plaintiff does not satisfy the reasonable medical probability standard when the evidence establishes a "less than 50-50 possibility" of causation. *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) (emphasis in original).

Plaintiff's case for causation included three types of evidence. First, Plaintiff's expert witnesses testified about various epidemiological studies that purported to link the Formulation or glyphosate to cancer. Second, witnesses described animal and mechanistic studies that attempted to associate glyphosate exposure with rodent tumors or cell damage. Third, based on a differential diagnosis, a single physician testified that Plaintiff's exposure to the Formulation caused his MF. But Plaintiff's entire case for causation was flawed from the ground up because he did not present any evidence, much less substantial evidence, that there was more than a 50-50 possibility that the Formulation caused his disease. Plaintiff's failure to present substantial evidence of causation—general or specific—mandates JNOV in Monsanto's favor on all claims.

A. <u>Plaintiff's Epidemiological Studies Are Not Evidence of Causation.</u>

Plaintiff conceded at trial—including in counsel's closing argument—that the epidemiology does not support causation here. Tr. at 5072:16-20 ("Nobody is saying [the

epidemiology] gets you there. Nobody.").[1] Witness after witness agreed with this assessment. Dr. Portier, one of Plaintiff's experts, candidly testified: "**I can't conclude it's causal. . . . The effects are small**," (Tr. at 1964:13, 1965:1-3), "**I can't really rule out chance**," "I can't rule out that there aren't confounders," and "you can't make a firm statement about glyphosate from the epidemiology data alone." *Id.* at 1965:2-7. Another one of Plaintiff's experts, Dr. Neugut, agreed that "**the epidemiology alone is not sufficient to show a causal link**." Tr. at 2679:1-5, 2736:25-2737:3; 2679:1-5. These witnesses were right to affirmatively reject causation. There simply is no epidemiology study that satisfies the legally required standard for causation.

The strongest and most current evidence discussed at trial, a 2018 study by the prestigious National Cancer Institute ("NCI Study"), refutes any possible epidemiological basis for causation. An independent, long-term, prospective cohort study that followed over 50,000 pesticide applicators, the NCI Study is the largest and most statistically-powerful epidemiological study and unequivocally found "no association between glyphosate use and NHL overall or any of its subtypes." Neugut Tr. at 2745:7-13; Portier Tr. at 2357:19-23. The Formulation, the NCI Study found, was slightly *inversely* correlated with NHL (.87 relative risk ratio).

Moreover, what little Plaintiff's experts had to say about the NCI Study could not blunt its ultimate finding, rejecting any association between glyphosate-based products (such as the Formulation) and NHL at any level of exposure and for any subtype. Plaintiff touted a series of older, smaller studies but none of these studies satisfied California's threshold for causation. An epidemiological study is not competent evidence of causation unless it shows "a relative risk greater than 2.0." *Cooper v. Takeda Pharms. Am, Inc.*, 239 Cal. App. 4th 555, 593 (2015). This threshold ensures that there is at least a "50% probability that the agent at issue was responsible for a particular individual's disease." *Id.* In contrast, when the relative risk is "less than two" it "actually tends to disprove legal causation, as it shows that [the product] does not double the likelihood of [disease]." *Daubert v. Merrell Dow. Pharm., Inc.*, 43 F.3d 1311, 1321 (9th Cir.

[1] All trial transcripts, deposition transcripts, exhibits, and orders cited herein are attached for the Court's convenience to the Declaration of Sandra A. Edwards in Support of Defendant Monsanto Company's Motion for New Trial and Motion for Judgment Notwithstanding the Verdict.

1995);[2] *In re Johnson & Johnson Talcum Powder Cases*, 2017 WL 4780572, at *14 (Cal. Super. Ct. 2017) ("*Talcum* Order").[3]

Plaintiff's epidemiology evidence did not meet this standard. Plaintiff's expert Dr. Neugut—Plaintiff's only certified epidemiologist—testified that the risk ratio from epidemiology studies he examined fell below the mandated 2.0 ratio. The best he could do was to testify that the risk ratio from case control studies fell in a range between 1.3 and "*possibly* 1.5." Tr. at 2614:17-21 (emphasis added). Although he attempted to characterize this as "a statistically significant increased risk," *id*., Dr. Neugut's bottom-line concession that the risk ratio was less than 2.0 is all that matters under California law. *See Simmons*, 212 Cal. App. 3d at 702-703 ("A less than 50-50 possibility that defendant's omission caused the harm does not meet the requisite reasonable medical probability test of proximate cause."); *Daubert*, 43 F.3d at 1321 ("A relative risk of less than two ... actually tends to disprove legal causation....").

The small size of these studies, especially as compared to the NCI Study, is yet another reason to doubt their value, especially as compared to the NCI Study. Of the case-control studies Dr.Neugut presented to the jury, Hardell had 8 exposed cases,[4] Orsi had 12, Eriksson had 29, De Roos (2003) had 36, and McDuffie had 51.[5] By contrast, the NCI Study, which found no

---

[2] Whether addressing this issue in the context of expert admissibility or sufficiency of the evidence, numerous federal and state courts in and outside of California have agreed that a relative risk of 2.0 or greater is necessary for epidemiological evidence to be probative of causation. *See Daubert*, 43 F.3d at 1321 (holding under California law that expert testimony was inadmissible where epidemiology did not support a 2.0 risk); *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256 (Tex. 2011) (vacating judgment for insufficient evidence and holding "when parties attempt to prove general causation using epidemiological evidence, a threshold requirement of reliability is that the evidence demonstrate a statistically significant doubling of the risk"); *see also In re Lipitor*, 150 F. Supp. 3d 644, 650 (D.S.C. 2015); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1225-28 (D. Colo. 1998); *Sanderson v. IFF*, 950 F. Supp. 981, 1000 (C.D. Cal. 1996); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1403 (D. Ore. 1996).

[3] California Rules of Court 8.1115 permits citation to persuasive trial court orders such as this one.

[4] Exposed cases are an important metric of the statistical power of the studies and allow one to compare the relative sizes of different studies. Neugut Tr. at 2686:21-25.

[5] Neugut Tr. at 2690:21-23; 2692:4-13, 2695:8-2698:7; *see also* Mucci Tr. at 4238:12-18 (describing number of exposed cases in Hardell as "quite low"), 4248: 9-17 (Eriksson had "only 29 exposed cases"), 4247: 7-14 (Orsi had "very small number of exposed cases, only 12"), 4246:20-22 (De Roos 2003 "by pooling together these three studies, they had 36 exposed cases,

association between the Formulation and NHL, had 440 exposed cases. Mucci Tr. at 4285:21-4286:9. It is thus *8.6 times* larger than McDuffie (Plaintiff's largest case-control study), and *55 times* larger than Hardell (Plaintiff's smallest). It is more than three times larger than all of the case-control studies *put together*. Neugut Tr. at 2690:21-23, 2692:4, 2695:8-2698:7; *see also* Mucci Tr. at 4238:12-18, 4248: 9-17, 4247: 7-14, 4246:20-22, 4242:3-8.

There are still more reasons why the small studies Plaintiff's counsel relied upon do not constitute substantial evidence of causation. Reflecting on their small size and lack of power, all of the case-control studies Plaintiff relied on presented enormous confidence intervals, and in the analyses adjusted for other pesticides that Dr.Neugut presented to the jury, none yielded statistically significant results. Tr. at 2702:25-2703:3; 2682:10-15; (Hardell: 1.85 (.55 to 6.2); Orsi: 1.0 (.5 to 2.2); Eriksson: 1.51 (.77 to 2.94); De Roos (2003) 1.6 (.9 to 2.8); McDuffie 1.2 (0.83 to 1.74).[6] Because Dr.Neugut admitted that a statistically significant increased risk was essential to determine whether there is a causal association (Tr. at 2685:4-8), the lack of statistical significance effectively ended Plaintiff's epidemiology argument. *See, e.g., McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, 2013 WL 3487560, at *15 (W.D. Pa. July 12, 2013) ("Step one looks to whether there is a statistically significant association between a substance and a specific disease.... If no association between the exposure and the disease is supported by the scientific literature, there is no basis to find a causal relationship exists and the analysis should end there."); *In re Lipitor Mktg.*, 174 F. Supp. 3d 911, 924-925 (D.S.C. 2016) (collecting cases). As shown in the confidence intervals, none of these point estimates was statistically significant, meaning that chance could not be ruled out as the explanation for any apparent association,

---

so, again, not a really large study"); 4242:3-8 (McDuffie was "larger than Hardell, [but] still a fairly small number of exposed cases.").

[6] Dr. Portier agreed: Tr. at 1878:12-15 (McDuffie 2001: "It's clearly not a statistically significant result."); 1885:17-22 (Hardell 2002: "The second [line] is adjusted for pesticides, other pesticide use. . . . And there you see it's clearly not statistically significant . . . ."); 1887:3-6 (DeRoos 2003: "The second method of analysis of the same data but a different method of analysis, using what's called Bayesian statistics, shows a positive finding but not statistically significant."); 1895:13-20 (Eriksson 2008: "A. If I remember correctly, I think they did two different types of analyses, but, yes, they adjusted for other pesticides. Q. And what happens to the risk ratio when they did that? A. It dropped. It drops to 1.5, and it's no longer statistically significant."); 1898:19-21 (Orsi 2009: "Q. And it has a ratio of .5 and 2.2, so it's not statistically significant? A. Correct.").

making them meaningless for Plaintiff's case. Neugut Tr. at 2702:25- 2703:3 ("Q. On the Forest plot that you presented to the jury, there was no statistically significant result. A. Correct."). *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."); *Caraker v. Sandoz Pharm. Corp*., 188 F. Supp. 2d 1026, 1034 (S.D. Ill. 2001) ("This Court, however, rejects the plaintiffs' experts' opinions inasmuch as they rely on selective use of statistically insignificant data from epidemiological studies.").

Moreover, when the small studies Plaintiff relied on were pooled together, they showed a lower relative risk ratio. The NAPP study—a pooled study of North American case control studies (including the De Roos (2003) data)—showed an even lower, non-statistically significant risk ratio of **1.13** (CI = 0.84 to 1.51), which was further reduced to **0.95** (CI = 0.69 to 1.32) when proxy respondents were eliminated. Portier Tr. at 2451:3-5; 2338:24-2339:7. And meta-analysis of the epidemiology studies on which Plaintiff's experts relied–which did not include either the NAPP or NCI studies—still demonstrated a risk ratio of only **1.3**. Neugut Tr. at 2613:6-12; Portier Tr. at 1914:5-8. That is too low to establish causation.

Finally, Monsanto anticipates Plaintiff may point to alleged "dose-response" findings in McDuffie and Eriksson in which estimates above 2.0 were calculated at certain exposure levels. Apart from being inconsistent with Dr. Neugut's actual conclusion, these publications do not aid Plaintiff for multiple reasons. *See, infra* at 12-14. These data are (1) confounded by other pesticides, contrary to the requirements of California law, *see In re Lockheed Litigation Cases*, 23 Cal. Rptr. 3d 762, 777 (2005), *rev. dismissed by* 83 Cal. Rptr. 3d 478; (2) inconsistent with later and more comprehensive analyses in the NAPP and NCI Study showing no increased risk whatsoever even at the highest dose levels (Portier Tr. at 1914:5-8, 2451:3-5, 2338:24-2339:7; Neugut Tr. at 2613:6-12); and (3) insufficient under California law, which looks at the epidemiology evidence overall and do not find substantial evidence of causation based on an isolated data point above 2.0. *Talcum* Order, at *14.

B. The Animal and Genotoxicity Studies Are Not Evidence to Support Causation as a Matter of Law.

Plaintiff also relied on animal and genotoxicity studies to prove causation but the evidence about these studies fell short in multiple ways.

No evidence tying animal studies to disease in humans or Plaintiff. Plaintiff's reliance on animal studies could not establish causation because none of his witnesses ever linked the results in any way to cancer in humans or to NHL or MF—the studies were legally irrelevant and not evidence of causation. Indeed, missing from Plaintiff's case was evidence that addressed either of the extrapolation problems associated with animal studies: species extrapolation, which is the "differences between human beings and the animals studied," and dosage extrapolation, which is "how to extrapolate from the high doses given to animals to the lower doses to which human beings may be subjected." *Lockheed Litig. Cases*, 23 Cal. Rptr. 3d at 779; *see also General Electric Co. v. Joiner*, 522 U.S. 136, 144 (1997) (rejecting use of animal studies to prove causation in humans because doses, routes of exposure, and types of cancer all differed); *Redfoot v. B.F. Ascher & Co.*, 2007 WL 1593239, at *11, n.18 (N.D. Cal. June 1, 2007) ("Extrapolations of animal studies to human beings are generally not considered reliable in the absence of a scientific explanation of why such extrapolation is warranted.").

Dr. Portier's testimony highlights this evidentiary void. He testified about his analysis of various rodent tumors (which the worldwide regulatory bodies rejected) but offered no reliable extrapolation of that analysis to any form of cancer in humans. Without this missing evidence, the jury had no way to know if the same mechanisms associated with rodent tumors exist in humans and, if so, what exposure levels are required to produce the same outcome. In fact, one of Plaintiff's experts even admitted that some scientific, epidemiological basis must exist before animal studies can support a finding of causation in humans. Sawyer Tr. at 3683:13-17. There was no such evidence here.

Plaintiff also offered no evidence that linked any of the animal studies with his specific cancer, MF. Again, Dr. Portier's testimony is instructive. He testified about an old study involving mice and kidney tumors but never provided any link between that type of mouse tumor

and MF in humans. *See Joiner*, 522 U.S. at 144 (rejecting animal data as showing cancer where, *inter alia*, animals developed different type of tumors than plaintiff). While Dr. Portier also testified about mice lymphomas, the evidence did not even support extrapolating the lymphoma results from male to female mice or even to another species of animal—rats—which are indisputably more biologically similar to mice than humans. Tr. at 2200:13-15; 2151:16-2155:1; Foster Tr. at 4539:1-4540:7. Whether the same studies can be extrapolated to MF in humans was left to pure guesswork.

Equally unavailing was Plaintiff's reliance on the so-called "tumor promotion" or 2010 George study. Again, the study was irrelevant to causation because none of Plaintiff's experts attempted to extrapolate the results—which purported to show *non-cancerous*[7] "tumors" in rats—to the occurrence of NHL or MF in humans.[8] In any event, the study is also well known for its flaws, leading every reviewing agency and scientific body (as well as IARC) to dismiss it as unreliable. Portier Tr. at 1863:21-25.[9]

Mechanism studies not linked to human outcomes. The mechanism studies Plaintiff introduced are similarly irrelevant to causation. The reason for this is that mechanism studies are one step further removed from what Plaintiff must prove to establish causation: these studies only purport to show possible pathways by which a substance might cause cancer. As Dr.Portier explained, genotoxicity does not show that a substance can cause cancer generally because a genotoxic compound "may not lead to critical mutations that are important for carcinogenesis." Tr. at 2257:10-20; 2258:15-17. Plaintiff's experts, however, made no claim that his MF was caused by the types of effects (e.g., "oxidative stress") allegedly seen in high-dose cell testing systems used in the mechanistic studies. This is unsurprising considering it was undisputed at trial that MF is likely of unknown or epigenetic origin. Kuzel Tr. at 4790:3-4. If no one knows

---

[7] Dr. Portier admitted they were *benign* skin growths, not carcinomas. Tr. at 1863:3-12, 2229:13-2230:6.

[8] As set forth in Monsanto's Motion for New Trial, both IARC and EPA declined to use the George study, finding it to be "poor" and "inadequate in protocol, conduct or reporting." *See* Motion for New Trial at 13-14.

[9] *See* PX 784 at p. 34 (IARC); DX 2481 at 0070 (EPA).

precisely what causes MF, it logically follows that Plaintiff's experts could not, and did not, link the mechanism studies to MF.

* * * * *

Plaintiff's reliance on animal and mechanistic studies lacked any evidence of the critical bridge to human outcomes that was necessary for them to prove causation under California law. Without this evidence, the jury was improperly allowed to make its own extrapolation and fill in the missing link to causation that Plaintiff failed to provide. *See Domingo ex rel. Domingo v. T.K*, 289 F.3d 600, 606 (9th Cir. 2002) (excluding expert testimony where proffered opinion did not provide sufficient support to extrapolate animal studies to humans).

C. Dr. Nabhan's Differential Diagnosis Was Insufficient To Establish Causation.

Plaintiff's final piece of causation evidence was the differential diagnosis offered by Dr. Nabhan, the only expert who attempted to link Plaintiff's MF specifically with the Formulation. For his differential diagnosis, Dr. Nabhan purported to "rule in" the plausible causes of Plaintiff's MF and then "ruled out" the least plausible causes of Plaintiff's MF, so he was left with only Plaintiff's race and his exposure to the Formulation. Tr. at 2853:19-2854:2. *See Cooper*, 239 Cal. App. 4th at 593-94 (explaining differential diagnosis). But there is every reason to doubt Dr. Nabhan's conclusion considering his concession that Plaintiff "could well be someone who would have developed mycosis fungoides when he did, whether he was exposed to glyphosate or not." Tr. at 3002:21-3003:4. Given this testimony, it is perhaps unsurprising that Dr. Nabhan's differential diagnosis was legally flawed at every step: he did not properly rule in the Formulation as a potential cause of Plaintiff's MF, he failed to rule out unknown causes of MF, and he entirely ignored the timing and extent of Plaintiff's exposure.

1. Dr. Nabhan Had No Scientific Basis To Rule In the Formulation as a Possible Cause.

Given the lack of any scientific basis for concluding that the Formulation causes cancer (discussed above), there was no scientific basis for Dr. Nabhan to "rule in" the Formulation as a potential cause. None of the putative bases Dr. Nabhan offered for doing so are legally sufficient.

a. The IARC Monograph Does Not Support Specific Causation.

The threshold flaw in Dr. Nabhan's differential diagnosis was his uncritical reliance on the methodologically flawed IARC Monograph as the primary basis for "ruling in" the Formulation. The Monograph, however, did not even attempt to establish causation as to NHL, much less MF. Rather, IARC merely performed a "hazard assessment," *In re Roundup Prod. Litig.*, 2018 WL 3368534, at *7 (N.D. Cal. July 10, 2018), and did not seek to determine whether there is actually a risk of "carcinogenic effects expected from exposure to a cancer hazard," Neugut Tr. at 2671:9-14. Because IARC "conduct[]ed its inquiry at a higher level of generality than what the [jury] must do here," *In re Roundup*, 2018 WL 3368534, at *7, Dr. Nabhan could not rely on the Monograph on its own as evidence of causation.[10] Yet that is precisely what he did, even though "IARC's hazard assessment considers the evidence . . . without the attention to the effects of current human exposure." *Id.*

Dr. Nabhan's use of the IARC Monograph to justify ruling in the Formulation is further undermined because IARC itself describes the epidemiology as "limited," even admitting that "chance, bias, or confounding could not be ruled out with reasonable confidence." Neugut Tr. at 2677:3-10. IARC notably made these concessions before the NAPP and NCI studies were published, both of which were far more thorough in their methodologies and definitive in their findings that the Formulation is *not* associated with cancer. The "limited" association that IARC found—one that cannot rule out "chance, bias, or confounding"—cannot justify Dr. Nabhan's decision to rule in the Formulation. Underscoring the difference between the IARC Monograph and the type of evidence that would be necessary to prove causation, IARC did not even reach a

[10] Judge Chhabria held that expert opinions, such as Dr. Nabhan's, "that simply parrot IARC's analysis and conclusions are somewhat off topic and are unduly limited, rendering them insufficient to satisfy the plaintiffs' burden at the general causation phase. A 'hazard assessment,' as IARC and other public health bodies define that inquiry, is not what the jury needs to conduct when deciding whether glyphosate actually causes NHL in people at past or current exposure levels. An expert who recites IARC's conclusions and analysis therefore may be offering a sound scientific opinion, but not an opinion that speaks squarely to the issue the jury must decide. And in addition to the fact that such opinions are not enough to get the plaintiffs past the general causation hurdle, there is a significant possibility that, if there ever is a jury trial (that is, if any plaintiff can get past summary judgment on the issue of specific causation), expert opinions that go no further than IARC's analysis will be excluded." *In re Roundup*, 2018 WL 3368534, at *7.

conclusion about what dose of glyphosate could possibly cause cancer in humans. *Id*. at 2673:5-8 ("Q. . . . IARC reached no conclusion about a dose of glyphosate that could cause cancer in humans, right? A. I don't think they typically do that."). IARC's self-described limitations in the Monograph preclude it from being used to determine that Plaintiff's exposure to the Formulation was a plausible cause of Plaintiff's MF.

b. Dr. Nabhan's Cherry-Picked Epidemiology Does Not Establish Specific Causation.

Dr. Nabhan's other basis for "ruling in" glyphosate involved plucking three data points from various studies—which he claimed showed a "doubling" of the risk—while ignoring all contrary data, including the conclusions of Plaintiff's actual epidemiologists. This methodology is also legally insufficient to support "ruling in" glyphosate.

Two of the three data points Dr. Nabhan selected—from the Eriksson and McDuffie studies—were legally incapable of evidencing causation because they were not adjusted for other pesticide use at all. A study that analyzes chemicals together and without distinguishing between them cannot logically, or legally, prove that any particular chemical causes cancer. *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."); *see also In re Roundup*, 2018 WL 3368534, at *8 (explaining that reliable epidemiology must determine whether the study adequately considered confounding variables and possible sources of bias, and "[o]ne important possible source of confounding in the studies relevant here is exposure to other pesticides"). Yet despite admitting the importance of separating out and adjusting for other factors,[11] (Nabhan Tr. at 2917:13-16), the risk ratios Dr. Nabhan relied on from the McDuffie and Eriksson studies were *not* adjusted for other pesticides. Tr. at 2915:7-12 (McDuffie); 2917:8-10, 2918:10-12 (Eriksson).[12] In the case of Eriksson, Dr. Nabhan chose to present unadjusted data

[11] All of Plaintiff's experts who discussed epidemiology testified about the problem of confounding and the importance of adjusting for other factors. Neugut Tr. at 2679:1-5; Portier Tr. at 1964:23-25; Nabhan Tr. at 2922:5-2924:17.

[12] Tr. at 2913:11-15 ("Q. Okay. And, Doctor, this McDuffie study, it does not adjust for -- let me

despite the fact that the same paper had presented another analysis ("multivariate" analysis) that was at least partially adjusted for other pesticides,[13] and found a non-statistically significant risk ratio of 1.51. Portier Tr. at 1895:13-20.[14] Dr. Nabhan's reliance on this unadjusted data was litigation advocacy and "junk science," as Judge Chhabria observed in conjunction with the federal MDL proceedings. 3/14/18 MDL Hearing on Daubert Mot at 54:3-5.

For his third data point—De Roos (2003)—the authors published *both* logistical and hierarchical regression analyses. According to the authors, the goal of the hierarchical regression analysis was to *decrease false positives*, and they found a non-statistically significant risk ratio of 1.6 using that method. Portier Tr. at 1887:3-6; Nabhan Tr. at 2826, 2935:20-22. Nevertheless, Dr. Nabhan chose the "logistic regression" number—despite the fact that Plaintiff's own epidemiology expert (Dr. Neugut) used the "hierarchical" regression number. Nabhan Tr. at 2928:18-25; Neugut Tr. at 2693:9-22. Dr. Nabhan also ignored that the data from De Roos (2003) was included into the larger NAPP dataset, and then showed an attenuated 1.13 RR (0.95 when adjusted for proxies), which was not statistically significant. And, perhaps most egregiously, he ignored that the De Roos (2003) paper stated a chemical-specific study was necessary, and then further ignored that very study (the NCI study), (Tr. at 2936:2-23), which concluded that "glyphosate exposure was not associated with cancer incidents overall." Tr. at 2942:12-2943:4.[15]

In short, cherry-picked data that ignores most of the epidemiology evidence, including the largest study (the NCI Study), is not competent evidence to "rule in" glyphosate as a potential cause, particularly where Dr. Nabhan's testimony is contrary to the conclusions of the actual

---

just say this: There's no control for other pesticides in this study; is that right? A. Not that I'm aware of."); *id.* at 2917:4-10, 2918:10-14; 2919:6- 2920:15.

[13] Nabhan Tr. at 2920:11-15 ("Q. And, actually, Doctor, you didn't tell the jury this morning, but when you do the multi-variate analysis, you get no statistically significant result for glyphosate; isn't that right? A. In this paper, that is correct.").

[14] Even before adjusting for other pesticides, the risk ratio cited by Dr. Nabhan from Eriksson was not statistically significant. Nabhan Tr. at 2828:15-20 (Eriksson).

[15] In addition, none of these studies looked specifically at MF. Thus, as in the *Talcum* case, these studies do not support ruling in the Formulation as a cause of *Plaintiff's* illness. *Talcum* Order at *13-14. As Dr. Kuzel testified—unrebutted—the causes and risk factors for each subset of NHL are different, and there are known causes for some subtypes that are known not to be causes for others. Tr. at 4731:19-4734:20; 4742:10-15.

epidemiology experts Plaintiff called to testify. Dr. Nabhan's testimony thus compares unfavorably even with the testimony the Court in the *Talcum* case ruled insufficient as a matter of law. *Talcum* Order at *14 (although expert "ruled in" talc as basis for differential diagnosis based on two epidemiology studies showing relative risk above 2.0, testimony was insufficient because epidemiology did not support that conclusion and did not establish causation for specific subtype of plaintiff's cancer).

2. Dr. Nabhan Failed To Rule Out Idiopathic Causes.

Dr. Nabhan's "differential diagnosis" is legally inadequate to prove causation for the additional reason that he failed to rule out idiopathic causes—which constitute a *majority* of NHL causes—as potential causes for Plaintiff's cancer.

A differential diagnosis cannot support a finding of specific causation where the majority of the instances of the disease are of unknown origin. 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). Likewise, in *Tamraz v. Lincoln Elec. Co*., 620 F.3d 665, 675 (6th Cir. 2010), the Sixth Circuit reversed 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." In *Bland v. Verizon Wireless*, 538 F.3d 893, 897 (8th Cir. 2008), the Eighth Circuit found that "[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."[16] While "California has rejected the notion that an expert must 'exclude *all* possibilities' in reaching a specific causation opinion," the expert must do so when there is "substantial evidence of an

[16] *See Hall*, 886 F.3d at 1314-15 (collecting many cases); *Restatement (Third) of Torts* § 28 cmt 4 (2010) (noting that differential diagnosis is "most useful when the causes of a substantial proportion of the disease are known . . . When the causes of a disease are largely unknown, however, differential etiology is of little assistance"); Federal Judicial Center's *Reference Manual on Scientific Evidence*, at p. 618 ("[F]or diseases for which the causes are largely unknown . . . a differential etiology is of little benefit.").

alternative explanation for the disease." *Cooper*, 239 Cal. App. 4th at 585-586.[17]

The evidence here was undisputed and indisputable: NHL generally, and MF specifically, is an idiopathic cancer. Dr. Nabhan repeatedly admitted that the cause of *the majority* of NHL cases is idiopathic. Tr. at 2990:6-14; 2812:8-10; 2997:17-23; 2998:16-21. And the evidence of Drs. Kuzel and Kim that the causes of MF specifically are *entirely* idiopathic was also undisputed. Kuzel Tr. at 4790:3-4; Nabhan Tr. at 2994:21-2996:1. Dr. Kim—Plaintiff's own physician and a world renowned expert in MF—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: 12-14. Dr. Kuzel likewise testified, "I would say every case of mycosis fungoides is of unknown etiology." Tr. at 4790:3-4.

As *Hall*, *Tamraz*, and numerous other cases make clear, Dr. Nabhan could not possibly rule out unknown causes for NHL and MF when the majority of cases are of idiopathic origin. And Dr. Nabhan did not even try. Instead, he made a speculative leap from Plaintiff's exposure to the Formulation before his MF diagnosis to the unsupported conclusion that this exposure must have been the cause. A differential diagnosis that does not rule out causes of unknown origin when it is undisputed that they constitute a majority of the cases is speculative and cannot prove causation. *See Talcum* Order, at *15 (finding plaintiff's expert's testimony on specific causation to be "mere speculation" based, in part, on expert's testimony that it was "probable" the cause of plaintiff's cancer was unknown).

3. <u>Dr. Nabhan Did Not Consider Plaintiff's Exposure or Latency.</u>

Finally, Dr. Nabhan's differential diagnosis also failed to establish specific causation because Dr. Nabhan did not consider (1) Plaintiff's exposure level, and (2) whether it was possible for Plaintiff to have contracted MF within one to two years after his first exposure.

Dr. Nabhan, like Plaintiff's other experts, admitted that "minimal exposure may not be that significant" in causing NHL. Tr. at 2835:3-10. It follows that Dr. Nabhan could not rule in the

[17] In *Cooper*, the Court rejected the challenge to the differential diagnosis because the defendant had only raised a "bare conceivability of another possible cause," not substantial evidence of one. 239 Cal. App. 4th at 585-586. There is substantial evidence of an idiopathic cause here.

Formulation unless he considered what level of exposure *is* significant in causing NHL and whether Plaintiff was subjected to that amount of exposure. But Dr. Nabhan did not opine on either of these issues. *Id.; see Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1161-62 (E.D. Wash. 2009) (excluding specific-causation opinion as inherently unreliable where all experts agreed that benzene-induced diseases are dose dependent, yet specific-causation expert failed "to analyze or evaluate (his own *or any other expert's*)[18] information pertaining to dose or the actual level of Plaintiff's exposure.").

Dr. Nabhan also testified that he had no data on latency and no opinion about it. Tr. at 3010:22-3011:1. The most he could muster was that: "I think it's very difficult to pinpoint a particular duration, but I would say—I would struggle—or have I would have a tough time linking both together if the lag time was less than a year." Tr. at 3043:19-3044:8. In contrast, Dr. Kuzel testified—again unrebutted—that MF takes "years" to develop biologically. Tr. at 4748:5-14. Without competent evidence that Plaintiff's MF could have been caused in the short period between when he was first exposed to the Formulation and the onset of his disease (at most 18 months), Dr. Nabhan should not have been allowed to "rule in" the Formulation as a cause of Plaintiff's MF in his differential diagnosis.

D. Dr. Sawyer Did Not Opine on Specific Causation and His Testimony Does Not Demonstrate that the Formulation Was a Substantial Cause of Plaintiff's MF.

Dr. Sawyer's testimony was also insufficient to prove causation. He never actually testified that the Formulation substantially contributed to Plaintiff's MF. In fact, when asked about causation, Dr. Sawyer changed the subject and responded that Plaintiff was "heavily exposed" to the Formulation. Tr. at 3596:15-3597:4. But the level of exposure on its own does not necessarily mean anything about causation. To be sure, Dr. Sawyer later testified that Plaintiff's exposure "puts him approximately in the middle of the human epidemiologic studies that show human cancer." Tr. at 3674:25-3675:16. But those are the same studies that do not

[18] Although Dr. Sawyer testified that Plaintiff's exposure was theoretically sufficient to cause NHL, Dr. Nabhan did not rely on that opinion—or the opinion of any other of Plaintiff's experts. Tr. at 3674:25-3675:16; *see also Talcum* Order, at *14.

meet the legal threshold under California law to establish causation. Plaintiff cannot bootstrap these inadequate studies with Dr. Sawyer's testimony to reach causation especially when Plaintiff's counsel and experts agree the epidemiology is not sufficient to establish causation.

III. PLAINTIFF'S CLAIMS FAIL AS A MATTER OF LAW ON MULTIPLE INDEPENDENT GROUNDS.

Aside from failing to prove causation, each of Plaintiff's legal theories fails as a matter of law for other legal reasons. First, the design defect claim fails because Plaintiff chose to present a legal theory ("consumer expectation") that does not apply to this case as a matter of law and for which he presented no evidence. Second, the failure-to-warn claims fail because the evidence affirmatively refuted any duty to warn, given the undisputed state of the best prevailing scientific and medical knowledge.

A. Plaintiff's Design Defect Claim Fails as 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. In this case, Plaintiff elected to pursue its claim only under the consumer-expectation test for design defect, despite Monsanto's urging that the risk-benefit test was the only one that could possibly fit the case.[19] Plaintiff's "consumer expectation" theory fails for two reasons: first, the consumer expectation test does not, as a matter of law, apply in these circumstances; and second, there was no substantial evidence from which a jury could reach a verdict even under that theory.

1. The Consumer-Expectation Test Was Not Appropriate as a Matter of Law.

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. "[W]hen the ultimate issue of design defect calls

[19] Tr. at 4893:13-21, 4900:8-4904:17; Pl.'s Proposed Substantive Jury Instrs. at 1 (May 8, 2018).

for a careful assessment of feasibility, practicality, risk, and benefit, the case should not be resolved simply on the basis of ordinary consumer expectations." *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).

In *Trejo*, the court rejected the plaintiff's assertion that the consumer-expectation test should apply to his developing Stevens-Johnsons Syndrome from taking over-the-counter Motrin, since "it could be said that any injury from the intended or foreseeable use of a product is not expected by the ordinary consumer. If this were the end of the inquiry, the consumer expectation test always would apply and every product would be found to have a design defect." 13 Cal. App. 5th at 158-59. Given that the claim before it involved technical detail and medical testimony, the court held the consumer expectation test inapplicable. *Id.; see also Morson v. Superior Court*, 90 Cal. App. 4th 775 (2001). *See Trejo*, 13 Cal. App. 5th at 159 (noting that four other California cases "indicate that the consumer expectation test does not apply merely because the consumer states that he or she did not expect to be injured by the product"). In *Morson*, the Court recognized "the special problem here of reconciling products liability law that has developed in the context of merchandise, such as soda bottles and automobiles, with the body of knowledge that deals with medical and allergic conditions and their genesis." 90 Cal. App. 4th at 791. The court further acknowledged that "the consumer expectation test can be applied even to very complex products, *but only where the circumstances of the product's failure are relatively straightforward*." *Id.* at 792 (example of defective automobile exploding while idling at stoplight). 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." *Id.*

Like *Trejo* and *Morson*, Plaintiff's claims turn on complex scientific details about how the Formulation works *and* expert testimony about the "effect of the product upon [Plaintiff's] health." *See id.* As *Trejo* makes clear, the consumer expectation test does not apply simply

because Plaintiff did not expect the Formulation 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 the Formulation—like Motrin in *Trejo*—can be used safely reinforces that the test does not apply. Dr. Sawyer testified that the Formulation is safe to use and he has safely used it for decades. Tr. at 3601:14, 3602:10. This testimony makes the issue of whether a design defect exists complicated, as it shows that there are many factors that come into play as to when and how the product can be used safely. In short, 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. The extensive expert testimony presented in this case should be enough on its own to establish that the ordinary consumer could not reasonably appreciate the complex scientific issues of safety and risk at play here.

2. <u>The Evidence Under the Consumer Expectation Test Was Insufficient.</u>

For the jury's verdict to stand under "the consumer expectation" test, the Court must find substantial evidence that (1) the Formulation is a product about which an ordinary consumer can form reasonable expectations, (2)the Formulation did not perform as safely as an ordinary consumer would have expected, (3)causation, and (4) harm. Pl.'s Proposed Substantive Jury Instrs. at 17 (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 the Formulation 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 has presented no evidence that the *design of the product*, i.e. the Formulation as opposed to pure glyphosate, caused Plaintiff's MF. To the contrary, Dr. Nabhan testified that glyphosate and the Formulation are "interchangeable." Nabhan Tr. at 2788:7-9.[20]

[20] No substantial evidence established that the Formulation is more carcinogenic than pure glyphosate, particularly in the instance of Plaintiff's cancer. And Plaintiff cannot claim that the product at issue was glyphosate because (1) that was not the theory he presented to the jury; and (2) imposing categorical liability on glyphosate would be against California law. *See Poosh v. Philip Morris USA, Inc.*, 904 F. Supp. 2d 1009, 1025-26 (N.D. Cal. 2012) (applying California

The evidence also did not "support a finding that the ordinary consumer can form reasonable minimum safety expectations" about the Formulation. *See Saller*, 187 Cal. App. 4th at 1234; *see also* May 17, 2018 Order on Deposition Designations and Certain Proposed Jury Instructions at p. 4-5. There was no evidence the Formulation or its effects are part of the "everyday" experience of the ordinary consumer or that minimum safety standards for the Formulation are common knowledge of the ordinary consumer. Plaintiff himself was not an ordinary consumer; he was certified as a qualified applicator and purchased the product from a special distributor, not a retail store. Johnson Tr. at 3225:18-23, 3303:22-3304:19. He had specialized training on how to mix and apply the product safely. *Id.* at 3229:5-19, 3313:12-16.

In light of the complex expert evidence on the critical issues in this case, the consideration of safety expectations for the Formulation are simply beyond the purview of ordinary consumers. JNOV must be granted on the design-defect claim for this additional reason.

B. Monsanto is Entitled to JNOV on the Failure to Warn Claims.

The jury's verdicts on strict liability and negligent failure to warn are not supported by substantial evidence: there is no evidence any cancer risk was known or knowable generally or by Monsanto or that a failure to warn actually caused Plaintiff's injury.[21]

1. The Alleged Cancer Risks Were Not Known or Knowable in Light of the Prevailing Scientific and Medical Knowledge.

The jury's failure to warn verdict cannot stand unless there was 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." *Carlin*, 13 Cal. 4th at 1112, 1116; *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467,

---

law and rejecting that cigarette company could be liable for defective design of cigarettes because "[t]aken to its logical conclusion, the argument . . . would mean that the only remedy for this alleged design defect would be a ban on the manufacture and sale of any cigarettes containing nicotine"); *see also* Restatement (Second) of Torts 402A, cmts. k, j; *Brown v. Superior Court*, 44 Cal. 3d 1049, 1059-60 (1988); *Oaks v. E.I. Du Pont de Nemours & Co.*, 272 Cal. App. 2d 645 (1969).

[21] Judge Karnow's Order dated May 17, 2018, granted Plaintiff's motion for summary judgment on Monsanto's preemption defenses. Because that Order is a final adjudication of these defenses, Monsanto will not reassert them here but maintains that they are meritorious and preserves them.

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").

Even if Plaintiff had managed to prove a causal link between the Formulation and NHL or MF, 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 Formulation was distributed, which had to have been prior to Plaintiff's diagnosis in 2014.[22] The evidence showed just the opposite. As is true today, the scientific and regulatory communities were virtually uniform in the belief that glyphosate and glyphosate-based herbicides 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. Portier Tr. at 2100:18-2101:22, 2098:13-23, 2104:21-2105:18, 2111:2-9, 2121:11-19; *see also* CACI 1205 Comments (risk must be "generally recognized," "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"). And the NCI Study definitively refutes whatever tentative support the IARC Monograph might have provided for the existence of a connection between the Formulation and NHL.

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 distribution. Even putting the timing aside, 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 and thus does not support that cancer is a probable risk from exposure to the Formulation. Portier Tr. at 1717:7-12, 1741:25-1742:15. Plaintiff's own treating physicians told him that there was no known cause for MF and no evidence establishing the Formulation as a cause of MF. Johnson Tr. at 3324:20-3325:19. That was true at the time of his diagnosis and

[22] There was no evidence that Plaintiff's exposure after 2014 made his MF worse or changed his prognosis. Nabhan Tr. at 2864:19-2865:6; Kuzel Tr. at 4777:16-22.

remains true today. Thus, Plaintiff presented no evidence that any risk was known or reasonably knowable to the scientific community during the relevant time period.

2. Monsanto Did Not Know, Nor Should It Have Known, of the Alleged Risk and There Was No Evidence that a Reasonable Manufacturer Would Warn.

The negligent failure to warn verdict also cannot stand because there was not substantial evidence that Monsanto knew or should have known of the risk and that its conduct in failing to warn fell below the standard of care of a reasonable manufacturer under the same or similar circumstances. CACI 1222 (plaintiff must prove "that [defendant] knew or reasonably should have known that the [product] was dangerous"); *Kase v. Metalclad Insulation Corp.*, 6 Cal. App. 5th 623, 644 (2016). JNOV should be granted where the plaintiff fails to present competent evidence of the applicable standard of care. *Stephen v. Ford Motor Co.*, 134 Cal. App. 4th 1363, 1367 (2005) (affirming nonsuit in favor of defendant where plaintiff did not have any expert testimony or evidence establishing the applicable standard of care).

Plaintiff's evidence came up short in almost every way. He presented no evidence on the standard of care. And he presented no evidence that a reasonable manufacturer would warn given the status of the science. In short, there was no evidence—none—that a reasonable manufacturer knew or should have known that the Formulation could cause MF at any relevant time. To the contrary, the evidence established Monsanto reviewed the vast scientific data and concluded there was no risk to warn about, while complying with all regulatory requirements and gaining regulatory approval. Goldstein Dep. at 329:18-330:11. Indeed, Monsanto actually conducted *more* tests on the Formulation than required by regulators. Farmer Dep. at 433:9-434:2. Plaintiff failed to establish Monsanto did not act reasonably or in accordance with the applicable standard of care.

3. Any Failure to Warn Did Not Cause Plaintiff's Injury.

Finally, no substantial evidence supported a finding that a warning would have changed Plaintiff's exposure or prevented his disease. *See, e.g., Huitt v. S. Calif. Gas Co.*, 188 Cal. App. 4th 1586, 1604 (2010); *In re Zyprexa Prods. Liab. Litig.*, 2009 WL 1850970, at *14 (E.D.N.Y. June 22, 2009); *Rosburg v. Minn. Mining & Mfg. Co.*, 181 Cal. App. 3d 726, 735 (1986). Rather,

the unrefuted evidence established:

- Plaintiff already wore personal protective equipment because he thought the Formulation was dangerous. "Q. So why did you decide to wear all that? Because I knew I was applying a chemical, and if it could kill weeds, I'm pretty sure it could kill me, is the way I looked at it, so I didn't play with that stuff at all. I took it seriously, and that's why I wore anything I could to protect myself." Johnson Tr. at 3237:11-16.

- Plaintiff kept spraying after he suspected the Formulation caused cancer and allegedly was told by his employer that it caused cancer. *Id.* at 3235: 6-25.

- Plaintiff kept spraying after he asked his treating physician whether he should stop spraying and she wrote to the School Board requesting that Plaintiff not be exposed. *Id.* at 3154:2-16.

- Plaintiff kept spraying after the first acute exposure incident, even though he was concerned about his health and safety. *Id.* at 3266:13-15.

In short, because there was no evidence that a different warning would have changed his exposure or diagnosis, Monsanto is entitled to JNOV on the failure to warn claim.

IV. MONSANTO IS ENTITLED TO JNOV ON PUNITIVE DAMAGES BECAUSE THE EVIDENCE WAS NOT SUFFICIENT TO SUPPORT THE VERDICT.

Punitive damages cannot be warranted unless there was clear and convincing evidence that Monsanto *knew* or *should have known* the Formulation could cause NHL or MF and failed to take appropriate actions based on that knowledge. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 419 (2003). It would require extraordinary evidence to show that Monsanto did know such a thing when the consensus of those who make such evaluations for the public safety—EPA and the other national and international regulators—agree that the Formulation does *not* cause any human cancer. But no such extraordinary evidence (or *any* competent evidence) was offered to demonstrate such knowledge. This Court initially recognized the paltry evidence for punitive damages, noting that, even "cobbled together," the evidence "just barely meets the threshold to allow [punitive damages] to go to the jury." 7/30/18 Tr. at 4027:4-8. The evidence is now in and it was not enough. Reviewing the evidence in the light most favorable to Plaintiff, the "best that can be said is that there was (and is) an on-going debate in the scientific and medical community" about whether the Formulation "more probably than not" causes NHL; this does not and cannot give rise to a duty to warn, much less punitive damages. *Talcum* Order, at *16.

A. Punitive Damages Are Disfavored and Subject to Exacting Proof Requirements.

Punitive damages are "disfavored" because they create the "anomaly of excessive compensation." *Piscitelli v. Friedenberg*, 87 Cal. App. 4th 953, 980 (2001). The standard for punitive damages is deliberately high. California requires clear and convincing evidence of both (1) an "intent" to cause harm or a "willful and knowing disregard for the safety of others," and (2)a "despicable" act that is "so vile, base, or contemptible that it would be looked down upon and despised by reasonable people." CACI 3945; Cal. Civ. Code, § 3294(c)(1). The Legislature's amendment of Section 3294(c)(1) to add "despicable" in 1987 "represent[ed] a new substantive limitation on punitive damage awards," that "must be found" along with the preexisting intent or "willful and conscious disregard" element. *College Hosp. Inc. v. Superior Court*, 8 Cal. 4th 704, 725 (1994).

Not only must the wrongful actor engage in "despicable conduct" that "consciously disregard[ed] the safety of others," that conduct must be perpetrated, authorized, or ratified by an officer, director, or managing agent of the corporation. *Wilson v. Southern Cal. Edison Co.*, 234 Cal. App. 4th 123, 164 (2015); Cal. Civ. Code § 3294(b). 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." *Id.*

Finally, "[p]unitive damages . . . must be tied to oppression, fraud, or malice in the conduct which gave rise to liability in the case" *and caused plaintiff's harm. See Willis v. Buffalo Pumps Inc.*, 2014 WL 1028437, *5 (S.D. Cal. Mar. 17, 2014); *see also Holdgrafer v. Unocal Corp*., 160 Cal. App. 4th 907, 928 (2008) ("[W]e agree…that the…evidence should have been excluded from trial because it involves deplorable conduct that had nothing to do with the conduct that harmed Plaintiffs."); *State Farm*, 538 U.S. at 422-423 (requiring the wrongful conduct to "have a nexus to the specific harm suffered by the plaintiff").

B. There Is No Evidence Monsanto Willfully and Knowingly Disregarded Risk of NHL or Intended to Cause Harm.

There was no evidence, let alone clear and convincing evidence, that any Monsanto employee or scientist intended to harm Plaintiff or other consumers, or willfully and knowingly

disregarded a cancer risk. Indeed, the documents and testimony relied upon by Plaintiff were taken out of context, and the record establishes that they did not support Plaintiff's arguments or the imposition of punitive damages.

No Evidence Monsanto Willfully and Knowingly Disregarded a Risk that the Formulation Could Cause NHL. Plaintiff presented no evidence that any Monsanto employee believed that exposure to the Formulation causes NHL. All testimony from Monsanto employees was emphatically to the contrary. Dr. Farmer, for example, testified that there is no evidence to support the statement that the Formulation causes cancer. Farmer Dep. at 52:20-22. She further testified that the surfactants "are not carcinogenic" based on testing. *Id.* Dr.Goldstein testified from a clinical view that "sound science supports the contention that glyphosate does not cause cancer." Goldstein Dep. at 40:10-12.

Plaintiff relied on a sentence of one email in which Dr. Farmer correctly advised a public relations employee that he should not say that animal carcinogenicity studies show that "Roundup"—the Formulation—does not cause cancer, because glyphosate itself, not the formulation, was the subject of these studies. Farmer Dep. at 52:3-7; 53:15-18; PX 305. Everybody agreed that the U.S. EPA mandates long-term animal cancer bioassays on only glyphosate, not the Formulation—because, as Dr. Foster explained, bioassays of the Formulation are not feasible. Tr. at 4504:4-16. In the very same email, Dr. Farmer endorses the statement that "Roundup did not cause cancer, birth defects, or adverse reproductive changes at dose levels far in excess of likely exposure." PX 305. Plaintiff's misuse of Dr. Farmer's statement provides no basis for a finding of intent to harm Plaintiff.

Plaintiff also asked the jury to consider a 2002 internal memorandum acknowledging "six published studies that arguably associate glyphosate and other pesticides with lymphopoietic cancers or adverse reproductive outcomes." PX 282 (not admitted into evidence). But that was not Monsanto's view, or the views of any of the regulators (or IARC) reviewing those studies. Monsanto's view was stated in the very first sentence of the document, which makes explicit that "[g]lyphosate has very favorable toxicologic properties. It is not carcinogenic, mutagenic or neurotoxic and it is not a reproductive or developmental toxin." *Id.* With respect to the "six

published studies" the memo notes that "independent reviewers judge these studies to be poor quality." Further, the purpose of the memo is to address these "poor quality" studies with additional research—a proposal to conduct a family farm study to better understand "applicator pesticide exposure under 'real world' conditions." *Id.* And that is what Monsanto did.

By the time Plaintiff was exposed to the Formulation, glyphosate had developed one of the largest bodies of scientific data of any substance in the world. Portier Tr. at 2051:1-3; Martens Dep. at 194:9-14. There was, and is, a global consensus of safety both before and after IARC. Indeed, after IARC's evaluation, all of the worldwide regulators continue to find that the Formulation is safe and *not* carcinogenic—not only U.S. EPA, but also EFSA, ECHA, Australia, New Zealand, and the German BfR authority. Farmer Dep. at 395:7-15, 400:16-24; Portier Tr. at 2014:6-14, 2110:23-2111:1; Goldstein Dep. at 340:7-341.3; *BMW of North America v. Gore*, 517 U.S. 559, 575 (1996); *see also Willis*, 2014 WL 1028437, at *5; (holding that knowledge by defendant that "postdate[s] Plaintiff's exposure to Defendant's products . . . can lend no support to Plaintiff's claim that Defendant acted with malice" due to lack of nexus to specific harm). Even IARC's sister organization within WHO (JMPR) rejected a cancer link both before and after IARC's classification. Farmer Dep. at 396:5-20. Monsanto cannot be punished, consistent with the "elementary notions of fairness" for a risk that no regulatory or scientific body, or other manufacturer, had identified prior to Plaintiff's exposure and MF diagnosis. *See also* Prosser and Keeton on Torts § 36, at 233 n.41 (5th ed. 1984) ("In most contexts… compliance with a statutory standard should bar liability for punitive damages."). It is not consistent with Due Process to "punish" Monsanto based on an honestly-held scientific conclusion that Monsanto shared with the world's regulatory scientists and Plaintiff's own doctors.

Finally, Plaintiff presented no evidence that Monsanto had unique knowledge of risks associated with exposure to the Formulation unknown in the scientific domain available to public regulators.[23] Judge Nelson observed in the *Talcum* Order that, in light of "the fact that the

[23] Plaintiff alleges that Monsanto failed to properly respond to opinions expressed by Dr. Parry in the late 1990s with respect to various published and regulatory genotoxicity studies. This allegation is false for the reasons stated *infra* at 28-29, but in any event, the studies addressed by

scientific community was (and is) divided on the question of whether talc causes ovarian cancer," it was "significant" that plaintiff presented "no internal research or study by [defendant] that was not in the public scientific domain" suggesting the defendant "'knew or should have known' of the dangers of talc." *Talcum* Order, at *15-16. She held that where science is divided a "showing [of knowledge] beyond the publicly available literature" was required to support punitive damages. *Id.* That reasoning applies with equal force here.

No Evidence that Monsanto Intended to Cause Harm. There likewise is no basis in the record to conclude that anybody at Monsanto—at any time—intended to cause harm.

The Court cited two emails as a basis for denying Monsanto's motion for directed verdict on punitive damages—an email from Dr. Farmer discussing the McDuffie epidemiology study (PX 313) and another email from Dr. Heydens discussing the issue of allegedly "ghostwriting" the Williams (2000) paper (PX 362). 8/6/18 Tr. at 4908:22-4909:22. In the McDuffie email, Dr. Farmer approves of the decision by the study authors not to identify glyphosate in the study abstract. This email is in full accord with Dr. Farmer's belief glyphosate does not cause cancer, a conclusion with which regulators around the world agree. *See supra* at 21-22. Indeed, Plaintiff's own experts agree that there is no finding of any statistically significant association in that study which is fully adjusted for other pesticides. *See supra* at 3-4. Further, Dr. Farmer's reaction to the McDuffie investigator's drafting decision does not reflect *any* affirmative "act" much less the type of "despicable" one required for imposition of punitive damages.

The other email the Court cited is by Dr. Heydens in late 2015 and uses the word "ghostwrite" in reference to a review article by three other scientists published some 15 years prior. As Dr. Heydens testified, however, Monsanto scientists did not "ghostwrite" the Williams (2000) paper, unequivocally shown by the fact that both Dr. Heydens and Dr. Farmer, along with other Monsanto scientists, specifically appear in the Williams (2000) acknowledgements as making a "substantial contribution" to the paper. Heydens Dep. at 406:12-18. Nor was there any claim that there was anything false or misleading about the Williams (2000) publication; no one

---

Dr. Parry were published in the peer-reviewed literature and/or known to U.S. EPA.

claimed the review of the science was wrong or fraudulent. And to the extent that Plaintiff relies on purported ghostwriting of separate publications in late 2015, those allegations also ignore the testimony of Drs. Heydens and Farmer, the explicit acknowledgment of Monsanto support in the articles and, in any event, would have occurred *after* Mr. Johnson's use of the Formulation. Thus, there could be no conceivable nexus to any harm to him.

Plaintiff's Failure to Test Theory. The other charge levied against Monsanto's collective mental state was that Monsanto failed to adequately test its product. Not only is that allegation insufficient as a matter of law for punitive damages (it implies a negligence, not a malice standard), the charge is emphatically contrary to the evidence that glyphosate is among the most extensively studied chemicals of all time, backed by a massive regulatory body of studies over the course of decades. Plaintiff presented no evidence that Monsanto did not comply with ongoing regulatory requirements to support its product with GLP (Good Laboratory Practice)-quality testing. Indeed, the very documents Plaintiff presented to the jury of "bad intent" show Monsanto continuing to go above and beyond the regulatory requirements. For instance, PX 282 is an internal memorandum deciding to conduct a biomonitoring study in Formulation-exposed farm workers—above and beyond any regulatory requirements to do so—to determine whether there could be any cancer concern from real world exposures to the Formulation. The evidence further showed that *no regulatory agency* in the world requires the testing Plaintiff claims Monsanto failed to conduct—long-term carcinogenicity testing on the Formulation (as opposed to separate testing on the active or other ingredients)—and that no other glyphosate formulation manufacturer in the world does such testing. There was thus no evidence that Monsanto failed to comply with any applicable industry standard; in fact, evidence was presented (unrebutted) why such tests *cannot be* and *are not* conducted. Foster Tr. at 4504:4-21, 4505:9-14.

Finally, the charge that Monsanto's scientists "ignored" Dr. Parry's advice to do more genotoxicity tests (beyond the dozens already conducted and submitted to federal regulators) is also factually baseless. The evidence was that Monsanto conducted the majority of additional studies proposed by Dr. Parry and publicly presented the results. Martens Dep. at 127:11-129:3; 216:16-217:21, 218:18-25. Upon review the results of these studies, Dr. Parry agreed that the

Formulation was not genotoxic. *Id.* at 224:25-225:7, 227:20-228:5. Regulators around the world agree. This evidence cannot, as a matter of law, support a finding of malice.

The IARC Monograph does not support punitive damages. The Monograph was released *after* Plaintiff was diagnosed with MF, and thus cannot inform Monsanto's mental state at any relevant period of time. Nabhan Tr. at 2869:25-2861:25. Prior to that time (and since), worldwide regulators have concluded that the Formulation is safe for use and need not contain a cancer warning. Portier Tr. at 2010:4-25, 2098:21-23, 2106:12-15, 2110-2112, 2121-2122. Moreover, Monsanto's scientists testified that they all agreed with the EPA's review of the science (and EFSA, ECHA, BfR, etc.), which was indisputably more thorough than IARC's. IARC evaluated glyphosate (and the four other chemicals discussed in Monograph 112) during the course of a single week. Blair Dep. at 117:16-24. Plaintiff's expert Dr. Benbrook testified that U.S. EPA's ongoing review of glyphosate for its current reregistration has gone on for *several years* and reflects the state of the science at that time. Benbrook Tr. at 3965:1-6. U.S. EPA, not IARC, has access to all of the original study reports for each of the animal carcinogenicity studies. IARC considered only a fraction of the data that U.S. EPA and other regulators considered, including only a small fraction of the animal studies and genotoxicity studies that U.S. EPA reviewed. IARC also did not consider the NCI Study, the unpublished data in its chairperson's possession underlying that publication, or the NAPP pooling data. And IARC did not perform a real-world *risk* assessment. Portier Tr. at 1741:25-1742:15.

Thus, while Plaintiff argued that Monsanto had plans to "orchestrate outcry" with IARC's decision shortly before it issued, the evidence was that Monsanto legitimately disagreed with IARC's process. Goldstein Dep. at 209:7-15. First, anticipation of IARC's classification is entirely understandable, given the one-in-a-thousand historical odds that a chemical will be classified as Group 4 (probably not carcinogenic), or the unlikely outcome that a product with 40 years of science and data would be classified as Group 3 (not classifiable). Neugut Tr. at 2598:4-19; Nabhan Tr. at 3003:13-3005:25. Second, all of the Monsanto scientists who testified explained that they disagreed with IARC's classification after it was released.

At most, Plaintiff has shown that there is a bona fide scientific disagreement, with IARC's

hazard assessment on one side and the fulsome assessment of every Monsanto scientist and every regulatory body on the other. This Court, in considering the submissibilty of punitive damages, noted that "the science here is very much in dispute" and that the Court would "have to reconsider [punitive damages], depending on what the jury does with that." 7/30/18 Tr. at 4027:4-8; 8/6/18 Tr. at 4908:17-21. The Court should do so: a "bona fide disagreement" about a scientific dispute does not demonstrate clear and convincing evidence of malice as a matter of law. *See Kendall Yacht Corp. v. United California 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); *Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1316-17 (5th Cir. 1995) (debate concerning whether benefits of leg guards outweighed their risks militated against punitive damages); *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).

C. No Clear and Convincing Evidence Monsanto Acted Despicably.

Plaintiff also failed to present any evidence, let alone clear and convincing evidence, for the second element of punitive damages—a "despicable act" by Monsanto. Plaintiff argued to the jury that Monsanto's supposed "ghostwriting" of scientific articles, attempts to influence EPA, failure to return a phone call to Plaintiff, and failure to inform Plaintiff about IARC's classification in a later call was "despicable conduct." The actual evidence falls far short of "despicable conduct" under the JNOV standard.

1. Monsanto's Participation in Science Was Not Despicable.

Plaintiff's counsel repeatedly argued to the jury that Monsanto "made a choice to engage in ghostwriting" and that in "document after document . . . Monsanto's response to . . . legitimate scientific concerns, is to make up science." Closing Tr. at 5056:20-23. These assertions were unfounded. No evidence was presented purporting to show that Monsanto fabricated any scientific data. Plaintiff did not even try to present any such evidence; it appears the only reason these allegations were presented was to allow Plaintiff's counsel to make false assertions that Monsanto "made up" science.

The evidence does not suggest anything despicable. Dr. Farmer explained, generally, how Monsanto works with an independent author:

> [I]'s a draft for them to include or exclude in their final publication. And we provide input all the time because we have some more of the knowledge that they do, but there's nothing here that we're trying to hide. We're actually adding more information for them to include in that review. Again, under the umbrella of transparency, we're trying to make sure that it's a really thorough, complete document. And then they can choose in that sense to either complete them, change them, delete them, do whatever they want to do with them.

Farmer Dep. at 122:25-123:13. Dr. Farmer further explained that when Monsanto works with an independent author "they talk about us in their credits" so "everyone knows" Monsanto made contributions. *Id.* at 122:4-11. Again, the evidence bears this out:

- **Williams 2000**: Dr. Heydens explained repeatedly that Plaintiff's allegation he "ghostwrote" the Williams 2000 review is incorrect. (Heydens Dep. at 124:23-125:8). The Williams 2000 paper unambiguously acknowledges Monsanto "made significant contributions" to the paper, including specifically Dr. Heydens. (Portier Tr. at 1890:12-1891:22). Monsanto was helping to make public the findings of regulatory safety studies; it was not hiding its contribution from scientific or regulatory bodies, or the public at large.

- **Kier & Kirkland 2013**: Monsanto employee David Saltmiras did not and could not participate in the preparation of this paper because it required review of proprietary information of other glyphosate registrants. (PX 445). But what he did do—along with several employees of other glyphosate registrants—is "thoughtfully review" the paper after it was drafted, as well as coordinate the dissemination of information to Kier & Kirkland from all the glyphosate registrants, all of which is noted on the face of the Kier & Kirkland paper itself. (PX 799, p. 310-11).

- **Intertek Papers 2016**: These papers acknowledge on their face that they were sponsored by Monsanto. At the request of the coordinator of the Intertek expert panels, Dr. Heydens provided his "suggestions" as well as "minor edits" concerning an introductory summary paper recounting the findings of the separately published independent panel papers, for the coordinator to use "the way he saw fit." (Heydens Dep. at 168:1-10). Dr. Heydens had "no idea" what Intertek did with the edits before the summary paper was published, which, in any event, long post-dated Mr. Johnson's MF diagnosis and last exposure to the Formulation. (*Id.* at 175:1-22).

Evidence showing Monsanto follows, understands, and participates in scientific study and literature concerning glyphosate should be shocking to nobody.

Plaintiff's unfounded ghostwriting accusations are also irrelevant to punitive damages because they are entirely unrelated to the conduct that gave rise to liability. Plaintiff did not introduce any evidence that tied alleged "ghostwriting" or responses to IARC to any effect on him. He also did not present any evidence that such alleged conduct in any way altered the science or

was despicable. Although Plaintiff's accusations allegations may have inflamed the jury, without evidence that Monsanto's participation in meaningful scientific debate had any connection to harm to Plaintiff, they cannot support the award of punitive damages.

2. Petitioning a Regulatory Agency Is Not Despicable Conduct.

Plaintiff presented some testimony concerning Monsanto's interactions with regulators, including EPA, and argued during closing argument that this communication with EPA was "creepy." Tr. at 5067:21–5068:22. This is a straightforward attempt to punish First Amendment protected activity. And it is unlawful. Punitive damages may not rest on discussions Monsanto had with EPA, whether about glyphosate, the weaknesses of the IARC Monograph, or how the science might affect regulatory standards. The First Amendment protects Monsanto's right to advocate its interest to U.S. EPA. *Stern v. United States Gypsum*, 547 F.2d 1329, 1342 (7th Cir. 1977) (right to petition government is "fundamental to the very idea of a republican form of governance."). Under the *Noerr-Pennington* doctrine, which is derived from the First Amendment, civil liability may not rest on advocacy or lobbying efforts conducted before governmental bodies. *See United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965); *E.R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *accord Ludwig v. Superior Court*, 37 Cal. App. 4th 8, 21 (1996) ("Those who petition the government are generally immune from … liability."). The punitive damages award cannot rest on Monsanto's lawful and legitimate interactions with the EPA.

3. Monsanto's Failure to Return a Phone Call to Plaintiff Does Not Support Punitive Damages.

Plaintiff called Monsanto in November 2014 and the Missouri Regional Poison Control ("MRPC") in March 2015 to report that a rash appeared after an exposure to the Formulation. *See* PX 333; *see also* Johnson Tr. at 3324:1-16. During the initial 30-45 minute call, Plaintiff spoke to a Monsanto employee who "knows her product very well" and was accurately informed "we really don't have those symptoms along with this product." Nabhan Tr. at 2983:2-2984:22. Plaintiff's counsel argued to the jury that Monsanto "made a choice when they didn't call [Plaintiff] back." Closing Tr. at 5056:14-19; PX 332. Dr. Goldstein, a clinical physician employed by Monsanto,

was informed about the call, stated in internal correspondence that he intended to call him back, testified under oath that he intended to call Plaintiff back, but did not recall doing so. Goldstein Dep. at 37:13-17. Plaintiff made his second call in March 2015, when he spoke to MRPC at length about his condition. Closing Tr. at 5103:10-20; PX 334.

With no evidentiary support, Plaintiff's counsel attempted to insinuate nefarious conduct from this circumstance. Arguing to the jury, Plaintiff's counsel stated that Monsanto "made a choice when they didn't call [Plaintiff] back," (Closing Tr. at 5056:14-19; PX 332) because Monsanto was worried that calling Plaintiff back and warning about IARC would harm California sales of Roundup. But Plaintiff offered no evidence that Monsanto made a "choice" not to call Plaintiff, much less one motivated by greed or intent to deny Plaintiff any safety information. At worst, this isolated episode amounted to "mere carelessness," which "does not justify the imposition of punitive damages." *Lackner v. North*, 135 Cal. App. 4th 1188, 1210 (2006).[24]

Further, there is no nexus between the phone calls and Plaintiff's injury. At the time of the calls, Plaintiff had already contracted his disease and been diagnosed with MF. There is no evidence that disclosure of the IARC Monograph some 1-2 years after Plaintiff's MF became symptomatic could have had any impact on his existing cancer. As discussed above, the only "evidence" of "tumor" promotion were the benign growths from the 2010 George study—deemed by IARC itself to be an "inadequate study" with a "poor design." PX 784 at 0034; Portier Tr. at 1863:21-25 ("[IARC] reviewed it. I don't believe they used it."); 2229:13-2230:6.[25]

D. <u>No Clear and Convincing Evidence of Conduct by a Managing Agent.</u>

There was also no evidence in this case of conduct from an officer, director, or managing

---

[24] The allegedly unreturned phone call involving Dr. Goldstein took place months before IARC's classification, and there is no evidence that Monsanto made a "choice" or directed MRPC to suppress any information to Plaintiff during the second call, which occurred only days after IARC publicly announced its classification of glyphosate.

[25] EPA likewise declined to consider that study, on the basis that it was "inadequate in protocol, conduct or reporting." Portier Tr. at 2207:14-19; DX 2481 at 0070. Dr. Nabhan agreed that there is no evidence that Plaintiff's continued use of the Formulation contributed to his MF or somehow made it worse—Dr. Nabhan just did not know ("I don't think we know. You know, I mean, it's hard to tell."). Tr. at 2865:1-5. Dr. Kuzel testified that he had never seen "any evidence" that Plaintiff's MF progressed because he continued using the Formulation. Tr. at 4777:16-22.

agent of Monsanto. 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.").

At the jury instruction conference, the Court expressed the view that Kirk Azevedo and Steven Gould were not managing agents. 8/6/18 Tr. at 4908:5-9. The Court was correct: Azevedo, whose testimony was later stricken, was a former Monsanto sales representative located in California who serviced distributors (Azevedo Dep. at 34:1-35:19) and Gould is a sales account manager in California. PX 290. No evidence suggested either had any corporate responsibility outside of making sales and managing accounts.

The Court also expressed its view that it was "not convinced" that either Dr. Farmer or Dr.Goldstein were managing agents either. 8/6/18 Tr. at 4907:16-25. The evidence confirms that they were not. Dr. Farmer is a "toxicologist in [Monsanto's] product safety center" who has been "one of the spokespersons for the safety of Roundup when it comes to the toxicology." Farmer Dep. at 14:23-15:7. Her specific job responsibility is to "make sure as a regulatory toxicologist . . . [Monsanto] meets all the requirements by the regulators." *Id*. at 19:14-17. A "spokesperson" does not create the policies they are speaking on. Dr. Goldstein served as a "director" in medical toxicology" and a "lead" in "medical sciences and outreach." Goldstein Dep. at 151:8-13. He is a physician and clinical toxicologist who reviews "complaints of human health" made to Monsanto. *Id.* at 8:7-24. He is not formulating or directing corporate policy.

/////

/////

/////

/////

/////

/////

/////

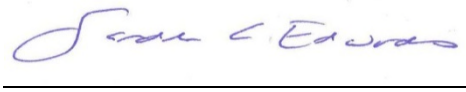
/////

CONCLUSION

The scientific evidence in this case falls far short of the sufficient and substantial evidence required to sustain this verdict. For all of the reasons stated above, Monsanto is entitled to judgment notwithstanding the verdict.

Dated: September 18, 2018

FARELLA BRAUN + MARTELLLP

By: 

Sandra A. Edwards

Attorneys for Defendant
MONSANTO COMPANY