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March 3, 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
Monsanto Opened the “Parry Door”**

Dear Judge Chhabria:

Monsanto’s letter misapprehends the issue here. The dispute is *not* about EFSA or regulatory criticism of Dr. Portier. The issue is genotoxicity.

Through Dr. Portier, Plaintiff presented competent testimony that glyphosate and glyphosate-based formulations (GBFs) are capable of inducing genetic damage in human cells, specifically, human lymphocytes. This opinion, which is directly relevant to general causation, is supported by Dr. Parry’s two reports—reports prepared by Monsanto’s hand-selected independent expert, outside of the context of litigation.¹

When the Parry reports were discussed at the January 23, 2019 hearing, the issue focused on whether Monsanto would open the door to their admissibility during Phase One by attacking whether glyphosate or GBFs were genotoxic, either through presenting an expert *or* through cross-examination. Tr. of Proceedings at 29:9-31:15 (Jan. 23, 2019). The Court specifically commented that:

The question would be -- you know, at trial would be: Is Monsanto opening the door to allowing this in? Is Monsanto creating some impression that’s contrary to? For example,

¹ In the first report, Dr. Parry concluded: (1) that “Glyphosate induces dose-dependent increase in chromatid aberrations *in vitro* in bovine lymphocytes[,]” (2) “Sister chromatid exchanges induced in human lymphocytes by both Glyphosate and Roundup mixture[,]” (3) “Both Glyphosate and Roundup mixture produced a positive result in the mouse bone marrow micronucleus assay[,]” (4) “The data of Bolognesi et al (1997) indicate that Glyphosate is a probable *in vivo* genotoxin[,]” and “Both Glyphosate and Roundup induced significant increases in DNA strand breaks in mouse liver and kidney. ... These data indicate that Glyphosate produces oxidative damage *in vivo* which leads to single strand breaks ... The unique positive result in mouse kidney with Roundup mixture suggests a synergistic effect of some component of the mixture[,]” and (5) The overall data provided by the four publications provide evidence to support a model that Glyphosate is capable of producing genotoxicity in both *in vivo* and *in vitro* by a mechanism based upon the production of oxidative damage.” Exh. 157 at MONGLY01312102-03. The second report, which was commissioned after giving Dr. Parry access to the full database, concludes that “glyphosate is a potential clastogenic *in vitro*. The study of Bolognesi et al (1997) indicates that this clastogenic activity may be reproduced *in vivo* in somatic cells... the genotoxicity observed may be derived from the generation of oxidative damage in the presence of glyphosate.” With regard to glyphosate mixtures, “[t]he studies of Bolognesi et al (1007) suggests that glyphosate mixtures may be capable of inducing oxidative damage *in vivo*.” Exh. 160 at MONGLY01314244.

if Monsanto were to create the impression during cross-examination that nobody has ever concluded, you know, or there's been no -- nobody's ever done a thorough analysis and concluded that it's possibly genotoxic, and you say, "Well, your own scientists didn't do a thorough analysis," then you probably would have opened the door to all of this coming in but that it wouldn't come in automatically.

Id. at 31:6-15. And, when Plaintiff's counsel spoke with the Court, this point was reaffirmed:

THE COURT: Okay. But what if Monsanto doesn't put on a genotoxicity expert?

MR. WISNER: Okay. So in that context we have a couple of issues; right? The cross-examination, we'll have to see how that goes of our expert.

THE COURT: And, of course, they may open the door depending on how they cross-examine your expert.

...

THE COURT: And it may be, I don't know that this is the case, but it's possible that -- it's Monsanto's choice; right? If Monsanto wants to cross-examine Dr. Portier on the EPA's conclusion about the genotoxicity of glyphosate in the way that you describe, that it is opening the door to this stuff coming in. I'm not sure, but I think that's -- you know, Monsanto obviously perceives itself as receiving a significant benefit at trial from having this -- you know, from having causation go first, but you only can, quote/unquote, enjoy that benefit if you don't unfairly take advantage of it at trial; right?

MR. WISNER: Sure.

Id. at 35:11-22. This point was memorialized in Pretrial Order 81, where the Court excluded the Parry report from Phase One unless: "Monsanto presents expert testimony on the genotoxicity of glyphosate, or otherwise ***opens the door through cross-examination on, for example, the EPA's conclusions about the genotoxicity of glyphosate***, then this evaluation could become admissible on redirect." PTO 81 at 7 (emphasis added).

During the cross of Dr. Portier, Monsanto opened the door to the Parry reports by challenging his genotoxicity opinions. They did this in several ways². The first, as pointed out in Monsanto's letter, was when Monsanto read the conclusions of EFSA about genotoxicity into the record:

Q. Do you see under their conclusion EFSA writes to you, "Considering a weight of evidence approach, taking into account the quality and reliability of all available data, it is concluded that glyphosate is unlikely to be genotoxic in vivo"? Did I read that correctly?

A. You read it correctly.

² During the March 1, 2019 discussion regarding this issue, Plaintiff's counsel read into the record several page and line citations from Dr. Portier's cross examination that further opened the door. Those citations are identified on page 875:14-876:20 and 879:22-880:15 of the trial transcript and are incorporated herein.

Tr. of Dr. Portier's Testimony at 457:20-458:3. This type of question was the very type of examination the Court stated would open the door. PTO 81 at 7 (Monsanto "opens the door through cross-examination on, for example, the EPA's conclusions about the genotoxicity of glyphosate[.]"). To be sure, the Court was discussing the EPA, not EFSA, but that is a distinction without difference, especially in light of the court's rulings on foreign regulatory bodies. *See* PTO 81 at 5-6 To be certain, the Court only allowed evidence on foreign regulatory decisions in Phase 1 for the limited purpose of cross-examining Dr. Portier on his efforts to convince European regulators to ban Roundup (in a way that reveals his efforts have thus far been unsuccessful). *Id.* The use of EFSA's genotoxicity decision went way beyond the limited exception allowed by the Court in PTO 81. Monsanto made a deliberate decision to open the genotoxicity door, even after the Court made it clear that it was their door to open. And, this was not some misstep in the heat of live cross examination—this was video testimony and Monsanto made a choice to *include* this question and answer as part of *its* designations after-the-fact.

The second was when Monsanto discussed the 2005 De Roos paper, published five years after the Parry report:

Q. And if you look, do you see that there's an abstract right at the top?

A. Yes, I do.

Q. Do you see that they write in their abstract, "Although there has been little consistent evidence of genotoxicity or carcinogenicity from *in vitro* and animal studies"? Do you see that?

A. I see that what's she writes.

Q. And I read that correctly, clear right?

A. You read it correctly.³

Tr. of Dr. Portier's Testimony at 431:11-431:23. Monsanto specifically made it look like there was inconsistent "evidence of genotoxicity" from *in vitro* and animal studies—the very conclusion that Dr. Parry's report (which were never made publicly available) refutes.

Finally, Monsanto challenged Dr. Portier about whether glyphosate is capable of causing mutations and attempted to impeach him on this very point (again over Plaintiff's overruled objection):

Q. So is it -- would you conclude that it's correct to say that the scientific evidence is insufficient to classify glyphosate as a mutagen or capable of causing mutations?

A. I would say that's incorrect.

³ And, if one reads the De Roos 2005 paper carefully, the authors note "Chronic feeding studies of glyphosate have not provided evidence of a carcinogenic effect in mice or rats (Williams et al. 2000)." Exh. 528 at 1. That Williams article is the very one that Dr. William Heydens, of Monsanto, claims was ghostwritten by Monsanto. *See* Exh. A at 1 ("A less expensive/more palatable approach might be to involve experts only for the areas of contention ... and we ghost-write the Exposure Tox & Genetox sections. An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. **Recall that is how we handled Williams Kroes & Munro, 2000.**" (emphasis added)).

... [following impeachment]

A. So I -- I misanswered because I didn't take the "are" into account.

Q. The rest of the answer is correct as to mutagen?

A. As to mutagen, per se. But as to capable of causing mutations, that answer's not correct.

Id. at 474:25-479:1. Monsanto, again, raised an issue that is rebutted by Dr. Parry's reports. For example, in the testimony Plaintiff proposes showing from Dr. Marten's deposition:

Q. Okay. All right. So overall conclusions -- "Overall Conclusions," let's look at it, page 42. What does class -- clastogen -- genetic mean?

...

A. Clastogenicity means chromosomal breakage.

Q. Okay. So once again, it's talking about mutation, right?

A. We like to talk about gene mutations and chromosomal breakage, and these all resort under the term "genotoxicology."

Q. Okay. So the overall conclusions, when you've given Dr. Parry more information, is there is published in vitro evidence that glyphosate is clastogenetic and capable of inducing sister chromatid exchange in both human and bovine lymphocytes, and then he cites papers, correct?

A. Correct.

Tr. Martens Depo. at 103:14-104:9.

Because this testimony was presented by video, Monsanto had complete control over what cross examination it presented to the jury. And, they raised issues that are directly rebutted by the Parry reports. By making genotoxicity an issue, they opened the door to the admission of the Parry reports.

Plaintiffs propose very specific testimony from Dr. Martens that deals with these issues without raising the other "internal" emails that Monsanto was concerned with. The proposed testimony is 33 mins total, with all counters included. And, Plaintiff's designations are about the science—the very science that Monsanto challenged in crossing Dr. Portier.

Monsanto's proposed "curative" instruction completely misses the point and would not close the door they opened. The only "instruction" that would fix this situation would be for Monsanto to stipulate that "Glyphosate and glyphosate-based formulations are capable of causing genetic damage in human lymphocytes which, in turn, can lead to mutations." If Monsanto were to agree to such a stipulation, Plaintiff would withdraw the proposed testimony.

Finally, playing the very short rebuttal testimony from Dr. Portier would not fix this either. That testimony was done in anticipation of a completely different issue, and Dr. Portier does not have any

personal knowledge about the formation or creation of the Parry reports. Dr. Martens, however, does have personal knowledge and testified competently about it.

Plaintiff requests that the Court allow Plaintiff to present the designated portions of the Martens' deposition.

Sincerely,

By: /s/ R. Brent Wisner
R. Brent Wisner, Esq.

By: /s/ Aimee H. Wagstaff
Aimee H. Wagstaff

By: /s/ Jennifer A. Moore
Jennifer A. Moore

Attachments