http://www.trialsjournal.com/content/13/1/146/comments#1130696

Research

Sponsors' participation in conduct and reporting of industry trials: a descriptive study

Andreas Lundh, **Lasse T Krogsbøll** and **Peter C Gøtzsche**

Trials 2012, **13**:146 doi:

Addressing the implication made by the authors that if medical writers "do not do a job that satisfies the sponsor's marketing department, they might go out of business."

Cindy Hamilton (2012-09-20 16:29) Global Alliance of Publication Professionals

To the Editor:

Having read with interest the article by Lundh, Krogsboll, and Gotzsche: Sponsors' Participation in Conduct and Reporting of Industry Trials: A Descriptive Study (1), we would like to take this opportunity to address the implication made by the authors that if medical writers "do not do a job that satisfies the sponsor's marketing department, they might go out of business." This comment may be relevant for ghostwriters, but we do not believe it holds for professional medical writers. As leaders of the Global Alliance of Publication Professionals (GAPP), we believe it is important for your readers, and indeed Lundh et al, to recognize the difference between these two types of writers.

In our experience, professional medical writers have to satisfy authors, journal editors, peer-reviewers, and, within industry, the medical and compliance departments, not marketing departments. The European Medical Writers Association (EMWA), the American Medical Writers Association (AMWA), and the International Society for Medical Publication Professionals (ISMPP) have ethical codes of behavior for writers (2-4). Although the specific wording might vary among these codes, the core principles of preparing documents that are objective, accurate, scientifically valid, and complete are held in common. Further, international guidelines (5), published in 2009 and followed by pharmaceutical companies, specifically highlight that sponsors can provide scientific comments back to authors; the guidelines provide no role for marketing department staff. Notably, pharmaceutical companies are issuing publication policies that categorically prohibit marketing staff from being involved in manuscript preparation review and approval (6-10). Further, budgets for medical writing services are increasingly being held by medical departments, not marketing departments. If Lundh, et al want to gain direct insight into current ethical writing practices (rather than speculate on the business futures of ghostwriters), we encourage them to review these codes and policies, and certainly welcome them to contact GAPP.

Like Lundh et al, we abhor ghostwriting and always encourage authors to be transparent about medical writing assistance. If authors use writers, we encourage use of the "anti-ghostwriting checklist (11). Incidentally, this checklist was included in a viewpoint series that involved leaders from GAPP and Peter Gotzsche, one of Lundh's co-authors, we were surprised that this important tool was not referenced in the Lundh article.

We also suggest that readers refer to a more detailed response to the Lundh article, to be posted on the GAPP website: www.gappteam.org/

With kind regards, Art Gertel on behalf of fellow GAPP members Dr Cindy Hamilton, Dr Adam Jacobs, Gene Snyder, and Dr. Karen Woolley.

Disclosures: All GAPP members have held, 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. Lundh A, Krogsboll L, Gotzsche P. Sponsors' participation in conduct and reporting of industry trials: a descriptive study. Trials 2012, 13:146

2. American Medical Writers Association (AMWA): http://www.amwa.org/default.asp?id=114

3. European Medical Writers Association (EMWA): http://www.emwa.org/Home/Ghostwriting-Positioning-Statement.html

4. International Society for Medical Publication Professionals (ISMPP): http://www.ismpp.org/ISMPP%20CODE%20OF%20ETHICS%2011_10.PDF

5. Good Publication Policies 2 (GPP2). Graf C, Battisti WP, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM, Field EA, Gurr JA, Marx ME, Patel M, Sanes-Miller C, Yarker YE; International Society for Medical Publication Professionals. Research methods and reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. BMJ 2009;339:b4330.

6. Merck Publication Policy: http://www.merck.com/research/discovery-and-development/clinical-development/Merck-Perspective-Clinical-Trials.pdf.

7. GSK Publication Policy: http://www.gsk.com/policies/GSK-on-disclosure-of-clinical-trial-information.pdf

8. Pfizer Publication Policy: http://www.pfizer.com/research/research_clinical_trials/registration_disclosure_authorship.jsp

9. PhRMA Clinical Trial Principles: http://www.phrma.org/sites/default/files/105/042009_clinical_trial_principles_final.pdf

10. Statements by Pharmaceutical Publication Planning Professionals at recent meeting of The International Publication Planning Association (TIPPA). Chicago, July 2012.

11. Gotzsche PC, Kassirer JP, Woolley KL, Wager E, Jacobs A, et al. (2009) What Should Be Done To Tackle Ghostwriting in the Medical Literature? PLoS Med 6(2): e1000023. doi:10.1371/journal.pmed.1000023

Competing interests

All GAPP members have held, 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.