SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON, ET AL. Plaintiffs, vs. MONSANTO COMPANY, ET AL. Defendants.	Case No. CGC – 16-550128 **ORDER ON (1) MONSANTO'S OMNIBUS *SARGON* MOTION; (2) MONSANTO'S MOTION FOR SUMMARY JUDGMENT; (3) PLAINTIFF'S OMNIBUS *SARGON* MOTION; (4) PLAINTIFF'S MOTION FOR SUMMARY ADJUDICATION**

Plaintiff Dewayne Johnson brought this products liability action against Monsanto alleging he contracted non-Hodgkin lymphoma (NHL) as a result of his exposure to glyphosate, which is contained in Monsanto's herbicides such as Roundup®. Complaint ¶¶ 74-75. Five motions are presently before me: (1) Monsanto's Motion to Exclude Johnson's Experts; (2) Monsanto's Motion for Summary Judgment or Summary Adjudication; (3) Johnson's Motion to Exclude Improper Opinions of Monsanto's Experts; (4) Johnson's Motion for Summary Adjudication; and (5) Johnson's Motion for Judicial Notice.

I heard argument May 10, 2018.

I. Requests for Judicial Notice and Evidentiary Issues

These rulings apply only to the motions decided in this order, and not to the trial.

Monsanto's Motion for Summary Judgment or Summary Adjudication

Monsanto requests judicial notice of 18 exhibits, all of which are either EPA decisions or publications, records in the Federal Register, Congressional testimony, or publications of the California EPA. Monsanto RJN, 1-3. These unopposed requests are granted. E.C. §§ 451(b), 452(c), 452(h).

Monsanto objected to Exhibits 1, 7, 9-40 on hearsay grounds.[1] Monsanto Objections, 2-9. However, many of the exhibits are offered to show Monsanto's state of mind, acts, or conduct. For these purposes, the hearsay objection is overruled. E.C. § 1250. The Exhibits that are admissible for those purposes and are considered here are Exs. 11-12, 14, 19, 21, 22, 24, 25.

Monsanto objected to Exhibit 6 and excerpts from Dr. Benbrook's testimony on the basis that his expert testimony is inadmissible. Monsanto Objections, 2, 5, 8-9. The objection is sustained only to the extent this Order grants the motion to exclude Dr. Benbrook's testimony.

Monsanto also objects to Johnson's original and amended separate statements—the latter filed after Monsanto had submitted its reply with a new section setting forth additional material facts. Monsanto Objections, 4-9; Monsanto Objection to Amended Separate Statement, 1-3. A deficient separate statement generally may be corrected. *Rush v. White Corp.*, 13 Cal.App.5th 1086, 1100 (2017). In that spirit, I consider the amended separate statement.

Monsanto asks me to strike, in whole or in part, Johnson's oversized opposition brief. I consider the impermissibly oversized brief as a late-filed paper, C.R.C. 3.1113(g), which is to say I may reject it. *Rancho Mirage Country Club Homeowners Assn. v. Hazelbaker*, 2 Cal.App.5th 252, 262 (2016) (citing C.R.C. 3.1300(d)). I rebuke Johnson's counsel, but I am

[1] While Monsanto also asserts foundation and personal knowledge objections, those objections are based on the ground that the declarant cannot attest to facts sufficient to establish a hearsay exception.

unwilling to impose the draconian penalty on his client of refusing to consider the brief because it was five pages too long.

Johnson's Motion for Summary Adjudication

Monsanto submitted eighteen objections to Johnson's evidence. Monsanto's Objections ¶¶ 1-18. None is material to the resolution of the motion.

Monsanto requests judicial notice of 10 exhibits, all of which are government documents available on the EPA website or in the Federal Register. Monsanto RJN, 2-3. These unopposed requests for judicial notice are granted. E.C. §§ 451(b), 452(c).

In reply, Johnson requests judicial notice of five exhibits, all of which are posted online by government entities. Johnson RJN, 1-3. These unopposed requests for judicial notice are granted, but the truth of the disputable factual representations in the documents – such as the factual representations in the glyphosate fact sheet – are not noticed. E.C. §§ 452(c), (h).

Johnson's Motion for Judicial Notice

Johnson moves for judicial notice of the fact that the Office of Environmental Health Hazard Assessment (OEHHA) added glyphosate to the Proposition 65 list and of a brief OEHHA submitted defending the decision in which the OEHHA explained that it was relying on IARC. The ostensible purpose of this request for judicial notice is to bolster Johnson's experts to the extent they, like the state of California, give weight to IARC's determination that glyphosate is a probable carcinogen. I will under E.C. § 452(c) take judicial notice of these matters for the purposes of the present motions, but not for purposes of trial.

II. Motions to Exclude Experts

1. The Reliability of Expert Opinion based on Peer Review Studies.

I make some preliminary observations concerning attacks on expert opinion based on the purported inadequacy of the studies relied on by the experts. This particularly applies to much of Monsanto's motions, because Monsanto argues that the studies relied on by Johnson's experts were shown by other studies (including subsequent studies), or by other experts, to be lacking. E.g., Motion at 2:8 ff.; 3:8 ff.; 4:8 ff.; 7:1 (touting the NCI 2018 as the "best" study); 18:11 ff.; 20:13. Johnson implicitly makes similar arguments when he says that Monsanto's experts failed to adhere to studies or guidelines issued by IARC, Motion at 7, and when Johnson accuses the defense experts of relying on some but not other studies. E.g., *id.* at 8:12 ff.; Reply at 8.

At argument, plaintiff's counsel took the position that except for undescribed extreme situations, courts in a *Sargon* hearing must accept expert testimony founded on peer review studies, essentially pretermitting my review of the validity of the studies underpinning plaintiff's experts' opinions. Plaintiff relies primarily relied on *Cooper v. Takeda Pharmaceuticals America, Inc.*, 239 Cal.App.4th 555, 592 (2015). One may ask whether *Cooper* really forecloses a court's investigation into the validity of peer review studies; the opinion does lend itself to that reading, chastising—and reversing—the trial judge because he

> did engage in settling a scientific controversy when it looked piecemeal at a large body of epidemiological studies before finding the expert's opinion based on those studies wholly lacking in foundation, when it engaged in an analysis of whether studies reporting secondary endpoints were inherently unreliable, and when it disregarded other studies because it found the methodology, which was fully explained to the scientific community in peer-reviewed journals, to be misleading.

Cooper, 239 Cal.App.4th at 592.

The flaws identified by the trial judge in *Cooper* were not for him in the *Sargon* hearing: they were to be explored with the jury. *Cooper*, 239 Cal.App.4th at 593. See also, e.g., *United*

States v. Malone, 828 F.3d 331, 337 (5th Cir. 2016) ("The studies relied upon by Dr. Trecki undoubtedly meet this bar. There is no dispute that these studies were conducted by professional scientists using established methods and many were subjected to peer review. *This is more than enough to qualify them as 'reasonably reliable.*'") (emphasis supplied).[2]

Cooper and *Malone* bar the trial judge's resolution of a scientific controversy, but this begs the question of what counts as a valid scientific controversy. Not every issue is scientifically debatable: there are, for example, peer review studies in astrology,[3] but presumably no court would accept those as creating a pertinent controversy. Not every peer reviewed study is valid science.

While published peer review studies are not a prerequisite for expert opinion,[4] when they are used, they surely cannot by reason of their publication status literally be immune from attack, even in the *Sargon* setting. Even if it is not true that most research finding are unreliable,[5] it is

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[2] While I cite federal cases in this *Sargon* context, it still remains unclear whether state courts should exercise their gate-keeping function as rigorously as federal courts under *Daubert*. E.g., David L. Faigman et al., "Wading into the Daubert Tide: Sargon Enterprises, Inc. v. University of Southern California," 64 HASTINGS L.J. 1665, 1687 (2013) (the authors were also the authors of the Loyola Law Review item relied on by *Sargon*).

[3] http://www.astrology.co.uk/tests/studies.htm ("These statistically significant results have been published in peer reviewed journals (including Correlation, a specialist astrological journal)"); Ken McRitchie, "The Good Science of Astrology: Separating Effects from Artifacts," April 2011 ("This article has been peer reviewed by subject matter experts refereed through the publisher"), http://www.theoryofastrology.com/effects/ISAR-April-2011-Journal-KM.pdf. (The question of course, is who the "peers" are for these articles.)

[4] *Summit 6, LLC v. Samsung Electronics Co., Ltd.,* 802 F.3d 1283, 1298 (Fed. Cir. 2015) (""[p]ublication ... is not a *sine qua non* of admissibility," and "in some instances well-grounded but innovative theories will not have been published,") (quoting *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 593); *U.S. v. Carlson,* 810 F.3d 544, 553(8th Cir. 2016), citing *Russell v. Whirlpool Corp.,* 702 F.3d 450, 458 (8th Cir. 2012).

[5] John P. A. Ioannidis, "Why Most Published Research Findings Are False," *PLoS Med* (August 2005) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1182327/ (from the Summary: "a research finding is less likely to be true when the studies conducted in a field are smaller; when effect sizes are smaller; when there is a greater number and lesser preselection of tested relationships; where there is greater flexibility in designs, definitions, outcomes, and analytical modes; when there is greater financial and other interest and prejudice; and when more teams are involved in a scientific field in chase of statistical significance. Simulations show that for most study designs and settings, it is more likely for a research claim to be false than true. Moreover, for many current scientific fields, claimed research findings may often be simply accurate measures of the prevailing bias."); Paul E. Smaldino, "The natural selection of bad science," *Royal Society Open Science* (21 Sept. 2016) available at http://rsos.royalsocietypublishing.org/content/3/9/160384 ("Many prominent researchers believe that as much as half of the scientific literature—not only in medicine, by also in psychology and other fields—may be wrong. Fatal errors and retractions, especially of prominent publications, are increasing. The report that emerged from this

clear that many peer review studies are infected by "innocent, yet sloppy, error in the methodology of the experiment that the authors themselves caught,"[6] outright misconduct,[7] bias and conflicts of interest,[8] and scams.[9] Given these issues and the number of retracted papers,[10] some commentators understandably contend the process is deeply flawed,[11] although it may be better than alternatives.[12] So if at a *Sargon* hearing a peer reviewed study were shown to be based on falsified data, presumably the court would not allow it, or an opinion based on it, to be presented to the jury.

But it remains unclear under California law whether studies can be rejected for other reason such as irreproducibility or p-hacking (cherry picking data until the results are

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symposium echoes the slogan of one anonymous attendee: 'Poor methods get results.' Persistent problems with scientific conduct have more to do with incentives than with pure misunderstandings. So fixing them has more to do with removing incentives that reward poor research methods than with issuing more guidelines.... This paper argues that some of the most powerful incentives in contemporary science actively encourage, reward and propagate poor research methods and abuse of statistical procedures.") (notes omitted).

[6] Christopher Wanjek, "Lies, Mistakes & More: These Scientific Papers Got Nixed in 2017," *LiveScience* (Dec, 27, 2017) https://www.livescience.com/61275-scientific-retractions-2017.html

[7] *Id.* (Wanjek)

[8] E.g., William L. Anderson et. al., "Daubert's Backwash: Litigation-Generated Science" 34 U. MICH. J.L. REFORM 619, 644 & n. 147 (2001); Ned Miltenberg, "Myths About 'Neutral' Scientific Experts," *Trial* (January 2000) at 62, 64 (noting "ethical lapses, in violation of peer review conflict-of-interest rules, plague the most renowned journals, not just the second-rate ones").

[9] Adam Marcus, "Phony peer review: The more we look, the more we find," STATNews: APRIL 28, 2017, https://www.statnews.com/2017/04/28/phony-peer-review/ (noting retractions of papers); Sneha Kulkarni, "What causes peer review scams and how can they be prevented?" Wiley Online Library https://www.editage.cn/insights/sites/default/files/What%20causes%20peer%20review%20scams%20and%20how%20can%20they%20be%20prevented.pdf; Cat Ferguson, et al., "The Peer-Review Scam" 515 *Nature* 480 (27 Nov 2014) (scams, retracted articles), https://www.nature.com/news/publishing-the-peer-review-scam-1.16400

[10] Christie Aschwanden, "Science isn't Broken" https://fivethirtyeight.com/features/science-isnt-broken/#part3

[11] Stuart Macdonald, "Emperor's New Clothes: The Reinvention of Peer Review as Myth," *Journal of Management Inquiry* (2014) ("vast literature has accumulated, the general tenor of which is that peer review is deeply flawed, capable of much improvement in all manner of ways, but better than the alternatives." https://www.researchgate.net/profile/Stuart_Macdonald5/publication/277886859_Emperor%27s_New_Clothes/links/5989ce17a6fdcc75626383b6/Emperors-New-Clothes.pdf. For a list of articles and other resources noting issues with peer review, see e.g., notes under "Reporting bias & related issues (peer reviews)" in Curtis Karnow, "Experts, Statistics, Science & Bad Science," https://works.bepress.com/curtis_karnow/26/

[12] Stuart Macdonald, op cit.; Mark Ware, "Peer review in scholarly journals: Perspective of the scholarly community – Results from an international study," 28 *Information Services & Use* (2008) 109–112 http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.453.7782&rep=rep1&type=pdf#page=36

"statistically significant"[13]) or sloppy work, primarily because state law has not developed a robust sense of what counts as "scientific" and what therefore is beyond that pale and so should not be seen by a jury. Even federal courts under the *Daubert* standard have admitted testimony that "did not flow naturally from disinterested research, [where the] methodology was not subject to peer review or publication, and [where the] theory had no known rate of error," because "these objections go to the weight of [the] testimony, not to its admissibility." *U.S. v. Carlson* 810 F.3d 544, 553 (8th Cir. 2016), citing *Russell v. Whirlpool Corp.* 702 F.3d 450, 458 (8th Cir. 2012).

The net result is that, at least in California courts, expert opinion actually founded on peer review studies, most especially when the credentials of the expert are unassailable, may be very difficult to exclude. This is so, as in *Cooper,* even when the studies have patent flaws, because those can be the subject of cross examination. *Cooper*, 239 Cal. App. 4th at 593. Experts are allowed to look a variety of inconsistent studies and decide—as experts—what the *net* effect is from that review. *Cooper*, 239 Cal. App. 4th at 589-90. See also *Wendell v. GlaxoSmithKline LLC,* 858 F.3d 1227, 1233 (9th Cir. 2017). The point may be that judges in *Sargon* hearings are not evaluating peer review studies as such, but rather the expert opinion (which may be founded on those studies). The standards for the two are not exactly the same.[14]

[13] Christie Aschwanden , "Statisticians Found One Thing They Can Agree On: It's Time To Stop Misusing P-Values," *FiveThirtyEight* (March 7, 2016) http://fivethirtyeight.com/features/statisticians-found-one-thing-they-can-agree-on-its-time-to-stop-misusing-p-values/; https://www.methodspace.com/primer-p-hacking/. A wonderful cartoon perfectly illustrates p-hacking: https://www.explainxkcd.com/wiki/index.php/882:_Significant

[14] An opinion which could not meet peer review standards may be good enough for a jury. *Wendell v. GlaxoSmithKline LLC,* 858 F.3d 1227, 1235–36 (9th Cir. 2017).

2. Monsanto's Motion

a. General Causation

Monsanto seeks an order prohibiting Drs. Aaron Blair, Chadi Nabhan, Alfred Neugut, Christopher Portier, Beate Ritz, Matthew Ross, and Dennis Weisenburger from testifying at trial regarding any opinion that glyphosate can cause any type of NHL in humans. Monsanto Proposed Order, 1. Monsanto separates the general causation issues into four categories: (1) Epidemiology; (2) Toxicology; (3) Genotoxicity/Mechanism; and (4) Applicability of the Bradford Hill criteria.

i. Epidemiology

Monsanto argues that all opinions of Drs. Ritz and Neugut and the epidemiology portions of the opinions of Drs. Weisenburger, Nabhan, Portier, Benbrook, and Sawyer should be excluded because: (1) Johnson's experts agree that the epidemiology does not establish a causal relationship; (2) Attacks on the Agricultural Health Study (AHS) (2018) do not provide a basis for affirmative claims made by Johnson's experts; (3) Attacks on the AHS are unavailing as a matter of fact; and (4) The studies on which Johnson's experts rely do not reliably support a causation opinion and, relatedly, Johnson's experts cannot rule out the possibility of chance or the impact of confounding factors. Motion, 5-11.

In opposition, Johnson contends (1) Numerous individual studies[15] and meta-analyses,[16] on which experts may reasonably rely, demonstrate a positive association between glyphosate exposure and NHL; (2) Epidemiological studies need not control for all other pesticide exposure because pesticide exposure is only meaningful if the pesticide could cause NHL; (3) Monsanto

[15] Johnson cites McDuffie (2001), Hardell (2002), De Roos (2003), Erickson (2008), and NAPP (2015). Opposition, 9-13.

[16] Opposition, 15 (discussing three meta-analyses).

places too much weight on the AHS; and (4) Johnson's experts take into consideration the full body of scientific evidence in reaching their opinions. Opposition, 7-22.

Monsanto replies that Johnson's experts did not follow a reliable methodology because they cherry-picked unreliable studies that would support their conclusions while ignoring studies that would undermine their conclusions. Reply, 4. Specifically Monsanto argues (1) No epidemiology study shows a statistically significant relative risk of 2.0 or greater when properly adjusted, meaning when adjusted for confounders that have not been taken into account; (2) The studies Johnson cites are unreliable because they do not contain adjusted risk ratios that are controlled for other pesticides and, if they are adjusted, there is no statistically significant association between glyphosate-based herbicides and NHL; (3) The studies Johnson discussed are biased because, at least, some contain involved different latency periods; (4) The meta-analyses are unreliable because they do not include the AHS; and (5) Johnson's experts improperly dismissed the AHS. Reply, 4-9.

Whether the epidemiological opinions are admissible turns on whether "there is support in the scientific literature for [the] expert opinion" and the opinion adheres "to standards applicable to [the experts'] field of expertise." *Davis v. Honeywell Intern. Inc.*, 245 Cal.App.4th 477, 492 (2016).

Preliminarily Monsanto challenges any epidemiology opinion that is not based on a study that shows a statistically significant relative risk of 2.0 or greater. *Cooper v. Takeda Pharmaceuticals America, Inc.*, 239 Cal.App.4th 555 (2015) adopted the reasoning of a Ninth Circuit opinion applying California law, stating that epidemiological studies are admissible to prove that a product was more likely than not the cause of a person's disease only if the relative risk is greater than 2.0. *Cooper*, 239 Cal.App.4th at 593. (The relative risk factor of 2.0 implies

a 50% chance that a specific person's disease was caused by the product.) So *Cooper* held that an expert opinion that the defendant's product was more probably than not the cause of the plaintiff's injury was admissible if based on epidemiological studies showing a relative risk factor of greater than 2.0 and ruled out other possible causes. *Id.*

But in *Cooper* the expert based a *specific* causation opinion on epidemiological studies. Here, Monsanto argues in the context of *general* causation. Johnson's experts discuss epidemiological studies just as one factor in their opinion that glyphosate-based herbicides cause NHL. Motion, 6 (arguing that Johnson's experts concede that epidemiology does not alone establish causality). *Cooper* does not mandate exclusion of these opinions for this purpose even if none of the studies shows a relative risk of greater than 2.0. Instead, the focus should remain on whether the epidemiological opinions offered by Johnson's experts have support in the scientific literature and adhere to standards applicable to epidemiological experts.

Monsanto focuses on Drs. Neugut and Ritz, basing this decision on its assertion that the remaining experts apply the same methodology but have less epidemiology experience. Motion, 5-6 n.14. Drs. Neugut and Ritz offer the ultimate conclusion that, to a reasonable degree of scientific certainty, glyphosate causes NHL and that glyphosate based formulations cause NHL. Hoke Decl., Ex. 8 at 25 (Dr. Ritz), Ex. 11 at 23 (Dr. Neugut).[17] Neither opinion is based solely on epidemiological evidence. Hoke Decl., Exs. 8, 11.

[17] (1) Dr. Portier opined that there were six epidemiological studies that showed a modest increase in the odds ratio and relative risk for NHL amongst those who were exposed to glyphosate, which collectively amounted to a strong association between glyphosate exposure and NHL and were a factor in his broader causality analysis. Hoke Decl., Ex. 13 at 18, 75, Ex. 13A at 18-19, 76. Dr. Portier subsequently explained why the AHS does not change his opinion. Hoke Decl., Ex. 15. (2) Dr. Nabhan discussed several epidemiological studies and incorporated a small association between glyphosate exposure and NHL in his Bradford Hill analysis. Hoke Decl. Ex. 18, 11-16, 19. Dr. Nabhan also supplied supplemental reports criticizing the AHS. Hoke Decl., Exs. 19-20. (3) Dr. Weisenburger discussed the epidemiological studies and considered the association shown in several of the case-control studies in his Bradford Hill analysis. Hoke Decl., Ex 21 at 4-6, 11. Dr. Weisenburger submitted a supplemental report criticizing the AHS. Hoke Decl., Ex. 22. (4) Although Matthew Ross is listed in the proposed order, Monsanto does not provide evidence of his opinions.

Dr. Neugut too does not base his conclusion solely on that epidemiological evidence. Hoke Decl., Ex. 11 at 11-17. Dr. Ritz did offer a predicate opinion about the epidemiological evidence – Dr. Ritz endorsed the IARC Working Group's Monograph insofar as it conducted a meta-analysis and reported a meta risk-ratio of 1.3. Hoke Decl., Ex. 8 at 16. Dr. Ritz also offered a rebuttal report and a supplemental report in which she responded to Monsanto's experts and criticized the AHS. Hoke Decl., Exs. 9-10.

Johnson's experts do not view epidemiological evidence as dispositive on causation. Monsanto Opening Brief at 6 n.16 (citing evidence). They conceded that confounding and bias may explain the association found in the epidemiological evidence if the epidemiological evidence were viewed in isolation. *Id.*

Monsanto's first attack on Johnson's epidemiology experts is this: when all of the data concerning the association between glyphosate and NHL is considered, there is no association between the two. Motion, 4-5. This attack is based on the AHS study. Monsanto argues that Johnson's experts cannot exclude the AHS from their analysis because it followed a sound methodology and was published in a respected journal. *Id.* at 7.[18]

Monsanto's second attack on Johnson's experts is this: the studies they rely on do not control for confounding factors, such as exposure to other pesticides.[19] Monsanto notes testimony suggesting that there could be a confounding problem (Edwards Decl., Ex. 29 at 90:15-20, 91:23-92:4) and that one of Johnson's experts chose not to rely on data from the NAPP

[18] Monsanto also argues that a plaintiff cannot establish causation through mere criticism of the AHS study. Motion, 7. But that's not Johnson's pitch. His expert reports were submitted before the AHS was published and based their causation opinions on a variety of other factors, including then-extant epidemiological evidence. After publication of the AHS, Johnson's experts articulated reasons why the AHS did not impact their conclusions.

[19] Monsanto argues that a chart in Dr. Ritz's report includes the same data multiple times. Motion, 9-10. While this may lead the casual reader to inflate the number of studies that have shown statistically significant associations between glyphosate and NHL, it does not rebut the fact that *some* studies have shown a statistically significant association between glyphosate and NHL.

study that was controlled for confounders because she questioned the validity of the approach used to control for confounders (Edwards Decl., Ex. 26 at 292:11-293:21, 305:10-306:17).[20]

This is not a suggestion that that there is no support in the scientific literature, but rather an attack on the studies that support the expert opinions. Where the validity, strengths, and weaknesses of studies are subject to scientific interpretation and debate, the trial court may not step in and resolve the debate over the validity of the studies. *Cooper*, 239 Cal.App.4th at 589.[21]

Johnson's epidemiology experts should not be excluded. While Johnson's experts concede the limitations of the epidemiological evidence, there is at least one study that controlled for other pesticides and still found a statistically significant association between glyphosate and NHL. Edwards Reply Decl., Ex. 8 at 22:23-24:6, Ex. 11 at 16:7-17:25 (Dr. Ritz's testimony regarding De Roos (2003); Hoke Decl. Ex. 8 at 19 (discussing De Roos (2003)); Ex. 11 at 14-15 (same). Johnson's experts appreciated the risk the confounders could create an unreliable association between glyphosate exposure and NHL but believed, in light of the studies they reviewed and the other information that they considered, that potential confounders were not the

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[20] In reply, Monsanto launches a third attack pursuant to which it charges Johnson's experts with changing their positions or selecting data on the basis of expediency in making their argument. Reply, 6-8. These misleading arguments are unpersuasive. First, Monsanto asserts that Dr. Ritz admitted to pulling out estimates that make sense for the argument she is trying to make. Reply, 6 (citing Edwards Reply Decl., Ex. 11 at 172:12-15). The cited testimony reflects that Dr. Ritz was limiting her analysis to data in studies that is relevant to the issue that she was considering, nothing more. Second, Monsanto argues that Dr. Weisenburger took the official position that the latency period for glyphosate based herbicides to cause NHL would be 20 years or more. Reply, 6-7 (citing Edwards Reply Decl., Ex. 12. The cited letter reflects that Dr. Weisenburg took the position that "the average latency period for development of NHL due to long-term, low-level exposure to organic solvents is about 20 years. Since exposure to glyphosate would be expected to be long-term, low-level exposure...I would expect the average latency period for glyphosate exposure in relation to potential for NHL to be at the upper end of [the range from 1-25 years], most likely 20 or more years from initial exposure." Third, Monsanto charges Dr. Ritz with flip-flopping on the De Roos (2003) study. Reply, 7 (citing report and testimony). The cited evidence is to the contrary: Dr. Ritz consistently gave significant weight to the De Roos (2003) study and consistently questioned whether it was indeed necessary to control for all of the pesticides for which De Roos controlled. Fourth, Monsanto asserts that Dr. Ritz refused to include the AHS in her meta-analysis because she never relies on summaries. Reply, 8. The testimony cited by Monsanto discloses that Dr. Ritz was simply making the point that a meta-analysis cannot be performed by lumping all of the extant studies into a single analysis without taking their quality into consideration. Edwards Reply Decl., Ex. 13 at 112:18-114:19.

[21] See my discussion above under the caption "The Reliability of Expert Opinion based on Peer Review Studies."

cause of the association. Motion, 6 n.16 (citing evidence), 8:9-9:3. And Monsanto has not identified any pesticides that may, in fact, have confounded the data. Finally, the supplemental expert reports demonstrate that Johnson's experts considered the strengths and weaknesses of the AHS and the strengths and weaknesses of the case control study in reaching their conclusions about epidemiology and causation. *E.g.*, Hoke Decl., Exs. 10, 12, 15. This is what was required of them. *See Cooper*, 239 Cal.App.4th at 589.

ii. Toxicology

Monsanto asserts that Dr. Portier used the same methodology as all of Johnson's toxicology experts and has the most expertise and the most detailed analysis. Motion, 11. Accordingly, Monsanto targets Dr. Portier's analysis and says all the remaining toxicology expert analyses fall with Dr. Portier's analysis. *Id.*

At the outset, Monsanto contends that there are fourteen toxicological studies, all of which are negative – i.e., there is no finding of carcinogenicity. Motion, 13. Monsanto asserts that all regulators that have reviewed the data have concluded that it shows that the animal data does not show evidence of carcinogenicity. *Id.*

Turning to Dr. Portier's methodology, Monsanto argues that Dr. Portier committed the following errors: (1) Dr. Portier analyzed the data that was the basis for statistical analyses of renal tumors in mice that were performed in 1983 and 1985 using a variety of different tests rather than using one methodology and sticking to it, a methodology that leads Monsanto to argue that Dr. Portier selected methods based on the result he wanted; (2) Dr. Portier pooled data from studies performed at different laboratories in different animals by different investigators at different times, a methodology that Monsanto claims is without scientific support, in a manner that suggests his approach was result-oriented because he included some studies in his pooled

analysis for some malignancies but not others; and (3) Dr. Portier recognized the possibility that some statistically significant results may occur by chance alone but did not attempt to control for such "statistical errors." *Id.* at 13-17.

In opposition, Johnson asserts (1) The animal carcinogenicity studies are a proper basis for an expert opinion; (2) Drs. Portier and Jameson reached their opinions prior to being retained; (3) Johnson's experts properly followed established guidelines; (4) All of the tests Dr. Portier performed to analyze the renal tumors in mice are recognized as appropriate tests; (5) Dr. Portier's pooling methodology is scientifically supported and supported by Dr. Portier's experience; and (6) Dr. Portier's analysis demonstrates that he did not perform an analysis with a pre-determined result in mind. Opposition, 22-29.

In reply, Monsanto contends that (1) Johnson does not have expert testimony that contains a reliable methodology for extrapolating animal toxicology data to humans; (2) Dr. Jameson's opinions were not disclosed and cannot be considered; and (3) Dr. Portier's pooling methodology was improper. Reply, 9-11.

At the most basic level, Dr. Portier opined that glyphosate causes cancer in mammals. Hoke Decl., Ex. 13A at 52, 74. To reach this conclusion, Dr. Portier analyzed 20 animal studies, of which he found eight unacceptable for use. Hoke Decl., Ex. 13A at 50, 52; Hoke Decl., Ex. 13A at 19-52.

Dr. Portier's predicate conclusion that glyphosate causes cancer in mammals was one of several predicate conclusions that, when considered together, led Dr. Portier ultimately to conclude that glyphosate probably causes NHL. Hoke Decl., Ex. 13A at 76-78. Dr. Portier considered the conclusion that glyphosate causes cancer in mammals "very strong" evidence that

a causal relationship between glyphosate exposure and NHL was biologically plausible. Hoke Decl., Ex. 13A at 77.

Monsanto seems to challenge Dr. Portier's opinion because he cannot reliably extrapolate animal toxicology data to humans. But Dr. Portier does not directly apply animal toxicology data to humans. Rather, he concludes the fact that, according to his analysis, glyphosate causes cancer in mammals (i.e., rodents) renders it *biologically plausible*, under the Bradford Hill rubric, that glyphosate could cause a specific form of cancer, NHL, in humans. Monsanto does not suggest this is a misapplication of the Bradford Hill criteria.[22] Hoke Decl., Ex. 13A at 76.

This leaves Monsanto's three challenges to Dr. Portier's calculations. First, Monsanto charges Dr. Portier with selecting a statistical test to reach a desired result in his analysis of renal tumors in mice in connection with a 1983 bioassay. Motion, 13-14. Monsanto begins with ambiguous deposition testimony that shows that Dr. Portier verified that the approximate p-value from an Armitage linear trend test, which was an approximate trend test, appeared to be correct. Edwards Decl., Ex. 21 at 47:1-17; Motion, 14. Dr. Portier subsequently used a different test and again achieved a statistically significant result. Edwards Decl., Ex. 35 at Document 5. Thereafter, a commenter criticized Dr. Portier for failing to use an exact trend test. Edwards Decl., Ex. 35 at Document 6. In response, Dr. Portier rebutted the criticism and stood by his analysis, but noted that the p-values would be marginal rather than statistically significant if an exact trend test was used. Edwards Decl., Ex. 35 at Document 7. Dr. Portier did not manipulate his methodology to attain a desired result; he selected a methodology and defended it against criticism from another commentator.[23]

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[22] These criteria are explained below under the caption "Bradford Hill Criteria" at p.20 of this order.
[23] Significantly, Monsanto does not challenge the reliability of the methods that Dr. Portier used to attain a statistically significant result.

Second, Monsanto argues that Dr. Portier's pooling methodology is unsupported in the literature and was executed by including studies only if they would facilitate a statistically significant result. Motion, 15-16. *Id.* Dr. Portier admitted that the scientific literature does not contain methods for the combined analysis of multiple animal cancer bioassays. Hoke Decl., Ex. 13A at 21. Dr. Portier imported a pooling methodology from epidemiology to combine animal carcinogenicity studies by merging the data from the studies for analysis. Hoke Decl., Ex. 13A at 21-22. Dr. Portier acknowledged that there is considerable genetic variability across animal strains over both time and space, but nevertheless decided that pooling was appropriate because it is no different from comparing results across studies. Hoke Decl., Ex. 13A at 51-52. Dr. Portier's testimony indicated that he selected his pools by including the studies that would, when combined, yield statistically significant positive findings. Edwards Decl., Ex. 21 at 210:6-212:15, 214:3-219:23, 236:17-240:1.[24] Dr. Portier's report and deposition testimony do not support the conclusion that it is scientifically acceptable or reliable to pool disparate rodent assays or that the manner in which Dr. Portier conducted pooling was reliable.[25] Accordingly, Dr. Portier's pooling opinions are excluded.

At argument Johnson contended excluding these pooling results does not invalidate his ultimate opinion that glyphosate causes cancer in mammals. See also Hoke Decl., Ex. 14 (responding to criticism from Monsanto's expert). To the extent Dr. Portier can support his ultimate conclusion on the basis of other rationales set forth in his expert reports, his ultimate conclusions are not excluded by this order.

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[24] This appears to be a classic case of cherry picking input to generate putatively statically significant results—sometimes derisively known as "p-hacking". See above n. 13.

[25] Johnson cites the December 2016 Scientific Advisory Panel as an endorsement of Dr. Portier's pooling analysis. Hoke Decl., Ex. 42. It is true that some Panel members recommended adopting a pooled analysis approach for combining multiple studies. Hoke Decl., Ex. 42 at 59. But they stated that such adoption would require the development of full guidelines on how to conduct and evaluate these analyses. Hoke Decl., Ex. 42 at 59. This does not endorse Dr. Portier's approach.

Third, Monsanto argues that Dr. Portier failed to adequately control for the fact that some statistically significant results will appear in the rodent studies by chance. Motion, 16-17. The argument is unclear and is not revisited in reply. Motion, 16-17. This is not a basis for exclusion.[26]

While Monsanto says the remaining experts will fall with Dr. Portier, it's not obvious the other experts relied on Dr. Portier's pooling analysis. Hoke Decl., Ex. 8 at 24-25; Ex. 11 at 17-18, Ex. 18 at 6-10, 20. Johnson's other experts opinions on this subject do not fall except to the extent they predicate their opinions on the pooling analysis.

Dr. Jameson is referenced in the opposition papers but may not have been disclosed as an expert in this case. Edwards Decl., Exs. 3, 5. For the purposes of this motion, it is enough to note that Dr. Jameson was not the subject of the pending motion. Reply, 10 (arguing, in response to references to Dr. Jameson in the opposition papers, that Dr. Jameson's testimony cannot be considered at trial or on summary judgment because he was not disclosed as an expert).

iii. Genotoxicity/Mechanism

Monsanto asserts that genotoxicity – i.e., whether a chemical causes DNA damage or other cellular changes – cannot alone establish carcinogenicity. Motion, 18. Monsanto also argues that the regulators uniformly view the tests that have been performed on glyphosate as not supporting a finding of carcinogenicity.

Monsanto asserts that genotoxicity or mechanistic data have only been found to be relevant under *Daubert* where scientifically sound human data is unavailable. *Id.* at 19.

[26] Because statistical significance is a measure of the odds that the results of a study are the result of chance, and commonly the significance level is set at .05, there is always some chance (1 out of 20) in any "statistically significant" set of results that they are in fact the result of chance. E.g. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 251 ff. (3rd ed. 2011).

Monsanto argues that the genotoxicity or mechanistic data are inadmissible here because (1) Dr. Portier improperly counted the studies showing positive and negative results; (2) In vitro studies cannot be extrapolated to this case; and (3) The Bolognesi (2009) and Paz-y-Mino (2007) studies on which Johnson's experts rely are methodologically flawed and, in any event, do not support the experts' conclusions. *Id.* at 19-20.

Plaintiff retorts (1) The Bolognesi and Paz-y-Mino studies are reliable and Dr. Portier properly relied on them; and (2) Dr. Portier reliably analyzed each of the genotoxicity or mechanistic studies, he did not "add up" positive studies. Opposition, 29-32. Monsanto does not address this topic in reply.

Monsanto does not specify which opinions it challenges. As a general matter, Monsanto suggests that it objects to any consideration of genotoxicity or mechanism testimony. This approach is unsupported by Monsanto's citations and conflicts with the Bradford Hill criteria, which require consideration of biological plausibility. Hoke Decl., Ex. 11 at 22 (considering biological mechanisms – genotoxicity and oxidative stress – adduced for glyphosate's mode of action in evaluating biological plausibility under Bradford Hill), Ex. 13A at 52-74.

Monsanto's concern that in vitro studies cannot be extrapolated to humans does not justify exclusion of the opinions in this case. The experts do not consider the genotoxicity studies to be direct evidence of causality, but instead consider it as a factor supporting *biological plausibility* under the Bradford Hill rubric. Hoke Decl., Ex. 11 at 22, Ex. 13A at 52-74. This seems to be supported by the scientific literature. *In re Zicam Cold Remedy Marketing, Sales Practices, and Products Liability Litigation*, 2011 WL 798898, at *9-*10 (D. Ariz. Feb. 24, 2011) (in vitro study was reliable so its results were admissible although it was not direct evidence of toxicity to humans, expert would be required to explain extrapolation theory).

Monsanto's argument that Dr. Portier simply added up the positive and negative studies does not support exclusion. Dr. Portier explained that the table was a summary of the studies that did not address the subtlety needed to interpret any one study, but instead was intended to enable the reader to see the experimental data in a single glance. Hoke Decl., Ex. 13A at 65-66. The inclusion of a summary table does not render the analysis flawed.

Finally, Monsanto's challenge to the Bolognesi and Paz-y-Mino studies are unpersuasive. Aside from Monsanto's facial challenge to the methodologies in those studies,[27] Monsanto relies on subsequent statements by authors that allegedly undercut the study findings. Motion, 20.[28] Specifically, Monsanto quotes a newspaper article, which in turn quotes a co-author of the Bolognesi study for the proposition that there was no difference in the micronuclei between exposed individuals and control individuals. *Id.*; Edwards Decl., Ex. 47.[29] Johnson responds by citing studies in which the primary Bolognesi author describes the study differently, albeit while expressing reservations about the conclusions that can be drawn from the study. Hoke Decl., Exs. 72-73. In addition, Monsanto cites a second study conducted by Paz-y-Mino that evaluated a separate instance of glyphosate spraying and found that the study population did not present significant chromosomal and DNA alterations. Edwards Decl., Ex. 48.

There is no argument that Johnson's experts afforded undue weight to these studies. *Compare* Hoke Decl., Ex. 13A at 55-56 (discussing all three studies). Nor is there any apparent

[27] Monsanto cites the studies themselves as evidence that they are methodologically flawed. Motion, 20 n.44.
[28] Monsanto cites *Arias v. DynCorp*, 928 F.Supp.2d 10, 24-25 (D.D.C. 2013) as excluding an expert NHL causation opinion based on the Bolognesi and Paz-y-Mino studies. Motion, 20. But *Arias* did not discuss the Bolognesi and Paz-y-Mino studies but instead excluded an expert opinion that failed to explain the basis for reliance on certain epidemiological studies vis-à-vis other epidemiological studies. *Arias*, 928 F.Supp.2d at 24-25.
[29] This quotation is in tension with Monsanto's simultaneous reliance on the statement in the Bolognesi study that there was a "low" genotoxic risk potentially associated with exposure to GBH. Motion, 20 (citing Edwards Decl., Ex. 45 at 986).

reason why Johnson's experts cannot offer opinions on these three published studies. The motion to exclude any testimony on these studies is denied.[30]

iv. Bradford Hill Criteria

Johnson's experts applied the Bradford Hill criteria. Motion, 21. Monsanto contends that this was improper because the Bradford Hill criteria can only be applied when there is epidemiology that demonstrates a "specific, clear-cut association between the two variables under examination" – i.e., an association that is positive and "strongly statistically significant" after confounders have been eliminated. Monsanto argues that Johnson's experts cannot use the Bradford Hill criteria here because (i) the epidemiological data does not demonstrate a sufficient association and (ii) the studies on which they rely cannot establish temporality or strength and because the AHS found no evidence of dose response.

The parties appear to agree generally that the Bradford Hill criteria and its nine factors or viewpoints are an acceptable means of evaluating causality if done correctly. Motion, 21-22. "None of [the] nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*." Edwards Decl., Ex. 49 at 11. Scientists apply the Bradford Hill criteria once an association has been found between an exposure to an agent and development of a disease. *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation*, 174 F.Supp.3d 911, 916 (D.S.C. 2016) (*Lipitor*). The nine factors are (1) strength of the association, (2) replication of the findings, (3) specificity of the association, (4) temporal relationship, (5) dose-response relationship (aka biological gradient), (6) biological plausibility, (7) consistency with other

[30] Monsanto also submits evidence to support the conclusion that glyphosate is not, in fact, genotoxic. Edwards Decl., Ex. 1 at 135 (containing only a conclusion without analysis), Ex. 43 at 10 (conclusion with limited analysis), Ex. 44 at 132 (concluding that the studies showing lack of genotoxic potential outweigh the studies showing positive results). In light of the other evidence in the record, this evidence at most indicates that there is a scientific dispute.

knowledge (aka coherence), (8) consideration of alternative explanations, and (9) cessation of exposure. *Id.* "Whether an established association is causal is a matter of scientific judgment, and scientists appropriately employing this method may come to different judgments about whether a causal inference is appropriate." *Id.* (internal quotations omitted).

As I have noted, there is some scientific evidence of an association between glyphosate exposure and NHL. To the extent Monsanto's motion to exclude any Bradford Hill opinions is based on the absence of an association, it is denied. *Compare Lipitor*, 174 F.Supp.3d at 924-25 (noting that Bradford Hill criteria only apply if there is an association that has been established through studies with statistically significant results); *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F.Supp.2d 434, 461 (W.D. Pa. 2003); *Dunn v. Sandoz Pharmaceuticals Corp.*, 275 F.Supp.2d 672, 679-80 (M.D.N.C. 2003); *Hollander v. Sandoz Pharmaceuticals Corp.*, 95 F.Supp.2d 1230, 1237 (W.D. Okla. 2000) (rejecting Bradford Hill analysis premised on case reports because those reports are not a scientific basis for a conclusion regarding causation).

Monsanto also makes specific challenges to the application of the Bradford Hill criteria.

With respect to the strength criterion, the cited secondary source does not appear to address the application of the Bradford Hill criterion but rather the strength of epidemiological evidence necessary to independently prove causation. Edwards Decl., Ex. 50 at 612 n.193. This does not suggest that Johnson's experts have misapplied the criterion or that all reasonable scientists would agree as to its application here. *See, e.g.*, Hoke Decl., Ex. 8 at 23 (finding a weak to moderate association), Ex. 11 at 22 (reciting the strength of the association in mathematical terms); Edwards Decl., Ex. 49 at 11.

With respect to the temporality criterion, it is at least true that case-control studies evaluate whether the glyphosate exposure preceded the contraction of NHL. *See, e.g.*, Hoke

Decl., Ex. 11 at 21, Ex. 13A at 11. Monsanto's criticism does not suggest a misapplication of this factor.

With respect to dose response, the absence of dose response in AHS does not foreclose the existence of other data supporting a positive dose response finding. *E.g.*, Hoke Decl., Ex. 11 at 22 (noting two studies that "suggest" there is a dose response relationship). And causality can be established without a positive or strong dose response finding. Edwards Decl., Ex. 49 at 11.

With respect to consistency, Monsanto's conclusory assertion does not establish that Johnson's experts erred in their evaluation of consistency. *See, e.g.*, Hoke Decl., Ex. 8 at 24 (discussing consistency factor), Ex. 11 at 22 (same).

For these reasons the motion to exclude the Bradford Hill analyses is denied.

b. Specific Causation

Monsanto seeks an order prohibiting Drs. Chadi Nabhan and William Sawyer from testifying at trial regarding any opinion that exposure to glyphosate caused Johnson to develop mycosis fungoides, including Dr. Sawyer's exposure analysis.

i. Dr. Nabhan

First, Monsanto argues that Dr. Nabhan improperly extrapolated from literature concerning NHL generally to mycosis fungoides specifically. Motion, 22-23. Second, Monsanto contends that Dr. Nabhan improperly based his opinion on the fact that Johnson was exposed to glyphosate before contracting mycosis fungoides to infer causation without ruling out other causes—he did not provide a proper methodology to "rule in" and "rule out" various risk factors. Reply, 12-13. Monsanto explains that Dr. Nabhan has no way of evaluating whether glyphosate was a more likely cause than other possible causes, no basis to extrapolate from NHL literature to mycosis fungoides, and has performed no exposure analysis. *Id.* at 13-14.

Dr. Nabhan submitted an expert report and supplemental report in support of general causation. Hoke Decl., Exs. 18-19, 20. Dr. Nabhan adopted his general causation opinions, discussed the history of Johnson's mycosis fungoides (a type of NHL), and discussed the history of Johnson's exposure to glyphosate through Monsanto's products, Hoke Decl., Ex. 20 at 2-9, and concluded that Monsanto's Roundup was a substantial causative factor in the development and progression of Johnson's NHL and that all other medically known causes of the disease had been ruled out based on Johnson's history. Hoke Decl., Ex. 20 at 8-9.

At deposition, Dr. Nabhan testified that there is presently insufficient data to evaluate whether or not glyphosate is associated with each *subtype* of NHL. Edwards Decl., Ex. 22 at 105:17-107:8. Nevertheless, he opined that the data pertaining to NHL generally can be used to draw conclusions about all of the subtypes, including the one at issue here, mycosis fungoides. Edwards Decl., Ex. 22 at 105:23-106:11; Edwards Decl., Ex. 51 at 105:16-107:2. Dr. Nabhan emphasized that the only risk factor in Johnson's record was his occupational exposure to glyphosate compounds. Edwards Decl., Ex. 51 at 138:6-16. Nevertheless, Dr. Nabhan agreed that Johnson "could have" developed mycosis fungoides even if he had never been exposed to glyphosate. Edwards Decl., Ex. 51 at 138:21-25; *see also* Edwards Reply Decl., Ex. 4 at 258:23-259:7 (Dr. Nabhan cannot give a percentage increase in the risk of NHL if an individual is exposed to glyphosate).

Monsanto relies entirely on Dr. Nabhan's own testimony to challenge the admissibility of his specific causation opinion.

First, I reject Monsanto's argument that there is no scientific basis for Dr. Nabhan to rely on studies that apply to NHL generally in the context of mycosis fungoides. There is a scientific basis for Dr. Nabhan's opinion – mycosis fungoides is a subtype of NHL. While Dr. Nabhan

admits uncertainty, his opinion is not mere speculation. His report explicitly lists the alternative known causes of NHL that he ruled out based on his review of Johnson's record. Hoke Decl., Ex. 20 at 8-9. Monsanto has not identified any known causes that Dr. Nabhan failed to consider. While Dr. Nabhan cannot rule out chance, he has a scientific basis to support his conclusion as to specific causation – his general causation opinion with respect to NHL, the fact that mycosis fungoides is a subtype of NHL, the temporal connection between Johnson's exposure to glyphosate and development of mycosis fungoides, and the absence of exposure to other known causes.

The parties have drawn my attention to two cases, *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017) and *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011). In *Wendell*, the Ninth Circuit held the trial court erred in excluding expert testimony that was not supported by epidemiological or animal studies because it improperly ignored the experts' experience, reliance on a variety of literature and studies, review of medical records and history, and performance of a differential diagnosis. *Wendell*, 858 F.3d at 1232-37. Here, Dr. Nabhan has extensive experience as a treating physician to support his conclusions. In *Milward*, the First Circuit held it was improper to treat the lack of statistically significant epidemiological evidence as a crucial flaw where the rarity of the disease and the difficulties of data collection made it difficult to conduct a statistically significant study. *Milward*, 649 F.3d at 24. Dr. Nabhan's unrebutted testimony supports the conclusion that the same conditions apply to mycosis fungoides.

An underlying issue in the parties' debate on specific causation—but not expressly addressed by them—is how to account for idiopathy.[31] Under *Daubert* in federal courts, it can

[31] I.e. a condition occurring for unknown reasons. *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 174 (6th Cir. 2009).

be fatal if an expert fails to explain why a specific plaintiff's disease should not be classified as idiopathic when generally speaking most of its instances are idiopathic. *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1343 (11th Cir. 2010) (expert cannot "explain why potentially unknown, or idiopathic alternative causes were not ruled out"); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1311 (11th Cir. 2014) (failed to consider idiopathic cause); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010) (same). Idiopathy need not be entirely ruled out, but there needs to be an explanation as to why an identified cause is considered likely. E.g., *Wendell,* 858 F.3d at 1235, 1237. Ruling out idiopathy only because another cause is ruled in—when there is no basis to rule it in—isn't admissible expert opinion. *Milward v. Rust-Oleum Corp.* 820 F.3d 469, 476 (1st Cir. 2016).

Thus I turn to the extent to which Dr. Nabhan ruled in the Monsanto product as a cause.

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

Dr. Nabhan's specific causation opinion is not excluded.

ii. Dr. Sawyer

Monsanto argues that Dr. Sawyer's specific causation opinion should be excluded because (1) Dr. Sawyer calculated a "slope factor" by extrapolating numerous rodent studies to humans without justifying his extrapolation; (2) Cancer slope factors should not be applied to reach a causation conclusion in an individual case; (3) Dr. Sawyer engaged in an outcome driven approach; (4) Dr. Sawyer's slope factor is not tailored to this case because it includes exposure to glyphosate beyond occupational exposure; and (5) Dr. Sawyer's slope factor does not support causation because the risk he states was caused by occupational exposure to glyphosate is less than the background risk for African-American males of Johnson's age. Motion, 24-27. Moreover, Monsanto argues that Dr. Sawyer's opinion on Tyvek permeability, which was offered on the basis of an experiment Dr. Sawyer conducted the night before his deposition, should be excluded because it was not timely disclosed and is not reliable. *Id.* at 27-28.

Johnson retorts that (1) Dr. Sawyer extrapolated a slope factor using appropriate scientific methodology to assess whether Johnson's exposure was within the range capable of causing him to contract NHL; (2) Dr. Sawyer relied on dose response data in epidemiology studies, as evaluated by epidemiological experts, to reach his specific causation opinion; and (3) Dr. Sawyer's experiment to determine whether Tyvek is permeable to water is admissible because it was disclosed at deposition and reliably assesses Tyvek's permeability. Opposition, 38-42.

Dr. Sawyer's permeability experiment is excluded. Dr. Sawyer poured water onto Tyvek to assess whether Johnson's testimony that Tyvek is water permeable was true. Hoke Decl., Ex. 68 at 17-18. Determining whether Tyvek is water permeable does not require expertise, so the experiment will not be helpful to the jury. E. C. § 801; Hoke Dec., Ex. 68 at 17-18. However,

this does not preclude Dr. Sawyer from crediting, and relying upon, Johnson's testimony that his Tyvek suit was permeable to both water and Roundup, as Dr. Sawyer did in his expert report. *See* Hoke Decl., Ex. 7 at 162.

Turning to Dr. Sawyer's specific causation opinion, Dr. Sawyer concluded, to a reasonable toxicological certainty, that Johnson's glyphosate exposures induced or significantly contributed to the onset of Johnson's T-cell lymphoma. Hoke Decl., Ex. 7 at 8, 166. Dr. Sawyer's conclusion was based on Johnson's exposure to glyphosate, the absence of other risk factors in his medical history, animal studies pertaining to glyphosate, and human epidemiological studies pertaining to glyphosate. *Id.*

Dr. Sawyer used a cancer slope factor as one element of his analysis. Hoke Decl., Ex. 68 at 11-13. Dr. Sawyer asserts that he derived the slope factor in humans from a rodent study consistent with U.S. EPA guidelines. *See* Hoke Decl., Ex. 7 at 121-22, 127-28, Ex. 68 at 9-11.

Monsanto criticizes Dr. Sawyer's extrapolation from rodent studies to calculate a slope factor applicable to humans. Motion, 24; Reply, 14. Monsanto cites cases for the proposition that experts must establish the validity of any extrapolation from animal studies to humans. *See* Motion, 24; Reply, 14; *Metabolife Intern., Inc. v. Wornick*, 264 F.3d 832, 842-43 (9th Cir. 2001) ("Difficulties with extrapolation might render animal studies unreliable under *Daubert*; however, such a determination must be made on problems inherent to the studies themselves, not a general apprehension at inter-species and inter-dosage extrapolation").

Dr. Sawyer himself seemed to agree that the cancer slope factor did not help analysis of specific causation. Edwards Decl. ¶ 55. Ex 54. Sawyer Depo. at 543:7-14; Hoke Decl., Ex. 68 at 15. As became clear at argument, Dr. Sawyer used software employed by the EPA to determine safe regulatory levels. But that is "[p]articularly problematic… [because r]egulatory standards

are set for purposes far different than determining the preponderance of evidence in a toxic tort case. For example, if regulatory standards are discussed in toxic tort cases to provide a reference point for assessing exposure levels, it must be recognized that there is a great deal of variability in the extent of evidence required to support different regulations." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 665 (3rd ed. 2011). See *id.* at 665-66. Thus Johnson's counsel agreed that the cancer slope opinion be excluded at trial, with the right to raise the issue if Monsanto in some way opens the door to its relevance.

Otherwise, Dr. Sawyer apparently relies on other factors to reach his specific causation opinion, which Monsanto leaves largely unaddressed. For these reasons, assuming Dr. Sawyer is willing to rely on grounds other than the cancer slope factor, his specific causation opinion is not excluded.

c. Corporate Conduct and EPA Regulations

Monsanto seeks an order prohibiting Drs. Charles Benbrook and William Sawyer from testifying at trial regarding any opinion of Monsanto's corporate conduct and prohibiting Dr. Benbrook from testifying regarding any alleged violations of EPA regulations.

i. Dr. Benbrook

Apparently Dr. Benbrook intends to testify that Monsanto should have warned the public about the risk of NHL associated with the use of and exposure to glyphosate and glyphosate-based formulations on the basis of a methodology that consists of reviewing Monsanto emails and memoranda and interpreting those documents. Motion, 28.

Dr. Benbrook's basic opinion is that Monsanto failed to adequately warn about the risk of NHL associated with the use of Roundup and RangerPro beginning in or before 2001. Hoke Decl., Ex. 23 at 5.

Dr. Benbrook has a B.A. in Economics and a Ph.D. in Agricultural Economics. Hoke Decl., Ex. 23 at 31. From 1981-1983, Dr. Benbrook was the Staff Director of the Subcommittee on Department Operations, Research and Foreign Agriculture of the House Committee on Agriculture. Hoke Decl., Ex. 23 at 31. From 1984 to 1990, Dr. Benbrook served as the Executive Director of the Board on Agriculture, a unit of the National Academy of Sciences/National Research Council. Hoke Decl., Ex. 23 at 33. Dr. Benbrook started Benbrook Consulting Services (BCS) in 1990. Hoke Decl., Ex. 23 at 35. Since that time, BCS has carried out several dozen projects involving pesticide use, risks, and regulation for federal and State government agencies, companies, private institutions, and non-governmental organizations. Hoke Decl., Ex. 23 at 35. From 1998-2005, Dr. Benbrook maintained a website that focused on Roundup Ready crops. Hoke Decl., Ex. 23 at 36. Dr. Benbrook has written papers on the impact of genetically engineered crops on pesticide use and trends in the use of glyphosate-based herbicides. Hoke Decl., Ex. 23 at 37-38. In recent years, Dr. Benbrook has taken professorial positions, one of which focused on developing and applying analytical tools to quantify the impact of agricultural technology and farm production systems on agriculture's environmental footprint and public health outcomes. Hoke Decl., Ex. 23 at 38-39. As Johnson notes, Benbrook has previously been approved by a court to testify: "(1) about the general roles of the EPA, the registrant, and the state in the registration process for pesticides; (2) the general regulatory framework set up by FIFRA; (3) the industry standards and the stewardship duty; (4) the factual circumstances surrounding the 1995 changes to the label and the obtaining of the 24(c) label; and (4) their opinions on whether DuPont's conduct satisfied industry standards and any stewardship duty." *Adams v. U.S.*, 2009 WL 1085481, at *3 (D. Idaho Apr. 20, 2009).

Dr. Benbrook's background does not demonstrate much familiarity with the EPA or Monsanto's internal knowledge or regulatory compliance. He does have some experience tracking the rise of glyphosate-based herbicides and some experience with the regulatory regime applicable to herbicides. Based on this experience, Dr. Benbrook may testify as to the general framework of the EPA regulatory decision making process. Hoke Decl., Ex. 23 at 40-44. But he should not testify on other subjects, as follows:

First, Dr. Benbrook may not offer any opinions as to the proper interpretation of documents, such as emails, or to argue that inferences of knowledge or intent can be derived from those documents. Opposition, 45 (stating that Dr. Benbrook is not being offered to provide such opinions); Edwards Decl., Ex. 4 at 9 (my order in other litigation); *see, e.g.*, Hoke Decl., Ex. 23 at ¶¶ 803-833. Dr. Benbrook's opinions about the knowledge and intent of Monsanto and other actors invade the province of the jury and are often speculative. E. C. § 801(a).

Second, Dr. Benbrook may not opine on Monsanto's legal obligations. *Summers v. A.L. Gilbert Co.*, 69 Cal.App.4th 1155, 1178 (1999) (expert may not opine on a question of law); *see, e.g.*, Hoke Decl., Ex. 23 at ¶ 1084.

Third, Dr. Benbrook may not relate case-specific facts asserted in hearsay statements unless they are independently proven by competent evidence or are covered by a hearsay exception. *People v. Sanchez*, 63 Cal.4th 665, 686 (2016); *see, e.g.*, Hoke Decl., Ex. 23 at ¶ 843.

Fourth, Dr. Benbrook may not offer an opinion as to whether the EPA would have approved an amendment to the Roundup label. Dr. Benbrook has no specific expertise pertaining to the EPA's approval of amended labels. *See* Hoke Decl., Ex. 23 at ¶ 61.

Fifth, while Dr. Benbrook might have experience regarding industry standards and stewardship obligations, at argument Johnson agreed these were irrelevant.

Sixth, Dr. Benbrook may not testify Monsanto misled the EPA. He brings no relevant expertise to the table on that issue.

ii. Dr. Sawyer

The only opinion specifically identified in the moving papers is Dr. Sawyer's opinion that the EPA applied a unique approach for glyphosate only, that was inconsistent with established methodology, guidelines, and procedures. Edwards Decl., Ec. 56 at 96-97; *see also* Motion, 40 (stating, without citation, that much of Dr. Sawyer's report copies texts from Monsanto's emails and offers personal opinions about those emails). As to the opinion identified in the moving papers, Dr. Sawyer's CV does not demonstrate an expertise in EPA regulations. *See* Hoke Decl., Ex. 7 at Appendix B. Dr. Sawyer is precluded from offering the opinion that the EPA departed from its regulations.

As to Dr. Sawyer's specific opinions with respect to the impact of non-compliance with the ethical obligations owed by toxicologists, Monsanto has not demonstrated that Dr. Sawyer disclaimed any such opinions. *See* Edwards Decl., Ex. 30 at 46:14-18 (Dr. Sawyer testified that he is neither an "ethicist" nor an expert on "corporate ethics"). Nor has Monsanto supplied a record sufficient to identify the opinions it challenges. While on the bases presented I do not exclude Dr. Sawyer's opinions concerning non-compliance with ethical obligations owed by toxicologists, these may be irrelevant for the same reasons Johnson agreed that Dr. Benbrook's opinions on industry standards and stewardship obligations are irrelevant.[32]

d. Damages

Monsanto seeks an order prohibiting James Mills from testifying with an opinion about either (1) Johnson's future loss of income or (2) punitive damages based on the income of Monsanto's CEO.

[32] The relevancy issue is reserved for the trial judge.

i. Loss of Income

Mills calculated Johnson's lost income on an annual basis from the year 2016 through the end of his life expectancy, less two years, rather than cutting off damages at an earlier retirement age such as 67, in response to a request from counsel. Hoke Decl., Ex. 24; Edwards Decl., Ex. 66 at 41:14-43:13.

Monsanto argues that Mills' opinion should be excluded because he based his opinions on counsel's request to assume that Johnson would work until 75 and did not conduct his own analysis of when Johnson was likely to stop working.

First, Monsanto has not offered any basis to exclude Mills' opinion that Johnson suffered $52,878 per year in damages for each year that he would have continued his employment as a pest manager at the Benicia Unified School District.

Second, Monsanto's argument that Mills should be barred from adding up the lost income to present a total lost income figure that includes wages through the year 2046 presents nothing more than the issue of whether there is other evidence to support that cut-off date. If (and only if) Johnson introduce evidence (or the trial judge is satisfied by an offer of proof) that he would have continued in his present employment until 2046, then Mills may use that as a predicate for his opinion.

ii. Punitive Damages

At issue is the compensation paid to Monsanto's chairman and CEO, Hugh Grant. This, says, Mills, is relevant to the financial condition of the company. Edwards Decl., Ex. 66 at 78:11-18; Hoke Decl., Ex. 82. Monsanto seeks to preclude Mills from citing Grant's compensation in support of an opinion on punitive damages. Monsanto does not now move to exclude Mills' entire punitive damages opinion. Reply, 23.

Monsanto does not dispute that the figure is relevant to Monsanto's financial capacity. But on reply Monsanto argues that the testimony will be unduly prejudicial. Reply, 23. The argument was not raised in the moving papers and is not treated here; as with other Evidence Code § 352 issues, it is reserved for the trial judge. This order does not exclude the evidence.

3. Johnson's Motion

a. General Causation

Johnson seeks an order excluding the opinions of epidemiologists Drs. Lorelei Mucci and Jennifer Rider. Hoke Decl., Exs. C at 1-2, D at 3-5.

In short, Dr. Rider discussed the epidemiological studies regarding glyphosate and concluded that "there is insufficient epidemiologic evidence to make a scientific conclusion that glyphosate-based herbicides are a cause of NHL" or that "the epidemiologic evidence does not provide a basis sufficient to opine that glyphosate-based herbicides are causally related to NHL." *See id.*, Ex. C at 3-4, 21-45, 47. Dr. Rider opines it is inappropriate to apply the Bradford Hill criteria to synthesize study results to evaluate whether a causal relationship exists between glyphosate and NHL. The reason for this opinion is that underlying studies may have been subject to confounding or systematic bias. *Id.*, Ex. C. at 43-44.

Similarly, Dr. Mucci discussed the epidemiology of NHL, discussed epidemiological studies regarding glyphosate, and concluded, "to a reasonable degree of scientific certainty, that the epidemiological evidence does not provide a scientific basis to support a causal relationship between exposure to glyphosate-based herbicides and the risk of NHL." *See id.*, Ex. D at 5-8, 29-60, 72. Dr. Mucci mentions the Bradford Hill criteria, but does not apply them. *See id.*, Ex. D at 26.

Johnson appears to suggest that these two witnesses cannot offer these opinions because they did not do a Bradford Hill analysis to evaluate biological plausibility, by which Johnson means they did not consider the totality of the evidence – e.g., animal and mechanistic data – before offering their opinions. Motion, 5-8. Johnson appears to be arguing that Drs. Mucci and Rider cannot offer an ultimate opinion on the question of whether glyphosate-based herbicides cause NHL without considering the Bradford Hill criteria, including non-epidemiological evidence. Reply, 9:17-18 (must consider Bradford Hill criteria before "making any conclusions about causality").

Drs. Mucci's and Rider's opinions bear on the conclusion that the *epidemiological evidence* does not by provide a sufficient basis to conclude that glyphosate-based herbicides cause NHL, stopping short of offering an opinion on the distinct issue whether glyphosate-based herbicides cause NHL. Hoke Decl., Exs. C at 47, D at 6, 72. Dr. Rider does, in one instance, state her conclusion in a way that is amenable to the interpretation that the epidemiological evidence precludes the conclusion that there is a causal relationship. *id.*, Ex. C at 4. But this does not appear to be Dr. Rider's proffered opinion.[33]

The motion is denied.

b. Specific Causation; Mitigation

i. Alternative Causes of Mycosis Fungoides

Dr. Kuzel stated that alcohol and sunlight were the only two environmental factors to which Johnson was exposed with a positive association with mycosis fungoides. Hoke Decl., Ex. A at 5-6. Johnson argues that it is improper for Dr. Kuzel to reference possible alternative causes of mycosis fungoides unless he holds the opinion, to a reasonable degree of medical

[33] In reply, Johnson criticizes Dr. Mucci's meta-analysis for the first time. Reply, 10. I ignore this argument, made in passing, because it was not raised in the moving papers.

probability, that these alternative causes actually contributed to or increased Johnson's chance of contracting mycosis fungoides. Motion, 3. Monsanto responds that pointing to alternative causes for which there is stronger evidence of an association will undermine the credibility of Johnson's evidence of causation. Opposition, 2.

Johnson does not dispute that Dr. Kuzel's opinions are based on matter on which he may rely and within the area of his expertise. Motion, 3. Rather, Johnson argues that the inferences that a jury may draw from these facts – i.e., that the other factors were more likely to cause Johnson to contract NHL than glyphosate-based herbicides – are speculative. *Id.* Johnson invokes *Cooper v. Takeda Pharmaceuticals America, Inc.*, 239 Cal.App.4th 555, 586 (2015). The court there concluded that "it was entirely speculative for Takeda to assert that other known risk factors *could have* played a role where it presented no *substantial evidence* to support such notions." *Id.* at 586.

This case is not *Cooper*. Here, Johnson is objecting to a foundational piece of evidence because it could in conjunction with other evidence support an argument that other factors could have contributed to Johnson's contraction of mycosis fungoides. Hoke Decl., Ex. A at 5-6 (stating that alcohol and sunlight exposure have a positive association with mycosis fungoides). Dr. Kuzel may offer his opinion.

ii. Latency

Dr. Kuzel opined that the latency period between Johnson's first exposure to glyphosate-based herbicides and the appearance of skin abnormalities ultimately recognized as a symptom of mycosis fungoides was too brief for the glyphosate-based herbicides to have caused Johnson's mycosis fungoides. Hoke Decl., Ex. A at 6. Dr. Kuzel based his opinion on the fact that "the most likely timeframe for the relevant exposure would be many years or even decades prior to its

clinical manifestation." *Id.* Dr. Kuzel also explained that a 1 cm. mass contains about one billion cells, and that it would likely take multiple years to go from single cells to hundreds of millions. *Id.* At deposition, Dr. Kuzel testified that he has "no comment about latency period in specifics of glyphosate and non-Hodgkin's lymphoma. I have specifics about latency in general," explaining that this was because "there is no link to glyphosate in non-Hodgkin's lymphoma so there is no way to calculate what the latency period would be" so it is "hard to speculate on latency periods. But latency periods for carcinogens are in general long, years." *Id.*, Ex. B at 105:18-24, 139:21-140:20. Dr. Kuzel did state that he would not consider it possible that glyphosate caused mycosis fungoides unless, in the absence of a fairly prolonged exposure, the exposure had been five to ten years prior. Edwards Decl., Ex. 15 at 145:2-13.

Johnson argues that Dr. Kuzel's latency opinions should be excluded because he did not employ any methodology to reach them. Motion, 3-4. In opposition, Monsanto focuses on testimony from Johnson's experts that it views as consistent with Dr. Kuzel's latency opinions and his discussion of the amount of time it takes for tumors to grow. Opposition, 3-4.

Dr. Kuzel's deposition testimony reveals that his opinion on latency periods relating to *Johnson's* specific mycosis fungoides is speculative, and it is excluded on that basis. Dr. Kuzel himself states that it is "hard to speculate on latency periods" and offers nothing to support his opinion except generalities about cell reproduction. *Sargon*, 55 Cal.4th at 771. But Dr. Kuzel does have sufficient expertise to discuss latency generally.

iii. Noncompliance with Treatment Recommendations

Dr. Kuzel opines that Johnson's condition "may have been exacerbated by his inconsistent compliance with and refusal of some treatments." Hoke Decl., Ex. A at 5. At deposition, Dr. Kuzel testified that it is impossible for him to know whether Johnson's condition

was exacerbated because he cannot observe what would have happened if Johnson had received the treatments he missed. *Id.*, Ex. B at 159:9-161:16. Dr. Kuzel also testified that a question about one specific missed treatment would be better directed to the treating physician. *Id.*, Ex. B at 160:22-161:12.

As Monsanto aptly describes Johnson's motion, "Because Dr. Kuzel could not say for sure whether noncompliance hurt Plaintiff, Plaintiff now moves to prevent him from saying that it may have." Opposition, 4-5.

The argument here is similar to Johnson's implicit position as to Dr. Kuzel's opinion as to other factors associated with mycosis fungoides. As was the case there, the motion to exclude Dr. Kuzel's opinion is denied. Dr. Kuzel's opinion is based on subject matter within his expertise.

c. Benefits of Glyphosate

Johnson seeks an order excluding the opinion of Dr. Kassim Al-Khatib. Proposed Order, 1. Johnson's motion is based solely on relevance and duplicative of a motion in limine. Motion, 8; Opposition, 7-8. The pertinent motion in limine was denied. *See* April 3, 2018 Order, 3. In Johnson's reply brief, which followed denial of the motion in limine, Johnson made no mention of Dr. Al-Khatib's opinion. Reply, 10 (requesting only exclusion of opinions of Drs. Kuzel, Mucci, and Rider). For the reasons alluded to in my order denying the motion in limine, some portions of Dr. Al-Khatib's opinion may be relevant. April 3, 2018 Order, 3:10-15. Whether or not the request has been abandoned, the motion to exclude Dr. Al-Khatib's opinion as irrelevant is denied.

III. Motions for Summary Judgment or Summary Adjudication

Monsanto moves for summary judgment on the basis of its motion to exclude Johnson's medical causation experts: if the experts are excluded, Johnson will be left without evidence to satisfy his burden of proving medical causation. Monsanto Motion, 6.

Monsanto also moves for summary judgment on the ground that all of Johnson's claims are preempted by federal law. Third, Monsanto moves for summary adjudication of Johnson's claim for punitive damages on the ground that Johnson cannot present any evidence to satisfy his burden of proof.

Johnson moves for summary adjudication of Monsanto's sixth and seventh affirmative defenses, which address preemption based on the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and continuing EPA approval, respectively.

a. Causation

Monsanto's motion for summary judgment based on causation turns on the admissibility of Johnson's experts. As discussed above, most of the opinions of Johnson's causation experts are admissible. These suffice as evidence of both general and specific causation. The motion for summary judgment on the basis of causation is denied.

b. Preemption

1. Express Preemption of Failure to Warn Claims[34]

Under FIFRA, a "State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter. ... Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(a)-(b).

[34] In reply, Monsanto seems to abandon this express preemption argument.

State law is preempted by FIFRA if (1) the state law must be a requirement "for labeling or packaging," rules governing the design of a product are not preempted; and (2) the state law must impose a labeling or packaging requirement that is "in addition to or different from those required under this subchapter." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005); *Mirzaie v. Monsanto Co.*, 2016 WL 146421, at *2 (C.D. Cal. Jan. 12, 2016) (holding that suit seeking injunction to require Monsanto to change its Roundup label was preempted). A state-law labeling requirement is not preempted if it equivalent to, and fully consistent with, FIFRA's misbranding provisions. *Bates*, 544 U.S. at 447; *Hardeman v. Monsanto Co.*, 216 F.Supp.3d 1037, 1038 (N.D. Cal. 2016).

Monsanto argues that 7 U.S.C. § 136v preempts any claim on the basis that Monsanto improperly failed to include a cancer warning on its label. Motion, 11. To reach that conclusion, Monsanto contends: (1) The EPA approved Monsanto's label without a cancer warning; (2) After the EPA approved Monsanto's label, Monsanto was required to use the EPA-approved label; and (3) A state law that requires a cancer warning on Monsanto's label would, in this context, impose a requirement that is in addition to or different from the requirements imposed by FIFRA. *Id.* at 10-12.

Under FIFRA, a pesticide is misbranded if "the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment[.]" 7 U.S.C. § 136(q)(1)(G). California law requires a manufacturer to warn either of any risk that is known or knowable (in strict liability), or at least those risks that a reasonably prudent manufacturer would have known or warned about (in negligence). *Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89, 101-02 (2008). California law is no broader than FIFRA. *Hardeman*, 216

F.Supp.3d at 1038. Indeed, Monsanto offers nothing to rebut the argument that a carcinogenic pesticide is subject to a misbranding under FIFRA if it is sold without labeling that alerts users to its carcinogenic properties.

Substantively, Monsanto's express preemption argument depends on the premise that Monsanto is immune from FIFRA liability so long as it uses a label that has been approved by the EPA or is otherwise consistent with the EPA's factual findings. That's not true. *Bates*, 544 U.S. at 434-35, 448, 451-53 (in an action where the pesticide had been approved by the EPA, state law claims would be allowed to go forward if it was determined, on remand, that the state law at issue was parallel to FIFRA); *Hardeman*, 216 F.Supp.3d at 1038-39; 7 U.S.C. § 136a(f)(2); *Carias v. Monsanto Co.*, 2016 WL 6803780, at *2-*7 (E.D.N.Y. Sept. 30, 2016); *Hernandez v. Monsanto Co.*, 2016 WL 6822311, at *8 (C.D. Cal. July 12, 2016) ("if the EPA's registration decision is not preemptive, it follows that the factual findings on which it relied in making that decision are also not preemptive").

2. **Conflict Preemption of Failure to Warn Claims**

Monsanto argues that *Wyeth v. Levine*, 555 U.S. 555 (2009) and its progeny give rise to the rule that warnings-based claims are impliedly preempted when the evidence shows that the federal regulatory agency considered the safety risk at issue in the lawsuit but nevertheless rejected concerns about the risk. Motion, 7. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017) (where, in rejecting citizen petition, FDA analyzed claims and data virtually identical to that submitted by plaintiffs, FDA's denial constituted clear evidence that the FDA would not have approved the plaintiffs' desired warning). *Wyeth* and its progeny do not apply here.

Wyeth noted that the FDCA did not have any express preemption provision applicable to prescription drugs, but it did have a savings clause indicating that a provision of state law would only be invalidated upon a direct and positive conflict with the FDCA. *Id.* at 567. Accordingly, *Wyeth* conducted a conflict preemption analysis. *See id.* at 568-73. Conflict preemption involves a two-step process of ascertaining the construction of the federal and state laws and then determining if they are in conflict. *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981). In *Wyeth*, the Court rejected Wyeth's argument that it was impossible to comply with both a state law that would have required Wyeth to strengthen its label and FDA regulations regarding updating prescription drug labeling in the absence of clear evidence that the FDA would not have approved the modified label pursuant to regulatory channels available to Wyeth. *Wyeth*, 555 U.S. at 568-73; *see also, e.g., Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017) (FDA's denial of citizen petition raising same issues posed by plaintiffs constituted clear evidence under *Wyeth*).

A fundamental premise of *Wyeth* and its progeny is that the state cannot outlaw the sale of a prescription drug that has been approved by the FDA. Put differently, the fact that a prescription drug manufacturer could avoid liability under both state law and federal law by refraining from selling the product within a state is irrelevant to FDCA preemption. *See, e.g., Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 488 (2013) (*Bartlett*).

Under FIFRA, on the other hand, Congress has spoken.[35] FIFRA contains an express preemption provision and it is limited to requirements "for labeling or packaging" that are "in addition to or different from those required under [FIFRA]." *Bates*, 544 U.S. at 444; 7 U.S.C. §

[35] Monsanto suggests that FIFRA's express preemption provision and case law interpreting its impact should be ignored in evaluating conflict preemption because express provision does not necessarily mean that conflict preemption is inapplicable. Reply, 6. But "the purpose of Congress is the ultimate touchstone in every pre-emption case," *Wyeth*, 555 U.S. at 565. The express preemption provision is relevant to Congressional intent.

136v(b). For example, the state is expressly permitted to ban a pesticide that is approved by the EPA. *Bates*, 544 U.S. at 446; 7 U.S.C. § 136v(a). Under the express terms of the statute, EPA approval of a pesticide is *not* a defense for the commission of any offense under FIFRA, it is just prima facie evidence that the pesticide and its labeling and packaging are compliant with FIFRA and, accordingly, any state law that imposes labeling requirements consistent with FIFRA is not preempted. *Carias*, 2016 WL 6803780, at *4-*6 (persuasively relying on statute to conclude that EPA approval does not preempt failure to warn claim); 7 U.S.C. § 136a(f)(2).[36]

It does not appear that any court has extended the *Wyeth* line of cases to FIFRA. *Hardeman*, 216 F.Supp.3d at 1038 (noting that EPA's approval of Roundup's label would preempt conflicting state law if it had the force of law under *Wyeth*, but finding no indication that EPA's approval of Roundup's label had the force of law); *Hernandez*, 2016 WL 6822311, at *6-*7; *see also Ansagay v. Dow Agrosciences LLC*, 153 F.Supp.3d 1270, 1283-85 (D. Haw. 2015); *Sheppard v. Monsanto Co.*, 2016 WL 362074, at *6-*9 (D. Haw. June 29, 2016).

3. Preemption of Design Defect Claims

Monsanto argues that Johnson's design defect theories are premised on the assertion that glyphosate is defective. Motion, 14. As a result, Monsanto contends that Johnson's design defect theories would preclude Monsanto from ever selling glyphosate-based products. Monsanto asserts that such a theory is preempted because it would conflict with EPA's approval of Monsanto's glyphosate-based products. Johnson argues that Monsanto's preemption

[36] Monsanto seeks to evade this interpretation of 7 U.S.C. § 136a(f)(2) by citation to *Reckitt Benckiser, Inc. v. Jackson*, 762 F.Supp.2d 34, 45 (D.D.C. 2011). Monsanto Opposition to Johnson's Motion, 10. *Reckitt* held that 7 U.S.C. § 136a(f)(2) does not authorize the EPA to bring an enforcement action against registered products without complying with FIFRA's provisions for canceling a registration. *Reckitt*, 762 F.Supp.2d at 41-42, 45. A subsequent district court opinion persuasively rejected the assertion that *Reckitt* has any bearing on the import of 7 U.S.C. § 136a(f)(2), as it is relied upon for present purposes. *Mendoza v. Monsanto Co.*, 2016 WL 3648966, at *4 n.3 (E.D. Cal. July 8, 2016).

arguments are based solely on FDCA authority that is inapplicable in the FIFRA context. Opposition, 21-22.

Monsanto's conflict preemption argument as to the design defect claims fails for the same reason as its conflict preemption argument as to the failure to warn claims. Monsanto relies on inapposite FDCA authority. *See, e.g., Bartlett*, 570 U.S. at 488. At the same time, Monsanto ignores FIFRA. But the touchstone of the preemption analysis is Congress' intent in enacting FIFRA. *Wyeth*, 555 U.S. at 565. As detailed above, Congress explicitly permitted states to ban products even if they are federally registered. *See Bates*, 544 U.S. at 446; 7 U.S.C. § 136v(a). The United States Supreme Court has stated that the statute does not preempt design defect claims. *Bates*, 544 U.S. at 444. Monsanto cannot ignore Congressional intent by pressing a theory of conflict preemption. Reply, 6. Monsanto's argument that Johnson's design defect claims may, if successful, force Monsanto to stop selling EPA-approved products in California does not demonstrate a conflict between state and federal law. Rather, it describes a situation that is expressly approved by federal law. *Bates*, 544 U.S. at 446; *Ansagay*, 153 F.Supp.3d at 1279-85.

4. Preemption of Claims Based on Misrepresentations to the EPA

Monsanto asserts that any argument that Monsanto made misrepresentations to the EPA are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Motion, 14-15. Monsanto is not entitled to summary adjudication of Johnson's "arguments." C.C.P. § 437c(f)(1). Monsanto's contentions do not dispose of any cause of action. This aspect of Monsanto's motion is denied as procedurally improper.

5. Johnson's Motion for Summary Adjudication of Preemption Defenses

Johnson's motion for summary adjudication of the sixth and seventh affirmative defenses turns on the same preemption arguments raised by Monsanto's preemption motion for summary judgment. Motion, 8-15 (FIFRA does not expressly or impliedly preempt Johnson's claims as a matter of law); Opposition, 2-15. The facts developed by the parties (e.g., Monsanto's evidence pertaining to the EPA's approval of glyphosate-based products and finding to the effect that glyphosate does not pose a carcinogenic risk to humans and the parties dispute as to whether the EPA would have approved a request to modify the labeling, if Monsanto had made such a request) are immaterial to the reasoning above.

Johnson's motions for summary adjudication of the sixth and seventh affirmative defenses are granted.

c. Punitive Damages

Monsanto argues that summary adjudication of the punitive damages claim is appropriate because: (1) EPA determined that glyphosate is not carcinogenic; (2) Monsanto and its scientists have long believed in good faith that glyphosate-based herbicides and glyphosate are safe and do not cause cancer; (3) A recent study supports the conclusion that glyphosate is not carcinogenic; and (4) A recent district court found in the preliminary injunction context, that it would be misleading to warn that Monsanto's glyphosate-based herbicides cause cancer against the current scientific backdrop. Motion, 16-20.

In opposition, Johnson contends that a punitive damages award may be based on Johnson's evidence that Monsanto: (1) Marketed and sold glyphosate-based herbicides without warning consumers of the known risk of contracting NHL; (2) Did not conduct studies recommended by the EPA and its own consultants to evaluate the risks of glyphosate-based

herbicides; (3) Did not evaluate the risks associated with the use of glyphosate in conjunction with surfactants; (4) Marketed products with a surfactant despite knowledge of safer alternatives; (5) Withheld information from the EPA regarding dermal absorption and consultant recommendations; and (6) ghostwrote articles to publish positive safety data. Opposition, 25.

In reply, Monsanto argues: (1) None of the conduct that Johnson identified implicates Monsanto, as opposed to its employees acting without authorization; (2) None of the conduct that Johnson identified was causally related to the injury he suffered; (3) The conduct Johnson identified was not sufficiently culpable to justify punitive damages; and (4) Johnson relies on assertions in his brief that lack citation to evidence. Reply, 7-10.

Even if Monsanto has carried its initial burden, Johnson has carried his burden of producing evidence that a reasonable jury could find amounts to clear and convincing evidence of malice, fraud, or oppression. *Johnson & Johnson*, 192 Cal.App.4th at 762 (setting forth standard). Johnson's theory of punitive damages is that Monsanto intentionally marketed a defective product knowing that it might cause injury and death. *Boeken v. Philip Morris Inc.*, 127 Cal.App.4th 1640, 1690 (2005) (intentionally marketing a defective product knowing that it might cause injury and death is highly reprehensible).

The internal correspondence noted by Johnson could support a jury finding that Monsanto has long been aware of the risk that its glyphosate-based herbicides are carcinogenic, and more dangerous than glyphosate in isolation, but has continuously sought to influence the scientific literature to prevent its internal concerns from reaching the public sphere and to bolster its defenses in products liability actions. Hoke Decl., Exs. 11-12 (introduced to show Monsanto employees reaction to an internal memorandum in 1999), Ex. 14 (introduced to show Monsanto's internal belief that glyphosate may be dangerous in combination with surfactants as

of 2002), Ex. 19 (introduced to show the Monsanto's employee believed it was inappropriate to say that Roundup does not cause cancer because Monsanto had not done carcinogenicity studies with Roundup as of 2009), Ex. 21 (introduced as evidence that Monsanto had a practice of ghostwriting scientific literature about glyphosate in and around 2015), Ex. 22 (introduced as evidence that Monsanto ghost wrote scientific literature about glyphosate as far back as 1999), Ex. 24 (introduced as evidence of Monsanto's sponsorship of literature for the purpose of defending products liability claims regarding glyphosate in 2012), Ex. 25 (introduced to show that Monsanto calculated the benefits of securing certain experts to lend credibility to their sponsored studies in 2012).

Thus there are triable issues of material fact and I must deny the motion.

Summary and Conclusion

(1) Monsanto's Omnibus *Sargon* Motion: I exclude (A) Dr. Portier's pooling analysis and any conclusions that depend on it; (B) Dr. Sawyer's water permeability test and cancer slope opinions; (C) Dr. Benbrook's testimony as listed above (6 topics); (D) Mills' opinion as to Johnson's total lost income assuming employment until two years before his life expectancy, unless and until evidence that Johnson would have worked until two years before his life expectancy is offered. Otherwise the motion is denied.

(2) Johnson's Omnibus *Sargon* Motion: I exclude (A) Dr. Rider's opinion that the epidemiological evidence precludes the conclusion that there is a causal relationship between glyphosate exposure and NHL (assuming she intends to express such an opinion); (B) Dr. Kuzel's mycosis fungoides latency opinion, although Dr. Kuzel may opine generally as to latency for cancers. Otherwise, the motion is denied.

(3) Monsanto's motions for summary judgment and adjudication: these are denied.

(4) Johnson's motion for summary adjudication: this is granted.

Dated: May 16 2018

Curtis E.A. Karnow
Judge Of The Superior Court

CERTIFICATE OF ELECTRONIC SERVICE
(CCP 1010.6(6) & CRC 2.260(g))

I, DANIAL LEMIRE, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On MAY 17 2018, I electronically served THE ATTACHED DOCUMENT via File & ServeXpress on the recipients designated on the Transaction Receipt located on the File & ServeXpress website.

Dated: MAY 17 2018

T. Michael Yuen, Clerk

By: _____
DANIAL LEMIRE, Deputy Clerk