

## PERSPECTIVES

## The Corporate Coauthor

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Drug marketing techniques include the sponsorship of articles signed by academic physicians or researchers and submitted to peer-reviewed medical journals. Some of these articles are authored or coauthored by ghostwriters who work for pharmaceutical companies or medical education companies hired by pharmaceutical companies. Conflicts of interest may be difficult to detect in the subset of articles and presentations sponsored by pharmaceutical companies that never mention the targeted drug, but focus on stimulating the perceived need for the targeted drug or highlighting problems with competing drugs. The current voluntary standards for declaring conflicts of interest to readers of medical journals and audiences at medical conferences are inadequate. A public database that contains conflicts of interest of physicians and researchers would be useful.

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No man but a blockhead ever wrote, except for money.

—Samuel Johnson, 1709-1784

Some conflicts of interest are invisible. Pharmaceutical companies routinely seed medical literature with reviews or commentaries that advantageously frame a marketed drug, but some sponsored articles never mention the targeted drug. Both types of articles are usually written by a medical education company (MEC) that receives funding from a pharmaceutical company.

Academic physicians are recruited to sign these articles. The division of labor for such a corporate-sponsored article is rarely equal; although the signer is invited to make changes, the primary obligation of the academic coauthor is to claim authorship. The primary author from the MEC remains anonymous, and any instructions given to the primary author regarding tone or emphasis are not shared with the named author, who is usually paid by either the MEC or the sponsoring pharmaceutical company. The true incidence of corporate ghost authorship or coauthorship is unknown; anecdotally, many of my colleagues who speak at national meetings have been approached with such offers. The arrangements made between drug companies or MECs and physicians are often discreet; negotiations are done over the phone, or in telegraphic e-mails. Paper trails are minimized; there are no invoices, no contracts, and no written scope of work. Payments may not be

traceable to services rendered, or to the sponsoring pharmaceutical company.

Writers and speakers are supposed to declare relevant conflicts of interest. The participation of the MEC may be acknowledged; the role of the pharmaceutical company usually remains invisible and may not be acknowledged. Even if a pharmaceutical company is mentioned, a conflict of interest with the subject of the article or speech may not be obvious. It is even possible that an incurious coauthor or speaker could be unaware of a funder's motivations.

## Writing with Ghosts

I was approached in the summer of 2004 by an MEC we will call XYZ Communications, to author a review of herb-warfarin interactions. The invitation stated that the sponsor of the article was a pharmaceutical company which we will call ABC Drugs,\* which did not to my knowledge manufacture warfarin or herbal products. My interest was piqued as to why the company would fund such an article. I asked XYZ Communications for more information, and several months later, on August 24, 2004, received a draft article, complete with a title page containing my name and institution, along with an e-mail stating:

Following on from our contact with you earlier in the year where you expressed an interest in authoring an anticoagulation paper, we are pleased to attach an initial draft of a review paper entitled, *Interactions between dietary supplements and warfarin: the hazards of self-administration*. We would be grateful if you could review this draft and forward on any changes or amends you would like to make. We do understand that there are many demands on your time, but wonder whether it will be possible for you to return your comments to us by Wednesday 1st September?

With regard to choice of journal, our initial thoughts are for either Am J Health-Syst Pharm or J Am Diet Assoc. Do you have any other suggestions or preferences?

In response to my question about what ABC Drug's interest was, I received the following:

This paper is a series of communications concerning the importance of anticoagulation therapy with warfarin for stroke prophylaxis, whilst simultaneously highlighting the difficulties and burden that such therapy places on the patient, clinician, and society. One such problem concerns warfarin's high interaction potential, which can give rise to problems with anticoagulation control. Whilst there is no promotion of any drug within this paper,

\*The original manuscript named the MEC and pharmaceutical company involved in this incident. We have deleted the names of the specific companies in order to focus on the issues at hand, not the individual companies involved.—The Editors.

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The author has received fees for talks sponsored by medical education companies.

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ABC Drugs is keen to set the scene for new anticoagulants that are not subject to the numerous limitations of warfarin.

Warfarin is the only oral anticoagulant approved in the United States. Approved in 1954, it is notable for having almost no competitors in a half-century of use. It is one of the few generic drugs that dominates its drug class. ABC Drugs had developed a competitor to warfarin. I informed XYZ Communications that I would not agree to be the named author and made a note to myself to monitor the medical literature for a possible flood of articles trumpeting the risks of warfarin.

The new oral anticoagulant marketed by ABC Drugs was approved for preventing venous thromboembolism after orthopedic surgery in France and a New Drug Application was submitted to the Food and Drug Administration (FDA) in 2003. However, it was not approved because of hepatotoxicity in some subjects.

## Invisible Conflicts

How does this conflict with my interest?

—Joe Staszak, a state senator and tavern owner in Baltimore, on being asked whether a bill he sponsored benefiting taverns constituted a conflict of interest.

As the author of a reference text on herbs and dietary supplements, I am regularly invited to lecture to physicians. When a university or medical society invites me to speak, I am often asked which company sponsors my talks. Not whether a company sponsors me, but which company.

While a suspicious audience member may discount the objectivity of a speaker who talks about a product manufactured by a company for whom that speaker consults, some conflicts of interest are difficult to discern. Companies regularly fund articles and talks that never mention the targeted drug, but are meant to disadvantage the competition. One of my colleagues was paid handsomely by a drug company to give a hundred talks a year presenting negative data on alternative therapies, a competitor for an infinitesimal share of the market dominated by the company's blockbuster drug. My colleague did not misrepresent the data, and there would be no reason for the audience to suspect that a talk that mentioned no pharmaceuticals was funded by a pharmaceutical company.

I sometimes speak at conferences organized by MECs. Although my talks do not directly help to sell drugs, unconflicted presentations serve as cover to the "message talks," reassuring the audience that all of the speakers are objective. Message talks, by the way, are not obviously advertising, and may mention a targeted drug, without emphasis, as one of several reasonable choices. The talk's usefulness may lie in convincing doctors that a particular condition is underdiagnosed or undertreated, or that an invented disease exists, or that medical management is a sound alternative to surgery, or that a currently used therapy is fraught with problems. It is the drug company sales force's job to sell a specific drug; it is the company-sponsored speaker's job to create a receptive atmosphere within the minds of physicians.

These efforts may begin years before a pharmaceutical is approved for sale. It is a bit like farming; weeds are removed, the soil prepared, perhaps a cover crop planted, to be tilled under before seeds are sown in the receptive soil. Some MECs

organize continuing medical education conferences, other specialize in writing articles, and some do both.

The placement of articles in peer-reviewed journals is a valued marketing technique. For example, an industry conference, titled "Publication Planning 2003: Utilizing Scientifically Accurate, Commercially Relevant Strategies for Optimal Drug Acceptance and Exposure" was held in Princeton, NJ in November 2003. The conference brochure states, "For a manufacturer, having research published in a highly regarded peer-review [sic] medical journal or presented at a leading conference is desirable. It demonstrates to the audience the validity of the data presented in these selective vehicles and adds credibility to its subsequent use in educational or promotional initiatives."

A workshop titled "An Overview of Contemporary Publication Planning" is described, with refreshing candor:

How pharmaceutical companies handle publications has changed dramatically over the past decade. These changes have seen publications shift from being an academic, data-driven pursuit to adopting a message-driven model that is part of a broader communication strategy and integral to pharmaceutical life-cycle management. Although publications have become a key item in the pharmaceutical sales kit, there is a need to ensure that commercial relevance is balanced with scientific credibility. In this session, our speaker addresses

- Data-driven vs. message-driven strategies
- Quality vs. quantity of publications
- The dichotomy of commercial relevance and scientific credibility
- Publications and the broader communications plan

The MEC that attempted to recruit me as a sham author apparently recruited someone else, and the herb-warfarin article was submitted to the *Journal of General Internal Medicine*. Quite coincidentally, I was asked to review the article, a revised but recognizable version of the manuscript that had been previously sent to me. On learning of its odd origins, the *Journal's* coeditors rejected the piece and have spearheaded an international discussion of ghostwriting by MECs among the members of the World Association of Medical Editors (WAME), alerting them to the fact that submitted papers may not properly acknowledge corporate funding and/or coauthorship.

Sir, there is no settling the point of precedence between a louse and a flea.

—Samuel Johnson, 1709–1784

It will be a tough job. Information bias is not pathognomonic for drug company funding. Certainly querying authors about unacknowledged coauthors or editorial assistance may help, although it will not prevent lying or deception. When a conflict is declared, the relevance may not be obvious. An editor, reviewer, or reader may find no cause for suspicion when a corporate-coauthored article mentions no products made by a company for which an author consults. In the case at hand, I did not immediately recognize ABC Drug's interest in herb-warfarin interactions because I did not know at first that the company had a warfarin competitor in the pipeline. Who would do that research, and how would important indirect connections be explained to readers?

Voluntary reporting of conflicts of interest does not work, and current safeguards are not enough. There should certainly be a way for medical editors to communicate ethical breaches to each other and to punish transgressors, but it should not be a secret process, which would be too open to abuse or error. Besides, this information should be available to journalists, employers, and consumers, as well as editors. I would advocate for a publicly available, regularly updated database of conflicts of interest and ethical transgressions. The Center for

Science in the Public Interest, one of the very few consumer groups in the country that takes no industry funding, has created a conflict-of-interest database that could be expanded, or used as a model. And we need a mechanism for academicians to expose the more subtle strategies used by drug companies to affect prescribing. I doubt I'll be asked to be a sham author ever again, but surely there are other physicians who would be willing to publicize such shenanigans.