

Roger O. McClellan, DVM, MMS, DSc (Honorary) Diplomate-ABT and ABVT Fellow-ATS, SRA, AAAR, HPS, and AAAS Member-National Academy of Medicine Editor, Critical Reviews in Toxicology Advisor, Toxicology and Human Health Risk Analysis

Albuquerque, NM 8 Tel: Fax: Fax: E-mail: roger.o.mcclellan@

September 20, 2017

TO: Dear Dr Roberts, authors and co-authors of Review Papers:

FROM: Roger O. McClellan

SUBJECT: Glyphosate Special Issue – CONFIDENTIAL

Attached is a copy of the memo I sent you on April 15, 2017 concerning the Special Issue of Critical Reviews in Toxicology that contained 5 papers you authored or co-authored. I am pleased to note that many of you have responded. The purpose of this memo is to ask those of you who have not responded to provide me a response with a copy to Charles Whalley, Taylor and Francis, at your earliest convenience. It is important that each of you respond, not just the corresponding or first author of each paper. Your individual responses are critical to our completing our investigation of this matter in a timely manner. If you have any questions please feel free to contact me. Thank you for your assistance.

If you are not able to respond by Friday, September 22, 2017, please acknowledge receipt of this memo and let me know when I can expect your response.

Attachment: Letter of April 15, 2017

Cc: Charles Whalley Mildred Morgan @tandf.co.uk) @hargray.com)

Summary of Responses from Authors and Co-Authors on 5 Glyphosate Papers

Marilyn Aardema

9/17/17

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Roger-I am not aware of any writing by anyone not listed as a coauthor on the papers I was involved in. I did not have any contact or relationship with Monsanto, or any influence from them during the writing of these papers. We undertook an independent review following scientific and professional standards.

Marilyn Marilyn Aardema Consulting

John Acqavella

9/15/17

Roger:

Thank you for the chance to respond. The epidemiology manuscript was authored jointly by the 5 listed (epidemiologist/biostatistician) authors and each author met every one of the ICJME authorship guidelines. No one from Monsanto had any role in the writing of the epidemiology manuscript, nor did anyone from Monsanto attend our in person expert panel meeting where the approach to our systematic review was decided and each article was critiqued according to standard criteria. The epidemiology section of the summary article also had no input from Monsanto.

Regards,

John

John Acquavella, PhD FACE FISPE Professor, Dept Clinical Epidemiology Aarhus University, Denmark +1 (office) +1 (mobile) Aarhus University email: <u>joac@clin.au</u>

9/20/17

Thank you Roger for the chance to provide additional information. I'll begin by drawing a distinction between the epidemiology paper per se, the epidemiology sections of the summary paper, and the other sections of summary paper. Bill Heydens didn't offer any input on the epidemiology paper or the epidemiology section of the summary paper. With regard to other sections of the summary paper, the gist of the suggested edits by the epidemiologists concerned the tone toward IARC, not the scientific assessment re exposure, genotox or chronic tox. We epidemiologists pushed for sticking to a scientific assessment of the available evidence with very limited explicit or implied criticism of IARC. We left it to Gary Williams, the primary author, to adjudicate where there were differing suggestions re tone and I didn't keep track of whose comments prevailed where there was disagreement. However, we 5 epidemiologists all read the final version of the summary paper and were satisfied with the tone. As far as I know, the edits in question concerned tone only. Regards.

John

9/20/17

Roger:

Thank you again for the chance to respond. I've included the published DOI below for reference.

I did not receive any compensation from Intertek. I already had a consulting contract in place with Monsanto prior to the initiation of the review, so there was no need for a contract with Intertek or payment from Intertek for my efforts on the review article. I charged Monsanto my usual hourly rate for my time spent on the review, just as the other panelists charged Intertek their usual hourly rate (for them, paid by Monsanto through Intertek). I thought that the important issue regarding compensation for the DOI was that we were all paid by Monsanto, not the contracting or invoicing/payment details.

I believe the DOI is very comprehensive. It notes: that Monsanto funded our work, my previous employment with Monsanto more than 10 years ago, and even the fact that I consulted on a legal case unrelated to glyphosate involving a former Monsanto chemical plant. I tried to include everything possible in the DOI that you might want to be disclosed. As I noted in my previous email, the glyphosate epidemiology review was conducted according to the highest standards of my profession. The work was conducted totally independent of the sponsor. All five authors contributed actual written sections to the manuscript and met every one of the ICJME authorship criteria. Monsanto did not contribute to or influence the writing at all. I and my coauthors had sole responsibility for the content of the paper, and the interpretations and opinions expressed in the paper were ours.

Regards, John

Sir Colin Berry

On Sunday, September 17, 2017 2:21 AM, Colin Berry < wei@sircolinberry.co.uk> wrote:

Dear Mr McClelland.

Thank you for your mail.

As a former Chairman of the UK Advisory Committee on Pesticides and a Chairman of Section four Committee of the Medicines Act, I have , for many years, dealt with information concerning toxicity of xenobiotics in a consistent manner. Since retirement from those duties I have seen no reason to change my procedures. Information may come from any source but is used to provide the basis of my independent opinion.

In this instance, the members of the panel dealing with carcinogenicity produced text on the various issues before us in this field and considered the database identified in the document. We then met, or discussed electronically the various sections, about which we harmonised our views. At no stage was anyone from Monsanto involved in any of the discussions. Our opinion and the resultant document was arrived at in the manner which has been used by many regulatory authorities, as for example, the WHO/FAO joint panels.

Drafting was carried out by regular exchanges by members of the panel alone.

Your sincerely. Professor Sir Colin Berry

David Brusick

9/15/17

Roger

These questions have been asked of me on more than one occasion. As the individual who assembled the manuscript describing the genetic toxicology results and interpretation, I can assure you that the entire manuscript content was drafted, reviewed and finalized only by the members of the genetic toxicology panel. I can assure Critical Reviews in Toxicology that there were no other authors directly or indirectly involved in preparing its content. David Brusick

Michele M. Burns

From: Burns, Michele [mailto _______@childrens.harvard.edu] Sent: 16 September 2017 13:07 To: Roger McClellan Subject: RE: Glyphosateae Papers Published in CRT [EXTERNAL]

Dear Roger,

I had no communication with Monsanto staff about the content of the papers listed below, nor know of anyone who did. The meetings and scientific discussions were conducted in a highly professional, ethical manner.

Williams GM, Aardema M, Acquavella J, Berry SC, Brusick D, **Burns MM**, de Camargo JL, Garabrant D, Greim HA, Kier LD, Kirkland DJ, Marsh G, Solomon KR, Sorahan T, Roberts A, Weed DL. A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment. Crit Rev Toxicol 2016 Sep; 46 (sup 1): 3-20.

Williams GM, Berry C, Burns M, de Camargo JL, Greim H. Glyphosate rodent carcinogenicity bioassay expert panel review. Crit Rev Toxicol 2016 Sep; 46 (sup 1): 44-55.

Thanks, Michele

Michele M. Burns, MD, MPH

Joao Lauro Viana de Camargo

On Monday, September 18, 2017 1:52 PM, João Lauro < idecam@uol.com r> wrote:

Dear Dr. McClellan,

I am not aware of any contribution to the manuscripts by someone not listed as coauthor of the published papers. I understand that the section on animal tumors – in which I did participate – was drafted and finalized solely by the panel members. I believe that the declaration of interests that appeared at the end of the articles accurately reflects my participation. During the panel activities and writing of these papers I did not have contact with anyone from Monsanto regarding the contents of the manuscripts. The published papers convey my own independent expert opinion.

J.L.V. de Camargo, MD, PhD, FIATP Professor of Pathology Botucatu Medical School 18618-000 Botucatu SP Brazil <u>idecam@uol.com</u> decam@fmb.unesp

PS - A copy of this email was sent to the other coauthors.

David Garabrant

9/22/17

Dear Dr. McClellan,

I am responding to your request of September 15, 2017 regarding authorship of the five papers published in a Special Supplemental Issue of Critical Reviews in Toxicology (CRT) entitled "An Independent Review of the Carcinogenic Potential of Glyphosate," Volume 46, 2016. Thank you for providing an opportunity to respond.

As far as I am aware, no employees of Monsanto were involved in the drafting of the two articles that I co-authored. I had no contact with any employees of Monsanto at any time during the drafting of these articles. As far as I am aware, no one other than the listed authors was involved in the drafting of the two articles that I co-authored.

The Declarations of Interest (DOI) that I provided for the two articles that I co-authored were accurate to the best of my knowledge at the time I wrote them. In both articles I wrote, "DG serves on a scientific advisory board to Dow Agro Sciences, which markets pesticides including

glyphosate, and has consulted on behalf of Bayer Corp. on litigation matters concerning glyphosate and leukemia."

In November 2016 after the publication of the five papers, in the course of responding to subpoenas from the plaintiffs' attorneys in the California litigation, two events occurred:

- I was reminded by the attorney for Bayer Corporation, who retained me to act as an expert in that litigation, that I was also retained to act as a joint expert for several defendants in the Walsh v BASF Corp. et al., case. Those defendants are: Bayer Corporation; Bayer CropScience LP; Bayer CropScience Holding, Inc.; Dow AgroSciences, L.L.C.; BASF Corporation; Syngenta Crop Protection, Inc., Deere & Company, Lesco, Inc.; and Monsanto. My point of contact for the group of Walsh defendants was the attorney for Bayer, which led to the statement I made in the DOI that I had consulted on behalf of Bayer Corporation on litigation matters concerning glyphosate and leukemia. When I wrote my DOI, I did not list the other defendants in that litigation because I did not recall (or did not know at that time) that they had jointly retained me.
- 2. I reviewed my consulting engagements and found that in February 2016 I had been retained by a law firm on behalf of Pharmacia LLC (formerly known as Monsanto) regarding litigation involving leukemia and benzene exposure, but not involving glyphosate. I spent a total of 0.3 hours on that case on 2/16/2016 and never did any further work. My company, EpidStat Institute, Inc., was paid \$187.50 for my work. I did not recall this engagement at the time I wrote my DOI later in 2016.

To the best of my knowledge, I have had no other relationships with Monsanto at any time prior to co-authoring the two articles, and I have never spoken with any Monsanto scientist about glyphosate or any other scientific issue. Subsequent to the publication of the two glyphosate reviews I have had contact with attorneys representing Monsanto, for the purposes of responding to subpoenas from the plaintiffs' attorneys in the California litigation.

I hope these clarifications assist you in your inquiry. I will be pleased to provide any further assistance you may need.

Sincerely,

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David H. Garabrant, MD, MPH

Ann Arbor, MI e-mail: <u>dhg3@</u> phone:

RM 000488

Helmut A. Greim

On Sunday, September 17, 2017 12:21 PM, "Greim, Helmut" <

@lrz.tu-muenchen.de> wrote:

Dear Roger, in my response to you and all otherparticipantsof our exercise the mail to you bounced back. I am sending my statement to you separately. Best Helmut

Dear Roger,

I only can support all the previous statements. There was no interaction or interference with Monsanto people before, during or after the meeting, the evaluation of data or preparation of the manuscripts I have been involved. Best regress Helmut Greim

Larry D. Kier

9/22/17

Dear Dr. McClellan:

Thank you for your communication providing the opportunity to respond to concerns.

With respect to the specific question of authorship I fully concur with my fellow authors that the genotoxicity expert panel report was the product of the listed authors. Neither Monsanto employees nor attorneys were "ghost-writers."

I was initially hired by Monsanto to serve as a consultant to support the Intertek genotoxicity expert panel. In this capacity I was in contact with Monsanto to facilitate providing the panel members with complete and accurate information, including supplemental information on regulatory genetic toxicology studies.

Subsequent to development of the genotoxicity expert panel manuscript I agreed to be added as a coauthor subject to the approval of the panel members.

Please note that my employment with Monsanto began in 1974 and not 1979.

Thanks.

Larry Kier

David J. Kirkland

From: David Kirkland [mailto: @genetoxconsulting.co.uk] Sent: 16 September 2017 17:55 Subject: RE: Glyphosate Papers Published in CRT

Dear Dr McClellan,

I am aware of the accusations of "ghostwriting" by Monsanto employees, and I can appreciate the need for an investigation. Because my name was mentioned in one or more of the released emails, I have been contacted on this issue by several journalists, and have given them the same assurance as I will now give you. As far as I am aware, there was no "ghostwriting", and the papers of which I was coauthor were written entirely by the authors. Certainly from my side there was no contact with or influence by Monsanto, and I believe that to be the case for the other co-authors. I would never let my name be used on an article ghostwritten by others.

I hope this is helpful.

Kind regards,

David Kirkland.

Gary Marsh

On Tuesday, September 19, 2017 3:22 PM, "Marsh, Gary M" <

@pitt.edu> wrote:

Dear Roger,

In response to your email of September 15, 2017, this is to confirm that I had no contact whatsoever with Monsanto staff about the contents of the glyphosate review articles. The members of the epidemiology panel on which I served had absolute control, at all stages of the effort, over the contents of the epidemiology review article as well as the epidemiology section of the comprehensive review article. The opinions and conclusions expressed in these epidemiology components of the project were exclusively those of the panel members.

Sincerely,

Gary

Ashley Roberts

9/27/17

Dear Roger:

In response to your enquiries, I can confirm that Monsanto did not participate in the preparation of the 4 critical subject evaluations. The summary paper required clarification on the history and regulatory processes for glyphosate and I shared that summary with Dr. Heydens to ensure the accuracy of this information once the underlying evaluations had been finalized. Dr. Heydens' comments on the summary had no impact on the viewpoints/interpretation or the independent conclusions that had already been reached and set out by the 4 expert panel groups in their evaluations. As such, Monsanto was not involved in the drafting of any of the evaluations and did not have any input into the evaluations or conclusions regarding the safety of glyphosate that was provided to the journal.

Ashley

Ashley Roberts, Ph.D.

Senior Vice President - Food & Nutrition Realth, Erv communal & Resolution of Society DURAS

Direct +1 Office +1

Keith R. Solomon

9/21/17

Dear Dr. McClellan et al.,

I have finally received computer (back from repair). I have checked the paper and the DOI. The DOI is completely correct in the statement that "Neither any Monsanto company employees nor any attorney reviewed any of the Expert Panel's manuscripts prior to submission to the journal"

As noted in the Acknowledgments "I thank Monsanto Inc. for providing access to reports from exposure studies for glyphosate in applicators". Obviously, to obtain those reports, I communicated with people at Monsanto and might have asked for clarification of material in the reports. The data from the reports that were used are part of the paper and are reported in the supplemental information.

The opinions expressed in this paper and mine only. Keith

Tom Sorahan

On Saturday, September 16, 2017 5:47 AM, Thomas Sorahan

@bham.ac.uk> wrote:

Dear Roger, i had no communications with Monsanto staff about the content of the reviews. Tom Sorahan

Douglas L. Weed

9/19/17

Dr. McClellan,

I appreciate the opportunity to respond to your questions. I can assure you that the manuscript on epidemiology was authored only by those listed as the co-authors, including myself. Similarly, the epidemiology section in the summary article was authored only by the co-authors. Monsanto had no role in writing either of these manuscripts. Furthermore, no one from Monsanto attended the meetings prior to submission of these manuscripts. Finally, my declaration of interests was correct.

Sincerely,

Doug Weed

Douglas L. Weed, M.D., M.P.H., Ph.D. Founder and Managing Member <u>DLW Consulting Services</u>, LLC

Salt Lake City, UT

Gary Williams

9/20/17

Dear Roger,

I will respond to your request at this time because the College is closed for the next two days by which you requested a response. I would have wanted to discuss some items with Dr. Roberts, but he is travelling.

My responses cover the three sections of the publication of which I am a co-author.

For the carcinogenicity section, I was assisted in pathology review by my colleague Dr. Michael latropoulos. He confirms that all materials provided to us came from Intertek.

Likewise, for other sections, source documents came from Intertek.

Any materials provided to one member of a working group were provided to all members.

In the many exchanges of drafts I saw no material changes that did not come from a member of the Panel. In other words, I saw no changes that could have come from Monsanto.

From the time of my recruitment to the Panel up to the present, I have had no contact with any Monsanto representative.

In summary, the DOI accurately reflects the absence of input from Monsanto.

In reviewing the DOI, however, I have found a couple of inaccuracies. In referring to the previous review of glyphosate supported by Monsanto (Williams et al, 2000), acknowledgement is made to the contribution of Barry Lynch of Cantox. In the paper, we actually thank Douglas W. Bryant. Also, in several places it is stated that I consulted for Monsanto on litigation matters in involving glyphosate. I have consulted for Monsanto on other matters, but I have no recollection of consulting on glyphosate.

I hope that these responses are helpful.

Yours sincerely,

Gary M. Williams, MD Professor of Pathology