UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC **ADMINISTRATIVE MOTION TO FILE UNDER SEAL**
This document relates to: ALL ACTIONS	

Pursuant to NDCal. Civil Local Rules 79-5 and 7-11, Plaintiffs hereby file this Administrative Motion to File under Seal.

I. Action Requested

A ruling on whether the full, unredacted Plaintiffs' Motion to Strike Confidentiality Designation of Deposition of William Heydens, PhD., and its attachments, should be filed under seal.

II. Reasons Supporting the Request

Pursuant to the Confidentiality Order in place for MDL 2741, any party wishing to use a document designated "confidential" in support of a motion must file an Administrative Motion such as this, to determine whether filing under seal is appropriate. Plaintiffs fully oppose such sealing for the reasons set forth in the substantive Motion, and based on the Court's strong admonitions on the subject but, in accordance with the Confidentiality Order and Monsanto's refusal to permit public filing yet again, are filing this Administrative Motion.

III. CONCLUSION.

For the foregoing reasons, the Plaintiffs seek that the substantive Motion to Strike and its accompanying exhibits be unsealed by the Court, and said Motion also be granted.

DATED: January 9, 2017

Respectfully submitted,

/s Robin Greenwald, Michael Miller and Aimee Wagstaff
Robin Greenwald
rgreenwald@weitzlux.com
Weitz & Luxenberg
700 Broadway
New York NY 10003
Ph 212-558-5500
F 212-344-5461

Michael Miller
mmiller@millerfirmllc.com
The Miller Firm LLC
108 Railroad Ave
Orange VA 22960
Ph 540 672 4224
F 540 672 3055

Aimee Wagstaff
Aimee.wagstaff@andruswagstaff.com
Andrus Wagstaff, P.C.
7171 West Alaska Drive
Lakewood CO 80226
Ph 303-376-6360
F 303-376-6361

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 6, 2017 I electronically filed this Administrative Motion and using the CM/ECF system which will send a notification of such filing to counsel of record. I have separately served by e-mail the unredacted version of the Motion to Strike Confidentiality Designation on counsel for Monsanto.

/s/ Michael Miller

DECLARATION PURSUANT TO CIVIL L.R. 7-11(a)

I, Michael Miller, declare:

1. I am a member of the executive committee of MDL 2741. I make this declaration in support of the above Administrative Motion to File Under Seal. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would competently testify thereto.

2. The proposed filing quotes from and attaches the following documents, deemed "confidential" by Monsanto:

William Heydens Deposition Transcript (Exhibit 6)
William Heydens Deposition Exhibits (attached to underlying Motion as Exhibits 7-10)
MONGLY00904753 (Exhibit 3)
MONGLY00904754 (Exhibit 4)

N.B. the underlying motion seeks to remove confidentiality from the Heydens deposition and exhibits (Ex. 6-10) only; Exhibits 3 and 4 are intended to form the Court's decision on that Motion; however, as a matter of principle Plaintiffs oppose the ultimate sealing of those exhibits as well.

3. Plaintiffs have met and conferred in good faith with Defendants on the filing of these documents publicly and could not reach an agreement.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 6th day of April 2017

/s/ Michael J Miller

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC **[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO STRIKE CONFIDENTIALITY DESIGNATION OF DEPOSITION OF WILLIAM HEYDENS PHD.**
This document relates to: ALL ACTIONS	

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION TO STRIKE CONFIDENTIALITY DESIGNATIONS OF DEPOSITION OF WILLIAM HEYDENS, PHD.

Having considered the papers and argument of counsel, it is hereby ORDERED as follows:

1. Plaintiff's Administrative Motion to File Under Seal is DENIED;
2. Plaintiffs' Motion to Strike Confidentiality Designations of Deposition of William Heydens, PhD. is GRANTED; and
3. Plaintiffs are to re-file each of the above in unredacted form, with the exhibits thereto, on the public docket within 7 days.

The Clerk is directed to send certified copies of this order to all counsel of record.

ENTER: this ___ day of _____ 2017.

_____

V. Chhabria, United States District Judge

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	MDL No. 2741 Case No. 16-md-02741-VC **PLAINTIFFS' MOTION TO STRIKE CONFIDENTIALITY DESIGNATION OF DEPOSITION OF WILLIAM HEYDENS PhD.** **Date: May 5, 2017** **Time: 2:00pm** **Ctrm: 4, 17th floor** **Hon. Vince Chhabria**
This document relates to: ALL ACTIONS	

PLAINTIFFS' MOTION TO STRIKE CONFIDENTIALITY DESIGNATION OF WILLIAM HEYDENS PH.D DEPOSITION

Introduction

Monsanto, not Plaintiffs, put forward their "regulatory toxicologist" William Heydens, Ph.D., as being one of the five most important personnel/witnesses on the subject of glyphosate carcinogenicity[1]. Accordingly, his custodial file was produced by Monsanto and his deposition taken by Plaintiffs on January 23 and 24, 2017. Dr. Heydens appears to have spent a great deal of his career ghostwriting "science" papers to protect Roundup, those efforts rivaled in time and scope only by his colleague David Saltmiras, PhD. This has been an important subject of this litigation so far, and is central to general causation; Monsanto relies heavily upon the scientific literature and governmental approvals of glyphosate for its general causation defense; as the Court is aware, however, the discovery process is yielding substantial evidence that Monsanto is often the puppetmaster behind scientific articles that are positive for the company, as well as U.S. EPA deliberations and reports. Several weeks ago, Monsanto Co. published an entry on their website, https://monsantoblog.com, entitled "MONSANTO DID NOT GHOSTWRITE THE WILLIAMS ET AL (2000) GLYPHOSATE PAPER." That article quoted directly from the Heydens deposition, selecting the most helpful portions to Monsanto, in which Dr. Heydens denied ghostwriting. It is rather rich that Monsanto, which accuses Plaintiffs and the World Health Organization constantly of "cherry picking" data and documents, now refuses to permit public disclosure of the rest of this deposition, despite having waived confidentiality with this strategic public posting.

PROCEDURE

[1] "'These aren't the droids you're looking for.'… 'These aren't the droids we're looking for.'" Star Wars Episode IV: A New Hope, (1977).

Paragraph 16 of this Court's Protective Order (Doc. 64) governs this matter; it directs the parties to meet and confer on challenged confidentiality designations; the parties have done so in good faith on several occasions, by email and telephone. In fact, Plaintiffs have significantly narrowed the scope of the material challenged, but disagreement remains as to the entirety of the Heydens deposition.

The Order goes on to state "the Challenging Party may file a motion challenging a confidentiality designation at any time if there is good cause for doing so, including a challenge to the designation of a deposition transcript or any portions thereof."

CONFIDENTIALITY HAS BEEN WAIVED BY DEFENDANT

Dr. Heydens was heavily involved in the ghostwriting of Safety Evaluation and Risk Assessment of the Herbicide Roundup and its Active Ingredient, Glyphosate, for Humans. Williams GM, Kroes R, Munro IC.; Regul Toxicol Pharmacol. 2000 Apr;31(2 Pt 1):117-65. Indeed, the phrase "ghostwriting" is not an inflammatory accusation made by Plaintiffs here, it is Dr. Heydens' own term for the process of Williams 2000, and his suggestion for how to write what became Williams 2016; see Doc. No. 187-12 p. 4 (email unsealed by Court wherein Dr. Heydens wrote "we ghost-write…..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…Recall that is how we handled Williams Kroes & Munro 2000".)

That publication and the related emails were discussed at great length at deposition. Dr. Heydens could not deny that this discussion had taken place, but said he had difficulty remembering why he wrote "ghostwriting" in 2015, claiming his memory of the 1999-2000 timeframe was much clearer and there had been no ghostwriting of that paper.

The day after this email was unsealed by this Court, Monsanto published on the front page of its public website, Monsantoblog.com, a piece called "MONSANTO DID NOT GHOSTWRITE THE WILLIAMS ET AL (2000) GLYPHOSATE PAPER." (Exhibit 1) Not only is that statement a blatant falsity, endangering public health well beyond the bounds of this litigation, but, almost unbelievably, Monsanto quoted directly from the Heydens deposition transcript on its website:

> Although 15 years later Dr. Heydens referred to such fully acknowledged contributions as ghostwriting, he described his actual role in the Williams et al paper under oath as follows: "I made some minor editorial contributions to that 2000 paper that do not mount to the level of a substantial contribution or an intellectual contribution and, thus, I was only recognized in the acknowledgements and not as an author, and that was appropriate for the situation."
>
> He further clarified, "It was things like editing relatively minor things, editing for formatting, just for clarity, really just for overall readability to make it easier for people to read in a more organized fashion."

Prior to this, the Heydens deposition transcript, like all the other depositions taken in this case, was mostly designated "confidential" by Monsanto after it occurred. Indeed, Monsanto had itself *specifically designated some of these portions as confidential, which it then turned around and disclosed publicly.* See Exhibit 2, March 10, 2017 letter with final confidentiality designations (portions quoted on Monsanto website include 417:13-20). Given this disclosure, by Monsanto to the public, of parts of the Heydens deposition that served Monsanto's interests, and mindful of the repeated admonitions by this Court as to what is to be considered confidential and/or filed under seal, Plaintiffs have met and conferred multiple times with Defendants on this issue, who refuse to de-designate any portions of the Heydens deposition, stating that "Monsanto needs to defend itself."

However, Monsanto is again attempting to control this litigation with pressures outside of the courtroom, and making knowingly false claims to the public about Williams 2000; far beyond attempting to influence the outcome of this litigation, this poses an acute danger to public health. Williams 2000 is but one of many papers written by Monsanto without disclosing authorship. While the witness had trouble remembering why he said he "ghostwrote" this paper, the documentary evidence has no such shortcomings, and the Plaintiffs have provided that documentation to Defendant in the context of this dispute.

For example, in an April 30, 1999 email between Dr. Heydens and Douglas Bryant (an employee of Cantox, now called Intertek, the organization that Monsanto retained to facilitate both Williams 2000 and Williams 2016 publications), [redacted]

Another source document directly contradicting Monsanto's recent public statements is [redacted]

The Heydens deposition goes into great detail about the efforts that Monsanto made to control the content and wording of this and other related scientific publications. While Dr. Heydens denied that Williams 2000 was "ghostwritten", he did remind his colleagues in 2015

that it was ghostwritten, and testified extensively on the subject in the deposition. Monsanto has chosen their favorite quote from Dr. Heydens denying this, and published it to the world.

According to the "sword and shield" doctrine, the rest of the deposition must now be deemed non-confidential. Corporations may not trot out advantageous portions of documents or depositions and then claim that the remainder is cloaked in confidentiality or privilege. This doctrine has more often been applied to attorney-client privilege, which privilege confers much stronger protection to documents than "confidential" designations made by Monsanto (pursuant to an agreement intended to promote fluidity and economy in mass discovery).

"Sword and shield" is a subset of subject matter waiver, which has been defined in decisions by this District when "fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading presentation of evidence to the disadvantage of the adversary." *Century Aluminum Co. v. ACGS Marine Ins. Co*., 285 FRD 468 (N.D.Ca. 2012)(citing FRE 502 advisory committee notes).

More specifically, this type of waiver has been well described as:

> [W]hen a party entitled to claim the attorney-client privilege uses confidential information against his adversary (the sword), he implicitly waives its use protectively (the shield) under that privilege.

Willy v. Admin. Review Bd., 423 F.3d 483, 497 (5th Cir. 2005).

This District, along with many others nationwide, has consistently applied the "sword and shield" doctrine to prevent this type of inequity. In *Marilley v. Bonham*, 2013 WL 896755 (N.D.Cal. 2013), Magistrate Judge Ryu explained its application thusly:

> This breadth of waiver prevents a party from employing the privilege as both a sword and a shield during litigation; "that is, it prevents the inequitable result of a party disclosing favorable communications while asserting the privilege as to less favorable ones.

And, Federal District Courts in California have applied the doctrine outside of attorney-client privilege as well, stating that disclosure depends on whether the party claiming privilege/confidentiality has put the protected information "at issue." *See Bertram v. Sizelove,* 2012 WL 273083 (applying in contect of protected health information). Indeed, Mag. Judge Cousins had before him a similar waiver issue in the *Century Aluminum* case; the Defendant had chosen to disclose a document that was "probably privileged" but then attempted to maintain privilege protection over related documents. The court rebuffed that attempt and ordered disclosure of all documents within that subject matter, despite the attorney-client privilege. Its holding, specifically, was:

> Here, [Defendant] has attempted to use the disclosed document as both a shield and a sword, that is, to reveal a limited aspect of privileged communications in order to gain a tactical advantage in litigation. The Court finds that by voluntarily producing a privileged document concerning "significant development in the weather investigation" drafted by Robb, [Defendant] has waived the attorney-client privilege and work product protection as to all Robb communications concerning defendants' weather investigation.

Century Aluminum Co., infra.

The situation at hand differs from that in the *Century Aluminum* case, for example, only in that the "confidentiality" stamp Monsanto puts on nearly all discovery material has significantly less weight than the attorney-client privilege. Plaintiffs seek, as a matter of fairness, the disclosure of the entire Heydens deposition in light of Monsanto's selective disclosures of "confidential" portions of it, used for tactical advantage. This Court has explained to these parties repeatedly its position on secreting materials in this litigation from the public:

> And the parties, particularly companies, take a completely unreasonable view on what should be confidential and what material would cause them competitive harm. And so I just want to say at the outset, if I see a pattern of frivolous motions to seal, I will start sanctioning people. I'll start sanctioning parties and I will start sanctioning lawyers.

(January 27, 2017 hearing tr. at 7:5-10). Contrary to what Monsanto might say in opposition, Plaintiffs seek disclosure of materials created for/from this litigation: the deposition transcript of Dr. Heydens, who was put forward by Monsanto at the outset of discovery. Plaintiffs do not seek to abstractly disclose "trade secrets" or anything of the sort; and, to the extent Monsanto may argue that disclosure would hurt its business or embarrass it, the Court has made clear its position on those types of argument. And again, Monsanto chose Dr. Heydens and his custodial files *for this litigation*, not Plaintiffs.

[redacted] A Review of the Carcinogenic Potential of Glyphosate by Four Independent Expert Panels and Comparison to the IARC Assessment Gary M. Williams, Marilyn Aardema, John Acquavella, et al. Crit. Rev. Toxicology, Vol 24, 2016. This article has been cited by the EPA in multiple reports, and considered by regulators and scientists all over the world. The publication contains the following Declaration of Interest:

> The Expert Panel Members recruitment and evaluation of the data was organized and conducted by Intertek Scientific & Regulatory Consultancy (Intertek). The Expert Panelists were engaged by, and acted as consultants to, Intertek, and were not directly contacted by the Monsanto Company. Funding for this evaluation was provided to Intertek by the Monsanto Company which is a primary producer of glyphosate and products containing this active ingredient. Neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel?s manuscripts prior to submission to the journal.

[redacted]

[redacted]

The carcinogenicity of glyphosate has become a public health issue of intense global interest at present. And, Monsanto's ghostwriting has infected the scientific literature. The Williams (2000) paper alone has been cited **by five hundred fifty two (552)** other publications; all without a disclosure that Monsanto wrote it. As but one other real-world example, thirty (30) Members of the European Parliament wrote a letter dated March 24, 2017 to the President of the Executive Branch of the European Union, urging him not to re-approve glyphosate in the EU, and to take a critical look at the existing information and whether it was tainted by Monsanto's undisclosed hand. A short excerpt is instructive of the importance of these documents and depositions to human health globally:

> James Parry, a renowned genotoxicologist Monsanto had worked with, concluded that glyphosate had potential clastogenic effects in vitro and suggested to conduct more specific studies on the potential mutagenic effects of glyphosate. The revealed emails show Monsanto regretted to have worked with Parry and intended not to pursue the suggested studies. James Parry died in 2010.

(Exhibit 5, March 24, 2017 EU Parliament Letter). The 1999 Parry report, alerting Monsanto to the mutagenicity of glyphosate, became available to scientists and regulators only through this Court's Order last month, rejecting Monsanto's argument that it must remain under seal.

As a second example of many, Dr. Williams' medical school was contacted by Science Magazine, perhaps the most esteemed publication in the hard sciences, regarding the

ghostwriting allegations; the school undertook an "investigation" that lasted less than 24 hours and Science then published:

> After a quick investigation, officials at a medical school in New York State say they have found "no evidence" that a faculty member violated the school's prohibition against authoring a paper ghostwritten by others. The statement came one day after *Science* Insider reported that New York Medical College (NYMC) in Valhalla, New York, would examine a researcher who, according to internal documents released last week by a federal court in California, put his name on a 2000 paper partially ghostwritten by employees at Monsanto, the giant agricultural chemicals company based in St. Louis, Missouri. An NYMC spokesperson declined to provide details of how it conducted its investigation, saying in a statement that NYMC "does not disclose details of its internal investigations, but the college does consider the matter in question to be closed." (The school later amended its statement, adding: "**If new information is provided to us, we will evaluate it. If not, we have no further comment.")**

(http://www.sciencemag.org/news/2017/03/medical-school-examine-whether-professor-published-paper-partly-written-chemical).

These are but two brief examples showing that source material in this litigation is impacting human health worldwide. In the context of a blatant waiver of "confidentiality" by Monsanto, the Heydens deposition must not remain secret.

Conclusion:

Because Monsanto has selectively placed self-serving portions of the Heydens deposition in the public realm, the Court should deny Monsanto's continued claims of confidentiality over this litigation deposition transcript (Exhibit 6) and its exhibits (combined as Exhibits 7-10).

DATED: April 6, 2017 Respectfully submitted,

/s Robin Greenwald, Michael Miller and Aimee Wagstaff
Robin Greenwald
rgreenwald@weitzlux.com
Weitz & Luxenberg
700 Broadway
New York NY 10003
Ph 212-558-5500
F 212-344-5461

Michael Miller
mmiller@millerfirmllc.com
The Miller Firm LLC
108 Railroad Ave
Orange VA 22960
Ph 540 672 4224
F 540 672 3055

Aimee H. Wagstaff
Aimee.wagstaff@andruswagstaff.com
Andrus Wagstaff, P.C.
7171 West Alaska Drive
Lakewood CO 80226
Ph 720-255-7623

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 6, 2017 I electronically filed this Opposition using the CM/ECF system which will send a notification of such filing to counsel of record.

/s/ Michael Miller

DECLARATION

I, Michael Miller, declare:

1. I am a member of of the executive committee of MDL 2741. I make this declaration in relation to Motion to Strike Confidentiality of the Deposition of William Heydens, PhD.. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would competently testify thereto.
2. Plaintiffs have met and conferred with Monsanto on several occasions on this disagreement, and bring it before the Court only because the parties could not resolve it without intervention.
3. The documents attached hereto as exhibits are true and correct copies of:
    a. Monsanto produced, bates stamped discovery documents (Ex 3, 4)
    b. A public web posting on monsantoblog.com (Ex 1)
    c. A letter from defense counsel to plaintiffs' counsel in this matter (Ex 2)
    d. A letter from members of the European Parliament (Ex 5)
    e. The deposition transcript of William Heydens, PhD. (Ex 6)
    f. The exhibits to said deposition, with stenographers' identifying stickers (Ex 7-10)

I declare under penalty of perjury that the foregoing is true and correct.

Executed this April 6 2017

/s/ Michael Miller

FEATURED ARTICLE

MONSANTO DID NOT GHOSTWRITE THE WILLIAMS ET AL (2000) GLYPHOSATE PAPER

Recently, in the context of personal injury litigation filed against Monsanto, plaintiffs' attorneys have cherry picked a single email – out of more than 10 million pages of documents produced – to allege that Monsanto scientists ghostwrote "Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans," a paper on glyphosate safety by internationally recognized experts Gary M. Williams, Robert Kroes and Ian C. Munro published in Regulatory Toxicology & Pharmacology in 2000.

These allegations are false. Monsanto scientists did not ghostwrite the paper. The paper and its conclusions are the work of Dr. Williams, Dr. Kroes and Dr. Munro. The paper also underwent the journal's rigorous peer review process before it was published.

Because plaintiffs' attorneys are taking a single comment in a single email out of context to attempt to mischaracterize the role of a Monsanto scientist, Dr. William Heydens, who earned his PhD. in Toxicology from the University of Michigan in 1984, we are setting the record straight and taking the unusual step of publicly disclosing some of his sworn and transcribed testimony from a deposition regarding his involvement with the Williams et al (2000) paper.

Consistent with standard practices for academic and scientific peer-reviewed publications, the contributions of Dr. Heydens and other Monsanto experts were fully and publicly listed in the "Acknowledgements" section of the Williams et al (2000) paper, which stated, "[We] thank the toxicologists and other scientists at Monsanto who made significant contributions to the development of the exposure assessments and through many other discussions. The authors were given complete access to toxicological information contained in the great number of laboratory studies and archival material at Monsanto in St. Louis, Missouri, and elsewhere. Key personnel at Monsanto who provided scientific support were William F. Heydens, Donna R. Farmer, Marian S. Bleeke, Stephen J. Wrattens, and Katherine H. Carr."

Although 15 years later Dr. Heydens referred to such fully acknowledged contributions as ghostwriting, he described his actual role in the Williams et al paper under oath as follows: "I made some minor editorial contributions to that 2000 paper that do not mount to the level of a substantial contribution or an intellectual contribution and, thus, I was only recognized in the acknowledgements and not as an author, and that was appropriate for the situation."

He further clarified, "It was things like editing relatively minor things, editing for formatting, just for clarity, really just for overall readability to make it easier for people to read in a more organized fashion."

The authors of the Williams et al (2000) paper are internationally recognized experts in the fields of toxicology, genotoxicity and carcinogenicity. Their paper synthesized a vast amount of scientific data on glyphosate developed from the 1970's through 2000. Based on this vast data set and the overwhelming weight of evidence, the authors wrote, "It is concluded that, under present and expected conditions of new use, there is no potential for Roundup herbicide to pose a health risk to humans."

More News and Views

THE GREAT PLAINS WILDFIRES: AGRICULTURE STEPPING UP IN A TIME OF NEED

(HTTP://MONSANTOBLOG.COM/2017/03/23/THE-WILDFIRES-AGRICULTURE-STEPPING-UP/)

MONSANTO DID NOT GHOSTWRITE THE WILLIAMS ET AL (2000) GLYPHOSATE PAPER

(HTTP://MONSANTOBLOG.COM/2017/03/14/MONSANTO_DID_NOT_GHOSTWRITE_GLYPHOSATE_PAPER/)

MONSANTO EARNS 2ND CONSECUTIVE DIGITAL EDGE AWARD FOR INNOVATIVE IT, SUPPLY CHAIN PRACTICES

(HTTP://MONSANTOBLOG.COM/2016/12/14/MONSANTO-EARNS-2ND-CONSECUTIVE-DIGITAL-EDGE-AWARD-FOR-INNOVATIVE-IT-SUPPLY-CHAIN-PRACTICES/)

Tags: Glyphosate (http://monsantoblog.com/tag/glyphosate/) Monsanto (http://monsantoblog.com/tag/monsanto/)

The conclusion of (Williams et al 2000) is consistent with the findings of regulatory authorities around the world, a branch of the World Health Organization that analyses pesticide residues, and one of the largest databases ever compiled on an agricultural product. To be clear: No regulatory body in the world considers glyphosate to be a carcinogen.

Plucking a single email out of 10 million pages doesn't change this fact.

Science is always a collaborative process. Our scientists often exchange ideas with, provide information to, and collaborate with third-party experts. As a company built on sound science, these collaborations are critical to our ability to deliver new tools and innovations for farmers, and they are governed by the highest principles of integrity and transparency.

AUTHOR

avatar

Nick Weber
More → (http://monsantoblog.com/author/jlckoh)

Originally published March 14, 2017 by Nick Weber

<< PREVIOUS POST (HTTP://MONSANTOBLOG.COM/2016/12/14/MONSANTO-EARNS-2ND-CONSECUTIVE-DIGITAL-EDGE-AWARD-FOR-INNOVATIVE-IT-SUPPLY-CHAIN-PRACTICES/)
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loading

Hollingsworth LLP

Erica T. Klenicki
dir 202 898 5836
eklenicki@hollingsworthllp.com

March 10, 2017

Via Electronic and First-Class Mail

Aimee H. Wagstaff, Esq.
Andrus Wagstaff, PC
7171 W. Alaska Drive
Lakewood, CO 80226

Robin Greenwald, Esq.
Weitz & Luxenberg, P.C.
700 Broadway
New York, NY 10003

Michael J. Miller, Esq.
The Miller Firm LLC
The Sherman Building
108 Railroad Ave.
Orange, VA 22960

Re: MDL 2741; In re Roundup Products Liability Litigation
Confidentiality Designations for Farmer Transcripts

Dear Counsel:

Pursuant to Paragraph 8 of the Protective and Confidentiality Order, we are maintaining the following confidentiality designations from William F. Heydens' deposition transcripts, taken on January 23 and 24, 2017:

14:12-18:6

18:7-23:19

23:21-24:5

29:24-49:18

50:8-55:20

63:9-64:24

68:11-18

69:23-79:22

82:5-89:9

91:7-106:22

107:20-109:18

110:25-118:6

119:3-125:8

125:23-152:18

153:19-174:8

177:14-178:23

180:15-186:8

187:4-201:15

203:11-211:4

215:18-237:12

238:10-243:3

251:20-254:4

258:9-261:7

264:16-276:17

309:8-314:25

318:3-321:23

389:24-391:9

394:11-396:25

407:14-409:17

412:6-420:15

421:9-21

455:8-23

458:3-461:8

463:8-467:3

Sincerely,

Erica T. Klenicki

Brussels, 24/03/2017

Dear President Juncker,

The EU approval of the world's most used herbicide active substance, glyphosate, will expire 6 months from the date the Commission receives the opinion of the Committee for Risk Assessment of the European Chemicals Agency or on 31 December 2017, whichever the earliest is.

Last week, on March 15th, the European Chemical Agency communicated that its "Committee for Risk Assessment (RAC) agrees to maintain the current harmonised classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects. RAC concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction."

This assessment follows the one made by the European Food Safety Authority in a report issued on 12 November 2015 that concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans. The report was nevertheless proposing a new safety measure to tighten the control of glyphosate residues in food.

Meanwhile in the United States, a litigation has been brought by people who claim to have developed non-Hodgkin's lymphoma as a result of exposure to glyphosate.

It was echoed in press reports that last March 13th, a U.S. District Judge ruled that documents obtained by plaintiffs could be unsealed. The court documents include internal emails from Monsanto, a member company of the Glyphosate Task Force (GTF), which is a "consortium of companies joining resources and efforts in order to renew the European glyphosate registration with a joint submission". Later on those documents were called "Monsanto Papers" by Le Monde.

According to an article in Le Monde on March 18th, the information revealed through the emails is that already in 1999 Monsanto knew about genotoxic effects of glyphosate. James Parry, a renowned genotoxicologist Monsanto had worked with, concluded that glyphosate

had potential clastogenic effects in vitro and suggested to conduct more specific studies on the potential mutagenic effects of glyphosate. The revealed emails show Monsanto regretted to have worked with Parry and intended not to pursue the suggested studies. James Parry died in 2010.

Furthermore, internal emails from the summer 2012, and referred to in an article from Huffington Post, suggest that Monsanto had ghost-written research that was later attributed to academics. The reasoning appearing in the emails at that time was that "*it unfortunately turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility*". A so-called "*need to re-group and redesign the approach to the manuscript*" was identified.

As Members of the European Parliament, we are deeply concerned to see that one of the published studies used in the *Renewal Assessment Report of glyphosate: Risk assessment provided by the rapporteur Member State Germany and co-rapporteur Member State Slovakia* (see Final addendum uploaded on EFSA's website on 19/11/2015) was the *Review of genotoxicity studies of Glyphosate and Glyphosate-based formulations*, Critical Reviews of Toxicology, 2013; 43(4): 283–315.ASB2014-9587.

This study was co-authored by Kier and Kirkland. Both of them are cited in the "Monsanto Papers": L. Kier is a former Monsanto expert and now toxicology consultant. The released emails show concern about the level of credibility he would bring: "*given his geography and industry alignment, other highly credible genotoxicologists coauthors from European were sought. David Kirkland was the first choice*".

An internal email dated from July 12, 2012 refers to the signature of a contract between Monsanto and David Kirkland: "*this will enable him to coauthor the genotoxicity review paper with Larry Kier, as well as engaging him on any other projects which may come up...it may be necessary to have an EU based expert in genotoxicity on hand if issues arise during the regulatory review*".

The authors concluded that "*an overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and its formulations were not genotoxic in these core assays*." On page 57 of the *Final addendum*, you can read that "*Taking a weight of evidence approach, it may be concluded that there is no in vivo genotoxicity and mutagenicity potential of glyphosate or its formulations to be expected under normal exposure scenarios, i.e., below toxic dose levels.*"

In the final EFSA *Peer Review Report on Glyphosate* uploaded on EFSA's website on 23/11/2015 you can read on page 1392 that during the meeting of 27 February 2015, notably based on this study, the Pesticides peer review meeting "*confirmed that the active substance glyphosate is devoid of genotoxic potential*", despite comments raised by PAN-Europe, PAN-UK and Agrar Koordination that "*genotoxic effects on the contrary are already long known and available to the reviewers*".

Contrary to EFSA and ECHA, IARC concluded in March 2015 that glyphosate is probably carcinogenic to humans. On page 45 of IARC's monograph on glyphosate, one can see that IARC did not include the study in question by Kier and Kirkland in their evaluation: "*The Working Group determined that the information in the supplement to Kier & Kirkland (2013) did not meet the criteria for data inclusion as laid out in the Preamble to the IARC Monographs, being neither "reports that have been published or accepted for publication in the openly available scientific literature" nor "data from governmental reports that are publicly available" (IARC, 2006). The review article and supplement were not considered further in the evaluation*."

In light of all the above elements and of the non-selective properties[1] of glyphosate, for the sake of credibility of EU institutions and agencies, we urge you as President of the European Commission:

1/ with regard to glyphosate, to **take any urgency measure** necessary to guarantee the immediate protection of public health - including occupational health - and of the environment, based on Regulation (EC) No 1107/2009;

2/ to **recommend ECHA and EFSA to critically revise the validity of the GTF studies used,** and take all the necessary steps to investigate the impact of the 2013 *Review of genotoxicity studies of Glyphosate and Glyphosate-based formulations* led by Kier and Kirkland on both EFSA and ECHA conclusions on the carcinogenicity of glyphosate;

3/ **not to propose any new approval of glyphosate in the EU** as long as point 2/ has not been clarified and before all the restrictions on its use as adopted in the resolution of the European Parliament in April 2016 are put in place;

4/ to **urgently grant financial and technical support to the agricultural sector** for a rapid transition towards glyphosate-free agriculture;

5/ to **propose a revision of the pesticides legislation that would ensure that the scientific evaluation of pesticides** for EU regulatory approval is based only on published peer-reviewed and independent studies, which are commissioned by competent public authorities instead of the pesticide industry;

6/ to **set up a black list of the companies which use lies** as a common policy and, similarly to article 5.3 of the UN Framework Convention on tobacco control (FCTC), to **forbid undisclosed direct contacts** of European Commission and Agencies officials with any lobbyist working with or for Monsanto.

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[1] A recalled in the European Parliament resolution of April 2016, glyphosate is a non-selective herbicide that kills not only unwanted weeds, but all plants, as well as algae, bacteria and fungi, thereby having an unacceptable impact on biodiversity and the ecosystem; as such, glyphosate fails to comply with point (e)(iii) of Article 4(3) of Regulation (EC) No 1107/2009

7/ to **fully investigate whether Monsanto has deliberately falsified studies** on the safety of glyphosate and, should it be established, take appropriate legal action against the corporation.

Yours sincerely,

Philippe Lamberts, Co-President of the Greens/EFA group,
Guillaume Balas MEP (S&D),
Jose Inacio Faria MEP (EPP),
Stefan Eck MEP (GUE/NGL),
Piernicola Pedicini MEP (EFDD),
Bart Staes MEP (Greens/EFA),
José Bové MEP (Greens/EFA),
Martin Häusling MEP (Greens/EFA),
Benedek Jávor MEP (Greens/EFA),
Michèle Rivasi MEP (Greens/EFA),
Maria Heubuch MEP (Greens/EFA),
Molly Scott Cato MEP (Greens/EFA),
Claude Turmes MEP (Greens/EFA),
Ernest Urtasun MEP (Greens/EFA),
Florent Marcellesi MEP (Greens/EFA),
Marco Affronte MEP (Greens/EFA),
Pavel Poc MEP (S&D),
Karin Kadenbach MEP (S&D),
Maria Noichl MEP (S&D),
Nessa Childers MEP (S&D),
Gilles Pargneaux MEP (S&D),
Marc Tarabella MEP (S&D),
Nicola Caputo MEP (S&D),
Christel Schaldemose MEP (S&D),
Eric Andrieu MEP (S&D),
Isabelle Thomas MEP (S&D),
Edouard Martin MEP (S&D),
Younous Omarjee MEP (GUE/NGL),
Eleonora Evi MEP (EFDD),
Marco Zullo MEP (EFDD).