

## **Publication planning: distorting the discourse in medical journals**

Adriane Fugh-Berman MD (corresponding author and guarantor)  
Associate Professor, Department of Physiology and Biophysics  
School of Medicine, Georgetown University  
Box 571460  
Washington DC 20057-1460  
(202) 687-7845 mobile (202) 550-4855  
fax (202) 687-7407  
E-mail [ajf29@georgetown.edu](mailto:ajf29@georgetown.edu)

Deliveries:  
3900 Reservoir Rd. Basic Sciences, Room 229, Washington DC 20007

Susanna J. Dodgson PhD  
Director, Biomedical Writing Program  
Professor of Biomedical Writing  
University of the Sciences in Philadelphia  
600 South Forty-third Street  
Philadelphia, PA 19104-4495  
(215) 596-8512 E-mail: [s.dodgso@usip.edu](mailto:s.dodgso@usip.edu)

word count 2451

Funding: This work was partially funded through the Attorney General Consumer and Prescriber Education grant program, created as part of a 2004 settlement between Warner-Lambert, a division of Pfizer, Inc., and the Attorneys General of 50 States and the District of Columbia, to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin® (gabapentin) that violated state consumer protection laws. The funders had no input into this article.

## Abstract

Publication planning is the process by which pharmaceutical companies plan exposure to their therapies and devices in national and international medical meetings through presentations and posters, and in medical journals with reports of clinical trials, review articles, and commentaries. Medical writers employed by industry may ghostwrite these talks, posters and articles under the names of academic and clinical guest authors. Medical decisionmaking about drugs may be orchestrated by industry in a manner that affects prescribing of both approved and off-label use of therapies. The continuing presence of articles in which the true authors and sponsors are not disclosed distorts the discourse on drugs in medicine.

Publication planning is the finely choreographed process through which pharmaceutical companies orchestrate the production and release of clinical trial reports, reviews, talks and commentaries into the biomedical literature to maximize sales of drugs, devices and biologics. As an industry article states, publication planning “provides essential, appropriate sources for other communications, whether promotional or scientific. ‘Appropriate’ in this context means peer-reviewed publication of the pivotal database (core publications) as a foundation for derivative publications, marketing communications, drug information communications (whether corporate or third party), detail pieces and advertising copy.”(1) Publication planning also “influences regulatory authorities globally”, and “influences disease perception and management through citation, discussion, and recommendation”.(1)

Core publications or primary publications are clinical efficacy studies that support a new chemical entity (a novel drug) or a new indication for a currently marketed drug. Government agencies approve a drug for one or more indications (diseases or conditions). All studies on a drug must be disclosed to government regulators, but publication is not required.

It is in the interests of pharmaceutical companies to publish studies favorable to their drugs. The timing, placement and readability of these publications are vital to enhancing receptivity of clinicians to a new drug or new

indication. The named clinical researchers may have had no or marginal input into the clinical trial design, analysis and conclusions. Consequently they are rarely, if ever, asked to write clinical trial reports and submit them to medical journals in time for product launch, and therefore sponsoring companies hire medical writers to ghostwrite these reports. Once published, these scientific articles help achieve the following publication planning goals: “Provide authoritative sources for marketing communications and other promotional materials”; “Support the positioning and selling platform, and coordinate with the overall marketing plan”; and “Accelerate the adoption of a new chemical entity or new indication.” (1)

An industry article states, “For a pharma company, getting research published in a peer-reviewed medical journal is like winning a stamp of approval from its most influential audience. It’s an automatic validation unmatched by any other medium.” (2) Primary or core research publications are used to generate secondary publications, including reviews and commentaries, and marketing aids, including detail pieces, which are reprints and visual aids used by pharmaceutical sales representatives, also known as drug reps. Core publications are also referenced in product websites, meeting abstracts, monographs, symposia, journal supplements, and marketing materials sent to prescribers via direct mail or electronically. “Third party” communications may be sponsored publications that come from medical societies, medical education companies, and nonprofit organizations.

Within the medical literature, ghostwritten review articles and commentaries, signed by “thought leaders,” (prominent physicians or other healthcare professionals) are key to maximizing acceptance of a new therapy or new indication for a marketed therapy. These derivative publications reference core publications, and serve to broaden recognition of a drug, device or biologic and the conditions this therapy is meant to treat.

Ghostwritten reviews and commentaries in the medical literature are an insidious and vital form of drug promotion. As one industry article states, “Peer-reviewed publications offer pharma companies shelter from often-stormy regulatory waters. FDA views published articles as protected commercial speech so doesn’t regulate their content.” (2)

Articles in the medical literature can increase awareness of a drug’s indications, but the use of drugs “off-label” (for conditions other than those approved by the Food and Drug Administration) may also be legally championed in reviews and commentaries. Drug companies cannot legally promote their wares for non-approved indications, but they are permitted to distribute articles from the medical literature. Article reprints that promote off-label uses may be considered off-label promotion unless the physician requests this information, but it is an easy matter for a drug rep to solicit such inquiries. Physicians can legally prescribe any drug for any purpose, and off-label use enhances drug sales.

Marketing messages in sponsored opinion pieces may be quite subtle, and may not mention the targeted drug. For example, one of us (AFB) was approached by an MEC to “author” a ghostwritten review of herb-warfarin

interaction (3). The project was funded by Astra-Zeneca, which makes neither warfarin nor herbs. However, the company had developed a new anticoagulant, ximelagatran, which had fewer drug interactions than warfarin. Ximelagatran was not yet on the market in the U.S. (it later failed to win FDA approval because of hepatotoxicity concerns) (4), so even if sponsorship had been disclosed, the reason for sponsorship would have been difficult to discern.

Commentaries highlighting the dangers or disadvantages of existing therapies before the launch of a new product pave the way for the new therapy. If drug X is normally dosed three times daily, and a competing company develops a similar drug that is dosed once daily, the launch of the new therapy might be preceded by commentaries on how the inconvenient dosing of drug X decreases compliance and subsequent effectiveness, resulting ultimately in tragic outcomes. Increasing the number of diagnoses boosts drug sales as well, so articles claiming that disease Y is widespread, underdiagnosed, undertreated, and debilitating are part of the publication plan.

### **The role of the medical writer**

*Medical writing exists because of the need for medical writers to create knowledge in the pharmaceutical industry.*

Danny A. Benau, PhD, Associate Professor of Biomedical Writing, University of the Sciences in Philadelphia

Medical writers are crucial to publication planning, ensuring that manuscripts are professional, persuasive, and submitted on a timeline consistent with marketing goals.

One of us (SD), a PhD physiologist and professional medical writer, directs the Biomedical Writing Programs, the only degree-granting graduate program for medical writers in the world, at the University of the Sciences of Philadelphia (USP). The vast majority of medical writers have been women; enrollment in the USP Biomedical Writing Programs has shifted from 95% female in 2002 to 80% female in 2007. About a third of the students in the USP program have earned a PhD in life sciences, or are physicians, nurses, optometrists or pharmacists.

The USP Biomedical Writing Programs educate medical writers to fit the following definition: "trained scientists who translate data that they have analyzed, and may have created, into prose, tables, and figures, on behalf of a sponsor from the private or public sector."<sup>(5)</sup> This definition prevails because of lack of competition as no other group, including the American Medical Writers Association (AMWA), The European Medical Writers Association (EMWA), the Drug Information Association (DIA), and the International Committee of Medical Journal Editors (ICMJE) define the term.

AMWA and EMWA are the primary professional organizations of medical writers. Once an organization limited to physicians editors with extensive publications, editing experience, or leadership experience, AMWA began as the Mississippi Valley Medical Editors Association in 1940 and became AMWA in

1949. During the 1950s, more than 90% of AMWA members were physicians; that number dropped to 70% by the 1960s, and by 2005, less than 5% of AMWA's 5,000 members were physicians (5).

Today, writing a check is sufficient to join the American Medical Writers Association (AMWA), which states, "If you write, edit, or are employed in the field of biomedical communication as a teacher or a specialist in multimedia, public relations, advertising, or marketing, you belong in AMWA." About half of the corporate sponsors for AMWA are pharmaceutical companies (6).

EMWA, founded in 1989, was affiliated with AMWA for more than a decade. Now independent, EMWA has about 550 members. Although EMWA does not restrict membership, more EMWA members (80% to 90%) than AMWA members (40% to 60%) have undergraduate or graduate degrees in life sciences (4).

Medical writing is better remunerated than other types of writing and most other jobs for scientists. A typical ad for a full-time medical writing position requiring a graduate degree and three years of experience offered an annual salary of \$85,000-\$125,000. A freelance medical writer known to SD claims to earn more than \$300,000 annually.

Medical writers are generally categorized as regulatory or publications writers. Most regulatory writers work directly for industry, generating clinical trial reports and other documents to support new and continuing marketing authorization for drugs, devices or biologics. Regulatory writing requires both data analysis skills and extensive knowledge of regulatory requirements for drug



approval. Clinical trial reports were previously signed by the lead medical writer, the statistician and the medical officer involved with a study; the trend is now towards eliminating the medical writer's signature from documents submitted to regulators.

Publications writers take over from where regulatory writers end, preparing meeting materials and manuscripts from clinical study reports, and reviews from clinical trial report papers and abstracts.(7) Publications writers (also called marketing writers) have rarely, if ever, seen their names on any of their work. Publications writers often work on contract, either for pharmaceutical companies or medical education and communications companies (MECCs), which are hired by drug companies to create and implement publication plans.

In SD's experience with a now-defunct MECC, the marketing department of a pharmaceutical company worked closely with the MECC on ideas for review articles.(8) Writers were sometimes supplied with specific marketing messages to work into manuscripts. (Even when specific messages are not provided, medical writers know what sponsors want).

After the outlines were approved by the sponsoring pharmaceutical company, a medical writer researched and wrote the papers, which were most commonly review articles. Another MECC medical writer edited the manuscript, which then went back to the pharmaceutical company.

Once the product was approved, a pharmaceutical company–selected author (PCSA) was selected. The PCSA, frequently an academic physician, was anointed the named author on the paper. The PCSA signed a letter claiming the

article as his or her original work, and then sent the manuscript to a pharmaceutical company-selected medical journal.

If a journal asked for changes or clarifications, the medical writer wrote the response, again for the guest author's signature. The medical writer's name was included neither in the submitted manuscript nor the published paper. Medical writers are sometimes acknowledged, a practice encouraged by the American Medical Writers Association. A limited study of 1,000 research articles in ten international journals found that a medical writer was acknowledged in about 6% of the articles. (9)

Peer-reviewed, well-known journals are not always preferred for commissioned articles; sometimes other factors outweigh prestige. For example, an undistinguished journal may be chosen because of higher likelihood of acceptance, lack of conflict-of-interest disclosure requirements, or speed of publication. A study that is not entirely favorable to a sponsor's drug but which is deemed important to publish may be buried in an obscure journal that is unlikely to have any impact.

### **The role of the guest author**

Publications are needed to promote academics as well as drugs. The practice of adding one's name as an author of articles that one has not written may be common among academic physicians. "Academic authors serve as celebrity sponsors..." writes Sergio Sismondo. (10) Colleagues of AFB's have defended guest-authoring on the grounds that physicians are too busy to write

the articles they “author”. Some physicians try to make ethical distinctions; for example, always rewriting at least part of an article, or only allowing one’s name to appear on articles with which he or she agrees.

The signing author does have the option to contribute to the final product. This tinkering is voluntary, and authors know that changes that are not advantageous to the sponsor will result in the article not being published – or another signer being selected. (11)

For guest authors, branding articles with their names has no downside. Besides publication credit, named “authors” are often paid by industry, usually through an MECC. And although conflicts of interest with pharmaceutical companies must sometimes be declared, financial arrangements with MECCs are seldom required, and rarely disclosed.

### **Revealing ghosts**

Publication planning, as currently practiced, undermines the medical literature. It is impossible to know how many named authors of medical journal articles are really guest-authors, or how many ghost authors have been omitted. A survey of named authors of articles in six medical journals found that 11% (93/809) of articles met criteria for ghost authorship, in which “an individual who was not listed as an author made contributions that merited authorship” or “an unnamed individual participated in writing the article.” Nineteen percent (156/809) of articles met criteria for honorary or guest authorship.(12) These numbers,

based on voluntary reporting, undoubtedly underestimate the true prevalence of guest and ghost authorship.

A unique study that examined protocols and corresponding publications for industry-sponsored trials in Denmark found that 75% (33/44) studies showed evidence of ghost-authorship, defined as present if 'individuals who wrote the trial protocol, performed the statistical analysis, or wrote the manuscript were not listed as authors of the publication, or as members of a study group or writing committee, or in an acknowledgement'. (13) The prevalence of ghost-authorship increased to 91% when cases in which someone who qualified as an author was instead listed in the acknowledgements were included. Most ghostwriters identified in this study were statisticians. An accompanying commentary notes that the study "probably underestimated the number of writers who worked on the publications" (14) because it could not identify medical writers assigned to write up publications.

Medical writers must remain anonymous in order to hide the influence of sponsors. The profession prides itself on its discretion; Principle 6 of AMWA states in part, "Biomedical communicators should respect the confidential nature of materials provided to them."(15)

As Sismondo puts it, "Ghost-writing thus stands at some distance from practices and norms of scientific authorship, and pharmaceutical companies would not meet their objectives were their ghostly roles known."(10) Moffatt and Elliott note that "ghostwritten papers conceal the interests of authors and

sponsors in a way that makes it difficult to assess and contest the scientific data, which undermines the objectivity of science itself.”(16)

Pharmaceutical companies have defended the use of medical writers on the grounds that many scientists and physicians lack writing skills, or find writing onerous. This is disingenuous; medical writers serve the industry that pays them, and reflect and hone the ideas of sponsors, not authors. Linda Logdberg, a former medical ghostwriter, has described ghostwriting as “advertising that calls itself education” and “marketing masquerading as science”. (17) Sponsored writing reflects sponsored messages.

Medical writers are highly skilled professionals who can transform mountains of clinical trial data into readable documents. Medical writers are needed by the pharmaceutical industry; but the documents that they produce should not pretend to be the work of others. Additionally, transforming data into publishable prose is highly important to entities other than industry. Government agencies, universities and non-profit organizations all benefit by employing medical writers to create articles, reports, conference proceedings, grant proposals, and educational materials. We look forward to greater recognition of the profession of medical writing -- and the elimination of sponsored plagiarism in publication planning.

## References

1. Beebe FA. Publication planning. Medical Marketing Media. 2004 July: 41-46.

2. Balter W, Skelton M, Safir PO. The P's and Q's of publication planning. Pharmaceutical Executive 2003 May:130-136.
3. Fugh-Berman A. The Corporate Coauthor. J Gen Int Med 2005; 20(6): 546-548. Available: <http://www.blackwell-synergy.com/links/doi/10.1111/j.1525-1497.2005.05857.x/full/> Accessed 3/2/07.
4. Food and Drug Administration Hepatotoxicity Working Group. Concept paper (Draft): Premarketing evaluation of drug-induced liver injury ([http://www.fda.gov/cder/livertox/concept\\_paper2007.pdf](http://www.fda.gov/cder/livertox/concept_paper2007.pdf)). Accessed 3/2/07.
5. Dodgson SJ. Medical writers: who are we? J Clin Res Best Pract 2006;2(3):1-6.
6. American Medical Writers Association. (<http://www.amwa.org/default.asp?Mode=DirectoryDisplay&id=114>). Accessed 3/2/07.
7. Moghadam RG. Scientific writing: a career for pharmacists. Am J Health Syst Pharm 2003;60:1899-1900.
8. Dodgson SJ (2005) From over the pond: Plagiarism in the pharmaceutical industry. The Write Stuff (J Eur Med Writers Assn) 14(3):87-90.

9. Woolley KL, Ely JA, Wooley MJ, Findlay L, Lynch FA, Choi Y, McDonald JM.  
Declaration of medical writing assistance in international peer-reviewed journals.  
JAMA 2006; 296 (80):932-933.
10. Sismondo S. Pharmaceutical maneuvers. Social Studies Science  
2004;34(2):149-159.
11. Healy D. Let them eat Prozac: the unhealthy relationship between the  
pharmaceutical industry and depression. New York, NY: New York University  
Press, 2004.
12. Flanagin A, Carey LA, Fontanarosa PB, Phillips SG, Pace BP, Lundberg GD,  
et al. Prevalence of articles with honorary authors and ghost authors in peer-  
reviewed medical journals. JAMA 1998; 280(3):222-4.
13. Gøtzsche PC, Hróbartsson A, Johansen HK, Haahr MT, Altman DG, Chan A-  
W. Ghost authorship in industry-initiated randomised trials. PLoS Medicine 2007;  
(4)1:e19.
14. Wager E. Authors, ghosts, damned lies, and statisticians. PLoS Medicine  
2007;4(1): e34.

15. American Medical Writers Association Code of Ethics.

(<http://www.amwa.org/default.asp?Mode=DirectoryDisplay&id=114>). Accessed 3/3/07.

16. Moffatt B, Elliott C. Ghost marketing: pharmaceutical companies and ghostwritten journal articles. *Persp Biol Med* 2007;50 (1): 18-31.

17. Kassirer, Jerome P On the take: how America's complicity with big business can endanger your health. New York, NY: Oxford University Press, 2005.