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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 3:16-md-02741-VC
This document relates to: ALL ACTIONS	**Hearing Date:** **December 11, 2017** **Time:** **9:00 a.m.**

MONSANTO COMPANY'S REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS *DAUBERT* AND SUMMARY JUDGMENT MOTION BASED ON FAILURE OF GENERAL CAUSATION PROOF AND OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO STRIKE CERTAIN OPINIONS OF MONSANTO COMPANY'S EXPERT WITNESSES

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ISSUES TO BE DECIDED

I. Whether plaintiffs have satisfied their burden to present expert testimony that is scientifically reliable and relevant within the meaning of *Daubert* and that is sufficient to prove general causation, *i.e.*, "whether there is sufficient admissible evidence that glyphosate and/or Roundup is capable of causing cancer (specifically, Non-Hodgkin's Lymphoma ["NHL"]) in humans." Pretrial Order 15 (filed Mar. 3, 2017), ECF No. 186.

II. Whether plaintiffs' failure to present sufficient admissible expert testimony to prove general causation entitles Monsanto Company ("Monsanto") to summary judgment in all Roundup® lawsuits pending before this Court.

III. Whether the challenged opinions of Monsanto's experts are admissible.

INTRODUCTION

"Under *Daubert*, the trial court must act as a 'gatekeeper' to exclude junk science that does not meet Federal Rule of Evidence 702's reliability standards by making a preliminary determination that the expert's testimony is reliable." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). *Daubert* challenges are "preliminary" admissibility questions under Federal Rule of Evidence 104(a), *see Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 & n.10 (1993) (quoting Rule 104(a)), and contrary to plaintiffs' claims here,[1] the proponent of the expert testimony under evaluation does not benefit from any inferences in its favor. Where an expert's causation opinion is based on unreliable methodologies or the expert's own *ipse dixit*, it must be excluded. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Plaintiffs' expert proof is all of this – unreliable, *ipse dixit* and junk science – which is only confirmed by their Opposition. For *epidemiology*, plaintiffs agree it is at the "heart of the general causation inquiry." Opp. at 19. Undisputedly, when properly controlled for chance, bias and confounding, the epidemiology literature demonstrates ***no*** statistically significant positive findings involving exposure to glyphosate-based herbicides ("GBHs"), such as Roundup®, and NHL,

[1] Plfs' (1) Resp. in Opp. to Monsanto Co.'s *Daubert* and Summ. J. Mtn. Based on Failure of General Causation Proof and (2) *Daubert* Mtn. To Strike Certain Ops. of Monsanto Co.'s Expert Witnesses at 1, ECF. No. 647 (hereinafter "Opposition" or "Opp.").

meaning ***the epidemiology shows no association between GBHs and NHL***, *infra* at 7-10; *see, e.g.*, *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1172 (N.D. Cal. 2007) (epidemiologic study cannot provide evidence of general causation unless, among other criteria, it "properly accounts for potential confounding factors"). This conclusion is once again confirmed in the newest (November 2017) publication from the government-sponsored Agricultural Health Study ("AHS"), which finds "***no association*** was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL and its subtypes."[2] Plaintiffs' experts' contrary epidemiological opinions, which are based on the use of uncontrolled and confounded data, do not satisfy either the scientific or legal requirements for admissibility under *Daubert*, *infra* at 7, 11-17.

Regarding *animal toxicology*, plaintiffs' experts concede that no scientifically accepted basis exists that allows them to extrapolate animal data to the human incidence of NHL. *See Joiner*, 522 U.S. at 144 (approving exclusion of expert testimony based on "seemingly far-removed" animal studies where expert failed to explain why extrapolation to humans was scientifically proper); *infra* at 25-26. They also offer no basis for the admissibility of their novel, untested, and unsupported interpretations of the animal data. Instead, the record establishes that plaintiffs' experts apply different statistical methodologies – none of which has been subject to peer-review or other validation and each of which was developed and continues to evolve only for litigation – across different studies, subjectively including or excluding data in their analyses as needed to reach their desired pre-determined conclusions, *infra* at 26-29. It is not surprising that such made-for-litigation *ipse dixit* is contrary to 40 years of conclusions by original study authors and scientists at numerous regulatory and scientific agencies, Mtn. at 2, 24-25.

Finally, regarding *mechanistic data*, plaintiffs concede it does not prove carcinogenicity or causation and fail to identify any reliable scientific methodology employed by their experts to support the admissibility or "fit" of this data, *infra* at 32-36.

[2] G. Andreotti et al., *Glyphosate Use and Cancer Incidence in the Agricultural Health Study*, 110 J. Nat'l Cancer Inst. (published online Nov. 9, 2017) ("AHS 2017") (emphasis added).

Ultimately, the simple truth is that the science on glyphosate and GBHs – which is vast and overwhelmingly attributable to scientists and entities having nothing to do with Monsanto – points in a single direction. The epidemiology shows *no association* between human GBH exposure and NHL; the animal testing (conducted at doses that are orders of magnitudes above any human exposure) shows glyphosate is *not carcinogenic* in animals; the mechanistic data shows glyphosate is *not genotoxic or mutagenic*, meaning it does not cause harm to mammalian cells. Plaintiffs' experts can only opine against the scientific consensus by applying unreliable, untested, and unsupported methodologies in a results-driven manner using confounded and flawed data and arguing for a lower standard to be applied than is required in a court of law. This is unreliable methodology; this is *ipse dixit*; this is junk science. Under *Daubert*, the Court must exclude such opinions.

Plaintiffs contend that rather than scrutinize each step of their experts' methodologies as required by *Daubert*, this Court should accept the amorphous weighing of the evidence standard putatively employed by several of their experts.[3] *See, e.g.*, Opp. at 2, 22. This Court should decline that invitation, as the "weight of the evidence" method has been repeatedly rejected as the applicable scientific standard in tort cases. For example, in *Joiner*, the Supreme Court held that a district court's gatekeeping role under *Daubert* required a detailed examination of the reliability of the individual studies upon which the plaintiffs' experts' opinions were based, and that a group of epidemiology studies that are unreliable individually cannot become admissible simply because more than one appears to reach a similar result. *Joiner*, 522 U.S. at 146-47 (holding that because "the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions ... the District Court did not abuse its discretion in excluding their testimony"); *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1216 n.21 (10th Cir. 2002) (rejecting plaintiffs' argument that "even though each individual category of evidence

[3] *See, e.g.*, Opp. at 5 ("Dr. Jameson … utilized a weight-of-evidence methodology utilized by NTP and IARC … "); *id.* ("Dr. Nabhan … concluded that '[t]he weight of the scientific evidence supports causality …'"); *id.* at 56 ("Dr. Portier's approach … contributes further to a weight of the evidence analysis.").

may be insufficient, all of the evidence considered as a whole raises factual questions [concerning causation]" as "inconsistent with *Daubert*"); *Caraker v. Sandoz Pharm. Corp.*, 188 F. Supp. 2d. 1026, 1040 (S.D. Ill. 2001) (evidence in aggregate "amounts to a hollow whole of hollow parts" where "the data points pulled from each 'type' of evidence are too limited, too disparate and too inconsistent"); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1371 (N.D. Ga. 2001) (an expert "cannot lump together lots of hollow evidence in an attempt to determine what caused a medical harm"), *aff'd sub nom.*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1196 (11th Cir. 2002).[4]

In short, to satisfy *Daubert*, "the expert's testimony must be reliable at each and every step or else it is inadmissible. The reliability analysis applies to *all aspects* of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, *et alia*." *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 355 (5th Cir. 2007) (internal citation omitted) (emphasis added); *see id.* ("Even if [some of the studies relied upon by plaintiff's expert] provided a plausible basis for general causation," the district court, after considering the "'reliability' and 'relevance'" of such evidence, "could still reach the conclusion that [expert's testimony] was inadmissible.").[5] Here, plaintiffs' expert proof is *unreliable* at each

[4] *United States v. W.R. Grace* is not inconsistent. Opp. at 46. There, the district court granted defendant's motion *in limine* to exclude a specific study under Rule 702 without any consideration under *Daubert* of plaintiff's experts' methodology, the "reliability of the methods, as well as the fit of the methods to the facts of the case." *U.S. v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007); *see U.S. v. Grace*, 597 F. Supp. 2d 1143, 1144 (D. Mont. 2009) (on remand). Finding that the court "failed to consider the Rule 702 requirements with regard to causation" and misapplied Rule 403, the Ninth Circuit reversed. *Grace*, 504 F.3d at 765-66. Far from supporting application of the "weight of the evidence" standard, the case underscores the importance of reviewing each piece of scientific evidence under *Daubert*.

[5] Plaintiffs' reliance on *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 23 (1st Cir. 2011) is misplaced. Importantly, *Milward* differs from this case in that it addressed a relatively sparse body of scientific evidence related to a rare disease. Here, NHL is among the most common cancers and has been the subject of decades of research, and there is a robust data set regarding glyphosate and GBHs. *See* Monsanto Co.'s Notice of Mot. & *Daubert* & Summ. J. Mot. Based on Failure of Gen. Causation Proof at 4-6, ECF No. 545 (hereinafter "Motion" or "Mtn."). Therefore, even assuming that the First Circuit accepts the elsewhere-rejected proposition that a kind of "weight of the evidence" approach can pass muster under *Daubert* in the factual scenario under which the case arose, it is not applicable here. Further, as explained thoroughly herein, plaintiffs' experts' methodologies here fail to satisfy *Milward*'s criteria. *See id.* at 17-18 (describing "six general steps"). Finally, where the "weight of the evidence" methodology is faithfully employed, as is the case with regulatory agencies making public health-driven risk assessments of

step of the way, requiting its exclusion. Conversely, their motions to exclude several of Monsanto's experts' opinions must be denied as lacking any basis in fact, law, or science. *Infra* at 40-50.

I. PLAINTIFFS MISREPRESENT THE GENERAL CAUSATION INQUIRY.

In their Opposition, plaintiffs for the first time attempt to redefine the parameters of the general causation inquiry, claiming that Monsanto has improperly "inject[ed] issues related to dose and absorption" into the general causation phase of this case. Opp. at 42-45. They do so despite previously agreeing that the general causation inquiry must be assessed at human-relevant doses:

> THE COURT: So you get the difference between the two questions? One is simply, can Roundup cause non-Hodgkin's lymphoma, and the other question is, can Roundup cause non-Hodgkin's lymphoma in a particular dose, that dose being, you know, the highest exposure to which a plaintiff was subject. So like I said, I don't want to hear argument on that right now. I just want to get people's positions on that. What is the plaintiffs' position on what is the question to be answered in phase I?
>
> …
>
> MR. MILLER: If I could, your Honor, then – Mike Miller – we believe the questions ultimately are the same, because what epidemiology does is look at exposures in real-world dosing. It doesn't look as a laboratory test would. So I know your Honor doesn't want argument, but ***our position is the questions merge into one question in the face of epidemiology, because that is looking at real-world exposures,*** when you compare people exposed in the real world to people not exposed.

Tr. of Official Proceedings 5:1-21 (Feb. 24, 2017), ECF No. 546-7. Monsanto's position is the same.[6] Numerous courts, including in bifurcated proceedings such as this one, agree as well. *See, e.g.*, *In re Bextra*, 524 F. Supp. 2d at 1174; Mtn. at 9 (providing additional citations).

The inclusion of human-relevant exposures in the general causation inquiry is crucial. As described in more detail in Monsanto's Motion and *infra* at 25-26, 29, 33, neither animal testing nor much of the mechanistic data at issue here relates to real-world human exposures. Only human epidemiology makes that assessment, and plaintiffs concede in their Opposition that

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carcinogenicity, it uniformly leads to the opposite conclusion of that urged by plaintiffs. Mtn. at 2. Thus, plaintiffs cannot establish their experts' opinions admissibility even under the inappropriate "weight of the evidence" method.

[6] *See* Tr. of Official Proceedings 14:9-12 (Feb. 27, 2017) (Ex. 1) ("yes, dose does matter to general causation, because the question in general causation is can a substance cause a disease at a real world dose or a dose that we are concerned about.").

"epidemiology [is] at the heart of the general causation question." Opp. at 19. Therefore, any scientific methodology addressing even generally whether GBH exposure causes NHL in humans must consider exposure levels.

Plaintiffs incorrectly rely on *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1139 (9th Cir. 2002), to support their new contention. Opp. at 42. In fact, before the passage cited by plaintiffs, the Ninth Circuit found that "the appropriate understanding of [general] causation is … whether exposure to a substance for which a defendant is responsible, *such as radiation at the level of exposure alleged by plaintiffs*, is capable of causing a particular injury or condition in the general population." *In re Hanford*, 292 F.3d at 1133. Plaintiffs' citation refers only to the analysis and dismissal of individual plaintiffs' claims, which the Ninth Circuit found would be more appropriately considered during the specific causation phase, if necessary. *Id.* at 1139.

Plaintiffs' attempt to distinguish the *In re Bextra* decision cited by Monsanto as involving a pharmaceutical product where exposure levels are known versus a chemical exposure where they are not is similarly without merit. Opp. at 42. In fact, a variety of long-accepted studies establish the maximum exposure levels of agricultural workers, the group that most frequently uses GBHs. For example, the Farm Family Exposure Study ("FFES") (an epidemiological study of agricultural pesticide applicators) found that the highest estimated systemic dose of glyphosate is .004 mg/kg/day.[7] Mtn. at 5. And agricultural workers are the focus of many epidemiology studies, including those relied upon by plaintiffs, examining whether an association between GBHs and NHL exists in humans. Opp. at 24-28. This Court should reject plaintiffs' efforts to deviate from the well-settled requirement that human-relevant exposure levels must be considered as part of the general causation inquiry.[8]

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[7] Plaintiffs criticize the FFES as "doctored" based on an alleged "admission" from a decades-old corporate memo. Opp. at 44. But, as Dr. Acquavella – the author of the study – explained at his deposition, the invalid urine sample discussed in that memo was excluded from the published study and therefore had no influence on the results. *See* Dep. of John Acquavella 465:1-466:17 (Apr. 8, 2017) ("Acquavella Dep.") (Ex. 2). No expert offered contradictory testimony.

[8] Plaintiffs also now claim that they are alleging exposure pathways beyond dermal exposure. Opp. at 44-45. However, plaintiffs have presented no evidence on exposure pathways for GBHs beyond a brief discussion of dermal absorption in the expert report of Dr. Nabhan. Expert Report of Chadi Nabhan at 8, ECF No. 546-10 ("Nabhan Report"). Moreover, in addition to plaintiffs'

II. PLAINTIFFS' EXPERTS' OPINIONS ARE UNRELIABLE BECAUSE THEY DISREGARD THE EPIDEMIOLOGIC EVIDENCE IN FAVOR OF CONFOUNDED, BIASED, AND STATISTICALLY INSIGNIFICANT DATA.

Plaintiffs acknowledge that epidemiology is "at the heart of the general causation question" and provides "the best proof of the general association of a particular substance with particular effects." Opp. at 19-20. Plaintiffs thus concede that epidemiologic evidence is the critical evidentiary basis that would be necessary to support a reliable expert opinion on general causation. *Id.* at 19. Their experts' testimony confirms that they cannot meet their burden of proof on this issue. Plaintiffs' experts (and IARC, on which they rely) concede that the epidemiologic evidence is, at best, "limited" because "chance, bias, and confounding could not be excluded as explanations" for any purported association between GBHs and NHL.[9] Given those concessions,

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statements at the February 24, 2017 CMC, Mtn. at 5, plaintiffs' counsel has also disclaimed that any plaintiffs developed NHL from exposure to glyphosate from food, *see* Dep. of David Saltmiras 33:7-11 (Jan. 31, 2017) ("Saltmiras Dep.") ("Q: Okay. And you understand that none of my clients nor any filed case in this litigation is suing Monsanto claiming they got non-Hodgkin's lymphoma from eating food?") (Ex. 3), and plaintiffs' experts have explicitly adopted IARC's methodology and conclusions in reaching their expert opinions in this case, *see, e.g.*, Mtn. at 3-4; *see also* Opp. at 9 (IARC conclusions are "based on sound, reliable evidence"), without disputing or somehow exempting IARC's otherwise unrebutted conclusion that "[i]nhalation of glyphosate is considered to be a minor route of exposure in humans." IARC, Monograph Vol. 112 on the Evaluation of Carcinogenic Risks to Humans, Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos at 41 (2015), http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf. Bare allegations in a complaint cannot substitute for admissible expert testimony where required. *See, e.g.*, *In re Mirena IUD Prod. Liab. Litig.*, 202 F. Supp. 3d 304, 316 (S.D.N.Y. 2016) ("[T]he issue of secondary perforation is outside the realm of common knowledge and experience of a lay juror, which in all jurisdictions means that expert testimony is required."), *aff'd,* No. 16-2890-cv(L), 2017 WL 4785947 (2d Cir. Oct. 24, 2017).

[9] *See* Dep. of Alfred Neugut 61:16-20 (Aug. 7, 2017), ECF No. 546-3 ("Neugut Dep.") ("Q. So, looking just at the epidemiological data, bias and confounding cannot be excluded as an explanation for the findings in those studies; correct? A. Yes."); Nabhan Dep. 102:2-7 ("Q. So you agree that the epidemiology evidence with regard to glyphosate and NHL is credible but chance, bias, or confounding cannot be ruled out without reasonable confidence; is that right? A. If this is what the IARC said, then I do agree with that."). IARC reached the same conclusion without the benefit of recent epidemiologic data from the AHS and North American Pooled Project ("NAPP") that the IARC Working Group Chair, Dr. Blair, conceded show no association between GBHs and NHL, Dep. of Aaron Blair 119:13-25, 145:25-148:6, 172:11-15, 173:6-23 (Mar. 20, 2017), ECF No. 546-17 ("Blair Dep."). In her expert report, Dr. Ritz stated that she "concur[red] with the IARC conclusions after conducting my own independent analysis of the studies included in the IARC review." Expert Report of Beate Ritz at 16, ECF No. 546-9 ("Ritz Report"). However, in her deposition taken after this same concession was highlighted in deposition cross of plaintiffs' other epidemiology experts, Dr. Ritz claimed that the statement in her expert report was not addressing IARC's conclusion regarding the epidemiologic evidence. Dep. of Beate Ritz

plaintiffs' experts also agree that the epidemiologic evidence is insufficient to show a causal relationship between GBHs and NHL.[10]

These concessions about the "best proof" are fatal to plaintiffs' experts' causation methodology. As the Reference Manual's Reference Guide on Epidemiology explains: "Three general categories of phenomena can result in an association found in a study to be erroneous: chance, bias, and confounding. Before any inferences about causation [] are drawn from a study, the possibility of these phenomena must be examined." M. Green et al., *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 549, 572 (3d ed. 2011), https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf ("Reference Manual"); *see also Nelson v. Tenn. Gas Pieline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) ("[b]efore any inferences are drawn about causation, the possibility of other reasons for the association must be examined, including chance, biases … , and confounding causes"); *In re Denture Cream Prod. Liab. Litig.*, No. 09-2051, 2015 WL 392021, at *24 (S.D. Fla. Jan. 28, 2015) (granting defendant's *Daubert* motion where epidemiologist failed to assess exposure, "adjust for confounders, and account for bias"), *aff'd sub nom. Jones v. SmithKline Beecham*, 652 Fed. App'x 848 (11th Cir. 2016).

Plaintiffs seek to distract the Court's attention from these dispositive concessions by presenting a chart prepared prior to the publication of AHS 2017 with confounded and overlapping data from other epidemiologic studies to create a misimpression of a body of statistically significant positive associations between GBHs and NHL. Opp. at 23; *see* Expert Report of Lorelei Mucci at 63, ECF No. 546-18 ("Mucci Report"); *In re: Zoloft (Sertraline Hydrocloride) Prod. Liab. Litig.*, No. 12-md-2342, 2015 WL 7776911, at *9–11 (E.D. Pa. Dec. 2, 2015)

57:10-58:2 (Sept. 18, 2017), ECF No. 546-13 ("Ritz Dep.").

[10] *See, e.g.*, Neugut Dep. 40:2-8 ("Q. You agree that the epidemiology alone is not sufficient to show a causal relationship between glyphosate and non-Hodgkin's lymphoma; is that correct? A. For – for the purposes for which they were evaluating it, I would say ***that's correct***."); Dep. of Christopher Portier 140:16-141:15 (Sept. 5, 2017), ECF No. 546-2 ("Portier Dep.") ("A. [T]he question was whether the epidemiology data, by itself, demonstrates causality, and the answer to the question is no" because "for the epidemiology data to exhibit clear causality, it would have had to be sufficient instead of limited in the IARC review. I still believe it's limited and not sufficient by itself to demonstrate causality.").

(excluding testimony of expert epidemiologist who improperly claimed replication of study results based upon studies using overlapping data), *aff'd*, 858 F.3d 787 (3d Cir. 2017).[11] They do not dispute, however, that all of the epidemiologic findings for GBHs and NHL arise out of just four data populations: the AHS cohort study and case-control studies from North America, France, and Sweden. Nor do they dispute that the most fully-adjusted relative risks and odds ratios for GBHs and NHL in each study population are directly contrary to their misleading chart, with findings that hover above and below the null result of 1.0 and that do not report any statistically significant positive associations. As discussed in Monsanto's Motion, statistical significance is "an important metric to distinguish between results supporting a true association and those resulting from mere chance." Mtn. at 11 (citing *In re Zoloft*, 858 F.3d at 793). And where confidence intervals, *such as all of those listed below*, "do not show any increased risk, and indeed, show a decreased risk, [because they] include[] values less than 1.0, we would say the study does not demonstrate a 'statistically significant' increased risk of an adverse outcome." *Id.* (quoting *In re Bextra*, 524 F. Supp. 2d at 1174).

[11] None of the individual odds ratios presented on plaintiffs' chart are adjusted for other confounding pesticide exposures, despite the fact that adjusted odds ratios or relative risks are reported in most of the studies. *See, e.g.*, Ritz Dep. 155:14-25, 157:20-158:5. The chart multiplies these confounded data points by presenting separate odds ratios for the Lee, De Roos, Cantor, McDuffie, and Hohenadel studies despite the fact that the data from each of those studies is incorporated into the pooled analysis of the NAPP, which is separately listed, albeit only through an odds ratio that is not adjusted for other confounding pesticide exposures. *See* Mucci Report at 37 & Figure 3. The chart likewise double dips by presenting sub-analyses of confounded data from the same primary studies, including eight subtype odds ratios from M. Eriksson et al., *Pesticide Exposure as Risk Factor for Non-Hodgkin Lymphoma Including Histopathological Subgroup Analysis*, 123 Int'l. J. Cancer 1657, 1658 (2008), ECF No. 652-8 ("Eriksson 2008"), four subtype odds ratios from L. Orsi et al., *Occupational Exposure to Pesticides and Lymphoid Neoplasms Among Men: Results of a French Case-Control Study*, 66 Occupational Envtl. Med. 291 (2009), ECF No. 654-3 ("Orsi 2009"), and four subtype odds ratios from M. Pahwa et al., *An Evaluation of Glyphosate Use and the Risk of Non-Hodgkin Lymphoma Major Histological Sub-Types in the North American Pooled Project* at Slide 26 (Aug. 31, 2015), ECF No. 651-12. Plaintiffs' counsel's attempt to characterize these overlapping odds ratios as independent for purposes of their concocted probability calculation, Opp. at 24, is spurious.

Study	Relative Risk/Odds Ratio	Rows on Plfs' Chart (Opp at 23)[12]
AHS Study (2005, 2013, 2017)	1.1 (0.7, 1.9)[13] 0.9 (0.7, 1.1)[14] 0.87 (0.64, 1.2)[15]	13, 14, 15
NAPP (2015)	1.13 (0.84, 1.51)[16] 0.95 (0.69, 1.32)[17]	1, 3, 4, 5, 6, 7, 8, 9, 14, 15, 20, 23, 29, 33
Eriksson (2008)	1.51 (0.77, 2.94)[18]	2, 14, 15, 17, 18, 21,24, 27,30, 31, 32
Orsi (2009)	1.0 (0.5, 2.2)[19]	11, 14, 15, 19, 21, 25, 27

Although their experts seek to rely on meta-analyses conducted before disclosure of the Alavanja 2013 and the 2015 NAPP data, plaintiffs also do not and cannot deny that the same analyses using that adjusted epidemiologic data yields a meta-relative risk of 1.0 (0.86, 1.12), a completely null result.[20] This null finding is further bolstered by AHS 2017. Plaintiffs' experts' assertions that they can nonetheless offer a reliable expert opinion that the GBH epidemiology supports a finding of general causation rests upon a series of flawed methodologies.

A. Plaintiffs' Experts Improperly Rely on Confounded Data.

"To make a judgment about causation, a knowledgeable expert must consider the possibility

[12] The rows from plaintiffs' chart listed in this column set forth unadjusted findings that are either encompassed within the adjusted null findings of the study identified in column 1 or, for the meta-analyses on lines 14-15 of plaintiffs' chart, are included within the those findings.

[13] A. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study*, 113 Envtl. Health Perspectives 49 (2005), ECF No. 653-12 ("De Roos 2005").

[14] M. Alavanja et al., *DRAFT-Lymphoma Risk and Pesticide Use in the Agricultural Health Study* (Mar. 15, 2013), ECF No. 650-4 ("Alavanja 2013"); E. Chang et al., *Meta-Analysis of Glyphosate Use and Risk of Non-Hodgkin Lymphoma*, Exponent 1, 4 (2017), ECF No. 652-10.

[15] AHS 2017 Table 2 (highest quartile intensity weighted exposure).

[16] *See* Ritz Dep. 280:15-22 (including data from both proxies and self-respondents).

[17] *See* Ritz Dep. 306:9-17 (self-respondents only).

[18] Eriksson 2008 at Table VII.

[19] Orsi 2009 at Table 3.

[20] *See* Mucci Report at 60; Blair Dep. 182-83, 189 (acknowledging that incorporation of updated AHS data and NAPP pooled data would reduce the meta-relative risk for GBHs and NHL and show no statistically significant association). This updated meta-analysis underscores this Court's proper skepticism of meta-analyses of observational studies. *In re Bextra*, 524 F. Supp. 2d at 1174. That skepticism is warranted because it demonstrates that the associations reported in the earlier meta-analyses were due in their entirety to the failure of the underlying North American case-control studies to properly adjust for confounding by other pesticide exposures and publication bias that excluded consideration of the most updated and comprehensive findings from the AHS and the NAPP. *See infra* at 15-16, 19-21.

of confounding factors." Reference Manual at 591. As this Court has recognized, an epidemiologic study cannot provide evidence of general causation unless it "properly accounts for potential confounding factors." *In re Bextra*, 524 F. Supp. 2d at 1172 (internal quotations omitted); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 604 (D.N.J. 2002) ("When evaluating the internal validity of a study, the researcher or scientist must account for the roles of bias, confounding factors, and the likelihood that the observed association is due to chance.") (granting motion to exclude plaintiff's expert), *aff'd*, 68 Fed. App'x 356 (3d Cir. 2003).

The possibility of confounding is particularly important here because, as plaintiffs' experts concede, epidemiologic studies have reported an increased risk of NHL in farmers that *predates* the introduction of GBHs.[21] Accordingly, plaintiffs' experts acknowledge that other pesticide exposures may be a "major confounder for the issue of whether glyphosate can cause [NHL]," Weisenburger Dep. 93:16-23, and that scientists need to "control for those other possible confounders to be sure [one is] actually studying glyphosate." Blair Dep. 91:23-92:4; *see also* Neugut Dep. 67:19-68:21 (agreeing that "an epidemiological analysis of glyphosate and non-Hodgkin's lymphoma should control for exposures to these other pesticides"); Ritz Report at 16 (use of most fully-adjusted odds ratios, such as those that adjust for other pesticide exposures, "gives the reader confidence that the findings are most likely due to glyphosate/Roundup exposure, instead of another potential cause that acts as a confounder").[22]

Notwithstanding this case law and their experts' concessions, plaintiffs now argue, without *Daubert*-based precedent, that their experts should be allowed to rely on odds ratios that have not

[21] *See* Neugut Dep. 66:19-67:7 ("there is something going on with farmers and their exposures that is leading to an increased risk of non-Hodgkin's lymphoma that we know for a fact is not glyphosate"); Dep. of Dennis Weisenburger 179:24-180:5 (Sept. 11, 2017), ECF No. 546-16 ("Weisenburger Dep.") (same); Blair Dep. 90:15-20 (same); Ritz Dep. 331:10-23 (same).

[22] Plaintiffs' argument that Monsanto is estopped from pointing out this flaw in their experts' methodology based upon its objections to plaintiffs' request for admissions regarding other pesticides is spurious. Monsanto is not a manufacturer of the other pesticides and has no expert knowledge regarding those pesticides, therefore its uncontested objections to discovery requests regarding those pesticides cannot in any event give rise to estoppel. *See Posen v. Ozier*, No. CV17-07, 2017 WL 4269957, at *3 (D. Mont. Sept. 26, 2017) (quoting *Hamilton v. State Farm Fire Cas. Co.*, 270 F.3d 778, 783 (9th Cir. 2001) (The Ninth Circuit restricts "judicial estoppel to cases where the court relied on, or 'accepted,' the party's previous inconsistent position.")).

been controlled for other pesticide exposures. Plaintiffs are forced to take this extraordinary position because, as their own expert Dr. Neugut concedes, there is no fully-adjusted odds ratio anywhere in the epidemiologic literature that reports a statistically significant positive association between GBHs and NHL. Neugut Dep. 158:23-159:6. Indeed, as shown in the chart on page 10, without resorting to this improper methodology, the GBH epidemiology consistently demonstrates no association whatsoever between GBHs and NHL. Plaintiffs cannot avoid this fatal methodological flaw.

Plaintiffs contend that there is one study (A. De Roos et al., *Integrative Assessment of Multiple Pesticides as Risk Factors for Non-Hodgkin's Lymphoma among Men*, 60 Occup Envtl. Med. 1 (2003), ECF No. 652-9 ("De Roos 2003")) that reports in its logistic regression analysis a statistically significant positive association adjusted for exposure to other pesticides, and they argue that Dr. Neugut "misspoke" *twice* in response to "a misleading question" in testifying to the contrary. Opp. at 25 n.70; Errata Sheet to the Dep. of Alfred Neugut (served Nov. 5, 2017) (Ex. 4). Notably, plaintiffs first made this argument in their opposition brief, which they filed *nine days before serving Dr. Neugut's purported errata sheet* and *almost a month after receiving Monsanto's motion* discussing why Dr. Neugut's admissions regarding this study doomed their claims. Plaintiffs' convenient argument that Dr. Neugut "misspoke" is undercut by his unambiguous testimony:

> Q. There is no odds ratio anywhere in the epidemiological literature that reports for glyphosate and non-Hodgkin's lymphoma an adjusted odds ratio positive association statistically significant; correct?
>
> MR. TRAVERS: Objection, misstates the evidence.
>
> A. Not that -- correct, for the herbicides, for the -- um-hum.
>
> ***
>
> Q. Did not -- De Roos did not control for these other pesticide exposures in the logistic regression analysis; correct?
>
> A. No.
>
> Q. Again, the answer is unclear from my question. Is it correct that Dr. De Roos did not control for the other pesticide exposures in the logistic analysis?
>
> A. That's correct.

Neugut Dep. 158:23-59:6; 234:7-15.[23] Plaintiffs' efforts to alter Dr. Neugut's initial testimony

[23] Plaintiffs point to deposition testimony of a study co-author, Dr. Weisenburger, as confirmation

after realizing it is fatal to their claims must be rejected. *Hambleton Bros. Lumber Co. v. Balkin Enters., Inc.*, 397 F.3d 1217, 1224-26 (9th Cir. 2005) (refusing to consider deposition errata sheet where "'corrections' were not corrections at all, but rather purposeful rewrites tailored to manufacture an issue of material fact").[24]

In any event, as their expert Dr. Ritz acknowledges, all of the data in De Roos 2003 was pooled into the subsequent NAPP study, which plainly does not report a statistically significant increased risk for GBHs when controlled for other pesticides. *See* Ritz Dep. 276:23-277:12.[25] Plaintiffs struggle mightily to avoid the adjusted OR = 1.13 (0.84, 1.51) null finding in the NAPP, arguing that a native file of a slide deck presentation of the NAPP data indicates that one of the slides in which this odds ratio was reported was removed from the presentation. Opp. at 27 n.76 (citing Expert Rebuttal Report of Beate Ritz at 8, ECF No. 653-2). Plaintiffs do not explain how the decision of whether to present this slide at a conference is relevant to the scientific inquiry, but in any event, the same odds ratio is included in an earlier slide (slide 10) that was presented at the conference. The same null 1.13 odds ratio also is included in the draft manuscript of the NAPP study upon which plaintiffs otherwise rely. Opp. at 27; M. Pahwa et al., *An Evaluation of Glyphosate Use and the Risk of Non-Hodgkin Lymphoma Major Histological Subtypes in the North American Pooled Project (NAPP)* at 12 (Sept. 21, 2015) (unpublished draft), ECF No. 653-6.

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that this logistic regression analysis adjusted for other pesticide exposures. Opp. at 25. In his full testimony, however, Dr. Weisenburger made clear that he did not know how the logistic regression was calculated. *See* Weisenburger Dep. 115:3-122:9.

[24] *See Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 902-03 (N.D. Cal. 2016) (same); *Stevens v. CoreLogic, Inc.*, No. 14-cv-1158, 2016 WL 8729928, at *6 (S.D. Cal. May 6, 2016) (same); *Garcia v. Pueblo C.C.*, 299 F.3d 1233, 1242 n.5 (10th Cir. 2002) ("We do not condone counsel's allowing for material changes to deposition testimony and certainly do not approve of the use of such altered testimony that is controverted by the original testimony."); *Rios v. Welch*, 856 F. Supp. 1499, 1502 (D. Kan. 1994) ("[A] plaintiff is not permitted to virtually rewrite portions of a deposition, particularly after the defendant has filed a summary judgment motion simply by invoking the benefits of Rule 30(e) ... . [A] deposition is not a 'take home examination' and an 'errata sheet' will not eradicate the import of previous testimony taken under oath.").

[25] Plaintiffs' experts agree that "once you pool those studies into a larger study, it's that later pooled study that provides all the data relevant to a causation theme." *See* Neugut Dep. 228:17-21; Ritz Dep. 284:9-19; *see also* Ritz Dep. 218:5-14 (opining that pooled analyses are more powerful than studies upon which they are based).

Plaintiffs alternatively argue that Dr. Ritz appropriately relied on unadjusted NAPP odds ratios, pointing to her deposition testimony that the NAPP adjustment for three other pesticides would only be appropriate if those pesticides were themselves risk factors for NHL. Opp. at 27 & n.75.[26] This argument is directly contrary to Dr. Ritz's statement in her expert report that use of the most fully-adjusted odds ratios "gives the reader confidence" in the analysis of the GBH NHL studies, Ritz Report at 16, which was made before Dr. Ritz learned of the null findings in the adjusted NAPP analysis. *See* Ritz Dep. 277:18-278:4. Dr. Ritz's abrupt about-face upon learning of this important evidence itself casts doubt on her methodology.[27] Moreover, Dr. Ritz conceded that at least two of the three pesticides in the NAPP adjustment are risk factors for NHL, *see* Ritz Dep. 424:9-19, and she could not opine which NAPP analysis (adjusted or unadjusted) she believed was more valid, stating "[t]hat's a question I cannot answer." *Id.* 296:5-15.

Plaintiffs likewise ignore confounding in relying on unadjusted findings in the Eriksson 2008 study.[28] As Dr. Neugut explained, because of the failure to adjust for other pesticide exposures, it is "impossible to tell" whether the odds ratios for GBHs upon which plaintiffs rely would be elevated if controlled for the use of such pesticides. Neugut Dep. 291:11-16.

B. Plaintiffs' Experts Improperly Rely on Biased Data.

Courts routinely reject expert causation opinions based upon epidemiologic studies that fail to exclude the possibility of bias.[29] Plaintiffs' experts agree that bias must be taken into account

[26] Even here, Dr. Ritz inexplicably relies on outdated data, citing unadjusted odds ratios contained in an earlier abstract that were each recalculated and lowered by the time the data was presented at the conference, long before she submitted her expert report. *See* Occupational Cancer Research Centre, *An Detailed Evaluation of Glyphosate Use and the Risk of Non-Hodgkin Lymphoma in the North American Pooled Project (NAPP)*, CSEB Conference (June 3, 2015), ECF No. 650-3.

[27] See *Lemmermann v. Blue Cross Blue Shield of Wis.*, 713 F. Supp. 2d 791, 807 (E.D. Wis. 2010) ("[P]ropelling the court's conclusion that Dr. al-Saghir's methodology … is unreliable is the fact that the [opinion] appears to have been 'cooked up' in the haste of deposition testimony after the doctor's original [opinion] ... could not survive even the slightest scrutiny in the form of the opposing counsel's questioning.").

[28] *See* Ritz Dep. 308:2-10 (conceding that the only odds ratio in Eriksson 2008 adjusted for other pesticide exposures is the multivariate analysis that finds no statistically significant association between glyphosate and NHL); Neugut Dep. 209:5-11 (Eriksson study's latency, dose-response and subtype analyses do not adjust for exposures to other pesticides).

[29] *See, e.g.*, *In re Denture Cream*, 2015 WL 392021, at *24; *In re Prempro Prod. Liab. Litig.*, 765 F. Supp. 2d 1113, 1119 (W.D. Ark. 2011); *Maras v. Avis Rent A Car System, Inc.*, 393 F. Supp. 2d

before any causal inference can be reached. As Dr. Ritz explained, "[w]hat I teach my students is that what we have to make sure is that there's no bias and that [is] before everything else we are ever considering. So I would not even consider data unless we would go through a rigorous analysis of all of the biases." Ritz Dep. 47:12-18; *see also* Neugut Dep. 71:10-19 (bias can lead to a "reported odds ratio, a risk ratio, that is actually not reflective of the true association, because it has been artificially shifted in a certain direction, either higher or lower").

Plaintiffs' experts each identified a variety of biases that must be considered in interpreting epidemiologic data. Expert Report of Alfred Neugut at 7-9, ECF No. 546-11 ("Neugut Report"); Ritz Report at 7-8. They failed, however, to conduct a "rigorous analysis" of these biases in reaching their opinions, relying instead on any cherry-picked data point they could find that might support their causation opinion. Two illustrations demonstrate the impact of this flawed methodology.

First, Dr. Ritz relies heavily on the Eriksson 2008 study, which plaintiffs' Opposition highlights at pages 24-25 and in multiple rows of the chart on page 23. But as Dr. Neugut concedes, Eriksson 2008 suffers from a systemic flaw that renders all of its analyses illegitimate. *See* Neugut Dep. 276:11-277:22, 281:7-18. This flaw arises from the authors' decision to limit their comparison group of unexposed individuals to those who were not exposed to any pesticides whatsoever. *Id.* 280:8-14. Because individuals exposed to GBHs routinely have exposure to other pesticides that have been identified as potential NHL risk factors, the Eriksson odds ratios do not measure whether exposure to GBHs is associated with NHL but rather measure whether exposure to a mixture of pesticide exposures is associated with NHL. This can best be understood by recalling the basic structure of a case-control study, in which the odds of an exposure in a diseased case population is compared to the odds of exposure in a healthy control population:

$$\frac{\text{(NHL, with exposure)/(NHL, with no exposure)}}{\text{(Healthy, with exposure)/(Healthy, with no exposure)}} = \text{Odds ratio}$$

801, 807-09 (D. Minn. 2005); *Magistrini*, 180 F. Supp. 2d at 604-05.

This systemic flaw in Eriksson 2008 makes it impossible to separate out the effects of different pesticide exposures, including exposures to other pesticides that were banned because of safety concerns, and helps explain why the study reports elevated NHL odds ratios for every pesticide analyzed in the study. *See* Eriksson 2008, Tables II, III, IV, V, and VI. This universal finding of elevated odds ratios suggests that the study suffers from recall bias, *i.e.*, an exaggeration of odds ratios, because cases (with NHL) are more likely to recall exposures than controls.[30]

Second, Dr. Ritz seeks to rely on NAPP data that includes proxy respondents (*i.e.*, data provided by spouses or family members rather than the study subject), despite the generally accepted epidemiologic concern that proxy respondent data is less reliable than self-respondent data. *See* Neugut Dep. 264:10-17, 265:23-266:4; Blair Dep. 140:15-23; Reference Manual at 586 ("Bias may also result from reliance on interviews with surrogates who are individuals other than the study subjects."). The bias introduced through the use of proxy respondents in the North American case-control studies was not identified until the data was pooled in the NAPP. When the NAPP looked solely at the more reliable self-respondent data, the NAPP odds ratio dropped from an already null finding of OR= 1.13 (0.84, 1.51) to an OR = 0.95 (0.69, 1.32). *See* Mucci Report at 46-47. This proxy bias also is evident in other analyses conducted with the same North American case-control study populations. *See* Blair Dep. 139:18-141:4; Mucci Report at 21.

C. Plaintiffs' Experts Improperly Rely on Non-Significant Data.

Dr. Neugut acknowledged that he "would not label an exposure as being associated with an outcome unless there is a finding of an increased risk that is statistically significant." Neugut Dep. 45:7-18. But faced with their own experts' concessions that chance cannot be excluded as an explanation for the findings in the GBH epidemiologic literature, plaintiffs now argue that statistical significance is not necessary. Opp. at 38-39. Plaintiffs contend that their argument is

[30] *See* Mucci Report at 55; Expert Report of Jennifer Rider at 29-30, ECF No. 652-6 ("Rider Report"); *see also* Reference Manual at 585 ("Research has shown that individuals with disease (cases) tend to recall past exposures more readily than individuals with no disease (controls); this creates a potential for bias called recall bias."); Ritz Dep. 310:2-312:4 (admitting that recall bias is a concern if all chemicals in a study report elevated odds ratios but contending – contrary to the data – that this did not occur in Eriksson).

supported by *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40-41 (2011), but the Supreme Court in that case was addressing a separate issue of materiality for purposes of securities disclosure requirements and expressly disavowed any opinion regarding whether expert testimony based on non-significant findings is properly admitted. When it was confronted with this issue in the *Daubert* context, the Supreme Court rejected expert general causation testimony based upon non-significant findings. *See Joiner*, 522 U.S. at 145.

Numerous courts have faithfully followed *Joiner*'s guidance. Those courts have recognized that "[i]n [] the absence of a statistically significant difference upon which to opine, [an expert's general causation] opinion must be excluded under *Daubert*." *Good v. Fluor Daniel Corp.*, 222 F. Supp. 2d 1236, 1243 (E.D. Wash. 2002).[31]

D. Plaintiffs' Experts Improperly Dismiss the Findings of the Only Prospective Cohort Study to Examine GBHs and NHL.

Plaintiffs' experts concede that cohort studies generally are preferred over case-control studies because case-control studies are more susceptible to bias.[32] Plaintiffs' experts also concede that the AHS is the only cohort study to examine a putative association between GBHs and NHL and is specifically designed to address some of the limitations in the case-control studies, including recall and selection bias. *See* Neugut Dep. 124:1-4; Blair Dep. 94:6-96:1; 155:25-157:21. These concessions highlight a significant flaw in their experts' causation methodologies because the 2005 published AHS study of GBHs unambiguously concluded that "[n]o association was observed between NHL and [GBH] exposure in any analysis, including an analysis comparing the highest with the lowest quintile of exposure." De Roos 2005 at 51. And the just-published 2017 updated

[31] *See Burst v. Shell Oil Co.*, Civ. Action No. 14-109, 2015 WL 3755953, at *13 (E.D. La. June 16, 2015), ("[T]he guidance of the Supreme Court and the Fifth Circuit instructs that [studies that do not demonstrate statistically significant results] do not reliably support epidemiologists' general causation opinions in the context of toxic tort litigation."), *aff'd,* 650 F. App'x 170 (5th Cir. 2016), *cert. denied*, 137 S. Ct. 312 (2016); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1080 (D. Kan. 2002) (expert must have statistically significant studies as the basis of a general causation opinion).

[32] Neugut Dep. 72:1-73:1, 73:17-74-4, 77:6-78:25; Ritz Dep. 317:2-318:11 (conceding that the scientific community views cohort studies as having greater validity than case-control studies); *see also Carl v. Johnson & Johnson*, Nos. ATL-L-6546-14, ATL-L-6540-14, 2016 WL 4580145, *19 (N.J. Super. Ct. Sept. 2, 2016) (case-control studies "are considered less reliable than a prospective cohort study").

AHS study (with 11 years of additional follow-up and four times the number of GBH-exposed cancer cases) likewise "observed no associations between glyphosate use and NHL overall or any of its subtypes." AHS 2017 at 7.

Prior to the publication of the AHS 2017 study, plaintiffs proffered three arguments to cure their experts' error. First, they argued, in sharp contrast to the study investigators' conclusions, that De Roos 2005 study actually supports their experts' causation opinion. Opp. at 32. But plaintiffs' own experts disagree. *See* Neugut Dep. 127:11-18 (agreeing that De Roos 2005 "does not provide evidence that would validate the hypothesis that glyphosate exposure causes non-Hodgkin's lymphoma"); Weisenburger Dep. 190:18-191:20 (agreeing that De Roos 2005 was a negative study); Ritz Dep. 323:8-12 (testifying that De Roos 2005 "contributes very little" evidence in support of the hypothesis that GBHs causes NHL); Blair Dep. 155:11-157:21 (De Roos 2005 dose response analysis found a negative association between GBH exposure and NHL).[33]

Second, plaintiffs sought to flip the *Daubert* evidentiary burden by arguing that Monsanto's evidence of a lack of carcinogenicity is itself limited. As an initial matter, they suggest that Monsanto is relying solely on the AHS cohort findings of no association between GBHs and NHL. Opp. at 1. As set forth in Monsanto's opening brief and *supra* at 8-10, this is false. While the GBH case-control studies do suffer from a series of methodological flaws, the fully adjusted findings in the case-control studies likewise show no association, with the most reliable self-respondent data from the pooled analysis of all of the North American case-control studies reporting a negative association of OR = 0.95.

Third, Plaintiffs and their experts raised a number of criticisms regarding De Roos 2005. But even assuming their experts would persist in those criticisms in light of the new AHS 2017 study, criticisms of existing tests are not a proxy for admissible expert testimony under *Daubert*.

[33] The defense expert testimony cited by plaintiffs is not to the contrary. The cited testimony speaks only to association, not causation. *See Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 n.16 (11th Cir. 1999) ("[s]howing association is far removed from proving causation"); *Nelson*, 243 F.3d at 253 (same); Reference Manual at 574 (same); *see also* Rider Dep. 262:5-22 (explaining that study reporting modest increased incidence of prostate cancer did not make any claims about evidence of causality).

See, e.g., *Caraker*, 188 F. Supp. 2d at 1034 ("Plaintiffs' experts' broad criticisms of the existing epidemiological evidence do [] not help them meet their burden," as "plaintiffs' burden is an affirmative one, not served by such attacks."); *Sanderson v. Int'l Flavors & Fragrances, Inc*., 950 F. Supp. 981, 1000-01 (C.D. Cal. 1996) (holding that there is "no authority whatsoever for [plaintiff's] outlandish contention" that where "the lack of scientific evidence regarding the effects of a product is the result of the manufacturer's failure to test" plaintiff should be "excused from the burden" of proving causation); *Norris v. Baxter Healthcare Corp*., 397 F.3d 878, 886 (10th Cir. 2005) ("Mere criticism of [existing studies] cannot establish causation."); *Hollander*, 289 F.3d at 1213 (same).[34] Moreover, plaintiffs' experts abandoned many of their criticisms of De Roos 2005.[35]

E. Plaintiffs' Experts' Outcome-Driven Treatment of Unpublished Studies Likewise Demonstrates the Unreliable Nature of Their Methodology.

In an attempt to avoid the powerful evidence of no association between GBHs and NHL in the Alavanja 2013 cohort study, plaintiffs and their experts rely heavily on the fact that the herbicide findings in the study were not published. Opp. at 34-38; *see* Neugut Dep. 189:14-190:3 (testifying that he did not even read Alavanja 2013); Ritz Dep. 347:16-348:19 (acknowledging that

[34] Plaintiffs reliance on two reports prepared for CropLife America is likewise unavailing. Neither of these reports makes any mention of glyphosate or De Roos 2005 and they each observe that the AHS study design is more reliable than the case-control study designs used in the other agricultural epidemiology studies. *See, e.g.*, G. Gray et al., *The Federal Government's Agricultural Health Study: A Critical Review with Suggested Improvements*, 6 Hum. & Ecological Risk Assessment 47, 50 (2000), ECF No. 653-11 ("We are particularly enthusiastic about the prospective cohort study of cancer outcomes because it responds directly to some of the methodological weaknesses of prior epidemiologic studies of farmers and pesticides."); Exponent, *Design of Epidemiologic Studies for Human Health Risk Assessment of Pesticide Exposures*, CropLife America at 15 (Jan. 4, 2016), ECF No. 652-7 ("The Agricultural Health Study Questionnaires were highly detailed, thorough, and thoughtfully designed. Few, if any, other epidemiologic studies have conducted more exhaustive questionnaire-based assessments of pesticide exposures."); *id.* at 18 ("The [AHS] questionnaires were particularly extensive … and the cohort was sufficiently large as to enable simultaneous statistical adjustment[s] for several potential confounders."); *id.* at 22 ("The [AHS] … cohort[] went farther than most in terms of conducting validation studies and sensitivity analyses, acknowledging sources of error and bias, and documenting exposure assessment approaches."). Plaintiffs' reliance on Monsanto employee statements made six years before De Roos 2005 is likewise unavailing.

[35] *See* Neugut Dep. 141:20-142:7 (abandoning criticism that De Roos 2005 underestimated glyphosate risk based on confounding from 2,4-D exposure in other farmers); *id.* 162:8-15 (conceding that latency is not a major problem in De Roos 2005); *id.* 152:22-153:10 (acknowledging that De Roos 2005 may be the most powerful epidemiologic study regarding glyphosate and NHL); *id.* 180:11-25 (withdrawing criticism of De Roos 2005 based on non-differential exposure misclassification).

she had not read Alavanja 2013 prior to preparing her expert report). These arguments are moot given the recent AHS 2017 peer-reviewed publication including even more updated AHS data. Notably, however, both Drs. Neugut and Ritz readily rely upon unpublished studies when they believe the studies *support* their opinions. *See* Neugut Dep. 192:15-24 (admitting that he relied upon an unpublished study to support his causation opinion in a separate litigation for the same plaintiffs' law firm representing plaintiffs here); Opp. at 27 n.76 (discussing Dr. Ritz's reliance on unadjusted odds ratios in unpublished NAPP manuscript); *see also Siharath*, 131 F. Supp. 2d at 1357-58 (excluding causation testimony of expert who, among other things, failed to account for contrary findings in unpublished epidemiologic study); *Lust v. Merrell Dow Pharm. Inc.*, 89 F.3d 594, 598 (9th Cir. 1996) (courts "should be wary that the [expert's] method has not been faithfully applied").

Moreover, Dr. Neugut concedes that authoritative guidelines governing meta-analyses of epidemiologic literature expressly instruct scientists to seek out and incorporate unpublished data.[36] As those guidelines explain, there is a bias against publishing studies that fail to find positive associations. Neugut Dep. 104:11-19. This publication bias improperly pushes any meta-analysis risk ratio above its true level if only published studies are analyzed. *Id.* 105:17-106:8. Dr. Blair likewise has warned of the risk of publication bias and the need to take unpublished epidemiologic studies into account, particularly in the field of environmental epidemiology.[37] Indeed, while plaintiffs make much of the fact that a portion of Alavanja 2013 excluding herbicides initially was rejected for publication, this rejection was attributed to the fact that the study did not find associations between pesticide exposures and NHL. *See* E-mail from Michael Alavanja, to Dale Sandler et al. (Feb. 27, 2014 1:05 PM), ECF No. 653-17; Blair Dep. 201:19-202:21. Moreover, the peer-reviewer for the journal that then published the study in 2014

[36] Neugut Dep. 93:2-18, 105:7-16 (citing E. Walker et al., *Meta-Analysis: Its Strengths and Limitations*, 75 Cleveland Clinic J. Med. 431 (2008), ECF No. 651-1); *see also In re Bextra*, 524 F. Supp. 2d at 1175 (discussing meta-analysis of published and unpublished studies).

[37] *See* A. Blair et al., *Guidelines for Application of Meta-Analysis in Environmental Epidemiology*, 22 Reg. Toxicol. & Pharm. 189, 191 (1995) ("Publication bias is a critical issue in environmental health studies just as in other fields.").

specifically criticized the authors for their decision to ***exclude*** their findings for herbicides (including GBHs). *See* E-mail from PLoS One editorial manager to Michael Alavanja (June 21, 2014 1:56 PM), ECF No. 653-15. Plaintiffs' argument that the 2013 and 2014 studies had different NHL counts ignores the fact that the 2014 study included different pesticides and an additional three years of NHL diagnoses.[38] And, of course, the published AHS 2017 study disposes of any suggestion that the updated and powerfully negative AHS data can be ignored.

Plaintiffs' experts' failure to account for the Alavanja 2013 cohort study is inexcusable. *See In re Zoloft*, 2015 WL 7776911, at *9 (excluding testimony of expert who failed to account for more recent epidemiologic findings contrary to his causation opinion); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Prac. & Prod. Liab. Litig.*, 174 F. Supp. 3d 911, 932 (D.S.C. 2016) ("[F]ailing to adequately account for contrary evidence is not reliable or scientifically sound."). With an additional seven years of follow-up to De Roos 2005, Alavanja 2013 was, prior to the new and likewise negative AHS 2017 publication, by far the largest study to analyze GBHs and NHL and includes hundreds of NHL cases in a cohort of more than 50,000 pesticide applicators. Alavanja conducted a series of analyses of GBHs and found no association whatsoever for NHL in general, for any NHL subtypes (to the contrary, Alavanja reported a statistically significant negative trend for large B-cell lymphoma), or for NHL and GBHs in combination with other pesticides. *See* Blair Dep. 171:21-176:1, 190:12-199:16. This powerful data was not available to IARC and was not available to any of the numerous regulatory agencies around the world which, even without this data, have concluded that GBHs do not cause cancer. *Id.* 178:1-7, 231:3-232:18.

Plaintiffs attack Alavanja 2013 for its use of imputation to account for cohort members who provided exposure data upon entry to the study but who did not respond to a subsequent, second-phase exposure survey. Opp. at 34-35. But Dr. Ritz concedes that (1) the AHS investigators have used the same imputation approach for every pesticide study they have published that includes data

[38] C. Alavanja et al., *Non-Hodgkin Lymphoma Risk and Insecticide, Fungicide and Fumigant Use in the Ag. Health Study*, PLoS One 9(10): e109332, at 2 (2014), ECF No. 653-16 (including cancer diagnoses through Dec. 31, 2011); Alavanja 2013 at 7 (including cancer diagnoses through Dec. 31, 2008).

from the phase 2 surveys, Ritz Dep. 357:4-16, (2) the AHS investigators have conducted and published a validation study that specifically measured the accuracy of their imputation methodology for each of 40 different pesticides (including GBHs which fell in the middle of the pack), *id.* 365:9-366:8, and (3) she is not aware of anyone other than herself who has stated that the imputation methodology used in the AHS is uniquely inappropriate for GBHs, *id.* 382:2-10. Moreover, the just-published AHS 2017 study used the same imputation approach and confirmed through a number of different sensitivity analyses that Dr. Ritz's criticisms are without merit. AHS 2017 at 2-4.

F. Plaintiffs' Experts Fail to Faithfully Apply the Bradford Hill Criteria.

Plaintiffs seek to cure the flaws in their experts' methodologies by claiming that their experts applied the Bradford Hill factors for assessing causation. Opp. at 16-19. This argument fails at the outset because – as even Dr. Neugut concedes, Neugut Dep. 314:7-15 – they did not apply the methodology in the manner prescribed. As Dr. Hill explained – and the Reference Manual and numerous courts have recognized – application of the guidelines absent epidemiologic evidence of an association "does not reflect accepted epidemiologic methodology." Reference Manual at 599 n.141 (citing same case law cited by Monsanto in its Mtn. at 37 n.72). The *starting point* is where epidemiological observations "reveal an association between two variables, perfectly clear-cut and beyond what we would care to attribute to the play of chance." A. Bradford Hill, *The Environment and Disease: Association or Causation*?, 58 Proc. R. Soc. Med. 295, 295 (1965), ECF No. 649-17. Thus, "[i]n assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors … . We emphasize that these [Bradford Hill] guidelines are employed only *after* a study finds an association to determine whether that association reflects a true causal relationship." Reference Manual at 598-599.[39] As IARC and plaintiffs' experts concede, the (by their measure) "limited" epidemiologic evidence on

[39] *See also In re Lipitor*, 174 F. Supp. 3d at 916 ("in assessing causation, epidemiologists 'first look for alternative explanations for the associations, such as bias or confounding factors,' and then apply the Bradford Hill factors to determine whether an association reflects a truly causal relationship") (citing Reference Manual and other case law).

GBHs and NHL does not meet this predicate requirement and the Bradford Hill factors accordingly do not come into play.

Moreover, plaintiffs' claim that the Bradford Hill factors support causation again is undermined by their own experts' testimony. For example, while plaintiffs argue that the *strength* factor weighs in favor of causation, Dr. Neugut opined that even by his accounting the strength of association between GBHs and NHL is "not a number that would … build your confidence that this was a – that there is a causal relationship." Neugut Dep. 333:7-16. The epidemiologic data likewise does not provide *consistent* evidence of an association, but rather shows no association with non-significant odds ratios and relative risks both above and below 1.0. Neugut Dep. 324:22-327:9. *Temporality* is not satisfied in the GBH U.S.-based case-control studies because of the latency period necessary for NHL to develop. Dr. Weisenburger claims that 6.7 years is too short of a time to detect the development of NHL and that a minimum of 10 years of latency is required to detect a relationship between GBHs and NHL. Weisenburger Report at 5. Likewise, at her deposition, Dr. Ritz opined that "ten years out is a good time frame" to allow for the development of NHL. Ritz Dep. 198:9-14. But the U.S. based case-control studies of farmers are based mainly on NHL cases diagnosed between 1979 and 1983, Neugut Dep. 230:15-231:3, no more than 8 years after GBHs were first approved for agricultural use. *See* EPA Mem. from Robert Taylor to Monsanto (Dec. 22, 1975), ECF No. 652-12; Reference Manual at 601 ("exposure outside a known latency period constitutes evidence, perhaps conclusive evidence, against the existence of causation").[40]

Finally, while plaintiffs claim that the Eriksson 2008 and McDuffie studies demonstrate a dose response, their experts did not agree. *See* Neugut Dep. 292:25-293:8 (conceding that there is no way to tell from the Eriksson study whether there is any difference between the odds ratios

[40] While plaintiffs argue that case-control studies can establish temporality, Opp. at 17-18, Dr. Neugut (and the Reference Manual) explain that cohort studies are needed to establish temporality. Neugut Report at 8 (noting one advantage of cohort studies is that they can ensure temporality); Reference Manual at 558 ("one advantage of the cohort study design is that the temporal relationship between exposure and disease can often be established more readily than in other study designs, especially a case-control design").

presented for less than ten days exposure compared to more than ten days exposure to GBHs); *id.* 220:5-11 (agreeing that under the McDuffie "dose-response" analysis, someone with three days of exposure to GBHs could be classified as high exposure and someone with 20 days of exposure could be classified as low exposure); Ritz Dep. 265:4-18 (McDuffie study does not provide evidence of a dose response). Indeed, Dr. Neugut agreed that "there is no data anywhere in the epidemiologic literature reporting a higher risk of non-Hodgkin's lymphoma with greater intensity exposure to glyphosate." Neugut Dep. 133:16-20. To the contrary, as reproduced below, the data presented in AHS 2017 (Table 2 and Supp. Table 1) both for duration and intensity-weighted duration exposure to GBHs shows no such dose response:

GBH [exposure quintiles]	**NHL Cases**	**RR (95% CI) Total days of exposure**	**NHL Cases**	**RR (95% CI) Intensity-weighted days of exposure**
None	135	1.0 (ref)	135	1.0 (ref)
Q1	103	0.76 (0.57-1.01)	113	0.83 (0.59-1.18)
Q2	117	0.87 (0.66-1.14)	104	0.83 (0.61-1.12)
Q3	107	0.85 (0.64-1.13)	112	0.88 (0.65-1.19)
Q4	116	0.80 (0.60-1.06)	111	0.87 (0.64-1.20)

G. Plaintiffs' Experts Improperly Seek to Lower Their *Daubert* Burden By Relying on Purported Epidemiologic Associations Below 2.0.

When properly evaluated for chance, bias, and confounding, the epidemiologic literature does not show any positive association whatsoever between GBHs and NHL. *See supra* at 7-10. But even if one could accept their experts' flawed methodology in full, plaintiffs' expert epidemiologists rest their causation opinions on an alleged association in the range of 1.3 to 1.5. Neugut Dep. 331:7-15. This purported association cannot support their causation opinion under *Daubert* given the Ninth Circuit's holding that anything less than a doubling of the risk "actually tends to disprove legal causation" because it means that there is a less than 50% chance that GBHs caused any exposed individual's NHL rather than some other cause. *See Daubert v. Merrell Dow Pharm., Inc.* (*Daubert II*), 43 F.3d 1311, 1321 (9th Cir. 2005); *see also Schudel v. Gen. Elec. Co.*, 120 F.3d 991, 996 (1997), *abrogated on other grounds by Weisgram v. Marley Co.*, 528 U.S. 440 (2000); *McManaway v. KBR, Inc.*, 852 F.3d 444, 454 (5th Cir. 2017) (granting summary judgment

for defendant where "studies relied on by the Plaintiffs and their experts do not reflect a statistically significant doubling of the risks of their injuries"); Mtn. at 12 n.17.[41]

As a Los Angeles court very recently explained in reversing a $417 million jury verdict based in part upon the inadmissibility of the plaintiff's epidemiologist's causation testimony, "it is to be recalled that the risk ratios being cited are *relative* risk-ratios – comparing the risk that someone who uses talc will develop ovarian cancer to the risk that someone who did not use talc will also develop cancer. A relative risk ratio of 1.3 is well below the two-fold risk level necessary to show that talc 'more probably than not' causes cancer." Order Granting New Trial and Granting Motion for Judgment Notwithstanding the Verdict, *Lloyd v. Johnson & Johnson*, Case No. BC628228, slip op. at 29 (Cal. Super. Ct., L.A. Cty. Oct. 20, 2017) (Ex. 5) (citing *Daubert II* and *In re Lipitor (Atorvastin Calcium) Mktg., Sales Prac. & Prod. Liab. Litig.*, 185 F. Supp. 3d 786, 791-92 (D.S.C. 2016)).

III. PLAINTIFFS' OPPOSITION BRIEF HIGHLIGHTS RATHER THAN RESOLVES THE METHODLOGICAL DEFICIENCIES THAT RENDER THEIR EXPERTS' OPINIONS REGARDING THE ANIMAL DATA UNRELIABLE.

Plaintiffs agree with Monsanto that the epidemiology studies are the keys to answering the general causation question here because they address what happens in humans. *Supra* at 7. And plaintiffs cannot overcome their experts' concessions that there is no scientific basis to extrapolate to humans any of the findings they reached in evaluating the rodent glyphosate carcinogenicity studies.[42] Either of these facts alone is sufficient to resolve any *Daubert* inquiry in Monsanto's

[41] *In re Hanford* reaffirmed the doubling of the risk requirement in cases like this where there is no definitive evidence that the exposure at issue is capable of causing disease and plaintiffs' experts accordingly must rely on epidemiology to establish causation, 292 F.3d at 1135-37, while rejecting the requirement in cases where there is a scientific consensus that the exposure can cause the disease at issue. *Id.* at 1137. *In re Bextra* raised but did not rule on the issue because the doubling argument was put forth only as to specific causation, which was not before the court (and plaintiffs in any event relied upon a large randomized clinical trial that reported statistically significant risk ratios of 2.6 and 3.4). *See* 524 F. Supp. 2d at 1181, 1183.

[42] *See* Portier Dep. 163:7-23 (rodent models "are not developed for the purpose of identifying tumors that arise in humans from exposure to chemicals"); *id.* 158:14-159:16 ("it has always been a challenge to extrapolate from effects observed in experimental animal bioassays to potential effects in humans in order to protect humans from potentially harmful chemical exposures"); Dep. of Charles Jameson 28:10-15 (Sept. 21, 2017), ECF No. 546-6 ("Jameson Expert Dep.") ("[T]he purpose of doing an animal bioassay study is to determine if the chemical can cause cancer in the experimental animals. And it's not – not looking to investigate does it form a specific kind of

favor. Mtn. at 23-24.[43] Plaintiffs' failed attempts to explain away the numerous methodological flaws in their experts' opinions also require the same result.

A. Despite Plaintiffs' Specific Efforts to Buttress the Admissibility of Dr. Portier's Testimony, They Still Fail to Meet *Daubert*'s Standards.

Dr. Portier's opinions must be excluded because they are nothing more than a series of made-for-litigation assertions employing whatever methodology – no matter how untested or novel – supports the outcome Dr. Portier pre-determined he would reach. Mtn. at 24-29. Plaintiffs do not dispute, for example, that Dr. Portier's statistical machinations ignore data that does not support his desired result, Mtn. at 24, 26-27, continually reinterpret the same data using methods that differed from the study protocols dictated by the original study investigators, Mtn. at 24-25, and are instead designed to ensure statistical significance, despite criticisms published by regulators, scientific panels (such as several members of the Scientific Advisory Panel ("SAP") upon which plaintiffs so heavily rely and misrepresent as endorsing Dr. Portier's opinions here, Opp. at 53),[44] and independent scientists worldwide.[45] Finally, plaintiffs claim Dr. Portier followed various EPA

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tumor that is the same as found in humans."); *id.* 9:3-6 ("[T]he fact that something causes a kidney tumor in a mouse, I don't know what that says about causing non-Hodgkin's lymphoma in humans."); *id.* 23:24-24:3 ("I don't know that anybody has done an investigation to see – to see if there is a correlation between the formation of hemangiosarcomas in laboratory animals and non-Hodgkin's lymphoma in humans."); *see also* Mtn. at 30 n.48 (citing additional examples).

[43] Plaintiffs concede that none of their experts other than Drs. Portier and Jameson are qualified to discuss the rodent carcinogenicity data. Opp. at 46 (stating that two "highly qualified experts … reviewed the animal data" on their behalf). Monsanto's motion to exclude the other experts' toxicology opinions must therefore be granted. Mtn. at 22.

[44] *See* EPA, FIFRA Scientific Advisory Panel (SAP) Open Meeting Tr. 998:16-1000:2, EPA-HQ-OPP-2016-0385 (Dec. 13-16, 2016), https://www.epa.gov/sites/production/files/2017-02/documents/glyphosate_transcript.pdf (Dr. Ken Portier describing need for proper consideration of false-positives); *id.* 1006:13-18 (Dr. Crump criticizing pooling of results across sexes and species); *id.* 1018:12-19 (Dr. Sheppard acknowledging that false positives arise when doing multiple statistical tests with many different tumors).

[45] *See, e.g.*, J. Tarazona et al., *Response to the Reply by C.J. Portier and P. Clausing Concerning Our Review "Glyphosate and Carcinogenicity: A Review of the Scientific Basis of the European Union Assessment and its Differences with IARC,"* 91 Archives of Toxicology 3199, 3201-3202 (2017) ("Tarazona 2017") (discussing variety of factors to be considered in analyzing rodent carcinogenicity data and noting Dr. Portier's analysis of the glyphosate data does not do so); G. Kabat, *IARC's Glyphosate-gate Scandal*, Forbes (Oct. 23, 2017), https://www.forbes.com/sites/geoffreykabat/2017/10/23/iarcs-glyphosate-gate-scandal/#4996ec931abd (criticizing IARC's review and discussing Dr. Portier's IARC involvement).

guidelines, Opp. at 51-52, but omit any discussion of why his interpretation of the data differs so significantly from EPA's, yet another sign that Dr. Portier's only "methodology" is to change applicable criteria however necessary to get the result he wants. Mtn. at 24-29.[46]

Plaintiffs attempt to attribute Dr. Portier's spinning wheel of statistical opinions to the timing of his access to data from the three Monsanto rodent bioassays. Opp. at 53. This argument is absurd. A peer-reviewed article published in 2015 included all of the tumor incidence data from the Monsanto studies. *Infra* at 38 n.68. The idea that Dr. Portier would wait two years to review that data strains credulity and, if true, raises a variety of additional questions about the methods he used in gathering and evaluating the data on which his opinions are based. The changes in his opinions that have occurred over time have had nothing to do with the tumor counts in the Monsanto studies. Instead, they track his results-oriented statistical test selection, his willingness to change statistical endpoints years after the study to better support his opinions, and the selective inclusion or exclusion of non-Monsanto studies in his unproven pooling analysis in order to manufacture statistically significant results. Mtn. at 24-29.

In his expert report, Dr. Portier claimed that his pooling methodology was novel, yet at his deposition, Dr. Portier claimed without citation that his pooling methodology had appeared in the peer-reviewed literature. Mtn. at 26. Plaintiffs' opposition belatedly identifies the articles Dr. Portier purportedly relies upon, Opp. at 53-54, but plaintiffs fail to even attempt to carry their burden to explain how those articles, which involve the pooled presentation of results within individual studies,[47] reliably ground Dr. Portier's methodology of pooling results across different studies with "considerable genetic variability." Mtn. at 26 (citing Portier Amended Report at 51).

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[46] Nor did plaintiffs identify any published support for using historical controls to generate Dr. Portier's novel "p-hist" values. *See* Mtn. at 27-28. That EPA guidelines suggest that analysis of non-statistically significant uncommon tumors *may be informed* by the experience of historical controls, *see* EPA, Guidelines for Carcinogen Risk Assesment (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf, is a far cry from using historical control values, as Dr. Portier has done here, to run novel statistical tests.

[47] *See, e.g.*, M. Dourson et al., *Mode of Action Analysis for Liver Tumors from Oral 1,4-Dioxane Exposures and Evidence-Based Dose Response Assessment*, 68 Reg. Toxicology & Pharm. 387, 391, 395 (2014), ECF No. 655-15 (discussing re-evaluation of a single 1978 rodent study and graphical representation of pooled incidence of certain endpoints).

For example, plaintiffs have no response or justification for Dr. Portier's choice to include three studies in rats (Brammer, Suresh, and Wood) in his pooled analysis for skin tumors, but then exclude one of those studies (Suresh) in his pooling analysis of two other tumor types. Mtn. at 27. Monsanto's motion must therefore be granted.[48]

In response to methodological flaws identified by Monsanto, Mtn. at 21-29, plaintiffs claim that Dr. Portier conducted a false-positive analysis via his modified Table 15. Opp. at 55. This assertion is contradicted by Dr. Portier's own testimony in which he explained that the Table's reported "expected" number of tumors – from which he derives his opinion that it is "extremely unlikely" the tumors in the rodent studies arose by chance – is nothing more than an "approximation" because he "cannot figure that number out." Portier Dep. 317:10-318:6. Dr. Portier does not provide any scientific methodology as to how he arrived at even his approximation – he just said "I feel I've probably put a number in here which is more than the number of evaluations which were actually done." Portier Dep. 308:7-23. Dr. Portier's unsubstantiated feelings cannot pass *Daubert* muster, and his "false-positive" analysis in Table 15 as well as the array of toxicology opinions that the analysis supposedly supports should be excluded. *See Friend v. Time Mfg. Co.*, 422 F. Supp. 2d 1079, 1081 (D. Ariz. 2005) (noting it is appropriate to exclude expert testimony when "it is based on subjective beliefs or unsupported speculation which is no more than unreliable *ipse dixit* guesswork.") (citations omitted).

Finally, plaintiffs' claims that Dr. Portier's methodology appropriately included consideration of factors (such as the use of historical controls) present a misleading picture of what Dr. Portier actually did. From the large body of historical control data available, Dr. Portier cherry-picked only the data that might support his opinion when plugged into his novel "p-hist" analysis. Both the decision to ignore unhelpful data and to use his own made-for-litigation analyses are methodological flaws that ensured his "test" would gin up the desired result. Mtn. at 27-28. Such

[48] *See Bolbol v. City of Daly City*, 754 F. Supp. 2d 1095, 1115 (N.D. Cal. 2010) ("[P]laintiff fails to address this issue in her opposition brief and apparently concedes that she may not proceed on this claim. Accordingly, the court grants summary judgment in favor of defendants as to this claim."); *see also In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, 218 F. Supp. 3d 700, 718 (N.D. Ill. 2016) (same); *Wick v. Wabash Holding Corp.*, 801 F. Supp. 2d 93, 105 (W.D.N.Y. 2010) (same).

methodological hijinks cannot withstand scrutiny under *Daubert*. *Id*.

B. No Matter How Plaintiffs Describe It, Dr. Jameson's Methodology Fails To Satisfy *Daubert*.

Plaintiffs' claims that Dr. Jameson's hazard assessment, which he referenced at least 43 times during his deposition, Mtn. at 4, must be admitted, Opp. at 57, and that his "weight of the evidence" approach must be adopted by this Court, Opp. at 56, are based on erroneous legal standards that must be rejected. *See supra* at 3-5, *infra* at 36.[49]

Plaintiffs claim that Dr. Jameson's methodology "is designed to answer" the question of whether glyphosate can cause NHL in humans. Opp. at 57. They admit that the methodology he employed is only designed to evaluate carcinogenicity in animals, but then claim without identifying any scientific support other than Dr. Jameson's own *ipse dixit* that "one can usually rely on the fact that a compound causing an effect in one mammalian species will cause it in another species." *Id.* Even assuming that plaintiffs' claims of "usual reliance" were true (which they are not), their argument ignores that when questioned specifically about the studies at issue here, Dr. Jameson could not support such an analytic leap from the glyphosate rodent data to the question of causation of NHL in humans. Mtn. at 30 n.48. Without that link, his testimony has no scientific "fit" and cannot advance any issue in this case. *Id.* at 58.

In a last ditch effort to support the admissibility of Dr. Jameson's opinions as consistent with his pre-litigation methodology, Mtn. at 30-31, plaintiffs claim that the rodent studies show "replicated findings of malignant lymphomas in mice," *id.* at 46, ignoring Dr. Jameson's concessions that mice generally have a "high spontaneous incidence" of malignant lymphoma and that he is aware of scientific literature *objecting* to the use of mice as a model for evaluating

[49] Plaintiffs, without citation, claim that Monsanto criticized Dr. Jameson for not conducting a risk assessment. Although Monsanto did not do so, plaintiffs' explanation highlights why a hazard assessment is simply not enough to address the general causation question here. Risk assessments, according to Dr. Jameson, include an assessment of dose, whereas hazard assessments do not. Opp. at 57 (citing Jameson Expert Dep.). Dose and exposure levels are essential components of the general causation inquiry, *supra* at 5-6, and any analysis that does not include that assessment is inadmissible.

whether a chemical can cause lymphoma precisely "because of the high background level."[50] They also ignore Dr. Jameson's admission that his methodology depends upon his unsupported belief that disregarding the rate of spontaneous tumors is appropriate, Jameson Expert Dep. 146:12-14 ("[J]ust because something occurs because of a spontaneous rate is no reason to discount it from being an effect in a carcinogenicity study.").[51]

There is no dispute that animals used in rodent bioassays have high rates of spontaneous tumors, including lymphoma, meaning that tumors are observed in every study even absent compound-related effects. *See* Jameson Expert Dep. 133:17-134:8; *id.* 146:2-11. The issue here is not whether tumors were observed; it is whether plaintiffs' experts employed a scientific methodology to support their speculation that those tumors were glyphosate-related, an assumption that cannot be made on tumor presence alone. From his own testimony it is clear that Dr. Jameson has failed to rule out spontaneous tumors as the cause of the rodent study results on which he relies. Further, he applies the wrong methodology in assessing causality both of the animal tumors themselves and their biological relevance to humans. As such, his opinions must be excluded. Mtn. at 29-31.

C. Plaintiffs' Other Arguments for Admissibility Are Equally Meritless.

Plaintiffs nevertheless claim that their experts' opinions must be admitted because they are part of the evaluation of the data by the Bradford Hill criteria. Opp. at 48, 50, 58. Invoking the term "Bradford Hill" does not allow plaintiffs to escape the plain result of their experts' testimony, which proves their opinions are grounded in speculation, not science. *See Joiner*, 522 U.S. at 146 (rejecting causation opinion based on animal studies that plaintiffs' experts could not reliably extrapolate to humans); *O'Hanlon v. Matrixx Initiatives*, No. CV 04-10391, 2007 WL 2446496, at *2 (C.D. Cal. Jan. 3, 2007) ("[W]hen extrapolating from studies concerning one substance, one

[50] Mtn. at 23 (citing Jameson Expert Dep. 29:13-30:5, 133:17-134:8); Jameson Expert Dep. 146:12-14 (type of mice used in two of three studies have among the highest reported rates of spontaneous lymphoma); *see also* Rosol Dep. 301:14-18 (increased incidence of lymphoma in mice is well-known).

[51] Plaintiffs also have no answer for Dr. Jameson's departure from his published pre-litigation methodology cautioning against using statistics inflexibly as he does here. Mtn. at 31 n.51.

species, one dose level or one manner of exposure, it is incumbent upon the expert to explain and demonstrate why the extrapolation is scientifically proper. … [P]ositive results in other animal studies, standing alone, cannot establish positive results for the human claiming the same impact from the drug or chemical element."); *see also* Mtn. at 24 n.34 (providing additional citations); *supra* at 22-23 (predicate requirements for use of Bradford Hill).[52]

Plaintiffs' claims that the testimony of Drs. Portier and Jameson satisfies *Daubert*'s fit requirement fail. Expert testimony which is not the product of a reliable scientific process does not become admissible simply because plaintiffs believe it "enhances causation." *See Daubert II*, 43 F.3d at 1315-16 ("something doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive"). The determination that testimony is "relevant to the task at hand" and "logically advances a material aspect" of the proponent's case *only happens if the testimony itself is scientifically reliable*. *Id.* at 1315 ("fit" requirement is "second prong of the analysis").

Finally, plaintiffs claim that the similar conclusions of a few members of a non-binding EPA SAP confer "acceptance within the relevant scientific field" on the methodology of both experts. Opp. at 48. This is a gross misstatement of both the law and the facts. *See infra* at 26 n.44 (discussing SAP members' rejection of Dr. Portier's flawed statistical analyses). The admissibility under *Daubert* of any opinion based on a putative scientific methodology, such as Dr. Portier's ever-changing statistical analyses or Dr. Jameson's "extrapolation without evidence" approach, is not established by the alleged agreement of a handful of people as to a set or sub-set

[52] Plaintiffs blatantly mischaracterize the testimony of Dr. Rosol in an effort to buttress their own experts' opinions. Opp. at 49. Far from agreeing that a finding of a compound-related tumor in an animal can be extrapolated to humans as plaintiffs claim, Dr. Rosol testified that such findings in rodent studies are the first, but by no means last, step in assessing human relevance. Dep. of Thomas Rosol 324:8-325:15 (Sept. 15, 2017), ECF No. 655-7 ("Rosol Dep."). The scientific propriety of extrapolating rodent findings to humans requires research support beyond the rodent bioassay itself. *See supra* at 30-31 (citing *Joiner* and *O'Hanlon*). Even assuming their interpretations of the animal data were correct – which they are not – plaintiffs' experts concede no such support exists here with regard to glyphosate and NHL in humans. *See supra* at 25 n.42; Mtn. at 21-24.

of conclusions, especially where it has not been established that those individuals have expertise in animal toxicology, employed the same methodologies as the experts, or would agree with the experts' proposed use of a particular shared conclusion. Nor is the agreement germane – the opinions are inadmissible where the expert's conclusion is derived using a different methodology that would not pass *Daubert* scrutiny to begin with.[53]

IV. PLAINTIFFS' EXPERTS' OPINIONS REGARDING MECHANISTIC DATA ARE INADMISSIBLE.

Plaintiffs' opposition brief fails to meaningfully respond to the key arguments raised by Monsanto regarding the mechanistic data's failure to satisfy the "fit" requirement of *Daubert*. Mtn. at 31-35. For example, plaintiffs do not dispute the discrete objectives of the experiments or the fact that genotoxicity does not equate to carcinogenicity, Mtn. at 33, and they concede that mechanistic data alone cannot prove causation. Opp. at 58 ("mechanistic data are probative ... where [there is] epidemiology ..."). [54] Given these concessions and because their interpretations of the epidemiologic data are not based upon any reliable scientific method, Monsanto's Motion must be granted and this Court need not address the details of the mechanistic data. Mtn. at 33.[55]

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[53] Mtn. at 3 (citing case law that even formal regulatory findings are not dispositive of the *Daubert* inquiry); Monsanto Co.'s Br. re Relevance of IARC and EPA to Gen. Causation at 3-7, ECF No. 134 (discussing differences between regulatory and *Daubert* standards).

[54] Plaintiffs' experts concede that cell change due to both genotoxicity and oxidative stress occurs and is repaired naturally on a daily basis, precluding reliance on genotoxicity studies, including human *in vivo* studies, to establish causation. Mtn. at 32 n.54 (citing concessions in depositions of Drs. Weisenburger and Portier). Nor do plaintiffs challenge that "explicit relationships" between oxidative stress and adverse outcomes in the human body "have yet to be defined," Mtn. at 31 (citing EPA), precluding reliance on oxidative stress to prove carcinogenicity.

[55] Monsanto also moved to exclude the opinions of Drs. Neugut, Weisenburger, Nabhan, Jameson, Ritz, and Blair regarding the mechanistic data based on their lack of qualifications to offer such opinions. Mtn. at 32 n.53. Plaintiffs do not address this argument, and Monsanto's motion as to those five experts must be granted. Plaintiffs do rely on statements by non-retained expert, Dr. Ross, to establish the "importance" of the human *in vivo* studies. Opp. at 59. These statements, which refer to *IARC's* conclusion regarding the mechanistic data, came after Dr. Ross testified that he "did not review the genotox" data and that he "was so focused on toxicokinetics [data]" that he doesn't "know the specific details" about the studies, such as whether they controlled for exposures to pesticides and other chemicals. *See* Dep. of Matthew Ross 58:22-59:1, 197:25-198:9 (May 3, 2017), ECF No. 546-15 ("Ross Dep."). Plaintiffs' reliance on Dr. Ross's descriptions of the opinions of others, but which he does not hold and does not have a basis to evaluate, is improper. *See Villagomes v. Lab. Corp. of Am.*, No. 2:08-CV-00387, 2010 WL 4628085, at *4-5 (D. Nev. Nov. 8, 2010) (excluding testimony of expert who was not qualified to opine on significance of relevant issue but would "simply be parroting or serving as a spokesman" for another's opinion);

Plaintiffs' arguments regarding the mechanistic data also fail for other reasons. First, plaintiffs concede that their experts' opinions are based primarily on two methodologically unsound human *in vivo* studies (Paz-y-Mino 2007 and Bolognesi 2009).[56] Opp. at 58-59.[57] As detailed in Monsanto's Motion, the significant methodological flaws in these studies render any opinion based on them unreliable and inadmissible under *Daubert* as well. Mtn. at 35 n.65, 36 n.66-68. Plaintiffs' Opposition offers no basis under *Daubert* to support the admissibility of these studies. For example, in response to Monsanto's arguments regarding Bolognesi 2009, Mtn. at 35 n.65, plaintiffs cite two post-study statements by one of the study's authors about one piece of data that was deemed of low relevance in the study itself.[58] Plaintiffs' argument misses the point – the

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Dura Auto Sys. of Ind., Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science.").

[56] C. Paz-y-Mino et al., *Evaluation of DNA Damage in an Ecuadorian Population Exposed to Glyphosate*, 30 Genetics & Molecular Biology 456 (2007) ("Paz-y-Mino 2007"); C. Bolognesi et al., *Biomonitoring of Genotoxic Risk in Agricultural Workers from Five Columbian Regions: Association to Occupational Exposure to Glyphosate*, 72 J. Toxicology Envtl. Health, Part A 986 (2009) ("Bolognesi 2009").

[57] Plaintiffs claim that these studies somehow establish that the "opinions extrapolating the results of other genotoxicity experiments to humans are substantiated." Opp. at 58. That argument is wrong on multiple levels. As discussed earlier, *supra* at 3-5, each piece of scientific evidence must be evaluated individually to determine whether a proper methodology was utilized. As noted in Monsanto's Motion, numerous deficiencies prevent such a conclusion here. *E.g.*, Mtn. at 34-35 (plaintiffs rely on studies in which rodents were exposed to glyphosate directly by intraperitoneal ("IP") injection at doses thousands of times higher than real-world human exposures). Further, plaintiffs cite no authority – and there is none – allowing the court to conclude that if these two studies were the product of reliable methodologies, which they are not, then reliability is somehow established for other studies. *See generally Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267, 270 (2d Cir. 2002) (in deciding whether an expert's opinion is reliable, "the district court should undertake a rigorous examination" of "all of the materials" on which the expert relies). And "assumptions" of reliability are particularly unsupported here, where the "other studies" to which plaintiffs refer include many conducted on cells from plants, fish, or other non-human subjects, were conducted *in vitro*, which is a different and dissimilar test system, and did not use the same or even similar test protocols or methods. For example, Drs. Portier, Jameson, Nabhan, Ritz, and Weisenburger rely on M. Lioi et al., *Genotoxicity and Oxidative Stress Induced by Pesticide Exposure in Bovine Lymphocyte Cultures In Vitro*, 403 Mutation Res. 13 (1998), a study that reported glyphosate-induced genotoxicity based on tests conducted with blood cells "drawn from the jugular vein" of three cows. *See id.* at 14.

[58] Plaintiffs completely ignore that all five study authors acknowledged the study's limitations *in the publication itself*, instead extracting select statements from Claudia Bolognesi's subsequent publications in which she reported "significant increases in MN frequency." Opp. at 60 n.172. That increases in one measure of chromosomal damage were reported does *not* mean that that damage can be reliably attributed to GBHs; instead, as the authors cautioned, the "smaller number

Daubert inquiry is whether a study's findings are *the product of a methodology that withstands scientific scrutiny*, not whether plaintiffs' expert accurately quotes cherry-picked text extracted from the paper.

Further, Dr. Portier failed to reconcile his opinion that the study's findings "must carry the greatest weight," Am. Expert Report of Christopher Portier at 67, ECF No. 546-8 ("Portier Amended Report"), with the study authors' conclusion that "[o]verall, these results suggest that genotoxic damage associated with glyphosate spraying … is small and appears to be transient … [and] the genotoxic risk potentially associated with exposure to glyphosate … is of low biological relevance," Bolognesi 2009 at 994-995.[59] Nor did Dr. Portier address the study's methodological shortcomings, including those identified by the study's authors in the body of the study.[60] And although Dr. Portier claims that the genotoxic potential of GBHs is "worse" than glyphosate alone, *see* Portier Amended Report at 70, he concedes that the GBH mutation tests are consistently negative. Portier Dep. 347:10-20. His methodological failures require exclusion of his opinions regarding the mechanistic data.[61]

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of subjects recruited in this study and small amount of information about the exposure precluded any conclusions." *See* Bolognesi 2009 at 995.

[59] *See In re Accutane Prod. Liab. Litig.*, No. 8:04-MD-2523-T-30, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009) ("When an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study."), *aff'd*, 378 F. App'x 929 (11th Cir. 2010); *Williams v. Mosaic Fertilizer, LLC*, No. 8:14-CV-1748-T-35, 2016 WL 7175657, at *11 (M.D. Fla. June 24, 2016) (excluding expert who relied on data from studies to "reach conclusions that are at odds with the authors' conclusions"); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1169 (E.D. Wash. 2009) ("Nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.") (citation omitted).

[60] *See* R. Arnason, *Toxicologist Pans UN Glyphosate Report*, The Western Producer (Mar. 27, 2015), http://www.producer.com/daily/toxicologist-pans-un-glyphosate-report/ (co-author Dr. Solomon stating that IARC's misinterpretation of the study as showing a relationship between GBHs and genotoxicity is "certainly a different conclusion than the one we [the authors] came to"); Bolognesi 2009 at 995 ("Although temporality was satisfied in the increase in frequency of BNMN after spraying, this response did not show strength as it was not consistently correlated with the rate of application. Recovery was also inconsistent with decreases in frequency of BNMN in the areas of eradication spraying but not in the area where lower rates were applied on sugar cane .... The smaller number of subjects recruited in this study and small amount of information about the exposure precluded any conclusions ….").

[61] *See U.S. v. Lester*, 234 F. Supp. 2d 595, 600 (E.D. Va. 2002) ("[Expert] was required to show his work, so to speak, and he did not. In the absence of any evidence respecting the scientific

Similarly, plaintiffs' claim that Dr. Goodman conceded his methodological criticisms of Paz-y-Mino 2007 are "speculative," Opp. at 59, misconstrues the scientific issue before the Court. By failing to provide adequate information, *the authors required any reader to speculate about the reliability of the study's methodology*. Where such speculation is required, reliability of the methodology cannot be assumed as a matter of sound science. Dep. of Jay Goodman 225:3-18 (Sept. 22, 2017) ("Goodman Dep.").[62] Under *Daubert*, studies that omit key details necessary to evaluate their methodologies are unreliable and must be excluded.[63]

Plaintiffs also erroneously claim that the publication of both studies means the *Daubert* inquiry is satisfied as to their admissibility. Opp. at 58. Instead, "[p]eer review and publication

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foundation for his opinions, the Court cannot conclude that [expert's] proffered testimony is scientifically reliable."); *Abold v. City of Black Hawk*, No. Civ.03-CV-00299, 2005 WL 5807816, at *11 (D. Colo. July 18, 2005) ("[Expert's] conclusions and the information available in this case is speculative, tenuous at best, and severely lacking in sufficient support ... . As a result, [expert's] opinion ... is unreliable under Fed. R. Evid. 702 and *Daubert* ...").

[62] Dr. Goodman testified that the Paz-y-Mino 2007 authors used a test method that involves some "subjectivity," Goodman Dep. 222:21-224:14, but did not implement measures to prevent that possibility from improperly influencing the results. *See* Paz-y-Mino 2007 at 458 (noting samples from "exposed" and "unexposed" groups were not evaluated simultaneously); Goodman Dep. 224:15-225:2. Similarly, plaintiffs claim that the authors' failure to assess how the study subjects' poor health, *see* Expert Report of Jay Goodman at 12, ECF No. 649-8 ("Goodman Report"); Paz-y-Mino 2007 at 457 (describing clinical history of exposed individuals), may have contributed to the perceived genotoxic effects reported runs contrary to the scientific rigor required by *Daubert*. Plaintiffs go one step further, declaring Dr. Goodman's testimony that the subjects' poor health may in fact be the sole cause of the effects observed is "speculative" because, according to them, the symptoms described in the article are consistent with acute glyphosate poisoning. Opp. at 63 n.179. But nowhere in Paz-y-Mino 2007 do the study authors attribute these symptoms to glyphosate poisoning. Nor do the authors, who describe the study subjects as "24 randomly selected individuals" living near an area "where aerial spraying with a glyphosate-based herbicide" had occurred, claim that the subjects exhibited similar clinical signs as individuals intentionally drinking glyphosate in attempt to commit suicide. *See* Paz-y-Mino 2007 at 457. With no way to ascertain *what* caused the study subjects' illnesses or *how* their condition affected the DNA damage observed based upon the information in the paper, that damage cannot be reliably attributed to glyphosate.

[63] *See King ex rel. King v. Sec'y of HHS*, No. 03-584V, 2010 WL 892296, at *67 (Fed. Cl. Mar. 12, 2010) (studies that had "analytical methods [that] were 'not transparent' and omitted 'important details'" making it "impossible to evaluate the studies" were "*not* reliable, and [could not] be accorded any weight.") (quotation marks omitted); *Brantley v. Int'l Paper Co.*, No. CV 2:09-230, 2017 WL 2292767, at *6 (M.D. Ala. May 24, 2017) ("While experts are not required to rule out every alternative cause, [expert's] failure to account for alternative causes … in this instance substantially impairs his already questionable theory .... The excessive number of variables in this study, combined with the apparent margin of error render the study totally unreliable.") (granting summary judgment for defendant).

mean little" if a study is based on unreliable methodology.[64] As proponents of the scientific evidence at issue, it is *plaintiffs' burden* to prove that opinions based on the studies are admissible under *Daubert*, meaning that they are "grounded in the methods and procedures of science," not "subjective belief or unsupported speculation." Mtn. at 7 (citing *Daubert*). Plaintiffs are unable to do so here. This outcome is not surprising given the studies' limited experimental purposes and many methodological flaws, because of which both have been deemed "low quality" by EPA and excluded from the agency's 2016 evaluation of glyphosate's carcinogenic potential.[65] "[T]here is simply too great an analytical gap between the data" presented in the human *in vivo* studies "and the opinion proffered," *i.e.*, that GBHs are genotoxic (and therefore cause NHL in humans). *See Joiner*, 522 U.S. at 146.[66]

V. TO AVOID ADDRESSING THE DEFICIENCIES IN THEIR EXPERTS' OPINIONS RAISED BY MONSANTO, PLAINTIFFS SEEK TO SHIFT THE FOCUS TO NON-*DAUBERT* ISSUES.

Lacking any legitimate basis for their proffered opinions, plaintiffs spend numerous pages of their brief trying to prop up IARC's credibility, making spurious claims that Monsanto's scientists "ghostwrote" various articles, and providing other distractions that have nothing to do with the reliability of their proffered testimony. These arguments are irrelevant to the *Daubert* inquiry and do not cure the deficiencies of their proffered testimony.

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[64] *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 936, 944-45 (D. Minn. 2009) (excluding expert's opinion based on unreliable published study as "lack[ing] sufficient indicia of reliability to be admitted as a general causation opinion"); *Daubert*, 509 U.S. at 593 (1993) ("Publication ... is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability ... ."); *Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 600 (S.D.W. Va. 1998) ("[M]ere publication of an article is not the end of the peer review process; it is but the beginning.").

[65] EPA Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 196 (Sept. 12, 2016), https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094.

[66] It is telling that although plaintiffs repeatedly refer to the SAP report as an authoritative evaluation of the glyphosate epidemiology and animal data, Opp. at 10, 48, 51, 53, they conceal from the Court that the SAP concluded "that [EPA's] overall weight-of-evidence and conclusion that ***there is no convincing evidence*** that glyphosate induces mutations *in vivo* via the oral route are sound." EPA, FIFRA Scientific Advisory Panel, *Meeting Minutes and Final Report No. 2017-01, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: EPA's Evaluation of the Carcinogenic Potential of Glyphosate*, Dec. 13-16, 2016 at 19, ECF. No. 648-10 (emphasis added).

First, plaintiffs' attempt to buttress the credibility of IARC's hazard assessment is meaningless. Opp. at 6, 7, 9-10, 17, 29, 34, 56-57. Although a subject of intense disagreement between the parties, the credibility of IARC is not a component of the *Daubert* inquiry. Plaintiffs' experts' methodologies are. Plaintiffs do not dispute that a hazard assessment methodology such as IARC's – which does not take into account dose or human relevance – is insufficient to satisfy *Daubert* because it applies a "*threshold of proof*" that is "*lower than that appropriate in tort law*." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 464 (5th Cir. 2012) (emphasis in original) (quoting *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996)). Plaintiffs also do not dispute that Drs. Neugut, Jameson, and Nabhan employed ***only*** such a hazard assessment methodology. Thus, no matter how credible IARC is (or is not) in making a hazard assessment, these experts' opinions do not rise to the level of admissible evidence. Mtn. at 3-4.

Plaintiffs' efforts to discredit all regulatory agencies who disagree with IARC even though those agencies apply scientific standards far more stringent and reliable than IARC's is equally irrelevant. Opp. at 10-11. Remarkably, plaintiffs would have the Court give more credence to ***non***-scientific statements by a few members of the ***European Parliament*** who have joined plaintiffs' counsel in lobbying efforts, than to the European regulators that painstakingly reviewed the science and found no cancer link. *See, e.g.*, Ltr. from Six Members of the European Parliament (July 4, 2017), ECF No. 385 ("European Parliament Letter"); Monsanto Papers: Proof of Scientific Falsification, YouTube (Sept. 27, 2017), https://www.youtube.com/watch?v=1_s18Qetabo ("Monsanto Papers Press Conference") (press conference held by Kathryn Forgie of the Andrus Wagstaff firm and MEP Michèle Rivasi).[67]

[67] Plaintiffs also attempt to mislead the Court about certain regulatory reviews. For example, they claim that California "reviewed the IARC classification" and "concluded that glyphosate is a substance known to the state of California to cause cancer." Opp. at 9-10. Proposition 65, a California ballot initiative, requires that substances classified by IARC as group 2A automatically be listed as carcinogens without any further scientific analysis of whether IARC's conclusion is grounded in sound science. Cal. Labor Code § 6382(b) (providing for automatic listing of substances classified by IARC); Cal. Code Regs. tit. 27, § 25904(c) ("Comment is restricted to whether the identification of the chemical or substance meets the requirements of this section. The lead agency shall not consider comments related to the underlying scientific basis for classification of a chemical by IARC as causing cancer."). The California EPA reviewed the actual science in 2007, and the agency reached a conclusion consistent with that of regulators worldwide for 40 years – that glyphosate and GBHs are not carcinogenic. *See* California Environmental Protection

Finally, plaintiffs' assertion that Monsanto influenced the science by ghostwriting articles is irrelevant and wrong. GBHs have been on the market and the subject of independent scientific research by academicians, government agencies, and other independent scientists for over 40 years. Other than funding one meta-analysis and its update to include the Alavanja 2013 and NAPP data, Monsanto had ***no role*** in the epidemiology studies. Of the 12 rodent carcinogenicity studies relied upon by plaintiffs' experts, only three are studies conducted by Monsanto. The remaining nine are studies conducted by or on behalf of other registrants without any Monsanto involvement, and the original tumor data from each study has been published in the peer-reviewed literature.[68] Plaintiffs' allegation that the unanimous conclusion of these studies – that glyphosate does not cause compound-related tumors in rodents – was somehow engineered by Monsanto is absurd on its face.

Plaintiffs' "ghostwriting" allegations regarding three articles that provide summaries, or reviews, of primary data are also nothing more than an effort to distract the Court from their own burdens as proponents of their experts' opinions and methodologies. Opp. at 14-15.[69] Notably, much of the primary data discussed in these reviews comes from non-Monsanto studies, meaning, once again, that Monsanto had no role in its generation. Further, one of the three articles discloses that a listed author is a former Monsanto employee, *see* Kier & Kirkland 2013 at 311, and all three articles expressly disclose Monsanto's funding and/or involvement.[70] Since plaintiffs' counsel

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Agency, Office of Environmental Health Hazard Assessment, Pesticide and Environmental Toxicology Branch *Public Health Goals for Chemicals in Drinking Water: Glyphosate* at 1 (June 2007), https://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907_0.pdf ("Based on the weight of evidence, glyphosate is judged unlikely to pose a cancer hazard to humans.").

[68] *See* H. Greim et al., *Evaluation of Carcinogenic Potential of the Herbicide Glyphosate, Drawing on Tumor Incidence Data from Fourteen Chronic/Carcinogenicity Rodent Studies*, 45 Critical Revs. Toxicology 185 (2015).

[69] *See* G. Williams et al., *Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans*, 31 Reg. Toxicology & Pharma. 117 (2000), ECF No. 648-25 ("Williams 2000"); L. Kier et al., *Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations*, 43 Critical Revs. Toxicology 283 (2013), ECF No. 649-1 ("Kier & Kirkland 2013"); G. Williams et al., *A Review of the Carcinogenic Potential of Glyphosate by Four Independent Expert Panels and Comparison to the IARC Assessment*, 46 Critical Revs. Toxicology 3 (2016) ("Williams 2016"). At one point, plaintiffs contended that Monsanto ghostwrote the Greim paper as well, but they have abandoned that contention for good reason – a Monsanto employee is clearly listed as one of the study's four authors.

[70] *See* Kier & Kirkland 2013 at 310-11 (authors "thank the following individuals for their

began their unsubstantiated media campaign to brand these papers as ghostwritten, many of the authors (one of whom, Dr. Acquavella, is a former Monsanto employee whose e-mail mentioning the term "ghostwriting" is often taken out-of-context and cited by plaintiffs to support their arguments) have publicly stated that no ghostwriting occurred.[71]

Plaintiffs' affirmative burden of proof cannot be satisfied by criticizing Monsanto or articles allegedly ghostwritten by Monsanto.[72] That Plaintiffs even raise such distractions confirms the bankruptcy of their case on the merits. *E.g.*, *Waite v. All Acquisition Corp.*, 194 F. Supp. 3d 1298, 1307-08 (S.D. Fla. 2016) (rejecting similar argument; "[a]lthough perhaps narratively interesting, [that argument] is irrelevant to the instant *Daubert* inquiry, which focuses solely on the reliability and helpfulness of any given theory and/or the qualifications of the expert positing such theory.").[73]

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contributions … David Saltmiras (Monsanto Company)"); Williams 2000 at 160 ("[W]e thank the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions. … Key personnel at Monsanto who provided scientific support were William F. Heydens, Donna R. Farmer, ..."); Williams 2016 at 16 ("Funding for this evaluation was provided to Intertek by the Monsanto Company which is a primary producer of glyphosate and products containing this active ingredient.").

[71] *See* D. Hakim, *Monsanto Weed Killer Roundup Faces New Doubts on Safety in Unsealed Documents*, N.Y. TIMES (Mar. 14, 2017), https://www.nytimes.com/2017/03/14/business/monsanto-roundup-safety-lawsuit.html (co-author David Kirkland said in an interview, "'I would not publish a document that had been written by someone else.' He added, 'We had no interaction with Monsanto at all during the process of reviewing the data and writing the papers.'"); D. Hakim, *Monsanto Glyphosate Case: Select Documents Suggest Company Tried To Influence Public Debate over Weed Killer*, Genetic Literacy Project (Aug. 3, 2017), https://geneticliteracyproject.org/2017/08/03/monsanto-glyphosate-case-selected-documents-suggest-company-tried-influence-public-debate-weedkiller/ (co-author John Acquavella said "there was no ghostwriting"); W. Cornwall, *Update: After Quick Review, Medical School Says No Evidence Monsanto Ghostwrote Professor's Paper*, Science (Mar. 23, 2017), http://www.sciencemag.org/news/2017/03/update-after-quick-review-medical-school-says-no-evidence-monsanto-ghostwrote (officials at New York Medical College found "'no evidence' that [Dr. Gary Williams] violated the school's prohibition against authoring a paper ghostwritten by others").

[72] *See Norris*, 397 F.3d at 886 ("Mere criticism of epidemiology cannot establish causation."); *Hollander*, 289 F.3d at 1213 ("[Plaintiffs] have the burden of demonstrating the harmful effect of [the drug]. Accordingly, it was not unreasonable for the district court to conclude that [plaintiffs' expert's] attack on the [epidemiology] study did not constitute reliable [general causation] evidence ... ."); *Caraker*, 188 F. Supp. 2d at 1034 ("Plaintiffs' experts' broad criticisms of the existing epidemiological evidence do[] not help them meet their burden," as "plaintiffs' burden is an affirmative one, not served by such attacks.").

[73] The court rejected plaintiffs' argument that studies directly or indirectly funded by the

In addition to being baseless, plaintiffs' ghostwriting accusations do not satisfy their affirmative *Daubert* burden to establish the admissibility of their experts' causation opinions.[74]

OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO STRIKE CERTAIN OPINIONS OF MONSANTO'S EXPERT WITNESSES

I. THERE IS NO SCIENTIFIC BASIS TO EXCLUDE DR. ROSOL'S OPINION, AS ALL MATERIALS HE REVIEWED WERE AVAILABLE TO BOTH PARTIES.

As the only veterinary pathologist among the experts designated in this litigation, Dr. Rosol is uniquely qualified to opine on pathogenesis and human relevance of cancer and other findings from rodent studies. Plaintiffs do not challenge Dr. Rosol's qualifications or the robust methodology used to reach his conclusions under *Daubert*, but instead claim that Dr. Rosol's opinions should be excluded because he reviewed information "withheld from [P]laintiffs." Opp. at 62. This argument is baseless and must be denied.

In addition to the 101 items on his materials considered list (all of which are either publicly available or produced to plaintiffs in this litigation), Dr. Rosol visited a public Reading Room in Brussels, Belgium, which housed eleven of the twelve rodent carcinogenicity studies at issue here.[75] Two of those studies were conducted by or on behalf of Monsanto and produced to

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manufacturer defendant are inherently inadmissible for the same reason. *Id.*; *see Mullins*, 178 F. Supp. 3d at 904 ("That these studies appearing in peer-reviewed journals are industry-funded … [is a] factor [] that determine[s] the weight of the [expert's] opinions, not their admissibility."); *Garlick v. County of Kern*, Case No. 1:13-CV-01051, 2016 WL 1461841, at *3-4 (E.D. Cal. Apr. 14, 2016) (rejecting *Daubert* challenge to defendants' expert in civil rights/excessive force lawsuit whose studies "were funded by the City of San Diego in preparation for litigation" because that argument goes to bias and weight, not admissibility); *Pirolozzi v. Stanbro*, No. 5:07-CV-798, 2009 WL 1441070, at *5-6 (N.D. Ohio May 20, 2009) (rejecting *Daubert* challenge and holding that issue of industry-funded studies goes to "the weight to be accorded [to] the experts' testimony, rather than the admissibility of the testimony").

[74] Plaintiffs' claims that Monsanto's experts "relied" on these three articles are incorrect. Dr. Foster looked at the review papers and therefore placed them on his materials considered list as required by Fed. R. Civ. P. 26(a)(2(B)(ii), along with over 180 *other* materials. Dr. Goodman likewise included the articles on his nearly 400-reference long materials considered list and testified that he did not base his opinions on the content of the papers, instead reviewing and relying upon the original study data itself, where available. Goodman Dep. 158:11-15 ("I made an independent, in-depth, constructively critical evaluation of this large body of data here related to genotoxicity and reached my conclusion and then I said, like, [a]nd by the way, it's consistent with."); Goodman Report at 31-33 (same). Further, Dr. Goodman testified that his opinion would have been the same even if these review papers had not existed. Goodman Dep. 158:24-159:5.

[75] Because the studies could not be printed or removed from the Reading Room due to their commercial and trade secret nature, Dr. Rosol handwrote over 50 pages of notes during his review,

plaintiffs in this litigation.[76] As plaintiffs concede, the remaining studies were conducted by or on behalf of other GBH registrants; they are not and have never been under Monsanto's possession, dominion, or control. *See* Email from Rosemary Stewart, to Jeffrey Travers (Dec. 30, 2016, 9:13 AM), ECF No. 656-14. Monsanto could not "withhold" from plaintiffs studies it does not have.

Accompanied by significant publicity and in connection with the EU glyphosate re-registration process, the Reading Room opened on August 24, 2016 and closed at the end of October 2016.[77] Plaintiffs do not – and cannot – dispute that the Reading Room was open to anyone who cared to visit. Access was free and required only that visitors complete an online registration form to make an appointment. Rosol Dep. 59:5-10, 61:13-64:1.

Plaintiffs' decision not to visit or to have their experts visit the public Reading Room is a calculated litigation ploy, not a basis for exclusion of Dr. Rosol's testimony. To be clear, Dr. Portier, who lists Switzerland as his home address, *see* C. Portier Consultations, LobbyFacts.eu (Dec. 21, 2015), ECF No. 655-1, is closely following EFSA's decision-making vis-à-vis glyphosate. He has actively engaged with European authorities through public and private criticisms of EFSA's assessment of glyphosate and presentations before the European Parliament and other EU-based entities, *all of which occurred after he agreed to serve as an expert in this*

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all of which were produced to plaintiffs prior to Dr. Rosol's deposition. *See* Ltr. from Heather Pigman to Robin Greenwald and Kathryn Forgie (Sept. 5, 2017), ECF No. 655-7. *See Bd. of Trs. of the AFTRA Ret. Fund v. JPMorgan Chase Bank, N.A.*, No. 09-civ-686, 2011 WL 6288415, at *11 (S.D.N.Y. Dec. 15, 2011) ("Where the substance of [undisclosed reliance materials] is incorporated into the body of [expert's] report, exclusion is not an appropriate remedy for failure to produce [those materials].").

[76] *See* Expert Report of Charles Jameson, Exhibit B at 7, #72 (MONGLY00586054, 1983 mouse study), #73 (MONGLY00593610, 1990 rat study), ECF No. 648-6 ("Jameson Report"). A third rodent study conducted on behalf of Monsanto, but not available in the Reading Room, also was produced to plaintiffs in full and was available to plaintiffs' experts. *See* Jameson Report, Ex. B at 7, #71 (MONGLY01767038, 1981 rat study).

[77] *See* Business Wire, *Glyphosate Task Force Opens Reading Room for Public Access to Studies* (Aug. 24, 2016), http://www.businesswire.com/news/home/20160824005470/en/Glyphosate-Task-Force-Opens-Reading-Room-Public; *GTF Response to Commissioner Andriukaitis' Letter Re: Publication of Studies*, MONSANTO BLOG (Apr. 6, 2016, updated Aug. 24, 2016), https://monsantoblog.eu/gtf-response-to-commissioner-andriukaitis-letter-re-publication-of-studies/; Glyphosate Facts, *Glyphosate Task Force Opens Reading Room for Public Access to Studies* (Aug. 24, 2016), http://www.glyphosate.eu/gtf-statements/glyphosate-task-force-opens-reading-room-public-access-studies.

litigation and while he was receiving financial compensation from plaintiffs' counsel. *See* Portier Dep. 71:8-75:4, 113:2-115:23, 122:10-132:23. For example, leading up to the opening of the Reading Room, Dr. Portier:

- Testified in September 2015 to German regulators regarding the differences between their assessment of glyphosate and that of IARC, *see* Portier Dep. 114:22-25; Corporate Europe Observatory, *Setting the Record Straight on False Accusations, Dr. C. Portier's Work on Glyphosate and IARC* (Oct. 19, 2017), https://corporateeurope.org/food-and-agriculture/2017/10/setting-record-straight-false-accusations-dr-c-portier-work-glyphosate;
- Commented in an October 2015 email to NIEHS scientist Linda Birnbaum that he was "having a bit of fun pushing the IARC Glyphosate finding into the European decision on [sic] re-registration," *see* E-mail from Linda Birnbaum to Sharon Evans (Oct. 21, 2015, 8:10 AM), ECF No. 655-1;
- Penned a November 2015 letter to EFSA expressing his "deep concern" over the agency's determination that glyphosate is "unlikely to pose a carcinogenic hazard to humans," *see* Ltr. from C. Portier, Sr. Contributing Scientist EDF, to V. Andriukaitis, Comm'r Health and Food Safety, European Comm'n (Nov. 27, 2015), ECF No. 655-1;[78]
- Commented to a European news outlet regarding EFSA's refusal to adopt IARC's scientific conclusions, A. Neslen, *Vote on Controversial Weedkiller's European Liscense Postponed*, The Guardian (Mar. 8, 2016), https://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate; and
- Wrote to German regulators regarding his preference for IARC's analysis over theirs. Ltr. from C. Portier to Federal Institute for Occupational Safety and Health (July 8, 2016), http://www.eomsociety.org/images/PDF/PortierOLII.pdf.

Plaintiffs' familiarity with European regulatory affairs goes beyond Dr. Portier. Counsel enjoys a relationship with the very MEPs who requested the opening of the Reading Room and then protested outside of it.[79] For example, on October 15, 2016, *while the Reading Room was still*

[78] Although he enlisted a variety of co-signatories to this so-called impartial letter, Portier apparently did not disclose to them his close financial relationship with plaintiffs' counsel or his financial conflict of interest, nor did he disclose those conflicts to the EU officials to whom the letter was addressed. *See* Portier Dep. 73:18-75:4 (conceding that he failed to disclose to co-signees or EFSA the fact that he had been working as a private consultant for plaintiffs' counsel); Jameson Expert Dep. 277:11-278:5 (Dr. Jameson, a co-signee, "wasn't aware" that Dr. Portier had started working for plaintiffs' counsel when he participated in the letter to EFSA).

[79] *See* Ltr. from H. Hautala, Member of the European Parliament and others, to Bernhard Url, Exec. Director of the European Food Safety Authority (Mar. 15, 2016), https://www.asktheeu.org/en/request/is_glyphosate_safe_we_have_the_r (request by four MEPs (Bart Staes, Heidi Hautala, Benedek Javor and Michèle Rivasi) to EFSA demanding "access to all documents that have been used during the EFSA peer review" of glyphosate); Reddit, *Glyphosate Task Force Opens Reading Room for Public Access to Studies*, (May 26, 2017) https://www.reddit.com/r/farming/comments/4zcr4z/glyphosate_task_force_opens_reading_room_for/; GMWatch, *MEPs Protest Industry "Reading Room" for Secret Glyphosate Studies* (Sept. 28, 2016) http://gmwatch.org/en/news/latest-news/17241-meps-protest-industry-reading-room-for-secret-glyphosate-studies (describing protests by MEPs).

open, attorney Timothy Litzenburg, of the Miller Firm, another co-lead counsel in this MDL, and one of the MDL plaintiffs traveled to The Hague, just over 100 miles from Brussels, to hype their theories regarding glyphosate's impact on human health. *See* International Monsanto Tribunal: Program (Oct. 14-16, 2016), http://www.en.monsantotribunal.org/program. In July 2017, the same MEPs and plaintiffs' counsel filed a letter with this Court requesting access to deposition transcripts of Monsanto's corporate witnesses and "any accompanying and relevant documents or other evidence." *See* European Parliament Letter. Shortly thereafter, plaintiffs' counsel at Baum Hedlund, a firm which is, for now, a member of the MDL Executive Committee, made that happen by, among other things, providing the MEPs with 86 confidential documents. *See* Ltr. from R. Brent Wisner, Baum Hedlund Aristei and Goldman, PC, to Bart Staes, Member of the European Parliament at 4 (Aug. 1, 2017), ECF No. 435-1 ("We hope that the European Parliament will be better informed in proceeding with their evaluation and classification of glyphosate as a result of having access to these documents."). In September 2017, another plaintiffs' attorney, Kathryn Forgie of the Andrus Wagstaff firm, another co-lead counsel firm in this MDL, held a press conference in Paris, France, alongside one of the same MEPs to lobby European regulators not to re-approve the registration of glyphosate. *See* Monsanto Papers Press Conference. In October 2017, the Baum Hedlund firm and two other MDL plaintiffs appeared in Brussels to lobby European lawmakers to ban or restrict glyphosate. *See* D. Hakim, *Monsanto's Roundup Faces European Politics and U.S. Lawsuits*, N.Y. TIMES (Oct. 4, 2017), https://www.nytimes.com/2017/10/04/business/monsanto-roundup-europe.html?_r=0. In the same month, Baum Hedlund provided summaries and copies of plaintiffs' expert reports from this litigation to EU officials, advising them that the firm "expect[s] more documents from the ongoing U.S. litigation to be declassified in the near future … that may be of interest to European lawmakers."[80]

[80] *See* Ltr. from Michael L. Baum, to Members of the European Commission, Parliament and Member States (Oct. 31, 2017), https://www.politico.eu/wp-content/uploads/2017/11/Letter20Re20Expert20Reports.pdf. Notably, ***two congressional committees are investigating IARC*** and considering eliminating its U.S. funding based on concerns about the "scientific integrity" of the monograph program and the "lack of transparency" in the group's meetings, deliberations, and drafts. *See* K. Kelland, *Exclusive: Congressional Committee Questions Operation of WHO Cancer Agency*, Reuters (Nov. 1, 2017), https://www.reuters.com/article/us-health-who-congress-exclusive/exclusive-congressional-

Tactics aside, plaintiffs' experts' decision not to visit the public Reading Room is not a basis for exclusion of Dr. Rosol's testimony, and is instead more evidence of their improper methodological practice of ignoring unhelpful data.[81] Moreover, plaintiffs' argument is also meritless because, as Dr. Rosol explained at his deposition, key tumor data from the eleven carcinogenicity studies he reviewed in the Reading Room is also available in other public sources, including the Greim publication, which Drs. Jameson and Portier cited no less than 41 times. *See* Portier Amended Report at 22-44; Jameson Report at 19-28.

Plaintiffs mischaracterize Dr. Rosol's testimony by claiming that review of the underlying pathology reports in the Reading Room was "essential" to his opinions. Opp. at 62; *id.* ("all of Dr. Rosol's opinions are predicated upon information to which Monsanto had access but that were withheld from Plaintiffs"). At his deposition, Dr. Rosol made clear that he did *not* need the data in the Reading Room to conclude that the rodent carcinogenicity studies show no evidence of a carcinogenic effect; rather, even if he had never stepped foot in the Reading Room, he had sufficient data from Greim 2015 and the three Monsanto studies to reach the same opinion. *See* Rosol Dep. 205:5-206:1 (explaining that the "major value of the reading room experience to me has been the reading of the pathology reports. It was interesting to read that none of the pathologists thought there was a compound-mediated effect" but "for me to render my conclusion I actually didn't have to go to the reading room. The data that was available to me without going to the reading room would have led to the same conclusion."); *id.* 208:5-209:3 (agreeing that the carcinogenicity data from the 12 studies is "appropriately and adequately captured in the Greim report"). Accordingly, plaintiffs' attempt to exclude Dr. Rosol's testimony must be denied.

committee-questions-operation-of-who-cancer-agency-idUSKBN1D15TU.

[81] *See Assurance Co. of Am. v. Nat'l Fire & Marine Ins. Co.*, No. 2:09-CV-1182, 2012 WL 1970017, at *4 (D. Nev. June 1, 2012) (no duty to produce documents that were equally available to all parties), *aff'd,* 595 Fed. App'x 670 (9th Cir. 2014); *Princeton Digital Image Corp. v. Office Depot Inc.*, No. 13-239, 2017 WL 3264068, at *5 (D. Del. Aug. 1, 2017) (where expert's report "fairly disclose[d] the theory on which he relie[d]," plaintiff lacked a "meritorious basis for exclusion" of materials in publicly-available internet archive); *Fitts v. Unum Life Ins. Co. of Am.*, 98-00617, 2007 WL 1334974, at *19 (D.D.C. May 7, 2007) (denying party's motion to exclude public records of which the party was aware and had authority to view).

II. DR. GOODMAN'S ROBUST AND WELL-SUPPORTED EVALUATION OF ALL AVAILABLE MECHANISTIC DATA IS ADMISSIBLE.

Dr. Goodman is a board certified toxicologist specializing in the mechanisms underlying carcinogenesis. For over 45 years, Dr. Goodman has taught and conducted research on toxicology as a faculty member of Michigan State University's Department of Pharmacology and Toxicology. Goodman Report at 1. Plaintiffs do not challenge Dr. Goodman's qualifications to opine on the mechanistic data. Instead, plaintiffs claim that because he "discount[ed]" the two methodologically flawed human *in vivo* studies described above and applied a "result driven methodology," his testimony should be excluded. Opp. at 62-65. Both of plaintiffs' arguments hinge on mischaracterizations of Dr. Goodman's testimony and a fundamental misunderstanding of plaintiffs' burden at the *Daubert* stage. Accordingly, this motion must be denied.

A. Dr. Goodman Applied a Rigorous Methodology to Both Positive and Negative Studies To Reach His Opinion That Glyphosate and GBHs Should Be Regarded as Non-Genotoxic.

In contrast to plaintiffs' experts' cursory review of select studies and parroting of IARC, Mtn. at 32 & n.55, Dr. Goodman critically evaluated all relevant mechanistic data involving glyphosate and GBHs. Based on his review of over 200 genotoxicity and oxidative stress studies, including studies published in the peer-reviewed literature and unpublished regulatory studies performed according to well-established, standardized guidelines, Dr. Goodman concluded that glyphosate and GBHs are non-genotoxic.[82] *See* Goodman Report at 3. To evaluate this enormous and complex data set, Dr. Goodman applied a clear methodology, emphasizing the four types of tests "employed internationally for registration/approval of chemicals" for their ability to reliably "cover [] a spectrum of potential genotoxic events," *id* at 9; and, considering whether there were potential confounding factors present in each study that could impact the results. *Id.* at 6. This

[82] Further, consistent with EPA's view that "explicit relationships" between oxidative stress and adverse outcomes in the human body "have yet to be defined," Mtn. at 31, Dr. Goodman concluded that "while GBFs and/or glyphosate might be capable of causing oxidative stress under certain experimental conditions," oxidative stress is not a "reliable biomarker of [a chemical's] ability to cause cancer." *See* Goodman Report at 3-4, 39. Dr. Goodman further explained at his deposition that "the role of oxidative stress in carcinogenicity is really unclear" and there is insufficient data to conclude that oxidative stress can cause cancer. Goodman Dep. 190:3-4, 190:18-191:1.

methodology has been published, peer-reviewed, generally accepted, and tested – the hallmarks of reliability under *Daubert*.[83]

Plaintiffs mischaracterize Dr. Goodman's testimony, arguing the false predicate that he "accepts all negative findings at face value – even when these findings are the product of methods he deems unreliable in positive studies." Opp. at 65. At his deposition, Dr. Goodman made clear that he employed the same rigorous criteria "regardless of whether it was a study where the author reported a positive effect or the author reported a negative effect." Goodman Dep. 230:17-22. For example, where negative studies utilized a non-physiological route of administration, like IP injection (akin to intravenous injection) or extreme doses potentially resulting in cytotoxicity (generalized cell toxicity precluding genotoxicity), Dr. Goodman did not simply accept those studies at face value. Instead, based on decades of scientific experience, he critically evaluated the data and determined that where no genotoxic effect is observed under "extraordinar[ily] … harsh testing conditions," then that effect is not going to occur under "physiologically relevant" conditions. Goodman Dep. 96:5-10, 238:8-17.

Plaintiffs further attempt to obfuscate Dr. Goodman's thorough methodology by implying that because he was unable to recall specific details or titles of some of the hundreds of materials he reviewed when questioned at his deposition, his testimony is unreliable. Opp. at 66 n.192. This weak attempt to preclude Dr. Goodman's testimony fails for the same reasons discussed in connection with their similarly baseless challenge to the admissibility of Dr. Foster's opinions. *See infra* at 47-49.

Moreover, the four references identified by plaintiffs as studies "conducted with neither

[83] *See* K. Dearfield et al., *Use of Genetic Toxicology Information for Risk Assessment*, 46 Envtl. Molecular Mutagenesis 236 (2005) (describing the tests identified by Dr. Goodman as the "most widely recommended" genetic toxicology battery and explaining that "[i]t is insufficient to determine that a chemical is positive in one of many genotoxicity assays and then assume that all adverse health outcomes will have a mutagenic [mode of action]."); *id.* at 240 (discussing the need to consider "maximum concentration level(s) for cytotoxicity"); M. Cimino, *Comparative Overview of Current International Strategies and Guidelines for Genetic Toxicology Testing for Regulatory Purposes*, 47 Envtl. Molecular Mutagenesis 362, 363 (2006) (genotoxicity test battery [emphasized by Dr. Goodman] developed to assess a "spectrum" of genetic damage); *id.* at 386 (explaining that positive responses in genotoxicity tests are "not sufficient to conclude that [a chemical] has a mutagenic [mode of action] for carcinogenicity").

GBFs nor glyphosate," are, as described in Opp. at 66 n.194, Ames tests on surfactants used in GBHs. Despite plaintiffs' willingness to implicate the "cocktail of other ingredients in the formulated product, such as surfactants," Opp. at 44, plaintiffs' experts failed to consider most of the genotoxicity testing conducted with surfactants, including those four Ames tests.

B. Plaintiffs Mischaracterize Dr. Goodman's Valid Criticisms of Paz-y-Mino 2007 and Bolognesi 2009, Studies Considered "Low Quality" By EPA.

With all their eggs in the "human *in vivo*" basket, plaintiffs devote almost three pages of their Opposition brief to addressing Dr. Goodman's criticisms of those studies. Opp. at 62-65. In doing so, and as discussed in more detail above, *supra* at 32-36, 46, plaintiffs again mischaracterize both Dr. Goodman's testimony and the serious weaknesses in the human *in vivo* studies – as acknowledged by the authors and regulators including EPA – that preclude reliance on those studies to conclude that glyphosate or GBHs are genotoxic.

III. DR. FOSTER'S OPINIONS ARE WELL-SUPPORTED AND HIS TESTIMONY SHOULD BE ADMITTED UNDER *DAUBERT*.

Dr. Foster is well-qualified to opine about glyphosate's lack of carcinogenicity. He is a toxicologist with three decades of experience conducting and evaluating rodent toxicology studies, including studies of cancer in rodents. The first decade of his career was spent at Health Canada – the Canadian equivalent of EPA – and while there he evaluated the carcinogenicity of various pesticides. Dep. of Warren Foster 70:4-71:2 (Sept. 15, 2017), ECF No. 656-17 ("Foster Dep."). Since leaving Health Canada, Dr. Foster has worked in academia, where he has continued his research into rodent toxicology, including endpoints such as chemical carcinogenesis. *Id*. 8:22-9:2, 22:7-14. He has published more than a dozen articles on chemical carcinogenesis in rodents, *id*. 118:18-122:15 (referring to articles on CV focused on cancer in rodent models).

Plaintiffs claim that Dr. Foster utilizes an "inconsistent and erroneous" methodology by alleging that he applies certain analytical factors in a manner designed to reach his desired outcome. Opp. at 67. This argument has no factual support and ignores both the clear language in Dr. Foster's report and his deposition testimony about his methodology. For example, in his report, Dr.

Foster clearly outlines the factors he finds important when examining the rodent toxicology data. Expert Report of Warren Foster at 6-7, ECF No. 649-7 ("Foster Report") (discussing importance of tumor progression, replication, dose, dose-response and other qualitative and quantitative factors to evaluation of rodent carcinogenicity data). As he explained, the relative importance of each factor may vary depending on the data, meaning that although each factor is always considered, not all factors are always of identical value in interpreting individual pieces of data.[84] It is Dr. Foster's refusal to elevate one factor over another rather than plaintiffs' experts' sole focus on statistics that is the reliable method for reviewing animal toxicology data.[85]

Plaintiffs attempted, but failed, to paint Dr. Foster's methodology as shifting. *See, e.g.*, Foster Dep. 195:19-196:20 (explaining that his methodology involves "evaluating the entire study" using all factors identified in his report); *id.* 65:5-6 ("Again, I think you have to look at the study in its totality"); *id.* 181:14-17 ("[T]he way you're phrasing your question is - - is difficult for me, because it sounds like I do something at the exclusion of something else; that I just ignore it, and I - - I don't."); *id.* 218:23-24 ("I don't rely upon [one factor] to the exclusion of other factors. It's something that I look at.").[86] Dr. Foster's methodology is consistent both across studies and with

[84] Foster Report at 12 (discussing evaluation of various factors in addition to statistical significance in interpreting rodent carcinogenicity data); Foster Dep. 82:9-83:2, 181:11-24 (explaining that he evaluates all of the data when interpreting a study but that certain issues within a given data set may be given greater value once the data is analyzed).

[85] Foster Report at 7-11; *see also* Jameson Report at 19 (discussing evaluation of similar factors as part of the "assessment of the experimental animal data"); J. Huff & C. Jameson et al., *Carcinogenesis Studies: Results of 398 Experiments on 104 Chemicals from the U.S. National Toxicology Program*, 534 Ann. N.Y. Acad. Sci. 1, 7 ("[s]cientific judgment [] must entail full consideration of all the available relevant information together with the statistical findings in an attempt to assess the truth"); Tarazona 2017 at 3, 4 (discussing variety of factors to be considered in analyzing rodent carcinogenicity data and noting Dr. Portier's analysis of the glyphosate data does not do so).

[86] Plaintiffs claim that Dr. Foster incorrectly compared the high dose group in one study (Lankas) with the low dose groups in two others (Atkinson and Suresh). Opp. at 67-68. However, Dr. Foster evaluated each study independently and found no evidence of carcinogenicity in any study. Foster Report at 14-25. And, unlike Dr. Portier's novel and speculative pooling "methodology," Dr. Foster only compared the studies *in response to plaintiffs' request* that he identify a study that used a dose within 500 ppm of the doses used in Lankas. Foster Dep. at 203:14-204:18. Plaintiffs attempt to insinuate that Dr. Foster does not understand which dose groups can be compared between studies, but as Dr. Foster explained, his ultimate opinion was in fact based on comparing the doses found in Lankas to "similar doses through to much higher doses." *Id.* 204:10. Plaintiffs other objections to Dr. Foster's testimony (opinions regarding tumor progression and loss of body weight) are similarly without merit as Dr. Foster's methodology is based upon established

accepted scientific methods.

Finally, plaintiffs claim Dr. Foster's testimony is unreliable because he could not recall the specific page – out of the thousands he reviewed in forming his opinions – that referenced weight loss in certain rodents in one of the rodent bioassays. An expert's "memory failures at his *deposition* … [do not] mean that the analysis in his *report* was flawed." *Network Prot. Scis., LLC v. Fortinet, Inc.*, No. C 12-01106, 2013 WL 5402089, at *5 (N.D. Cal. Sept. 26, 2013) (emphasis in original).[87]

IV. PLAINTIFFS' EFFORTS TO EXCLUDE DR. CORCORAN'S TESTIMONY LACK ANY FACTUAL BASIS AND MUST BE DENIED.

Plaintiffs' challenge to Dr. Corcoran's expertise, Opp. at 56 n.165, is without basis. Dr. Corcoran is a widely respected biostatistician – over the course of his career he has received millions of dollars largely from government agencies to conduct research on health and statistics issues. Expert Report of Chris Corcoran at 2, ECF No. 655-12 ("Corcoran Report"); Dep. of Chris Corcoran 104:22-105:4 (Sept. 20, 2017), ECF No. 656-20. He has over 20 years of experience applying biostatistics principles to the study and evaluation of categorical data, including rodent carcinogenicity data, and has published on the appropriate design of the statistical analysis of rodent carcinogenicity studies.[88] Given his decades of work performing analyses similar to the one

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scientific factors. *See, e.g.*, Tarazona 2017 at 4 (noting "reduced body weight").

[87] *Brown v. China Integrated Energy, Inc.*, CV 11-02559, 2015 WL 12720322, at *5 (C.D. Cal. Feb. 17, 2015) (rejecting argument to exclude defendants' expert due to failure to recall at deposition certain specific details of cited material); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *15 (S.D.W. Va. Feb. 7, 2015) (declining to exclude expert's opinions "on the grounds that he was unable to recall the literature during his deposition"); *In re Chantix (Varenicline) Prod. Liab. Litig.*, No. 2:09-CV-2039, 2012 WL 12920549, at *2 (N.D. Ala. Dec. 3, 2012) (expert's inability to "remember details from the records he reviewed" is not a proper matter for the court's consideration at *Daubert* stage); *Quad/Graphics, Inc. v. One2One Commc'ns, LLC*, No. 09-CV-99, 2011 WL 4478440, at *8 (E.D. Wis. Sept. 23, 2011) ("no reason to exclude [expert's] testimony" for lack of reliability where, at deposition, he could not recall specific numbers or closing rates).

[88] *See* Corcoran Report Curriculum Vitae at 1-2; D. Collett, Modelling Binary Data 1-2 (1st ed. 1991) (describing rodent carcinogenicity data as a good example of categorical data); C. Corcoran et al., *Power Comparisons for Tests of Trend in Dose-Response Studies*, 19 Statistics in Med. 3037 (2000); C. Corcoran et al., *Exact Methods for Categorical Data Analysis*, in *Encyclopedic Companion to Medical Statistics* (2010).

he conducts here, his testimony should be admitted.

V. PLAINTIFFS' MOTION TO EXCLUDE DRS. MUCCI AND RIDER'S RELIANCE ON RECENT EPIDEMIOLOGICAL DATA MUST BE DENIED.

Plaintiffs argue that Drs. Mucci and Rider inappropriately rely on the unpublished Alavanja 2013 paper. Opp. at 34-38. However, plaintiffs' experts acknowledge that unpublished data should be incorporated into epidemiology reviews and have relied upon it in formulating their opinions. *Supra* at 19-22. Contrary to plaintiffs' argument, it is their experts' methodology of willfully closing their eyes to this important epidemiologic data that is unreliable.[89]

CONCLUSION

For all of these reasons, Monsanto's motion to exclude plaintiffs' expert testimony under *Daubert* must be granted and summary judgment in Monsanto's favor entered. Plaintiffs' motions to exclude certain Monsanto experts are baseless and should be denied.

DATED: November 10, 2017

Respectfully submitted,

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[89] *See also Salomon v. Andrea C.*, No. 06CV484, 2008 WL 686795 at *3-4 (S.D. Cal. Mar. 11, 2008) (admitting expert testimony based on unpublished data); *Gaddy v. Blitz U.S.A., Inc.*, No. 2:09-cv-52, 2011 WL 13193319, at *9 (E.D. Tex. Jan. 18, 2011) ("Plaintiffs' arguments [regarding expert's reliance on] non-peer-reviewed articles go more to weight than admissibility."); *Obesity Res. Inst., LLC v. Fiber Res. Int'l, LLC*, No. 15-cv-595, 2017 WL 1166307, at *3 (S.D. Cal. Mar. 29, 2017) (alleged flaws in data relied upon by expert go to weight afforded to opinion and not to admissibility of opinions).

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC
This document relates to: ALL ACTIONS	

DECLARATION OF JOE G. HOLLINGSWORTH IN SUPPORT OF MONSANTO COMPANY'S REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS *DAUBERT* AND SUMMARY JUDGMENT MOTION BASED ON FAILURE OF GENERAL CAUSATION PROOF AND OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO STRIKE CERTAIN OPINIONS OF MONSANTO COMPANY'S EXPERT WITNESSES

I, Joe G. Hollingsworth, hereby declare as follows:

1. I am an attorney at law and am a member of the law firm of Hollingsworth LLP, counsel for defendant Monsanto Company ("Monsanto"). I make this declaration in support of Monsanto Company's Reply Memorandum of Points and Authorities in Support of Its *Daubert* and Summary Judgment Motion Based on Failure of General Causation Proof and Opposition to Plaintiff's *Daubert* Motion to Strike Certain Opinions of Monsanto Company's Expert Witnesses. I make this declaration based on my personal knowledge and, if called as a witness, I

would and could testify competently to these matters.

2. Annexed hereto as Exhibit 1 is a true and correct copy of an excerpt of the Transcript of Official Proceedings, MDL No. 2741 (N.D. Cal. Feb. 27, 2017), ECF No. 184.

3. Annexed hereto as Exhibit 2 is a true and correct copy of an excerpt of the Deposition of John Acquavella, Vol. II (Apr. 8, 2017).

4. Annexed hereto as Exhibit 3 is a true and correct copy of an excerpt of the Deposition of David Saltmiras (Jan. 31, 2017).

5. Annexed hereto as Exhibit 4 is a true and correct copy of the Errata Sheet to the Deposition of Alfred Neugut (served Nov. 5, 2017).

6. Annexed hereto as Exhibit 5 is a true and correct copy of the Order Granting New Trial and Granting Motion for Judgment Notwithstanding the Verdict, *Lloyd v. Johnson & Johnson*, Case No. BC628228, Slip op. (Cal. Super. Ct., LA Cnty Oct. 20, 2017).

I hereby declare under penalty of perjury that the facts set forth herein are true and correct.

Executed this 10th day of November 2017.

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Exhibit 1

Pages 1 - 64

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Vince Chhabria, Judge

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION,) NO. C 16-2741 VC

San Francisco, California
Monday, February 27, 2017

TRANSCRIPT OF PROCEEDINGS

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causation standard, that that statement is not made in isolation with respect to general causation.

And I wonder -- you know, obviously we don't need to sort of reach a final meeting of the minds, or we don't have to have a final agreement to disagree on this question right now, but I don't understand -- I mean, if the question, at the general causation phase, is is this substance capable of causing cancer, then how is that different from the question that IARC is asking?

MR. LASKER: Okay, Your Honor. We actually -- I went back and looked at the Roberts opinion after our conversation to make sure we were understanding what your question was. And I actually also pulled out a case from the Northern District of California that addresses this exact issue, which is the question of how does dose apply in connection with general causation? Because dose -- and actually the exposure level -- and Your Honor actually hit upon a very key point here -- it sort of straddles specific -- it has different meanings with respect to general and specific causation. And in the *In Re Bextra* opinion, and that is 524 F.Supp.2d, 11 --

THE COURT: In Re what?

MR. LASKER: In re Bextra -- I'm sorry -- B-E-X-T-R-A. And that is a case that was cited by this Court in 2007, and that's at 524 F.Supp.2d 1166. And the question that the Court was posed with is -- actually was MDL, and there were general

causation *Daubert* briefs before the Court. And one of the issues that was posed that the Court addressed -- and this is at page 1174: A threshold question raised by Pfizer's motion is whether a particular dose of Celebrex is relevant to the general causation inquiry.

So I think it's very similar to what Your Honor was probing on Friday.

And when the Court explained, what the Court held was, yes, dose does matter to general causation, because the question in general causation is can a substance cause a disease at a real world dose or at a dose that we are concerned about. And what the Court held -- and this is something that was in Judge Roberts' opinion, it's the *In Re Bextra* opinion, and, frankly, it's in cases in every circuit. And I've actually looked at this issue. Every circuit has the same standard, which is that when you're talking about general causation and specific causation, and you're thinking about dose, the general causation question is, is the level of exposure that is at issue generally in this case, is that capable of causing an adverse event? It's not is a chemical capable of causing whatever the disease is, it is, is an exposure capable of causing a disease.

THE COURT: Well, that's kind of what I was asking on Friday. You all said no.

MR. LASKER: That's why we're back, because I looked

Exhibit 2

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	)	MDL No. 2741
THIS DOCUMENT RELATES TO ALL CASES	)	Case No. 16-md-02741-VC

SATURDAY, APRIL 8, 2017

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- - -

Videotaped deposition of John Acquavella, Ph.D., Volume II, held at the offices of HUSCH BLACKWELL, L.L.C., 190 Carondelet Plaza, Suite 600, St. Louis, Missouri, commencing at 9:11 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri & Kansas Certified Court Reporter.

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- - -

Q. Did that one valid -- one invalid urine sample on glyphosate affect the study outcome or evaluation?

MR. MILLER: Objection. Leading.

THE WITNESS: No. In fact, if you look at my publication with colleagues from 2004, I can just show you very easily that it had --

QUESTIONS BY MR. COPLE:

Q. You have the 2004.

A. Oh, I have the 2004.

Q. Yes.

A. Okay. So I will -- that's cancer incidence. That's De Roos.

Q. Which exhibit are you on, Doctor?

A. I'm on 10-35.

So if you look at Table 3, as I mentioned, there was one invalid sample for glyphosate that couldn't be included in our analysis. You can see that it was a sample from the day before the glyphosate application. It was a preapplication sample.

There we have 47 out of 48

applicators contributing a valid urine sample. But for the day of application, the day after the application, and for the following two days after the application, we have valid samples for every applicator.

And the preapplication samples actually don't figure into the calculations for glyphosate body burden. And in fact, if you look in that table, because virtually all of the preapplication samples, 85 percent of them, that were valid were less than the limited detection, we didn't even calculate an average value for those samples.

So there's no analysis that we present in this 2004 paper that's influenced by the person who participated in the study submitting an invalid sample.

Q. Let me turn now to what was marked as Exhibit 10-13 by counsel for your deposition yesterday.

A. I don't have that yet.

Q. No, I'm going to hand it to you, Doctor.

A. Okay.

Q. I'm handing it to you now.

Exhibit 3

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	)	MDL No. 2741
THIS DOCUMENT RELATES TO ALL CASES	)	Case No. 16-md-02741-VC

TUESDAY, JANUARY 31, 2017

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

- - -

Videotaped deposition of David A. Saltmiras, Ph.D., held at the offices of HUSCH BLACKWELL, L.L.C., 190 Carondelet Plaza, Suite 600, St. Louis, Missouri, commencing at 9:03 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri & Kansas Certified Court Reporter.

- - -

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- - -

looking at exposure through food or other exposure?

A. My understanding is the Joint Meeting on Pesticide Residues looks at residues of the material that they're evaluating in food.

Q. Okay. And you understand that none of my clients nor any filed case in this litigation is suing Monsanto claiming that they got non-Hodgkin's lymphoma from eating food?

MR. COPLE: Object to the form of the question. Lacks foundation.

THE WITNESS: No, I'm unaware of that.

QUESTIONS BY MR. LITZENBURG:

Q. Okay. I'll just -- for background purposes today, sir, I am here on behalf of a lot of plaintiffs who have contracted the disease after applying glyphosate or -- Roundup, rather, glyphosate-containing products.

This JMPR, are you aware of them having done any assessment on exposure for applicators?

Exhibit 4

STATE OF NEW YORK) Pg. of Pgs.

COUNTY OF NEW YORK)

I wish to make the following changes for the following reasons:

PAGE	LINE		
159	6	CHANGE:	All "Except for DeRoos (2003)"
		REASON:	misspoke
234	15	CHANGE:	Replace answer with "that's incorrect"
		REASON:	misspoke
		CHANGE:	
		REASON:	
		CHANGE:	
		REASON:	
		CHANGE:	
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		REASON:	
		CHANGE:	
		REASON:	
		CHANGE:	
		REASON:	

ALFRED NEUGUT, M.D.,

Exhibit 5

SUPERIOR COURT OF CALIFORNIA

COUNTY OF LOS ANGELES

Coordinated Proceeding Special Title (Rule 3.550) Johnson & Johnson Talcum Powder Cases	Case No. BC628228 JCCP No. 4872 ORDERS REGARDING DEFENDANTS JOHNSON & JOHNSON CONSUMER, INC. AND JOHNSON & JOHNSON'S COMBINED MOTION FOR NEW TRIAL, DEFENDANT JOHNSON & JOHNSON CONSUMER, INC.'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT, AND DEFENDANT JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT Hearing Date: October 12, 2017 Time: 10:00 a.m. Dept.: 307
Charmaine Lloyd, et al. v. Johnson & Johnson, et al., BC628228 Plaintiff Eva Echeverria	

I. BACKGROUND

A. Brief Overview of the Case

This case involves the first trial of claims by plaintiffs in coordinated proceedings contending they developed ovarian cancer as a result of their use of defendants' products (Johnson's Baby Powder and Shower to Shower)[1] in their perineal area. The products contain talc.

Plaintiff Eva Echeverria[2] ("Echeverria") testified that she began using Johnson's Baby Powder when she began menstruation in approximately 1965 at age 11 and used the product on a daily basis, and more frequently when menstruating, until 2016. She used Shower to Shower less frequently. She was diagnosed with high grade serous ovarian cancer in 2007. The action was filed July 26, 2016. An expedited trial was ordered given her medical situation and commenced July 21, 2017.

Prior to trial summary judgment was granted as to defendant Imerys Talc America, Inc. ("Imerys"), who supplied the raw talc for the products. The case went to trial against defendants Johnson & Johnson and JJCI. It was tried on a theory of negligent failure to warn.

The evidence showed that Johnson's Baby Powder was first sold in 1893. The evidence focused largely on epidemiological studies that show a statistical correlation between talc usage

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[1] The evidence at trial was that Johnson & Johnson manufactured talcum powder until 1967. Thereafter, the product, as well as Shower to Shower, was manufactured by Johnson & Johnson Consumer Inc. ("JJCI"). For purposes of this Order the defendants are referred to jointly except when separate reference is needed.

[2] Eva Echeverria died September 20, 2017. Her daughter, Elisha Echeverria, Acting Trustee of The 2017 Eva Elaine Echeverria Living Trust, was substituted as plaintiff on October 12, 2017. For ease of reading reference to "plaintiff" is to Eva Echeverria. No disrespect is intended.

and ovarian cancer. The first study mentioning talc and cancer apparently was published in 1971 (Henderson, et. al.) but the study was not admitted into evidence. The only reference to it in the record is a citation to it in another study (Boorman 1994) (Ex. L-97) wherein Boorman reported that there was "some concern reported about the perineal exposure to talc and the occurrence of ovarian cancer in women...although other studies have failed to find such an association" and cited to Henderson. (Tr. 1271:25-1272:14.) The reports in evidence were to the effect that since at least 1982 there has been an ongoing debate in the scientific community as to whether talc usage may cause ovarian cancer or whether the science supported only a finding that there was a statistical association between talc use and cancer. The jury was called upon to resolve this complex scientific question.

B. A Brief Summary of the Law, the Evidence, and the Verdict

In an action alleging that a product causes cancer, giving rise to a duty to warn, causation must be proven with a reasonable medical probability based upon competent expert testimony. Mere possibility alone is insufficient to establish a prima facie case.

> 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 a result of its action. This is the outer limit of inference upon which an issue may be submitted to the jury. (See *Parker* v. *Employers Mutual Liability Ins. Co. of Wis.* (Tex. 1969) 440 S.W.2d 43, 47.)...With cancer the question of causation is especially troublesome....Under the present state of scientific knowledge...it is frequently difficult to determine the nature and cause of a particular cancerous growth....Although juries are normally permitted to decide issues of causation without guidance from experts, 'the unknown and mysterious etiology of cancer' is beyond the experience of laymen and can only be explained through expert testimony. (*Parker* v. *Employers Mutual Liability Ins. Co. of Wis., supra*, at p.

> 46.) Such testimony, however, can enable a plaintiff's action to go to the jury only if it establishes a reasonably probable causal connection between an act and a present injury.
>
> *Jones v. Ortho Pharm. Corp.* (1985) 163 Cal. App. 3d 396, 403-404.

As discussed in further detail below, Echeverria's expert witnesses testified as to various epidemiological studies, as well as studies on animals, and opined as to general causation. Laura Plunkett, Ph.D. ("Plunkett") testified that in her opinion perineal use of talc can cause ovarian cancer. She characterized talc as a toxin that causes changes in cell formation that become cancerous over time and extended use, relying on studies that showed talc initiates an inflammatory response in cells, leading to the production of reactive oxygen species and changes in gene expression. (Tr. 1048:22-1051:23; 1009:3-1009:6; 1622:9-27; 1623-1624:25.)

John Godleski, M.D. ("Godleski"), testified that evaluation by electron microscopy showed talc was present in Echeverria's ovarian tissue.

Evidence was introduced that since at least 1982 (and possibly 1971 if the 1994 Boorman statements regarding Henderson's work are considered) several epidemiological studies showed a statistically valid correlation between talc exposure and ovarian cancer. Jack Siemiatycki, Ph.D. ("Siemiatycki") testified that in 2006 the International Agency for Research on Cancer ("IARC"), a division of the World Health Organization, categorized talc as "possibly" carcinogenic if used perineally. This term was defined to mean that "chance, bias, and confounding" could not be excluded as explaining the epidemiological results. IARC declined to find talc was a known or probable cause of ovarian cancer. (Ex. P-29; Tr. 1196: 7-23; 1198:8-1200:2; 2162:18-2163:10; 2282:5-2283:28; 2285:23-26; 2291: 15-23.) Siemiatycki, who chaired the IARC working group that classified talc as "possibly" carcinogenic, testified that in his view the present epidemiology results, including a pooled study (Terry 2013) sufficiently show a probable association between ovarian cancer and perineal talc use as that term is used by IARC (TR 2173:11-2176:19; 2401:22-28; 2412:20-2413:17) but conceded that the epidemiology was

insufficient prior to 2007 to conclude that there was a causal association between perineal use of talc and ovarian cancer. (Tr. 2300:15-19; 2362:11-22.) Siemiatycki authored a paper to the same effect, published in 2008. (Ex. P-105; Tr. 2300:9-14.)

Numerous epidemiologic studies were put to the jury showing a range of "relative risk" ratios. Siemiatycki explained that "relative risk" is the ratio of the risk among persons exposed to the risk compared to the risk among the unexposed, explaining that "if the risk of cancer in the general population… is 4 percent in the general population but among a group of people with a certain environmental exposure it is 6 percent, the relative risk of cancer due to that environmental exposure would be 6 percent divided by 4 percent equals 1.5." (Tr. 2126:17-2127:21.) He further explained that a ratio resulting in 2.0 is "the point at which the probability of causation, which is the probability that a given agent causes a specific disease, exceeds 50 percent …." (Tr. 2434: 15-27.)

Annie Yessaian M.D. ("Yessaian"), Echeverria's treating physician, engaged in a "differential etiology" analysis and opined that that it was more probable than not defendants' products caused Echeverria's illness.

Echeverria emphasized at trial that condom manufacturers ceased using talc on their products in the 1990s. However, no admissible evidence was introduced suggesting that they did so because of information suggesting that talc was linked to ovarian cancer and the jury was instructed to disregard any such inference or suggestion.

Echeverria also introduced documents from defendants' files referencing a "talc/ovary problem" and documents that showed they engaged in efforts to persuade regulators and the scientific community, including the National Toxicology Program ("NTP") and IARC, that the studies were insufficient to conclude that talc was a probable cause of ovarian cancer, including evidence that Johnson & Johnson provided funding to a trade association known as the

Cosmetics, Toiletry, and Fragrance Trade Association ("CFTA") and that it also took steps on its own to advance the debate in its favor.

Defendants introduced evidence there was no peer reviewed literature suggesting any causal mechanism (i.e. that extended use of talc caused inflammation leading to cancer). No published peer-reviewed articles have determined talc to cause ovarian cancer. (Tr. 2276:21-2277:19; 2280:2-10; 3695:19-3696:7; 3749:12-3750:1.) Further, defendants' experts testified to the effect that the epidemiology relied upon by Echeverria's experts, with four exceptions, discussed *infra,* showed a relative risk ratio of less than 2.0.

Defendants also showed that talc is not recognized as an ovarian cancer risk by the Centers for Disease Control or medical associations such as the American Congress of Obstetrics and Gynecologists or Society of Gynecological Oncology. (Tr. 2714:2-2721:9; 3580:9-3590:5.) The federal Food and Drug Administration has been requested to require manufacturers of talc powders to warn of a potential link to ovarian cancer but declined to do so. The most recent Physician Data Query published by the National Cancer Institute concluded that "[t]he weight of the evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer." (Tr. 1619:6-1620:8.) Although some manufacturers have recently placed a warning on their product and Imerys advised of IARC's 2006 findings on its Material Safety Data Sheet ("MSDS"), the evidence showed most manufacturers' products do not contain a warning today. There was no evidence of any warning by a manufacturer prior to 2007.

Defendants moved for nonsuit and a directed verdict, which were denied.

The jury was instructed based on CACI 1222, 430 and 431, with additional special instructions. Those instructions required Echeverria to show that each defendant manufactured and sold Johnson's Baby Power and Shower to Shower to Echeverria and that prior to 2007 the products were dangerous or likely to be dangerous when used in a reasonably foreseeable manner, giving rise to an obligation to warn. The jury was also given Special Instruction No. 1

that required Echeverria to show that exposure to talc was a substantial factor in causing her illness by showing through expert testimony that there was a reasonable medical probability that talc causes ovarian cancer and a reasonable medical probability that it was a substantial factor in causing Echeverria's ovarian cancer. The jury was instructed under CACI 103 that liability as to both actual and punitive damages was required to be shown as to each defendant separately. The jury was also instructed under CACI 3945 as to the burden of proof on punitive damages. Echeverria requested instructions on agency and alter ego liability. Those instructions were not given.

After a three week trial, including extensive expert testimony, the jury found in favor of Echeverria, awarding $68,000,000 in non-economic damages from Johnson & Johnson and $2,000,000 in non-economic damages from JCCI. It assessed $340,000,000 in punitive damages against Johnson & Johnson and $ 7,000,000 against JCCI.

Defendants move for new trial or for judgment notwithstanding the verdict ("JNOV").

C. Summary of Rulings and Orders

Mindful of the heavy burdens imposed on the moving parties, and the deference to be given to the jury's verdict, for the reasons that follow the Court concludes that defendants' trial motions should have been granted and now grants the defendants' motions for JNOV. It also grants defendants a new trial on the grounds of (1) insufficiency of the evidence as to causation as to both defendants (Cal. Code of Civ. Pro. 657(6)); (2) error in law occurring at trial and excepted to by defendants (Cal. Code of Civ. Pro. 657(7); (3) misconduct of the jury (Cal. Code

of Civ. Pro. 657(2)); and (4) excessive compensatory damages as to Johnson & Johnson and excessive punitive damages as to both defendants (Cal. Code of Civ. Pro. 657(5)).[3]

II. JOHNSON & JOHNSON'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

A. Procedural Requirements and Legal Standard for JNOV Motions

A JNOV motion must be made within the time for filing and serving a notice of intention to move for new trial, and if a motion for new trial has been made the court is to rule on both motions at the same time. Cal. Code of Civ. Pro. §629(b). Notice of this motion was timely filed and the motion was argued concurrently with the new trial motion.

"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. Code of Civ. Pro. §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.* (1990) 225 Cal.App.3d 310, 327-328.) A motion for JNOV is akin to a demurrer to the evidence. Where a demurrer assumes all facts pleaded are true, a JNOV motion assumes all evidence supporting the verdict is true; the issue to be determined is whether such evidence constitutes a prima facie case. (*Moore v. San Francisco* (1970) 5 Cal.App.3d 728, 733.)

While evidence must be accepted as true and viewed in a light most favorable to the verdict, it must be substantial. (*Sweatman v. Dept. of Veterans Affairs* (2001) 25 Cal.4th 62, 68; *Osborn v. Irwin Memorial Blood Bank* (1992) 5 Cal.App.4th 234.) "'Substantial evidence' is not synonymous with 'any' evidence. To constitute sufficient substantiality to support the verdict,

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[3] The Court is also mindful that this case was prepared and tried in an expedited manner. Trial counsel, as well as JCCP liaison counsel, were required to do an extraordinary amount of work on behalf of their clients in a short period of time and are to be commended in this regard.

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.'" (Id. at 284, citing *Kruse v. Bank of America* (1988) 202 Cal.App.3d 38, 51.)

B. The Parties' Arguments

Johnson & Johnson argues that JNOV must be granted as there was no evidence that it manufactured Johnson's Baby Powder or Shower to Shower. Further, it argues that if the evidence could be inferred to show that prior to 1967 it manufactured Johnson's Baby Powder there is no evidence to show it knew or should have known in the period 1965-1967 that talcum powder was linked in any way with ovarian cancer, as the first scientific work in this regard was published in 1982. It argues that as a matter of law it had no on-going duty to warn and further argues that it cannot be liable for the acts of its subsidiary absent a showing of agency or alter ego liability and that no such evidence was adduced.

Echeverria contends that witness Lorena Telofski ("Telofski"), designated as the "person most knowledgeable" by both defendants, as well as various experts and third parties, referred to "Johnson and Johnson" in their testimony without distinguishing between the two entities. She further contends that after 1967 Johnson & Johnson had knowledge that talc was the probable cause of ovarian cancer and thus had an on-going duty to warn consumers, notwithstanding that it did not manufacture the product because Johnson & Johnson "kept responsibility" over JCCI and directed it to manufacture the products, thereby justifying the imposition of liability against it.

C. The Evidence As To Johnson & Johnson

The uncontradicted evidence was that Echeverria used Johnson's Baby Powder beginning at age 11 (approximately 1965) and until 2016.

The evidence as to who manufactured the products at issue during that time period was limited and consisted of (1) an interrogatory asking the defendants "to state the first and last dates of sale of each product" it manufactured or sold that contained talc. The joint response stated that Johnson's Baby Powder "debuted" in 1893 and Shower to Shower debuted in the 1960s (Tr. 3111: 19-27); (2) an interrogatory stating JJCI is a wholly owned subsidiary of Johnson & Johnson existing since 1967 (Tr. 3111:2-3112:10); (3) testimony through Telofski that JJCI was responsible for the marketing and internal procedures and safety assessments of both products (Tr. 811:8-14; 812:27-813:23; 852:18-853:1; 861:27-862:10; 863: 18-22); and (4) demonstrative exhibits showing that the labeled packages show JJCI as the manufacturer of the products. (Ex. P-49; P-50) .

The only document in evidence dated prior to 1967 was a 1964 memorandum. (P-343). That document discussed the development of a potential consumer research test with respect to a powder made with a cornstarch product called "Dry Flo." The penultimate paragraph states that a Johnson & Johnson employee (William Ashton) established that "the largest commercial uses of Dry Flo are…as a condom lubricant where it replaced talc because it was found to be absorbed safely in the vagina whereas, of course, talc was not." No witness was called to explain the meaning of this sentence, which is capable of two interpretations (whether talc was absorbed in the vagina at all or whether, if absorbed, it was "safely" absorbed). Echeverria argues this document is sufficient to show both that Johnson & Johnson manufactured the products at issue prior to 1967 and had a duty to warn and that it acted with malice in not doing so, supporting the verdict against it.

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D. Analysis

(1) Duty to Warn

A duty to warn arises when a manufacturer fails to warn of facts that it knows or should know make a product likely to be dangerous. (*Trejo v. Johnson & Johnson* (2017) 13 Cal. App. 5th 110, 131, citing *Valentine v Baxter Healthcare Corp.* (1999) 68 Cal. App. 4th 1467, 1482.) As to Johnson & Johnson before a duty to warn could be imposed Echeverria was required to show that it manufactured the products at issue; that talc was the more likely than not cause of her ovarian cancer; and that Johnson & Johnson knew or should have known that talc probably would cause cancer. In this regard a manufacturer will not be "charged with knowing more than what would come to light from the prevailing scientific or medical knowledge" at the time. (*Valentine,* 68 Cal. App. 4th at 1483-1484. *See also Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal. 3d 987, 1002 ["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, i.e., what a reasonably prudent manufacturer would have known and warned about."]; *Carlin v. Superior Court* (1996) 13 Cal. 4th 1104, 1112, (citing *Anderson*) ["Stated another way, a reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles."])

Echeverria alleged that Johnson & Johnson designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and sold the products (Echeverria First Amended Complaint, ¶¶ 14, 18, 20, 21, 85, 94, 131), made specific advertising claims (Id. at ¶¶ 25, 26), have continuously advertised and marketed the products since the 1970s (Id. at ¶31), and failed to warn (¶¶ 89, 90).

After initially referring to both Johnson & Johnson and JJCI in the pleading, for the most part the two parties are jointly referred to as Johnson & Johnson. This is made clear in Paragraph 9 where, after introducing Defendant Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer, Inc.) as a wholly owned subsidiary of Johnson & Johnson, Echeverria indicates that the two companies will thereafter be referred to jointly as the "Johnson & Johnson Defendants." Echeverria did not allege any theory for holding the parent liable for the acts of the subsidiary (such as alter ego or agency), but instead alleges the same wrongful acts as to both. However, Echeverria did not establish this at trial.

Echeverria failed to put on direct evidence as to who manufactured the products in the period 1965-1967. The interrogatory response read into the record is ambiguous but taken together with Exhibit P-343 and the testimony of Telofski the jury could infer that Johnson & Johnson manufactured the product prior to 1967.

The sole evidence argued to impose a duty to warn on Johnson & Johnson that existed prior to 1967 is Exhibit P-343, authored in 1964. Interpreting the disputed sentence in the light most favorable to Echeverria, the document states only that talc was not "safely absorbed" in the vagina but does not discuss in any way the alleged consequences of that fact, i.e. that it was a probable cause of ovarian cancer. There was no showing that as of 1967 there was any suggestion by the scientific or medical community that talc was associated with ovarian cancer. And, no internal documents from the company prior to that date suggest that conclusion. Thus, one cannot infer from the document that Johnson & Johnson knew or should have known prior to 1967 that talc more probably than not caused ovarian cancer, such that any duty to warn of that fact arose at that time.

The further evidence at trial was that after 1967 JJCI manufactured the products at issue and was responsible for assessing their safety and determining whether warning labels should be put on them. At oral argument and in her briefing Echeverria conceded that the documents and

evidence showed that Johnson & Johnson ceased making Johnson's Baby Powder in 1967. However, she argues that because Johnson & Johnson called no witness to show that Johnson & Johnson's "involvement" with talc products ended in 1967 the jury could infer that Johnson & Johnson was liable for failure to warn. (Echeverria's Opposition to Johnson & Johnson's motion for JNOV at page 2, lines 24-25.)

This argument fails. Echeverria bore the burden of proof on this issue. She presented no evidence to contradict Telofski's testimony or the demonstrative exhibits. The law is well-established that a holding company ordinarily cannot be held liable for the acts of its wholly owned subsidiary absent a showing of agency or alter ego liability. (*Sonora Diamond Co. v. Superior Court* (2000) 83 Cal.App.4th 523, 538-540.) "As a practical matter, the parent must be shown to have moved beyond the establishment of general policy and direction for the subsidiary and in effect taken over performance of the subsidiary's *day-to-day* operations in carrying out that policy." (Id. at 542, emphasis in original.)

While evidence was introduced that JCCI is a wholly owned subsidiary of Johnson & Johnson, no evidence was adduced as to why JCCI was created; that JCCI was created to make the products on behalf of Johnson & Johnson; who JCI's officers and directors are or whether they overlap with Johnson & Johnson's; that JCCI is undercapitalized; that Johnson & Johnson controlled JCCI's day-to-day operations, nor any other evidence suggesting that an alter ego or agency theory could be put to the jury. Further, the jury was not instructed on these theories of liability as the evidence adduced was insufficient to support such instructions.

Echeverria argues that Telofski, who was designated as the person most knowledgeable for both Johnson & Johnson and JJCI (Tr. 800:11-18), distinguished between the two companies on only three occasions in her testimony. (Id. at Tr. 801:23-802:4; 804:7-19; 813:10-23.) She argues that for the vast majority of her testimony, Telofski used the words, "Johnson & Johnson." Echeverria, however, does not indicate the subject matters on which Telofski was

designated to testify. Further, Echeverria's counsel was aware when Telofski' s deposition was taken that Telofski was an employee of JJCI and that there were two separate corporations. To the extent counsel asked questions regarding Johnson & Johnson, Telofski properly answered them on behalf of that entity.

Finally, Echeverria notes the experts all referred to "Johnson & Johnson." That experts or third parties referred to "Johnson & Johnson" does not save the verdict. None were asked to opine that Johnson & Johnson (as opposed to JCCI) manufactured or distributed the products after 1967 and indeed it was not shown that any would have had such knowledge.

Apparently recognizing that the oral testimony does not support a finding that Johnson & Johnson manufactured or distributed the products after 1967 Echeverria orally argued that Johnson & Johnson "hired someone" (JCCI) to make the products for it after 1967 but "kept responsibility" for them, thereby imposing on Johnson & Johnson responsibility for placing a warning on the products at all times. The documentary evidence and oral testimony that supports these factual assertions is not of a quality sufficient to sustain the verdict.

First, and as noted above, there was no evidence that Johnson & Johnson "hired" JCCI to make products for it. Further, the documents do not support an alter ego or agency theory of liability. The documents may be grouped into several categories: those written by Johnson & Johnson employees evidencing consideration of the marketing opportunities and obstacles for talc (Ex. P-9 and Ex. P-10); documents showing that Johnson & Johnson sought to assert its views in the scientific community as to what the scientific evidence showed vis-a-vis talc (Ex. P-16, P-20, P-59, P-204, P 261 through P-264, P2-66, P-267); those that Echeverria argues show that Johnson & Johnson declined to fund studies into research concerned with the possible link between talc and ovarian cancer or would fund only if favorable results would be guaranteed (Ex. P-55, P-262); and those that show that condom manufacturers and Imerys either ceased using talc in their products or warned about its potential harm (Ex. P-19, P-27, P-396). In

addition, Echeverria argues that a document written by a JCCI employee shows that after 1967 Johnson & Johnson should be liable for its' subsidiary's failure to warn (Ex. P-764).

Considered individually or as a whole, and drawing all inferences in support of the verdict, these documents could not be read by the jury as giving rise to a duty to warn on the part of Johnson & Johnson after 1967.

The document on which Echeverria primarily relies to show that Johnson & Johnson was "responsible" for JCCI is Exhibit P-764, dated January 11, 1994. This is a draft document (not on letterhead) entitled "Talc Questions and Answers" that posed various questions and answers regarding the state of knowledge regarding scientific research on the issue of the linkage between talc and cancer and responding to various studies to date. The evidence at trial was that this document was drafted by Don Jones who was in the research and planning group at JCCI. (Tr. 895:22-896:12; 902:4-19.) It made various references to Johnson & Johnson's decisions regarding its labeling of Johnson's Baby Powder, indicated "Johnson & Johnson uses the highest standards in making its baby powder," and stated "Johnson & Johnson had joined independent researchers and the government in testing talc and that no link with cancer was found."

No showing was made as to what use, if any, the draft document was put. There was no showing that Johnson & Johnson expressly or impliedly authorized these statements. Jones was not called to testify and did not indicate the facts on which he based the statements related to "Johnson & Johnson." In short, that a JCCI employee of unknown authority stated in a draft document that "Johnson & Johnson" made decisions regarding labeling of the product or used the highest standards in makings "its" baby powder or engaged in research is insufficient to show, as a matter of law, that Johnson & Johnson in fact manufactured and labeled the product or "kept responsibility" for JCCI after 1967. (*Young v. Horizon West, Inc.* (2013) 220 Cal.App.4th 1122, 1133; *van't Rood v. County of Santa Clara* (2003) 113 Cal. App. 4th 549, 571).

As to Johnson & Johnson's own acts, the assertions by Echeverria that Johnson & Johnson employees considered marketing obstacles for talc based products is insufficient to create an inference that Johnson & Johnson was liable for the acts of its subsidiary after 1967.

Exhibit P-9, a 1986 memo from Ashton's files referenced the fact that "safety of cosmetic powders has been a concern, especially among health professionals. They have decided that powders provide no health benefit. Therefore, the potential for harm from respirables or accidental exposure should be avoided. Mothers are now being advised not to use baby powder, especially talc baby powders." The document goes on to say that "retrospective studies have implicated talc use in the vaginal area with the incidence of ovarian cancer. While a CFTA sponsored animal study has shown talc does not migrate, this concern does affect use of powders for adult women.... Based on the scientific evidence and extensive experience and use we believe that cosmetic powders are safe for use in babies and adults." The document observes that Johnson & Johnson holds patents for segregation of "super talc" and a cornstarch products well as other patents and concludes that "J&J" is probably working at the limits of cosmetic powders technology and "must pursue technologies which will provide a proven health benefit for use of powders on babies." It also noted that it was possible to hypothesize that "pursuit of technologies which would create talc based powders of higher interest (than JBP) to adults could be profitable."

No evidence was adduced as to why this document was written or to whom (if anyone) it was sent. Fairly read it suggests that a scientist at Johnson & Johnson (Ashton) was suggesting that baby powder use was impacted by the health community and that Johnson & Johnson might in the future pursue technologies to increase the use of cosmetic powders. It could not be fairly inferred from this document that Johnson & Johnson controlled JCCI, or "kept responsibility" for it.

Likewise, Exhibit P-10, a memo dated August 5, 1992, from a Johnson & Johnson file but without testimony as to its author or recipients, indicated that an obstacle to marketing the product was "negative publicity from the heath community on talc (inhalation, dust, negative doctor endorsement, cancer linkage)" and recommended investigation of an additive to reduce dust. But, the document's vague reference to negative publicity from a "cancer linkage," without more, was insufficient for a jury to find Johnson & Johnson "kept responsibility" for JCCI.

Nor are documents referencing the funding of studies sufficient to impose liability on Johnson & Johnson. Exhibit P -55 was heavily relied upon by Echeverria. It is a 1975 memo on Johnson & Johnson letterhead documenting that an employee named Gavin Hildick-Smith sent a "small donation" to Keith Griffiths of the Tenovus Institute for Cancer Research in Cardiff, England and suggesting that "it might be of value to identify the precise scientific data available to Tenovus concerning talc and ovarian cells." A handwritten note attached by D. Petterson inquired as to whether Hildick-Smith advised in advance of this donation and opined that the donation "has certainly given Griffiths the opening to put us on notice of the talc/ovary problem." Other than adducing testimony that Hildick-Smith was a doctor and Johnson & Johnson employee (Tr. 883:19-28) no evidence was introduced as to the capacities of any of the employees receiving the memo, or the role of "D. Petterson" at Johnson & Johnson or the meaning of the term "talc/ovary problem." Nor was there any showing that Griffiths ever had or provided any research to Johnson & Johnson which might have actually put it on notice of a "talc/ovary problem," let alone that Johnson & Johnson controlled JCCI.

Nor does Exhibit P-262 support Echeverria's argument. This e-mail chain indicates Johnson & Johnson would financially support "the Huncharek/Muscat narrative on ovarian cancer" but was not "Yet" prepared to support a "diaphragm/ovarian epidemiological study." That Johnson & Johnson declined to fund research could not be inferred by the jury to support a finding that it controlled JCCI.

Exhibits P- 57 and P-27 are also insufficient to impose liability on Johnson & Johnson for acts taking place after 1967. Exhibit P-57 is an agreement by Johnson & Johnson dated June 4, 1994 guaranteeing funding of $10,000 to CFTA for the "management, coordination, and development of scientific data …pertaining to the safe use of talc," agreeing to indemnify CFTA with respect to same, and further acknowledging that any CFTA reports "will become public documents." While this document clearly indicates Johnson & Johnson sought to bring to the public's attention its views regarding the safety of talc it cannot be said, by inference or otherwise, that it demonstrated that Johnson & Johnson exercised day-to day control over JCCI sufficient to implicate the doctrines of alter ego or agency. Similarly, that either Johnson & Johnson or JCCI sought to bring their views forward either on their own or through CFTA, to IARC and others in the scientific community (Ex. P-16, P-20, P-59, P-204, P-238, P-261-264, P-266, P-267) and strategized about how to do so did not create evidence that Johnson & Johnson controlled JCCI to such an extent as to make it liable for JCCI's decisions.

Documents from third parties also could not be relied upon to meet Echeverria's burden of proof. Exhibit P-16 to JCCI from a consultant (Wehner) suggesting that Johnson & Johnson point out to the FDA the flaws in a proposed study and decline to fund same and Exhibit P-16 from Wehner to JCCI criticizing the manner in which CFTA analyzed certain data and noting that its inaccuracies subject the industry to being perceived as the cigarette industry also could not be used by the jury to infer that Johnson & Johnson was "responsible" for JCCI. As an initial matter, Wehner goes on to state that the public perception "would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position." More importantly, that a third party consultant advised JCCI as to what he believed its parent should do vis-à-vis the CFTA does and cannot establish that Johnson & Johnson is liable for warnings on products it did not make or distribute. (*Young v. Horizon West, Inc.* 220 Cal.App.4th at 1133; *van't Rood v. County of Santa Clara* 113 Cal. App. 4th at 571).

Similarly, Exhibit P-27, from Imery's Director of Product Safety, to Ashton, cautioning that IARC could classify talc as potentially carcinogenic and suggesting that Ashton counsel his management regarding same, as well as Exhibit P-396 between the same two persons, transmitting an April 2004 scientific paper which the Imery's employee characterized as "compelling" evidence of a theory as to how talc could cause ovarian cancer and cautioning that the NTP could classify talc as a "causative agent" based thereon cannot be the basis for liability against Johnson & Johnson. A third party (Imerys) cannot create a relationship showing that Johnson & Johnson had "responsibility" for JCCI, any more than the acts of a purported agent suffice to show a principal-agent relationship. (Id.)

Finally, the fact that Johnson & Johnson was aware that condom manufacturers discontinued the use of talc in its products in 1994 (Ex. P-19) or that Imerys put a warning on its MSDS (Ex. P-37) in 2006 does not establish that talc was known or should have been known to cause ovarian cancer prior to 2007 or that Johnson & Johnson was "responsible" for JCCI thereby. As to the condom issue, Echeverria introduced evidence that another of her experts (Plunkett), in her report, relied on a 1994 newspaper article that opined that condom manufacturers removed talc from their products "in part due to ovarian cancer concerns." No evidence was admitted, however, as to what those concerns were (i.e. whether the condom industry ceased to use talc because the available science supported a conclusion that talc was a *probable* cause of ovarian cancer or because the concerns surrounded publicity of the *possibility* of such a link) and the jury was specifically instructed that the facts set forth in the article were not admitted for their truth. As such, evidence as to what the condom industry did could not have properly been considered by the jury to establish knowledge on the part of Johnson & Johnson, much less determine it was "responsible" for JCCI's decisions regarding warnings.

Likewise, the decision by Imerys in 2006 to put a statement on its MSDS that restated IARC's 2006 conclusion that talc was a "possible" carcinogen could not be used to show that in 2007 Johnson & Johnson had a duty to warn, or that it was responsible for JCCI.

Following oral argument on these motions Echeverria argued for the first time (in supplemental papers filed October 13, 2017 and not authorized by the Court but nonetheless considered) that Johnson & Johnson had an on-going duty to warn consumers and to recall the products. The cases cited by Echeverria, however, stand for the proposition that a manufacturer of equipment *who continues to market the equipment* and determines it is likely to be dangerous has a duty to recall the product or retrofit it. (*Hernandez v Badger Constr. Equip Co.* (1994): 28 Cal. App. 4th 1791, 1827; *Lunghi v Clark Equip. Co. Inc.* (1984) 153 Cal. App. 3d 485, 494.) Echeverria cites no authority for the proposition that a manufacturer who has ceased to make the product must cause a warning to be placed on the product by another manufacturer or cause that manufacturer to recall the product. Moreover, Echeverria did not ask the jury to be instructed on this basis under CACI 1223 or otherwise and cannot assert it for the first time after oral argument on post-trial motions.

(2) Punitive Damages

As to punitive damages Echeverria was required to show by clear and convincing evidence that Johnson & Johnson acted with malice, i.e. "despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights and safety of others." Cal. Civ. Code § 3294 subd. (c)(1).

The term "'despicable,'" though not defined in the statute, is applicable to "circumstances that are 'base,' 'vile,' or 'contemptible.' " (*College Hospital Inc. v. Superior Court* (1994) 8 Cal.4th 704, 725 [34 Cal. Rptr. 2d 898, 882 P.2d 894],

quoting 4 Oxford English Dict. (2d ed. 1989) p. 529.) Under the statute, "malice does not require actual intent to harm. [Citation.] Conscious disregard for the safety of another may be sufficient where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences. [Citation.] Malice may be proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences. [Citation.]" (*Angie M. v. Superior Court* (1995) 37 Cal.App.4th 1217, 1228 [44 Cal. Rptr. 2d 197].)

Pfeifer v. John Crane, Inc. (2013) 220 Cal. App. 4th 1270, 1299.

Because Johnson & Johnson is a corporate defendant Echeverria was also required to show by clear and convincing evidence that a director or managing agent acted with malice. Cal. Civ. Code, § 3294, subd. (b). "A plaintiff may satisfy the 'managing agent' requirement of Civil Code section 3294, subdivision (b), through evidence showing the information in the possession of the corporation and the structure of management decisionmaking that permits an inference that the information in fact moved upward to a point where corporate policy was formulated. These inferences cannot be based merely on speculation, but they may be established by circumstantial evidence, in accordance with ordinary standards of proof." (*Romo v. Ford Motor Co.* (1999) 99 Cal. App. 4th 1115, 1141, disapproved on other grounds in *People v. Ault* (2004) 33 Cal. 4th 1250.)

The only employee of Johnson & Johnson referenced in the pre-1967 documents that Echeverria contends support punitive damages against Johnson & Johnson was William Ashton. There was no showing as to Ashton's capacity at Johnson & Johnson sufficient to support a punitive damage award. The testimony offered by Telofski was that Ashton was deceased, had retired some years earlier, and was in "research and development" at the time he left the company. Telofski testified she was "not sure if he was a manager or director level" when he

left the company. Telofski went on to say she "really just doesn't know." (Ex. 1 and 2 to Defendants' Compendium of Trial Transcripts.) No questions were asked as to Ashton's position in 1964.

Post 1967 the only Johnson & Johnson employees identified were Neal Matheson, who signed Exhibit P-57 in 1994 and was Executive Vice President of Research & Development and identified by Telofski as a "vice president in R &D" (Tr. 805:25-27) and Steve Mann, who "worked" at Johnson & Johnson (Tr. 805: 15-17) and whose title was shown as "Director, Toxicology." Mann communicated regarding funding the "Huncharek/Muscat study" (Exhibit P-262) and Matheson and Mann exchanged e-mail correspondence regarding the CFTA Task Force and steps Johnson & Johnson might take to bring its views to the attention of IARC and others in the scientific community and monitored IARC's conclusions (Exhibits P- 204, P-261 through P-264, P-266, P-267). Assuming that the jury could infer that these persons were managing agents of Johnson & Johnson there was no showing that either engaged in manifest disregard of safety or was reckless in not causing Johnson & Johnson to warn that talc was a "probable" cause of cancer. The best that can be said from the evidence is that they were aware IARC classified talc as "possibly" carcinogenic, a standard insufficient as a matter of law to require any warning, even had Johnson & Johnson been the manufacturer of the product.

In short, there was simply no evidence that Johnson & Johnson knew in the 1965-1967 time period that talc more likely than not caused ovarian cancer, giving rise to a duty to warn, much less that a managing agent acted with requisite malice in failing to give the warning. Nor is the verdict saved by reference to argument that documents existing after 1967 can create a basis for liability as to Johnson & Johnson based on JCCI's failure to warn. The documents and testimony, granting all inferences in favor of Echeverria, as a matter of law do not support liability on an agency or alter ego theory, much less support a finding by clear and convincing

evidence that a punitive damage award was appropriate. For these reasons alone the JNOV motion must be granted as to Johnson & Johnson.

Further, and as discussed below, Echeverria failed to meet her burden of proof to show that her use of Johnson's Baby Powder and Shower to Shower were the probable cause of her ovarian cancer. Thus, as to both Johnson & Johnson and JCCI the motion for JNOV must be granted.

III. JCCI'S MOTION FOR JUDGMENT NOTWITHSTANDING THE VERDICT

A. Summary of the Argument

Defendants advance three arguments as to why JNOV must be granted based on the argument that Echeverria failed to present evidence sufficient to show that her use of talc based products was the probable cause of her ovarian cancer. Specifically, they argue that Echeverria's specific causation expert, Yessaian, failed to present epidemiology showing talc was the more probable than not cause of her cancer and used an improper methodology for determining the cause of her cancer (differential etiology) given the lack of epidemiology. JCCI also argues that no substantial evidence was presented to show that it had a duty to warn prior to 2007 and that as a result JNOV on both the general and punitive damage awards must be granted.

Echeverria contends that the motion is not well taken, as she had no obligation to present epidemiologic evidence. She further argues that Yessaian properly engaged in a differential etiology. She argues further that other experts (Plunkett, Godleski, Siemiatycki) established general causation. Finally, she argues that internal documents pre-dating 2007, discussed supra, showed that genital use of talc was not safe and knew that others in the industry warned of its dangers, supporting the punitive damage award against JCCI.

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B. The *Sargon* Ruling and a Summary of Yessaian' s Testimony

In evaluating defendants' causation arguments, background concerning the general causation testimony that was offered is necessary, as is an understanding of the permitted scope of Yessaian's testimony.

Prior to trial defendants made a series of motions under *Sargon Enterprises, Inc. v. University of Southern Cal.* (2012) 55 Cal.4th 747 to exclude various expert testimony. Certain general causation experts were excluded and the testimony of others was limited. A written order issued, as did an oral clarification. (Tr. of July 18, 2017 at 5: 23-6:27.) Yessaian was permitted to opine that, using a "differential etiology methodology," it was "more probable than not" that Echeverria's cancer was caused by her use of talc based on Echeverria's medical history; the fact that talc was found in her ovarian tissue; 4 epidemiological studies involving women using talcum powder who were diagnosed with ovarian cancer which showed an "odds ratio" in excess of 2.0 thus permitting Yessaian to "rule in' talc as a causative agent; and other studies generally showed an odds ratio of 1.22 to 1.39. She was not permitted to testify that inflammation of cells was involved in Echeverria's cancer.

The testimony at trial by Yessaian on specific causation was to the effect that her methodology in determining the probable cause of Echeverria's cancer was to engage in a "differential diagnosis," or "differential etiology," (Tr. 2609:16-18.) She explained that this process involved identifying risks for a disease; ruling out risk factors that you don't believe apply; and ruling in what you believe is the cause of the cancer. (Tr. 2812:18-21.) She testified that she ruled out 13 other potential known risk factors for ovarian cancer that could be applicable to Echeverria (genetics; history of family members with cancer at an early age or breast or ovarian cancer; early onset of menarche; age, age at menopause; obesity; polycystic ovarian syndrome; endometriosis; tobacco and alcohol use; use of hormone replacement therapy) and considered "protective factors" (number of pregnancies and births; breast feeding; use of

birth control pills; tubal ligation) (Tr. 2647:9 - 2648:18). She testified she considered talc use a risk factor based on epidemiological studies as well as the number of applications of talc Echeverria had, which she estimated to exceed 30,000 and the number of years of talc usage prior to diagnosis (32) (Tr. 2612:15 - 2613:2) and also considered the "mechanism" by which it is theorized that talc migrates to the ovaries, the fact that talc was found in Echeverria's ovarian tissue, and the literature suggesting that talc exposure causes cancer by inflammation that ultimately leads to malignant transformation of cells (Tr. 2613:10 - 2614:11; 2618:3- 2618:25; Tr. 2611:11 - 2612:4; 2621:21-2630:6; 2675:8-2676:21).

As to the testimony that inflammation was considered the mechanism by which talc caused Echeverria's cancer, the opinion including that testimony was stricken as no inflammation was found in Echeverria's tissue. (Tr. 2645: 18-20.) Yessaian then testified more generally that she considered the mechanism by which talc is hypothesized to cause ovarian cancer is by way of inflammatory processes. (Tr. 2646: 1-9.)

In reaching her conclusion that talc was a risk factor to be considered Yessaian relied on four epidemiologic studies (Cramer 1982; Rosenblatt 1992; Cramer 1999; and Wu 2009) that showed odds ratios in excess of 2.0 that a woman using talc would develop ovarian cancer (i.e. that she had 50% or greater chance of developing cancer than women who did not use talc), as well as 26 case controlled studies, 5 cohort studies showing "odds ratios" of 1.2 or 1.3, which she opined showed that the women in those studies had a "trend of thirty percent increase in risk," and meta-analysis and pooled analysis (Tr. 2658:5-12; 2820: 6-28; 2818:1-15). Yessaian admitted at trial that she knows of no studies showing a risk ratio over 2.0 for serous invasive ovarian cancer, which is the type of cancer with which Echeverria was diagnosed (Tr. 2896:1-2897:16) and that one study on which she relied (Cramer 1999) showed an odds ratio of 1.70 for serous ovarian cancer (Tr. 2672: 6- 20) and a second (Wu 2009) also showed an odds ratio of 1.70 for serous ovarian cancer (Tr. 2672:21-2673:5). She interpreted those results as a 70%

increased risk (Tr. 2896: 12-13.) She further testified that other studies on which she relied that showed an odds ratio of less than 2.0 were useful because they showed an increased risk of cancer developing in talc users and testified that specific studies showed this. She testified a study by Gertig (2000) showed a 1.4 odds ratio and interpreted this as meaning the subjects had a 40% increase in risk for serous ovarian cancer in women using talc (Tr. 2668:12-2669:19) and that a study by Gates (2008) showed an odds ratio of 1.6, which she interpreted as meaning that women who used talc had a 60% increase in the risk of developing serous ovarian cancer compared to those who did not (Tr. 2669:20-27) and that a "pooled" study by Terry (2013) had an "odds ratio" of 1.20 for serous ovarian cancer, which she interpreted as translating to a 20% increase in risk (Tr. 2670:11-15). She further acknowledged that Wu (2009) showed that a person with genital use of talc with 15,600-52,000 applications showed an odds ratio of 1.34 and acknowledged that the number was statistically insignificant (Tr. 2910: 21-25).

Yessaian also testified that because Echeverria was obese the estrogen effects of an increased body mass index might serve in combination with other factors to increase her ovarian cancer risk (Tr. 2870: 24-26) but stated that obesity more probable than not did not contribute to her cancer because elevated BMI is not associated with high grade serous ovarian cancer. (Tr. 2866: 16-22.) She testified she "ruled out" age as a possible cause of cancer although "it could have gone either way." (Tr. 2870:19-21.) She admitted that Echeverria's risk of ovarian cancer was increased by her number of ovulations but stated it was "less likely than not." (Tr. 2881:15-22.) She acknowledged that cancer is "multifactorial" (Tr. 2875: 4-10) and admitted that when she "ruled" out risk factors she ruled them out because it was "less than 50 percent likely that they were the factor." (Tr. 2883: 18-19).

She further testified that although many cancers have no known cause, she did not "rule out" unknown causes and that it was not possible to do so. After admitting idiopathic causes are the leading cause of ovarian cancer and that it was probable Echeverria's cancer was caused by

some risk factor science does not yet know about (Tr. 2864:26-2688:27), Yessaian testified that there was less than a 50% chance Echeverria's cancer was idiopathic. (Tr. 2888:19-26; 2890:28-2891:1; 2894:13-18.) However, she could not put a "percentage" on how less likely that was. (Tr. 2894: 20-21.)

C. Analysis

Following trial if the Court is convinced that there is no substantial conflict in the evidence and that the tendered expert opinions do not show specific causation (which, under *Jones v Ortho. Phar. Corp.* (1996) 163 Cal. App. 3d 396, must be shown by expert testimony in a case alleging cancer) a JNOV is properly granted. *See Osborn v. Irwin Mem'l Blood Bank* (1992) 5 Cal. App. 4th 234, 275. After considering it in totality and weighing all inferences in favor of Echeverria, the Court is persuaded that Yessaian' s opinion is insufficient as a matter of law to support the verdict.

(1) Specific Causation Was Not Shown

(i) Yessaian Did Not Have a Basis to "Rule In" Talc

Yessaian was the only expert called on specific causation. She did not rely on the testimony of Plunkett or Siemiatycki in forming her opinions. Thus, while the jury could well have evaluated the credibility and reliability of her opinions by comparing them to information provided by Plunkett and Siemiatycki, her determination that talc was a cause of ovarian cancer and was the "more probable than not" cause of Echeverria's cancer is dependent only upon her testimony and that of Godleski. As to the latter, there was no dispute that he testified to locating talc in Echeverria's pathology tissue. Thus, the evidence is not in conflict.

In conducting a differential etiology[4] Yessaian was required first to establish talc is a probable cause of ovarian cancer. Without establishing that fact, she could not "rule in" talc as a probable cause of Echeverria's disease. As Yessaian explained, and as case law makes clear: "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.* (8th Cir. 2001) 252 F.3d 986, 989. *See also Cooper v. Takeda Pharmaceuticals America, Inc.* (2015), 239 Cal. App. 4th 555, 593-594.)

The only basis upon which Yessaian opined that talc is a scientifically plausible cause of ovarian cancer was epidemiology and general reference to inflammation. But, none of the four studies on which she was permitted to rely (Cramer 1982; Rosenblatt 1992; Cramer 1999; and Wu 2009) showed odds ratios in excess of 2.0 that a woman using talc would develop serous ovarian cancer (i.e. that she had 50% or greater chance of developing cancer than women who did not use talc). Two did not break out serous ovarian cancer, although Yessaian admitted that

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[4] Defendants argue that the use of a differential etiology methodology was not proper in the first instance because the testimony at trial was to the effect that when the causes of a disease are largely unknown (as was testified to by both Yessaian and defense experts), a differential etiology "is of little assistance." Restatement (Third) of Torts: Phys. & Emot. Harm § 28 cmt. 4 (2010); S. Breyer et. al., *Reference Manual on Scientific Evidence* 3d Ed. (2011) 618 & n. 214. The Court need not reach this issue as, even if the methodology could be used here, it was employed improperly.

it was important to focus on histological type (Tr. 2896:1-4; 2834:27-2835:12.) The two that did (Cramer 1999 and Wu 2009) showed a relative risk ratio of 1.70.

The other studies on which Yessaian relied to show talc was a scientifically plausible cause of serous ovarian cancer all showed relative risk ratios well below 2.0, i.e. in the range of 1.3. Those statistics tend to *disprove* causation, as they show talc does not double the risk of harm. (*Daubert v. Merrell Dow Pharm., Inc.* (9th Cir. 1995) 43 F. 3d 1311, 1321 (Emphasis in original); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Prac. & Prod. Liab. Litig.*, (D.S.C. 2016) 185 F. Supp. 3d 786, 791-92.) In this regard, it is to be recalled that the risk ratios being cited are *relative* risk-ratios—comparing the risk that someone who uses talc will develop ovarian cancer to the risk that someone who did not use talc will also develop cancer. A relative risk ratio of 1.3 is well below the two-fold risk level necessary to show that talc "more probably than not" causes cancer. *See Marder v. G. D. Searle* (1986) 630 F. Supp. 1087, 1092.

Further, defendants showed (and it is not disputed) that the most recent study (Cramer 2016) found the relative risk ratio for serous ovarian cancer for persons like Echeverria who were post-menopausal when they developed cancer; had not used hormone replacement therapy; and had used talc for 24 years was 1.0—i.e. no greater and no less than women in the population at large.

Echeverria argues that epidemiological studies were not required to prove causation, citing *In re Neurontin Marketing, Sales Practices, and Products Liability Litigation* (D. Mass.2009) 612 F.Supp.2d 116, 132. (Opposition at 16, FN 8.) However, the fact is that in ruling talc "in" Yessaian relied almost entirely on epidemiological studies. To argue that epidemiological studies are not *required* to establish causation is not persuasive given they were utilized for such purpose.

Nor is it sufficient to argue that Yessaian did not rely solely on epidemiological studies or that such studies formed only one facet of the factors she considered. (Opposition at 16:25 – 26.)

Although Yessaian testified that epidemiology was just one of the factors she looked at, she did not mention any others. (Tr. 2657:25- 2658:12 and 2673:10-2674:8.) She did reference prior testimony wherein she, "listed all the factors and elements that I evaluated." Presumably she was referencing testimony at Tr. 2629:20-2630:6, cited in Echeverria's Opposition at 14:28, along with a picture of the board on which Yessaian wrote her list. Within that testimony, Dr. Yessaian ruled out other causes of Echeverria's ovarian cancer, but did not find any other factor to rule in talc as a disease agent other than epidemiology.

In this regard it should be noted that Yessaian also did not "rule in" talc as a disease agent based on the testimony of Godleski or her general understanding that that there is a plausible biological mechanism (inflammation) by which it may be hypothesized that talc causes cancer, nor could she in the absence of evidence that Echeverria had such inflammation.

The undisputed evidence was that epidemiology was the *only* basis that Yessaian could and did "rule in" talc as a disease agent. That evidence was extremely limited and, at best, consisted of two studies (Cramer 1982 and Rosenblatt 1992) showing a relative risk ratio in excess of 2.0. In light of the other studies presented and, in particular the studies on which Yessaian relied that showed that when stratified for serous ovarian cancer, the risk was 1.7 and for those with characteristics most closely aligned with Echeverria's (serous ovarian cancer, no use of hormone replacement therapy, and use of 24 years) no increased risk was shown, substantial evidence was not provided by Yessaian to "rule in" talc.

(ii) Yessaian Did Not "Rule Out" Other Causes of Cancer

As to what Dr. Yessaian "ruled out" in her differential etiology, Yessaian was able to testify based on Echeverria's medical and personal history that some disease agents (genetics; history of family members with cancer at an early age or breast or ovarian cancer; polycystic ovarian syndrome; endometriosis; tobacco and alcohol use; use of hormone replacement therapy) could be "ruled out." However, as to others (age, number of ovulatory cycles, obesity) Yessaian

did not rule them out. She testified instead that in her opinion it was less probable than not that they caused Echeverria's disease. She testified that "nobody" could eliminate obesity (Tr. 2876:28-2878:12) or age (Tr. 2876:4-14), and that although a high number of ovulatory cycles was a risk factor for ovarian cancer, Echeverria's number of ovulatory cycles was "less likely than not" the cause of the disease (Tr. 2881:20-2882:23). Thus, she did not eliminate these potential causes but instead, "discounted" them. As to obesity she did so on the basis of studies showing that obesity was not statistically linked to serous ovarian cancer (although it is linked to breast and uterine cancer) but as to age and number of ovulatory cycles, her testimony had no underpinning.

Likewise, she conceded that idiopathic causes are the leading cause of ovarian cancer and that it was *probable* Echeverria's cancer was caused by some risk factor science does not yet know about (Tr. 2864:26-2688:27), yet testified that there was less than a 50% chance Echeverria's cancer was idiopathic. (Tr. 2888:19-26; 2890:28-2891:1; 2894:13-18.) However, she could not put a "percentage" on how less likely that was. (TR 2894: 20-21).

The Court is of the firm view that Yessaian's "ruling out" of age and ovulatory cycles, amounted to no more than speculation. Her testimony that it was "probable" the cause of the cancer was unknown, but then putting a "less than 50% chance" on same (with no reasoning) likewise amounted to mere speculation. Those facts show that the expert did not properly employ the methodology she espoused and independent of the fact that there was no evidence of substance to rule talc "in," persuade the Court that JNOV must be granted to JCCI and Johnson & Johnson on the basis that no specific causation was shown.

(2) Defendants' Arguments Regarding Scientific Knowledge

Defendants argue that there was no substantial evidence supporting a duty to warn because such duty only arises when a product is shown to be dangerous based on scientific knowledge available to the manufacturer. Echeverria argues that pursuant to *Carlin v. Superior*

Court (1996) 13 Cal.4th 1104, 1112-1113, in negligent failure to warn cases there is no "generally recognized and prevailing best scientific and medical knowledge" requirement. This is a misreading of the case. As the *Carlin* court explained, the difference between a strict liability failure to warn and a negligence based failure to warn case is that in a strict liability setting, even a reasonably prudent defendant manufacturer (with no duty to warn under a negligence standard) may be liable if the trier of fact concludes based on scientific information available to the manufacturer, the failure to warn rendered the product unsafe. (Id. at 1113.) Conversely, a manufacturer who is aware of scientific evidence of a level of risk may be found to have acted within the standard of care by not warning of the risk if, for example, it had other contrary evidence. (Id. at 1112.) Under either scenario, scientific knowledge is required for liability. "Under a negligence standard, a reasonable manufacturer would not be charged with knowing more than what would come to light from the prevailing scientific and medical knowledge." (*Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1483-1484.) However, defendants did not ask for an instruction in this regard and cannot now use that as a ground for JNOV.[5]

(3) JNOV to JJCI As To Punitive Damages Is Warranted

JJCI argues that at a minimum a partial JNOV on the issue of punitive damages should be granted as there was no substantial clear and convincing evidence of malice. Cal. Civ. Code §3294(a). Echeverria contends that notwithstanding the fact that the scientific community was (and is) divided on the question of whether talc causes ovarian cancer, internal documents showed that JJCI "knew or should have known" that talc was dangerous or likely to be dangerous giving rise to a duty to warn and that its failure to do so was in callous disregard of the

[5] Defendants asked for and received an instruction as to custom and practice (CACI 413)

safety of the public. Specifically, she contends that JJCI was on notice that condom manufacturers ceased using talc in the early 1990s and was aware of the scientific studies both from its consultant (Wehner) and from the literature generally. At trial Echeverria argued that the literature, in particular Ex. P- 105 (Harlow 1992) and Ex. P- 107 (Cramer 1999) demonstrated that ten percent of ovarian cancer cases in the United States are *caused* by the use of talc based powders and from that fact Echeverria argued that JCCI should have warned about the risk associated with the use of talc.

This is a misreading of the evidence. Ex. P-105 was an epidemiologic study that concluded that *if* a cause association were to pertain to daily users or users with more than 10,000 exposures applying the odds ratios in the study to the exposure rate among cases the proportion of ovarian cancer incidence was approximately 10%. Exhibit P-107 stated that there was a consistent association between talc and ovarian cancer that appeared to be unlikely to be explained by recall or confounding. The dose response relationship was deemed weak. The authors hypothesized a biologically plausible causation mechanism and called for appropriate warnings noting that avoidance of talc in genital hygiene use might *reduce* the occurrence of ovarian cancer by at least 10%. Other research, both before and after this, and in particular in the time period 1980 to 2008, including a published 1995 report based on a joint symposium co-sponsored by the FDA, the CFTA, and The International Association of Regulatory Toxicology & Pharmacology in January 2004 (Ex. D-205) reported that "while some weak association between talc exposure and ovarian tumors has been reported it was not sufficient warning for concern" and concluded that "the possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health concern. However, this association remains a research hypothesis whose verification or falsification needs additional study." These additional studies took place, were considered by IARC in 2006, and led it to conclude that talc

was a "possible" rather than "probable" cause of ovarian cancer. (Ex. P-29; Tr. 1196:7-23; 1198:8-1200:2; 2162: 18- 263: 10; 2282:5-2283: 28; 2285:23-26; 2291: 15-23.)

Significantly, Echeverria cites to no internal research or study by JCCI that was not in the public scientific domain. Thus, there was no showing beyond the publicly available literature that would show JCCI "knew or should have known" of the dangers of talc prior to 2007.

She also contends that internal documents, referenced above, showed that JCCI was attempting to influence the scientific debate at NTP, sought to influence opinion leaders, and sought to cause IARC not to list talc as "probably" carcinogenic, and declined to fund studies that it did not believe were favorable to it. These documents and theories are discussed, supra. The documents, beyond showing that Johnson & Johnson did not control JCCI, also do not constitute substantial evidence to support the punitive damages verdict against JCCI. The only document shown to have been written by a JCCI employee was P-764, the draft "Q & A". While that document demonstrates JCCI had knowledge of the science available at that time, it does not show that anyone at JCCI (much less a managing agent or employee) determined or should have determined that talc was a probable cause of cancer based on the science available.

Further, and as discussed above, that condom manufacturers ceased using talc in its products, without further information as to why they did so and that the information was known to JCCI, or that Imerys disclosed the IARC classification on its MSDS, does not show a conscious disregard for safety. Echeverria's own expert, who chaired the IARC panel giving rise to its classification of talc as "possibly" carcinogenic testified that in his opinion the scientific evidence was insufficient to show as of 2007 that there was a causal relationship between perineal talc use and ovarian cancer risk. (TR: 2300:9-14; 2300:15-19; 2362:11-22; 2355:24-2359:2; 239:3-13; 2363:10-2364:14; 2368:11-25.) The Merritt study (2008) (Ex. L-811) also concluded "chronic inflammation does not play a major role in the development of ovarian cancer."

Reviewing all of the evidence in the light most favorable to Echeverria the best that can be said is that there was (and is) an on-going debate in the scientific and medical community about whether talc more probably than not causes ovarian cancer and thus giving rise to a duty to warn. Clear and convincing evidence of malice is lacking. In such circumstances an award of punitive damages based on theory of negligent failure to warn of the dangers cannot be sustained. *Cf. Kendall Yacht Corp. v. United California Bank* (1975) 50 Cal. App. 3d 949, 959; *Satcher v Honda Motor Co.* (5th Cir. 1995) 52 F. 3d 1311.

IV. MOTION FOR NEW TRIAL

A. Procedural Requirements and Legal Standard

(1) Timeliness

A party intending to move for a new trial must file notice of intention to move for new trial designating the grounds upon which the motion is made, after a decision is rendered and before entry of judgment, or within 15 days of the date of mailing notice of entry of judgment. CCP §659. The Court mailed notice of entry of judgment on August 21, 2017. Defendants filed their Notice of Intention to Move for New Trial on September 5, 2017. The motion is timely.

A motion for new trial must be ruled on within 60 days of mailing of notice of entry of judgment by the clerk or any party (whichever is earlier), or if no notice is given, 60 days after filing of the first notice of intent to move for new trial; after such time the court loses its power to rule on a motion for new trial. Cal. Code of Civ. Pro. §663a.

The last day for the Court to rule on the motion is October 20, 2017 (60 days from August 21, 2017).

(2) Legal Standard

Courts have no inherent right to order a new trial; the right is purely statutory and must be based on one of the grounds enumerated in the statute. (*In re Marriage of Herr* (2009) 174

Cal.App.4th 1463, 1465; *Fomco, Inc. v. Joe Maggio, Inc.* (1961) 55 Cal.2d 162, 166.) The potential bases for granting a new trial are enumerated in Cal. Code of Civ. Pro. §657.

Defendants' motion is based on the following:

(1) Insufficiency of the evidence to justify the verdict, or the verdict is against the law - §657(6)

(2) Irregularity in the proceeding of the court, jury, and/or adverse party, or orders of the court or abuse of discretion by which Defendants were prevented from having a fair trial - §657(1)

(3) Error in law occurring at trial and excepted to by Defendants - §657(7).

(4) Misconduct of the jury - §657(2)

(5) Excessive damages - §657(5)

B. Analysis

(1) Cal. Code of Civ. Pro. §657(6) –Insufficiency of evidence arguments

"Insufficiency of the evidence is one of the most frequent grounds for new trial motions. It is also one as to which the trial judge has the broadest power." (Civil Trials and Evidence at 18:170.) The trial court is said to sit as the thirteenth juror and to have plenary power to order a new trial based on insufficiency of evidence. (*Barrese v. Murray* (2011) 198 Cal.App.4th 494, 503.) "While it is the exclusive province of the jury to find the facts, it is the duty of the trial court to see that this function is intelligently and justly performed, and in the exercise of its supervisory power over the verdict, the court, on motion for a new trial, should consider the probative force of the evidence and satisfy itself that the evidence as a whole is sufficient to sustain the verdict." (*People* v. *Robarge* (1953) 41 Cal.2d 628, 633 [262 P.2d 14].) Insufficiency of the evidence in this context means "an absence of evidence or that the evidence received, in

the individual judgment of the trial judge, is lacking in probative force to establish the proposition of fact to which it is addressed." (*People* v. *Capps* (1984) 159 Cal.App.3d 546, 552, fn. 5 [205 Cal.Rptr. 898].) The court must independently assess the evidence supporting the verdict. (Ibid.) The court's plenary power includes the power and duty to reweigh evidence (*Tice v. Kaiser Co.* (1951) 102 Cal.App.2d 44, 46; *Armstrong v. Svoboda* (1966) 240 Cal.App.2d 472, 473), and to consider the credibility of witnesses and draw inferences that differ from those of the jury (*Casella v. SouthWest Dealer Services, Inc.* (2007) 157 Cal.App.4th 1127, 1159-1160). In reweighing evidence, trial courts are to be guided by a presumption that the verdict is correct. (*Ryan v. Crown Castle NG Networks, Inc.* (2016) 6 Cal.App.5th 775, 785.)

Put another way, a trial court may uphold a jury verdict resting on sufficiently weighty evidence, even if the court itself might have reached a different conclusion. However, the trial court must conduct its own independent evaluation of the evidence, including weighing the evidence and judging the credibility of witnesses. *Id.*

In their combined Motion for New Trial, Johnson & Johnson and JJCI argue that the verdict is against the weight of evidence. They contend the evidence presented was insufficient to establish causation, and that mere possibility is insufficient to establish a prima face case. (*Jones v. Ortho Pharm. Corp.* 163 Cal.App.3d at 402.)

As to general causation, defendants argue that:

(1) The epidemiology studies do not show a strong association between genital talc use and ovarian cancer, noting that the epidemiology studies reveal average risk ratios of 1.24-1.3. (Tr. 1398:23-1402:8, 2459:5-2461:13, 3700:10-3701:8.). This relatively weak association could be the result of chance. (Tr. 1443:12-1444:19 (Exhibit L-1769); Tr. 2332:25-2345:18; 2430:12-28; 2456:19-2458:4; 2448:14-2489:13; 3178:22-3180:20; 3361:21-3370:19; 3700:10-3705:4.)

(2) The results of studies are inconsistent. (Tr. 1426:2-15, Exhibit P-104, at 3; 1430:5-1433:5; 3714:2-3716:28; 1433:25-1438:5; Exhibit L-1769 Tr. 3705:9-3707:19; 3176:14-3178:7; 3361:2-20; 3721:10-3723:5; 3603:12-3607:13.)

(3) The studies fail to establish a dose-response relationship. (Tr. 3723:19-3724:1; 2389:21-2394:1; 2383:10-2389:5; 2823:3-2824:9 (L-1811); 3182:14-3183:25; 3723:8-3736:2.) Echeverria's expert, Siemiatycki, testified that although a study by Terry (2013) showed "compatibility" with dose response, it was equally compatible with no dose-response. (TR 2383:10-2389:5).

(4) No animal study has ever shown that talc causes ovarian cancer. (Tr. 3186:11-3195:20 (Hamilton 1974); 1239:23-27; 1253:26-1255:2, 3186:11-3195:20 (Ex.P-47); 1270:19-1276:28 (1995 Boorman).

(5) The proposed biological mechanism is speculative. (Tr. 3476:13-3480:23; 3492:20-26; 3464:9-3465:23; 3475:23-3480:23; 3492:20-26; 3536:4-13; 3567:12-3568:6; 3601:12-3602:1; 1359:3-10; 1363:12-19; 1383:3-9; 2483:11-2486:28; 1354:23-1357:9; Exhibit L-811; Exhibit P-47 at 3-5.)

(6) The consensus view in the regulatory, scientific, and medical community is that the science does not support a causal relationship. (Exhibit P-47; Exhibit P-29; Tr. 1196:7-23; 1198:8-12002:2; 2162:18-2163:10; 2282:5-2283:28; 2285:23-26; 2291:15-23; 1619:6-1620:8.) Talc is not recognized as an ovarian cancer risk by the Centers for Disease Control or medical associations such as the American Congress of Obstetrics and Gynecologists or Society of Gynecological Oncology. (Tr. 2714:2-2721:9; 3580:9-3590:5.) No published peer-reviewed articles declare talc to cause ovarian cancer. (Tr. 2276:21-2277:19; 2280:2-10; 3695:19-3696:7; 3749:12-3750:1.) The Clyde 2017 study, which was comprehensive, did not include talc as a risk factor even though it was considered as part of its analysis. (Tr. 1448:26-1459:9.)

As to specific causation, Defendants argue Yessaian's testimony was insufficient as a matter of law to prove specific causation for the reasons set forth above regarding JNOV. They further argue Yessaian's testimony was speculative and unreliable, and her credibility was undermined, because she focused only on studies that supported her conclusion while disregarding any contradictory data or cohort studies, including more recent studies, and ignored the studies she cited. They suggest "cherry-picking" metrics from different studies is not good science. (Tr. 2428:16-26; *In re Zoloft (Sertaline Hydrocloride) Prod. Liab. Litig.* (E.D. Penn.

2014) 26 F.Supp.3d 449, 460-462.). In addition, even as to the four studies on which she relied Yessaian used only data or metrics she considered helpful. Her report indicated she would apply data based on Echeverria's estimated 30,000 lifetime genital applications of talc (Exhibit PP at 8), which would have produced a statistically insignificant relative risk ratio under the Wu 2009 study (Tr. 2908:6-2910:28). They argue that to find a "better" odds ratio Yessaian switched to a different measure of use (years), which she had previously deemed less accurate. When questioned about this at trial Yessaian testified that the category for 50,000 lifetime applications applied to a combined genital and non-genital use, even though previously she testified that talc could not reach the ovaries through non-genital applications. (Tr. 2802:8-12.)

In contrast to Yessaian's testimony, Defendants assert their experts provided persuasive testimony that there was no inflammation in Echeveria's ovarian tissue, that most ovarian cancers are idiopathic, and that Echeverria had multiple risk factors that could account for her disease regardless of her talc use.

Echeverria asserts that sufficient evidence supporting the jury's verdict was presented, Echeverria agrees that the evidence showed that the relative risk ratio suggested by the bulk of the epidemiological studies was 1.3 (Tr. 2236:1-13, 3787:14-16.) She characterizes this number as statistically significant because talc is a nongenotoxic carcinogen requiring a series of mutational events to lead to ovarian cancer. (Tr. 1127:7-1128:15.) Echeverria argues based on the 6 meta-analyses and the Terry pooled analysis, plus the consistency of the 28 epidemiology studies, it is almost impossible that association is attributable to chance or bias. (Tr. 1563:5-18, 2314:1-20, 2236:1-13, 2249:7-14, Ex. 27 (P-47).)

Echeverria's opposition also argues that as to biological plausibility, she presented evidence that inflammation is a valid hypothesis as to how talc causes cancer.

She notes that animal studies in 1992 by the NTP found lung cancer in rats exposed to high levels of aerosolized talc.

Finally, repeating arguments made in opposition to the motion for JNOV, she argues that since 1964 Defendants have been aware of "the talc/ovary problem" and yet failed to warn (Opposition at 5:13-14) or donate to cancer research (Ex P-55).

Defendants respond that Echeverria's inflammation hypothesis is not supported by studies and there was no evidence presented that the kind of inflammation specific to talc is linked to cancer. As to Echeverria's argument that based on meta-analysis and the Terry study, it is almost impossible that the 1.3 association is attributable to chance or bias, Defendants note that Echeverria does not dispute that the association could be based on confounding, something her own expert admits is not eliminated in meta-analysis. (Tr. 2430:12-25.)

Defendant also argues that the weight of evidence did not establish a duty to warn because such a duty is only triggered when the prevailing scientific and medical knowledge supports it. (*Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1483-84.)

Finally, defendants suggest the jury was likely confused by repeated suggestions that the possibility of risk alone was sufficient to impose a duty to warn. (Tr. 656:15-689:27-691:19 (mistrial requested on argument in opening statement); 3997:19-3998:4; 4005:22-27 (closing argument.)

Sitting as the thirteenth juror the Court is of the firm conclusion that the evidence of specific causation is not sufficient to support the verdict, for the reasons set forth above respecting the JNOV, which are incorporated here in their entirety, and for the additional reason that Yessaian did not consider all available epidemiology and apply it to the facts relative to Echeverria except when it favored Echeverria. There was a lack of any proper testimony as to specific causation. In addition, and as to general causation, the Court respects the testimony of Siemiatycki to the effect that there have been many instances in history where a disease agent was identified notwithstanding that the exact mechanism by which the disease was caused was not identified. Further, given the nature of inflammatory responses, it is understandable that inflammation may not be easily shown, as Echeverria's experts testified. However, given the lack of anything other than a hypothesis about causation and the nature of the epidemiological evidence presented, defendants are entitled to a new trial pursuant to Cal. Code of Civ. Pro. § 657(6), as both specific and general causation evidence was lacking.

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(2) CCP §657(1) (7) - Erroneous Rulings and Improper Arguments

In order to grant a new trial based on errors in law at trial, the error must have been prejudicial (Cal. Const. Article VI, §13), and erroneous as a matter of law (*Tun v. Wells Fargo Dealer Services, Inc.* (2016) 5 Cal.App.5th 309, 323). Additionally, the error must have been raised at trial. In support of their motion defendants submitted the Declarations of Jurors 1 and 2. Echeverria countered with the Declarations of Jurors 8 and 10.

1. Yessaian

Defendants argue that Yessaian's testimony should have been excluded or stricken because she relied on the false assumption that an odds ratio of 1.51 was sufficient to show probability. Additionally, her testimony should have been stricken when she violated the Court's order limiting it to the four epidemiology studies as her basis for ruling in talc as the cause of Echeverria's cancer. They argue Yessaian violated that order by testifying that the four epidemiological studies were not the sole studies she relied on (Tr. 2820:11-15; 2820:1-5), but instead that she relied on other epidemiological studies with risk ratios of 1.2 to 1.3 which, in her view, showed in increase in risk that supported finding talc the probable cause of Echeverria's cancer. (Tr. 2820:26-28.) This was misleading because a risk ratio of less than 2.0 actually tends to disprove causation. Defendants moved to strike this testimony but the Court denied the motion. (Tr. 2940:1-2953:28.)

Echeverria contends these criticisms go to the weight, not admissibility of Yessaian's testimony. In addition, they argue the Court indicated that Yessaian was not limited to the four studies but could also testify as to Echeverria's medical history, general literature, and risk factors that she ruled out, citing the ruling on the motion in limine. Echeverria argues there was no showing of prejudice, noting that the juror declarations (which Echeverria argues should be stricken) do not say the outcome would have been different without Yessaian's testimony. Jurors 8 and 10 say they considered all the evidence and even Jurors 1 and 2 do not say the outcome would have been different without Yessaian's testimony. Finally, Echeverria points out

that Defendants were free to, and did, criticize Yessaian's testimony by way of cross-examination and in closing arguments. (Tr. 4060:22-4063:7.)

Echeverria is correct that in the absence of affidavits showing prejudice, the Court may not grant a new trial under Cal. Code of Civ. Pro. §657(1). See Cal. Code of Civ. Pro §658. Accordingly, the motion for new trial on this ground is denied.

However, for the reasons set forth above the Court is persuaded that the testimony of Yessaian was insufficient to establish specific causation and should therefore have been stricken. The motion is granted on this basis under Cal. Code of Civ. Pro. §657(7) as to both defendants.

2. CACI 431

The Court relied upon *Cooper v. Takeda Pharmaceuticals America, Inc*. (2015) 239 Cal. App. 4th 555 in instructing under CACI 431 (multiple causation), although it indicated that it had some doubt this was appropriate. "[W]hen deciding whether an error of instructional omission was prejudicial, the court must also evaluate (1) the state of the evidence, (2) the effect of other instruction, (3) the effect of counsel's arguments, and (4) any indications by the jury itself that it was misled." (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 580-581.)

Defendants argue that, unlike in *Cooper,* there was no factual basis to instruct on CACI 431 because Echeverria did not present evidence of any specific concurrent cause. Here, Yessaian did not rule in other causes while opining that talc was the most substantial factor. (Tr. 2676:1-3, 2929:21-2930:7; 2931:4-14.)

Defendants argue given the Court's rulings that Yessaian was precluded from testifying as to a possible "synergistic effect" that cause Echeverria's cancer, the fact that neither Godleski nor Yessaian testified to the biological plausibility of combined concurring causes, and the fact that defense expert Juan Felix, M.D. testified without contradiction that talc-based adhesions would not promote the growth of existing ovarian cancer (Tr. 3535:8-16), there was no basis for a multiple cause instruction. They contend giving the instruction likely prejudiced the results by diluting Echeverria's burden to show that talc was the "but for" cause. Defendants argue that at a critical point in deliberations, the jury discussed multiple causation (Juror #1 Declaration, ¶¶ 2-

3), making it reasonably probable the jury would have reached a different result if properly instructed.

Echeverria argues that on cross-examination, Yessaian testified to Echeverria's family history of cancer, obesity, smoking, age, age at menarche, and genetics as possible factors in causing her cancer. (Tr. 2118:18-2119:9; 2869:15-2870;27; 2875:4-10; 2876:1-14; 3597:5-15.) But, she also testified that as to each factor she determined that it was not a "probable" cause of Echeverria's cancer. It is also true, however, that defendants argued to the jury there could be other causes for Echeverria's cancer, including unknown causes.

There are no admissible juror affidavits that suggest prejudice, confusion or the like. Thus, the motion cannot be granted under Cal. Code of Civ. Pro. §657(1). As to whether there was error of law the Court notes, as it did at trial, that in a case involving whether an agent causes cancer, where it must be shown by a more probable than not standard (in excess of 50%) that the agent caused the disease, CACI 431 is inherently confusing because, by definition, alternate "causes" must be less than 50% probable. That is, there cannot be more than one "probable" cause in a cancer case as a mathematical matter. Nonetheless, given defendants' arguments that alternate unknown causes were possible causes of Echeverria's cancer, the Court is bound by *Cooper* and denies the motion on the basis of improper instruction under Cal. Code of Civ. Pro. § 657(7).

3. Condom Article—Ex. 19

Defendants argue that the Court improperly allowed Exhibit P-19 to be shown to the jury. The article asserts that concern about talc as an ovarian carcinogen in the medical literature goes back 50 years and that condom makers removed talc from condoms in the 1990s for that reason. Defendants argue that the Court struck Echeverria's attempt to introduce the article through Plunkett's testimony and then improperly allowed it to be introduced through defendants' expert (Andersen) even though the condom article was not part of the testimony Plunkett actually gave at trial and was only reviewed by Andersen as part of his consideration of Plunkett's testimony and report. (Tr. 3395:9-3396:18.) Echeverria did not ask Andersen anything about the article

other than whether he had seen it. (Tr. 3397:7-22.) Although the Court gave a limiting instruction, Echeverria's counsel referred to it several times in closing argument. (Tr. 3928:10-21; 3947:21-3948:1; 3948:4-9; 3950:14-15; 3995:25-26: 4003:3-6), stating to the jury that "concern about talc as an ovarian carcinogen goes back 50 years in the medical literature" (Tr. 3947: 22-248) and arguing that the condom industry removed talc from condoms in 1996 because of ovarian cancer concerns (Tr. 3950: 14-16).

Echeverria contends there was nothing wrong with permitting cross-examination of Andersen about the article (since he said he relied on it in forming his opinion) (Tr. 3395:9-3396:18; 3396:16-22), or about allowing Echeverria's counsel to refer to it in closing arguments. Further, the Court gave a limiting instruction that it was not admissible for its truth but only for purposes of notice. (Tr. 3928:4-21.)

The Court concurs that Ex. 19 should not have been admitted and counsel's reference to it was both prejudicial and undermined the limiting instruction. The Supreme Court held in *People v. Sanchez* (2016) 63 Cal. 4th 665 that an expert may not testify as to case specific hearsay or use same as the basis for his opinion without establishing an applicable hearsay exception. The reasoning behind the opinion was the Court's recognition, among other things, that "[w]hen an expert relies on hearsay to provide case-specific facts, considers the statements as true, and relates them to the jury as a reliable basis for the expert's opinion, it cannot logically be asserted that the hearsay content is not offered for its truth. In such a case, 'the validity of [the expert's] opinion ultimately turn[s] on the truth.'" (Id. at 682-683, quoting *Williams v Villinos* (2012) 567 U.S. 90). The court disapproved the use of a limiting instruction in these circumstances.

Here, the only evidence was that Andersen read the newspaper article because it was attached to Plunkett's report and was the basis of *her* opinion. Contrary to the representation of counsel that he would "link up" the article to his cross examination of Andersen as to the basis of Andersen's opinion, he did not do so but simply read it into the record and then proceeded to argue to the jury that the facts contained within it were true. This resulted in a situation akin to

what *Sanchez* sought to avoid—having the jury receive a fact as true through expert testimony when the fact as not been established in any reliable way. And, repeated references to it were clearly prejudicial as it was a key piece of evidence that Echeverria's counsel (Mr. Smith) relied upon in arguing that defendants knew or should have known that talc caused cancer and failed to warn of the risks in derogation of safety to the public.

Together with the other evidentiary failures a new trial on this basis is proper as to both defendants under Cal. Code of Civ. Pro. § 657(7).

4. Lobbying

Defendants argue that Echeverria's counsel disregarded limitations on use of lobbying evidence. After rejecting Echeverria's theory of conspiracy to influence regulatory agencies, (Tr. 1487:10-1488:5), the Court allowed in certain documents about attempts to influence NTP or IARC. (Ex. P-27, P-263, P-264, P-396) for the limited purpose of showing Defendant's knowledge that talc was being considered a carcinogen. (Tr. 3933:13-21.) Defense counsel objected to various lobbying exhibits and moved for a mistrial after Echeverria's counsel argued about lobbying in opening statement. (Tr. 691:20-693:1.)

Defendants contend Echeverria'ss counsel disregarded the limiting instruction, and this conduct was repeated and unmistakably intentional. (Tr. 3982:25-3981:1; 4094:1-8; 4094:10-14; 4090:5-11; 4093:27-28; 3989:24-3991:18; 3984:17-18; 4002:27-4003:2; 3318:20-28; 670:2-15; 3978:4-8; 4083:3-16.)

Echeverria takes the position that there was nothing improper about referring to lobbying evidence in closing argument. Echeverria argues that counsel are entitled to state their views as to what the evidence shows, citing Wegner, Civil Trials and Evidence (2017) at 13:42. Further, the Court gave a limiting instruction. (Tr. 39906:9-3908:23), while allowing the jury to consider evidence of lobbying to show knowledge of the danger of the product. (Tr. 3933:13-28; 4000:21-4001:3.)

While counsel are entitled to argue the evidence, they must do so consistent with a limiting instruction. (*Love v. Wolf* (1964) 226 Cal. App. 2d 378, 389.) Echeverria's counsel did not limit his argument to suggesting that the lobbying evidence suggested that defendants knew that there was scientific evidence concerning the possible link between talc and ovarian cancer. Rather, Echeverria's counsel (Mr. Smith) argued that defendants improperly "fended off" the NTP and stated that "if Johnson & Johnson would have just stayed out of it, let the scientists do their work at the U.S. government, the NTP would have listed talc as a carcinogen as far back as 2000. (TR 3982:25-3984:1.) Counsel went on to argue that what defendants did to "prevent regulation" was reprehensible conduct supporting an award of punitive damages. (TR 3984:17-18.)

Although the jury was instructed that lobbying activity was permissible, the totality of this argument disregarded the Court's limiting instruction and must be viewed as prejudicial and further grounds for a new trial as to both defendants under Cal. Code of Civ. Pro. Code of Civ. Pro. §657(7).

(3) Cal. Code of Civ. Pro. § 657(2) --Jury Misconduct

Defendants argue that the jury engaged in misconduct by considering attorneys' fees and taxes in its compensatory award and by setting the amount of compensatory damages based on the net worth of the defendants. Defendants offer the declaration of Juror #1 (M.M, the foreperson) and Juror #2 (J.D.H.) Echeverria offers the affidavits of Juror #8 (P.C.) and Juror #10 (N.F.).

The three-step inquiry into jury misconduct includes (1) whether the affidavits supporting the motion are admissible, (2) whether the facts establish misconduct, and (3) if so, whether it was prejudicial. (*Whitlock v. Foster Wheeler, LLC* (2008) 160 Cal.App.4th 149, 160.)

Under California law juror affidavits attesting to the jury's "mental processes" are prohibited. However, consideration of "statements made" or "conduct occurring" during

deliberations is permissible. (Cal. Ev. Code § 1150; *Krouse v. Graham* (1977) 19 Cal.3d 59, 80; *In re Stankewitz* (1985) 40 Cal. 3d 391, 397-402.)

Defendants argue that the jury engaged in two forms of misconduct.

First, the jury improperly considering attorney fees, appellate costs and taxes in determining Echeverria's noneconomic damages. (Declaration of Juror No. 1, ¶4; Declaration of Juror No. 2, ¶6.) Echeverria argues this evidence should be disregarded because it is hearsay and goes to the jury's mental process. She also argues that the conduct does not amount to misconduct in any event because Jurors 8 and 10 disagree. Finally, Echeverria argues that if there was misconduct, it was not prejudicial because Jurors 1 and 2 at most say they did not participate in the deliberations regarding damages; Defendants have not shown that absent the alleged misconduct a different result would have been reached. Defendants argue in Reply that the declarations provide clear testimony that jurors discussed and agreed to base compensatory damages on attorneys' fees, appellate costs, taxes, and Defendants' wealth, which establishes prejudicial misconduct.

The evidence in the jury declarations is mixed as to its admissibility. Specific rulings on the objections are appended. Briefly, however, the statements by Jurors 1 and 2 that "[Jurors] stated that taxes, appeal costs and expenses would be taken out of Ms. Echeverria's compensation" and "After jurors raised these arguments, other jurors expressed an agreement to raise the amount of damages" are admissible. The statements are proof of an overt act (an agreement to raise damages based on impermissible considerations). They are not hearsay. The statements are not admitted to show they are true (that Echeverria would pay fees and taxes) but to show the statement was made. As the Supreme Court explained in *Weathers v. Kaiser Found. Hospitals*: "hearsay is defined as 'evidence of a statement that was made other than by a witness while testifying at the hearing and *that is offered to prove the truth of the matter stated.* '" (Evid. Code, § 1200, subd. (a).) (Italics added.) However 'there is a well-established exception or departure from the hearsay rule applying to cases in which the very fact in controversy is whether certain things were said . . . and not . . . whether these things were true or false, and in these cases the words… are admissible not as hearsay, but as original evidence.'" (*Weathers v.*

Kaiser Found. Hosps., (1971) 5 Cal. 3d 98, 109-110, citing *People* v. *Henry* (1948) 86 Cal.App.2d 785, 789. See also *Enyart v. City of Los Angeles*, 76 Cal. App. 4th 499, 508, n. 5 [Statements reflecting on the bias of the jurors who uttered them are not hearsay]).

Although Echeverria secured juror declarations they did not refute what Jurors 1 and 2 reported. An agreement to exclude improper items of compensation such as taxes and fees in a verdict is improper, particularly where the jury was instructed as to what they could consider. (*Krouse*, 19 Cal. 3d at 80-81; *Trammell v. McDonnell Douglas* (1984) 163 Cal. App. 3d 157, 172). On the evidence here the Court is constrained to conclude that consideration of items of damages such as taxes and fees was serious misconduct, giving rise to a presumption of prejudice. No rebuttable evidence was offered. A new trial on this basis is thus required as to both defendants under Cal. Code of Civ. Pro. § 657(2), particularly given that this was a 9-3 verdict. (*Weathers v. Kaiser*, 5 Cal. 3d at 110.)

Defendants also argue that the jury improperly based compensatory damages on Defendants' wealth and apportioned the damages according to net worth. The jury awarded $68 million in noneconomic damages against Johnson & Johnson as compared to the company's $68 billion net worth, and $2 million against JJCI as compared to its $2 billion net worth. While it may be inferred that the verdict was the result of consideration of wealth, statements regarding the manner in which the jury deliberated are inadmissible. A new trial cannot be granted on this basis.

(4) Cal. Code of Civ. Pro. §657(5) – Excessive Damages

(i) Compensatory Damages

Defendants argue the compensatory damage award is excessive on its face, and grossly disproportionate to the verdicts in prior talc-cancer cases and similar cases where plaintiff established that he or she was diagnosed with terminal cancer caused by defendant's product. Defendants contend this is due to improper arguments by Echeverria's counsel.

The evidence was that Echeverria was diagnosed with cancer in 2007. She underwent surgery and multiple rounds of chemotherapy, including clinical trials, and endured their side effects, for ten years. She testified that she has pain from tumors that have developed since her surgery. (Tr. 3010:1-3011:3; Tr. 2574: 26-2577: 28; 3008:22-3009:17.) She testified that she feared death when she became ill in late 2016 and was hospitalized with sepsis. (Tr. 2998:28-2999:2.) She testified to her fears and to the impact that her illness has had on her family, particularly her daughter, who took on the responsibility for her care at age 16 and delayed graduation from high school as a result, as well as her sadness at the potential of losing her relationship with her young grandson. (Tr. 3011: 4-19.) Yessaian testified that Echeverria had complications from the chemotherapy, resulting in multiple hospitalizations. She also testified that for a woman of Echeverria's age the average life expectancy is 81 years. (Tr. 2683:23-28.)

Given this testimony the Court is not persuaded that the compensatory damages against JCCI ($2 million) can be deemed excessive if liability were established. The number is well in line with other verdicts in comparable cases. Accordingly, as to JCCI the motion for new trial on grounds of excessive damages is denied.

As to Johnson & Johnson, however, the court is convinced that the jury should have reached a different verdict. The compensatory verdict ($68 million) is plainly excessive. As found, *infra*, there is no evidence Johnson & Johnson manufactured baby powder after 1967 and there is no evidence it manufactured Shower to Shower. Yet, the jury apportioned the damages 97% to Johnson & Johnson. Given the misconduct of the jury in considering matters that were not to be included, and the arguments of counsel that were in violation of the Court's in limine motions, and given the other reasons why a new trial is required, a remittitur is not appropriate. A new trial is required on the basis of excessive noneconomic damages is granted as to Johnson & Johnson under Cal. Code. of Civ. Pro. § 657(5).

(ii) Punitive Damages

Defendants argue that the punitive damage award is against the weight of evidence and excessive. Defendants contend Echeverria failed to establish by clear and convincing evidence that Defendants acted with malice. Even if allowed, Defendants contend the Court should reduce

the damages as excessive and the product of passion and prejudice, driven by improper arguments seeking to punish Defendants for protected First Amendment activity and in violation of due process. *BMW of North America v. Gore* (1996) 517 U.S. 559, 574-575 indicates that punitive damages are to be reviewed based on (1) the degree of reprehensibility, (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damage award, and (3) a comparison to civil penalties in comparable cases. Focusing on the second factor, Defendants cites case law showing historical practice is to compare the ratio of punitive to compensatory damages, and, although bright-line rules are to be eschewed, awards of more than four times the amount of compensatory damages, "might be close to the line of constitutional impropriety" (*State Farm Mutual Auto Ins. Co. v. Campbell* (2003) 538 U.S. 408, 425), but where compensatory damages are substantial, a lesser ratio (1:1) can reach the due process limit. (Ibid.) Ratios of 9:1 are inherently suspect. (*Simon v. San Paolo U.S. Holding Co.* (2005) 35 Cal.4th 1159, 1182.) Echeverria points out that the 5:1 ratio here is well within the limits that have consistently been upheld but does not identify a case upholding a very significant punitive damages award layered on top of a substantial compensatory damage award.

It is sufficient to state for these purposes that the evidence was insufficient to uphold a punitive damage award of any kind. Analysis of what constitutes a "proper" amount of punitive damages is thus unnecessary. The punitive damages were excessive based on the evidence. A new trial is required as to both defendants under Cal. Code of Civ. Pro. § 657(5).

V. ORDER

For the foregoing reasons:

(1) The motions for JNOV by Johnson & Johnson and JCCI are granted;

(2) The motions for new trial by Johnson & Johnson and JCCI on grounds of (1) insufficiency of the evidence as to causation as to both defendants (Cal. Code of Civ. Pro. 657(6)); (2) error in law occurring at trial and excepted to by defendants (Cal. Code of Civ. Pro. 657(7); (3) misconduct of the jury (Cal. Code of Civ. Pro. 657(2);

Civ. Pro. 657(2); and (4) excessive compensatory damages (as to Johnson & Johnson) and excessive punitive damages (as to both defendants)(Cal. Code of Civ. Pro. 657(5) are granted.

Dated: 10/20/17

MAREN E. NELSON
Judge of the Superior Court

PLEADINGS CONSIDERED

Filed September 5, 2017

- Defendant Johnson & Johnson's Notice of Intention to Move for a New Trial
- Defendant Johnson & Johnson's Notice of Motion for Judgment Notwithstanding the Verdict
- Defendant Johnson & Johnson Consumer Inc.'s Notice of Motion for Judgment Notwithstanding the Verdict

Filed September 15, 2017

- Defendants' Motion for New Trial (Combined Memorandum of Points and Authorities)
  - Defendants' Compendium of Trial Transcripts (Volumes I and II)
  - Declaration of Bart H. Williams in Support of Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Motions for New Trial and Motions for Judgment Notwithstanding the Verdict
    - Notice of Lodging Exhibits G and L to the Williams Declaration Conditionally Under Seal
    - Notice of Lodging Exhibits F, H, I, O, P, T, U, V, W, W and Y to the Williams Declaration Conditionally Under Seal
  - Declaration of Juror Number 1
  - Declaration of Juror Number 2

Filed September 25, 2017

- Plaintiff Eva Echeverria's Opposition to the Johnson & Johnson Defendants' Motion for New Trial
- Plaintiff Eva Echeverria's Opposition to Defendant Johnson & Johnson's Motion for Judgment Notwithstanding the Verdict
- Plaintiff Eva Echeverria's Opposition to Defendant Johnson & Johnson Consumer, Inc.'s Motion for Judgment Notwithstanding the Verdict
  - Declaration of Mark P. Robinson, Jr. (Under Seal and Redacted Versions)
  - Plaintiff Eva Echeverria's Compendium of Trial Transcript Excerpts
  - Evidentiary Objections to Declarations of Juror No. 1 and Juror No. 2
  - Request by Plaintiff and Motion to Strike Declarations of Juror Nos. 1 and 2 Submitted by Defendants
  - Affidavit of Juror Number 8 (P.C.)
  - Affidavit of Juror Number 10 (N.F.)

Filed October 3, 2017

- Defendants' Reply in Support of Motions for New Trial
  - Defendants' Response to Plaintiff's Request to Strike and Evidentiary Objections re Juror Declarations Submitted in Support of Motion for New Trial
  - Defendants' Objections to Plaintiff's Juror Affidavits re Defendants' Motions for New Trial
  - Defendants' Supplemental Compendium of Trial Transcript Excerpts
- Defendant Johnson & Johnson Consumer, Inc.'s Reply in Support of Motion for Judgment Notwithstanding the Verdict

- Defendant Johnson & Johnson's Reply in Support of Motion for Judgment Notwithstanding the Verdict

Filed October 13, 2017

- Plaintiff's Supplemental Brief re Court's Questions at Hearing on Post-Trial Motions

Filed October 16, 2017

- Defendants' response to Plaintiff's Supplemental Post-Hearing Brief

II. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 1 (M.M.)

Material Objected to:	Grounds for Objection:	Ruling:
"3. There were extensive *discussions* among the jurors about the distinction between 'possible' and 'probable' causes. I raised that distinction several times. At one point while we were *discussing* this issue, one of the jurors *raised* and pointed to the jury instruction on 'Multiple Causes,' which said in effect that there could be more than one substantial cause. After that, jurors in favor of the plaintiff *relied heavily* on that instruction in their arguments to other jurors." Juror No. 1 Decl., at ¶ 3 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 3 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.27. "When a juror . . . gives the reasons for his or her vote, the words are a verbal reflection of the juror's mental processes, and consideration of such a statement as evidence of those processes is barred by Evid. Code § 1150." *Id.*	☑ Sustained ☐ Overruled re to what the jurors relied on.
	Hearsay. Juror No. 1's statements about what other (unidentified) jurors discussed or raised verbally is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation. Juror No.1's statement about what he thinks other jurors thought was important or what they "relied heavily on" is speculation, lacks foundation and personal knowledge as to the thinking and decision-making of other jurors.	☑ Sustained ☐ Overruled
	Lacks foundation, lacks detail, and conclusory.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"4. ~~When discussing~~ non-economic damages, jurors initially *discussed* an amount much lower than what was ultimately awarded. Jurors who voted in favor of liability *argued* that there was going to be an appeal process and that the plaintiff's lawyers needed to be paid and were going to ~~take much of the money~~. They also *stated* that taxes, appeal costs, and expenses would be taken out of Ms. Echeverria's compensation or out of the money received by Ms. Echeverria's daughter when Ms. Echeverria passed away. After jurors *raised* those *arguments*, other jurors *expressed* an agreement to raise the amount of the damages." Juror No. 1 Decl., at ¶ 4 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 4 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. The statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.27. "Juror declarations that purport to show a deliberative error by one or more jurors are inadmissible to impeach the verdict, as are juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages." Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.29 (citing *Maxwell v. Powers* (1994) 22 Cal.App.4th 1596, 1604-05). **Hearsay.** Juror No. 1's statements about other (unidentified) jurors' "discussions," their "arguments" or what they "argued," what they "stated," what they "expressed," or "raised" verbally is inadmissible hearsay. **Lacks foundation, lacks detail, and conclusory.** Neither the substance of any such statements by others nor their identity is provided. The statements are vague and conclusory.	☐ Sustained ☑ Overruled as to "They also stated... damages" ☐ Sustained ☑ Overruled ☐ Sustained ☑ Overruled

SUSTAINED

Material Objected to:	Grounds for Objection:	Ruling:
"5. ~~At the beginning~~ when the jury first turned to *discussing* damages, one of the jurors who favored the plaintiff *expressed* that jurors who were in favor of the defense should not participate in the ~~discussion~~. The jury took a poll on the issue of whether defense jurors should participate in the damages discussion. After the vote, although I (as the foreperson) facilitated the damages discussion by calling on jurors on writing things on the board, I did not express my views on the amount of compensatory damages. The other two defense jurors did not participate in the discussion of compensatory damages after the poll was taken regarding their participation." Juror No. 1 Decl., at ¶ 5 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 5 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code 1150(a) (emphasis added).	☐ ~~Sustained~~ ☑ Overruled as to "The jury" participated
	Hearsay. Juror No. 1's statements about what one or more jurors (unidentified by name or juror number) supposedly said, discussed or expressed is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Lacks foundation, lacks detail, and conclusory. Juror No. 1 does not have personal knowledge regarding the extent of participation of other jurors in discussions in the deliberation process.	☐ Sustained ☑ Overruled

Sustained

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Material Objected to:	Grounds for Objection:	Ruling:
"6. ~~When deciding how to~~ apportion damages between the two defendants, the only thing the jury *discussed* as the basis for the division was the relative ~~net worth of the two companies~~. Jurors *agreed* to assess a larger amount for non-economic damages from the parent company (Johnson & Johnson) because of the ratio between the net worth of Johnson & Johnson and that of JJCI." Juror No. 1 Decl., at ¶ 6 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 6 of Juror No. 1's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. These statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.27. "Juror declarations that purport to show a deliberative error by one or more jurors are inadmissible to impeach the verdict, as are juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages." *Id.* at § 2.29 (citing *Maxwell v. Powers* (1994) 22 Cal.App.4th 1596, 1604-05).	☐ Sustained ☑ Overruled • Jurors agreed . . . JJCI
	Hearsay. Juror No. 1's statements about what other (unidentified) jurors "discussed" or "agreed" regarding their decision-making process in awarding damages is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge, conclusory. In paragraph 5, Juror No. 1 said that he and the other "defense jurors" did not participate in the damages discussion. If that was true, it would mean that he lacks foundation and personal knowledge to state why or how other jurors "agreed" to assess damages.	☐ Sustained ☑ Overruled

sustained

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Material Objected to:	Grounds for Objection:	Ruling:
7. "When the jury was *discussing* the amount of punitive damages, the jurors who voted in favor of liability *discussed* and *agreed* to set the number based on a percentage of the Defendants' net worth, as Allen Smith had argued in closing argument." Juror No. 1 Decl., at ¶ 7 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 7 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Statements in "juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages" are inadmissible. Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.29.	☐ Sustained ☑ Overruled
	Hearsay. Juror No. 1's statements about what other (unidentified) jurors "discussed" or "agreed" regarding their decision-making process in awarding damages is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge. Juror No. 1 lacks personal knowledge and his statements lack foundation as to what other jurors discussed or how or why they decided or "agreed" to award damages.	☐ Sustained ☑ Overruled
	Not relevant. Evid. Code § 350. It is not misconduct to consider the defendant's net worth in awarding punitive damages. CACI 3945. *See also* Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.53 ("[P]unitive damages must be supported by . . . evidence of the defendant's financial condition" and "the defendant's net worth is the critical determinant.").	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"8. When the jury was at a six-to-six impasse on the Friday before the verdict, one plaintiff juror *expressed* that she no longer wanted to participate. She even turned her chair away from the table. I wrote a note to the Court about the impasse. After we received a note back from the Court, we continued to deliberate, but the jury continued to be divided and could not reach the nine votes necessary to reach a verdict. The same juror *told* me that she was going to write to the judge and ask to be taken off the jury because of her frustration. She began writing a letter in front of the other jurors." Juror No. 1 Decl., at ¶ 8 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 8 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. The statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a).	☑ Sustained ☐ Overruled
	Hearsay. Juror No. 1's statements about what some other (unidentified) juror "expressed" or "told" him or said she was going to "ask" is inadmissible hearsay.	☑ Sustained ☐ Overruled
	Speculation, lacks foundation, lacks personal knowledge. Juror No. 1's statements regarding why he thinks some other juror (who is not even identified) was frustrated is speculation and lacks foundation.	☑ Sustained ☐ Overruled
	Not relevant. *See* Evid. Code § 350. The fact that one juror at one point in time was frustrated or supposedly said that she was going to write a letter to the judge is not relevant. The statements do not show misconduct, that the juror refused to continue to deliberate or did anything improper.	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"9. After the jury received the note from the Court in response to the jury note, one of the plaintiff jurors *argued* vociferously that the jury was being *told* it needed to reach a verdict. At that point, the jury took a vote using a one to ten scale to indicate how strongly we favored a given side ('1' being strongest for defense, and '10' being strongest for plaintiff). Using that methodology, the 'average' was about a '7,' even though the jury remained divided. The jury continued to deliberate through the end of the day on Friday." Juror No. 1 Decl., at ¶ 9 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 9 are inadmissible because they concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "'Evidence about a jury's 'subjective collective mental process purporting to show how the verdict was reached' is inadmissible.'" *English v. Lin* (1994) 26 Cal.App.4th 1187, 1367.	☑ Sustained ☐ Overruled
	Hearsay. The statements about what some other jurors "argued" regarding what they were "told," and methodology referenced is hearsay.	☑ Sustained ☐ Overruled
	Speculation, lacks foundation, lacks personal knowledge, lacks detail, conclusory. Juror No. 1's statements about what he recalls the overall "average" numbers referenced in the methodology being "about" for the other jurors is speculation, lack foundation, lack detail, and are vague and impermissible conclusions.	☑ Sustained ☐ Overruled
	Not relevant. Jurors can consider the evidence and "express opinions regarding it." *People v. Steele* (2002) 27 Cal.4th 1230, 1266. There is nothing wrong with "jurors employ[ing] their own reasoning skills in a demonstrative manner . . . to the evidence admitted at trial." *People v. Vigil* (2011) 191 Cal.App.4th 1474, 1485.	☑ Sustained ☐ Overruled

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III. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 2 (J.D.H.)

Material Objected to:	Grounds for Objection:	Ruling:
"2. On Friday August 18, 2017, the jury was split 6 to 6. Our foreperson sent a note to the Judge telling her that the jury could not reach a verdict. One plaintiff juror *said* she no longer wanted to participate in discussions. She turned her chair away from the table and began writing something. After we received the note from the Judge and were still not able to reach a verdict, someone *said* we should just tell the Judge that we are a hung jury. At that point, one of the jurors angrily *said* that the note we received from the Judge said we had no choice but to reach a verdict." Juror No. 2 Decl., at ¶ 2 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 2 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a).	☐ Sustained ☑ Overruled
	Hearsay. Juror No. 2's statements about what some other juror (unidentified by name, juror number or even gender) supposedly said or meant is inadmissible hearsay.	☐ Sustained ☐ Overruled
	Speculation, lacks foundation, lacks personal knowledge, lacks detail, and conclusory. Juror No. 2's statements are vague, lack foundation, are speculative, conclusory and lack sufficient detail.	☐ Sustained ☑ Overruled
	Not relevant. *See* Evid. Code § 350. The fact that one juror at one point in time may have been frustrated or supposedly said that she was going to write a letter to the judge is not relevant. The statements do not show misconduct, that deliberations did not continue, or anyone did anything improper.	☑ Sustained ☐ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"3. We were not able to reach a verdict on Friday August 18. My best memory is that the jury was still divided 7 to 5 in favor of the plaintiff at the end of the day." Juror No. 2 Decl., at ¶ 3.	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 3 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. The statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a). "Evidence Code 1150 may be violated not only by the admission of jurors' testimony describing their own mental processes, but also by permitting testimony concerning statements made by jurors in the course of their deliberations." *People v. Sanchez* (1998) 62 Cal.App.4th 460, 475-76. "[T]he mental processes of jurors are beyond the hindsight probing of the trial court." *Maple v. Cincinatti, Inc.* (1985) 163 Cal.App.3d 387, 394. The rule prevents one or two jurors "from upsetting a verdict of the whole jury by impugning his own or his fellow jurors' mental process or reasons for assent or dissent." Wegner, at ¶ 18:288.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
4. "On Monday August 21, 2017, after ~~almost no~~ discussion, two more jurors switched to the plaintiff side, giving the plaintiff 9 votes." Juror No. 2 Decl., at ¶ 4.	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 4 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code § 1150(a). "'Evidence about a jury's 'subjective collective mental process purporting to show how the verdict was reached' is inadmissible to impeach a jury verdict.'" *English v. Lin* (1994) 26 Cal.App.4th 1187, 1367. "[T]he mental processes of jurors" is not admissible. *Maple v. Cincinatti, Inc.* (1985) 163 Cal.App.3d 387, 394.	☐ Sustained ☑ Overruled 5. 4 in part
	Speculation, lacks foundation, lacks detail and conclusory. Juror No. 2 lacks personal knowledge and her statements lack foundation as to the reasons and decision making process of the other jurors – after "almost no discussion" – whatever that means, and what they considered or deemed important in reaching their verdict. She does not say which jurors "switched" and she does not say or know why.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"5. Once the *discussion* of ~~damages began,~~ one of the jurors who favored the plaintiff angrily *said* that those of us who had favored the defense should not participate in the discussion of damages. A vote was taken regarding whether we should be allowed to participate in the discussion of damages. After the majority of jurors voted that we should not participate, the three of us who had voted for the defense did not participate in the discussion of how to decide on an amount for compensatory damages, or on the amount of damages." Juror No. 2 Decl., at ¶ 5 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 5 of Juror No. 2's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such are inadmissible statements pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*. "No evidence is admissible to show the effect (of improper influences) upon a juror in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." Evid. Code 1150(a) (emphasis added). The rule prevents one or two jurors "from upsetting a verdict of the whole jury by impugning his own or his fellow jurors' mental process or reasons for assent or dissent." Wegner, at ¶ 18:288.	☐ Sustained ☑ Overruled
	Hearsay. Juror No. 2's statements about what one of jurors (unidentified by name or juror number) supposedly said, discussed or expressed is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Lacks foundation, lacks detail, and conclusory. Juror No. 2 does not have personal knowledge and her vague statements lack foundation regarding the extent of participation of other jurors in discussions in the deliberation process.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"6. The jurors who favored the plaintiff *said* they should increase the amount of damages that they had been *discussing* because Ms. Echeverria was going to have to pay taxes on the money, pay her lawyers, and pay for an appeal. After the jurors *raised* those possible costs, other jurors agreed to raise the amount of the damages. ~~The amount that the~~ plaintiff-favoring jurors *agreed* on for compensatory damages for Ms. Echeverria was based on the net worth of the defendant companies. The jurors *decided* to award a larger amount of money against the larger company just because ~~they were a bigger company.~~" Juror No. 2 Decl., at ¶ 6 (italics added).	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 6 of Juror No. 2's declaration concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible pursuant to Evid. Code § 1150 and cannot be used to try to impeach the verdict. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, at § 2.27. "Juror declarations that purport to show a deliberative error by one or more jurors are inadmissible to impeach the verdict, as are juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages." *Id.* at § 2.29.	☐ Sustained ☑ Overruled in part
	Hearsay. Juror No. 2's statements about what other (unidentified) jurors "said," were "discussing," or verbally "raised" or "agreed" regarding their decision-making process in awarding damages is inadmissible hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge, conclusory. In paragraph 5, Juror No. 2 said that she and the other "defense jurors" did not participate in the damages discussion. If that was true, it would mean that she has no basis to say why or how other jurors "decided" or "agreed" to assess damages.	☐ Sustained ☑ Overruled

Material Objected to:	Grounds for Objection:	Ruling:
"7. When the jury *discussed* the amount of punitive damages, the jurors who voted in favor of liability did what Allen Smith asked them to do in his closing argument – they set the number based on a percentage of the Defendants' net worth."	**Inadmissible pursuant to Evid. Code § 1150.** The statements in paragraph 7 concern the mental processes, deliberative thinking, and subjective reasoning of the jury regarding how the verdict was reached. Such statements are inadmissible. *See* Evid. Code § 1150(a); *see also* § I.A. *supra*; Statements in "juror declarations that purport to show . . . [h]ow the jurors arrived at the award of damages" are inadmissible. Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.29.	☑ Sustained ☐ Overruled
	Hearsay. Juror No. 2's statements about what other (unidentified) jurors said or their decision-making process in calculating damages based on what Juror No. 2 heard them say is hearsay.	☐ Sustained ☑ Overruled
	Speculation, lacks foundation, lacks personal knowledge. Juror No. 2 lacks personal knowledge and her statements lack foundation as to what other jurors discussed or how or why they decided or "set" to award damages.	☑ Sustained ☐ Overruled
	Not relevant. Evid. Code § 350. It is not misconduct to consider the defendant's net worth in awarding punitive damages. CACI 3945. *See also* Cal. Judges Benchbook Civ. Proc. After Trial, Chp. 2, § 2.53 ("[P]unitive damages must be supported by . . . evidence of the defendant's financial condition" and "the defendant's net worth is the critical determinant.").	☐ Sustained ☑ Overruled

motion to Strike: Denied. MG

10/20/17

I. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 8 (P.C.)

Material Objected to:	Grounds for Objection:	Ruling:
¶ 4, lines 10-11: "[E]veryone in the jury room was free to participate in the damages deliberations . . . ."	**Vague and ambiguous.** The phrase "everyone in the jury room was free to participate in the damages deliberations" appears intended to address the contention in defense jurors' declarations that they were directed not to deliberate on damages, without actually refuting it. Two sentences later in the juror's declaration, she professes being unable to remember "whether or not" defense jurors were requested not to participate in damages deliberations. The two contentions—that defense jurors were requested not to deliberate on damages and that they were nonetheless "free to participate in the damages deliberations"—are not necessarily mutually exclusive, where being "free to participate" means something short of having a vote on the final awarded amount. *See* Evid. Code §§ 352, 765.	☑ Sustained ☐ Overruled
	Evidence Code § 1150 (Improper Statement of Jurors' Subjective Reasoning/Mental Process). While testimony that specific jurors were told not to participate in damages deliberations, or did or did not in fact participate in them, could be admissible as observable conduct, this juror's subjective opinion about whether defense-leaning jurors were "free to participate in the damages deliberations" is an improper statement of mental processes to the extent it is based on the juror's vague feeling or sense of the room, rather than on actual statements made.	☑ Sustained ☐ Overruled
¶ 4, lines 12-13: "Everyone was given a chance to say what they thought about the amount to award Ms. Echeverria, including the jurors who voted for the defendants."	**Vague and ambiguous** as to the phrase "[e]veryone was given a chance to say what they thought." That language appears to be a lawerly non-refutation of the contention in defense jurors' declarations that they were directed not to deliberate on damages. Indeed, the very next sentence of the juror's declaration states that she cannot remember	☑ Sustained ☐ Overruled

	"whether or not" defense jurors were asked not to participate in damages deliberations. The two contentions—that defense jurors were requested not to deliberate on damages and that, notwithstanding, they could have interposed "what they thought about the amount"—are not necessarily mutually exclusive, where having "a chance to say what they thought" means something short of being permitted to vote. *See* Evid. Code §§ 352, 765. **Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). While testimony that specific jurors were told not to participate in damages deliberations, or did or did not in fact participate in them, could be admissible as observable conduct, this juror's subjective opinion about whether "[e]veryone was given a chance to say what they thought" is an improper statement of mental processes to the extent it is based on a vague feeling rather than on actual statements made in the jury room.	☑ Sustained ☐ Overruled
¶ 4, lines 13-15: "I do not remember a request to exclude jurors from these deliberations, but whether or not that happened, everyone on the jury participated in reaching the verdict, and no one was excluded."	**Vague and ambiguous** as to the phrase "everyone on the jury participated in reaching the verdict, and no one was excluded." That artfully worded phrase appears calculated to distinguish between the finding of liability and the damages the jury ultimately awarded. It cannot be true both that there was a "request to exclude jurors from these deliberations" (about which, the juror avers, she cannot remember "whether or not that happened") and that "everyone on the jury participated in reaching the verdict, and no one was excluded" if "verdict" includes deliberations respecting damages. *See* Evid. Code §§ 352, 765.	☑ Sustained ☐ Overruled
¶ 5, lines 16-17: "Along with the other jurors, I voted based on the evidence that was presented against each of the defendants and the law that we were instructed to follow."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The statement as to what this juror purports to have subjectively considered in voting is inadmissible both as it concerns her own	☑ Sustained ☐ Overruled

	vote and particularly as it concerns the votes of other jurors. The statement goes to the subjective reasoning of the jury in reaching its verdict and is not verifiable and/or based on observable facts/expressions. **Conclusory, and lacks foundation and personal knowledge** as to the basis for other jurors' votes. *See* Evid. Code § 702.	☑ Sustained ☐ Overruled
¶ 6, lines 22-23: "The evidence presented was considered and was interpreted by me based on my thinking about the evidence."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The statement as to how this juror purports to have interpreted the evidence and her subjective "thinking" is an example of her subjective reasoning, not verifiable and/or based on observable facts/expressions.	☑ Sustained ☐ Overruled
¶ 6, lines 23-24: "We all worked together and we used our own reasoning skills in a demonstrative manner based on the evidence that was presented in the trial."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The statement as to how this juror perceives the collective reasoning skills of the jury (and each juror individually, including herself) is not verifiable and/or based on observable facts/expressions. **Conclusory, and lacks foundation and personal knowledge** as to the basis for the other jurors' deliberations and the manner in which they reached a verdict. *See* Evid. Code § 702. **Vague and ambiguous** as to the phrase "demonstrative manner," which appears to have been inserted merely in order to avoid the prohibition of Evidence Code § 1150 on juror declarations concerning "mental processes." *See* Evid. Code §§ 352, 765.	☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled

II. EVIDENTIARY OBJECTIONS TO THE DECLARATION OF JUROR NO. 10 (N.F.)

Material Objected to:	Grounds for Objection:	Ruling:
¶ 3, line 10: "The compensatory damages verdict was a reasonable compromise."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). Whether the juror believes the damages verdict was a "reasonable compromise" is not verifiable and/or based on observable facts/expressions. **Conclusory and lacks foundation** as to whether the verdict was "a reasonable compromise." *See* Evid. Code § 702.	☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled
¶ 3, line 11: "Even though I wanted to award her more, I agreed to the lower amount."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). Whether the juror wanted to award any more or less is not verifiable and/or based on observable facts/expressions."	☑ Sustained ☐ Overruled
¶ 3, lines 20-21: "From my standpoint, I am proud of the fact that all of us were very conscientious in a way that we considered all of the evidence that was presented."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The juror's statement about what "all of us [the jury]" "considered" goes to her subjective reasoning and is not verifiable and/or based on observable facts/expressions. **Conclusory, and lacks foundation and personal knowledge** as to whether the other jurors were conscientious or considered all of the evidence. *See* Evid. Code § 702.	☑ Sustained ☐ Overruled ☑ Sustained ☐ Overruled
¶ 3, lines 22-23: "I believe that the process was fair to both the plaintiff and the defendants."	**Evidence Code § 1150** (Improper Statement of Jurors' Subjective Reasoning/Mental Process). The juror's statement of belief as to the fairness of "the process" goes to her subjective beliefs/reasoning and is not verifiable and/or based on observable facts/expressions.	☑ Sustained ☐ Overruled

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