Medical Ghost- and Guest-Writing as Corrupt Practices and How to Prevent Them

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Ordinary Ghostwriting as Wordsmithing

In the ordinary sense of the word, a ghostwriter is the often (but not always) anonymous ***wordsmith*** who helps another person, often a semi-literate celebrity, get his or her ideas or memoirs into print.

Sometimes an ordinary ghostwriter will receive credit, as a co-author, as an editorial assistant or in some other way. Sometimes not. A *ghost* may be invisible, transparent or merely *translucent*.

The ordinary ghostwriter's work is similar to that of a *scribe*, writing love-letters addressed to the love-interests of less literate customers.

Medical Ghostwriting defined

Medical ghost-writing and its parallel phenomenon, ***guest***-writing, involve the production – by persons directly or indirectly in the pay of the manufacturer of the product being studied – of publishable articles concerning medicines and other health care products. These articles are subsequently signed by and attributed to a "guest author" whose scientific or academic credentials enhance both the article's credibility and its chances of being published.

Meliorative, euphemistic language

A guest author is – as Mark Twain might say – like horse radish, i.e. neither horse nor radish, not really a "guest" and often the actual "author" of very little.

One is reminded of the French term, ***prête-nom***, designating someone who *lends* his or her name, a proxy.

In a well-known strategy used to circumvent legal limits on contributions to political parties, contractors seeking political favour transfer sums of cash to their employees with the understanding that the money is to be "donated" to the party or candidate in question, thereby disguising a much larger-than-legal donation. The employee in this situation is acting as a *prête-nom*.

Ordinary Ghostwriting vs. Medical Ghostwriting

1. ***Ordinary*** ghostwriters are typically remunerated by the named author. ***Medical*** ghostwriters are typically remunerated, directly or indirectly, by a pharmaceutical company – not by the named author.

2. In ***ordinary*** ghostwriting, the named author typically seeks out the ghostwriter. In ***medical*** ghostwriting, it is the other way around. The named author is identified and sought out as a ***key opinion leader*** by the study's sponsor, as part of the sponsor's ***publication plan***.

Ordinary Ghostwriting vs. Medical Ghostwriting

3. In ***medical*** ghostwriting, there are documented cases where the offer to have an academic sign on as the named author of a study was *withdrawn* after the academic who had been approached proposed modifications or additions *which the sponsor judged to be unacceptable*.

   In ***ordinary*** ghostwriting, on the other hand, it is hard to imagine that a ghostwriter might withdraw the manuscript of a ghostwritten autobiography and offer it to someone else!

Ordinary Ghostwriting vs. Medical Ghostwriting

4. In the testimony of at least one former professional medical ghostwriter, it is claimed that actual, personal exchanges between the writer and the named author were strongly discouraged by the medical communi-cations firm which employed the writer. This sort of interaction, or non-interaction, with the client would seem to be ill-adapted to the work of an ordinary ghostwriter.

Ordinary Ghostwriting vs. Medical Ghostwriting

5. The process of ***ordinary*** ghostwriting basically involves ***two*** persons: namely the named author and the wordsmith. In the process of ***medical*** ghostwriting, on the other hand, there are typically interactions between at least ***three*** actors, namely the named author, the professional writer and the medical communications agency hired by the sponsor. (The actual sponsor of the study may also actively intervene as a fourth actor in the process.)

Ordinary Ghostwriting vs. Medical Ghostwriting

6. In ***ordinary*** ghostwriting, the named author of a ghostwritten (auto- or authorized) biography may wish that certain embarrassing events in his or her life not be emphasized. In ***medical*** ghostwriting, on the other hand, it is the good reputation of the ***sponsor's product*** which is the dominant consideration (not the good name of the guest author).

   This is eloquently documented by Adrian J. Fugh-Berman (2010) and by Kate Mittleman's testimony (2006) in the context of the Prempro Products Liability Litigation over HRT.

Fugh-Berman (2010) writes:

- ★ "Dozens of ghostwritten reviews and commentaries published in medical journals and supplements were used to promote unproven benefits and downplay harms of menopausal hormone therapy (HT), and to cast raloxifene and other competing therapies in a negative light."
- ★ "Specifically, the pharmaceutical company Wyeth used ghostwritten articles to mitigate the perceived risks of breast cancer associated with HT, to defend the unsupported cardiovascular 'benefits' of HT, and to promote off-label, unproven uses of HT such as the prevention of dementia, Parkinson's disease, vision problems, and wrinkles."

[The following slide is excerpted from the deposition of Karen D. Mittleman (2006) in the Prempro Products Liability Litigation, available via the Drug Industry Documents Archive (DIDA) created by the University of California San Francisco Library. See the references provided on the last two slides.]

* * *

BY MR. SZALLER:

Q. In the first paragraph of the document that you are now looking at, it indicates that there was a twenty-five-thousand-dollar charge for the development of the paper by Dr. Warren, and it also indicates that there was a similar charge for the paper by Dr. Bachmann.

Does the document so reflect that?

A. Yes, it does.

Q. By the way, when you were working on that document, Dr. Marren --

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or Mittleman, you were not working on behalf of the Council on Hormone Education. You were working simply as a DesignWrite employee on behalf of Wyeth; correct?

A. I'm not quite sure I understand the question. You're just asking me if I was employed at the time of DesignWrite --

Q. It was not a clear question.

The deposition of Dr. Warren's been taken. You're aware of that.

A. Yes.

Q. Okay.

And she said that -- that you worked on it in your position as a representative of the Council on Hormone Education. I'm asking you whether that's accurate. I don't think it is accurate. I want to make the record clear.

A. It is not accurate.

Q. All right. Thank you.

You were working on it in

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behalf of -- an employee of DesignWrite on behalf of Wyeth.

A. We were -- the funding for the paper was paid for by Wyeth, yes.

MR. SZALLER: Okay. Thank

[The following two slides are excerpted from the website of the medical communications firm DesignWrite® mentioned in Mittleman (2006) as the employer of Karen D. Mittleman. See DesignWrite (2016) in the references provided on the last two slides.]

DesignWrite®

YOUR SUCCESS IS IN OUR CAPABILITIES

Our Team

DesignWrite's employees come from varied professional backgrounds, bringing with them a wealth of experience, applied knowledge, and creativity. They work together in a team-based environment to produce educational and promotional programs and materials without parallel. They represent the core of what DesignWrite has to offer.

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Advocacy Development:

Identifying and partnering with key thought leaders to provide cutting-edge medical information

Through its many years of working with opinion leaders, DesignWrite quickly identifies and engages key thought leaders, who work with our clients to provide cutting-edge medical information. more...

Oncology Thought Leader Identification

Our client recently launched a product into the oncology supportive care market. Feedback from the sales force indicated that the product was eliciting interest from a wider group of health care providers involved in cancer patient care than expected. DesignWrite was tasked with identifying potential thought leaders in radiation-induced and chemotherapy-induced oral mucositis. Additionally, we were asked to find supplementary thought leaders who specialized in xerostomia, a distinct but related chronic condition.

We initially identified five relevant specialty groups:

- Radiation Oncologists
- Medical Oncologists
- Hematology Oncologists
- Oncology Nurses
- Oral Surgeons

Ghostwritten vs. Non-Ghostwritten Studies

THE QUESTION OF DATA OWNERSHIP

An important difference between many ghostwritten and non-ghostwritten studies in the medical literature concerns proprietorship of the raw data. In the ideal case – in what should be the ***normal*** case – the named author of a study not only designed and supervised it but, in addition, maintains access to the raw data which were collected, along with the authority to grant access to other researchers. *In ghostwritten studies, however, this is typically not the case*. The so-called guest author may never even have seen the raw data.

In an ideal (uncorrupted) world ...

"Readers of legitimate science expect that stated authors are truly the authors [of the studies they sign], that they vouch for the work, and that they would be able to defend their findings if challenged. They expect that authors have seen and scrutinized raw data, and would be able to provide that data if asked. That it is necessary to write this indicates how much we have lost." (Blumsohn 2006)

Corruption exemplified (1)

- A police officer accepts a sum of money in exchange for the cancellation of a speeding ticket. (The beneficiary is later involved in an accident involving multiple fatalities.)
- The employees of a contractor build a swimming pool at the house of the Minister of Public Works. No invoice for this work is forthcoming. (The contractor in question subsequently obtains a government contract.)

Corruption exemplified (2)

- An inspecting engineer avoids annoyance and expense for persons important to his future career by "closing his eyes" to the fact that the workers building a highway overpass are not respecting the design and have already installed some of the metal reinforcements incorrectly. (Thirty-six years later, the overpass collapses, crushing vehicles underneath and killing their occupants.)

Corruption exemplified (3)

- An academic researcher "signs off" as the stated principal author of a research study on the safety and efficacy of, say, a pain-killer, without insisting on having the opportunity to notice that early "drop-outs" from the experimental group in the clinical trial have been surreptitiously placed in the control group and their "undesirable events" counted as having occurred among subjects with no exposure to the new pain-killer. (A number of years later, the pain-killer is withdrawn from the market because of an unacceptable frequency of "undesirable events".)

Corruption (breezily) defined

The abuse of power by a public official in order to obtain a personal advantage.

The provision or offer of a personal advantage to a public official in exchange for some kind of inappropriate favour (abuse of power).

Corruption somewhat less breezily defined

Corruption involves non-performance or mis-performance of a ***special duty*** incumbent on an agent in the hope of some kind of inappropriate or illicit advantage, where by 'special duty' is meant a duty incumbent on the agent by virtue of the agent's status, role or position.

An attempt (successful or otherwise) to obtain the non-performance or mis-performance of a special duty by the offer of an inappropriate or illicit advantage to the agent on whom the performance of that duty is incumbent also counts as corruption.

The position of the ghostwriter

There seems to be no inherent moral infraction involved, *as such*, in making one's living as a professional medical writer, except to the extent that in particular cases one may find oneself complicit in deliberate attempts to corrupt a recognized researcher as part of a campaign to mislead health professionals and other members of the public in ways deleterious to their health and well-being.

The corruption associated with guest-*authoring*

1. To the extent that a guest author does not provide due recognition of the contribution of others to the actual writing, design and conduct of the study, he/she is certainly guilty of ***plagiarism***. This is a serious ethical problem, but not necessarily (yet) a case of corruption. The term 'misattribution' has been suggested (Matheson 2016).
2. The plagiarism / misattribution issue distracts us from yet more important ethical problems (cf. Matheson 2016), associated with the ***corruption*** of scientists and medical researchers.

The corruption associated with guest-authoring

3. ***One*** of the duties of the scientific researcher is to avoid plagiarism. But the attractive addition to one's c.v. provided by the ghost publication constitutes the illicit inducement to mis-perform a pressing ***special duty*** which is incumbent upon all those who invoke the name of science, namely that of *exercising due diligence in the pursuit of objectivity and truth, in addition to the special duty of having concern for the health and well-being of people* that is incumbent upon those who associate their research with the practice of ***medicine***.

The corruption of the sponsor

If a researcher becomes corrupt by agreeing to sign an article which he or she has not written, describing a study which he or she has neither designed nor supervised and over the raw data of which he or she has no control, the *sponsor* who provides illicit motivation for the guest author to become corrupt in this way is, by that very fact, also corrupt. The very situation of promoting research into one's own products generates a conflict of interest, which is compounded by attempts to obscure the source of the research.

Solutions

1. **Anti-plagiarism**. The adoption of codes of ethics for authors and for the editorial teams of medical and scientific journals, requiring that the stated main author provide a declaration concerning the role of all contributors to the design of the research and the writing of the text.

   This measure has the potential of reducing the misattribution associated with medical ghostwriting – but does not address the main harms associated with the practice and provides little in the way of deterrents. Ghostwritten studies still appear, even when they must be identified as such.

Solutions

2. **Financial Transparency**. The same codes of ethics can (and do) require transparency concerning the actual funding of research projects – as well as the competing interests and financial involvement of the researchers with the manufacturers of the drugs which are studied.

   This measure has improved the situation somewhat. But once again, it provides little deterrence in the way of sanctions applied and does little to remedy the harms already produced.

Solutions

3. **Insistence on data ownership**. The codes of ethics for editors and publishers should require, in addition to anti-plagiarism and financial transparency statements, that the first listed author of a study must be able to prove that he/she has ownership of the raw data. This would be a major improvement.

Solutions

4. ***Radical*** **insistence on data accessibility**. Data ownership is one of the Intellectual Property Rights (IPCs) which member countries of the World Trade Organization are required to protect under the 1994 TRIPs Agreement, along with patents and copyrights, etc. The laws concerning intellectual property and trade secrets – and the relevant sections of the TRIPs Agreement – should be modified to make it ***illegal to refuse access*** to the raw data associated with published research on any prescription medication which is currently under patent or which was ever at any time under patent.

Solutions

5. **Significant disciplinary measures** should be applied against academics who make fraudulent declarations under requirements (1), (2) and (3), above. These measures could and should – but currently hardly ever do – include dismissal. Journal editors should adopt means of identifying authors with a record of fraudulent declarations of compliance with (1), (2) and (3) and should demand exceptional guarantees of compliance from such authors when and if they submit new manuscripts for publication. (A lifetime publication ban would perhaps be going too far, for various reasons.)

Solutions

6. **Imposing Fraud Liability on Guest Authors of Ghostwritten Articles**. This suggestion is taken from the subtitle of Stern & Lemmens (2011). Currently, most civil action suits launched by persons claiming to have been harmed by a prescription drug target the manufacturer.

   By agreeing to be considered as the principal author of a study, an academic or other researcher is implicitly claiming to be in a position to vouch for the quality of the design of the study and for its execution. If this is not the case, it is reasonable to allege fraud resulting in harm if the drug turns out to be harmful in a way which should have been detectable in a properly conducted trial.

Solutions

7. **Well-funded programs should be launched for actively searching out and identifying ghost-corrupted studies in the archival literature**. This could also include the identification of past publications which are not in conformity with *the data ownership rule* in (3).

   Articles could be "rated" in a way similar to the way that films and television programs are rated as suitable or not for viewing by children and the faint of heart. Two ratings could be provided: 1) the degree of ghostliness and 2) the degree to which the data are accessible for verification and re-analysis by subsequent researchers.

Solutions

8. **Eliminating commercially funded research on health-related products altogether**. Such research should be done in the public interest and not funded out of revenue from sales.

   This solution runs counter to the idea which has become fashionable over the past two or three decades according to which it is supposed to be a good thing that the private sector should help to finance research.

   An analogy: It should not be up to a private supplier of asphalt to advise us *whether* we need a new highway, *where* it should be built and out of *what materials*. The job of an asphalt manufacturer is to supply the asphalt in a cost-efficient manner, once the other decisions have been made in the public interest.

Solutions

9. **Supporting the creation and maintenance of data bases** like the Drug Industry Documents Archive (DIDA) created by the University of California San Francisco Library:
   www.industrydocumentslibrary.ucsf.edu/drug/docs.

Solutions

10. **Basing government decisions concerning which prescription drugs will be authorized for sale and, more particularly, which ones will be authorized for reimbursement by public health insurance plans on their proven "health impact".**

11. **Eliminating patent-protection on prescription-only medicines and other health-related products**. This would remove a lot of the motivation for fraud and simultaneously solve certain other problems concerning pricing and equity of access.

Solutions

12. **Publicizing and using independently funded sources of evidence-based information and research on drugs and health-related products.** These include the following:

- the Cochrane Group (www.cochrane.org)
- la revue *Prescrire* (www.prescrire.org)
- Worst Pills, Best Pills (worstpills.org)
- PharmedOut (pharmedout.org)
- Elena Pasca's *Pharmacritique* (pharmacritique.20minutes-blogs.fr)
- Red de Medicamentos (medicamentos.alames.org)

Thank you for your attention !

References

Anekwe, Tobenna D. (2010). Profits and plagiarism: the case of medical ghostwriting. *Bioethics*. Volume 24 No. 6, pp. 267–272. Available doi:10.1111/j.1467-8519.2008.00705.x. Accessed 15 November 2016 via proxy.usainteanne.ca.

Angell, Maria (2004). *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*. New York & Toronto: Random House, 2004.

Borch-Jacobsen, Mikkel, *et al.* (2014). *La Vérité sur les médicaments: Comment l'industrie pharmaceutique joue avec notre santé*. Paris: Édito. First edition Paris: Éditions des Arènes, 2013.

Blumsohn, Aubrey (2006). Authorship, Ghost-Science, Access to Data and Control of the Pharmaceutical Scientific Literature: Who Stands Behind the Word? *Professional Ethics Report*. Volume XIX, No. 3, Summer, Washington: American Association for the Advancement of Science. Pdf. Available: www.aaas.org/sites/default/files/migrate/uploads/per46.pdf. Accessed 14 November 2016.

Brian, Danielle & Thacker, Paul (2010). POGO Letter to NIH on Ghostwriting Academics. Washington: Project on Government Oversight. Html. Available www.pogo.org/our-work/letters/2010/ph-iis-20101129.html. Accessed 12 November 2016.

COPE Committee on Publication Ethics (2011). *Code of Conduct and Best Practice Guidelines for Journal Editors*. Available http://publicationethics.org/files/Code_of_conduct_for_journal_editors_Mar11.pdf. Accessed 2 December 2016.

DesignWrite (2016). Case Studies. Tab of Corporate Website. Princeton NJ. Html. Available www.dwrite.com/CaseStudies.aspx. Html. Accessed 13 November 2016.

Elliott, Carl & Snow Landa, Amy (2010). What's Wrong with Ghostwriting? *Bioethics*, volume 24, no. 10, pp. 284-286. Available http://onlinelibrary.wiley.com/doi/10.1111/j.1467-8519.2010.01828.x/pdf Accessed 15 November 2016.

Fugh-Berman, Adriane J. (2010). The haunting of medical journals: how ghostwriting sold ‘"HRT". *PLoS Medicine*. September 2010, Volume 7, Issue 9, e1000335 (11 pages, including tables and references). Available doi:10.1371/journal.pmed.1000335. Accessed 12 November 2016.

Gagnon, Marc André & Sismondo, Sergio (2012). Des auteurs-fantômes discréditent la recherche médicale. Opinion piece. *Le Soleil*, daily newspaper, electronic edition of 2 October 2012. Available www.lapresse.ca/le-soleil/opinions/points-de-vue/201210/01/01-4579239-des-auteurs-fantomes-discreditent-la-recherche-medicale.php. Accessed 15 October 2013.

Goldacre, Ben (2012). *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*. Toronto: McClelland & Stewart.

Gøtzsche, Peter C., Hróbjartsson, Asbjørn *et al*. (2007) Ghost Authorship in Industry-Initiated Randomised Trials. *PLoS Medicine*. January 16. Available http://dx.doi.org/10.1371/journal.pmed.0040019. Accessed 15 November 2016.

Gøtzsche, Peter C. (2013). *Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Healthcare*. London: Radcliffe Publishing. The Kindle edition was used. Digital conversion by Vivianne Douglas. References by "locations" – page numbers not given.

Grassley, Senator Charles E. (2010). *Ghostwriting in Medical Literature*. Minority Staff Report, 111th Congress, United States Senate Committee on Finance. 17 pages plus attachments. Available in pdf format www.grassley.senate.gov/sites/default/files/about/upload/Senator-Grassley-Report.pdf Accessed 12 November 2016.

Healy, David (2012). *Pharmageddon*. University of California Press.

ICMJE International Committee of Medical Journal Editors (2015). *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*. Also known as the *ICMJE Recommendations*. Previously known as the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM)*. The URM was first published in 1978. Pdf document of 17 pages. Available http://www.icmje.org/icmje-recommendations.pdf. Acc

Kleinert, Sabine & Wager, Elizabeth (2011a). *Responsible research publication: international standards for editors*. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22 -24, 2010. Chapter 51 in: Mayer, T. & Steneck, N. (eds). *Promoting Research Integrity in a Global Environment*. Imperial College Press / World Scientific Publishing, Singapore, pp. 317- 28. Available http://publicationethics.org/files/International%20standard_editors_for%20website_11_Nov_2011%20%281%29.pdf. Accessed 15 November 2016.

Kleinert, Sabine & Wager, Elizabeth (2011b). *Responsible research publication: international standards for authors*. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Chapter 50 in: Mayer, T. & Steneck, N. (eds). *Promoting Research Integrity in a Global Environment*. Imperial College Press / World Scientific Publishing, Singapore, pp. 309-16. Available http://publicationethics.org/files/International%20standards_authors_for%20website_11_Nov_2011_0.pdf. Accessed 15 November 2016.

Logdberg, Linda. Being the Ghost in the Machine: A Medical Ghostwriter's Personal View. *PLoS Medicine*, Vol. 8, Issue 8, August 2011. Available www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001071. Accessed 29 March 2012.

Matheson, Alastair (2016). Ghostwriting: the importance of definition and its place in contemporary drug marketing. *British Medical Journal* (30 August). Available http://www.bmj.com/content/354/bmj.i4578. Accessed 12 November 2016.

Mittleman, Karen D. (2006). Deposition (sworn testimony) on May 03, as transcribed from a video recording by Kimberly A. Cahill, approved reporter of the United States District Court. In Re: Prempro Products Liability Litigation, Mdl Docket No. 4:03CVL507 WRW. Available via the Drug Industry Documents Archive (DIDA) created by the University of California San Francisco Library: https://www.industrydocumentslibrary.ucsf.edu/drug/docs/qxww0217. Accessed 11 November 2016.

Moynihan, Ray (2008). Key opinion leaders: independent experts or drug representatives in disguise? *British Medical Journal* (19 June 2008). BMJ 2008;336:1402 Available http://www.bmj.com/content/336/7658/1402. Accessed 12 November 2016

Sample, Ian. Scientists credited on ghostwritten articles 'should be charged with fraud' : Legal experts call for severe sanctions against scientists who 'guest author' papers written by drugs companies. *The Observer*. Edition of 2 August 2011. Available www.guardian.co.uk/science/2011/aug/02/scientists-ghostwritten-articles-fraud. Accessed 29 March 2012.

Sismondo, Sergio (2007). Ghost Management: How Much of the Medical Literature is Shaped Behind the Scenes by the Pharmaceutical Industry? *PLoS Medicine* 2007; 4(9): e286. Available http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040286. Accessed 2 December 2016.

Sismondo, Sergio & Doucet, Mathieu (2010). Publication Ethics and the Ghost Management of Medical Publication. *Bioethics*, volume 24, no. 6, pp. 273-283. Available http://onlinelibrary.wiley.com/doi/10.1111/j.1467-8519.2008.01702.x/pdf Accessed 15 November 2016.

Stern, Simon & Lemmens, Trudo (2011). Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles. *PLoS Medicine*. Published: August 2. Available http://dx.doi.org/10.1371/journal.pmed.1001070. Accessed 12 November 2016.

Vailloud, Jean-Marie (2008). Le “ghostwriting” ou l’écriture en sous-main des articles médicaux: Quand l’auteur d’un article de recherche n’est pas celui qu’on croit. Essay published 15 July 2008 on the website of the NGO Formindep (founded in 2004). Available www.formindep.org/Le-ghostwriting-ou-l-ecriture-en.html. Accessed 19 November 2016.