

# If a misinformed voice speaks out in the wilderness and no one refutes it, does it make a sound? A call to advocacy

Art Gertel

TFS, Inc., Flemington, New Jersey, USA

## Correspondence to:

Art Gertel  
VP, Regulatory and  
Medical Affairs, TFS Inc.  
Flemington  
NJ 08833, USA  
art.gertel@tfsco.com

## Abstract

The pharmaceutical industry has been a soft target for many years. Attacks by journalists, politicians, and the lay public tend to be triggered by publications with which professional medical writers are associated. Fault is found, either in the content, perceived obfuscation of content, or on perceived deceptive authorship practices. The term 'ghostwriter' is used with great frequency and is often misapplied, or ill-defined (if it *is* defined, at all). For the most part, these criticisms have gone unanswered. We must understand that we represent the potential for the strongest and most influential voice in refuting misinformation and misunderstanding about our role. We must educate our critics about the value that we bring to communications about new therapies. We are our own best advocates in ensuring that critics of our profession are brought out of the wilderness.

**Keywords:** Authorship, Pharmaceutical industry, Medical writer, Medical writing, Ghostwriting, Advocacy

As professional medical writers, we often play a role in developing the materials that are submitted to regulatory authorities, as well as medical journals, industry white papers, and those used in promotion and advertising.

Public perception of the industry and those who work within it can have a profound effect on how the development of new therapeutics is viewed, both by the lay public and by healthcare providers. This, in turn, can significantly suppress participation in clinical studies, raise concerns about the safety of new medicines, and divert attention from, perhaps, more egregious offenses.

These perceptions are shaped by increasingly virulent attacks in the media on Pharma and, by

extension (either implicitly or explicitly) medical writers. It was bad enough back in 2002 when the infamous *TIME* cover story represented clinical trial participants as Guinea Pigs, but there seems to be a new wave. Marcia Angell's book: *The Truth About the Drug Companies*,<sup>1</sup> and other publications and editorials, articles, blogs, and Letters-to-the-Editor – many appearing in prestigious peer-reviewed medical and scientific journals – certainly seem to have fanned the flames. The latest salvo comes from Ben Goldacre in his diatribe: *Bad Pharma*.<sup>2</sup> While Goldacre makes some valid points on his review of Pharma practices, he goes out of his way to impugn not only the pharmaceutical industry, but medical writers, specifically. He, as do many other critics, conflates professional medical writers with Ghostwriters, failing to distinguish those who provide value in terms of clarity, accuracy, and comprehensibility – with full disclosure, from those who are less transparent regarding their contributions. He drags out the outdated example of the nefarious Ghostwriter and Ghost Publication Manager, creeping behind the curtain. He states, 'In reality, academic articles are often covertly written by a commercial writer employed by a pharmaceutical company, with an academic's name placed at the top to give it the imprimatur of independence and scientific rigour'. '... the entire academic literature, used by doctors to guide decisions – the only tool we have – is ghost managed, behind the scenes, to an undeclared agenda'. It is interesting that someone who is trained in a field depending on empirical evidence defaults (as do many critics) to anecdotal statements. He states that 'Since this activity (ghost authorship) is so hard to trace, it is, I think, legitimate simply to ask people who work with academic authors about their experiences'. Goldacre, and others, ignore the changes that have occurred over the

past five years, including creation and enforcement of authorship standards – including those requiring transparency; establishment of Codes of Ethics for professional associations (including EMWA's); and the attempts at educating all stakeholders about the clear difference between a professional medical writer's disclosed legitimate contributions and 'ghostwriting'.

Most critics are still confused. There are three main unethical authorship practices: ghost authorship, ghostwriting, and guest authorship (Table 1). Regardless of whether these practices occur in industry or academia, they should not be tolerated.

Professional medical writers (NOT to be confused with ghostwriters!) have to comply with a number of guidelines (e.g. Good Publication Practice) or legally binding contracts (e.g. Corporate Integrity Agreements) to ensure that authors do, indeed, meet authorship criteria. For industry-sponsored research, formal authorship agreements, which include authorship criteria, must be signed *before* the authors start developing the manuscript. Professional medical writers must maintain audit trails to document the 'substantial contributions' made by each author. Pharmaceutical companies now impose strict 'firewalls' between their editorial groups and marketing departments.

Although the standards are in-place and widely adopted, there are still challenges involved in determining authorship and for identifying relevant criteria. Annette Flanagin agrees that 'substantial contribution' has not been adequately defined.<sup>4</sup> She hypothesises that failure to define the term might be intentional to allow wider application of the ICMJE criteria for authorship. For those seeking further clarification, she defines 'substantial contribution' as 'an important intellectual contribution, without which the work, or an important part of the work, could not have been completed or the manuscript could not have been written and submitted for publication'.

For the most part, criticisms of our profession have gone unanswered. We must understand that we represent the potential for the strongest and most influential voice in refuting misinformation and misunderstanding about our role. We must educate our critics about the value that we bring to communications about new therapies. There is a great deal of interest among our colleagues in trying to turn around these public perceptions; however, there have been few formal and coordinated attempts to do so.

The importance of educating the public with respect to the positive value of clinical trials and the value that the industry brings to the public welfare via the development of new therapeutic products cannot be understated. The role and contributions of the professional medical writer, likewise, must be clarified and emphasised.

Given the lack of a concerted voice, I believe that what is required is a grassroots movement to engage in more proactive efforts to try to turn public opinion around. We should discuss how we might create an effective coalition to change the public perception on this key issue.

One collective voice in the wilderness is that of GAPP (Global Alliance of Publication Professionals – <http://www.gappteam.org>). GAPP, a multinational collaboration, advocates for ethical publication practices in industry and non-industry-sponsored research. In particular, GAPP supports professional medical writing and condemns ghostwriting, ghost authorship, and guest authorship.<sup>5</sup> Over the past two years, GAPP has issued timely and data-supported rebuttals to misguided criticisms of the profession and, in many cases, the efforts to educate our critics have reached the larger audience through the journals in which the responses have been published. Thus, editorials and letters-to-the-editor can effectively use the publication (on-line or hardcopy) as a multiplier for the message.

Table 1: Unethical authorship practices

Type of contributor	Authorship criteria met?	Identified in manuscript?	Definition
Ghost author	Yes	No	A contributor who meets authorship criteria but is not listed as an author
Ghost writer <sup>a</sup>	No	No	A contributor who does not meet authorship criteria but whose involvement is not disclosed (i.e. not listed in the acknowledgments)
Guest author (or gift or honorary author)	No	Yes (as an author)	A person who does not meet authorship criteria but is listed as an author. The person may or may not have made any contribution to the manuscript; authorship is 'given' rather than earned

<sup>a</sup>Ghost writers are not the same as professional medical writers. Professional medical writers disclose their involvement and funding source (usually in the acknowledgments section), and they adhere to ethical publication practices throughout the manuscript development process.<sup>3</sup>

Each of us, as professional medical writers, can exercise an effective voice by joining in the chorus of corrective response. In doing so, we should not ignore the many opportunities to discuss the issues with friends, colleagues, and family. They too, once they appreciate our position, may act as effective ‘vectors’ of correct information, spring-boarding the message to the broader audience.

We are our own best advocates in ensuring that critics of our profession are brought out of the wilderness.

### Conflicts of interest and disclaimers

The author declares that he has, or does, provide ethical medical writing services to academic, biotechnology, or pharmaceutical clients; neither he nor his spouse have any financial relationships that may be relevant to the submitted work; and that

he is active in national and international not-for-profit associations that encourage ethical medical writing practices. No external sponsors were involved in this study and no external funding was used.

### References

1. Angell M. The truth about the drug companies: how they deceive us and what to do about it. New York: Random House Inc.; 2004.
2. Goldacre B. Bad Pharma: how drug companies mislead doctors and harm patients. New York: Faber & Faber Inc.; 2012.
3. Woolley KL. Goodbye Ghostwriters!: how to work ethically and efficiently with professional medical writers. *Chest* 2006;130(3):921-3.
4. Iverson C, et al. *AMA Manual of Style*. 10th ed. New York: Oxford; 2007. p. 125-300
5. Woolley KL, Gertel A, Hamilton C, Jacobs A, Snyder G. Don't be a fool – don't use fool's gold. *Am J Med* 2012; 125(10):e21-2.

### Author information

**Art Gertel** has 35 years' executive-level experience in the fields of medical writing, publications, and regulatory affairs. He is a Past-President of AMWA and a Fellow of both AMWA and EMWA. Art is the Vice President,

Regulatory and Medical Affairs for TFS, Inc. He is also a Senior Research Fellow for the Centre for Innovation in Regulatory Science (CIRS).

## Relaunch of the Medical University of Innsbruck Master's in Medical Writing

The Medical University of Innsbruck will be relaunching the Master's in Medical Writing in October 2014.

This two-year Master's program will combine on-site summer and winter school in Innsbruck, Austria and distance learning. The course will provide students with the basic medical knowledge required by medical writers and will cover the three main areas of professional medical writing:

- Scientific Writing
- Medical Communications
- Regulatory Writing

Students will be taught by international experts in each field and will have to write and complete two full professional documents, one as a first-year project and a second as a Master's thesis.

### Teachers sought

Currently the program is also looking for teachers with expertise in the following areas:

- Drug development and regulatory affairs
- Medical communications
- Advanced English skills
- Quality assurance
- Good clinical practice and medical ethics

For further information or to express interest in teaching, please contact:

Mag Dennis Huber  
Medical University of Innsbruck  
dennis.huber@i-med.ac.at