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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 Two

Dear Judge Chhabria:

Issue: Monsanto's Scientists Criticism of the Agricultural Health Study (AHS) and Actions Taken to Pressure the National Cancer Institute to Publish

Plaintiff Hardeman's Position

Monsanto's experts and corporate witnesses rely heavily on the AHS to argue that glyphosate does not cause cancer. Plaintiffs, however, would like to present evidence that Monsanto's own scientists have severely criticized the AHS in email, memorandums, and publications. Additionally, Plaintiffs would like to present evidence that Monsanto orchestrated pressure on the National Cancer Institute to publish the latest AHS publication, leading to a rushed peer-review and sloppy paper.

Monsanto's Scientists Criticisms of the AHS Before They Learned of its Results

Although the AHS is now the centerpiece of Monsanto's causation defense, before it learned it was negative, Monsanto was highly critical of the study. In 1997, Dr. John Acquavella of Monsanto, prepared a memorandum detailing problems with the AHS. *See* Exh. 1 at 2-3. Dr. Acquavella explained that: (1) the AHS investigators are "inexperienced in agricultural epidemiology;" (2) the study population "have limited contact with pesticides;" (3) "[t]he exposure assessment in the AHS will be inaccurate" because it "will be based on historical usage as reported by the farmer or applicator on the study questionnaire(s);" (4) "[i]naccurate exposure classification can produce spurious results" and "obscure exposure disease relationships;" (5) "sophisticated statistical analysis can't correct for . . . exposure misclassification;" and (6) the AHS investigators had not developed study protocols for any particular analyses, electing to do them "on the fly" which "circumvents some of the scrutiny they might get[.]" *Id.* at 3-5; *see also* Exh. 2 at 1-2 ("We had not expected to have to deal with (spurious) epidemiologic findings for glyphosate until the year 2000, given the schedule of publications from the Agricultural Health Study (AHS)."). Monsanto's Dr. Daniel Goldstein, a witness testifying on behalf of Monsanto, admitted that he agreed with Dr. Acquavella's criticism. *See* Exh. 6 at 284:20-285:20.

Similarly, Dr. Donna Farmer, Monsanto's head toxicologist, prepared a presentation in 1999

characterizing the AHS as a "flawed study" and "Junk Science" criticizing the AHS because of its "retrospective question[naire] on pesticide use[.]" Exh. 3 at 4. She explained "[t]here will be associations identified between glyphosate use and some health effects[.]" *Id.* In another email, dated May 31, 1999, Dr. Farmer comments "[m]any groups have been highly critical of the study as being a flawed study, in fact some have gone so far as to call it junk science . . . the retrospective questioneer [sic] on pesticide usage … is thought to be unreliable … but the bottom line is scary." Exh. 4 at 1.

These criticisms prompted the American Crop Protection Association, a Monsanto-sponsored industry group, to commission scientists from the Harvard School of Public Health to review AHS's design. *See* Exh. 5 at *69. The Harvard scientists raised concerns about the "potentially biased and imprecise exposure assessment … variable rates of subject response to administered surveys" and "limited understanding of the reliability and validity of self-reporting of chemical use[.]" *Id.* at *48. Indeed, the scientists specifically noted that "[i]f low response rates occur with the follow-up questionnaires, the potential for bias will increase[.]" *Id.* at 52. Both Dr. Acquavella and Dr. Aaron Blair were consulted on the publication. *Id.* at 69.

These documents and testimony undermine Monsanto's (and its experts') assertion that that the AHS is the best and most reliable epidemiology study.

Monsanto's Efforts to Pressure Publication of AHS

In February 2015, before IARC issued its classification for glyphosate, Monsanto's Dr. Heydens noted that one of the "most important things" Monsanto needed was "the Ag Health Study Follow-up publication[.]" Exh. 7 at 1. Then, when the IARC classification for glyphosate was announced in March 20, 2015, Monsanto put together plans to combat and discredit IARC. *See* Exh. 7 at 2. Monsanto was concerned about the "[s]evere stigma attached to Group 2A Classification" and the fact that Dr. "Aaron Blair continues to defend work & exaggerate number of studies w/association while ignoring AHS[.]" *Id.* at 2. Monsanto wanted a strategy to "[p]rovide additional support ('air cover') for future regulatory reviews" and give "[l]itigation support." *Id.* at 2. Monsanto proposed five projects, one of which was to "[p]ublish updated AHS study data." *Id.* at 3. Monsanto considered the AHS project "low" risk because "[w]e already know data is 'negative'" and "'Seasoned' rational experts would be doing the analysis[.]" *Id.* at 6. Monsanto's legal team indicated that of the options, publishing an updated AHS was "most appealing[.]" *Id.* at 9. Monsanto first attempted to collaborate with the AHS to get the data published. Exh. 8, Emails re. AHS Collaborative Investigation at 1. ("[C]ollaborative projects are always welcome by AHS if … all parties to the proposed research agree to the terms of confidentiality, conflicts of interest etc."). If that collaborative effort never materialized—which it did not—Monsanto considered obtaining the data from AHS using the Freedom of Information Act. *See* Exh. 7 at 1.

This changed when Monsanto gained access to Dr. Blair through this litigation. Specifically, on March 20, 2017, Monsanto deposed Dr. Blair, and as part of that deposition, Dr. Blair provided two draft documents, dated February and March 2013, respectively, of a manuscript containing preliminary results from the AHS relating to lymphoma and pesticide use, one of which included glyphosate. Monsanto asked Dr. Blair about the drafts and asked him to opine about how those preliminary results would have affected the IARC classification of glyphosate had they been published in 2013. Exh. 9 at 201:1-2010:10. Dr. Blair confirmed that IARC only considers published reports as part of its deliberative process, that the AHS data was flawed, and that, regardless, the updated AHS data would

not have changed the classification of glyphosate as a probable human carcinogen. *Id.* at 27:10-28:1; 218:1-229.

Seizing on the chance to discredit and attack Dr. Blair, on April 27, 2017, Sam Murphey from Monsanto sent an email to Kate Kelland[1] at Reuters, with a slide deck of talking points and portions of Dr. Blair's deposition, asking Reuters to publish an article accusing Dr. Blair of deceiving the IARC working group by concealing the unpublished draft manuscripts. Exh. 10 at 1 ("The deposition and other documents clearly show that Dr. Blair concealed information from the IARC working group . . . [w]e think this is vitally important information that needs to be reported."). Then, on June 14, 2017, Ms. Kelland and Reuters published the requested article and accused Dr. Blair of hiding information from IARC. Exh. 11 at 1-14.

Monsanto then used the Reuters article to exert political pressure on the National Cancer Institute[2] to publish the follow-up data. Specifically, on August 8, 2017, various Republican congressmen from the House Committee on Oversight and Government Reform sent a letter to the National Cancer Institute—the organization involved in the 2017 AHS publication—claiming Dr. Blair "withheld information that could change" the IARC assessment, citing the Reuters article as its only source. Exh. 15 at 2-3. Monsanto received a copy of this letter from its lobbying firm, FTI Consulting, the day it was sent. *Id.* at 1. The letter queried "why the NCI did not publish the AHS results on glyphosate" and demanded a response by August 22, 2017. *Id.* As if on cue, on August 22, 2017, researchers from the NCI submitted the follow-up results on glyphosate from the AHS to the Journal of the National Cancer Institute (a privately-owned journal, not controlled by the NCI or the federal government). Exh. 16 at 1. The journal conducted its peer-review and accepted the article for publication in record time, August 22, 2017 – October 6, 2017. *Id.*

This evidence shows that Monsanto orchestrated pressure on the NCI to publish the AHS data. It is relevant because it helps explain why the recent AHS study contains so many errors and mistakes and why it was rushed to publication.

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

[1] According to Monsanto's IARC response plan, Ms. Kelland was a key media contact in their efforts to discredit IARC. Exh. 13 at 2.

[2] This was not Monsanto's first attempt to influence NCI using a Kelland article. On May 2, 2016, Monsanto's Todd Rand ghostauthored a letter to be sent by Alabama Congressman Robert B. Aderholt, attacking IARC, and the NCI for supporting IARC, citing another article by Ms. Kelland. Exh. 12 at 1-5. It is unknown whether this letter was ever sent to Congressman Aderholt or if he ever sent the letter to NCI, but that is topic at issue in the upcoming Rule 30(b)(6) deposition. And, in another letter from Monsanto to Senators Lamar Alexander and Patty Murray, Monsanto again cited a Kelland article to attack IARC. Exh. 14 at 2-4.

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* Exh. 17, 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* Exh. 17, 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.

Alleged criticism of the Agricultural Health Study. It is no surprise that Plaintiffs seek to

criticize the Agricultural Health Study—the largest and most informative epidemiological study of glyphosate, which showed no association between exposure to glyphosate and NHL. And Monsanto does not dispute that science-based critiques of the AHS study, through examination of the many expert witnesses in the case, would be appropriate at Phase 1. But the evidence Plaintiffs seek to introduce via their letter brief involves a series of irrelevant sideshows. What matters in Phase 1 is what the scientific studies show, not what Monsanto employees said about them in internal communications (especially where, as here, the communications took place years before the 2018 results were published by the National Cancer Institute scientists in an elite, peer-reviewed journal). Similarly, Monsanto's alleged efforts to speed up the publication of the AHS study likewise have nothing to do with what the study actually says—Plaintiffs notably do not, and cannot, argue that the results of the AHS study are in any way tainted. Plaintiffs should not be permitted to pollute the jury's consideration of the science with the irrelevant sideshows and misleading "spin" that pervades their briefing.[3]

Dated: January 15, 2019

Respectfully submitted,

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[3] Here too, many of the topics in Plaintiffs' letter brief will be the subject of motions *in limine*, including IARC's classification of glyphosate and Monsanto's constitutionally-protected lobbying activity.