



April 2008

# Ghostwriting and Speakers Bureaus

*The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing to physicians.*

*It is promoting policy change by working with*

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

*Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.*

## A Toolkit for Academic Medical Centers

### I. Introduction

#### Ghostwriting

Ghostwritten articles play a key role in the pharmaceutical industry's marketing campaigns. Pharmaceutical companies or medical education and communication companies (MECCs) hire medical writers to draft editorials, review articles, or to summarize findings from original research. The drafts are sent to prominent physicians in the field to sign-on to as "authors." Often, the identity of the true writer is not disclosed. Such articles are part of any industry publication plan and "lay the groundwork for [...] marketing"<sup>1,2</sup> a new medication by highlighting the "under-diagnosed or new disease" it treats, or by highlighting unrecognized side-effects of its competitor.

One physician has described her experience with ghostwriting in detail. Dr. Adriane Fugh-Berman, of Georgetown University Medical School, was asked by a MECC to put her name on an almost complete review of interactions between warfarin and herbal remedies. Dr. Fugh-Berman declined to do so, but later, in her role as a peer-reviewer for the *Journal of General Internal Medicine*, was sent the same, only slightly altered article to review. As Dr. Fugh-Berman learned from representatives of the company, the purpose of the piece was to set the stage for the introduction of a new anti-coagulant that did not interact with herbal remedies.<sup>3</sup>

It is difficult to gauge the prevalence of ghostwritten articles, but published estimates suggest that 25 percent to 90 percent of published pharmaceutical research involves some form of invisible authorship.<sup>4, 5, 6</sup>

Articles ghostwritten by medical writers hide conflicts of interest

- When an industry-paid writer is not credited as an author, his or her ties to industry go unreported. Journal editors and readers assume that the authors are conflict free. The lack of transparency hinders

*This toolkit is one in series prepared by the Prescription Project to assist medical schools and teaching hospitals developing new policies to address the conflicts of interest that arise from pharmaceutical and medical device industry marketing. For further assistance or more information, please email [policy@prescriptionproject.org](mailto:policy@prescriptionproject.org).*

readers' abilities to interpret the article and its findings. The practice becomes most concerning when physicians sign their names to articles for which they have not reviewed, and may not have access to, the original data. Under these circumstances, the behavior crosses into academic dishonesty.

The International Committee of Medical Journal Editors has adopted a set of authorship principles that are seen as the gold standard (see policies below).<sup>7</sup> These principles are a good guide for physicians. Academic medical centers (AMCs) should hold their faculty members responsible for upholding these standards, as they would other academic regulations.

### **Speakers Bureaus**

Research relationships with industry may entail beneficial public presentations and speeches by individual researchers. However, industry also uses academic physicians to support marketing goals by identifying and cultivating speakers who give a positive message about the drug in question. A 2007 study of 459 medical school department chairs found that 21 percent of clinical chairs had ongoing speaking relationships, sometimes referred to as 'speakers bureaus'.<sup>8</sup>

Such participation in industry marketing by academic leaders is unnecessary and detrimental. Often, the physician is provided with slides and background by industry representatives. Physician talks are also one strategy used by industry to skirt FDA guidelines that prevent marketing for off-label indications (indications not approved by the FDA).

## **II. Policy Considerations**

Some AMCs explicitly prohibit participation in speakers bureaus. Others have implemented institutional oversight policies that seek to ensure editorial independence and ensure financial propriety. Consideration may be given to the total amount of remuneration and to the nature or duration of the speaker-industry relationship. At a minimum, any such relationship should be defined by a formal contract.

At a minimum, all faculty members should be aware of the ICMJE authorship principles: Faculty members need to know that it is academically dishonest to claim authorship on a paper to which they did not substantially contribute. Similarly, every person who has made contributions to an article that satisfies the qualifications for authorship outlined by the ICMJE needs to be included in the list of authors, with a full disclosure of their conflicts of interest.

## **III. Example Policies**

### ***University of Pittsburgh Medical Center***

#### **Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the Schools of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations<sup>9</sup>**

##### **8. Frequent Speaker Arrangements (Speakers Bureaus) and Ghostwriting**

While one of the most common ways for the SOHS and UPMC to disseminate new knowledge is through lectures, "speakers bureaus" sponsored by Industry may serve as little more than an extension of the marketing department of the companies that support the programming. Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to determine whether the event meets the criteria set forth in Section 6 of this policy,

relating to Industry Sponsored Meetings. SOHS or UPMC personnel may not participate in, or receive compensation for, talks given through a speakers bureau or similar frequent speaker arrangements if: (a) the events do not meet the criteria of Section 6; **or** (b) if the content of the lectures given is provided by Industry or is subject to **any** form of prior approval by either representatives of Industry or event planners contracted by Industry; **or** (c) the content of the presentation is not based on the best available scientific evidence; **or** (d) the company selects the individuals who may attend or provides any honorarium or gifts to the attendees.

Under no circumstances may SOHS and/or UPMC personnel be listed as co-authors on papers ghostwritten by Industry representatives. In addition, SOHS and/or UPMC personnel should always be responsible for the content of any papers or talks that they give, including the content of slides.

Speaking relationships with company or company event planners are subject to review and approval of the participant's administrator, department chair, or dean as delineated in Section 2, Consulting Relationships.

### ***Stanford University School of Medicine<sup>10</sup>***

Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries("Industry")

#### **V. Disclosure of Relationships with Industry**

A. Individuals are prohibited from publishing articles under their own names that are written in whole or material part by industry employees.

### ***The Committee of Medical Journal Editors***

#### **Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication**

#### **II.A Authorship and Contributorship**

##### ***II.A.1. Byline Authors***

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. (1) In the past, readers were rarely provided with information about contributions to studies from those listed as authors and in acknowledgments. (2) Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, it leaves unresolved the question of the quantity and quality of contribution that qualify for authorship. The International Committee of Medical Journal Editors has recommended the following criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship.

## REFERENCES

- <sup>1</sup> Moffatt, B., Elliott, C. "Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles." *Persp Bio & Med.* 50(1): 18-31.2007.
- <sup>2</sup> The Prescription Project. Ghosts in the Machine: invisible pharmaceutical industry authorship of academic journal articles (report) 2008
- <sup>3</sup> Fugh-Berman, A. The Corporate Coauthor. *J Gen Intern Med.* 2005 June; 20(6): 546–548.  
doi: 10.1111/j.1525-1497.2005.05857.x.
- <sup>4</sup> Flanigan et al. "Prevalence of Articles with Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals." *JAMA* 280(3). 222-224.1998.
- <sup>5</sup> House of Commons Health Committee, *The Influence of the Pharmaceutical Industry*, Vol. 1, London: The Stationary Office, 2005: 53.
- <sup>6</sup> Gøtzsche, P.C., Hróbjartsson, A., Johansen, H. K., Haahr, M.T., Altman, D. G., Ghost Authorship in Industry-Initiated Randomised Trials, *PLoS Medicine*, 2007, 4: e19.
- <sup>7</sup> <http://www.icmje.org/>
- <sup>8</sup> Campbell EG, Weissman JS, Ehringhaus S, et al. Institutional academic industry relationships. *JAMA.* 2007;298:1779-1786.
- <sup>9</sup> Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the Schools of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations  
<http://www.coi.pitt.edu/IndustryRelationships/> Accessed 28 Mar 2008
- <sup>10</sup> Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry")  
[http://med.stanford.edu/coi/siip/documents/siip\\_policy\\_aug06.pdf](http://med.stanford.edu/coi/siip/documents/siip_policy_aug06.pdf) Accessed 28 Mar 2008