GAPP Responses to CardioBrief Editor's Questions

http://www.forbes.com/sites/larryhusten/2012/02/14/a-defense-of-professional-medical-writers/

Editor's Note: In response to a recent guest post by Tom Yates on industry sponsored editorial assistance, the following comment was submitted by Karen Woolley on behalf of the Global Alliance of Publication Professionals. This thoughtful statement deserves attention, but I would point out that Woolley does not actually address the problems raised by Yates about industry sponsorship of articles. Specifically, I would invite Woolley and her group to respond to these questions posed by Yates:

- *What expertise do publications professionals have have in the field about which they are writing?*
- *Can Woolley point to industry-sponsored publications that do* ***not*** *recommend prescribing a drug manufactured by the sponsor?*
- *Will the industry sponsor or the communications company make public the details of their contract?*

Dear Editor,

Although the Global Alliance of Publication Professionals (GAPP) cannot answer the questions that Mr Yates posed directly to Isabelle Leach and PAREXEL, we welcome the opportunity to answer the questions you have asked.

1. **What expertise do publications professionals have in the field about which they are writing?**

This question provides a great platform to identify the expertise that professional medical writers do and (typically)* do not bring the publication process. Professional medical writers have scientific communication expertise; the authors have therapeutic area expertise. These areas of expertise complement each other. Is it helpful for a medical writer to be familiar with the therapeutic area? Yes. Is it necessary? No. The authors take full responsibility for the content;* the medical writer's role is to ensure that content is communicated in a timely and compliant manner. The situation with professional medical writers is analogous to the situation with statisticians. Statisticians do not need to be therapeutic area experts – the authors do.

Statisticians need to excel at their job; so, too, do medical writers. Manuscripts are often a team effort and, increasingly, professional medical writers are part of the manuscript team.

Notably, the international competency model for professional medical writers does not list the need for therapeutic area expertise, but it does include a long list of competencies for scientific communication (eg, knowledge of regulatory, publication, and style guidelines; English language skills; computer skills, project management skills; attention-to-detail etc…).[1]

** If a professional medical writer does have recognized expertise in a therapeutic area (eg, worked as a clinician in that area or completed their PhD or post-doctoral studies on the topic) or was instrumental in data collection (eg, for a systematic review manuscript), the writer may meet the criteria for authorship. If so, the medical writer should be listed as an author.*

2. Can Woolley point to industry-sponsored publications that do not recommend prescribing a drug manufactured by the sponsor?

Yes. The following papers do not recommend prescribing a drug manufactured by the sponsor. Please note that these papers were identified through a quick search of MEDLINE – a proper search of the literature would no doubt identify others.

- http://www.hindawi.com/journals/prt/2011/239501/
- http://bja.oxfordjournals.org/content/103/4/576.full
- http://onlinelibrary.wiley.com/doi/10.1002/cncr.25639/full
- http://jco.ascopubs.org/content/27/5/672.long
- http://www.ncbi.nlm.nih.gov/pubmed/17909804
  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2442407/?tool=pubmed

At a broader level, your question relates to the publication of "negative" trials. The Joint Position Statement from the International Federation of Pharmaceutical & Manufacturers Associations (to which most large pharmaceutical companies belong) directly addresses the issue of negative trials.[2] The Statement should be read in full, but we have included a relevant extract below:

All industry-sponsored[3] clinical trials[4] should be considered for publication in the scientific literature irrespective of whether the results of the sponsors' medicine(s) are positive or negative. At a minimum, results from all phase 3[5] clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This includes investigational clinical products whose development programs are discontinued.

Industry sponsors are well aware of the need to develop medicines that actually help patients and represent true value to the healthcare system (the "carrot" to do the right thing). Industry sponsors are also well aware of the threat of litigation should one of their employees or contractors do the wrong thing (the "stick" to do the right thing). No industry is without its "bad apples". Anyone who knowingly pushes inappropriate prescribing faces the threat of fines and litigation - not to mention the lifelong guilt of hurting patients (if these type of people feel such guilt). No professional medical writer wants to work with industry or academic authors who want to publish misleading research. Indeed, the questions that professional medical writers ask and the fact checking they do may dissuade these types of authors from working with professional medical writers. Perhaps this is one of the reasons that papers with disclosed professional medical writing support are rarely retracted from the literature because of misconduct.[3]

3. Will the industry sponsor or the communications company make public the details of their contract?

In the same way that sponsors and authors do not make public the details of their contracts with statisticians, lab assistants, technical support staff etc… sponsors and authors do not make public the details of their contracts with professional medical writers.

At a very practical level, nobody within GAPP (and collectively we have more than 100 years of experience) has ever come across or signed a contract that includes any clause that requires the medical writer to comply with the sponsor's wishes – right or wrong; nor have we ever seen any punitive clauses that prevent a medical writer from expressing disagreement.

Given concerns about "arrangements" between sponsors and authors, it is also worth highlighting the efforts made by advocates of ethical publication practices (including editors, publishers, sponsor employees, and professional medical writers), to develop guidelines that clearly stipulate the roles and responsibilities of publication team members (eg, sponsors, authors, writers). These guidelines were published in the BMJ in 2009.[4] Your readers may be most interested in the responsibilities of sponsors and authors (extract below). Authors, as is right and proper, have the most responsibilities when it comes to a manuscript.

Sponsors

- Grant authors full access to study data
- Confirm the authors' freedom to make public or publish the study results
- Provide authors with copies of the sponsor's publication policy.

Authors

- Plan and produce articles or presentations that are accurate and complete in a timely manner
- Avoid premature publication or release of study information
- Avoid duplicate publication
- Make decisions about practical issues concerning presentation and publication (for example, choice of congress or journal)
- Disclose potential conflicts of interest in all articles and presentations
- Identify funding sources in all articles and presentations
- Ensure authorship is attributed appropriately
- Acknowledge in all articles and presentations all significant contributions made by individuals and organisations

`• Provide the sponsor with copies of publication policies from the authors' institutions

We hope these comments from GAPP provide you and your readers with additional insight into the role of a professional medical writer and the environment in which we work. Thank you for your questions.

Professor Karen Woolley

On behalf of fellow GAPP members Dr Cindy Hamilton, Dr Adam Jacobs, Art Gertel, and Gene Snyder (www.gappteam.org).

Disclosures: All GAPP members have or do hold leadership roles at associations representing professional medical writers (eg, AMWA, EMWA, DIA, ISMPP, ARCS), but do not speak on behalf of those organizations. GAPP members have or do provide professional medical writing services to not-for-profit and for-profit clients.

References

1. Woolley KL, Clemow D. Development and practical use of a medical writer competency model. DIA Global Forum 2010;2:8-11.
2. Joint Position on the Publication of Clinical Trial Results in the Scientific Literature; http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/20100610_Joint_Position_Publication_10Jun2010.pdf (accessed 15 February 2011)
3. Woolley KL, Lew RA, Stretton S, et al. Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study. Curr Med Res Opin 2011;27:1175-1182
4. Graf C, Battisti WP, Bridges D, et al. Research Methods & Reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. BMJ 2009;339:b4330