



Journal watch:

Ghostwriting

by Adam Jacobs

Regular readers of *Journal Watch* will know that it's usually written by one of my highly trained team of medical writers, not by me. But since I'm such a generous boss, I'm giving my team the day off and writing this one myself. Well, actually, the articles I'm going to describe in this article have piqued my interest to such an extent that I can't resist writing it myself.

So what are these fascinating articles? The first is an article in *JAMA* published in April by Ross et al, which described an analysis of Merck's authorship practices, based on documents obtained during litigation against Merck [1]. I'm also going to discuss a couple of editorials that appeared in response to it: one in the same issue of *JAMA*, written by *JAMA* editors [2], and the other in *Nature Biotechnology* [3].

The stated objective of Ross et al's article was to 'describe the practice of guest authorship and ghostwriting related to rofecoxib'. A good place to start would be to define 'guest authorship' and 'ghostwriting'. As most EMWA members will know, a guest author is someone who is listed as an author on the paper but has not made sufficiently substantial contributions to the paper to deserve authorship status, and a ghostwriter is someone (usually a paid medical writer) who has written the paper and not been acknowledged for their work, either as an author (often inappropriate anyway for medical writers) or even through a mention in the acknowledgements section (which is always appropriate).

Ross et al do indeed start there, and their definition of guest authorship is sensible enough: 'the designation of an individual who does not meet authorship criteria as an author'. OK, that's not completely precise, as there is no universally agreed definition of authorship criteria (although the ICMJE criteria are widely accepted as the best definition we have), but that's the way the world is and there's not much that Ross et al can do about it. However, their definition of ghostwriting is more problematic: 'failure to designate an individual (as an author) who has made a substantial contribution to the research or writing of a manuscript'. The problem there is that professional medical writers frequently don't merit designation as an author, but rather a mention in an acknowledgements section. Ross et al's failure to appreciate that important point leads to many problems with the interpretation of their results.

Another limitation of their paper is that they don't actually present any numerical results relating to guest authorship

and ghostwriting. We are told that the practices were 'frequent', but nowhere are we shown actual numbers or percentages. Much of the paper is given to examples of supposed guests and ghosts in individual papers, but we have no information on how representative those papers are. And some of the examples aren't very convincing. An external author appears to be assumed to be a guest if there is evidence that a Merck employee drafted the manuscript. That's applying an unusually broad definition of guest authorship. Only one person can draft a manuscript, so by that definition, every paper that's ever published with more than one author would have guest authors. Provided someone makes important intellectual contributions, there is no reason why that person can't qualify for authorship even without drafting the paper.

What constitutes an 'important intellectual contribution'? It's hard to say. There is no universally agreed definition. Ross et al maintain that if an author makes only 'minor edits' to a draft, that doesn't count. I'm not convinced. A medical writer who is not qualified to write about the subject, but is nonetheless good at her job, may write an excellent first draft that needs very little editing. No-one would want the author to make sweeping changes just for the sake of it, if in fact the draft is already pretty good. But it is nonetheless important for an expert to validate the work of the medical writer, even if few changes need to be made to a draft, and I would argue that that constitutes an important intellectual contribution. It is, of course, possible that the supposed guest authors had already made some contribution before the first draft was produced, as indeed is recommended in the EMWA guidelines [4].

As an aside, we can get some idea of what the authors of the paper consider to be important intellectual contributions from looking at their own output. One of the authors of the paper, Harlan Krumholz, was a named author on 70 papers indexed in Medline that were published in 2006 alone. That's more than one a week. On the assumption that Dr Krumholz has other things to do besides writing papers, I think we can assume that his 'important intellectual contributions' don't take very long.

Examples of ghostwriting are equally woolly. We are given evidence that a medical communications company was involved in writing some of the papers, and this is presented as automatic evidence of ghostwriting. According to the definition of ghostwriting accepted by EMWA and other bodies such as the World Association of Medical Editors

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(WAME), it would only be ghostwriting if the medical writers were absent from the acknowledgements section, but we are not told anything about whether the medical writers are acknowledged or not. One of my greatest annoyances with Ross et al's paper is that it presents professional medical writers as automatically a bad thing, and completely fails to recognise that, when properly acknowledged, they have a perfectly legitimate role.

The conclusions of the paper don't follow from the data. We are told that 'Merck used a systematic strategy to facilitate the publication of guest authored and ghost written literature'. That's quite a leap of faith from seeing that some papers might have had guest authors and ghostwriters to saying that there is a 'systematic strategy', for which no evidence whatsoever is presented. One might be tempted to speculate that if Ross et al had had the benefit of a professional medical writer to help with their paper, such logical fallacies could have been avoided. One sensible conclusion they do draw, however, is that medical writing assistance should be fully disclosed, although disappointingly, they present this as if it were their novel idea. This was, of course, an important part of the EMWA guidelines, published in 2005 [4], and also mentioned in the GPP guidelines in 2003 [5], and I'm pretty sure that the GPP authors weren't the first to think of it.

Perhaps none of this should be too surprising, coming from a group of authors involved in litigation against Merck (who, to their credit, are at least completely honest about that involvement). What is frustrating is that the tone of the article by Ross et al is mirrored by the accompanying editorial by DeAngelis and Fontanarosa [2]. There is again a presumption against Merck, with statements such as how Merck 'manipulated' publications, despite a complete lack of evidence that a single article was 'manipulated' in the sense of inappropriate influence of the content. The editorial also reiterates *JAMA's* previously published and utterly bizarre policy that all industry-sponsored studies submitted to *JAMA* for publication must have been independently analysed by an academic statistician. It's not clear whether the academic statisticians are supposed to do this out of the goodness of their heart, or if they are not, how they are to maintain their independence while being paid by the pharma company. But more importantly, there is a worrying assumption by *JAMA* here that analyses by industry statisticians are somehow less trustworthy than those by academic statisticians. Anyone who appreciates the highly regulated environment in which industry statisticians have to work will find that assumption as astonishing as I do.

The editorial in *Nature Biotechnology* [3] takes a much more balanced approach. It makes some of the same points I have made above. It also points out that the data in Ross et al's paper come from documents collected a good few years in the past (the cut-off date for the documents examined was 2004), and a lot has changed since then. At the

time of the earliest documents (1996), no-one thought much about ghostwriting. Things have changed greatly in the present decade, with the publication of GPP guidelines in 2003 [5] and the EMWA guidelines in 2005 [4], and a whole host of other commentaries as well. Perhaps if some of Merck's papers were ghostwritten, it is more to do with the fact that no-one had appreciated the need for transparency then, rather than any 'systematic strategy'.

The *Nature Biotechnology* article also highlights the important roles that journals have to play in ensuring all contributions to papers are properly acknowledged and transparent. The *JAMA* editorial makes much of how dreadful it is that medical writers' contributions go unacknowledged, but very few journals ask specific questions about the role of medical writers, and those who do so have only started to do so recently. I am currently involved in an international team of medical writers who have been preparing a checklist designed to help journal editors assess whether a medical writer has been involved in a paper, and, if so, whether that involvement was ethical and appropriate, and thus to ensure proper acknowledgements are given in the paper. We intend to publish this checklist soon (watch this space!), and hope that journal editors will take it up to help make ghostwriting become increasingly rare as medical writers are properly acknowledged for their role.

Now, given some of the flaws in their paper, it is tempting to dismiss the article by Ross et al as simply anti-industry rantings and thus something that we can happily ignore. In my opinion, this would be a mistake. Although it is certainly true that there is much unfounded industry-bashing in the article, there are also some genuine and important criticisms hidden among it. For example, there is at least one example of a paper that was apparently written in complete first draft form before the named author was identified. If true, that is something I certainly would not condone, and is a clear breach of the EMWA guidelines. If Merck did write papers in this way in the past, I very much hope they no longer do. And whether or not ghostwriting is as common as Ross et al would have us believe, there is no doubt that it still exists, so there is no room for us to be complacent.

So, despite the temptation to go on the defensive when faced with an article like the one by Ross et al, we should resist that temptation, and redouble our efforts to make sure that the manuscripts we produce are absolutely in accordance with best practice. This means not only that the role of the medical writer must be transparent, but that the named authors must play a genuine part in the development of the manuscript. Recently, and particularly while writing this article, I have been thinking about the way we prepare manuscripts at Dianthus Medical. While I am confident that we ensure named authors play their full part in developing manuscripts, I have nagging doubts about whether we could prove it if any of our clients were to find themselves in a similar position to Merck, with all their documents opened to public scrutiny. Our regulatory writing is

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thoroughly documented at every step of the way, to ensure compliance with Good Clinical Practice (GCP), but our documentation is less thorough in the unregulated process of manuscript development. One of my next tasks will be to review our SOPs to ensure that author involvement is always thoroughly documented. If you are involved in writing manuscripts, could I suggest that this could be a good time to look at your SOPs with a similar eye?

As a final thought, at the recent EMWA conference in Barcelona, I led a lunchtime discussion session devoted to the articles I have described here. I went into it expecting lively discussion, but it was rather sedate. With hindsight, I should have realised that lively discussion was not to be expected: there is nothing controversial in the ghostwriting and guest authorship debate. Almost everyone agrees that guest authors and ghostwriters are a bad thing. The challenge for all of us is to ensure that the unethical practices that still persist be rapidly consigned to the dustbin of history.

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2. DeAngelis CD, Fontanarosa PB. Impugning the integrity of medical science: the adverse effects of industry influence. *JAMA* 2008;299:1833–1835
3. Anonymous. Nothing to see here. *Nature Biotechnology* 2008;26:476
4. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21:317–321
5. Wager E, Field EA, Grossman L. Good Publication Practice for Pharmaceutical Companies. *Curr Med Res Opin* 2003;19:149–154

Can things do anything but develop over time?

The passage of time from one state to a later state is inherent to the meaning of *develop*, so adding the adverbial phrase *over time* in this sentence adds nothing to the meaning of *develop*: *CRPV-induced papillomas in rabbits become strongly keratinised and develop a crusty appearance over time, which may have compromised drug delivery to the affected skin layers*. The author here actually wanted to bring in the idea of *slowly*, and my empirical observation is that this is usually the intent when *over time* is thoughtlessly tagged on to the verb *develop*. If this is what you want to say, you should say it, and better still: quantify it in some way if you can. In this case it was possible: *... and develop a crusty appearance after about 10 days of treatment*.

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Ghost management: Beyond ghostwriting

“Ghost management of medical research and publishing: when pharmaceutical companies and their agents control or shape multiple steps in the research, analysis, writing, and publication of articles.”

This definition was coined by an essay in *PloS Medicine*¹ which considers the extent to which the entire medical literature and research behind it is managed by the pharmaceutical industry for marketing purposes. The writing of the manuscript may not be the key point at which behind-the-scenes influence is exerted; study design, statistical analysis, or the choice of placement of manuscripts may be equally important. Compounding this some publication planning firms that service the industry are part of businesses run by publishers, e.g. Excerpta Medica which advertises that its “relationship with Elsevier allows... access to editors and editorial boards who provide professional advice and deep opinion leader networks.” This is not uninteresting in view of the Committee of Publication Ethics’ (COPE)—an editors’ organisation that promotes publication ethics in peer-reviewed journals—recent announcement that it has entered into a partnership with Elsevier.²

The article points out that twice as much funding is provided by industry for clinical trials and related research than by not-for-profit organisations. 70% of industry funding is allocated to CROs and 30% to academic researchers. The CRO research is by its nature ghostly because CROs do not own or take public responsibility for the data and conditions relating to academic research funding such as absence of full access to data allow for ghost management.

The conclusion reached is that as articles in medical journals have real effects on physician prescribing behaviour ghost management exerts a huge force on the shape of scientific opinion on new drugs and does so in the service of marketing.

1 Sismondo S. Ghost Management: How much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry? *PLoS Med* 2007;4(9): e286. Available at <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040286>

2 See <http://www.publicationethics.org.uk>.

How to save three words

It is never necessary to say *over a period of*.

Drug X was investigated in two groups of three female animals (0.1 mL or 1.0 mL 3 times daily) over a period of 9 days.

Just say *for 9 days* and you save your reader three unnecessary words—**every time!**

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