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Attorneys for Defendant
MONSANTO COMPANY

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY,

Defendant.

Case No. CGC-16-550128

DECLARATION OF SANDRA A. EDWARDS IN SUPPORT OF DEFENDANT MONSANTO COMPANY'S OPPOSITION TO PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE

Trial Date: June 18, 2018
Time: 9:30 p.m.
Department: 504

I, Sandra A. Edwards, declare as follows:

1. I am an attorney duly admitted to practice before this Court. I am a partner with Farella Braun + Martel LLP, attorneys of record for Monsanto Company ("Monsanto"). I submit this Declaration in support of Monsanto's Opposition to Plaintiff's Request for Judicial Notice.

2. Attached hereto as **Exhibit 1** is a true and correct copy of Deposition of Charles Benbrook, Ph.D. at 148:15 – 149:6 (Feb. 8, 2018)).

3. Attached hereto as **Exhibit 2** is a true and correct copy of a OEHHA's Initial Statement of Reasons: Glyphosate, available at https://oehha.ca.gov/media/downloads/crnr/glyphosate032917isor.pdf).

4. Attached hereto as **Exhibit 3** is a true and correct copy of the Order on Sargon and Summary Judgment at p. 28 (May 17, 2018).

5. Attached hereto as **Exhibit 4** is a true and correct copy of May 10, 2018 hearing transcript in this matter.

6. Attached hereto as **Exhibit 5** is a true and correct copy of *National Ass'n of Wheat Growers v. Zeise,* CIV. No. 2:17-2401 WBS EFB, Memorandum and Order Re: Motion to Alter or Amend Preliminary Injunction Order (E.D. Cal. June 12, 2018) (ECF No. 97).

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on June 19, 2018, at San Francisco, California.

Sandra A. Edwards

Exhibit 1

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

-vs- Case No. CGC-16-550128

MONSANTO COMPANY,

Defendant.

CONFIDENTIAL VIDEOTAPED DEPOSITION OF

DR. CHARLES M. BENBROOK

9:04 a.m. to 7:45 p.m.

February 8, 2018

Orange, Virginia

Job No. 137478

REPORTED BY: Rhonda D. Tuck, RPR, CRR

down? Is that what you're referring to, or a subsequent one?

Q. I don't know what premature posting is, but I'm talking about the one that was published by EPA's OPP formally in 2016, as is referenced in this document.

A. Again, put it in front of me, and it will trigger my --

Q. You have -- you have the --

A. This is 2017 document.

Q. Correct. And it says right on Page 13 of the document that it asks for an SAP to evaluate the 2016 issue paper. The CARC was in 2015.

A. Right. Okay.

[redacted]

[redacted]

Q. Do you know what a cancer assessment peer review committee is?

A. Yes.

Q. What is that?

A. It's the committee that OPP convenes to render final judgments at their -- sort of typically among the toxicologist, statisticians, pathologists, the cancer experts within OPP. That committee is convened periodically when it comes time for OPP as an institution to render a final judgment about where a particular active ingredient should be classified relative to EPA's classification system for oncogenicity.

Q. So in 1991, the cancer assessment peer review committee looked at carcinogenicity and exposure to glyphosate and concluded that the proper classification was Category E under the cancer risk guidelines, right?

A. Correct.

DR. CHARLES M. BENBROOK

COMMONWEALTH OF VIRGINIA AT LARGE, to wit:

I, Rhonda D. Tuck, RPR, CRR, Notary Public in and for the Commonwealth of Virginia at Large, and whose commission expires on May 31, 2020, do certify that the aforementioned appeared before me, was sworn by me, and was thereupon examined by counsel; and that the foregoing is a true, correct, and full transcript of the testimony adduced.

I further certify that I am neither related to nor associated with any counsel or party to this proceeding, nor otherwise interested in the event thereof.

Given under my hand and notarial seal at Charlottesville, Virginia, this 12th day of February, 2018.

_____

Rhonda D. Tuck, RPR, CRR

Notary Public Registration No. 224847

Commonwealth of Virginia at Large

Exhibit 2

INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENT TO:
SECTION 25705(b) SPECIFIC REGULATORY LEVELS
POSING NO SIGNIFICANT RISK

GLYPHOSATE

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

PURPOSE AND BACKGROUND OF PROPOSED AMENDMENTS OF REGULATION

This proposed regulatory amendment would adopt a No Significant Risk Level (NSRL) for glyphosate under Proposition 65[1] in Title 27, California Code of Regulations, section 25705(b)[2]. The proposed NSRL of 1100 micrograms per day (µg/day) is based on a carcinogenicity study in rodents and was derived using the methods described in Section 25703.

Proposition 65 was enacted as a ballot initiative on November 4, 1986. The Office of Environmental Health Hazard Assessment (OEHHA) within the California Environmental Protection Agency is the lead state entity responsible for the implementation of Proposition 65[3]. OEHHA has the authority to adopt and amend regulations to implement and further the purposes of the Act[4].

The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water. When exposures are insignificant, warnings are not required and the discharge prohibition does not apply. The NSRL provides guidance for determining when this is the case for exposures to chemicals listed as causing cancer.

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1 The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et. seq., commonly known as Proposition 65, hereafter referred to as "Proposition 65" or "The Act".
2 All further regulatory references are to sections of Title 27 of the Cal. Code of Regs., unless otherwise indicated.
3 Section 25102(o).
4 Health and Safety Code, section 25249.12(a).

The default human body weight is 70 kg. In the absence of animal body weight data from the male mouse study, the default[18] average body weight of 0.03 kg for male mice was used. The derivation of the human cancer slope factor using the default body weight values and the animal cancer slope factor of 0.0000897 $(mg/kg\text{-}day)^{-1}$ is shown below:

$$CSF_{human} = 0.0000897\ (mg/kg\text{-}day)^{-1} \times (70\ kg / 0.03\ kg)^{1/4} = 0.00062\ (mg/kg\text{-}day)^{-1}$$

[redacted]

$$NSRL = \frac{10^{-5} \times 70\ kg}{CSF_{human}} \times 1000\ \mu g/mg.$$

[redacted]

PROPOSED REGULATORY AMENDMENT

Section 25705(b)

The proposed change to Section 25705(b) is provided below, in underline and strikeout.

(1) The following levels based on risk assessments conducted or reviewed by the lead agency shall be deemed to pose no significant risk:

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[18]Gold LS, Zeiger E (1997). Handbook of Carcinogenic Potency and Genotoxicity Databases. CRC Press, Inc., Boca Raton.

[19] Section 25703(a)(8)

Exhibit 3

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]articuarly 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

Exhibit 4

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs. Case No. CGC-16-550128

MONSANTO COMPANY,

Defendant.
_____/

Reporter's Transcript of Proceedings

San Francisco, California

Thursday, May 10, 2018

Reported by:
SHEILA PHAM
CSR NO. 13293

PAGES 1 - 79

SUPERIOR COURT OF THE STATE OF CALIFORNIA

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Reporter's Transcript of Proceedings, taken at SAN FRANCISCO SUPERIOR COURT, 400 McAllister Street, Department 304, San Francisco, CA 94102, beginning at 9:10 a.m. and ending at 11:00 a.m., on Thursday, May 10, 2018, before Sheila Pham, Certified Shorthand Reporter No. 13293.

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San Francisco, California, Thursday, May 10, 2018

9:10 a.m. - 11:00 a.m.

THE COURT: I'm required to read the following: The parties and counsel are advised in connection with the June judicial election, a list of contributions is available on the board outside the courtroom door. The list is updated weekly.

Counsel got my written tentative yesterday perhaps.

(Counsel nodding.)

THE COURT: Great.

MR. LASKER: Yes, Your Honor.

MR. MILLER: We have, Your Honor.

THE COURT: My proposal -- and if you've discussed it among yourselves that you'd like to handle this differently, that's fine with me. But my proposal is simply to let perhaps Monsanto go first. They can use whatever time they want. I've told you I'm going to give you each just about an hour, maybe a little bit more than that. You can use it really as you wish. I think you have a better grip as to what needs time and what doesn't need time, and I'm happy to do it that way. I'll turn it over to the plaintiffs and then go back and forth until your time has expired.

Is there any other way you'd like to handle things? Okay.

MR. MILLER: That's agreeable, Your Honor.

MR. LASKER: Thank you, Your Honor. Eric Lasker for Monsanto. And as Your Honor knows, the issues that are before you today, particularly on our Sargon motion and general causation, has been the issue of a seven-day adventure hearing in front of Judge Chhabria and also Judge Petrou, who is the JCCP judge.

And that hearing was continued through until early April when Judge Chhabria, at supplemental adventure hearings specifically on the epidemiology, sort of crystallized the issues and focused the issues similarly to how Your Honor has with the understanding, as Judge Chhabria recognized as well, that the epidemiology really is the key issue here.

And I think the parties, in their briefing, also recognized that fact. That to get to causation in humans and/or Mr. Johnson, general causation, and frankly, given their experts, also specific causation, the epidemiology is really the focus of the inquiry that Your Honor needs to make under Sargon.

And I'd like to focus obviously on the questions Your Honor has raised in the tentative ruling with respect to the epidemiologic issues, how that

impacts the admissibility of experts' opinions both with general causation and specific causation.

And the first point that is obvious, I think, from the briefing but important also in the Sargon analysis is: There is a significant body of epidemiological evidence that the experts are citing to here and relying upon here. This is not a case with an absence of epidemiology, in which case, you might resort or need to resort to other types of evidence.

THE COURT: When you say "other types," do you mean Bradford Hill or --

MR. LASKER: One of -- I'm sorry.

THE COURT: Go ahead.

MR. LASKER: Yeah. The Bradford Hill criteria is actually an analysis assuming epidemiology.

THE COURT: Right.

MR. LASKER: That is an analysis where if you have epidemiological evidence, what Sir Bradford Hill was recognizing in his criteria and as courts have recognized as well --

THE COURT: Excuse me, let's take a break. Go off the record for a moment.

(Off the record.)

MR. LASKER: Under the Bradford Hill criteria, you start with epidemiology. And as the cites we've

provided and the Reference Manual make clear, and In re Lipitor case, which is in 2016, the cite for that, Your Honor, is -- just a second -- 174 F. Supp. 3d 911 at 925. There's a long citation of cases dealing with how courts address the Bradford Hill in the context of a Daubert analysis or the type of analysis here.

What Sir Bradford Hill was presenting was: Even if you have statistical association in an epidemiological study and you do the best you can to deal with confounding and bias, which is epidemiologists can only do so much, you then need to look at other factors to determine whether or not, in fact, you can go from association to causation.

So the Bradford Hill criteria is recognizing that epidemiology, even if you have association, is not enough, but it is a threshold to be able to even get to those other criteria.

THE COURT: And if you're going to get to this, just tell me that you will, but is it your view that the admissibility of the epidemiology is exactly the same? Whether we're looking at only it or whether we are looking at it as a piece of a broader Bradford Hill analysis, it's exactly the same issue?

So, for example, the 2.0 factor or whatever the other sorts of criteria might be that we use to

determine the admissibility of epidemiological conclusions are identical regardless of whether we're looking at it in isolation or as part of that broader spectrum, or is it different?

MR. LASKER: No, it's the same, Your Honor. In fact, that, again, is exactly the point made in In re Lipitor, in the cases that are cited in that case, in the Reference Manual. And, in fact -- we'll get to this point specifically with respect to the 2.0 analysis -- the Cooper case also sort of looked at the issue of confounding, and whether or not there's epidemiology that adjusted for those factors in deciding whether or not plaintiffs had gone over the 2.0 bar.

So the Bradford Hill criteria is recognizing that you need to start with that, but then you need more. It's an added -- it's a recognition of how science works. That epi is necessary and statistically significant -- properly adjusted epi is necessary, but there's also more to get from association to causation.

And, Your Honor, with respect to the epidemiology, the other issue that is important particularly where you have a body of epidemiological evidence is that it's not reliable to pick out one study and say, "That's the right study and the others are not correct studies," or "We don't have to consider all the

epidemiology as a whole in reaching an opinion."

And, in fact, in the one federal court case -- or the one case that has dealt with this exact issue, which is whether or not scientific -- an expert can testify to general causation under Daubert, which is the Arias versus Dyncorp case. And the cite there is 928 F. Supp. 2d 10, and specifically at Pages 24, 25, the Court specifically focused on the epidemiology and the plaintiff's expert's attempt to rely upon one study and not look to the other study.

And the Court held that that was not reliable. You can't just pick out one study as a basis for your opinion in this context where you have a large body of studies unless you can explain why that's the only study you look at.

THE COURT: So if there's some sort of explanation, then it's good enough? In other words, I'm not going to be the person -- under Cooper, I'm not going to be the person to decide, for example, which studies are worthy of attention and which are not; right? So an expert is going to do that, and if an expert says, "Look, I think Studies 1, 2, and 3 are the only ones we really need to look at," and if that person has some kind of explanation for why they didn't look at the others, then my inquiry is at an end?

MR. LASKER: Well, no, I don't think that's right, Your Honor. First of all, I would say that none of the experts have opined to that. All of the experts present all of the studies in their report. They identify various strengths and weaknesses of the studies. But the courts, in analyzing epidemiologic evidence under Daubert and also under Sargon, have also looked at various methodological issues as far as how the experts address those studies.

So, for example, on the issue of confounding -- and this was -- we cited a number of cases in our briefing, but I'll focus on the cases in California. The In re Lockheed case, which is 115 Cal. App. 4th at 558, and specifically -- well, 564, 565 is where the Court is addressing the issue of confounding. And this is the case, Your Honor, as you might recall, that the Supreme Court cited in Sargon in adopting the Daubert-type analysis. That was a case in which the Court said plaintiff's expert is relying upon a study that is confounded, and that's not a reliable basis for an expert opinion.

There's also the In re Bextra case, which is 524 F. Supp. 2d 1166 at 1178. That's the Northern District of California --

THE COURT: Is it your point that the experts

on the plaintiff's side did not account for confounding; and if so, is it part of your job to say what the confounding variables might have been?

MR. LASKER: Yes, Your Honor, it is our position. It actually was the focus of the Daubert hearing as well. That's why Judge Chhabria called plaintiff's experts back because, as we pointed out to Your Honor, Judge Chhabria was of the view that to rely upon confounded epidemiology studies -- epidemiological studies that did not adjust for the pesticides was junk science. He stated that in the oral argument we had in March.

And the issue here is not as it is and, to some extent, was in Cooper. That there's some potential confounders. We don't know what they are, but there may be confounders out there, and therefore, the study isn't reliable. In this case, every one of the epidemiological studies, in the studies themselves, when they adjust for other pesticides -- and they do. We do have adjustment for other pesticides in all of the studies now -- in every case, the odds ratio goes down, and it is no longer statistically significant when they do those adjustments. So this is not a hypothetical situation or an abstract issue. It's a concrete issue based upon the data in the studies.

And Your Honor focused in your tentative ruling on the De Roos 2003 study. And that is a study that, frankly, there is dispute even among plaintiff experts as to when adjustments were made for other pesticides. There are two odds ratios presented in that study. One is a statistically significant finding. The other, which is the more fully adjusted model, and there's a debate as to what was adjusted to bring it to that fully adjusted model, is no longer statistically significant.

And that is set forth in the record. The argument that plaintiff's expert makes -- Dr. Ritz makes is that there was some adjustment for confounders in De Roos. And Your Honor cited to her testimony at -- the reply declaration, Exhibit 8, at Pages 22 to 24.

And what Dr. Ritz stated is that in the De Roos 2003 study, they tried to adjust. They actually didn't do a very good approach to it. They adjusted for everything, for all 40 pesticides. And she said that's not really a reliable way of doing it, but that's what they did.

As it happens, though, we're now in a situation again where we have additional analyses. The De Roos 2003 study, and this is not disputed by any of the experts, was pooled, along with McDuffie, into what is known as the North American Pooled Project. It's also

referred to as the "Pahwa study," P-A-H-W-A.

And that study was able to do a more refined adjustment for other pesticides. And what the investigators did is: They looked for other pesticides that were associated -- in other words, correlated use of glyphosate, and that also were risk factors for non-Hodgkin lymphoma independently in that study.

And when they adjusted for those three pesticides, and, again, it's not disputed, the calculations that were made, their odds ratio for all of the North American case-control studies, that includes all the data from De Roos 2003 and also from McDuffie, was not statistically significant.

THE COURT: I appreciate that. The problem, though, is -- maybe it's not a problem, but the issue is: Even if there could be more persuasive evidence such as what you have just described, maybe it's a meta-study, and I'm not sure if the North American Pooled Project was technically a meta-study or not, but pooling all of that information, even if that's better, is it inadmissible to rely on the 2003 De Roos study? That's a real question; right?

MR. LASKER: Yes, Your Honor. And we would submit that it is for two reasons. One, as I said, going back to the Arias decision, there is -- you pick

out one data, one study, without the other, and we do know with the full analysis of the data and the other studies, for example, the Agriculture Health Study. I believe that was conducted and published just this year, it's not the case that there is a consistent body of studies that show only one thing.

The second case I would refer you to, Your Honor, which is, frankly, directly on point on this issue, is the In re Zoloft case. And that is a Third Circuit case, 882 F.3d 787. And the issue that the district court dealt with and then the Third Circuit affirmed on was exactly this: There were earlier studies that had found reported statistically significant results, but they were not adjusted. And the investigators then conducted a later analysis in which they pooled that data into a later pooled analysis in which they were able to do the proper adjustments.

And the Court in that case, affirmed by the Third Circuit, held it's not reliable when you have -- when you know that that same data, when you do the proper adjusting for confounders, does not show association, it's not reliable for you to continue saying, "I'm going to look at that data and put blinders on the fact that it does not show significant association when known confounders are adjusted for."

And that's the issue that comes up in a lot of the cases that we cite for Your Honor. And, again, the issue is: What is the proper methodology for an expert to follow in reaching a causation opinion? Is it the proper methodology for an expert to rely upon data that they know is confounded, where they know that -- and where data has been adjusted for known confounders and does not show an association, is it reliable for the expert, nonetheless, to rely upon those unadjusted numbers?

That's the issue that Judge Chhabria is dealing with right now. And as Your Honor knows, that his -- at least his initial indication of his view on that. It's an issue that comes up again in the cases we cite where courts have said not proper methodology to rely upon what you know to be confounded data. Maybe if you're just sort of speculating as to whether or not they're confounding but you have no evidence of it, then maybe there's a debate among the experts as to whether or not there is confounding. But if you actually have the analysis that shows that there's no association, you can't then just put blinders on. That's not a proper methodology.

THE COURT: And we're still talking about general causation right now; right?

MR. LASKER: We are. But, Your Honor, the issue also goes into and is relevant to a specific causation --

THE COURT: Because in that latter context of specific causation, would it matter whether or not there was any kind of record in this case that the potential confounding, say, pesticides were actually a source of perhaps damage to the plaintiff, that the plaintiff was actually exposed to them? Would we care about that being in the record or not if we were looking at this issue in the context of specific causation?

MR. LASKER: Yes, Your Honor. I can read to you from the Cooper case, which actually addresses this. The question with specific causation, particularly in this case, is: When a plaintiff's expert for opining on specific causation is basing their conclusion on the existence of epidemiology -- and I'll get into in a moment how that is in this case because it's pretty clear from the testimony of Dr. Nabhan and also from Dr. Sawyer that that's what they're doing -- then the issue is: Do you have epidemiologic evidence that is reliable that shows a statistically significant association greater than 2.0?

And the reasoning, as set forth in the Cooper case, is that this legal standard for plaintiff is more

likely than not. And if the odds ratio is less than 2.0, then you're not going to have more likely than not. Because 2.0 is basically a doubling of the background risk. If you're below 2.0, then the background risk is a greater proportion of the risk for the outcome.

And Cooper at 239 Cal. App. 4th 555 at 593 states that "When statistical analyses or probabilistic results of epidemiological studies are offered to prove specific causation, under California law, those analyses must show a relative risk greater than 2.0 to be 'useful' to the jury."

And getting back to what Your Honor was asking about with respect to confounding and what other analyses might be done, when you look at the Cooper court's discussion of the expert's opinion in that case, again, it's at Page 594, these were the steps that the Cooper court pointed to. I'm quoting. "Thus, having considered and ruled out other background causes of bladder cancer based on his medical records" -- so the differential diagnosis -- "Dr. Smith could conclude based on the studies that it was more likely than not that Jack Cooper's exposure to Actos caused his bladder cancer. In other words, because the studies, to varying degrees, adjusted for race, age, sex, and smoking, as well as other known causes of bladder cancer, Dr. Smith

could rely upon those studies to make his differential diagnosis ruling in Actos, as well as smoking, and concluding that Actos was the most probably cause of Jack Cooper's disease."

So the issue here is: Can plaintiff's experts in this case make that same showing? And the evidence that they presented makes it clear that they cannot. There is no body of adjusted epidemiological evidence that demonstrates a 2.0 odds ratio. Plaintiffs, in fact, in their brief, point to meta-analyses. And these are, I think, in their opposition brief at Pages 14 and 15. They point to meta-analyses that were conducted, in fact, prior to the 2018 NCI study and prior to the NAPP, which are numbers that would actually pull those odds ratios down. But even before those studies, the meta relative risk that they're pointing to were in the vicinity of 1.3, 1.4 as being what the body of epidemiological evidence could show at that point in time, and it's lower now. But it's clearly below the requisite odds ratio of 2.0.

And there's, actually, Your Honor, a very interesting case, a trial court decision in Los Angeles. It's a case called In re Johnson & Johnson. And this is 2017 Westlaw 4780572. And this was a case that dealt with a very similar issue. The Court had before it a

couple of epidemiological studies that plaintiffs argued had greater than 2.0 odds ratio, but the body of the epidemiological data as a whole was closer to at least 1.3, 1.4 odds ratio.

And the Court in that case, and it was unfortunately after they had gone through the expense of a trial, but on JNOV, the Court went back and said that's not an odd for specific causation under California law. You have not reached that 2.0 threshold in the body of epidemiologic data.

And if I could focus, Your Honor, specifically -- and, again, that's an issue for Your Honor in Sargon, specifically with respect to what the methodology is for Dr. Nabhan's specific causation opinion. And the key pages in his deposition -- and his full deposition is in the record. It was attached by the plaintiffs as Exhibit 76 to their Sargon opposition brief. But the key passages here are from Pages 138 to 140 -- 141.

And Your Honor raised the question whether or not Dr. Nabhan only relies on the fact that the disease developed after the use of the spray as the basis for the conclusion. And reading, Your Honor, from Page 138, Lines 8 to 16, the question is:

"How are you making this argument that the exposure to Roundup caused the plaintiff's mycosis

fungoides?"

What Dr. Nabhan said is: "In his situation, that's the only type of risk factor that I was able to gather from looking at his record and his occupational history and what he has done. The only thing that stares at you in the eye, you know, he was doing well until he started working at the school district, started using glyphosate compounds, and a couple of years later, he developed a skin disease that ultimately was diagnosed as mycosis fungoides."

And he goes on to state that it's possible that he would have had the same disease without the exposure, that there's no mechanism -- no mechanism of action here that he can point to.

And then on Page 140, Lines 20 to 25, he states, "So there is a known carcinogenic compound, in my opinion, that he was exposed to, and he subsequently developed a malignancy that has shown to be associated and caused by this compound. So it's hard to dismiss that and assume that he could have developed it without it."

And then finally, when we say, "Well, then what's your basis for that," he points to the epidemiologic evidence. And he says at Page 140, starting at Line 23, going through to the next page,

141, Line 10.

And the question was: "How could you say that -- if he had been exposed to some other compound, not glyphosate, if he had been exposed to nicotine, would you say that that was the cause of his mycosis fungoides?"

And he answers: "No, because to my knowledge, there is no epidemiologic studies that have linked nicotine to lymphoma in general. I think that if -- you know, the reason you would conclude in Mr. Johnson's case is because you have to link this particular individual case, you know, with the body of evidence, with the epidemiologic studies. To my knowledge, there is no studies to link smoking or nicotine exposure to non-Hodgkin lymphoma, so I would not have linked these together. But there is epidemiologic evidence with glyphosate and non-Hodgkin lymphoma, and that's why I linked them together."

And Dr. Nabhan was also very clear, and he says this, for example, at Pages 124 and 125 of his deposition when he was being asked about individual epidemiologic studies and his opinion with respect to individual studies, and this is 124, Line 23, going on to 125, Line 6. "As I said several times, I don't believe you can rely on any one particular study versus

another to make the association of why glyphosate caused mycosis fungoides in Mr. Johnson's case. You rely upon the particular individual case of the patient, his exposure, and the collective evidence of epidemiologic studies. I did not rely on one sole paper versus another. I relied on all of the literature collectively."

And Dr. Sawyer, to the extent that he offered a specific causation opinion, also is relying upon the epidemiologic studies. And plaintiffs make this point and acknowledge this in their opposition brief at Page 41.

So the methodology of plaintiff's specific causation experts in this case is very straightforward. Mr. Johnson was exposed to glyphosate, and I believe two years later -- and there is a big scientific issue there as to whether or not that's long enough, but we'll put that to one side. Two years later, he developed mycosis fungoides. And they looked at the collective body of the epidemiologic evidence to then reach their specific causation opinion.

And there's no argument in this case that a collective body of the epidemiologic evidence supports a 2.0 association between glyphosate-based herbicides and non-Hodgkin lymphoma. Again, plaintiffs themselves, in

the brief, point to 1.3, 1.4 as a meta-analysis, and that number actually is inflated at this point because it doesn't include the more recent studies.

So given that body of epidemiologic evidence, as we've argued in our brief, we don't think there is the epidemiologic evidence that would be necessary under the case law that we cited, In re Lockheed, In re Bextra, In re Zoloft, to reach a general causation opinion, but for specific causation, it's even a more difficult hurdle for them here because they need to pass that 2.0 threshold, and they plainly do not.

THE COURT: I'm just concerned that, and maybe there's more to be said about this, but I'm just concerned that what you're asking me to do, at least under the rubric of general causation, is to pick and choose among studies. That is, for me to say, "Well, these are later studies. They look better to me because they seem to have accounted for earlier results," "they seem to perhaps have done more work," or "they have been more thorough," or something like that, "and so I'm going to adopt those. And as a judge, I'm not going to evaluate the earlier studies because I don't think they're very good," "they weren't as advanced," "they didn't account for Factors 1, 2, and 3," or something like that. I'm just concerned that I'm picking and

choosing in a way that has not been countenanced by the Court of Appeal either, you know, in the Cooper case and then the equivalent case that we had out of the Ninth Circuit that had a similar view of the range of flexibility that the judge has in these sorts of motions.

I don't know if there's anything more that can be said about that.

MR. LASKER: I guess I'll say one more thing and then I'll move on, Your Honor.

THE COURT: Yeah.

MR. LASKER: It's not a question of picking and choosing among the studies because none of the studies -- the issue is whether or not methodologically, plaintiff's experts can rely upon data that they know is confounding. That's an overarching methodological issue that applies to all the studies. It's not picking one study over the other, it's just what is the data that -- what do each of the studies show? Where do you look to in a study to find evidence that an epidemiologist can rely upon?

And as we've submitted and as the cases I cite make clear in the Daubert context, under California admissibility rules, the data that you look at at each individual study is the study that is properly adjusted.

And so you're not choosing between studies at all. You're just asking whether or not the expert applied the appropriate methodology in interpreting the results of all of the studies.

And then with respect to specific causation, Your Honor, okay, and which I think is an even easier issue in this context, you are looking at what is the methodology that the plaintiff's expert used. Not an abstract argument that a counsel, attorney, may make, but what did this expert say?

And Dr. Nabhan made very clear he's not relied upon one individual study. He doesn't believe it's appropriate to point to one study versus another. You look at the collective body of epidemiologic evidence. And looking at the collective body of epidemiologic evidence, we have the meta-analyses that were dated. Dr. Mucci has, and it's in the record, provided an updated meta-analysis that shows an odds ratio now of about 0.9, actually. It's not as significant, but it shows absolutely no association whatsoever.

But even going back to the old meta-analysis, they don't get to the 2.0 threshold. So that's undisputed scientific evidence in plaintiff's own brief, and it shows why they don't meet the requirement for specific causation.

Your Honor, I think I'd like to move on now and talk about some of the other issues, specifically with respect to Dr. Sawyer. And there is the issue of his cancer slope factor and the issue of whether or not -- I think there's two issues that are raised by this. One is whether or not it is appropriate to extrapolate from animal studies.

And I would point Your Honor to Dr. Portier's testimony on this. In our opening brief, the Edwards declaration, Exhibit 21, at Pages 158 to 159 and Exhibit 31 at Pages 677 to 678, is Dr. Portier explaining why you can't extrapolate from rodent studies to human cancer or to human NHL, which is the issue here.

But I think a broader issue also, Your Honor, is: What did he actually do? He calculated -- and it's very clear from his report and from his opinions, he calculated a regulatory cancer slope. And cancer slope as applied by regulators, and Dr. Sawyer states this is not something they can use to establish causation in any individual case. The purpose of the cancer slope factor is not causation, it's a regulatory tool used for protective purposes.

And that's made clear in the Reference Manual, the case that the plaintiffs cite, which is a regulatory

standard in the level of a monitoring context. But the Reference Manual on Scientific Evidence at 665 and 666 also makes clear that that's a different standard at a different level in a regulatory context than it is in court.

Because as Your Honor may be aware, in the regulatory context, you have protective factors. And Dr. Sawyer acknowledged that his slope factor was the upper bound estimate of risk. And you want to have protective factors in the regulatory context to protect populations. You can't take that data point, which is what Dr. Sawyer is -- and that's what we're trying to do here, and say, "Given this cancer slope index, we can say that Mr. Johnson's exposure was above the level that is required to cause cancer." That's not what a cancer slope factor is for. It's a protective factor with levels of conservatism in them to set regulatory standards.

And there's a long list of cases. The Rider case -- and the Reference Manual has other cases. That Rider versus Novartis that we cite in our brief, that made clear that regulatory standards are not the proper standard for causation in a case like this.

And the question then is: Even if one assumes, okay, it was appropriate for him to calculate a cancer

slope factor the way that he did, and we don't agree with it for reasons we've raised, how does that fit with anything the jury is going to be to asked to decide? And, in fact, wouldn't it confuse the issue? Because you're putting up a number there in front of the jury that, in fact, is not intended to be related to causation and does not provide evidence of causation. And why are they seeing that number? How does that fit with the burden of proof the plaintiffs have in this case?

So it may be, and, again, we don't think it is, that he calculated this cancer slope factor correctly, but it has no place in this litigation. So for that reason, we believe that testimony should be excluded.

If I could turn briefly, just very briefly, to a question you asked about Dr. Portier and his failure to control for statistically -- for the fact that some statistically significant results could appear in rodent studies by chance. The issue here very briefly is that there were 12 different animal studies with hundreds of different analyses.

And it's well established and not disputed by Dr. Portier that when you have all of these analyses, an individually statistically significant finding actually is not meaningful. Because what you're looking for when

you do those statistics is: What is the chance of this happening -- what is the likelihood of this happening by chance?

And to have a statistically significant finding in an individual point, you're saying it's a 1 in 20 that this could happen by chance. If you have hundreds of them, then you are going to have a bunch of these individual analyses that you would expect to have by chance, and Dr. Portier acknowledges that.

And the problem he has in his analysis is: There are very well-established methodologies that deal with multiple comparisons to be able to determine whether they are actually statistically significant in this context. He doesn't apply any of them. Instead, he presents a table in which he purports to show how many statistically significant findings you would expect to see by chance and how many you actually see.

But the problem with that, as we support in our briefing, is: He doesn't actually count up the number of analyses that were done to be able to determine how much he'd expect to see. He sort of estimates that. So he's not doing a calculation that --

THE COURT: Does that table underlie any of his opinions? I mean, is your pitch here just that the jury shouldn't see that particular table --

MR. LASKER: Well --

THE COURT: -- or is it --

MR. LASKER: I think that certainly, they should not see that table and they should not see that analysis. It's not a scientifically reliable approach for looking at the issue. I think without that, he doesn't have a basis for his opinion. I think his whole opinion falls apart because he does acknowledge that you need to do something to deal with that fact. You can't just say, "Okay. There's a p-value less than 25."

But certainly, that analysis, given his testimony that he actually just estimated the numbers, is not a reliable methodology. You can't just estimate and then sort of speculate as to what that means. So certainly, that analysis, which is his table analysis, we think should be excluded.

I'd like to turn now briefly to Dr. Benbrook. And for the most part, we are in an agreement with Your Honor's tentative ruling, but one additional point we wanted to make on this, and I'll reserve my time to respond to plaintiff's counsel on any issues they may have, is that it's very clear from Dr. Benbrook's testimony that he does not have any expertise in any scientific discipline. He doesn't have expertise in epidemiology, he doesn't have expertise in toxicology,

he doesn't have expertise in exposure science or genotoxicology, and he acknowledges that repeatedly. He's a PhD, but it's in economics. He doesn't have any background in any scientific discipline.

But again and again, the opinions that he seeks to proffer are based upon his opinion of what the science shows. He talks about what the science was as of 2002, and whether or not that scientific evidence was sufficient for Monsanto to now be having to put a warning on their label. He talks about genotoxicity studies, and he raises a lot of argument about Dr. Perry and how he interprets certain studies. All of these underlying studies have been in a peer-reviewed published literature, and Dr. Benbrook doesn't have any expertise to be able to say what those studies actually say -- what the conclusions are.

The same thing with the TNO study, which is a study on exposure and how well glyphosate-based herbicides pass through the skin. The actual study -- investigators say that that study was not reliable because they couldn't replicate the results and they had a bad model. Dr. Benbrook disagrees and says this is a significant finding, an important finding, but he doesn't have any expertise to opine on any of those issues.

Dr. Benbrook tries to dismiss the fact that the EPA has determined that surfactants -- none of the surfactants that are used in glyphosate-based herbicides cause cancer. And he goes and says, "Well, they use this structure-activity relationships analysis." That's not particularly reliable. He doesn't have expertise to talk about any of those issues.

So we would ask that Your Honor also add language to the Court's order that makes clear that Dr. Benbrook does not have the qualifications, and therefore, should not be speaking to issues that require that sort of scientific expertise.

And we also believe along the same lines that Dr. Benbrook does not have expertise on any issues relating to whether Monsanto misled the EPA. Again, a lot of those opinions with respect to, for example, the TNO study or for Dr. Perry, depend upon his interpretation of what those studies mean.

His conclusion as to whether or not the studies are actually reliable data that the EPA would care about, or should have been produced, in any event, not to mention the fact that he doesn't have the expertise within the EPA or the legal expertise to talk about whether or not these are the type of data that would be reported, those are the things that you need to have

expertise in, both scientific and legal.

And a lot of the cases we cite to -- there is an expert that is sort of infamous, Dr. Parisian, who provided testimony and had been excluded in a whole bunch of cases for perfectly appropriate reasons. But at least Dr. Parisian was a medical doctor. She had been a chief medical officer at the FDA. She at least could purport to have some scientific expertise. Dr. Benbrook does not. And so that, we believe, should be noted in Your Honor's opinions to guide the Court going forward.

The final point I'd make, and then I'll yield and reserve the rest of my time, is with respect to preemption issues. And as I understand Your Honor's ruling -- or tentative ruling, the Court's view is that because there is an express preemption clause in the different statutes, the Court did not need to reach the issue of implied preemption. The express preemption clause basically forecloses that analysis.

We believe that's inconsistent with the ruling in the Nathan Kimmel case at 275 F.3d at 1204 where the Court expressly states that in a different context, even though there is an express preemptive provision, that doesn't mean you don't look at the implied preemption analysis if the facts are sufficient to make out that

defense.

And if, in fact, we are looking at implied preemption, then the standard we believe, as we've set forth, is the clear evidence standard that was set forth in the Wyatt case. And I know Your Honor is familiar with that from the Court's ruling in the Plavix case, and also citations to the Fosamax case.

In the Fosamax case, the Court ruled that this is a jury issue as to whether or not the level of evidence is such that a jury could conclude that the regulators would not have approved a label. We think the undisputed evidence here is ridiculously strong on that fact given that we now have, as of December 12th, 2017, the EPA's, you know, analysis after a Scientific Advisory Panel, after comments submitted by the plaintiff's experts in this case.

We have Dr. Portier, his report was submitted into the record which attaches his admissions to the EPA laying out the exact arguments that the plaintiff's experts are making in this case, and the EPA seeing all that evidence, and then concluding not that -- you know, they have five choices under the regulatory scheme as to the levels of confidence or the levels of evidence for carcinogenicity. They took the very lowest they could, that there's no evidence of carcinogenicity here.

So if we honor the clear evidence standard, then we think as a matter of law under Nathan Kimmel, the Court needs to reach that. The evidence is overwhelming in this case that implied preemption would apply. And, of course, we have specific approvals of the warning labels well after -- both before and after Mr. Johnson used the product.

And with that, Your Honor, I'll reserve the rest of the time.

THE COURT: I appreciate that. Thank you very much.

Does anybody need a recess? I bet the court reporter does.

(Short break.)

THE COURT: Let's continue with plaintiffs.

MR. MILLER: Thank you, Your Honor. Again, Michael Miller for plaintiff, and good morning.

Your Honor, I'll go back to the beginning and review our position on some of the issues raised by defense counsel. I think defense counsel agreed with us ultimately that the Cooper case is the most controlling case here on the issue. And what Cooper tells us is, and I'm looking at the holding too, it was a fact issue for the jury, whether epidemiological studies were so flawed as to be unreliable.

Where I take issue with Mr. Lasker is that Cooper stands for the proposition that all epidemiological studies have to adjust for all confounders that could possibly cause a disease process. Point of fact, Cooper says the opposite.

In the Cooper case, and the Court may know I was the lead trial and appellate counsel, and I'm just arguing from the opinion, though, of course, they considered the Azoulay study. And the defendants there, like the defendants here, screamed mightily that Azoulay didn't adjust for another possible cause of, in that case, bladder cancer. In that case, everyone agreed smoking was a cause -- risk factor for bladder cancer. And the Azoulay study studied the association between Actos and bladder cancer, but did not adjust for smoking.

And the defendants, like Mr. Lasker, said, "You can't even consider the Azoulay study. And the fact that Dr. Smith considered it, his testimony should be stricken." And the trial court agreed. And also, the Neumann study did not adjust for smoking, and the trial court agreed and struck his testimony.

And the appellate court tells us no, the trial judge does not go there. He does not weigh into the validity the scientific literature and pick and choose

which studies based upon which side wants to use this study or that study. As long as there is a peer-reviewed body of epidemiological literature that by the authors and by the peer reviewers is deemed to be reliable, and those experts for that party, for plaintiffs in this case, rely upon that to get to their opinions as part of their opinions --

THE COURT: Is it your view, then, that if a study is published in a peer-reviewed journal and therefore, by definition, is peer reviewed, that's the end of the judge's inquiry, period, we're finished?

MR. MILLER: I think Cooper tells us that, and I can quote it, that pretty much, yes. I mean, unless there is -- let me go to the precise quote. And I'm on Page -- California Daily Op., Page 9107. But yes. "In finding Dr. Smith's testimony unreliable, the Court examined the epidemiological studies upon which Dr. Smith relied and pointed out specific problems and 'flaws' in each of them..." "In doing so," this is quoting the appellate court, "the trial court was substituting its opinion for the opinion of Dr. Smith and the opinions of the authors of the studies. This is not the proper function of the trial court."

THE COURT: There's a tremendous amount of material out there which is "peer reviewed," which is

terrible, terrible science. Right? I mean, there's a huge amount of these things that have now been withdrawn over the years. There's a lot of these things, let's say that there was, I don't know, if that's your position, that's your position. Let me just repeat your position, I think, and then you'll correct me if I'm wrong. Trial judges do not have the power or the discretion to withhold from the jury peer-reviewed studies.

MR. MILLER: I think that court is taking -- I'm not doing a good job of explaining to you my position. That would be the extreme case.

THE COURT: Okay.

MR. MILLER: And whether or not what the Court would do with that, I don't know. But this isn't that case, thank goodness. Right? I can see the Court's consternation if there was -- someone brought you a case. There's one study in a very suspect journal that looks shaky, it might be withdrawn later, sure. But this is -- not this case. This case has an entire body of consistently repeated, well-respected epidemiology that constantly shows a doubling of the risk that has been now reviewed by 17 preeminent scientists at IARC who universally concluded the reliability of that epidemiology. And it is such an impressive body, IARC,

that this state, California, embraced it and now declares --

THE COURT: We embraced it for regulatory purposes?

MR. MILLER: For the Proposition 65.

THE COURT: Yeah.

MR. MILLER: That glyphosate is a known cause of non-Hodgkin lymphoma.

THE COURT: But you're not suggesting, are you, that everything on the Prop 65 list is, by definition, something which you could present to a jury as, therefore, a potential cause, or a reasonable cause, or a cause with assurance of 2.0 for a disease; right?

MR. MILLER: No, Your Honor. I'm not making such a proffer. That's not my job and I wouldn't make that proposition.

THE COURT: It doesn't strike me that Prop 65 lists -- or things that meets criteria to be on the Prop 65 list are something that's going to be useful in a jury trial. Do you think I'm wrong about that?

MR. MILLER: I think it's admissible in a jury trial.

THE COURT: Really?

MR. MILLER: And I think it's a piece of evidence that the jury can consider.

Now, in the Actos trial, we did not have it at trial because IARC had not promulgated that yet. It was promulgated after trial. And we asked the appellate court to take judicial notice of it, and they did. And we used it at trial -- every other trial after that as a piece of evidence.

And invariably, the defense lawyers come back and say, "Sure, they do red meat, they do coffee, and there's signs everywhere." And the jury deals with that and they deal with it the way they see fit. I think that's the way it's been handled and ought to be handled.

But that's certainly not this case. I mean, this case has a doubling of the risk in peer-reviewed research and study after study regardless of what defense counsel says. He's simply wrong. And it's here. It starts in Hardell in 2002 with a doubling of the risk for exposure and tripling of the risk.

And it's a study that's controlled. It's controlled for age, it's controlled for county, and it's controlled for vital statistics. It's not controlled for other pesticides, but again, in this case, defense counsel has not pointed to one other pesticide that increases a risk, and even if they had, they haven't pointed to one other pesticide that Mr. Johnson has been

exposed to that increases the risk.

And moreover, when they did, in Hardell, adjust for other pesticides, the odds ratio came down to 1.85, but the authors noted that multivariate analysis, which controlled for other things, should be interpreted with caution. So they thought that the univariate analysis was the more proper of the two. And, again, the classic example of letting the jury, the factfinder, weigh into this with various experts and decide that issue.

THE COURT: Are there any other -- as far as the record for today is concerned, within that record, is there any evidence that anything other than the chemical at issue in this case is responsible for the specific disease that your client suffers from?

MR. MILLER: I'm sorry, Your Honor, could you repeat that, please.

THE COURT: With respect to the record that we have today --

MR. MILLER: Yes.

THE COURT: -- is there any evidence that anything other than the Monsanto chemical at issue today could be responsible for the disease that your client has, or is it the case that outside of the work that you've identified, pointing to the Monsanto chemical, it's just idiopathic after that, there's nothing else

available?

MR. MILLER: It's idiopathic. Our expert, Dr. Nabhan, and again, they proffered no expert to say otherwise, has said that there are idiopathic causes.

THE COURT: Right.

MR. MILLER: Mycosis fungoides --

THE COURT: Which is --

MR. MILLER: -- and there is a genetic component possibly, because in the black community, there is a higher risk. And those are the only two things that he can see. But he has seen nothing, nor have any defense experts seen anything, that they can say Mr. Johnson was exposed to this chemical and it could be a cause. There's been no such challenge.

So after Hardell -- and this is where defense counsel says, "You have to have a study that's peer reviewed that shows after adjustment" -- "that shows after adjusting for other pesticides, it's doubling the risk." Here it is. It's the De Roos study. In 2003, it adjusted for 41 other pesticides and found a doubling of the risk statistically significant.

And Dr. De Roos still to this day -- she wrote a letter with nine other scientists recently that it's still her opinion that, in fact, glyphosate causes non-Hodgkin lymphoma. So the suggestion that somehow

some modern study out there has made this less than reliable is just false.

THE COURT: But your position would be that even if -- do you want to hand that note to Counsel?

MR. TRAVERS: Sorry (handing).

THE COURT: There's too much tension in the room as you're waiting to hand that note out.

MR. MILLER: I'm sorry, Your Honor.

THE COURT: That's okay. I don't mind. I've been in both chairs.

So your position, though, is that even if there were a more recent study that cast aspersions on an earlier 2003 study, or even if there was a meta-study, for example, that included the De Roos study but concluded that it was an outlier in some way, your position would still be that the De Roos study and the opinions based on it still get to the jury; right?

MR. MILLER: Yes, Your Honor.

THE COURT: Right.

MR. MILLER: Yes, Your Honor. And it's certainly not an outlier. And, in fact -- and I'm going to have to factually disagree with Mr. Lasker because the NAPP study that did incorporate the De Roos study shows a doubling of the risk. It's not accurate for Mr. Lasker to stand up here and tell you that it doesn't

because it does. And it does that after adjusting for other pesticides.

And we know that because Mr. Lasker has deposed Dr. Weisenburger, one of our experts, who is one of the authors of this study. And he knows that. It shows a dose-dependent response, and this is a 2015 study that incorporated De Roos and incorporated Hardell. And it shows a peer-reviewed abstract. NAPP reported an elevated risk of NHL with any glyphosate use statistically significant, 1.14, and a dose-response effect was seen with greater than two days' use with an odds ratio of 2.42, statistically significant. So if you use glyphosate more than two days a year, you have a 2.42 increased risk, and Mr. Johnson used it 20 days a month, six months a year for two years. So he far exceeds that metric.

And so the authors, including our expert, Dr. Weisenburger, go on to say, and this is in our papers, "Our results are also aligned with findings from epidemiological studies of other populations that found an elevated risk of non-Hodgkin lymphoma for glyphosate exposure with a greater number of days/year of glyphosate use, as well as a meta-analysis of glyphosate use and non-Hodgkin lymphoma risk. From an epidemiological perspective, our results were supportive

of the IARC evaluation of glyphosate as a probable carcinogen for non-Hodgkin lymphoma."

So that's the latest information that we have. That's the newest science we have, except for their reliance on one study. Their sole reliance is on a 2017 study that they claim disproves all of this. And that's a jury issue. We're more than happy to talk to the trier of fact about why that study is worthless -- why they said it was worthless before the results came out and only embraced the study after the results came out.

And worse still for the defendants, if that study is valid, it shows a quadrupling of the risk for T-cell lymphoma, which is the precise lymphoma that Mr. Johnson has. He has T-cell lymphoma starting from skin exposure. It's a follicular form of non-Hodgkin lymphoma. And that's what they say in their study, which we don't think is that accurate. But if that study is that accurate, it's a quadrupling of the risk.

So that gets -- and we'll make a different argument when we get to a B-cell case because it shows no increased risk for B-cell. I will argue that one when we get to a B-cell case. But this one is a T-cell, and it's right on point. So if their study is good, we've got a quadrupling of the risk, and they have no epi to support them whatsoever.

So it's not a question of -- and I appreciate the Court's original question, in the extreme, sure. I'm not suggesting every trial judge in California has his hands tied because somebody comes up with one peer review. That's an issue for another day, and I don't think we need to argue that one because it's sure not the issue here.

Take a sip of water...

Your Honor made the point, and I just want to reiterate because it's in Cooper, it permeates the Cooper opinion. The Court is correct that Cooper does not allow the trial judge to weigh into the validity of studies. And that is precisely what he wants you to do. And he cited to cases from the First Circuit and the Third Circuit that, with all due respect, I don't believe stand for the proposition supported. But I don't think it really matters. I don't think we need to hyperanalyze them because we're not in the First Circuit, we're not in the Third Circuit. We're in San Francisco. So I think we stick with Cooper and its progeny.

I want to get to, I think, Dr. Nabhan, unless the Court has any further questions about our general epidemiology and our general causality. And I think I would like to spend one more minute on that, if I could.

I think the Court was very precise and accurate in your tentative in that it's unquestionable from Cooper, it's unquestionable from the scientific manual that the appropriate way to do science is not to look, as Your Honor's example, at one piece of peer-reviewed literature. You've got to look at the whole body of evidence, all the epidemiology, all the animal data, all the carcinogenic mechanistic data, and then you've got to synthesize that data. That's proper science.

So that's what all --

THE COURT: Suppose that's not what your experts did. Suppose what actually happened was that your experts took one or two studies, and they have no explanation for why they ignored all the other studies that point the other way, so that it looks like, for example, they're cherry picking things they believe help them out and they're ignoring the bad stuff. It may well be that with an explanation, that would be okay. But is it my place to point that out and then say with the failure to explain, that becomes the basis to exclude their opinion?

MR. MILLER: I'm not saying there isn't a case in the extreme where that would be appropriate for the trial judge to do, but certainly, it wasn't in Cooper. And this case is stronger than Cooper.

THE COURT: Well, do you think that your experts actually looked at what you call the whole body of evidence? Did they really do that?

MR. MILLER: They looked at an enormous amount of evidence. I could start --

THE COURT: It's a rhetorical question. I mean, you're free to answer, "Yes, they did."

MR. MILLER: I think they did. I mean, I spent a fortune to have them do it, I guess is one honest answer. We gave them all the epidemiology, we gave them all the animal studies, we gave them mechanistic studies. We met with them. They've been deposed. We've got 28 days of depositions or something. They've been torn up one side and down the other. It's in our brief the exact number of days, but it's enormous. And then seven days in front of Judge Chhabria. But yes, they looked at everything reasonably possible.

And they say put it all, you know, in one big picture. And that's why I was shocked when I flew to Harvard and deposed the two young nonoccupational epidemiologists that Monsanto proffered and asked them: "What did you look at? Did you look at everything."

"No. We didn't look at the animal data."

"Were you told not to?"

"Yeah, pretty much. We were just supposed to

look at the epi."

"Did you look at the mechanistic data?"

"No. Uh-uh. It wasn't provided to us."

"Did you look at any company documents?"

"None. Just looked at some epi studies and commented on them."

I'm like, that's not science. That's somebody strategizing from a law firm on what they want an expert to look at. Because if they were to look at everything, I think they were worried they wouldn't like what they would hear. So that, I guess, is one way to handle things. We handled them a whole different way. Our experts looked at everything.

And the quality of our experts, just so I could talk about it for a minute, I would think a trial judge -- and they tell that in the Wendell case and they tell us in the Cooper case, if the experts -- the more respectable these experts are, the more deference the trial judge ought to give.

Well, Dr. Portier is the number one toxicologist in America, period. He was head of the National Toxicology Program for many years. Every lab in America now follows the protocol that he set out in his PhD thesis for how to handle rat and mice studies. I mean, this man is impressive, and they don't like it.

But when IARC did their review of glyphosate, they invited one person to be an invited specialist to observe those events and to make sure the science was followed. They invited Chris Portier, that's who they invited.

And the man who chaired the IARC is also a nonretained expert here, Aaron Blair. We tried to get him to be a retained expert. He's like, "No, I don't want to be tainted by money." So we subpoenaed him and took his deposition. And he said, "Yeah, after everything that's said and done, everything we looked at, including the new study that the defendants walked way around, I still say glyphosate is the probable cause of non-Hodgkin lymphoma."

So that's the number one guy for the National Cancer Institute, the number one guy for the National Toxicology Program. Let's go to the West Coast. We have the chairman of epidemiology from UCLA, an occupational epidemiologist. Unlike the two epidemiologists that they have, this is an occupational epidemiologist. And she's chairman of UCLA. And she's been grilled at deposition, been grilled two days in front of Judge Chhabria. She stood like a rock on her opinions. This stuff causes non-Hodgkin lymphoma. And it's just that simple.

Then we go to New York, to Columbia, with Dr. Neugut who's written 500 articles on the causes of cancer, four textbooks on the causes of cancer, is retained as the chief investigator for three countries in Africa -- or two countries, I'm not sure, to set up cancer programs.

Before you can call yourself a cancer hospital in America, the Joint Commission for accreditation of hospitals sends in a team to set you up. That's Dr. Neugut. He leads those teams. This man has written articles on hematopoietic cancer, solid tumors. That's all he does, and he's been doing it for 40 years.

So, yes, he testified for us in Actos, turned us down on a bunch of other stuff, but he's agreed to testify on this. He says he reviewed it all, and it causes cancer. It causes non-Hodgkin lymphoma.

One more, if I could, before we get to the others, but Dr. Nabhan, University of Chicago. He's the case-specific expert. Only treats non-Hodgkin lymphoma at University of Chicago, one of the top four schools in the country. Written over 100 articles, many of them about non-Hodgkin lymphoma. One of the few doctors in the world that sees more than five cases a year of mycosis fungoides. I mean, this is -- they're hard to find. This is a rare disease. They say he just looked

at the exposure, then looked at the diagnosis, and came to the conclusion. That's nonsense.

And the facts absolutely tell the real story. He read all the literature. He came to his own general causation opinions. Looked at the animal data, he took his background, education, and experience, then he demanded to see the patient. Flew the patient to Chicago where he examined the patient. He took a thorough history from the patient. He read the patient's entire deposition. He ruled in and ruled out various causes of non-Hodgkin lymphoma and reached a differential diagnosis. That's even more than Dr. Smith did in Cooper. And you can't do any more than that.

And he reached the conclusion. And in fairness to the defense, he said there was also a genetic component. We don't know why, but sometimes black folk get mycosis fungoides. That's a factor. But the predominant factor, substantial contributing factor, for this man now dying from mycosis fungoides is his constant exposure to glyphosate for over two years. Very admissible evidence.

So those are the experts that I think make a general causation case and case-specific causation. They're very powerful evidence that we think we have on our side. And they're always entitled to put up a

defense, and they will, and the jury will decide it. And I think Your Honor's tentative is correct and I stand by it.

Your Honor asked defense counsel, "You're asking me to pick and choose between the studies," and we agree. That's exactly what he's trying to do. And not only the Cooper case, I won't go over it again. We just went over it, but the Wendell case that came after Cooper, it says the same thing. Don't do that.

All right. Let's move on, if I can, unless the Court has any further questions, to Dr. Sawyer and cancer slope. It's only a small part of his opinion, but it is a part of his opinion. And what he did, he used the exact same software used by EPA, used by others. And what that does, it just shows you how much exposure in some sort of mathematical -- you know, the quantity a person who has this amount of exposure is getting. And they use dermal absorption studies and that sort of thing. It's the same software used by the EPA and throughout the world for dose-response analysis.

Also, there's a California regulation called quantitative risk assessment at 27 CCR, Section 25703, which prescribes the methods used to determine whether a chemical poses a significant risk to humans. The software implemented there was created by the EPA. And

it's the standard software used to extrapolate from. That's what he used.

THE COURT: I understand. But you understand the argument coming from the other side here, which is: They don't disagree with anything you've just said in the last minute or two.

MR. MILLER: Sure.

MR. MILLER: And I understand the Court's argument. Perhaps I think the best thing to do would be to punt that to the trial judge --

THE COURT: Okay.

MR. MILLER: -- to see what is kind of shaping up there.

THE COURT: Say something like if the door is open to these things --

MR. MILLER: Yeah.

THE COURT: -- that you have a right to re-raise it or something like that?

MR. MILLER: I think that seems very reasonable. Yeah.

I'll move on then.

THE COURT: Okay.

MR. MILLER: I believe we've covered that issue.

Dr. Portier. And I think Your Honor has issues about the pooling of the mice studies. We can talk about that. But I think defense counsel, in his argument, tried to ram that through and say Portier can't testify at all, which is completely wrong. Dr. Portier spent more time than anyone reviewing this. Had opinions before litigation was ever filed. He's been reviewing this for years. Reviewed all the epi, reviewed the animal data, reviewed the mechanistic data, and has strong opinions about this causing non-Hodgkin lymphoma. What he's done with the pooling of the animal

data does not affect that in any way, shape, or form. So if the Court is inclined to keep the pooling data out, it doesn't affect his opinion. I'm going to spend a few minutes trying to suggest to the Court that you ought not keep it out.

So his pooling data was actually peer reviewed by the Environmental Protection Agency Scientific Advisory Panel, and I think we'll talk a little bit more at the end about the Scientific Advisory Panel. But when they reviewed it, they explicitly approved of Dr. Portier's pooling methodology, noting that it provided "compelling statistical evidence" of animal carcinogenicity. And that's at 59 of our Hoke declaration that is attached to our opposition brief. These members went further and recommended that the EPA adopt Dr. Portier's "pooled analysis approach for combining multiple studies." And that, again, is the same page, 59 of the Hoke.

And one last point, his pooling has been peer reviewed. Well, not his, but pooling has been peer reviewed in the article by Dourson, "Update: Mode of Action for Liver Tumors Induced by Oral Exposure." So that's not about Roundup, but it's about the process and methodology of pooling.

THE COURT: Pooling across studies, across a

variety of different studies?

MR. MILLER: I believe so, yes. Yes, yes. And that's at 88 Regulatory Toxicology and Pharmacology, Pages 45 to 55.

Wasn't that in our brief?

MR. TRAVERS: Yeah.

MR. MILLER: Yes, it was in our brief. Okay.

So that's our Portier argument, and obviously, he's admissible irrespective of pooling. We think pooling has been important and is significant enough.

Now, I'll turn to Dr. Benbrook. I think the Court, in your -- let me -- where is my copy of the Court's tentative? Excuse me one second, Your Honor. I apologize.

THE COURT: Of course.

MR. MILLER: There it is. Thank you, Your Honor.

In your tentative, you cite to the four ways that Dr. Benbrook has been previously allowed to testify. And I understand that by that, you intend to allow him to testify in those areas here. If I misunderstand, I'd better argue the point. And then you do go on to limit some things, but I wasn't sure what all those things meant. I have no intention to have him look at an e-mail and say that proves the corporation is

bad, or that proves the corporation wanted to put profit over people, or anything of that sort.

THE COURT: What would you do with the e-mail, if anything?

MR. MILLER: Well, that's a good question. Do you have an opinion as to whether Monsanto sought outside help to determine whether Roundup was genotoxic?

THE COURT: How would he possibly have a basis to know that, and what expertise does he bring to that question? He would have to know everything that Monsanto ever did during some huge time period.

MR. MILLER: Not if they did it -- I mean, not if they have -- not if we have clear documentation that they asked.

THE COURT: Well, then you give the jury the documentation. You don't have an expert. I just don't understand how an expert -- is he an expert in e-mail reading? Surely not.

MR. MILLER: I'm certainly not.

THE COURT: Do you see my point?

MR. MILLER: But I think when you ask an expert an opinion, I think you're entitled for the jury to hear the basis of it.

THE COURT: Yeah, but you're flipping the issue. The question is whether you're entitled to ask

him the opinion. It's got to be something the jury can't figure out on their own as laypeople, it's got to be an issue that matters to the case, and it has to be that he has a basis -- a factual basis to do it.

I just don't understand what he would do with respect to any e-mails at all. If you think the e-mail shows something dastardly that Monsanto has done and there's, you know, communications there, a smoking gun that you'd really love the jury to read, then wouldn't you just give the jury the e-mails.

MR. MILLER: Well, I'd generally like to have a witness sort of walk through the story. I think that's --

THE COURT: That's the problem. That's actually the problem with experts, when people use experts to sort of gild the story. You have a story, that's the actual evidence. And then sometimes people just use an expert to try to put sort of a gold patina around a particular story, and that could be problematic unless you meet these criteria as to what experts are really for.

So I won't belabor your time, but that's the problem.

MR. MILLER: I understand. So he can testify about the general rules of the EPA for register -- and

the statement and registration process for pesticides.

THE COURT: I'm sure he can provide some sort of general overview as to how that works. I'm not sure where it gets you in the case, but he may have the background to be able to do that.

MR. MILLER: All right.

THE COURT: Do you think industry standards, for example, and stewardship duty, which in Adams versus U.S. were, apparently, in that case held relevant? Is this a case where industry standards and so-called stewardship duty or ethical obligations -- I'm sorry, industry standards and stewardship obligations are relevant?

MR. MILLER: I think industry standards -- I'm sorry, Your Honor.

THE COURT: That's it.

MR. MILLER: I think industry standards are relevant, and I think there's a standard to warn. When you know about a risk of cancer and you violate that standard, that is an area uniquely requiring expert testimony.

THE COURT: How does that fit into the specific causes of action that are at stake in this case?

MR. MILLER: Because Monsanto certainly knew by 1999 that Roundup was carcinogenic.

THE COURT: I understand that position. But why does it matter that that violates or doesn't violate industry standards? I mean, let's say it turned --

MR. MILLER: I see your point.

THE COURT: Let's say it turned out it doesn't violate any industry standards at all. The reason being, let's make this up, the industry colluded and made sure there were no such standards, would that then defeat your case?

MR. MILLER: No, Your Honor --

THE COURT: No, I wouldn't care less.

MR. MILLER: -- you're quite correct. I'm losing this argument, Your Honor.

THE COURT: I mean, I don't care about industry standards. You're just going to prove that they knew and they didn't tell.

MR. MILLER: Right.

THE COURT: Right.

MR. MILLER: Well, then, now I've been whipped, so I'll move on.

THE COURT: No, I'm just asking --

MR. MILLER: I don't know what else to say, I'll be honest with you. And we'll be guided by the Court's overall ruling here.

Some e-mails -- and I've been handed a note

that I'd better bring it up. Some e-mails are very technical. And I know he's not an expert in reading e-mails, so I'd ask you to punt it to the trial judge for this e-mail or for that e-mail.

Sure, again, a general ruling -- look, we can't just stand up there and gild the case and put e-mails up on the board. I get it. But there will be some e-mails that are technical that involve an understanding of the EPA, and he may need to interpret those. And I'd just ask that you'd punt that to the trial judge for specific instances is all.

THE COURT: And you would tell me that when you disclosed him as an expert, you disclosed him for that purpose as well?

MR. MILLER: Oh, yes, Your Honor. If it's not on our expert report, I certainly won't talk about it to the jury.

THE COURT: I understand.

MR. MILLER: So just moving on to the last issue, which is preemption. We agree with the Court's tentative of -- I mean, it's clear from the Bates case, it's clear from the seven Roundup cases where they tried this and lost that the Court's tentative is right in line with all those, and it's quite correct. And moreover -- and I just want to end with this because we

factored this in as well. The EPA has not said Roundup doesn't cause cancer. Some people at OPP have said that. "OPP" being a division within the EPA. But two of the EPA scientists were on the IARC panel that said Roundup is probably the cause of non-Hodgkin lymphoma. Two of them.

So it's not true that -- it's true that there's some people at OPP that wrote a report that said it doesn't cause cancer, that's true. But it's also true that that report was reviewed by an independent Scientific Advisory Panel, which concluded that OPP, for whatever reason, did not follow their own guidelines.

And we don't know what number because the EPA won't tell us the vote, but a significant number of scientists on the SAP said this could be causing cancer. Some said no, but they didn't tell us the actual vote, so we don't know. But we know that you can buy a book here that has the EPA imprimatur on it, and it's cited in our papers, that tells you product exposure to Roundup studies out there show a risk for non-Hodgkin lymphoma.

We also know if you call the EPA hotline, you'll be put over to an operator who will tell you that there are animal studies and some epidemiological studies that shows an association between Roundup and

non-Hodgkin lymphoma. So to say that blanketly and universally, the EPA has concluded that it doesn't cause non-Hodgkin lymphoma is not squaring with the facts.

But I think we stand on the Court's tentative for preemption. Unless something extraordinary is said in the next couple of minutes, I'm about done.

THE COURT: I appreciate your help.

MR. MILLER: Thank you, Your Honor.

THE COURT: Thank you, sir.

MR. LASKER: Thank you, Your Honor. I just want to revisit a few things that --

THE COURT: Sure.

MR. LASKER: -- Mr. Miller stated in his argument. I'm going to do them largely sequentially.

The first issue that Mr. Miller raised dealt with the Cooper case. And obviously, we have the opinion in the Cooper case. And Dr. Miller -- Mr. Miller noted that there were a couple of studies in that case where the defense experts argue there could be some confounding with smoking, and you didn't adjust for that. And that was the issue that I mentioned in my argument. They were raising a hypothetical situation where you didn't adjust for smoking and we don't know what would have happened if you had.

So the first point, as I mentioned initially,

is: We don't have that situation here. We have a situation where we have studies that were adjusted for confounding for pesticides, and when they're adjusted for confounding for pesticides, did not show an association. So it's a much different situation here.

Secondly, if you look at the Cooper opinion -- and I would cite Your Honor again to the opinion at 239 Cal. App. 4th at 563 and 564 where they're talking about Dr. Smith's general causation testimony. The Court goes through and discusses the fact that Dr. Smith was relying upon studies that showed statistically significant increased risks, over doubling of the risks, when there was adjustment for smoking. I'm going to actually go through the fact that there were these studies with adjustments for smoking that doubled the risk. And there's a number of them that the Court goes through, and then there's one that's 4.3 increased risk, 2.5 -- well, you can read it as well, Your Honor.

And again, as I mentioned in my initial argument, when you go to the specific discussion at Page 594 of the specific causation opinion and relying upon epidemiology, the Court again talks about the fact that the experts had epidemiological studies that adjusted for these various factors, including smoking.

So the Cooper court spent enough time talking

about where there were studies that did adjust for smoking and continued to find this increased risk. And the situation we have here is that that's not the case.

Now, plaintiff's counsel made a number of statements, representations, about what the various studies showed. He talked about the NAPP study showed a doubling of the risk after adjustment for pesticides, and he talked about quadrupling the risk of T-cell lymphomas.

And this is a situation where the Court is -- and we are in sort of an awkward position here, and we suggest maybe we can supplement the record. Because there is testimony on these exact issues. Certainly with respect to the NAPP, there was testimony we're now hearing from plaintiff's experts in which they testified directly contrary to what Mr. Miller just said to the Court. I can, on this record, cite Your Honor to Exhibit 25 in our opening brief in which we're talking with Dr. Ritz about the NAPP study. And in that context, she's talking about the finding of the NAPP study after adjusting for the pesticides, also a sensitivity analysis for proxy. And she believes that the final odds ratio from all of the North American case-control studies with that adjustment was 0.95.

So that already is in the record in this case,

Your Honor, but we would suggest, Your Honor, that if the Court is inclined to credit or to rely upon any of the representations that Mr. Miller made about the studies, there is specific testimony that we can supplement Your Honor from plaintiff's experts that contradict what he said.

Dr. Nabhan, for example, Mr. Miller stated that there's a quadrupling of the risk of T-cell lymphomas in the 2008 NCI study. We showed Dr. Nabhan that specific odds ratio in his testimony in the MDL in his deposition. He said there's nothing there. It's not statistically significant. The numbers are too small. He doesn't rely upon that. So again, if that's an issue for Your Honor, we suggest that you allow us to supplement the record on that.

Likewise, with respect to Dr. Portier and his pooling analysis and whether the Dourson studies pool data across studies, we asked Dr. Portier that in front of Judge Chhabria and Judge Petrou in the Daubert hearing. He acknowledged that Dourson doesn't do that. There is pooling of male and female mice within the study, but there is no pooling across studies. He acknowledged that what he did has not been done by anybody else.

So, again, if Your Honor is interested in those

issues, you know, we would suggest a supplementing of the record so that you can see the actual testimony of the plaintiff's experts as opposed to the argument of Counsel.

With respect to the issue of -- well, the Court -- Mr. Miller mentioned the Wendell case in the Ninth Circuit. And as Your Honor may recall, having read that case, the issue in Wendell was: There was no epidemiology -- because it was such a rare cancer, there was no epidemiology. And in this case, plaintiff's experts, and Dr. Nabhan in particular, all say, "We can rely upon the general epidemiology for NHL," and they do rely upon that. There is a large body of epidemiologic evidence. So the Wendell case really doesn't apply in this circumstance.

With respect to Dr. Nabhan and his cancer slope, Mr. Miller stated that the cancer slope analysis is just a small part of Dr. Nabhan's opinion, and if that's the case, given the prejudice, as Your Honor recognized, and confusion that would arise from presenting that data to the evidence (sic), clearly the prejudice outweighs what Mr. Miller stated, which is a small part of their case. There's not a large, if there's any -- and we don't think there's any probative value. We think that also requires and calls for the

cancer slope opinions to be excluded.

Just quickly, with respect also to Mr. Miller's comment that the pooling analysis was somehow accepted or adopted by the EPA through the Scientific Advisory Panel, there is a document in the record, it's Exhibit 10 to the Edwards declaration. I think this is in connection with the motion for judicial notice -- which shows EPA's response to the SAP process and to the materials that were submitted, which included Dr. Portier's pooling analysis in which the EPA expressly rejects that pooling analysis, and that's in the record for Your Honor.

A couple of final points. With respect to Dr. Benbrook and this issue of whether or not there are some e-mails that raise technical issues that Dr. Benbrook could respond to and whether there should be something reserved for the jury on that -- or for the trial judge on that, again here, as we set forth and I think as I disputed, Dr. Benbrook does not have expertise in a wide variety of areas. When you're talking about technical documents, the e-mail he's talking about dealing with scientific studies, how Monsanto responded to scientific studies, whether they were submitted, whether they were not, these are not issues where Dr. Benbrook has any expertise to be able to read those e-mails in a way that

would be of any assistance to the jury.

So certainly, laying out in your ruling these areas where he does not have expertise, to provide guidance on exactly -- and I frankly can't imagine -- I don't know any document where he does have any expertise -- any e-mail that he has any added expertise above a lay juror, but certainly the Court's ruling should make clear that he does not have expertise in these areas.

Finally, with respect to the issue of preemption that Mr. Miller was arguing about and whether there were people within the EPA that disagreed, I think it's kind of interesting to call the document that was submitted, which was a 270-some-odd-page, confining that goes through all the scientific evidence after notice and comment, after the SAP, as an EPA conclusion that some people at OPP said this and just sort of gave it the back of their hand.

But, you know, at the very least, all that Mr. Miller is arguing there is that there's something that he would want to argue about as to what exactly the OPP did. And that's an issue with In re Fosamax, so that's an issue for the jury to decide. I don't think that argument actually gets him a disputed issue of material fact where you have this document after --

after notice and comment and after plaintiff's experts have already submitted all of their arguments to the EPA and the EPA rejected them, that strikes me as pretty clearly in line with the clear evidence standard that Your Honor applied in Plavix and that a number of other courts have applied.

So we don't think that they even raised a disputed issue of fact on that, but if Your Honor has issues or questions based upon what Mr. Miller said, that then, at most, gets him a fact issue. I think the legal question is, as we stated, whether or not the Court can just ignore the -- or hold that evidence of the EPA's actions in finding glyphosate not being carcinogenic and approving the labels to be irrelevant as a matter of law on the question of preemption.

And we don't think that is appropriate under Kimmel. The Kimmel court had many of its -- based upon Supreme Court rulings like Geier and I think Freightliner has stated that you can't just say there's an express preemption clause and I'm not going to consider implied preemption. You have to look at the implied preemption issues.

Of course, there is a burden there that would need to be shown for an affirmative defense to make out that implied preemption. If those facts don't exist,

you don't have implied preemption, conflict preemption. But those legal standards, you still need to look at those and reach a determination. So we think that's a legal issue for Your Honor, but I think Nathan Kimmel basically answers that question.

And unless you have further questions, Your Honor...

THE COURT: Thank you.

MR. MILLER: Your Honor, may I have just two minutes?

THE COURT: Of course.

MR. MILLER: Thank you. We both know there's a lot at stake here, but supplemental briefing is just another way to prevent us from trying to get ready for trial. I would ask the Court not to do supplemental briefing. You don't need it. What he wants supplemental on is what he wants to cross-examine our experts upon in trial. What I represented to be in the studies, Your Honor can look in the studies. They're there.

THE COURT: I'm going to try to decide this based on the papers I have.

MR. MILLER: Your Honor, thank you. I said that the NAPP study showed a doubling of the risk. You can look at the NAPP study. It's right in there. It's

not my suggestion. What he's referring to is a cross-examination where there was a subanalysis where they took out proxy responders. And with a subanalysis without proxy responders, the risk went away.

And we could debate forever why that happened. Proxy responders are inherently inaccurate, and we can both debate it back and forth. There's no bearing on the fact that on the NAPP study, there was a doubling of the risk. It's right in the study.

And on their study, the 2018 study, he's right, there is a quadrupling of the risk, but Dr. Nabhan did not rely upon it. And that's exactly what I said. So we agree Dr. Nabhan didn't rely upon that quadrupling of the risk because he doesn't think the study is done right. But if they want to rely on that study, that study shows a quadrupling of the risk. That was my point. And I think we're arguing the same issue.

He brought up the Wendell case as after Cooper. And I think that's a very instructive case because there, they allowed Dr. Weisenburger, the same expert that we're using here, to testify without any epi because he's such a highly qualified individual. He looked at the animal studies and he analyzed it, and they reversed the trial court, right, because he wasn't going to allow Dr. Weisenburger, and Dr. Weisenburger --

THE COURT: She wasn't. The trial judge was a woman.

MR. MILLER: Excuse me, I'm sorry.

THE COURT: That's okay.

MR. MILLER: I apologize. I think that's it. I think cancer slope was about Sawyer not Nabhan, but I think that's --

MR. LASKER: My mistake.

MR. MILLER: Yeah, it's all good.

Listen, thank you very much, Your Honor.

MR. LASKER: Can I just -- one thing, Your Honor.

THE COURT: You certainly can. You have more time.

MR. LASKER: With respect to the findings in the NAPP, they are in this record in our Sargon opposition brief, Exhibit 10. Dr. Mucci, in her report, goes through the various findings in that study, what the numbers were after adjustment for other pesticides, what the numbers were before adjustment for other pesticides. Mr. Miller was citing to data points particularly for the doubling of risk before adjustments for other pesticides. That does not exist after.

And if the study -- if the full study -- and there's a draft publication that writes up those

numbers, but there's also a slide that presents it. The data is not disputed. There just is no doubling of the risk after adjustments. Judge Chhabria raised that in the argument that he had with Counsel, and there's no dispute over that fact.

I don't know exactly what more to say about that, Your Honor. It's not a cross-examination point, it's just what the study shows.

THE COURT: Anything else?

MR. MILLER: We disagree.

THE COURT: Okay. That's what you're here for. Well, thank you. I appreciate everybody's help. The matter is submitted. It will be helpful, I think, to get a transcript of the argument. It will take me some time to write this up.

MR. MILLER: Your Honor, if I could, unrelated to the merits --

THE COURT: Of course.

MR. MILLER: -- we wanted to ask about one question about page and line, and we also wanted to ask the Court for a phone conference, if we could, next week. And I'm not going to argue the issue just to sort of alert the Court. We were deposing Daniel Goldstein. Your Honor allowed us to re-depose him. You'll recall, he was the Monsanto employee who took in the phone calls

from Wayne Johnson.

And during that deposition, we handed him a document from 2004, which we find to be a very important document in this case. I don't want to say what the document is in open court. But what happened is: After about ten questions, I took a break, counsel and witness left the room, they came back and claimed that it was prepared at the request of attorneys, and therefore, they weren't going to talk about it anymore and they wanted to claw him back.

We're waiting for them to do the proper procedures, but we're running out of time. Our argument is: There's nothing in there about lawyers. The metadata shows nothing --

THE COURT: We don't have to go into the details. You have a disagreement about this issue?

MR. MILLER: Yes, we have a disagreement and we'd like to have a few minutes. Yes, Your Honor.

THE COURT: So why don't we go off the record and pick a date that works for everybody's calendar.

MR. MILLER: Sure.

THE COURT: Off the record.

(Off the record.)

THE COURT: The informal conference will be at 9:00 on the 16th of May.

Off the record.

(Proceedings concluded at 11:00 a.m.)

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were duly sworn; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript [ ] was [ ] was not requested.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: May 14, 2018

<%signature%>

Sheila Pham
CSR No. 13293

Exhibit 5

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF WHEAT GROWERS; NATIONAL CORN GROWERS ASSOCIATION; UNITED STATES DURUM GROWERS ASSOCIATION; WESTERN PLANT HEALTH ASSOCIATION; IOWA SOYBEAN ASSOCIATION; SOUTH DAKOTA AGRI-BUSINESS ASSOCIATION; NORTH DAKOTA GRAIN GROWERS ASSOCIATION; MISSOURI CHAMBER OF COMMERCE AND INDUSTRY; MONSANTO COMPANY; ASSOCIATED INDUSTRIES OF MISSOURI; AGRIBUSINESS ASSOCIATION OF IOWA; CROPLIFE AMERICA; AND AGRICULTURAL RETAILERS ASSOCIATION,

Plaintiffs,

v.

LAUREN ZEISE, IN HER OFFICIAL CAPACITY AS DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT; and XAVIER BECERRA, in his official capacity as Attorney General of the State of California,

Defendants.

CIV. NO. 2:17-2401 WBS EFB

MEMORANDUM AND ORDER RE: MOTION TO ALTER OR AMEND PRELIMINARY INJUNCTION ORDER

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Before the court is defendant Xavier Becerra's Motion to Alter or Amend the Court's Order Granting Preliminary Injunction (Docket No. 81). The court held a hearing on the motion on June 11, 2018.

I. Legal Standard

A motion to reconsider a preliminary injunction is governed by Federal Rule of Civil Procedure 59(e).[1] See Credit Suisse 1st Boston Corp. v. Grunwald, 400 F.3d 1119, 11-2324 (9th Cir. 2005). A district court may reconsider its decision if it "(1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." Smith v. Clark Cty. Sch. Dist., 727 F.3d 950, 955 (9th Cir. 2013) (citation omitted).

Motions for reconsideration "are directed to the sound discretion of the court." Riley v. Giguiere, 631 F. Supp. 2d 1295, 1310 (E.D. Cal. 2009) (Karlton, J.); see also McDowell v. Calderon, 197 F.3d 1253, 1256 (9th Cir. 1999). However, reconsideration is an "extraordinary remedy" that should be used "sparingly in the interests of finality and [the] conservation of judicial resources." Kona Enters. v. Estate of Bishop, 229 F.3d 877, 890 (9th Cir. 2000). A party may not use a motion to reconsider "to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the

[1] Although defendant's motion is styled as a "motion to alter or amend" the court's prior order, the parties agree that this motion is governed by Rule 59(e).

litigation." Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co., 571 F.3d 873, 880 (9th Cir. 2009) (citing Kona Enters., 229 F.3d at 890).

II. Discussion

As discussed in the court's February 26, 2018 order, this case concerns California's Proposition 65, which, among other things, requires warning labels for products containing chemicals known to the state of California to cause cancer, as determined by certain outside entities.

The Attorney General now claims that reconsideration is warranted in light of new evidence and because the court

[2] Lauren Zeise, director of the Office of Environmental Health Hazard Assessment, was initially included in the court's injunction, though per the parties' stipulation, she was dismissed from the case and the injunction was amended to refer specifically to the Attorney General. (Docket No. 93.)

purportedly committed clear error by determining there is no possible warning that can comply with Proposition 65 and not violate plaintiffs' First Amendment rights. However, for the following reasons, the court finds that neither ground warrants the extraordinary remedy of reconsideration.

First, the court's order granting the preliminary injunction speaks for itself. The Attorney General has not shown that the court clearly erred in reaching its conclusions or that the injunction is manifestly unjust. See Smith, 727 F.3d at 955.

Second, the Attorney General's "new evidence" does not warrant reconsideration.

[3] Because plaintiffs do not oppose the Attorney General's Request for Judicial Notice (Docket No. 88) and the court finds the materials in the Request are properly subject to judicial notice, the court hereby GRANTS the Request.

[redacted].

The Attorney General also includes new citations to sources either supporting the IARC's determination that glyphosate is a probable carcinogen or criticizing agencies that found it was not. [redacted] Once again, the court's analysis here is not whether the IARC's determination is persuasive or supported by competent evidence, but rather whether a warning conveying the message that glyphosate causes cancer is factual and uncontroversial.

The court next turns to the Attorney General's newly proposed alternative warnings. Neither of these warnings constitute new evidence warranting reconsideration under Rule 59. The Attorney General's first proposed warning states: "WARNING: This product can expose you to glyphosate, a chemical listed as causing cancer pursuant to the requirements of California law. For more information go to www.P65Warnings.ca.gov." (Mot. 10 (Docket No. 81-1)). This warning is not significantly different from the existing safe harbor warning already rejected by this

[4] It appears that these sources could have been provided in the Attorney General's opposition to the Motion for Preliminary Injunction. See Marlyn, 571 F.3d at 880 (party may not use a motion to reconsider to raise arguments or present evidence that could reasonably have been raised earlier in the litigation).

court, which states that glyphosate is a chemical known to the state of California to cause cancer. Stating that a chemical is listed as causing cancer "pursuant the requirements of California law" conveys essentially the same message to consumers as stating that a chemical is known to the state of California to cause cancer. As the court previously stated, "[o]rdinary consumers do not interpret warnings in accordance with a complex web of statutes, regulations, and court decisions, and the most obvious reading" of this alternate warning is that exposure to glyphosate in fact causes cancer in humans. (See Prelim. Inj. Order 14.)

Further, California cannot remedy this warning by simply pointing consumers to a website discussing the debate. It would seem likely that few, if any, consumers will actually visit the www.P65warnings.ca.gov website, meaning that as a practical matter this website will not provide the necessary context that might render this warning factual and uncontroversial. Even if consumers were likely to visit this website, the Attorney General conceded at oral argument that whether a warning is factual and uncontroversial is determined by looking at the warning standing alone. A warning that is deficient under the First Amendment may not be cured by reference to an outside source.[5]

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[5] Similarly, the court rejects the Attorney General's suggestion that the warning does not violate the First Amendment because plaintiffs may provide their own additional information regarding glyphosate's carcinogenicity separate from the warning. Accord Masterpiece Cakeshop, Ltd. v. Colo. Civ. Rights Comm'n, No. 16-111, 2018 WL 2465172, at *27 (June 4, 2018) (Thomas, J. concurring) ("Because the government cannot compel speech, it also cannot 'require speakers to affirm in one breath that which they deny in the next.'") (quoting Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal., 475 U.S. 1, 16 (1986)).

The Attorney General's second proposed warning does provide additional context regarding the debate as to glyphosate's carcinogenicity, stating:

> WARNING: This product can expose you to glyphosate, a chemical listed as causing cancer pursuant to the requirements of California law. The listing is based on a determination by the United Nations International Agency for Research on Cancer that glyphosate presents a cancer hazard. The U.S. Environmental Protection Agency has tentatively concluded in a draft document that glyphosate does not present a cancer hazard. For more information go to www.P65warnings.ca.gov.

(Mot. 12.) However, this warning is not new evidence under Rule 59(e) because there is no reason the Attorney General could not have proposed such a warning in response to plaintiffs' request for a preliminary injunction. See Marlyn, 571 F.3d at 880 (on motion to reconsider, party may not raise arguments or present evidence that could have been raised earlier in the litigation). The Attorney General argues that he could not have offered such a proposed warning until he knew how the court would rule on the preliminary injunction, but such contention is not plausible. During oral argument on plaintiffs' Motion for a Preliminary Injunction, the court proposed multiple iterations of warnings providing more context regarding the debate on glyphosate's carcinogenicity, none of which were acceptable to the Attorney General. Indeed, the Attorney General specifically rejected the court's proposal of a warning that would state that glyphosate was a carcinogen as "determined by one of the agencies but not by the others" because such language would "dilute" the

warning.[6] (Hr'g Tr. at 51 (Docket No. 72).) In other words, the Attorney General could have proposed his second alternative warning, or agreed to a similar warning, before the court granted a preliminary injunction, but he chose not to. To the contrary, the Attorney General essentially took the position that the warning he now advocates was insufficient.

Even assuming the second alternative warning could not have been presented before and was binding on private enforcers of Proposition 65, this warning does not warrant reconsideration of the court's injunction. The court agrees that it is "an impossible task" to disclose "everything on each side on the scientific debate," see CTIA-The Wireless Association v. City of Berkeley, 139 F. Supp. 3d 1048, 1071-72 (N.D. Cal. 2015), aff'd, 854 F.3d 1105 (9th Cir. 2017), and the law does not require a warning label to disclose the details of the debate in the scientific community regarding glyphosate's carcinogenicity -- to do so would turn a warning label into an essay. However, it is not clear that even a lengthy discussion regarding the conflicting agency findings as to glyphosate's cancer risk would comply with the First Amendment. [redacted] See Central

[6] Notably, the Attorney General continues to argue that language providing more context is unnecessary and reserves the right to raise this argument on appeal. (See Mot. 3 n.3.) This reservation of a right to appeal even if the court grants reconsideration tends to weigh against granting the Attorney General's motion.

Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980); Cal. Chamber of Commerce v. Brown, 196 Cal. App. 4th 233, 258 (1st Dist. 2011).[7]

The Attorney General's second alternative warning is also deficient because it conveys the message that there is equal weight of authority for and against the proposition that glyphosate causes cancer, or that there is more evidence that it does, given the language stating that the EPA's findings were only tentative, [redacted][8] Accordingly, neither of the Attorney General's alternative warnings, nor any purported clear error by the court, weigh in favor of reconsideration.

[redacted]

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[7] It also appears that a warning properly characterizing the debate as to glyphosate's carcinogenicity would not comply with Proposition 65 and the applicable regulations and thus would not advance a substantial state interest. See Central Hudson, 447 U.S. at 566. The Attorney General's own Settlement Guidelines state that certain words or phrases are per se not clear and reasonable, "such as (1) use of the adverb 'may' to modify whether the chemical causes cancer . . . (as distinguished from use of "may" to modify whether the product itself causes cancer . . .); [and] (2) additional words or phrases that contradict or obfuscate otherwise acceptable warning language." Cal. Code Regs. tit. 11 § 3202(b). The Attorney General's second alternate warning, by discussing the EPA's contrary finding that glyphosate does not cause cancer, appears to "contradict or obfuscate otherwise acceptable warning language" in violation of this regulation.

[8] Once again, the court expresses no opinion as to whether a statement that a chemical causes cancer is factual and uncontroversial where there is stronger evidence in support of the chemical's carcinogenicity.

(redacted)

Dated: June 12, 2018

WILLIAM B. SHUBB
UNITED STATES DISTRICT JUDGE