BAUM HEDLUND ARISTEI GOLDMAN PC

– CONSUMER ATTORNEYS —

Washington, D.C. Office 12101 L Street, N.W. Suite 800 Washington, D.C. 20037-1524 Office (202) 466-0513 Fax (202) 466-0527 12100 Wilshire Boulevard, Suite 950 Los Angeles, CA 90025-7114 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

August 1, 2017

VIA ELECTRONIC MAIL

Bart Staes, Heidi Hautala, Benedek Javor, and Michel Rivasi Members of the European Parliament Brussels, Belgium Email: <u>Bart.Staes@ep.europa.eu</u> <u>Heidi.Hautala@ep.europa.eu</u> <u>Benedek.Javor@ep.europa.eu</u> <u>Michel.Rivasi@ep.europa.eu</u>

Re: Declassified Documents Relating to Monsanto and Roundup

Dear Members of the European Parliament:

Thank you for your interest in the ongoing federal litigation regarding the carcinogenic properties of the widely-used herbicide, glyphosate. We avidly share your commitment to the principles of transparent and rigorous scientific assessment in efforts to protect public and environmental health. Your July 4, 2017 letter to Judge Vince Chhabria raises a number of concerns which transcend the immediate exigencies of the litigation and implicate serious international regulatory, public health, and scientific issues. We hope to aid your European institutions in reaching a consensus on the safety profile of glyphosate based on an impartial and comprehensive review of the available data.

We would like to bring to your attention a number of documents discovered in the litigation which were declassified today. The docments are available by hyperlink in the email sent with this letter. On June 30, 2017, our firm, working in collaboration with the Plaintiffs' Steering Committee assigned to spearhead the federal litigation against Monsanto, sent a letter to Monsanto (attached) challenging the confidential designation of the documents that we are now turning over to you. Monsanto met with us and stated it would not retract claims of confidentiality over the documents we specifically challenged. However, pursuant to Paragraph 16.3 of the Protective Order entered in the MDL (attached), Monsanto was required to file a motion within 30 days of Plaintiffs' June 30, 2017 letter in order to seek continued protection of the documents. Failure to file such motion within 30 days, i.e., July 31, 2017, "automatically waive[s] the confidentiality designation for each challenged designation." *Id.* ¶ 16.3. Since Monsanto did not file any motion seeking continued protection of the documents, it waived confidentiality over them.

Staes, Hautala, Javor & Rivasi August 1, 2017 Page 2

These documents are particularly pertinent to the upcoming October 11 joint hearing before the Agriculture Committee and the Committee for Public Health and Environment of the European Parliament that will address the existing "Monsanto Papers" and the way European agencies assessed glyphosate. All of the declassified documents are included with this letter as well as a chart that we sent to Monsanto as an attachment to our June 30, 2017 correspondence, which groups the documents by category and provides a description of each (attached. The documents are organized according to four different "issues": "Ghostwriting, Peer-Review & Retraction"; "Surfactants, Carcinogenicity & Testing"; "Absorption, Distribution, Metabolism & Excretion"; and "Regulatory & Government." A review of the categories of documents demonstrates (1) the extent to which Monsanto was aware of the dangers of glyphosate and other substances in its commercially formulated product, Roundup, but refused to conduct further research into the potential carcinogenicity of glyphosate and Roundup (under Surfactants, *Carcinogenicity & Testing* at 10-16): (2) Monsanto's manipulation of the scientific literature through ghostwriting and retraction of unfavorable studies (under Ghostwriting, Peer-Review & Retraction at 1-10); (3) the extent to which Monsanto misrepresented glyphosate's rate of absorption by the human body and Monsanto's termination of studies which conflicted with the company's commercial interests by demonstrating higher absorption rates and thus increasing the likelihood of adverse health effects (under Absorption, Distribution, Metabolism & Excretion at 16-18); and (4) Monsanto's collusion with various U.S. regulatory officials in an effort to influence the assessment and classification of glyphosate (under Regulatory & Government at 19-28).

Of particular interest to the re-reregistration of glyphosate are documents indicating that Monsanto failed to conduct tests on the commercially available formulated product, Roundup, because of concerns of what the results would yield. Dr. Donna Farmer put it best: "you cannot say that Roundup is not a carcinogen...we have not done the necessary testing on the formulation to make that statement." MONGLY00922458 at *1-2. This was also confirmed by Monsanto employee, Mr. Stephen Adams: "With regards to the carcinogenicity of our formulations we don't have such testing on them directly..." at MONGLY01155974 *1. Indeed, as far back as 1999, Dr. Farmer was reluctant to evaluate glyphosate, the various ingredients in the Roundup formulation, or the Roundup formulation itself: "I will not support doing any studies on glyphosate, formulations or other surfactant ingredients at this time with the limited information we have on the situation." MONGLY00877683 at *2. Such concerns over the potential carcinogenicity of its product and reluctance to conduct further tests explains Monsanto's apprehension towards the important analysis conducted by IARC: "Just wanted to let you that what we have long been concerned about has happened. Glyphosate is on for an IARC review in March of 2015." MONGLY01208470 at *1.

However, Monsanto's head-in-the-sand approach regarding the harmful effects of its product were not limited to a refusal to conduct studies, but included terminating studies which demonstrated that glyphosate may be absorbed by the human body in greater rates than expected. Monsanto ceased such studies, (such as the "TNO" study, *available at* MONGLY00888353) "because a further study was not likely to help us meet the project objective."

- CONSUMER ATTORNEYS ------

MONGLY03737014 at *2. Monsanto personnel even conceded that by terminating the study "[w]e are left behind with too many questions after all this." at *Id.* *1. It is easy to see why European regulators may lack the information needed to properly assess glyphosate when Monsanto's 2010 regulatory goals for Germany included "Defend[ing] POEAs" and "push[ing] back on data requests." MONGLY02721133 at *10.

Indeed, Monsanto's European liaison, Mr. Richard Garnett, stated in 2008 that glyphosate would be classified in the EU as "T Toxic; R23 Toxic by inhalation" based on a study titled "An Acute Nose-Only Inhalation Toxicity Study in Rats with Mon 78623. MONGLY02335782 at*1; study available at MONGLY02335784). Dr. William Heydens of Monsanto had previously stated that rodent deaths observed in the study could be "treatmentrelated." MONGLY06722561 at *2. Indeed, Mr. Garnett knew that there were several unanswered questions with respect to glyphosate absorption, distribution, metabolism and excretion ("ADME") when he acknowledged that: "[t]he ADME has always been the weak link in our argument and the Spanish response highlights that we have not got rid of the problem." MONGLY06385823 at *1. Monsanto was also aware that the formulated product was absorbed by human bodies at higher rates due to the cocktail of other ingredients in Roundup: "certain coformulants like humectants that will make it highly likely we will get large amounts penetrating the skin." at *1. MONGLY06653096 at *1. Monsanto proactively sought to foster a public perception that glyphosate is safe for humans by influencing the scientific discourse though strategies such as not disclosing Monsanto employees' contributions to studies and articles. This was acknowledged by Monsanto Toxicology Manager, Dr. David Saltmiras, who in his own words "ghost wrote cancer review paper Greim et al. (2015)[.]"

We hope that the European Parliament will be better informed in proceeding with their evaluation and classification of glyphosate as a result of having access to these documents. If you have any questions, I would happy to speak with you.

Best, BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By:

R. Brent Wisner, Esq. Michael L. Baum, Esq. Pedram Esfandiary, Esq.

Encls.