BAUM HEDLUND ARISTEI GOLDMAN PC
CONSUMER ATTORNEYS

Washington, D.C. Office
2101 L Street, N.W.
Suite 800
Washington, D.C. 20037-1526
Office (202) 466-0513
Fax (202) 466-0527

10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
Office (310) 207-3233
Fax (310) 820-7444
www.baumhedlundlaw.com

Philadelphia Office
1500 Market Street
12th Floor East Tower
Philadelphia, PA 19102-2100
Office (215) 665-5659
Fax (215) 569-8228

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 One

Dear Judge Chhabria:

Issue: Monsanto's Discovery of a Tumor in the Control Group When it Re-Reviewed the Knezevich and Hogan Mouse Study

Plaintiff Hardeman's Position

The animal toxicology surrounding glyphosate is relevant to the issue of causation. These studies measure whether glyphosate, as opposed to formulated Roundup, can cause tumors in mice and/or rats, *i.e.*, oncogenicity. Both sides' experts dispute the data, and, in particular, the results of the Knezevich & Hogan (a/k/a 1983 Bio/Dynamic) mouse study.[1] Plaintiffs seek to admit evidence surrounding the Knezevich & Hogan study, including the study's background, as discussed below. This evidence will come in through a combination of corporate witness and expert testimony.

Notwithstanding Monsanto's claim that glyphosate has a forty-year record of safety, the Knezevich & Hogan mouse study, completed in 1983, was the first valid oncogenicity conducted on glyphosate (not formulated Roundup). The approval of glyphosate in the 1970s, and the EPA's conclusion that glyphosate was not likely carcinogenic, was based on a mouse study conducted by Industrial Bio-Test Laboratories ("IBT"). Exh. 1 at 19, 37. When the study was conducted, a former Monsanto toxicologist, Paul Wright, was working at IBT overseeing several toxicology tests. Exh. 6 at 2; *e.g.*, Exh. 2 at 1. Then, after IBT's oncogenicity test on glyphosate was submitted to the EPA, Dr. Wright returned to Monsanto. *E.g.*, Exh. 3 at 1 (1973 letter from IBT to Dr. Wright at Monsanto); *see also United States v. Keplinger*, 776 F.2d 678, 684 (7th Cir. 1985). A few years later, while Dr. Wright was at Monsanto, he was indicted for creating fraudulent science at IBT and, after a six-month trial, was found guilty. *Keplinger*, 776 F.2d at 683-84.

Because of the IBT scandal, the EPA deemed Monsanto's oncogenicity study invalid. Exh. 1 at 37; Exh. 4 at 1. This prompted Monsanto to contract a new laboratory, Bio-Dynamics, and submit a mouse study to the EPA in 1983. Exh. 5 at 1. The results of the original study showed no kidney

[1] For a discussion of Plaintiffs' view of this study, see Dr. Christopher Portier's expert report at pgs. 36-39.

tumors in the control group, one tumor in the mid-dose, and three tumors in the high dose groups. *See* Exh. 7 at 2. Monsanto, however, dismissed these findings as "unrelated to treatment" and nothing more than false positives. Exh. 11 at 1. In February 1985, the EPA rejected these arguments, concluding that "a prudent person would reject the Monsanto assumption that Glyphosate dosing has no effect on kidney tumor production" and that "Glyphosate is suspect." *Id.* at 3. The EPA also rejected Monsanto's false positive argument, noting "Viewpoint is a key issue: Our viewpoint is one of protecting the public health when we see suspicious data. [I]t is not our job to protect registrants from false positives." *Id.* at 4. Monsanto, in turn, learned the EPA had reviewed the study and concluded that glyphosate was "[o]ncogenic in mouse," and a "Possible Human Carcinogen[.]" Exh. 9 at 2. Monsanto was concerned with the EPA's findings and specifically inquired "[s]hort of … *finding tumors in the control groups*, what can we do to get this thing off group 'c'?" noting that his was a "serious matter." Exh. 9 at 3, 4 (emphasis added). Then, in March 1985, eight EPA scientists reached a consensus position, deciding that glyphosate was oncogenic, and "classified glyphosate as a Class C oncogen[.]" Exh. 8 at 3.

In response, Monsanto decided, on April 3, 1985, to hire "Dr. Marvin Kus[]hner [to] review kidney sections and present his evaluation of them to EPA *in an effort to persuade the agency that the observed tumors are not related to glyphosate.*" Exh. 10 at 1 (emphasis added). And, on April 14, 1985, Dr. Kushner received the tumor slides. *See* Exh. 12 at 1-2. As predicted, Dr. Kushner concluded that the kidney tumors observed in the study were not related to glyphosate by discovering a new "tumor" in the control group. *See* Exh. 13 at 1 ("The registrant has now submitted a report which shows that re-reading of the kidney slides has revealed one (1) kidney tumor in the control group but no additional tumors in the treatment groups."). This new tumor—which no EPA or Monsanto scientist had previously observed—prompted EPA's pathologists, on June 14, 1985, to order a complete re-sectioning and re-review of the kidney slides. *Id.* at 1.

While the EPA was re-reviewing the kidney sections, Monsanto discussed, internally, how to deal with an adverse ruling from the EPA. On August 20, 1985, Monsanto's Lyle Gingerich wrote:

> If the results of the kidney re-sectioning do not resolve the glyphosate issue within OPP, we will be faced with an adverse OPP decision. It is likely that OPP will ask the S.A.P.[2] for concurrence on its determination that there is a treatment-related effect in the glyphosate mouse study. … If we assembled 10 respected toxicologists, would all ten agree that the feeding level is too high to be meaningful? If so, I recommend that we bring all ten of the toxicologists to the S.A.P. meeting. There is a tendency to "count the votes" at S.A.P. meetings. We can make a difference by lining up a large number of experts on our side.

Exh. 14 at 1. And, on August 28, 1985, Monsanto's Frank Serdy wrote:

> We continue to feel it is important to identify and contact those outside "experts" who we feel would testify on our behalf to EPA and SAP that, based on the results, glyphosate is not oncogenic. … It seems imperative that we continue to do all that is possible in order to have the Agency reverse its decision. Hopefully, the testimony of several respected "experts" will be enough to cause EPA to change their minds.

[2] EPA's Scientific Advisory Panel.

Exh. 15 at 1-2.

The EPA re-reviewed the re-sectioned kidney slides and concluded that there was not a tumor in the control group. Exh. 17 at 2. This prompted the EPA to, on January 17, 1986, as predicted by Monsanto, to send the issue to the EPA's SAP, for a meeting on February 11 and 12, 1986. *See* Exh. 18 at 1. Before the SAP meeting, Monsanto submitted a position paper to the SAP, which included the expert opinions of five separate experts supporting Monsanto's position. *See* Exh. 19 at 3. And, during the SAP, each of Monsanto's experts testified against the EPA that they believed there was a tumor in the control animal. As a result, the SAP issued its conclusion, that "[t]he vast majority of the pathologists, which examined the proliferative lesion in the male control animal, agreed that the lesion represented a renal adenoma. Therefore, the statistical analysis of the data should utilize this datum." Exh. 20 at 4. But, nonetheless, the SAP concluded that it was not possible to "categorize Glyphosate clearly into Group C (possible human carcinogen) or Group E (no evidence of carcinogenicity for humans)" and proposed that "Glyphosate be categorized as Group D (not classified) and there be a data call-in for further studies in rats and/or mice to clarify unresolved questions." *Id.* This, in turn, prompted the EPA to issue a guidance document in June 1986, and request that "this study be repeated with a larger number of animals in each test group, so that the statistical power of the study is increased." Exh. 23 at 11 (pg.7).

Monsanto refused to redo the mouse study. *See* Exh. 21 at 1-3 (discussing various arguments Monsanto could make against doing a repeat mouse study). Monsanto requested an exemption from having to do the study, and the EPA disagreed, as illustrated in an EPA memo dated January 5, 1988. Exh. 22. There, the Toxicology Brach (TB) of the EPA discussed Monsanto's refusal to redo the mouse study, concluding that "TB does not concur with Monsanto regarding the waiver of the repeat mouse oncogenicity study[.]" Exh. 22 at 2. The memo explained that "TB believes the oncogenic potential of glyphosate in mice still remains unresolved and that a repeat mouse study is necessary to fully and adequately assess this potential." *Id.* at 4 (pg.2). In an effort to make the study less expensive, the EPA offered to let Monsanto do a study with only male mice, and only with kidney histopathology. *Id.* at 5-6. Monsanto, however, still refused, citing statements made by its paid experts at the SAP. *See* Exh. 25 at 1. Ultimately, it worked. After senior EPA officials met with the TB branch on June 7, 1989, the TB branch changed positions and concluded that "a repeat of the mouse oncogenicity study is not required at this time." Exh. 24 at 2. At no time has Monsanto ever repeated that oncogenicity study.

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* Exh. 26, 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. 26, 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.

Tumors in Knezevich and Hogan Study. A limited portion of the evidence in Plaintiffs' letter brief may relate to the science regarding causation and thus could potentially be a part of Phase 1 to the extent relied upon by any experts—namely, the Knezevich and Hogan study itself and Dr. Kushner's subsequent review of the tumor slides that revealed an additional tumor in the control group. But this issue ultimately is another misleading distraction. The EPA has repeatedly confirmed that there was an additional tumor in the control group. Plaintiffs' own expert, Dr. Portier, agrees as well. *See* Exh. 27,

Portier Rep. Table 9 (accepting existence of the control-group tumor. And any effort by Plaintiffs, like the one in their letter, to introduce evidence about the discovery of the control-group tumor without completing the narrative through the confirmation of the tumor by the EPA would be misleading and incomplete. Any such effort demonstrates why—if not presented fairly and related to causation only—none of the evidence should be admitted during Phase 1. Plaintiffs' contrary arguments are simply another effort to distract the jury from what the science actually shows. In all events, the vast majority of the evidence in Plaintiffs' brief involves Monsanto's internal correspondence about these two studies, which, again, does not pertain to causation in any way. *See, e.g.*, Exh. 26, Jan. 4 CMC Tr. at 21:15-17 ("[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.").[3]

Dated: January 15, 2019

Respectfully submitted,

/s/ Aimee H. Wagstaff

Aimee H. Wagstaff, Esq.
ANDRUS WAGSTAFF, PC
7171 W. Alaska Dr.
Lakewood, CO 80226
Email: aimee.wagstaff@andruswagstaff.com

[3] Monsanto also intends to file a motion *in limine* regarding fraud at Industrial Bio-Test Laboratories.