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**UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF CALIFORNIA**
**SAN FRANCISCO DIVISION**

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| IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION | MDL No. 2741<br>Case No. 16-md-02741-VC |
| This document relates to:<br><br>*Hardeman v. Monsanto Co., et al.*, 3:16-cv-0525-VC | Hon. Vince Chhabria<br><br>**PLAINTIFF'S MOTION FOR RECONSIDERATION UNDER FED. R. CIV. P. 60 OF THE COURT'S RULING ON MONSANTO'S MOTION IN *LIMINE* NO. 10 REGARDING SÉRALINI STUDY** |

## ARGUMENT

Pursuant to Rule 60 of the Federal Rules of Civil Procedure, Plaintiff, Edwin Hardeman, by counsel, respectfully requests the Court reconsider its ruling granting Monsanto's Motion in Limine No. 10, limiting evidence pertaining to the Séralini study as the deposition transcripts of two witnesses directly on this subject were not available at the time the parties exchanged their briefs. (*See* PTO 81, granting Monsanto's Motion in Limine No. 10.) Specifically, Plaintiff deposed Monsanto's corporate representative, Dr. William Reeves, on January 23rd, 2019 and Dr. Wallace Hayes on February 7th, 2019. Since the parties exchanged their briefs, both deposition transcripts have become available and this new evidence was not before the Court at the time of its ruling under PTO 81. As such, Plaintiff respectfully requests the Court reconsider its ruling based upon the new evidence.

Because causation is no longer at issue during the second phase, the Séralini story, which demonstrates that a long-term rodent carcinogenicity study with formulated Roundup® was feasible during the relevant time period and that such a study could have been conducted at a cost of 1.5 million dollars, is particularly relevant to Mr. Hardeman's Phase 2 claims including failure to test and punitive damages. The evidence from Dr. Reeves' and Dr. Hayes' depositions, which the Court did not consider at the time of its initial ruling, demonstrate that the Séralini story is central to Monsanto's failure to test as well as its efforts to manipulate public opinion.[1] *See* Reeves Dep. at 311:02-388:15, and Hayes Dep. Second, the testimony reveals that Monsanto responded to the study by attempting to undermine and discredit Dr. Séralini, which is further evidence "that Monsanto does not particularly care whether its product is in fact giving people cancer," but "[focuses] instead on manipulating public opinion and undermining anyone who raises genuine and legitimate concerns about the issue." *See* PTO 101.

Two-year rodent studies are designed to assess whether an agent is oncogenic, *i.e.*, capable of inducing tumors. They are required by EPA before a pesticide is allowed on the market. Although

[1] Since the Motion in *Limine* briefing was exchanged, the transcripts of Dr. Reeves and Dr. Hayes, which the Court did not consider in its initial ruling, became final and should be considered by the Court.

Monsanto conducted one mouse and two rat studies on *pure* glyphosate, it has never conducted such a study on a commercial formulation,[2] which contains a mixture of glyphosate, surfactant, contaminants, and water, such as Roundup. This lack of testing on the formulation is reflected in Monsanto's internal emails. For example, Dr. Donna Farmer, a prominent Monsanto toxicologist, explains in a 2003 email:

> [I]n the US we have some lawn and garden products with the Roundup name on them but they ***contain other active ingredients in addition to glyphosate and they may contain different properties from glyphosate***… The terms glyphosate and Roundup cannot be used interchangeably nor can you used "Roundup" for all glyphosate-based herbicides any more. ***For example, you cannot say that Roundup is not a carcinogen… we have not done the necessary testing on the formulation to make that statement***.

Exh. 1 at 1 (emphasis added).

Although Monsanto has never studied the formulated product in a long-term study, Dr. Gilles-Eric Séralini and his seven colleagues from the University of Caen and University of Verona conducted a study in rats, using Roundup[3], that spanned two years. As the authors explain, their study "was not designed as a carcinogenicity study" but was actually a "follow up investigation of a 90-day feeding study conducted by Monsanto" but instead of stopping the study at 90 days, the researchers continued it for two years. Exh. 2 at 1. Thus, the conclusion of the study does not "purport[] to stand" for "causation," which is not at issue in phase 2. Rather, the conclusion is simply that "[o]ur findings imply that long-term (2 year) feeding trials need to be conducted to thoroughly evaluate the safety of … pesticides in their full commercial formulation." *Id.* The study's findings with regard to those rats that consumed Roundup for two years were: (1) that 80% of the rats that consumed Roundup for two years developed tumors, whereas 30% of the control group had tumors, and (2) that rats treated with Roundup had larger (30% to 130%) tumors compared to the controls. *Id.* In support of these conclusions, the researchers provided photographs depicting the histopathological slides of various rat tumors and pictures of rats within the treatment groups, including a photograph of a rat that consumed Roundup for two years (as had, prior to this study,

[2] In Request for Admission No. 6, "Monsanto ADMITS that it has not conducted a long-term animal carcinogenicity study on any formulated pesticide product." Exh. 11 at 3.

[3] The study also looked at the effects of genetically modified foods on the rats. Plaintiffs have no intention of discussing those findings in any way at trial.

never been done). *Id.*[4]

None of the data in the study is incorrect or misrepresented. When the study was originally retracted (a result of Monsanto's machinations described below), but before it was republished in another journal, the editor of the journal where it was originally published, Dr. Wallace Hayes (who also happened to be a paid Monsanto consultant regarding glyphosate, *see* Exh. 3 at 1), conducted an exhaustive review of the raw data. *See* Exh. 4 at 1. Following that review, Dr. Hayes stated that "[u]nequivocally, the Editor-in-Chief found no evidence of fraud or intentional misrepresentation of the data" and that "the results presented (while not incorrect) are inconclusive[.]'" *Id.* The decision to retract was "only on the inconclusiveness of this one paper." *Id.* However, considering the authors drew no definitive conclusion and merely stated that the formulated product should be studied, this decision to retract was highly criticized in the academic community, including Dr. Christopher Portier (Plaintiffs' expert) before he was ever retained in this litigation. Exh. 5.

Because liability, and not causation, is at issue in Phase 2, evidence demonstrating the feasibility and cost of a study on formulated Roundup® is relevant and not unduly prejudicial. This study, its findings, and the story surrounding its original retraction are relevant for two reasons.

**A. The Séralini Study is Relevant to Liability and Punitive Damages.**

First, the study is probative of whether Monsanto's refusal to study formulated Roundup was done with malice or reckless disregard to human health—which goes to punitive intent. In addition to the Séralini *et al* study, there are numerous instances within the scientific literature where concerns regarding the possible synergistic effect of glyphosate and its formulation mixture were raised (including an internal study by an independent genotoxicologist James Parry). However, despite these repeated concerns, Monsanto refused to do long-term testing on the formulated product. This very issue came to a head in response to the Séralini publication.

In an internal email from October 2012 (shortly after the Séralini publication), Monsanto employee Dr. Daniel Goldstein summarizes the "key points" from the "Asia/Pacific and Americas/Europe/Africa Séralini phone conferences yesterday." Exh. 6 at 3-4. The first key point

[4] For the purposes of this motion, Plaintiff does not seek to introduce evidence pertaining to the Séralini book and/or video.

discussed how to get the study retracted. The second key point, however, discussed "[s]tudy needs moving forward" and describes "2 year/chronic studies on pesticide formulations." *Id.* Dr. Goldstein explains that "[t]his question is already being asked … the paper actually finds nothing – so there is no need to draw any conclusions from it – but the theoretical issue has been placed on the table." *Id.* In response to this, Dr. Shawna Lemke, the head of the Toxicology and Nutrition Center, explains:

> ***If we conduct a chronic study in response to Séralini efforts, there is significant risk that one study on one product would not end the debate.*** That is, detractors and possibly regulators may see this, despite our best positioning, as an admission that studies are needed and/or ***a demonstration that we are willing to do them, resulting in requests for these studies on a routine basis.*** Furthermore, what the Séralini study demonstrates is that chronic/carc studies will contain "background" findings such as common tumors and chronic nephropathy that, when viewed by the skeptic or novice regulator may be very difficult to convince them of lack of treatment relevance. ***Given the lack of scientific need, the time required to complete (3 yrs including reporting), the significant financial investment ($1.5 M) the Toxicology team considers conduct of such studies a dangerous precedent to be avoided.***

*Id.* at 2 (emphasis added). Monsanto reveals in this email why it refuses to test the formulated product and its reasons have nothing to do with protecting public health, and everything to do with avoiding "bad" findings and spending money on testing. This is highly relevant to the issue of punitive intent. And, all of these documents will be presented through competent Monsanto witnesses who have been cross-examined under oath, not through Plaintiffs' experts.

The email further reveals a long term study on formulated Roundup® could have been conducted for a relatively small amount of money, especially when juxtaposed with Monsanto's global Roundup® sales and is consistent with the "strong evidence from which a jury could conclude that Monsanto does not particularly care whether its product is in fact giving people cancer, focusing instead on manipulating public opinion and undermining anyone who raises genuine and legitimate concerns about the issue." *See* Hugh Grant Dep. at 26:20-27:6 ("A: So [Monsanto's average volume of Roundup® sales] was roughly it was about $2 billion in sales..."); PTO 101.

**B. The Séralini Story is Relevant to Monsanto's Efforts to Undermine Scientists Raising Concerns about Glyphosate.**

The second reason the study, its findings, and the story surrounding its original retraction are relevant focuses on what Monsanto did to attack Dr. Séralini and his colleagues following this publication. This evidence will be presented through a combination of testimony from Dr. William

Reeves (Monsanto's designated representative who was specifically proffered to testify about Monsanto's role in getting the Séralini paper retracted), Dr. Michael Koch (a Monsanto employee who was involved in getting the Séralini paper retracted), Dr. David Saltmiras (a Monsanto employee who worked closely with the Editor-in-Chief that ultimately retracted the article), and Dr. Wallace Hayes (the Editor-in-Chief that ultimately retracted the paper). Plaintiffs will present the following evidence: (1) Monsanto hired Dr. Hayes as consultant on glyphosate issues;[5] (2) Dr. Hayes, after being hired as a consultant, specifically requested that Monsanto have independent scientists send letters to the editor asking for the Séralini retraction;[6] (3) the next day, CropLife (a pesticide industry advocacy group) asked scientists to send in letters to the editor seeking retraction and provided bullet-point summary of what the letters should say;[7] (4) Dr. Hayes, because of these letters, proceeded to conduct an investigation in the Séralini study;[8] (5) Dr. Hayes decided, despite the study containing no false or incorrect information, decided to retract the study;[9] (6) Dr. Saltmiras claimed he was able to leverage his relationship with Dr. Hayes;[10] and (7) that Monsanto executives nominated the Monsanto employees that orchestrated the outcry against Séralini for a leadership award titled "I Smell a Rat – Response to Séralini" which described Monsanto's achievement as:

> The Séralini study was a multimedia event that was designed for maximum negative publicity The Monsanto Toxicology Team was mobilized to provide rapid assessment of the technical aspects while the Scientific Affairs team helped organize 3rd party scientists that were fully engaged to respond to the paper. In all, there was six months of effort to respond that included Monsanto's technical evaluation, a Letter to the Editor (longer than the original manuscript), responses by the Glyphosate Task Force, powerpoint presentations, responses to numerous Regulator inquires, blog posts and popular press articles. This was the result of coordinated efforts and synergies by people from multiple Regulatory Teams.

Exh. 10 at 2. These facts and evidence are highly relevant for establishing Monsanto's punitive

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[5] *See* Exh. 3 (contract between Dr. Hayes and Monsanto).
[6] *See* Exh. 7 at 2.
[7] *See* Exh. 8 at 2.
[8] *See* Exh. 4 at 1 (describing that the investigation was commenced after receiving letters to the editor).
[9] *Id.*
[10] *See* Exh. 9 at 6 ("Throughout the late 2012 Séralini rat cancer publication and media campaign, I leveraged my relationship the Editor if Chief of the publishing journal, Food and Chemical Toxicology and was the single point of contact between Monsanto and the Journal.").

intent, i.e., either malice or a reckless disregard to human health. As the Court explained in its recent order denying Monsanto's motion for summary judgment: "[T]here is strong evidence from which a jury could conclude that Monsanto does not particularly care whether its product is in fact giving people cancer, focusing instead on manipulating public opinion and ***undermining anyone who raises genuine and legitimate concerns about the issue***." PTO 101.

DATED: March 13, 2018

Respectfully submitted,

By: /s/ Aimee Wagstaff

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 13th day of March, 2019, a copy of the foregoing was filed with the Clerk of the Court through the CM/ECF system which sent notice of the filing to all appearing parties of record.

/s/ Aimee H. Wagstaff_____
*Counsel for Plaintiff*