

This 8-page letter was sent to Roger McClellan, Charles Whalley, and the Committee on Publication Ethics on 10/12/2017

Nathan Donley

Dear Editors of *Critical Reviews in Toxicology*,

We are writing to ask that you retract the summary review article¹ in the 2016 supplemental issue of *Critical Reviews in Toxicology* entitled "An Independent Review of the Carcinogenic Potential of Glyphosate." This supplemental issue was dedicated to reviewing the 2015 decision by an expert Working Group of the International Agency for Research on Cancer (IARC) to designate glyphosate, the active ingredient in Roundup weedkiller and many other herbicide formulations, as "probably carcinogenic to humans" (Group 2A). For the reasons described below, the summary review fails to comport with Taylor and Francis's publishing ethics and should be retracted for misconduct.

The 2016 supplemental issue contained five review papers, consisting of a summary and four in-depth reviews in the areas of exposure; epidemiology; cancer in experimental animals; and mechanistic and other relevant data, that were written by expert panels overseen by Intertek, a consulting firm that was hired by the primary producer of glyphosate – Monsanto. All five reviews were very critical of IARC's assessment and were touted as "independent" in the main title of the supplemental issue.

The declaration of interest (DOI) statement for the summary article² included the statement: "[t]he 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."

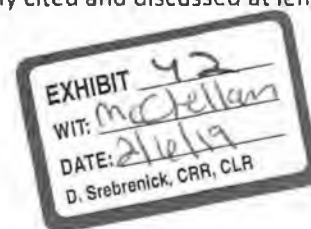
This DOI fails to accurately describe the events that preceded the publication of the summary manuscript, as demonstrated by emails recently released in the context of a lawsuit brought against Monsanto by sufferers of non-Hodgkin lymphoma. These emails provide information on the nature of Monsanto's involvement and interaction with some members of the expert panel during the research and writing phase of the analyses that were ultimately published in the 2016 supplemental issue.

Below are two excerpts of the DOI statement, followed by evidence that these statements did not accurately describe Monsanto's relationship to the summary manuscript.

- 1) "The Expert Panelists were engaged by, and acted as consultants to, Intertek, and were not directly contacted by the Monsanto Company."

This statement is inaccurate and misleading. At least two of the expert panelists were contacted directly by Monsanto regarding this review article and were paid directly by, and acted as consultants to, Monsanto *for this review specifically*. This DOI fails to disclose that these expert panelists worked as consultants for, and were directly paid by, Monsanto.

Emails released pursuant to litigation show that expert panelist Dr. John Acquavella invoiced Monsanto on August 31, 2015 for work relating to the "...glyphosate expert epidemiology panel."³ In the itemization of the invoice there were multiple references to the epidemiology panel. Dr. Acquavella billed Monsanto for research on numerous studies that were subsequently cited and discussed at length



in the epidemiology expert paper,⁴ and for drafting the expert panel report. Thus, contrary to the DOI, Dr. Acquavella was a consultant for and was in direct communication with Monsanto regarding this work.

Expert panelist Dr. Larry Kier signed a consulting agreement with Monsanto on August 20, 2015 for work relating to a project entitled: "Glyphosate Expert Panel."⁵ The objectives of this panel included: "1. Review glyphosate articles and generate summary 2. Attend the Intertek Scientific & Regulatory Consultancy ("Intertek") Expert Panel Meeting either in person or via teleconference. 3. Support the genotoxicity and oxidative stress portion of Intertek and support generation of a panel draft manuscript on glyphosate genotoxicity and oxidative stress." Thus, contrary to the DOI, Dr. Kier was a consultant for and was in direct communication with Monsanto regarding this work.

Internal correspondence between Monsanto employees confirmed both of these consulting agreements.⁶ Both Dr. Acquavella and Dr. Kier were co-authors of the summary review article.

- 2) "Neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel[']s manuscripts prior to submission to the journal."

This statement is false. At least one Monsanto employee, Dr. William Heydens, did extensive editing to the summary manuscript. He also applied pressure to make the overall tone of the article more critical of the IARC than multiple authors were comfortable with, and to have the articles published on a timeline that would be advantageous to the company.

Dr. Ashley Roberts, an Intertek employee who co-authored the summary review, was in direct contact with Dr. Heydens during the writing and editing phases of the summary article. Dr. Heydens reviewed and edited the summary manuscript at least twice after being emailed copies on two separate occasions by Dr. Roberts.^{7,8} In response to Dr. Acquavella's request to tone down the strident criticism of IARC, Dr. Heydens pushed to keep "inflammatory" language in the manuscript.⁹ And in an earlier draft of the manuscript, Dr. Heydens again tried to distort the messaging of the summary article by incorrectly asserting that IARC did not find glyphosate to pose a carcinogenic hazard.¹⁰

Some of the edits and suggestions that were made by Dr. Heydens ended up in the final manuscript. These were not neutral copy edits; these were edits that impacted the tone of the summary review and mischaracterized IARC's methodology and process in a way that was meant to cast doubt on its conclusions regarding glyphosate. Dr. Heydens also indicated his company's preference that the editing process move along quickly in order to keep to a timeline that Monsanto's management preferred.¹¹

In a separate email, Dr. Heydens mentioned writing an introductory section for the expert panel supplemental issue and tells Dr. Roberts that he would run it by her for edits.¹² Unfortunately, the draft section that Dr. Heydens wrote was not attached to the email, so it is unclear if, and to what extent, this ghostwritten section was adopted in – or influenced – the final summary manuscript.

Although Dr. Roberts at Intertek was supposed to be overseeing and directing the expert panels, her communications with Dr. Heydens indicate that many of the major decisions regarding these

manuscripts were vetted by Monsanto.¹³ Dr. Heydens proposed the order of authorship on the final manuscript,¹⁴ while Monsanto management initially insisted that two panelists who had made substantial contributions be inappropriately excluded from authorship because of their prior employment by Monsanto.¹⁵ These communications and edited manuscripts clearly demonstrate that Monsanto reviewed and edited the work product at issue, contrary to what was stated in the DOI.

Taylor & Francis Has an Obligation to Maintain the Scientific Integrity of its Journals

The DOI for the summary review article includes false, inaccurate, and misleading statements, and fails to disclose the important information that at least two of the expert panelists were engaged by Monsanto as consultants in addition to, or in lieu of, Intertek. These deficiencies violate Taylor and Francis conflict of interest guidelines, as clearly stated on the publisher's website.¹⁶

This was not simply a case of inadvertent error or ignorance of the rules. Dr. Roberts, the Intertek officer who had "overall oversight responsibilities"¹⁷ for the project and was also a co-author on the summary review, was told explicitly the type of information that needed to be disclosed in the DOI. Dr. Roberts received emailed instructions from *Critical Reviews in Toxicology* editor Roger McClellan that the DOI must include information on how the authors were engaged for the project and that any review by Monsanto personnel must be disclosed.¹⁸

The five review articles are represented as being "independent" in the title of the supplemental issue. The DOI statement for the summary review assures readers that Monsanto had no influence on the content of the reviews other than indirectly funding the work through an "independent" third party. This is false, and the scientific community and public were misled. At least one Monsanto employee edited the summary manuscript, vetted proposed decisions by the ostensible editor in charge, Dr. Roberts, and also had direct contact with at least two of the expert panelists, all in direct contradiction to the DOI.

The false, inaccurate, and misleading statements in the DOI served an obvious and critical purpose. In light of the high-profile controversy over the carcinogenicity of glyphosate, driven in large part by Monsanto, the company understood that the scientific community would have legitimate doubts as to the independence of a Monsanto-funded review effort. Assuaging these doubts was critical to the success of Monsanto's mission to discredit IARC's determination. This was accomplished in the summary review DOI by misrepresentation and omission. Intertek was presented as a firewall ensuring the freedom of panel members from Monsanto's influence. Monsanto was presented as entirely removed from the editorial process. However, as these emails reveal, Monsanto not only communicated directly with some Panel members, but the company paid them for their services directly – not solely through an intermediary. The company also reviewed and substantially edited the summary manuscript.

Based on the DOI, readers and reviewers of the glyphosate summary review expected an objective assessment, with Intertek serving as a firewall to protect panelists from the financially-interested influence of the funder, Monsanto. This "firewall" was a cynical ploy. As a result, readers and reviewers

were not given the opportunity to factor in Monsanto's substantial influence on the review – the critical purpose of a DOI.

It is clear that Taylor and Francis takes conflicts of interest very seriously. The company provides resources for authors to ensure that proper ethical considerations are taken into account prior to manuscript submission. The company states in its "Ethics for Authors" webpage: "If a conflict of interest is not declared to the journal upon submission, or during review, and it affects the actual or potential interpretation of the results, the paper may be rejected or retracted."¹⁹

Taylor and Francis policy is to issue a retraction for misconduct "...when there has been an infringement of publishing ethics...."²⁰ These are serious offenses and if left unanswered will ultimately undermine the work of many scientists who view scientific ethics to be sacrosanct. Based on the above information and Taylor and Francis's past commitment to ensuring that its authors are held to the highest ethical standards, we ask the publisher to issue a retraction for the summary review in this supplemental issue and to issue a public statement outlining the reasons for this action.

We also ask for an in-depth investigation into the other four review articles published in this supplemental issue.²¹ None of the below information is conclusive evidence that misconduct occurred as to these four review articles, only suggestive evidence that it may have occurred. Items that should be investigated further as they relate to the DOI's of these articles are as follows:

- 1) Email correspondence suggests that a Monsanto employee did review the "exposure" review article²² as well as the "epidemiology" and "mechanisms" review articles²³ prior to publication.
- 2) Email correspondence suggests a third expert panelist may have been paid by Monsanto for his work on the expert panel manuscripts.²⁴
- 3) In addition to stating that he wrote a draft introduction section²⁵ for the summary review, William Heydens suggested in an email that Monsanto might consider ghost writing some sections of the expert panel review to keep costs down.²⁶ A 2015 Monsanto work plan called for the company to ghost write a first draft of the "carcinogenicity in animals" review while the company looked for non-Monsanto scientists to author it.²⁷ Another Monsanto employee, Dr. Donna Farmer, compiled background information and documentation for the "carcinogenicity in animals" and the "exposure" experts to review.²⁸
- 4) A 2015 work plan indicated that Monsanto employees would engage possible authors regarding the "mechanisms" review.²⁹ A separate work plan stated that two Monsanto employees and Dr. Acquavella would engage with experts to plan for publications to push back against IARC's classification.³⁰ If these events were determined to have occurred, it would indicate that recruitment and engagement of the experts was initiated by Monsanto, not Intertek.
- 5) Email correspondence suggests that Monsanto employee William Heydens dictated the scope of the "exposure" review article by restricting the review to only analyze exposure to glyphosate in the absence of surfactants or inerts.³¹ That level of editorial control was not disclosed in the DOI.

We look forward to a quick and thorough response from your journal.

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¹ Williams, G. M., M. Aardema, J. Acquavella, S. C. Berry, D. Brusick, M. M. Burns, J. L. V. de Camargo, D. Garabrant, H. A. Greim, L. D. Kier, D. J. Kirkland, G. Marsh, K. R. Solomon, T. Sorahan, A. Roberts and D. L. Weed (2016). "A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment." *Critical Reviews in Toxicology* 46(sup1): 3-20.

² Reference 1.

³ Correspondence between John Acquavella and Monsanto Company. August 31, 2015. Available here: [http://baumhedlundlaw.com/pdf/monsanto-documents/25-Invoice-Showing-Monsanto-Paid-\\$20000-to-Expert-Panel-Member-Dr-John-Acquavella.pdf](http://baumhedlundlaw.com/pdf/monsanto-documents/25-Invoice-Showing-Monsanto-Paid-$20000-to-Expert-Panel-Member-Dr-John-Acquavella.pdf)

⁴ John Acquavella, David Garabrant, Gary Marsh, Tom Sorahan & Douglas L. Weed (2016) Glyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma or multiple myeloma, *Critical Reviews in Toxicology*, 46:sup1, 28-43, DOI: 10.1080/10408444.2016.1214681.

⁵ Consulting Agreement between Larry D. Kier and Monsanto Company. August 17, 2015. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/23-Email-Showing-Monsanto-Paid-a-Consultant-on-Expert-Panel-Believed-to-be-Composed-of-Independent-Scientists.pdf>.

⁶ Correspondence between Monsanto employees regarding Dr. Acquavella and Dr. Kier consulting agreements. August 6, 2015 - August 14, 2015. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/24-Email-Showing-Monsanto-Paid-Multiple-Individuals-on-Expert-Panel.pdf>.

⁷ Correspondence between William Heydens and Ashley Roberts. January 11, 2016 – January 13, 2016. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/3-Internal-Emails-Show-Monsanto-Made-Substantial-Contributions-to-Published-Expert-Panel-Manuscript.pdf>.

⁸ Correspondence between William Heydens and Ashley Roberts. February 8, 2016 - February 9, 2016. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/1-Monsanto-Executive-William-Heydens-Edits-and-Comments-on-Expert-Consultant-Manuscript.pdf>.

⁹ Reference 8. Dr. Acquavella writes that he and the epidemiology panelists felt that the draft manuscript was too “inflammatory” in its criticism of IARC and made edits to remove the criticism (Pgs 2-3). In response to those edits, comments by William Heydens to Ashley Roberts included: “The Deleted Statement Below Has Nothing To Do With IARC Criticism And Should Be Put Back In, John Over-Stepped The Bounds Here.” (Pg 31). “I Can Live With Deleting The Text Below, Assuming That Exposure Text Above (See Comment [V\ih39]) Is Added Back In.” (Pg 33). “I Would Ignore John’s Comment.” (Pg 14).

¹⁰ Reference 7. Commenting in response to the statement that IARC’s classification was based on the cancer hazard posed by glyphosate, William Heydens states: “While this is true to a degree, we have tried to steer away from such wording because it infers that IARC found a hazard when they in fact did not. Could we say something like “and noting that the IARC classification ignores the important role exposure plays in a proper overall risk assessment...”” (Pg 7). William Heydens is wrong. According to IARC: “[t]he Monographs are an exercise in evaluating cancer hazards...” (IARC Preamble 2006, p. 2). The suggested emendation unjustly denigrates IARC’s determination in the eyes of readers by implying that the Working Group was deficient in not conducting a full risk assessment, when in fact, that is not IARC’s role.

¹¹ Reference 7. William Heydens commenting to Ashley Roberts: “And I am going to thoroughly read the latest version of Keith’s paper tomorrow; but now I am not inclined to suggest substantial re-writing (adding of text) because I don’t want to slow progress down any more than necessary (my management would love to get all this off to CRT /Roger by very early February).”

¹² Correspondence between William Heydens and Ashley Roberts. January 6, 2016. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/2-Monsanto-Executive-William-Heydens-Admits-Ghostwriting-Introductory-Chapter-in-Expert-Panel-Manuscript.pdf>. William Heydens writes: “I had already written a draft Introduction chapter back in October/November, but I want to go back and re--read it to see if it could benefit from any ‘re-freshing’ based on things that have transpired over the last 10-12 weeks. I will do that in the next few days. Then I was thinking I would run it by you for your comments/edits.” (Pg 2).

¹³ See references 7, 8, 12, 15, 28 and correspondence between William Heydens and Ashley Roberts. November 2, 2015. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/33-Monsanto-Consultant-You-Cant-Say-That-There-is-no-Evidence-of-Roundup-Carcinogenicity.pdf>.

¹⁴ Reference 12. William Heydens stating to Ashley Roberts: “And then comes the question of who should be the ultimate author you or Gary? I was thinking you for the Introduction chapter and Gary for the Summary chapter, but I am totally open to your suggestions.” (Pg 2).

¹⁵ Email correspondences between William Heydens and John Acquavella. November 3-6, 2015. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/6-Monsanto-Consultant-Protests-Ghostwriting.pdf>. In response to who would be listed as authors on a poster presentation of the expert panelist’s findings, William Heydens states: “I thought we discussed previously that it was decided by our management that we would not be able to use you or Larry as Panelists/authors because of your prior employment at Monsanto - was that not your understanding?”

¹⁶ AUTHORSERVICES Supporting Taylor & Francis authors. What is a conflict of interest? Available here: <http://authorservices.taylorandfrancis.com/what-is-a-conflict-of-interest/>.

¹⁷ Reference 15. “Ashley is the final author as being the facilitator and having overall oversight responsibilities” (p. 5)

¹⁸ Correspondence between Ashley Roberts and Roger McClellan. July 5, 2016. Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/19-Editor-of-Journal-That-Published-Expert-Panel-Manuscript-States-Intention-of-the-Panel-was-to-Discredit-IARC.pdf>. Roger McClellan discussing what DOI’s needed to be disclosed prior to publication: ““The remainder of the DOI should make clear how individuals were

engaged, ie by Intertek. If you can say without consultation with Monsanto that would be great. If there was any review of the reports by Monsanto or their legal representatives that needs to be disclosed." (Pg 3).

¹⁹ AUTHORSERVICES Supporting Taylor & Francis authors. Ethics for authors. Available here:

<http://authorservices.taylorandfrancis.com/ethics-for-authors/>.

²⁰ AUTHORSERVICES Supporting Taylor & Francis authors. Taylor & Francis Corrections Policy. Available here:

<http://authorservices.taylorandfrancis.com/custom/uploads/2016/01/Author-services-correction-policy.pdf>.

²¹ The four remaining reviews are: Acquavella, J., D. Garabrant, G. Marsh, T. Sorahan and D. L. Weed (2016).

"Glyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma or multiple myeloma." *Critical Reviews in Toxicology* 46(sup1): 28-43; Brusick, D., M. Aardema, L. Kier, D. Kirkland and G. Williams (2016). "Genotoxicity Expert Panel review: weight of evidence evaluation of the genotoxicity of glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid." *Critical Reviews in Toxicology* 46(sup1): 56-74; Solomon, K. R. (2016). "Glyphosate in the general population and in applicators: a critical review of studies on exposures." *Critical Reviews in Toxicology* 46(sup1): 21-27; Williams, G. M., C. Berry, M. Burns, J. L. V. de Camargo and H. Greim (2016).

"Glyphosate rodent carcinogenicity bioassay expert panel review." *Critical Reviews in Toxicology* 46(sup1): 44-55.

²² Correspondence between William Heydens and Ashley Roberts. January 11, 2016 – January 13, 2016. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/3-Internal-Emails-Show-Monsanto-Made-Substantial-Contributions-to-Published-Expert-Panel-Manuscript.pdf>. William Heydens writes to Ashley Roberts that a section in the summary review "...read like a repeat of the entire Results section from Keith's Exposure paper/chapter..." and that "...I am going to thoroughly read the latest version of Keith's paper tomorrow..."

²³ Correspondence between William Heydens and Ashley Roberts. January 6, 2016. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/2-Monsanto-Executive-William-Heydens-Admits-Ghostwriting-Introductory-Chapter-in-Expert-Panel-Manuscript.pdf>. William Heydens writes "Back in mid-December, I forwarded the final Epidemiology & Genotoxicity manuscripts from John & Larry to our resident expert report/manuscript preparation person here at Monsanto to put them in the format (including references) specified by Critical Reviews in Toxicology."

²⁴ Correspondence between William Heydens and John Acquavella. January 7, 2016. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/26-Email-Demonstrating-Dr-Acquavellaslongstanding-consultancy-for-Monsanto.pdf>. William Heydens writes: "I was copied on an email yesterday regarding payment of hours billed by Tom Sorahan, and the budget folks made them split them out between regulatory (expert Panel) and the external law firm (litigation)..."

²⁵ Reference 12

²⁶ Correspondence between William Heydens and Donna Farmer, a Monsanto employee. February 19, 2015.

Available here: <http://baumhedlundlaw.com/pdf/monsanto-documents/key-documents-pages-203-4.pdf>. William Heydens writes: "For the overall plausibility paper that we discussed with John (where he gave the butadiene example), I'm still having a little trouble wrapping my mind around that. If we went full-bore, involving experts from all the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing \$250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add Greim and Kier or Kirkland to 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 so to speak. Recall that is how we handled Williams Kroes & Munro, 2000."

²⁷ Correspondence between William Heydens and Monsanto employees. May 11, 2015. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/5-Monsanto-Involvement-wlth-Scientific-Studies-Without-Disclosing-Conflicts-of-Interest.pdf>. Bullet points regarding a publication on animal data cited by IARC: "Manuscript to be initiated by MON as ghost writers" and "It was noted this would be more powerful if authored by non-Monsanto scientists (e.g., Kirkland, Kier, Williams, Greim and maybe Keith Solomon)

²⁸ Correspondence between Donna Farmer and Ashley Roberts. August 6-7, 2015. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/39-Email-Detailing-Monsanto-Suspicious-That-Formulated-Roundup-Can-Lead-to-Tumor-Production.pdf>. Donna Farmer writes: "Also Ashley I am pulling together the background info for the animal section and will sent [sic] that to you later today or tomorrow. After I meet

with Marian I will pull the exposure info together and get that off early next week” and “Ashley attached is a list of document [sic] I will be sending you for the Animal Bioassay Expert Group”

²⁹ Reference 27. Under the Genetox/MOA section of the work plan, the bullet point “Set-up 1 hr meeting with Gary Williams & Larry Kier to better understand what could be done...”

³⁰ Draft work plan regarding IARC classification. February 23, 2015. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/72-Document-Details-Monsantos-Goals-After-IARC-Report.pdf>. Bill Heydens, Donna Farmer and John Acquavella were slated to “Engage with experts to plan for publications and other activities in case IARC classification is unfavourable.”

³¹ Correspondence between William Heydens and Ashley Roberts. August 6, 2015. Available here:

<http://baumhedlundlaw.com/pdf/monsanto-documents/39-Email-Detailing-Monsanto-Suspicious-That-Formulated-Roundup-Can-Lead-to-Tumor-Production.pdf>. In response to a question about considering exposures other than pure glyphosate, William Heydens responds “I think the short answer is no. The focus of this is what is the carcinogenic potential of glyphosate.”