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January 15, 2019

VIA CM/ECF
Hon. Vince Chhabria
San Francisco Courthouse, Courtroom 4
450 Golden Gate Avenue
San Francisco, CA 94102

Re: ***In re Roundup Prods. Liab. Litig.*, No. 3:16-md-02741-VC**
Issues to Be Used During the Causation Phase of Trial – Plaintiff's Issue Three

Dear Judge Chhabria:

Issue: **Dr. James Parry's Evaluation of the Genotoxicity of GBFs**

Plaintiff Hardeman's Position

Plaintiffs plan to introduce evidence pertaining to Dr. James Parry's 1999 evaluation of the genotoxic potential of GBFs. In 1999, Monsanto hired Dr. Parry to review and evaluate the genotoxicity literature on glyphosate and the formulated Roundup product following the publication of several studies - Bolognesi (1997); Peluso (1998); Lioi (1998); and Rank (1997) – which indicated a genotoxic effect associated with exposure to GBFs. Specifically, Plaintiffs those documents and testimony related to the reasons Monsanto hired Dr. Parry are relevant because they provide a foundation for the jury's understanding of Dr. Parry's scientific conclusions and the weight of Dr. Parry's evaluation given his reputation and expertise in genotoxicity. *See e.g.*, Ex. 1 at 1 ("[We] agreed an external global network of genotox experts needs to be developed. As EU has an immediate need and is a critical area now. It was agreed that Mark Martens would contact Dr. Parry next week to discuss with him his participation in the support of glyphosate, glyphosate-based formulation gentox issues…It is a real concern that these papers may create an even bigger problem for us than the Peluso paper. Therefore we do some things quickly!"); Ex. 2, at 4 ("While Dr. Parry is a recognized genotoxic expert…what is not known is how he views some of the 'non-standard endpoints…' it was proposed that Mark Martens would contact Dr. Parry and ask him for a written review of the articles by Rank, Bolognesi, Peluso & Lioi."); Ex. 3, Depo. of Mark Martens at 29:7-10, 49:7-9 (agreeing that Dr. Parry was an expert in the field of genotoxicity).

Dr. Parry's evaluation of the genotoxicity literature goes to the heart of general causation because it addresses the issue of whether Roundup is, in fact, genotoxic. Ex. 4 at 1 ("Please find herewith Professor Parry's evaluation of the four papers…on the genotoxicity of glyphosate and Roundup"). Dr. Parry's conclusions with respect to the *in vivo* and in *vitro* data following review of the four papers, stated:

> The overall data provided by the four publications provide evidence to support a model that glyphosate is capable of producing genotoxicity both *in vivo* and *in vitro* by a mechanism based upon the production of oxidative damage. If confirmed, such a mechanism of genetic damage would be expected to be produced at high concentrations of the herbicide and would be relevant only when the anti-oxidant protective mechanisms of the cell are overwhelmed.

Id. at 11. In addition, Dr. Parry's recommended that Monsanto evaluate the individual components of the formulated product to gain a better understanding of the damage caused by the synergistic effects of the formulation (*see id.* at 11, 12).

Monsanto's reaction to Dr. Parry's first report, such as acknowledgment that Dr. Parry confirmed a genotoxic potential associated with GBFs, Monsanto's disappointment with the report, and the desire of Monsanto personnel to "move" Dr. Parry away from his position on the genotoxicity of GBFs by providing him with additional data, bolster the conclusions of Dr. Parry's second report, which reiterated Dr. Parry's earlier observations *albeit* based on a larger data-set. Ex. 5 at 1 ("I sent him a letter of authorization and all relevant reports and publications re mutagenicity of glyphosate, its formulations and the surfactants for which we have mutagenicity testing data."); Ex. 6 at 2-3; Ex. 7, MONGLY00891769, Email re Parry Evaluation at *1 ("almost landed us with Parry calling glyphosate genotoxic...."); *See* Ex. 3, Depo. of Mark Martens at 97:24-98:2; Ex. 8, MONGLY01314233, Second Parry Report.[1]

Having reviewed a significantly larger number of studies (the report was in excess of 50 pages compared to the earlier 12 page report), Dr. Parry concluded that "[t]hese studies provide some evidence that glyphosate may be capable of inducing oxidative damage under both *in vitro* and *in vivo* conditions." *Id*. at *5. Indeed, Dr. Mark Martens confirmed that this is the same conclusion that Dr. Parry reached in his February 11, 1999 report. Ex. 3, Depo. of Mark Martens at 100:16-20. Specifically with respect to the Roundup formulation, and arguably stated with more confidence this time, Dr. Parry also concluded that "[t]hese studies provide some evidence that Roundup mixture produces DNA lesions *in vivo*, ***probably due to the production of oxidative damage***." Ex. 7, Second Parry Report at *8 (emphasis added). This evidence supports the opinion of Plaintiffs' general causation experts that exposure to GBFs is associated with genotoxicity and oxidative stress. Moreover, Dr. Parry recommended that Monsanto evaluate the formulated Roundup product which, Dr. Parry observed, may lead to a necessity "to consider the possibility of susceptible groups within the human population." *Id*. at *33-34. Such an observation is relevant to opinions of Plaintiffs' experts – and Plaintiffs' individual exposures – that the genotoxic literature published subsequent to Dr. Parry's evaluations and recommendations indicate a genotoxic risk to exposed human populations.

Monsanto refused to carry out all of the recommendations for further testing proposed by Dr. Parry. As stated by Dr. Heydens:

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[1] For clarification, the Third Report was a summary of recommendations based on Dr. Parry's earlier reports and was submitted together with the Second Report, possibly as an appendix. *See* Ex. 3, Depo. of Mark Martens at 112:3-5. The Second Report and accompanying recommendations (Third Report) are part of the same 51-page document, MONGLY01314233 and are collectively referred to as the "Second Parry Report" in this letter-brief.

> We want to find/develop someone who is comfortable with the genetox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genetox issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. ***We simply aren't going to do the studies Parry suggests.*** Mark, do you think Parry can become a strong advocate without doing this work Parry? If not, we should *seriously* start looking for one or more other individuals to work with.

Ex. 9 at 1 (emphasis added). Such evidence undermines Monsanto's contention that the general causation literature – and Dr. Parry's conclusions – do not indicate a risk associated with GBFs given that Monsanto, by its own admission, has never conducted a two-year carcinogenicity study with the formulated Roundup product to which Plaintiffs were exposed.

Reply to Monsanto's Response Regarding Violation of the Court's Orders

Contrary to Monsanto's assertion, Plaintiffs' evidentiary submissions are not in violation of the Court's Orders. Pursuant to PTO-63, Plaintiffs submitted three evidentiary items—regarding the AHS, Dr. Parry's evaluation, and Monsanto's discovery of the tumor in the control group of Knezevich & Hogan mouse study—in separate letter briefs not exceeding 2.5 pages. *See* PTO-63 at 1 ("the parties will file letter ***briefs*** that include…three evidentiary items per side…") (emphasis added). Plaintiffs informed Monsanto via telephone conference of the specific items of evidence that Plaintiffs intended to submit for the Court's guidance in advance of sending Monsanto Plaintiffs' portions of the letter briefs, including the fact that each evidentiary item would reference multiple documents. Each evidentiary item is accompanied by a detailed background narrative which explains why the specific item is relevant to the causation issues of Phase 1. Instead of making such arguments in a vacuum, Plaintiffs cite specific documents to illustrate the relevance of each item to Phase 1 proceedings. Each of these issues requires a substantial discussion of numerous documents in order to demonstrate its relevance to causation, and Plaintiffs have conveyed the relevance of each item in 2.5 pages. Monsanto's request to strike Plaintiffs' briefs and exhibits should be denied.

Monsanto's Position

Plaintiffs' letter briefs flout the Court's clear and repeated guidance on the scope and format of the evidentiary briefing:

First, Plaintiffs' letter briefs encompass over *fifty* documents, as well as related deposition and trial testimony, even though the Court made clear that each side was to pick only *three* pieces of evidence. *See* Ex. 10, Jan. 4, 2019 CMC Tr. 58:20-23 ("I think it might be helpful for everyone involved to have a process where each side picks their top three items on which they would like a ruling about whether it comes in in Phase One or Two."); *id.* 59:21-60:2 ("So pick your favorite three. Each side pick your favorite three . . . Exhibits, depo designations, whatever tangible thing you want to put in front of me and get a ruling on that will help provide guidance going forward."); *id.* at 60:4-6 ("Pick your best three . . . pick the three that are really important to you. . . ."); *id.* at 60:11-12 ("The ruling on the six that are teed up will provide you with substantial guidance . . . ."); *id.* at 62:3-4 ("[A]ttach as

exhibits the six items that are teed up . . . .").

Second, Plaintiffs have submitted *three separate* five-page briefs on *just their* evidentiary submissions, even though the Court was explicit that the parties were to jointly file just one five-page brief, following the Court's well-established joint discovery letter process, Civil Standing Order ¶ 21. *See* Ex. 10, Jan. 4, 2019 CMC Tr. 58:23-59:2 ("So find the items that are important to you and you think there may be ambiguity about in terms of whether it would come in in Phase One or Two and tee those up in a joint discovery letter . . . in the format of our joint discovery process . . . ."); *id.* at 62:2-4 ("Why don't you file your 5-page discovery letter; attach as exhibits the six items that are teed up in the 5-page discovery letter . . . ."); *id.* at 62:8-9 ("Why don't you file this 5-page letter by January 10th?").

Upon receiving Plaintiffs' draft briefs, Monsanto requested that Plaintiffs conform their briefing to the Court's guidance. Plaintiffs declined. In light of Plaintiffs' willful disregard of the Court's direction, Monsanto respectfully submits that Plaintiffs' overlength and overbroad briefs and exhibits should be stricken for noncompliance. But understanding the need to move this process forward, and to provide a fair and complete presentation of the evidence in compliance with the Court's direction, Monsanto has responded to Plaintiffs' arguments and has made its own affirmative evidentiary arguments in no more than the 2.5 single-spaced pages permitted by the Court's rules. Monsanto is of course prepared to address Plaintiffs' submissions at the hearing on these issues, or in more extensive briefing if that would be helpful to the Court.

Dr. Parry's Evaluation of Genotoxicity. The Court has made clear that Phase 1 of this trial "is about what the science actually shows." Ex. 10, Jan. 4 CMC Tr. at 21:16-17. For that reason, Monsanto agrees that the four studies Dr. Parry reviewed could fit within Phase 1, subject to other evidentiary objections and to the extent relied upon by any experts. But the remainder of the evidence in this letter is an irrelevant sideshow. No causation expert on either side relies on Dr. Parry's initial reaction to those studies, or Monsanto's further testing in response to his suggestions. If the experts all agree that Dr. Parry's analysis is irrelevant to causation, then emails about it are not part of the science on which the jury must focus. Further, Monsanto's internal commentary regarding Dr. Parry's findings and recommendations is inadmissible because that non-scientific evidence does not pertain to causation in any way. Plaintiffs' arguments about that evidence are just further efforts to "spin" internal company documents to misrepresent "what [] the science [has] shown or not shown." *Id.* at 23:16-19. For example, Plaintiffs' brief concludes with an out-of-context quote from Dr. Heydens designed to suggest that Monsanto refused to conduct tests that Dr. Parry recommended. *See supra* (quoting MONGLY03734971). But as noted above, Monsanto did conduct those tests, and based on the results of those tests, Dr. Parry agreed that glyphosate is not genotoxic (a conclusion that is consistent with the overall weight of evidence on this topic). *See, e.g.*, Ex. 11, MONGLY02626553-54.

Dated: January 15, 2019

Respectfully submitted,

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