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Ghostwriting and Academic Medicine

By Jonathan Leo and Jeffrey Lacasse

Pharmaceutical companies are masters of marketing, as witnessed by their impressive ability to create blockbuster drugs.

Unfortunately, those include medicines like Vioxx (which was withdrawn from the market in 2004), Paxil (whose use in young people is being questioned), Fen-phen (the diet drug that was recalled), Zoloft, (which requires a "black box" warning about side effects), Zyprexa, (for which Eli Lilly agreed to pay up \$500-million to settle lawsuits), hormone-replacement therapy, (which has come into question), and the now much-debated Avandia.

While most Americans are familiar with the ubiquitous direct-to-consumer advertising found on television, the greatest marketing triumph of the pharmaceutical industry arguably lies elsewhere: the ghostwritten manuscript, composed by the employees of pharmaceutical companies in cooperation with their marketing departments and then published under the byline of academic researchers.

Last week the Senate Finance Committee, which has been investigating the marketing of Avandia, released internal e-mails from GlaxoSmithKline suggesting that Steven M. Haffner, an assistant professor at Baylor College of Medicine, was presented as the lead author on a company-written paper while he was a professor of medicine at the University of Texas Health Science Center at San Antonio. Baylor has announced that it will consider whether to punish the professor.

The practice of ghostwriting—an academic sleight of hand—has led some researchers to declare that many journal articles are little more than infomercials. But unbeknownst to the public, medical-school faculty members continue to use standards of authorship that would be unacceptable in any department in the humanities or the social sciences. Sen. Charles E. Grassley of Iowa, the ranking

Republican on the Senate committee, recently released a congressional report on "[Ghostwriting in Medical Literature](#)" that clearly indicates academic medicine has yet to take strong steps to eliminate ghostwriting.

While ghostwriting has lurked in the shadows of academe—and the true extent of the practice is hard to determine—some telling details can easily be found by surfing the Web. The promotional campaigns for all the best-selling drugs mentioned above used ghostwritten articles. For example, in 2003, an internal document from Current Medical Directions, a company that specializes in "promotional medical education," was published on the Web. The document ([still available](#)) listed a number of in-progress articles on the antidepressant Zoloft; some of the papers were complete, with the author listed as "to be determined." In other words, some were ghostwritten before the company had located academics willing to serve as the named authors.

As we discussed in an [article](#) published this year in *PLoS Medicine*—"Ghostwriting at Elite Academic Medical Centers in the United States"—by cross-referencing published articles with the CMD list, we discovered that some of the most prestigious academic psychiatrists in the United States put their names on articles created at the company and did not disclose the corporate authorship in the published article. For example, one review article managed by CMD recommended Zoloft as the preferred antidepressant, without disclosing Pfizer's role in the publication.

Similarly, because of legal action, behind-the-scenes documents are available regarding the most infamous of ghostwritten studies, Study 329. That study, a clinical trial of Paxil for children, failed to find a positive effect for the medication and found evidence of harm. However, a ghostwritten article, managed by the marketing department of SmithKline Beecham, reported that Paxil was generally safe and effective.

Given its scandalous flavor, it is not surprising that there has been a flurry of recent media attention on ghostwriting. In one case, reported by *Bloomberg Businessweek* but more fit for the tabloids, recent court documents show that AstraZeneca's former U.S. medical director for Seroquel—a drug used to treat schizophrenia—

was having sexual relationships with both a Seroquel researcher and a ghostwriter. Lawsuits allege that those relationships compromised how the Seroquel studies were reported and were one reason AstraZeneca was able to hide data about the medicine's risk of weight gain and diabetes.

While the media has tended to focus on "the professor who gets a freebie," usually a publication for one's résumé, there is a larger problem. When ghostwritten articles are published under the byline of esteemed researchers from prestigious institutions, they allow pharmaceutical companies to mislead the public.

Yet our study showed that the majority of academic medical centers do not have policies prohibiting ghostwriting. We found that only a few ban ghostwriting explicitly (they include Stanford and the Johns Hopkins Universities and the University of Iowa). And some have policies that are weak on enforcement or ambiguous about how the policies are even defined.

Like Senator Grassley, we believe that if someone is involved in writing a paper, then he or she should be listed as an author. In a sense, we are not really proposing anything new. We are only suggesting that the medical community follow the same definition of the word "author" as the rest of the academic world.

Unfortunately, several universities that are attempting to deal with the ghostwriting problem seem to be bypassing that simple, straightforward solution in favor of overly and needlessly complex policies. More and more frequently, for example, we see medical writers listed in the acknowledgments section "for editorial assistance." While that brings to mind the image of a copy editor, in reality a medical writer actually wrote the paper. If we were the pharmaceutical companies, that is exactly the tack we would take, but we are a little surprised that academic medicine seems to be buying the argument. To legitimize "acknowledging" the "editorial assistance" of the main (nonacademic) author of a paper is nothing more than tiptoeing around the definition of authorship—hardly different from the current practices. Those names are not mentioned in the abstract; they are not indexed in publication databases such as PubMed, not mentioned in subsequent citations, and, to the companies' certain pleasure, not mentioned in news-media accounts of the article.

Some universities have insisted that they do not need policies, since they categorize ghostwriting as plagiarism, something they already ban. But in many cases, since plagiarism rules have been in place for ages, that means that the academic medical center has not caught up to recent practices and is actually letting a form of plagiarism go unprosecuted. Other institutions say they do not "expect" their professors to be involved with ghostwriting, but it is unclear if that means the practice is banned or just that administrators frown upon it. Since we found that several famous ghostwritten papers in the medical literature have come from institutions that do not "expect" their professors to ghostwrite or that equate ghostwriting with plagiarism, such policies seem to be pointless.

Baylor has said that it will investigate the Avandia case. but there is nothing unique about it. In fact, given how clinical-trial literature has been produced over the past 10 years, it is probably representative of the norm. What about the rest of the ghostwritten literature?

The slogan "evidence-based medicine" has been the dominating message from academic medicine during the past decade. The idea is that the decision to use a certain treatment for a given condition should be based on evidence in the peer-reviewed literature. It is ironic that a practice that has tainted the entire clinical-trial literature has been tolerated during this era.

In addition to university administrators, the National Institutes of Health also has the power to curtail ghostwriting. Given that NIH grants are financed by taxpayers and the agency's mission is to promote public health, it is hard to see any justification for it to continue supporting researchers at medical schools that have inadequate ghostwriting policies.

Ghostwriting is not a harmless practice. Many of yesterday's blockbusters are today the subject of huge lawsuits over hidden side effects and inappropriate marketing practices. If the original authors had been listed on the byline of the articles endorsing the use of those blockbusters, would the medical community have so wholeheartedly embraced them?

Whether the byline includes a list of esteemed researchers from

prestigious institutions—essentially an endorsement by both the professors and the university—or it includes a list of company employees is certainly important to a reader forming an opinion about the conclusions. Banning ghostwriting by calling an author an author is straightforward and immediately enforceable.

Anyone from outside the academic-medical community must be wondering why such steps have not already been taken. With a stroke of their pens, medical schools and the NIH could put an end to ghostwriting and industry marketing masquerading as science, and promote a return to the promise of evidence-based medicine.

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