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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741
	Case No. 3:16-md-02741-VC
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	**MONSANTO COMPANY'S NOTICE OF MOTION AND MOTION *IN LIMINE* NO. 1 RE: IARC CLASSIFICATION DURING PHASE 1 OF TRIAL**

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 the IARC classification during Phase 1 of trial.

DATED: January 30, 2019

Respectfully submitted,

/s/ *Brian L. Stekloff*

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

In ordering reverse bifurcation, the Court reserved final judgment on whether jurors would, "during the causation phase, need to receive at least some limited information about the IARC classification through expert testimony (albeit with an appropriate instruction about its limited utility in this context)." PTO 61 at 1-2. Defendants respectfully submit that references to the IARC classification should be excluded. IARC's classification is irrelevant to Phase 1, because IARC reviewed only part of the scientific evidence, and produced only a hazard assessment that does not help answer the causation questions before the jury. *See* PTO 45 at 12. Moreover, admitting evidence of IARC's classification could confuse and distract the jury. If the jury hears that IARC reviewed scientific evidence regarding glyphosate, it might be tempted to substitute IARC's incomplete analysis and inapposite conclusions for its own independent assessment of the complete scientific evidence. Further, if IARC's assessment is admitted, basic principles of fairness and completeness would compel the admission of the worldwide regulatory consensus that glyphosate is safe. But admitting all this evidence would unavoidably turn Phase 1 into a referendum on what these various third parties have said about the science—which runs directly counter to the jury's charge to make its *own* assessment of the science.

Accordingly, the Court should exclude any evidence and argument regarding IARC's classification from Phase 1 of trial. But if the Court is inclined to admit IARC's classification, it should also permit Defendants to admit evidence of the multitude of worldwide regulators who have approved glyphosate for use both before and after IARC published its monograph. And if any of this evidence is admitted in Phase 1, it should be appropriately limited through restrictions on the frequency with which the parties can introduce it, and a firm instruction to the jury not to substitute other entities' conclusions for its own independent evaluation of the science regarding causation.

II. ARGUMENT

A. The Court Should Exclude Evidence and Argument Regarding IARC's Classification from Phase 1 Because It Is Irrelevant, Confusing, and a Distraction from the Science

This Court has made clear that Phase 1 of trial "is about what the science actually shows" regarding whether glyphosate generally can cause cancer in humans, and whether it caused the specific Plaintiff's cancer. 1/4/19 MDL CMC Tr. 21:15-17 (Ex. 1). IARC's classification should be excluded because it does not help the jury answer either of those questions, and could instead serve to confuse and distract the jury.

As the Court has already explained, IARC's carcinogenicity assessment does not bear on the issue of causation. IARC reviewed a subset of studies done by other scientists in the process of conducting a hazard assessment. And "[a] 'hazard assessment,' as IARC and other public health bodies define that inquiry, is *not what the jury needs to conduct* when deciding whether glyphosate actually causes NHL in people at past or current exposure levels." PTO 45 at 12 (emphasis added). Rather, it is just "the first step" in determining whether a substance actually "result[s] in an increased risk of cancer." *Frequently Asked Questions*, World Health Organization (May 27, 2016), https://www.who.int/foodsafety/faq/en/. Under IARC's analysis, "[a] substance could be cause for concern, such that it can and should trigger preventive public health measures and further study, even when it is not so clearly dangerous as to allow a verdict in favor of a plaintiff." PTO 45 at 2. Because IARC's assessment is of a materially different character than what the jury is being asked to decide, it is irrelevant to Phase 1.

Admitting IARC's conclusions would also run the risk of the jury's substituting another body's incomplete evaluations of the science for its own. The jury's task in Phase 1 is to consider all the available scientific evidence, including the body of "independent studies done" on glyphosate and Roundup, in addressing causation. 1/4/19 MDL CMC Tr. 25:23-24 (Ex. 1). If the jury hears that a public health body has reviewed the science and reached conclusions about carcinogenicity, it may feel compelled to defer to IARC's determination—even though

the question IARC addressed was different. That outcome would be problematic under any circumstances, but it is especially so here given that it is undisputed that IARC did not rest its decision on the full body of available scientific evidence. For example, the parties agree that IARC did not consider (among other things), the 2018 analysis of the Agricultural Health Study ("AHS")—the largest, longest, and most comprehensive epidemiological study of glyphosate—published in the Journal of the National Cancer Institute. To be sure, Defendants could highlight this flaw in IARC's evaluation during the course of cross-examinations, but having the jury consider all the science on its own, free of such distractions, is the better course. Otherwise, the trial would quickly become a dispute as to whether IARC did or did not look at all of the evidence—decidedly not the question the jury needs to answer.

Indeed, allowing Plaintiffs to introduce evidence of IARC's classification would change the jury's focus from what the scientific studies say to what various regulatory agencies and public bodies have said about the science. As the Court knows, IARC is not the only body that has reviewed scientific evidence and reached conclusions about glyphosate's carcinogenicity. Regulators worldwide have also reviewed the science (fully, rather than partially) and uniformly concluded that glyphosate is non-carcinogenic, both before and in response to the IARC monograph. Indeed, just in the past month, two major health authorities have rejected IARC's conclusion and reaffirmed their views that Roundup has not been shown to be carcinogenic. First, Health Canada last week reaffirmed its non-carcinogenic conclusion in the wake of IARC's determination: Allegations of glyphosate's carcinogenicity "could not be scientifically supported when considering the entire body of relevant data."[1] Likewise, in December, the U.S. Environmental Protection Agency Office of Pesticide Programs ("OPP"), describing its

[1] *Statement from Health Canada on Glyphosate*, Health Canada (Jan. 11, 2019), https://www.canada.ca/en/health-canada/news/2019/01/statement-from-health-canada-on-glyphosate.html (Ex. 2) (describing the regulator's finding that objections raised to its 2017 re-evaluation decision that glyphosate was non-carcinogenic "did not create doubt or concern regarding the scientific basis for the 2017 re-evaluation decision for glyphosate" and reiterating that "[n]o pesticide regulatory authority in the world currently considers glyphosate to be a cancer risk to humans at the levels at which humans are currently exposed").

independent reevaluation of its glyphosate risk assessment, with more than two dozen staff members across more than ten disciplines, reiterated "confiden[ce] in its conclusion that glyphosate is not likely to be carcinogenic to humans."[2]

Basic principles of fairness and completeness dictate that these regulators' conclusions should also be admissible if IARC's assessment is admitted, lest the jury have an incomplete picture of what third-party reviews of the science have shown. But introducing all this evidence would unavoidably distract the jury from the science itself, which should be the main event at Phase 1. In sum, IARC's assessment is irrelevant and potentially confusing to the jury, and introducing a whole swath of third-party evaluations of the science would be an unnecessary sideshow. The Court should therefore exclude IARC's classification from Phase 1.

B. If the Court Permits Plaintiffs to Introduce Evidence of IARC's Classification at Phase 1, Several Precautionary Measures Are Warranted to Avoid Undue Confusion and Distraction.

If the Court does allow Plaintiffs a limited opportunity to introduce IARC's assessment over Monsanto's objection, Defendants submit that at an absolute minimum it should take the following precautionary measures to attempt to minimize the risk of an unfair and misleading presentation of the evidence, and to appropriately focus the jury on the proper scope of Phase 1.

First, and for the reasons described above, the Court should permit Monsanto to introduce comparable evidence of both domestic and international evaluations and approvals of glyphosate by regulatory bodies. That evidence is necessary to put IARC's limited conclusions into context and avoid the improper and misleading suggestion that glyphosate has been deemed unsafe by the only body to evaluate it. Admission of the latest regulatory assessments would demonstrate that IARC's conclusions have been thoroughly reviewed (and rejected) by the leading health

[2] Letter from Richard P. Keigwin, Director, U.S. EPA Office of Pesticide Programs, to Jane Thompson, Committee Secretary, Australian Senate Standing Committee on Rural and Regional Affairs and Transport (Dec. 21, 2018) (Ex. 3). As Mr. Keigwin points out in his letter, EPA's "conclusion is consistent with other countries and regulatory authorities including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, the European Chemicals Agency, German Federal Institute for Occupational Safety and Health, The Joint FAO/WHO Meeting on Pesticide Residues, the New Zealand Environmental Protection Authority, and Food Safety Commission of Japan." *Id.* at 5.

authorities, thus avoiding the improper suggestion, addressed in a companion MIL, that the jury has a public health duty to send a message to Monsanto to get in line with IARC's conclusion.

Second, consistent with the Court's instincts in ordering bifurcation, the volume of evidence and testimony regarding IARC and regulators should be limited. *See* PTO 61 at 1-2. All of Plaintiffs' Phase causation experts have relied on the IARC monograph in their reports. But allowing witness after witness to repeat IARC's findings would bring undue focus to evidence that is not properly the focus of Phase 1.[3] Witnesses should be instructed to make limited mention of IARC (if at all) only to the extent it is relevant to a scientific evaluation of causation. Defendants are of course willing to abide by similar restrictions on the regulatory evidence.

Third, as the Court has indicated, *see* PTO 61 at 1-2, a limiting instruction would be warranted to make clear the IARC classification's "limited utility in this context." PTO 61 at 2. Monsanto submits that the following language would be appropriate:

> Regulatory agencies and other health organizations have reviewed science surrounding glyphosate and reached conclusions about it. These evaluations are not a substitute for your own review of the scientific evidence. They do not answer the question before you, which is whether the Plaintiff's use of Roundup caused his non-Hodgkin's lymphoma.

The foregoing steps will help mitigate some of the confusion and prejudice inherent in admitting evidence of IARC's inapposite and incomplete assessment. But again, as noted above, Defendants respectfully submit that the better approach is to exclude that assessment in its entirety, to ensure that Phase 1 is about the science, not sideshows.

III. CONCLUSION

Monsanto respectfully requests that the Court preclude evidence and argument regarding IARC's classification of glyphosate during Phase 1.

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[3] It should be beyond dispute that discussions of Monsanto's responses to IARC have no place in the causation phase of trial. Evidence of company conduct is relevant only to Phase 2. *See, e.g.*, 1/4/19 MDL CMC Tr. at 21:15-17 (Ex. 1) ("[T]he question is whether it causes cancer, not whether – not Farmer's opinion on what Monsanto can say or not say. It is about what the science actually shows.").

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*