

AMWA Responds to PLoS Medicine Article on Ghost Management

A recent article in *PLoS Medicine* (vol 4, no. 9, September 2007) explored the topic of publications planning and expanded an unfortunate lexicon by introducing “ghost management” as an extension of “ghostwriting.” AMWA’s position statement on the contributions of medical writers to scientific publications makes clear our tenet that the involvement and proper acknowledgment of medical writers is legitimate and ethical. It is just one of several important resources and guidelines that the article’s author did not encounter in his research. However, it was the author’s complete mischaracterization of AMWA as an organization whose membership and annual conference is dominated by medical education and communication companies that prompted a response posted online at *PLoS Medicine*. The open-access article and responses are available online at www.plosmedicine.org. The following are excerpts from the article and the response from AMWA.

Excerpt 1 from PLoS Medicine article:

PLOS MEDICINE

Essay

Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?

Sergio Sismondo

“What is the purpose of publications?...[The] purpose of data is to support, directly or indirectly, the marketing of our product.” [1]

From Ghost Writing to Ghost Management

There are many reports of medical journal articles being researched and written by or on behalf of pharmaceutical companies, and then published under the name of academics who had played little role earlier in the research and writing process [2–14]. In extreme cases, drug companies pay for trials by contract research organizations (CROs), analyze the data in-house, have professionals write manuscripts, ask academics to serve as authors of those manuscripts, and pay communication companies to shepherd them through publication in the best journals. The resulting articles affect the conclusions found in the medical literature, and are used in promoting drugs to doctors.

For example, as reported in *The New York Times* [4], an *Annals of Internal Medicine* article on Merck’s “Advantage” trial of Vioxx omitted some trial participants’ deaths. Distancing himself from the *Annals* article, first author Jeffrey Lisse said in an interview that “Merck designed the trial, paid for the trial, ran the trial...Merck came to me after the study was completed and said, ‘We want your help to work on the paper.’ The initial paper was written at Merck, and then it was sent to me for editing” [4].

Such incidents have provoked many commentaries about ghost writing in the medical press. This article enlarges the focus from ghost *writing* to the more general ghost *management* of medical research and publishing: when pharmaceutical companies and their

agents control or shape multiple steps in the research, analysis, writing, and publication of articles. Such articles are “ghostly” because signs of their actual production are largely invisible—academic authors whose names appear at the tops of ghost-managed articles give corporate research a veneer of independence and credibility. They are “managed” because those companies shape the eventual message conveyed by the article or by a suite of articles. As discussed below, a substantial percentage of medical journal articles (in addition to meeting presentations and other forms of publication, which are not the focus here) are ghost managed, allowing the pharmaceutical industry considerable influence on medical research, and making that research a vehicle for marketing.

Ghost writing and honorary authorship are not in and of themselves scientific problems, though they become so when they shape science to meet particular interests [1]. Some honorary authors are senior professors and chairs of departments, who are added to articles because of local academic politics rather than at the request of drug companies [15,16]. Some busy independent research units hire writers to improve manuscripts; Max Lagnado has argued that professional medical writers can “benefit the scientific community when used in a responsible manner” [15]. In any case, the writing of a manuscript may not be the key point at which behind-the-scenes influence is exerted: study design, statistical analysis, or the choice of placement of manuscripts may be equally important.

It has been repeatedly and firmly established that pharmaceutical company funding strongly biases published results in favor of the

company's products [17–19]. Ghost management amplifies that bias, because when one set of commercial interests exerts influence at multiple stages of research, writing, and publication, it will shape the resulting article. In turn, bias affects medical opinion and practice, and ultimately, patients.

How Common Is Ghost Management?

Because ghost management is hidden, we cannot tell how common it is from published exposés. Current practices in the medical sciences legitimately allow people to serve as authors on the basis of narrow contributions. Therefore many near-honorary authors find little reason to feel uncomfortable with their roles. Fully honorary authors may not see enough of the process of the production of their articles to know that they are ghost managed. Finally, it is not in the interests of writers, authors, or sponsors and their agents to reveal ghost management processes; hence a number of the published accounts of ghost management have stemmed from legal proceedings and investigative journalism. So how common is ghost management?

Much of the information on ghost writing does not help to answer this question. Surveys to quantify rates of ghost writing do not address the ghost management phenomenon, because management may not involve writing, and writing may not be managed [20,21]. However, information about ghost authors, people who should be receiving author credit, strongly suggests that ghost management is common. A study comparing protocols and corresponding publications for industry-initiated trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg in 1994–1995 found evidence of ghost authorship in 75% of these publications (95% confidence intervals, 60%–87%) [22]. Company statisticians were common unacknowledged contributors, but so were the creators of trial designs and protocols, and the writers of manuscripts. The study also found that most (172 of 274) trials for which protocols had been submitted were never begun, completed, or published.

Excerpt 2:

In addition to the publication planners, a much higher number of medical writing companies and individual writers create articles and presentations without engaging in broader publication planning; these may be adjuncts to publication planners. To provide an indication of the scale, the American Medical Writers Association boasts a membership of more than 5,000 [37]; judging from the organization's officers and the content of its conferences, it appears to be dominated by MECCs [38,39].

Several of the publication planning firms identified are owned by major publishing houses. For example, Excerpta Medica is “an Elsevier business” and writes that its “relationship with Elsevier allows... access to editors and editorial boards who provide professional advice and deep opinion leader networks” [40]. Wolters Kluwer Health draws attention to its publisher Lippincott Williams & Wilkins, with “nearly 275 periodicals and 1,500 books in more than 100 disciplines,” and to Ovid and its other medical information providers, emphasizing the links it can make between its different arms [41]. Vertical integration is attractive in the industry as a whole: at least three of the world's largest advertising agencies own not only MECCs, but also CROs [13].

Ghost management of medical journal publications is clearly a substantial business, employing thousands of marketers, writers, and managers. It is large enough that the industry has established the International Publication Planning Association. This organization, which appears to be dominated by pharmaceutical companies, organizes meetings, keeps a directory of experts, and gives awards to honor planners [42]. In addition, the International Society for Medical Publication Professionals also organizes meetings, has committees to develop policy, and posts job advertisements [43]. Both of these associations compete with for-profit companies offering similar services, such as the Center for Business Intelligence, which held forums for Strategic Publication Planning in 2005 and 2006 [44].

Excerpt 3:

There are no straightforward solutions, short of large changes to the nature of medical publishing and/or research, changes that would effectively sequester pharmaceutical company funding from research and publishing [45] or from marketing [46]. Until such changes come about, at least we can hope for more awareness of and responsiveness to the issue.

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AMWA Response

On October 3, 2007, Thomas Gegeny, AMWA Secretary, along with coauthors Tom Lang, Tad Coles, Melanie Fridl Ross, Sue Hudson, Marianne Mallia, Mary Royer, and Mary Whitman, responded to the article on behalf of AMWA.

The recent article by Sergio Sismondo (1) substantially mischaracterizes the American Medical Writers Association (AMWA).^{*} Specifically, Dr Sismondo states that AMWA's membership comprises mostly employees of medical education and communication companies (MECCs), "... judging from the organization's officers and the content of its conferences." Extrapolating the composition of a 5,500-member organization based on the affiliations of 2 of the 5 current volunteer officers is misleading. Our members work in a range of settings, including pharmaceutical and medical device companies, universities and medical schools, hospitals, non-profit organizations, government agencies, journals, and many other businesses and organizations. Fully a third are self-employed.

Equally incorrect is the statement that our conference is "dominated" by publication planning topics. As is readily apparent from our Web site, of the 250 educational lectures, workshops, and roundtable discussions at our upcoming national conference, none is on publications planning, and very few include topics even related to MECCs. Rather, AMWA has always provided a diverse spectrum of educational topics, including ethics in medical publications, critical appraisal of the medical literature, health literacy, copyright, writing research grants, regulatory writing, medical education, and principles of biomedical research. Our organization provides the opportunity to explore all current issues in medical writing, including MECCs, even if it does not necessarily endorse them.

The author also did not cite AMWA's Code of Ethics (2) and Position Statement on the Contribution of Medical Writers to Scientific Publications, (3) which are available on our Web site. These documents call for the routine and universal practice of acknowledging pertinent professional and financial relationships between all authors and sponsors and the substantial contributions of medical writers to manuscripts. In fact, we also note the absence from Sismondo's essay of references to other important advances in disclosure and authorship, including Good Publications Practice (4) and guidelines from the International Committee of Medical Journal Editors (ICMJE), (5) both of which AMWA endorses and

that are integrated within our educational program.

We wish to set the record straight concerning AMWA, an organization that has educated professionals in this field for almost 7 decades.(6) We hope that the misleading characterization of AMWA and its members in the *PLoS Medicine* article reflects only inadequate research and not outright bias because we agree wholeheartedly with the author's contention that scientific publications must be kept as free from bias as possible.

^{*}AMWA is a nonprofit, educational organization that was founded in 1940 by physicians seeking to improve the quality of medical writing and editing. Grounded in its Code of Ethics,(2) AMWA's mission is to promote excellence in medical communication and to provide educational resources in support of that goal.

Competing Interests: Although I (Thomas Gegeny) am employed by one of the companies cited as an MECC reference in the Sismondo article, the contents and perspective of this letter is written by me and the other authors solely in our roles as members of the American Medical Writers Association (AMWA). This letter represents no other interests, relationships, or purposes nor any other organizations or entities with which we as individuals may have affiliation, interest, or employment.

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