J Public Health Pol
https://doi.org/10.1057/s41271-018-0134-z

VIEWPOINT

Roundup litigation discovery documents: implications for public health and journal ethics

Sheldon Krimsky[1] · **Carey Gillam**[2]

© Macmillan Publishers Ltd., part of Springer Nature 2018

Abstract This paper reviews the court-released discovery documents obtained from litigation against Monsanto over its herbicide Roundup and through Freedom of Information Act requests (requests to regulatory agencies and public universities in the United States). We sought evidence of corporate malfeasance and undisclosed conflicts of interest with respect to issues of scientific integrity. The findings include evidence of ghostwriting, interference in journal publication, and undue influence of a federal regulatory agency.

Keywords Roundup · Monsanto · Ghost writing · Glyphosate · IARC · EPA

Introduction

Lead [1], vinyl chloride [1], pharmaceuticals [2, 3], asbestos [4], and tobacco litigation [5, 6] cases have resulted in 'discovery documents.' These documents, originally internally held by parties to a lawsuit, have become public in court records from cases filed in the United States (US). Such documents have revealed important information about the actions taken by corporate defendants to withhold, distort, invalidate, ghost-write, or fabricate scientific studies of their products. Among the revelations in the cases are ghost-written articles, withholding of critical public health information, hiring contract research companies to invalidate toxicology studies, funding of nonprofit research centers to create critical

✉ Sheldon Krimsky
sheldon.krimsky@tufts.edu

[1] Department of Urban & Environmental Policy & Planning, Tufts University, 97 Talbot Avenue, Medford, MA 02155, USA

[2] U.S. Right to Know, Oakland, CA, USA

Published online: 08 June 2018

reviews of published papers that had cast doubt on the safety of their products, and funding of university faculty to support their agendas. It is now possible for public health scholars to search for and in these documents on open databases [7, 8].

In 2015, the International Agency for the Research on Cancer (IARC), the specialized cancer research arm of the World Health Organization, determined that the chemical glyphosate, the active ingredient in many popular herbicides, is a "probable" human carcinogen. IARC said it found "limited" evidence of cancer links in studies of human exposures, mostly agricultural-related, that had been published since 2001. But IARC said studies in laboratory animals showed "sufficient" evidence that glyphosate can cause cancer. Research also showed "strong" evidence that glyphosate caused DNA and chromosomal damage in human cells, according to IARC [9].

Subsequent to the finding, several hundred people who believed they had been injured by the herbicide Roundup filed lawsuits against the Monsanto Corporation, its manufacturer [10]. Roundup is one of the most widely used glyphosate-based products. As of November 2017, roughly 3500 plaintiffs had cases ongoing against Monsanto. In each case, the plaintiff alleged that she or he, or their loved ones, developed non-Hodgkin lymphoma due to Roundup exposure. Moreover, the plaintiffs alleged that Monsanto had long covered up the risks of the glyphosate-based herbicide. More than 270 of the cases have been consolidated in multidistrict litigation (MDL) to be overseen by one judge in a federal court in the U.S., the District Court in San Francisco [11]. Many other lawsuits are proceeding in state courts. As part of the litigation, Monsanto has turned over millions of pages of its internal records to plaintiffs' attorneys, and many of those documents have been made public through the court docket [11]. Both these disclosed discovery documents and hundreds of other court documents have been placed in the public domain [12].

A number of journalists have brought these documents to the attention of the public. Among them are Stéphane Foucart and Stéphane Horel, who received the Varenne Award for their series published in *Le Monde* [13]. One of us, CG, has established a publicly accessible digital repository [10] of the Monsanto litigation documents and has written newspaper and magazine articles describing them [14]. CG has also obtained thousands of pages of documents from the United States (US) Environmental Protection Agency (EPA) through Freedom of Information Act (FOIA) requests. CG has accessed internal email communications emanating from public universities that reveal evidence of the manipulation of science. Much of this has been laid out in a chapter titled "Spinning the Science" in her book *Whitewash* [15]. Many of these FOIA documents are being made available to the public through a database established by the UCSF (University of California San Francisco) Industry Documents Library [16].

In this Viewpoint, we review the documents gathered through discovery as well as those obtained through Freedom of Information Act requests to regulatory agencies and public universities. We reviewed all these documents for evidence of unethical practices and undisclosed conflicts of interest with respect to issues of scientific integrity.

Ghost writing

Among the Roundup litigation discovery documents are multiple email exchanges authored by Monsanto employees that discuss, as an ostensibly normal business practice, 'ghostwriting' papers that, when published, appear to be authored by independent academic scientists or consultants with academic credentials. In some communications, Monsanto employees themselves used the term "ghostwrite," while in others, they simply describe the strategy and how it can be or has been employed.

A noteworthy example pertains to a paper published in 2000 by Williams, Kroes, and Munro [17]. In a February 2015 email, Monsanto scientist William Heydens discussed with colleagues various papers the company wanted to see published to counter what the company expected IARC to find with respect to glyphosate. (The company internally predicted a "possible" or "probable carcinogenicity classification by IARC.") Heydens wrote:

> A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA [mode of action] (depending on what comes out of the IARC meeting), and we ghostwrite 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. [18]

The Williams et al. paper has been cited hundreds of times and was among those referenced by the Environmental Protection Agency (EPA) in its finding, reported in 2016, that glyphosate was "not likely" carcinogenic [19].

Another example of Monsanto's surreptitious involvement in the science can be found in a memo dated August 4, 2015. Summarizing his "glyphosate activities," Monsanto scientist David Saltmiras, who at that time was a toxicology manager, stated that he "ghost wrote cancer review paper Greim et al. (2015)." [20]. That paper too, was among those cited by the EPA in its 2016 glyphosate determination [19].

A review of glyphosate, published along with four sub-papers in *Critical Reviews in Toxicology* (*CRT*) in September 2016 provides another example. Monsanto disclosed that it hired Intertek Scientific & Regulatory Consultancy, part of Intertek Group Plc, to develop the review, entitled "An Independent Review of the Carcinogenic Potential of Glyphosate." [21] The review concluded that IARC's classification of glyphosate as a probable human carcinogen was inaccurate and that glyphosate was "unlikely to pose a carcinogenic risk to humans." The internal emails obtained through discovery show that a key goal of the publication of the papers was to influence the European Chemicals Agency (ECHA): "These papers will also be useful for ECHA which is a European Agency that is reviewing the safety of glyphosate. We would very much like to share our manuscripts with them to aid in their deliberations." [22]

The 'declaration of interests' in the special issue of *Critical Reviews in Toxicology (intended for disclosure of any potential conflict of interest)* stated that the authors were "not directly contacted by the Monsanto Company," and that "Neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal." However, the documents obtained through discovery indicate those statements were not true. The documents demonstrate Monsanto was engaged in organizing, reviewing, and editing the drafts, even arguing with one of the authors and overruling him about language in the manuscript. In one exchange regarding a paper being prepared for publication, Monsanto scientist William Heydens wrote to Intertek: "Here are my suggested edits to the Draft Combined Manuscript… I think I caught all the differences and made the changes in the Combined Manuscript as part of my editing." [23] In a separate email, Heydens wrote to Intertek that he had reviewed the entire draft and indicated "what I think should stay, what can go." [24] The documents also reveal Heydens' direct correspondence by email with at least one of the authors about the papers [25]. Documents also demonstrate that at least one of the authors was under direct contract with Monsanto during the drafting and publication of the paper, a fact not disclosed in the declaration of interest in *CRT* involving that author [26].

In another email exchange, Heydens stated he had written an introduction to a paper and then proceeded to discuss "who should be the ultimate author" and that he had written a second paragraph in another paper, on neither of which he was listed as an author [27].

Influencing the retraction of a scientific peer reviewed paper

In 2012, G.-E. Séralini et al. published in the journal, *Food & Chemical Toxicology,* the results of a 2-year rat feeding study that found harmful impacts for animals exposed to Monsanto's glyphosate-based Roundup and to genetically modified corn, with and without Roundup application. The paper drew international attention in the media. This provoked a storm of criticisms from industry and academic scientists demanding the journal retract the article. Internal Monsanto documents show that Monsanto officials directed and organized the call for a retraction [28], while stating internally that it should not appear as though Monsanto was behind the actions [29].

Litigation discovery documents reveal one internal Monsanto email that stated: "He [editor-in-chief] directly told us [Monsanto] to give him something to work with or else his hands are tied and we will have to deal with the consequences." [30] Also a Monsanto-funded academic spoke directly to the *FCT* Editor-in-Chief and advocated retraction of the Séralini study. He wrote: "Failure of *JFCT* to retract the paper will force the community to be critical of the journal as well as the paper." [31, 32] And a Monsanto employee described how he "leveraged his relationship" with the *Food & Chemical Toxicology* Editor-in-Chief and became the "single point of contact between Monsanto and the journal" while he organized a letter campaign to the journal to advocate retraction of the paper [33].

The journal (*FTE*) published the criticisms and the authors' responses and ultimately withdrew the article, but not until after this journal appointed a former

employee of Monsanto to its editorial board. The *Journal of Environmental Science Europe* promptly republished the paper [34]. That former employee, a scientist named Richard Goodman, was then at the University of Nebraska and receiving funding from Monsanto and other chemical industry interests to maintain a food allergy database. Email communications obtained through Freedom of Information requests show that around the time Goodman was signing on to the *FCT* journal's editorial board and criticizing the Séralini study, he was also expressing concern to his chemical industry funders about protecting his income stream as a "soft-money professor." [35] In addition, documents reveal that the journal's editor-in-chief, A. Wallace Hayes, entered into a consulting agreement with Monsanto in 2012 for a fee of $400 an hour [36]. Neither Goodman nor Hayes disclosed their financial ties to Monsanto when the Séralini paper was retracted in 2013. In retracting the study, Wallace stated that he found "no evidence of fraud or intentional misrepresentation of the data" and that "the results were not incorrect." There was no misconduct [37]. The paper, he said, was retracted because its results were inconclusive. *Being inconclusive* is not a reason for retraction recognized by the international Committee on Publication Ethics [38].

Undue influence of a federal agency

The emails among discovery documents and Freedom of Information Act documents obtained from the EPA reveal that Monsanto worked very closely with at least three EPA officials to derail a review of glyphosate by the Agency for Toxic Substances and Disease Registry (ATSDR) that was underway in 2015 [39]. The ATSDR announced in February 2015 that it planned to publish a toxicological profile of glyphosate by October of that year. But by October, ATSDR had placed the review 'on hold,' and no such review has yet been published. The documents reveal this was the result of a collaborative effort between Monsanto and a group of high-ranking EPA officials. A series of emails detail how Monsanto sought assistance from EPA officials in persuading ATSDR to drop or delay the review, putting forth the argument that the ATSDR review was unnecessarily "duplicative." It should take a 'back seat' to the EPA review also underway at that time [39]. But internal documents show that Monsanto's concern was not that the review was a waste of government resources, but that it would find carcinogenicity concerns with glyphosate just as IARC had.

Documents show that Monsanto viewed ATSDR as "very conservative" [meaning too precautionary] and was too "IARC-like." [40] In a text message sent on June 21, 2015, Monsanto scientist Eric Sachs wrote to a former EPA toxicologist asking for contacts at ATSDR: "We're trying to do everything we can to keep from having a domestic IARC occur w this group may need your help." [41] Plaintiffs attorneys filed the text messages in the Federal Court docket and they became part of the court record. The full body of documents revealing the interactions of EPA officials and Monsanto executives is now publicly available [39].

The litigation discovery emails also reveal that Monsanto used its relationship with EPA regulators to influence the agency to abort convening a Scientific

Advisory Panel on glyphosate health risks. Federal regulatory agency personnel are permitted to interact with stakeholders, but they are not, by law, allowed to exhibit preferential treatment or play an advocacy role. The emails suggest that EPA did provide preferential treatment and advocacy for the Monsanto position.

Preparing presentations for "independent" scientists

The documents additionally reveal that Monsanto officials developed presentations for academic scientists to deliver at seminars or in other public fora. In one example from 2012, Monsanto scientist David Saltmiras told colleagues he was arranging for a European scientist to present in a seminar related to glyphosate and that he, Saltmiras, would "likely prepare his presentation and send to him to change/adapt as he sees fit." [42] Scientists who present their findings at scientific meetings are generally expected to disclose any conflicts of interest, as well as any collaborators. The documents show that in multiple instances involving multiple professors, Monsanto scientists prepared presentations for academic scientists. Nondisclosure of these relationships with Monsanto violates the accepted norms of acknowledging help from a commercial stakeholder, as well as failure to acknowledge collaborators.

Conclusion

When vital public health reports are published in refereed journals, there is a heightened expectation that they meet professional standards of scientific integrity. Those standards include full disclosure of conflicts of interest and sources of funding, plus authenticity of authorship. The Roundup litigation disclosure documents and FOIA documents show that these standards were egregiously violated, not by accident but by plan. Journals are the gatekeepers of reliable evidence and credible knowledge. They must set the highest standards of scientific integrity. Journal editors must never manifest a bias to some individual or organization. When a journal learns that an article has been ghost written or that there were undisclosed conflicts of interest, it has an obligation to act appropriately and inform readers. Our study has shown that two journals, *Critical Reviews of Toxicology* and *Food and Chemical Toxicology* did not measure up to these standards. An editor of a journal overseeing submitted papers on a health study of a product cannot be disinterested when he is under contract with the company that manufactures that product. Public regulatory bodies as the guardians of public health cannot allow their scientists to serve one special interest group and still achieve the public trust. The Roundup discovery documents signal serious flaws in the ethics of scientific publication and regulatory processes that must be addressed. The concerns raised in this paper have been discussed in a minority staff report of the congressional Committee on Science, Space & Technology [43].

References

1. Markowitz G, Rosner D. Deceit and denial: the deadly politics of industrial pollution. Oakland: University of California Press; 2002.
2. U.S. Department of Justice, Office of Public Affairs, GlaxoSmith Kline to plead guilty and pay $3 billion to resolve fraud allegations and failure to report safety data. July 2, 2012. https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report. Accessed 20 Oct 2017.
3. Plos Medicine Editors. Ghostwriting: the dirty little secret of medical publishing that just got bigger. PLoS Med. 2009;6(9):e1000156.
4. Castleman BL. Asbestos: medical and legal aspects. 5th ed. Frederick, MD: Aspen Publishers; 2004.
5. Delafontaine R. Historians as expert judicial witnesses in tobacco litigation. Studies in the history of law and justice. New York: Springer; 2015.
6. Oreskes N, Conway EM. Merchants of doubt: how a handful of scientists obscured the truth on issues from tobacco smoke to global warming. New York: Bloomsbury; 2010.
7. Rosner D, Markowitz G, Showkwanyun M. ToxicDocs (www.ToxicDocs.org): from history buried in stacks of paper to open, searchable archives online. J Public Health Pol. 2018;39:4–11.
8. Horel S. Browsing a corporation's mind. J Public Health Pol. 2018;39:12–4.
9. International Agency for Research on Cancer. IARC monographs, vol. 112. Evaluation of five organophosphate insecticides and herbicides. March 20, 2015 http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf. Accessed 12 Nov 2017.
10. U.S. Right to Know website of Monsanto litigation documents. https://usrtk.org/pesticides/mdl-monsanto-glyphosate-cancer-case-key-documents-analysis/. Accessed 17 May 2018.
11. Roundup Products Liability Litigation, U.S. District Court, Northern District of California, MDL No. 2741. Case No. 16-md-02741-VC. http://www.cand.uscourts.gov/VC/roundupmdl Accessed 20 Oct 2017.
12. www.usrtk.org is a publicly accessible Internet site.
13. Foucart S, Horel S. Monsanto papers: les agencies sous l'influence de la firm. La Monde April 10, 2017; May 10, 2017.
14. https://www.huffingtonpost.com/author/carey-gillam; http://careygillam.com/articles.
15. Gillam C. Ch. 6, Spinning the science. In: Whitewash. Washington DC: Island Press; 2017.
16. UCSF Industry Documents Library https://www.industrydocumentslibrary.ucsf.edu/.
17. Williams GM, Kroes R, Munro IC. Safety evaluation and risk assessment of the herbicide roundup and its active ingredient, glyphosate, for humans. Reg Tox Pharm. 2000;31:117–65.
18. Roundup Products Liability Litigation, U.S. District Court, Northern District of California, MDL No. 2741. Case No. 16-md-02741-VC Document 187-12 Filed 03/14/17 https://usrtk.org/wp-content/uploads/2017/03/187series.pdf p. 203. Accessed 12 Nov 2017.
19. Environmental Protection Agency, Glyphosate issue paper: evaluation of carcinogenic potential, September 12, 2016. https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf. Accessed 12 Nov 2017.
20. Roundup products liability litigation, document ID MONGLY01723742 https://usrtk.org/wp-content/uploads/2017/08/18-Monsanto-Scientist-Admits-to-Ghostwriting-Cancer-Review-Paper.pdf. Accessed 12 Nov 2017.
21. Williams GM, Aardema M, Acquavella J, Berry SC, Brusick D, Burns MM, de Camargo JLV, 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 Tox. 2016;46:3–20.
22. Email. Ashley Robert, Intertek to Roger McClellan, editor of Crit Rev Tox, July 5, 2016. http://baumhedlundlaw.com/pdf/monsanto-documents/0C-Challenged-Documents-Chart.pdf. Accessed 18 May 2018.
23. Email. William F. Heydens, Monsanto to Ashley Roberts, Intertek, January 13, 2016. http://baumhedlundlaw.com/pdf/monsanto-documents/3-Internal-Emails-Show-Monsanto-Made-Substantial-Contributions-to-Published-Expert-Panel-Manuscript.pdf. Accessed 13 Nov 2017.
24. Email. William F. Heydens, Monsanto to Ashley Roberts, Intertek, February 9, 2016. http://baumhedlundlaw.com/pdf/monsanto-documents/1-Monsanto-Executive-William-Heydens-Edits-and-Comments-on-Expert-Consultant-Manuscript.pdf. Accessed 13 Nov 2017.

25. Email. William F. Heydens, Monsanto to consultant Larry Kier, January 9, 2016. http://baumhedlundlaw.com/pdf/monsanto-documents/3-Internal-Emails-Show-Monsanto-Made-Substantial-Contributions-to-Published-Expert-Panel-Manuscript.pdf. Accessed 13 Nov 2017.
26. Consulting agreement between Larry D. Kier and Monsanto Company, Project Amendment Letter, August 17, 2015. https://usrtk.org/wp-content/uploads/2017/08/23-Email-Regarding-Monsanto-Paid-Consultant-and-Expert-Panel-of-Independent-Scientists.pdf. Accessed 13 Nov 2017.
27. Email. William F. Heydens, Monsanto to Ashley Roberts, Intertek, February 4, 2016. http://baumhedlundlaw.com/pdf/monsanto-documents/4-Internal-Email-Further-Demonstrating-Heydens-Involvement-Drafting-Expert-Panel-Manuscript.pdf. Accessed 13 Nov 2017.
28. Email. Email string between Monsanto employees September 26, 2012. http://baumhedlundlaw.com/pdf/monsanto-documents/7-Monsanto-Personnel-Discusses-Plan-Seeking-Retraction-of-Serlani-Glyphosate-Study.pdf. Accessed 13 Nov 2017.
29. Email. Email string between Eric Sachs, Monsanto and other Monsanto employees, September 28, 2012. http://baumhedlundlaw.com/pdf/monsanto-documents/14-Monsanto-Emails-Confirming-Undisclosed-Involvement-in-Successful-Retraction-of-Serlani-Study.pdf Accessed 13 Nov 2017.
30. Email. William Heydens, Monsanto to Eric S. Sachs, Monsanto. Sept. 26, 2012. http://baumhedlundlaw.com/pdf/monsanto-documents/7-Monsanto-Personnel-Discusses-Plan-Seeking-Retraction-of-Serlani-Glyphosate-Study.pdf. Accessed 13 Nov 2017.
31. Email. Bruce Chassy, University of Illinois, Monsanto Consultant to Wallace Hayes, September 26, 2012.
32. Lipton E. Food industry enlisted academics in G.M.O. lobbying war, Emails show, *New York Times* September 2, 2015. https://www.nytimes.com/2015/09/06/us/food-industry-enlisted-academics-in-gmo-lobbying-war-emails-show.html?_r=1.
33. Email. Monsanto Email chain. September 26, 2012; Business Goals of David Saltmiras, Monsanto, August 20, 2013. http://baumhedlundlaw.com/pdf/monsanto-documents/8-Monsanto-Scientist-Admits-to-Leveraging-Relationship-with-Food-and-Chemical-Toxicology-Journal.pdf Accessed 13 Nov 2017.
34. Séralini G, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, Spiroux de Vendômois J. Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Environ Sci Eur. 2014;26(14):1–17.
35. https://www.usrtk.org/wp-content/uploads/2016/07/GoodmanRG-000126-000001.pdf Accessed 13 Nov 2017.
36. http://baumhedlundlaw.com/pdf/monsanto-documents/10-Monsanto-Consulting-Agreement-with-Food-and-Chemical-Toxicology-Editor.pdf Accessed 13 Nov 2017.
37. WallaceHayes A. Retraction notice to "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize". Food ChemTox. 2014;63:244.
38. https://publicationethics.org/files/retraction%20guidelines.pdf Accessed 13 Nov 2017.
39. Gillam C. Collusion or coincidence? Records show EPA efforts to slow herbicide review came in coordination with Monsanto. Huffington Post. August 18, 2017. https://www.huffingtonpost.com/entry/collusion-or-coincidence-records-show-epa-efforts_us_5994dad4e4b056a2b0ef02f1. Accessed 13 Nov 2017.
40. Emails. Daniel Jenkins (Monsanto) to William Heydens (Monsanto), Jennifer Listello, (Monsanto). June 24, 2015. http://baumhedlundlaw.com/pdf/monsanto-documents/56-Email-Showing-Communications-Between-Monsanto-and-EPA-in-Furtherance-of-Avoiding-Roundup-and-Glyphosate-Testing.pdf Accessed 13 Nov 2017.
41. https://usrtk.org/wp-content/uploads/2017/08/Text-Messages.pdf. Accessed 13 Nov 2017.
42. Email. David Saltmiras, Monsanto to Monsanto colleagues, August. 13, 2012 http://baumhedlundlaw.com/pdf/monsanto-documents/11-Email-Confirming-Monsantos-Intention-to-Pay-Wallace-Hayes.pdf. Accessed 13 Nov 2017.
43. U.S. House of Representatives. Minority staff report prepared for members of the Committee on Science, Space & Technology. Spinning science & silencing scientists: a case study in how the chemical industry attempts to influence science. February 2018. https://www.baumhedlundlaw.com/pdf/monsanto-documents/Final-minority-report-glyphosate-spinning-science-silencing-scientists.pdf.

Sheldon Krimsky is Lenore Stern Professor of Humanities and Social Sciences in the Department of Urban & Environmental Policy & Planning in the School of Arts & Sciences and Adjunct Professor in Public Health and Community Medicine in the School of Medicine at the Tufts University. He received his B.S. and M.S. in physics from Brooklyn College, CUNY and Purdue University, respectively, and an M.A. and Ph.D. in philosophy at the Boston University. He is the author of 14 books including *Science in the Private Interest.*

Carey Gillam is a veteran journalist, researcher, and writer. She is former senior correspondent for Reuters' international news service, member of the Society of Environmental Journalists, and author of *Whitewash: The Story of a Weed Killer, Cancer and the Corruption of Science.* She is a Research Director for the U.S. Right to Know, a consumer group whose mission is "Pursuing Truth and Transparency in America's Food System."