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7	SUPERIOR COURT OF THE STATE OF CALIFORNIA	
8	FOR THE COUNTY OF ALAMEDA	
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10 11	COORDINATION PROCEEDING SPECIAL	JCCP NO. 4953
12	TITLE (RULE 3.550) ROUNDUP PRODUCTS CASES	Case No.: RG17862702
13	THIS DOCUMENT RELATES TO:	PLAINTIFF ALVA AND ALBERTA
14	Pilliod, et al. v. Monsanto Company, et al. Alameda Superior Court Case No.: RG17862702	PILLIOD'S RESPONSE TO MONSANTO'S MOTION TO EXCLUDE
15	Alameda Superior Court Case No.: RO17802702	DR. SAWYER
16		BY FAX
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18		Hon. Judge Winifred Smith Dept. 21
19		Hearing Date: March 7, 2019
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PLAINTIFFS' RESPONSE TO MONSANTO'S MOTION TO EXCLUDE DR. SAWYER

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TABLE OF AUTHORITIES In re Seroquel Prod. Liab. Litig., No. 6:06-MD-1769-ORL-22D, 2009 WL 3806436, at *4 (M.D. Fla. In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig., (S.D. Ill. Dec. 16, Mary B. FLEMING, Plaintiff, v NICHOLLS-WILCOX, INC., Defendant., (Ga.Super. May 10, 2005) No. Pulse Med. Instruments, Inc. v. Drug Impairment Detection Servs., LLC, 858 F. Supp. 2d 505, 512 (D.

PLAINTIFFS' RESPONSE TO MONSANTO'S MOTION TO EXCLUDE DR. SAWYER

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

William Sawyer, Ph.D. "is a highly qualified toxicologist - currently chief toxicologist of Toxicology Consultants and Assessment in New York. He is Board Certified in forensic medicine, toxicology and pharmacology and is well published." Mary B. FLEMING, Plaintiff, v NICHOLLS-*WILCOX*, *INC.*, *Defendant.*, (Ga.Super. May 10, 2005) No. 02-1-7632-42, 2005 WL 5419258. Dr. Sawyer has more than 28 years of experience in public health and forensic toxicology including five years of governmental service. See Hoke Decl. Ex. 1, (Sawyer Aff. at ¶¶ 2-10 & Curriculum Vitae). He has a Ph.D. in toxicology and a Master's degree in cellular and molecular biology and has consulted for numerous governmental agencies including "the United States Attorney's Office, US Navy, various prosecutors, Attorney State General of Montana, New York, New Jersey and other states." See Hoke Decl. Ex. 2 (Johnson Trial Tr. at 3586-3588). Dr. Sawyer qualifications "as an expert in toxicology, forensic toxicology and exposure assessments" were unchallenged by Monsanto in the first and only Roundup case to go to trial. Id. at 3594.

To date, he has given over 40 hours of testimony in the overall Roundup litigation through six days of deposition and one day of trial testimony. He has spent hundreds of hours reviewing published studies. medical records and internal documents written by Monsanto scientists. Monsanto has twice tried to exclude or strike Dr. Sawyer's causation opinions and has twice failed. See Hoke Decl. Ex. 3, Johnson v. Monsanto, CGC-16-550128 (Judge Karnow), Order re Monsanto's Omnibus Sargon Motion (Sargon Order), p. 26 (5/17/2018); See Hoke Decl. Ex. 4 Johnson v. Monsanto CGC-16-550128, (Judge Bolanos), Order Denying Motion for JNOV and New Trial ("JNOV Order"), (10/22/2018). In the *Johnson* trial, Dr. Sawyer's testimony along with the testimony of four other experts was sufficiently credible to unanimously convince a highly educated jury that Glyphosate based herbicides (GBHs) were a substantial contributing factor in causing the Plaintiff's non-Hodgkin Lymphoma (NHL).

Dr. Sawyer is being put forth as an expert to explain that glyphosate-based herbicides (GBH) cause non-Hodgkin lymphoma; to explain mechanism and rate at which GBHs are absorbed into the body; to explain the effects of the Pilliods failure to wear protective gear based on Monsanto's representations; and to explain that Mr. and Mrs. Pilliod were exposed to a sufficient amount of GBH to cause their NHL. Ex

1 to Def.'s Mot. to Exclude Dr. Sawyer (Sawyer Pilliods Rep. 115-117). Dr. Sawyer will also be offering testimony on the adequacy of the Roundup® label. Hoke Decl. Ex. 5 (Sawyer Dep. at 329-336) ("So my opinion within a reasonable toxicological certainty, as one who has prepared labels and MSDSs for corporations of products, I find this to be an insufficient and misleading label.")

All of these opinions are well-described and disclosed in his depositions, reports and notes. Dr. Sawyer used well-established methodologies in developing his opinion (which have been disclosed ad nauseam to defendants). He utilized the Bradford-Hill criteria for his causation opinion; he utilized the EPA Guidelines on assessing carcinogens in evaluating the animal studies; and he utilizes the well-accepted OECD guidelines for his opinions on dermal absorption.

Importantly Defendant offers no expert testimony and cites no scientific research that would contradict any of Dr. Sawyer's well-reasoned opinions. Rather, Defendants' motion is based on a willful ignorance of the exhaustive analysis and opinions that Dr. Sawyer has offered to date and gross misrepresentations of the record. Defendant's Motion should be denied.

II. LEGAL STANDARD

Under California law, "The court does not resolve scientific controversies. Rather, it conducts a 'circumscribed inquiry' to 'determine as a matter of logic the studies and other information cited by experts adequately support the conclusion that the expert's general theory or technique is valid." *Sargon Enterprises, Inc. v. Univ. of S. Cal.*, (2012) 55 Cal. 4th 747, 776¹. In the Court's gatekeeping role "[t]he gate tended is not a partisan checkpoint. It bars expert opinion only if it fails to meet the minimum qualifications for admission. If the opinion is based on materials on which the expert may reasonably rely in forming the opinion and flows in a reasoned chain of logic from those materials rather than from speculation or conjecture, the opinion may pass, even though the trial court or other experts disagree with its conclusion or the methods and materials used to reach it." *Davis v. Honeywell Int'l Inc.*, (2016) 245 Cal. App. 4th 477, 492, review denied (May 25, 2016).

III. ARGUMENT

¹ "Sargon did not announce a new rule, but instead relied on prior statutory and case law authority to evaluate foundational issues with expert testimony." Sargon Enterprises, Inc. v. Univ. of S. California, 215 Cal. App. 4th 1495, 1503, 156 Cal. Rptr. 3d 372, 378 (2013). Sargon did not involve questions concerning medical causation, but rather involved the exclusion of expert testimony on lost profit that were "wildly beyond, by degrees of magnitude anything Sargon had ever experienced in the past." Sargon, 55 Cal. 4th at 776, (2012).

A. Dr. Sawyer Will be Offering an Opinion Roundup® Causes NHL and that the Pilliods' Exposure to Roundup® was Sufficient to Cause the Pilliods' NHL.

1. Dr. Sawyer Disclosed His General Causation Opinion.

With respect to causation, Dr. Sawyer will be providing an opinion that Roundup® caused NHL; that the Pilliods were exposed to a sufficient amount of Roundup® to cause their NHL; and explain the manner in which Roundup® penetrated the Pilliods' body. This is similar to the type of testimony that Dr. Sawyer offered in the *Johnson v. Monsanto* trial and is the same type of testimony by Dr. Sawyer deemed admissible by the Ninth Circuit Court of Appeals. *Whitlock v. Pepsi Americas*, (9th Cir. 2013) 527 F. App'x 660, 661 (Finding admissible Dr. Sawyer's testimony that "exposure levels were 'within [a] reasonable range of that known [from several studies] to induce' the alleged injuries.").

Plaintiffs' explicitly stated that, as with Drs. Weisenburger, Portier, Nabhan, Ritz, and Jameson. Plaintiffs were incorporating Dr. Sawyer's previously disclosed testimony and reports on general causation from the *Johnson v. Monsanto* case. Hoke Decl. Ex. 6 (Plaintiffs' Expert Disclosure, ¶ 6) ("Plaintiffs hereby incorporate by reference all of Dr. Sawyer's previous deposition testimony in cases against Monsanto, his Daubert testimony in the Roundup MDL, his trial testimony in the Johnson v. Monsanto case; and all previously submitted reports and reliance lists."). In over 40 hours of testimony and reports in three cases, Dr. Sawyer's causation opinion have been disclosed in excessive detail. Dr. Sawyer's report in Johnson v. Monsanto was extensive and covered general causation and principles of dermal absorption of glyphosate, among other topics. Hoke Decl., Ex. 7 (Johnson v. Monsanto, Expert Report of Dr. Sawyer). For example, in the Johnson Report incorporated into this case, Dr. Sawyer opined that:

Animal and Human studies: It is my opinion to reasonable toxicological certainty that correct application of the U.S. EPA methodology results in a finding from the available animal studies, as referenced herein, that glyphosate is probably carcinogenic. Additionally, the prevailing objective human epidemiological evidence (as summarized in this assessment and as documented within the epidemiological expert reports and noted in numerous citations) supports the contention that glyphosate is a human carcinogen in doses applied in real world applications. Additionally, adjuvant formulations and various mixtures of glyphosate have greater potential for carcinogenic health risks primarily due to increased dermal absorption.

Id. at 5. Dr. Sawyer's Johnson Report devotes approximately 170 pages detailing the evidence and methodology he utilized in concluding that Roundup® causes NHL, including a detailed analysis of fifteen

long-term animal carcinogenicity studies. *Id.* at 97-145. He discussed the fact that Roundup® was genotoxic causing double strand breaks. *Id.* at 125-127, 133. He properly relies on IARC, Dr. Ritz and Dr. Portier with respect to detailed opinions on epidemiology. *Id.* at 143, 157. Dr. Sawyer read in detail EFSA and EPA's reports on glyphosate and details why these findings are in error. *Id.* at 92-97, 143.

Defendants' decision to simply ignore the Plaintiffs' expert disclosure in this case is done at their own peril. Their feigned ignorance does not provide a basis for excluding Dr. Sawyer's exhaustively disclosed general causation opinion. Defendant's experts likewise incorporated their expert reports and testimony from previous cases. Hoke Decl. Ex. 8 (Defendants' Expert Disclosure, p. 8) ("Monsanto hereby incorporates, by reference, Dr. Foster's previously submitted general-causation reports, reliance lists, and deposition testimony, which have been served on Plaintiffs and taken in In Re Roundup 16-MD-2741-VC.")

At the *Johnson* trial, Dr. Sawyer's general causation opinions were deemed admissible and he testified as follows:

- Q. And did you reach an opinion to a reasonable degree of scientific certainty that Roundup and Ranger Pro can cause non-Hodgkin's lymphoma?
- A. Yes. I have been following the peer-reviewed literature on glyphosate since mid-1990s.
- Q. And what is the opinion you've reached, generally?
- A. That, clearly, glyphosate and with its combinations of adjuvants, is a known carcinogen. ***

That glyphosate, based on animal test data, is carcinogenic by itself. However, there are additives to the product which increase and enhance its carcinogenicity by several mechanisms.

Hoke Decl. Ex. 2 (Johnson Trial Tr. at 3594-3596).

In this case, consistent with his expert report and disclosure, Dr. Sawyer confirmed at deposition that he was offering a similar general causation opinion:

- Q. I just had a follow-up on a question Mr. Kalas asked earlier, suggested that in ruling in glyphosate, you only looked -- you only considered three studies. But isn't it true that you also have a general causation opinion in this case?
- A. Yes.
- Q. And was that general causation opinion based just on three studies? ***
- A. No, not at all.
- Q. And you looked at the entirety of the data in coming to your general causation opinion; is that correct?
- A. Yes.

A. I have with respect to the mechanism of carcinogenicity, mutagenesis, co-formulates and agitants, co-contaminants, and other factors. Enhanced dermal too through the use of skin cream. *See* Hoke Decl. Ex. 5 (2/6/2019 Sawyer Dep. at 321).

Dr. Sawyer's testimony has thus been properly disclosed and is admissible.

2. Dr. Sawyer's Opinion that the Pilliods' Exposure to Roundup® is Sufficient to Cause NHL is Admissible

Defendant conflates the issues of admissibility of evidence with the Plaintiffs' burden of proof. An expert opinion is admissible even if it goes to only one aspect of the evidence that the jury must consider in coming to a verdict. In *Hernandez v. Amcord, Inc.*, a trial court excluded an expert who testified that a Plaintiffs' exposure to asbestos was sufficient to cause his case without making the ultimate conclusion that it was a legal cause of his cancer, where another medical expert did provide that opinion. 215 Cal. App. 4th 659, 674 (2013). The Appeals Court reversed holding that there is no requirement "that a medical doctor must expressly link together the evidence of substantial factor causation." *Id.* This makes sense as some experts will also give opinions only on general causation without opinion on the specific Plaintiff's injury.

Dr. Sawyer's same type of testimony was deemed admissible in *Johnson* and deemed admissible by the Ninth Circuit. In *Whitlock*, the Court held:

[T]he district court exceeded its gatekeeping function in excluding Dr. Sawyer's testimony that the alleged TCE and chromium exposure levels were "within [a] reasonable range of that known [from several studies] to induce" the alleged injuries. Plaintiffs' alleged exposures were not so low that the occupational studies were irrelevant. Because Dr. Sawyer's opinion "rests on a reliable foundation and is relevant to the task at hand,..., it is admissible. Whether it proves causation is not a question of admissibility

527 F. App'x at 661. Likewise, here, Dr. Sawyer's opinion that Roundup® exposure is sufficient to cause the Pilliods' cancer may not satisfy Plaintiffs' burden of proof, but it is admissible and helpful testimony, particularly where there are other experts have reviewed the Pilliods' medical records.

Dr. Sawyer stated that "what I am not doing in this case, I am not performing a differential diagnosis with respect to other potential confounding factors. That is deferred to the hematologists and oncologists." *See* Hoke Decl. Ex. 5 (2/6/2019 Sawyer Dep. at 77). "I'm not intending on providing that testimony. What my intent is, is that the dosage received was significant enough to cause or contribute to the development of [the Pilliods'] NHL." *Id.* at 160. Defendants 'attempt to disqualify this explanation is

puzzling. Due to time constraints and because other experts were giving other case-specific opinions based on differential diagnosis, Plaintiffs' counsel simply decided that, to avoid duplication, Dr. Sawyer's opinion would focus on whether the Pilliods' exposure to glyphosate was sufficient to cause their cancer

Dr. Sawyer provided the same testimony at the *Johnson* trial. In *Johnson*, Dr. Sawyer, undertook a review of the case in order to determine whether GBHs cause NHL and specifically determine whether Mr. Johnson's exposure was substantial enough to have caused his NHL. *See* Hoke Decl. Ex. 2 (Johnson Trial Tr. 3601-3602). In reaching his opinions, Dr. Sawyer spoke with Mr. Johnson by telephone and reviewed pertinent medical records, deposition transcripts, published studies, animal studies, and internal Monsanto documents. *Id.* at 3587-3598. Dr. Sawyer testified that up to 10% of the total exposure dose could have been absorbed through Mr. Johnson's skin each time that he sprayed the GBHs. *Id.* at 3649:8-20. Dr. Sawyer calculated Mr. Johnson's dose based on days of exposure and milligrams per kilogram per day using a tested model (UK POEM). *Id.* at 3747. Dr. Sawyer testified that Mr. Johnson's total exposure was sufficient to have caused his NHL. *Id.* at 3747, 3791.

As in the Johnson trial, Dr. Sawyer will opine here that glyphosate causes cancer, and opine the manner in which the Pilliods were exposed to glyphosate was sufficient to cause their cancer. Dr. Sawyer extensively reviewed the Pilliods' exposure through phone interviews, review of records, a review of their depositions, a review of their properties, a calculation of their dose; and a calculation of the total days and total gallons used by the Pilliods. Ex. 1 to Def.s' Mot to Exclude Sawyer (Pilliod Rep. at Cover Page and Report pp. 1-19). Dr. Sawyer also compared the exposure days of Roundup to the exposure days of applicators in epidemiological studies, *Id.* at 22-25. Dr. Sawyer opined that the dosage received by both Pilliods was significant enough to contribute to their NHL:

B. Dr. Sawyer Used a Proper Methodology in Assessing Causation.

As recognized by Defense Counsel, Dr. Sawyer consistently uses the Bradford-Hill methodology in his practice and in this case.

Q That's your methodology too, right?

A Yes.

Q To evaluate the weight of evidence used in Bradford Hill?

A Yes

Q Now, Dr. Sawyer, you've been testifying as to causation in toxic tort and product liability cases for roughly 25 years?

A No, closer to 30.

Q And during that time you've used a methodology that's stayed pretty consistent, right?

A Bradford Hill criteria and weight of evidence throughout, yes.

Hoke Decl. Ex. 10 (2/26/2018 Sawyer Dep. at 139, 145); Ex. 1 (Sawyer Aff. at ¶ 12). "The Bradford Hill methodology refers to a set of criteria that are well accepted in the medical field for making causal judgments." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235, fn. 4, (9th Cir. 2017). Dr. Sawyer has described in detail his application of the Bradford-Hill criteria. Ex. 1 (Sawyer Aff. at 33-39).

Dr. Sawyer did read, review and rely on the epidemiology, but notes a detailed analysis is "best handled by the epidemiology experts that we have. I am not an epidemiologist. I've taught a section of the course in medical school. I've been trained in epidemiology. I use it every day in my practice, but I am not specifically an epidemiologist." Hoke Decl. Ex. 10 (2/26/2018 Sawyer Dep. at 359:19-360:6); Hoke Decl. Ex. 7, Johnson Rep. at 157 ("However, I have reviewed and relied on various epidemiological literature as cited and the general character of IARC's recent classification of glyphosate as a "probable human carcinogen,"). Dr. Sawyer has been qualified to offer epidemiology opinions in other cases. Ex. 1 (Sawyer Aff. at ¶ 36).

Furthermore, it is entirely proper for an expert witness to rely on reports and opinions of other experts, particularly experts as qualified as Dr. Ritz and Dr. Portier. *People v. Campos*, (1995) 32 Cal. App. 4th 304, 308, 38 Cal. Rptr. 2d 113, 114 ("the expert witness may state the reasons for his or her opinion, and testify that reports prepared by other experts were a basis for that opinion."); *Asad v. Cont'i Airlines, Inc.*, (N.D. Ohio 2004) 314 F. Supp. 2d 726, 741 ("an expert's testimony may be formulated by the use of the facts, data and conclusions of other experts."). *Beck v. Koppers, Inc.*, (N.D. Miss. Feb. 2, 2006) No. 3:03 CV 60 PD, 2006 WL 270260, at *10 ("[Dr. William] Sawyer's dosage and risk assessment testimony (as long as the latter is based on Dahlgren's general causation testimony) meets the threshold requirements of Rule 702. It is undisputed that Sawyer is qualified by his knowledge and education to render his dosage and risk assessment testimony."); *Pulse Med. Instruments, Inc. v. Drug Impairment Detection Servs., LLC*, (D. Md. 2012) 858 F. Supp. 2d 505, 512 ("Courts in this circuit and across the country have consistently held that an expert may rely on the work of others when preparing an expert report, particularly when it is the sort of work that is reasonably relied upon by experts in the relevant area

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Dr. Sawyer's application of Bradford-Hill goes beyond epidemiology and incorporates animal studies and mechanistic studies. Dr. Sawyer noted, that in addition to epidemiology "[o]ne has to look at the mechanism, the animal studies..." See Hoke Decl. Ex. 2 (Johnson Tr. Trans. at 3683). Even if Dr. Sawyer was not permitted to rely upon the opinions of Dr. Nabhan and Dr. Portier, or his own evaluation of the epidemiology, he could still offer a general causation opinion. Dr. Sawyer stated that while he would not opine that a substance is a confirmed human carcinogen without epidemiology, he could opine that it is "a possible or probable" human carcinogen and that "is done routinely by various agencies with respect to classifications from animals in studies." See Hoke Decl. Ex. 10 (2/26/2018 Sawyer Dep. at 109). California law allows for causation opinions absent epidemiology. Davis v. Honeywell Internat. Inc., (2016) 245 Cal. App. 4th 477, 491, ("While Honeywell is generally correct that in many (or even most) instances epidemiological studies provide the best evidence of causation, its implied argument that it is improper for an expert to rely upon any other tools to determine causation, such as case reports, is not universally accepted.") Roberti v. Andy's Termite & Pest Control, Inc., (2003)113 Cal. App. 4th 893, 898 6 Cal. Rptr. 3d 827, 829 (Experts reliance only on animal studies was admissible where the EPA "policy prohibits human experimentation, relies on and adopts animal studies as the scientific basis upon which to set pesticide exposure, dose and risk levels.")

C. Dr. Sawyer's Opinions on The Pilliods' GBH Exposure Are Admissible and Based on Reliable Methodologies

Dr. Sawyer compared The Pilliods' exposure to GBHs to the exposure of subjects in epidemiological studies of glyphosate and further explained how he will calculate the Pilliods' dose at trial using the UK POEM methodology. Both of these opinions are reliable and will be helpful to the jury. Dr. Sawyer need not provide an exact amount of the Pilliods' exposure to glyphosate for his opinions to be admissible. Indeed, an exact figure would be impossible to calculate since it would require comprehensive testing for each day the Pilliods sprayed GBHs.

It is well-recognized that "While 'precise information concerning the exposure necessary to cause specific harm [is] beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic ... and need not invariably provide the basis for an expert's opinion on causation."

Clausen v. M/V NEW CARISSA, 339 F.3d 1049, 1060 (9th Cir. 2003), as amended on denial of reh'g (Sept. 25, 2003) (quoting Westberry v. Gislaved Gummi AB, (4th Cir. 1999)178 F.3d 257, 264; Wright v. Willamette Indus., Inc., (8th Cir. 1996) 91 F.3d 1105, 1107 ("We do not require a mathematically precise table equating levels of exposure with levels of harm, but there must be evidence from which a reasonable person could conclude that a defendant's emission has probably caused a particular plaintiff the kind of harm of which he or she complains..."); Heller v. Shaw Indus., Inc., 167 F.3d 146, 157 (3d Cir. 1999) ("...even absent hard evidence of the level of exposure to the chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff's illness.").

1. Dr. Sawyer's Application of the Facts in The Pilliods' Case to the Epidemiological Literature will be Helpful to the Jury

In arguing that Dr. Sawyer cannot testify about the Pilliods' exposure days. Defendants conflate the concept of "a factual basis" with the concept of an "expert opinion". The number of days and hours that the Pilliods was exposed to GBHs does not constitute an opinion, but rather constitutes a factual basis to support Dr. Sawyer's opinions. Although the jury can count up the days and hours the Pilliods used GBHs, it is still incumbent upon Dr. Sawyer to relate this factual basis to the jury and explain how it supports his opinions. *Owens v. Republic of Sudan*, (D.C. Cir. 2017) 864 F.3d 751, 790 ("For their conclusions to be admissible and credible, the plaintiffs' experts needed to disclose the factual basis for their opinions."). While a jury can certainly count days and hours, they do not have the necessary expertise to apply these facts to the epidemiological and scientific literature.

The epidemiological studies are not consistent nor well-described in their methodology when using days of exposure and it does require expert testimony for a jury to compare The Pilliods' exposure to the epidemiological studies. Having Dr. Sawyer guide the jury through the nuances inherent in the different epidemiology studies will only aid the jury in understanding each study's characteristics. The following line of questioning reveals that certain studies may not be what they appear at first glance:

- Q. And when we're comparing apples to apples, we need to compare the exposure dates of the Pilliods to the exposure days in epidemiology studies, correct?
- A. Yes.
- Q. But it is true that the Eriksson study does not give us any information on the actual amount applied by the individuals who were studied in the Eriksson study, right?
- A. That's right.
- Q. Okay. And so a farmer, for instance, could apply glyphosate once a month, but he could apply dozens of gallons of Roundup in one full-day application over a field, right?

A. Right.

Q. And those applicators, this hypothetical farmer I mentioned, would have applied for a matter of hours continuously as opposed to spot spraying for a single hour, right?

A. That's right.

Q. And they would be -- potentially be exposed to a much greater volume of Roundup than the plaintiffs in this matter, right?

A. No. Actually, that's not true, and I can pull out the studies right now and show you. The tractor-mounted sprayer, farmers putting down 150 gallons covering 500 acres or whatever, their daily dose is not much different than that of a backpack sprayer.

See Hoke Decl. Ex. 5 (2/6/2019 Sawyer Dep. at 238). In fact, Dr. Sawyer explained that "[y]ou could actually have a professional applicator working seven hours -- and I could show the tables -- with lower exposure than that of a --that is, if that person is wearing PPE -- a lower exposure than a home gardener working for one hour." Id. at 242. At trial Dr. Sawyer will explain how the studies generally apply exposure days; and as illustrated at Dr. Sawyer's last deposition (for a different plaintiff) he explained how the epidemiology assesses exposure days. Id. The Pilliods 1500 days of exposure to Roundup® far exceed the highest categories in the epidemiological literature. Hoke Decl. Ex.9 (Short Chronology of Pilliods Exposure); Ex. 1 to Def.'s Mot. to Exclude Sawyer (Sawyer Pilliod Rep. at 22).

2. Dr. Sawyer's Dose Calculation is Sufficiently Reliable

Dr. Sawyer will base his dose calculation at trial on a generally accepted pesticide modeling technique, the UK Predictive Operator Exposure Mode. (UK POEM). Defendant fails to present any evidence that this model does not yield reliable data. *Nw. Coal. for Alternatives to Pesticides (NCAP) v. U.S. E.P.A.*, (9th Cir. 2008) 544 F.3d 1043, 1048–49 (Rejecting argument that pesticide exposure modeling is unreliable where "Petitioners have presented no evidence that modeling does not yield reliable data. There is nothing inherently unreliable about the use of models..."). In, a 2015 published article written by Monsanto employee David Saltmiras cites the UK is predicted to be between 0.0034 (German BBA model, tractor-mounted ground-boom sprayer) and **0.226 mg/kg bw/day** (**UK POEM, hand-held-spraying to low targets, data not shown).** Defendants cite no evidence that the UK POEM is unreliable or not validated. ³ In fact, the UK POEM is a well-accepted methodology. By any account, the Pilliods'

² Greim, et al., "Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies" Crit Rev Toxicol. 2015 Mar 16; 45(3): 185–208. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819582/

³ Defendants cite to the following question from Defense counsel as proof that the UK POEM is unreliable "Have you seen that the UN World Health Organization international program on chemical safety has stated that the POEM model has not been validated? A. No." Defendant did not present the program they were referring to at Dr. Sawyer's deposition nor in their motion. A question by Defense counsel cannot be considered evidence.

dose of glyphosate would be among the highest doses of applicators studied in the epidemiological studies. *See* Hoke Decl. Ex. 5 (2/6/2019 Sawyer Dep. at 177).

The UK POEM was developed by the United Kingdom regulatory body. Hoke Decl. Ex. 2 (Sawyer Aff. at ¶ 82). It is recognized by the European Food Safety Authority (EFSA) as an available and reliable exposure modeling technique. *Id.* at 85. The latest regulatory body to review the UK POEM model notes that it "is an internationally developed model based on a robust dataset." *Id.* at 90. Dr. Sawyer notes that the UK POEM has been peer-reviewed and relied upon in "numerous studies" including "a 2017 risk assessment of small farmers exposed to plant protection products in the Niger River valley" and a "2017 assessment of farmers' exposure to pesticides in the urban and peri-urban areas of Northern Benin." *Id.* at 88. In fact the UK POEM has actually been found to under estimate exposure. Hoke Decl. Ex. 11 (Abukari, Pesticides Applicator Exposure Assessment: A Comparison between Modeling and Actual Measurement. Journal of Environment and Earth Science, Vol.5, No.11, 2015.)

The Purpose of Dr. Sawyer's sample dose calculation was not to develop a precise dose for the Pilliods. His calculation was simply to determine if their exposure to Roundup® was within the range of the applicators within the epidemiology studies; the calculation cannot be compared to a particular threshold of cancer causation. Hoke Decl. Ex. 5 (Sawyer 2/6/2019 Dep. at 265). Dr. Sawyer explained that "[e]ven though I'm using strong words like 'worst case,' which is scary and a very emotional word, when he did use the super concentrate, it was only 10 percent lower." *Id.* at 291. The fact that the Pilliods' exposure might have been slightly lower at different properties did not affect Dr. Sawyer's conclusions that the daily doses for both Pilliods' would still be in "the range of an applicator." *Id.* at 265.

D. Dr. Sawyer May Rely on and Explain Technical Details Contained in Internal Monsanto Documents

Plaintiff agrees that Dr. Sawyer will not testify about the intent or state of mind of Monsanto, but Dr. Sawyer will rely upon and discuss the scientific findings, opinions and data contained in internal Monsanto documents. Experts may rely and discuss corporate documents if the documents are relevant to their opinions. *In re Seroquel Prod. Liab. Litig.*, (M.D. Fla. July 20, 2009)No. 6:06-MD-1769-ORL-22D, 2009 WL 3806436, at *4 ("The Court determines that [experts] may appropriately rely on and discuss AstraZeneca's internal corporate documents for the specific purposes identified by Plaintiffs in

their response to the motion."). Also, there is "nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality." *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, (S.D. Ill. Dec. 16, 2011) 2011 WL 6302287, at *18 (internal citations omitted) (rejecting argument that regulatory experts review of corporate emails "does not require the "specialized knowledge" contemplated by Rule 702, but rather is mere advocacy on plaintiff's behalf."). Unfortunately, Monsanto has a corporate policy not to publish or publicize unfavorable data or scientific opinions on glyphosate. Therefore, much of the scientific data and opinions of Monsanto scientists and consultants are contained only in internal Monsanto documents and emails.

It is also entirely proper to apply one's expertise in a field to provide proper context to corporate emails and memoranda. *DePaepe v. General Motors Corp.*, (7th Cir.1998) 141 F.3d 715, 720 ("He could give an opinion as an engineer that reducing the padding saved a particular amount of money; he might testify as an engineer that GM's explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify as an expert that GM had a particular motive."). *See*, e.g., *United Food & v. Teikoku Pharma* USA, (N.D. Cal. Nov. 3, 2017) 2017 WL 5068533, at *25 (expert could opine as to what a reasonable company in the defendant's position would have done based on his understanding of the facts and in light of the record evidence he reviewed).

The emails cited by Dr. Sawyer are filled with technical knowledge that would not be easily comprehended by a lay juror. For example the following email would not be easily understood without an understanding of the terms: uncertainty factors, risk assessment, biomonitoring, pharmacokinetics, IV experiment, and topical in vivo:

Even though we can absorb additional 'uncertainty factors' in our risk assessment based on our biomonitoring results, I feel uncomfortable with this discussion. This approach by Spain sets a precedent and contradicts the fact that we always claimed to fully understand the glyphosate pharmacokinetics. The Wester IV experiment suggests that almost the entire 'systemically' available dose was excreted in urine. The low dose topical in vivo experiment suggests that almost the entire dose (82%) that was absorbed through the skin was excreted in feces (3.6% feces versus 0.8% in urine).

Hoke Decl. Ex. 1 (Sawyer Aff. \P 71-72).

E. Dr. Sawyer May Testify About Ethics in Toxicology and Monsanto's Breach Thereof

Dr. Sawyer as a toxicologist is obviously qualified to explain that toxicologists are "ethically bound to perform certain duties, regardless of the outcome of the specific test," and not to "adjust the evidence to meet a predetermined outcome." Hoke Decl. at Ex. 1 (Sawyer Aff. at ¶ 64). Dr. Sawyer can opine on the effect of the failure of Monsanto scientists to follow the ethical code of toxicologists. *Id.* at ¶ 54. Hoke Decl. Ex. 3, Sargon Order, p. 31 (denying Monsanto's motion to exclude Dr. Sawyer's "with respect to the impact of non-compliance with the ethical obligations owed by toxicologist, Monsanto has not demonstrated that Dr. Sawyer disclaimed any such opinions."). Testimony about Defendants' breaches of ethical codes are admissible. *MAR Oil Co. v. Korpan*, (N.D. Ohio 2013) 973 F. Supp. 2d 775, 785 ("Berman bases his opinion on industry associations' codes of ethics and training courses on ethics"); *United States v. Hoffman*, (D. Me. Dec. 12, 2006) No. 06-CR-66-P-S, 2006 WL 3691487, at *4 ("...the Court will permit testimony from Dr. Wartenberg regarding the prevailing standard of treatment, the doctor-patient relationship and whether given conduct violated ethical rules and norms.")

Dr. Sawyer's expertise on these matters will also help the jury understand why the true absorption rate of GBHs are inadequately reported in the published literature and how that affects regulatory reviews. *See* Hoke Decl. Ex. 12 (2/27/2018 Sawyer Dep. at 419-420). Had Monsanto acted ethically in testing glyphosate absorption and reporting these results, then restrictions would have been placed on glyphosate usage and greater warnings with respect to protective gear would have issued to consumers such as the Pilliods.

IV. CONCLUSION

For the aforementioned reasons, Defendants' Motion to Exclude Dr. Sawyer's Opinion should be excluded in its entirety.

DATED: February 21, 2019 Respectfully submitted,

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