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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION *Hardeman v. Monsanto Co., et al.*, 3:16-cv-0525-VC *Stevick v. Monsanto Co., et al.*, 3:16-cv-2341-VC *Gebeyehou v. Monsanto Co., et al.*, 3:16-cv-5813-VC	MDL No. 2741 Case No. 3:16-md-02741-VC **MONSANTO COMPANY'S NOTICE OF MOTION AND MOTION *IN LIMINE* NO. 9 RE: ADVERSE EVENT REPORTS**

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT in Courtroom 4 of the United States District Court, Northern District of California, located at 450 Golden Gate Avenue, San Francisco, CA 94102, or as ordered by the Court, Defendant Monsanto Company ("Monsanto") will and hereby does move the Court to preclude evidence regarding adverse event reports.

DATED: January 30, 2019

Respectfully submitted,

/s/ *Brian L. Stekloff*

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Defendant Monsanto Company ("Monsanto") respectfully submits this motion *in limine* to preclude Plaintiffs Edwin Hardeman, Elaine Stevick and Sioum Gebeyehou ("Plaintiffs'") from introducing any evidence, in the form of testimony or documents, argument, or reference, to adverse event reports ("AERs"). Monsanto is required by law to relay to the EPA such reports involving its products. *See* 40 C.F.R. § 159.184. Monsanto employees and contracted poison control centers compile these AERs with written notations to reflect what these personnel are told by physicians, researchers, customers, and lawyers, either in telephone conversations or through correspondence. As such, these AERs constitute inadmissible hearsay (and double hearsay). These are generally unverified, anecdotal patient reports of experiences with various products, that are not verified by physicians or other medical personnel, and are not the result of a differential diagnosis or medical analysis of causation. Thus, these reports are also irrelevant and unfairly prejudicial in that they involve allegations of injuries that have nothing to do with the claims in this case. Monsanto believe that this Motion may impact Phase 1 to the extent Plaintiffs suggest adverse event reports are evidence of causation, but principally impacts Phase 2.

II. ARGUMENT

A. Adverse Event Reports Are Inadmissible Hearsay

The AERs are out-of-court statements that cannot be offered to prove the truth of the matter asserted (*i.e.*, that Monsanto's product caused whatever injury is identified therein). *See* Fed. R. Evid. 801. The reports are not subject to any hearsay exceptions, and reflect the statements of third parties such as physicians, patients, and others who are not subject to cross-examination. AERs fail to identify the patients involved and often it is not possible to verify information from these reports. *See e.g. Klein v. TAP Pharm. Prod., Inc.*, 518 F. App'x 583, 584 (9th Cir. 2013) ("[T]he district court did not err in excluding the adverse event reports. They were hearsay reports of uncertain reliability, lacking information relevant to causation").

Furthermore, the AERs contain inadmissible hearsay within hearsay because the personnel responsible for compiling the reports do not witness the events and most are third party physicians merely recounting what their patients had told them. *See, e.g., Saari v. Merck & Co., Inc.*, 961 F. Supp. 387, 398 (N.D.N.Y. 1997) (explaining that an AER "was simply a report of what plaintiff told [the doctor] about what she believed was her reaction to the vaccine, and by making that report [the doctor] was neither confirming nor denying that there is any relationship between her symptoms and the vaccine."); *see also DeLuca v. Merrell Dow Pharm., Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (finding that AERs "have inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions"), *aff'd*, 6 F.3d 778 (3d Cir. 1993).

When previously faced with this argument, Plaintiffs did not dispute that AERs are inadmissible hearsay when offered for the truth of the matters asserted within them. *See* Plaintiff's Opposition to Defendant's Motion *In Limine* No. 9 To Exclude Or Limit Evidence, Argument, Or References To Adverse Event Reports, filed June 7, 2018 in *Johnson v. Monsanto* ("Plaintiffs' June 7, 2018 Opp.")(Ex.1).

B. Adverse Event Reports Are Not Admissible To Prove "Notice" of a Product Defect or Dangerous Condition that Requires a Warning

There is no merit to Plaintiffs' argument that AERs can be used not for their truth, but to show notice, *i.e.*, to "illustrate that Monsanto has continued to sell its products despite having notice and knowledge for decades of their potential safety issues" and that "Monsanto's knowledge" and "failure to warn [] of the risks" are an essential claim in these cases. *See* Plaintiffs' June 7, 2018 Opp., at p. 2 (Ex.1). Initially, Plaintiffs' notice argument is dependent on the AERs being true: AERs cannot provide notice to Monsanto of anything relevant without the jury concluding the allegations in the AERs were true -- an obvious hearsay purpose. The mere fact that Monsanto received notice about a claimed injury itself proves nothing.

Second, even if the AERs did not constitute inadmissible hearsay, most potential AERs are irrelevant because they do not involve the Plaintiffs' conditions. Plaintiffs have been diagnosed with diffuse large B-cell lymphoma and central nervous system B-cell lymphoma, subtypes of non-Hodgkin lymphoma ("NHL"). AERs involving unrelated events—eye irritation, skin rashes, or other

injuries—have no bearing on the central question in this case: whether Plaintiffs' use of Roundup® caused their individual injuries. Furthermore, since Plaintiffs make no claims that Roundup® causes human cancers other than NHL, AERs not involving NHL are also irrelevant. AERs dissimilar to Plaintiffs' claims do not have "any tendency to make a fact more or less probable than it would be without the evidence," and are, therefore, irrelevant and inadmissible. Fed. R. Evid 401. Indeed, courts look for a finding of "substantial similarity" to determine that evidence of other injuries or defects are relevant. *Akkerman v. Mecta Corp*., 247 F. App'x 895, 897 (9th Cir. 2007) ("a showing of substantial similarity is required when a plaintiff attempts to introduce evidence of other accidents as direct proof of negligence, a design defect, or notice of the defect.") (internal quotations omitted). As such, Plaintiffs must make a showing of "substantial similarity" between their NHL and the injuries alleged in the AERs. Plaintiffs cannot meet this burden; their own expert previously admitted that he does not claim that Roundup® causes other cancers. *See* August 23, 2017 Dep. of Chadi Nabhan, M.D. at 102:13-103:7 (stating he does not claim glyphosate causes any cancer other than NHL) (Ex. 2).

Third, there really is no dispute that Monsanto was aware of allegations that Roundup is associated with NHL, and thoroughly investigated the issue. Therefore, in addition to being unreliable, and irrelevant, any attempt to use AERs as evidence of notice would be needlessly presenting cumulative evidence. Fed. R. Evid 403.

C. Adverse Event Reports Not Relating To NHL Are Unduly Prejudicial and Would Mislead The Jury

The probative value of AERs is also substantially outweighed by the substantial danger of undue prejudice, confusing the issues, and misleading the jury. *See* Fed. R. Evid. 403. AERs unrelated to Plaintiffs' injuries distract from the specific issue, *i.e.*, whether the Plaintiffs' exposure to Monsanto's Roundup® caused their alleged injuries, and will induce the jury to award damages for injuries that have not been claimed in this case. Indeed, the introduction of these AERs would result in prejudicial mini trials about injuries not at issue in these cases that will cause undue delay at trial. *See Coursen v. A.H. Robins Co., Inc.*, 764 F.2d 1329, 1335 (9th Cir. 1985) (excluding evidence related to a side-effect other than the only alleged injury to avoid the "prejudice and confusion [that] would be generated by innuendos of collateral misconduct); *see also O'Banion v. Owens-Corning*

Fiberglas Corp., 968 F.2d 1011, 1012-13 (10th Cir. 1992) (excluding evidence of cancer where the alleged injuries did not include mesothelioma or other carcinogenic disease because these "purely speculative" damages are non-recoverable).

AERs involving Plaintiffs' injuries should also be excluded because they are only allegations, and not evidence of causation. *See, e.g., N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 53 (1st Cir. 2008) ("[T]he receipt of an adverse report does not in and of itself show a causal relationship between [a product] and the illness mentioned in the report.") (internal citation omitted); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (it is well settled that AERs are "one of the least reliable sources" to support opinions on general causation); *Saldo v Sandoz Pharm. Corp*., 244 F. Supp. 2d 434, 541 (W.D. Pa. 2003) ("[a]nectdotal reports . . . are not reliable bases to form a scientific opinion about a causal link") (internal citations omitted). Therefore, AERs related to Plaintiffs' injuries will mislead and confuse the jury on the issue of causation, have little (if any) probative value, and are unduly prejudicial.

III. CONCLUSION

For the aforementioned reasons, the Court should preclude Plaintiffs from introducing any evidence, in the form of testimony or documents, argument, or reference to the irrelevant and unfairly prejudicial AERs.

DATED: January 30, 2019

Respectfully submitted,

/s/ *Brian L. Stekloff*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 30th day of January 2019, a copy of the foregoing was served via electronic mail to opposing counsel.

/s/ *Brian L. Stekloff*