

Examining the Ethics of Ghostwriting in the Pharmaceutical Industry

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Introduction

The topic of “ghostwriting” in the pharmaceutical industry has recently gained increasing visibility because of the heightened level of scrutiny associated with the lack of transparency between clinical publications and the pharmaceutical industry. Furthermore, there is a lack of transparency regarding the potential conflicts of interests tied to academic researchers who are often the lead authors for key publications in peer-reviewed journals.

In 2008, Senator Charles E. Grassley wrote to the former Wyeth, now Pfizer, to inquire about ghostwriting practices specific to the promotion of hormone products used in women (Wilson, 2008).¹ The investigation revealed that Wyeth had hired a medical communications company in Princeton, New Jersey called DesignWrite Inc. to write articles regarding the breast cancer risk of hormone therapy and then invited academic researchers to sign these papers as lead authors. In effect, the writing company was authoring a document and then recruiting physicians to sign their names as lead authors after the manuscript had been written. In 2009, documents from the Wyeth investigation were publicly released on the Internet (Barbour, 2009).² These documents showed the public how Wyeth had engaged in ghostwriting practices around their hormone therapy products. Specifically, the *New York Times* posted one public document titled, “A Case Study in Medical Writing” (Singer, 2009).³ The article outline included the following: “DesignWrite, a medical writing company, drafted an outline for an article about menopausal symptoms like hot flashes and night sweats... It was part of a cache of documents unsealed by a court on Friday, July 31, 2009 in a personal injury lawsuit.”

In June 2010, Senator Charles E. Grassley released a report titled, “Ghostwriting in Medical Literature” (Grassley 2010).⁴ In that report, Grassley provided key findings that revealed the role of pharmaceutical manufacturers in the practice of ghostwriting. He emphasized the fact that there is a lack of transparency when articles get published in medical journals.

When a clinician reads a medical article in a peer-reviewed journal, he may not find information to answer questions such as:

- Did the lead author get paid by the pharmaceutical manufacturer to write the article?
- Was the article drafted by an outside writer or a medical writing company?
- What type of financial relationship do the authors have with the pharmaceutical manufacturer?

Prior to Senator Grassley's investigations with Wyeth, the practice of ghostwriting in the pharmaceutical industry had not been heavily scrutinized because the public were not aware of the practice and the lack of transparency that exists when a medical article is published in a scientific journal. Moreover, most practicing clinicians were also not aware that their academic colleagues were signing their names to articles that were written by other parties. Historically, medical writing and communications companies were involved in the practice of ghostwriting and the pharmaceutical industry was supportive of the practice. Now, most companies avoid the term ghostwriting because of the negative connotations associated with the term. Is the practice of ghostwriting in the pharmaceutical industry unethical? We will examine this question through the utilitarian and rights frameworks by exploring potential alternatives to ghostwriting.

Alternatives to Ghostwriting

There are several alternatives to the traditional practice of ghostwriting for the pharmaceutical industry. Before we can evaluate those alternatives, we must clarify what we mean by defining the term, "ghostwriting."

Traditional ghostwriting is the practice whereby an outside writer or a writing/communications company drafts a paper and then approaches an academic faculty member and invites that person to be the author for the paper. When the writing company

submits the paper for publication, the academic faculty member is designated the author and the writing company does not usually disclose its role in authoring the paper. Hence, there is a lack of transparency regarding the involvement of the writing company related to the published article. In most cases, the academic faculty member does not do much to revise or edit the paper that is submitted for publication. In some instances, the lead author faculty member may not even review the paper.

Under this traditional definition, three major alternatives to ghostwriting become evident. Although there are other possibilities, we will review and discuss the following concepts:

- Alternative #1: Academic authors write the entire paper themselves. They receive no editorial support or assistance from any medical education, marketing, or communication companies or writers. Thus, there is no role for an outside writer or company to assist in the process and influence the content that is generated by the author. This would place the burden of writing, editing, and publishing the paper entirely on the academic faculty author. Because the author is not receiving any type of editorial support from outside organizations, the content of the article will not be influenced by other parties. However, papers will not get published efficiently because many authors will be too busy to write, edit, revise, and review articles in a time-efficient manner.
- Alternative #2: Academic authors write the paper themselves, but they also receive editorial support or assistance along the way from an outside writer or writing company. In this example, all the content for the paper would originate from the academic authors and all document drafts would be reviewed and approved by the authors. An outside writer or writing company would have a moderate role in the process and this would be disclosed in the publication. This would not be considered “ghostwriting” because all parties involved in writing or editing the manuscript are identified within the publication. There would be full transparency regarding the role of the author, outside

writers, and writing companies. Furthermore, the academic faculty would be required to generate all the content and not simply provide an outline for another writer.

- **Alternative #3:** Scientific papers are written where the academic authors provide a content outline to a writing company and then rely on the writing company to fill in the details and to draft the document. Then, the academic authors review the content, make revisions after reviewing all drafts, provide feedback to the writing company, and approve the final draft prior to submission to a journal. A writing company would have a heavy role in the process, but the academic faculty members would also be heavily involved throughout the process of the document generation. The final document would reflect content that primarily originated from the faculty and the writing company would disclose its role in the publication. This may not be ghostwriting because all parties involved in writing or editing the manuscript are identified within the publication. Hence, there will be full transparency regarding the role of the author and outside writers. However, the content could be heavily influenced by writers who are not the main authors. Therefore, the paper may not accurately represent how much time the lead author spent on the paper compared to the supporting writers and editors.

Utilitarian Framework: Stakeholders & Alternatives

Under the utilitarian framework, we can evaluate the practice of ghostwriting against each of the three alternatives:

Stakeholders	Ghostwriting	Alternative #1	Alternative #2	Alternative #3
Pharmaceutical company	+++		+	++
Shareholders	+++		+	++
Writing/communication	+++		+	++

companies				
Academic faculty authors			+++	+
Journals		+	+++	
The medical community		+	+++	
Patients		+	+++	

The pharmaceutical company wants to get new drugs approved and wants a wealth of literature in the peer-reviewed journals supporting the safe and appropriate use of their approved products. The most efficient process to get articles published is to heavily rely on writing companies to do most of the work. This is why ghostwriting has been such a popular practice. Publishing clinical research requires a significant amount of work outlining research protocols, analyzing patient data, summarizing key clinical findings, and drafting conclusions. Alternative #1 would be the least efficient and alternative #3 would be the most efficient alternatives to traditional ghostwriting.

Shareholders are most interested in the financial performance of a pharmaceutical company, so they will benefit most from ghostwriting and alternative #3. These individuals want to see pharmaceutical companies generate high profits and have successful products on the market.

In order to stay in business, outside writers and writing companies rely on ghostwriting projects or on opportunities to provide editorial support to busy academic faculty members. Therefore, these organizations would gain the most by continuing the ghostwriting practice and through alternative #3. However, in order for them to maintain a role in an ethical manner, they would need to disclose their involvement and provide full transparency by listing all author names and funding sources.

Academic authors remain very busy with clinical responsibilities, research, teaching, and administrative duties. Most do not have the required support staff of writer and editors to assist them with writing research manuscripts. Therefore, the task of writing a paper can be a heavy burden for a busy physician who is also managing patients in a clinical setting. Traditionally, some academic faculty members have relied on fellows, residents, and medical students to provide some level of editorial assistance with publications. Faculty will gain the

most if the papers that are published reflect their own, original content. This can be achieved by the faculty writing the papers entirely themselves, but they are also burdened with time constraints. Alternative #2 would still allow faculty to author papers and receive editorial assistance to make the process more efficient. By allowing clinical findings to get published in an efficient manner, life-saving clinical evidence may get disseminated to practicing physicians and may improve patient outcomes. If these key findings are not published in an efficient manner, then valuable information that may include life-saving strategies and interventions will be hidden from practicing physicians.

Scientific journals provide an important service to the medical community. They allow clinicians to stay current regarding the latest clinical evidence that impacts patient care. Journals that publish peer-reviewed articles benefit from having a high volume of high-quality articles that include relevant information for clinicians. Alternative #2 yields the greatest benefit because this ensures the right balance to help faculty create articles relatively efficiently, but it also promotes high-quality papers because writing companies are able to assist faculty with editorial processes.

The medical community is mainly interested in credible, reliable scientific findings in peer-reviewed publications so that they can apply the latest evidence when they are treating patients. Therefore, they would benefit most from alternatives #2 because this results in a relatively efficient production of scientific articles that are authored by leading faculty.

Patients ultimately benefit when practicing clinicians are applying the latest evidence in the clinical setting. In order for this to happen, the production of scientific information should not be impaired by the time constraints of busy academic faculty but the papers must also accurately reflect authorship. Hence, alternative #2 achieves this balance appropriately.

Rights Framework: Stakeholders & Alternatives

When we examine the practice of ghostwriting through the lens of rights theory, we find that ghostwriting violates the rights of the medical community and patients because it is a form

of deception. Clinicians deserve to have access to honest, accurate information. They rely on this information when making clinical decisions that impact patient care.

Traditional ghostwriting deceived clinicians because the authorship of articles was masked. If clinicians knew that certain papers were authored by writing companies and not by academic authors, they may not apply that information in the setting of patient care unless they could validate its credibility and relevance against other sources.

Pharmaceutical and writing companies have a right to conduct business in an ethical manner, but they must conduct business in a way that will not infringe on the rights of the other stakeholders. Pharmaceutical shareholders have a right to profits, but not at the expense of violating the rights of clinicians who rely on scientific papers to make clinical decisions that ultimately impact patients. Academic faculty members who are very busy with clinical and research responsibilities have the right to receive editorial assistance from writing companies.

Alternatives #2 and #3 preserve the rights of pharmaceutical and writing companies to stay in business. These alternatives also ensure that clinicians are not being deceived because the faculty are authoring papers and receiving editorial support to make the process more efficient. Moreover, scientific papers would disclose that editorial support was provided by writing companies, so this level of disclosure will inform the medical community about the role of different parties in the publication process. Disclosure helps to preserve the right to honest information and protects the medical community from potential deception.

Alternative #1 does not protect the rights of pharmaceutical companies to get research data published in an efficient manner. It also does not protect the rights academic faculty to receive editorial assistance from writing companies.

Conclusion and Recommendations

Although ghostwriting may be acceptable in other industries outside of health care, lead authors who are publishing scientific papers in academic journals are called to a higher standard because the information they generate may directly impact patient care. As a result, clinicians who are relying on published scientific evidence have a right to know who drafted the

article and about potential conflicts of interests related to the article and pharmaceutical manufacturers. There is a need for increased transparency around all of these issues so that clinicians who read and evaluate these papers may have all the relevant facts to make judgments regarding the clinical utility of the published data.

In the past, the practice of ghostwriting in the pharmaceutical industry was invisible to the public and to most practicing physicians. Writing companies who were engaging in ghostwriting did not disclose their involvement in published articles. The medical community did not know when a published paper had been written by the stated author or by a third party. Moreover, some papers were published in peer-reviewed journals where the first author listed on the paper never even reviewed the manuscript.

The ethics behind ghostwriting has come under scrutiny recently and this has led to changes in the medical publishing industry. When we examine the ethics behind traditional ghostwriting and alternative options through the utilitarian framework, we find that alternative #2 achieves the greatest benefit for all stakeholders. We also find that alternative #2 preserves the rights of major stakeholders without compromising the rights of other stakeholders. For these reasons, alternative #2 appears to be an ethically acceptable method that balances the rights of all the stakeholders while allowing scientific research to get published in an efficient manner.

Alternative #2 should get endorsed by professional organizations including the Pharmaceutical Research and Manufacturers of America (PhRMA), the International Society for Medical Publication Professionals (ISMPP), the International Association of Scientific, Technical & Medical Publishers (STM), the American Medical Writers Association (AMWA), and other trade organizations. Furthermore, alternative #2 should get endorsed by the American Medical Association (AMA), the Association of American Medical Colleges (AAMC), and the Association of American Medical Colleges (AAMC). These organizations exist to provide guidance through a collaborative spirit of working together to improve patient care. By endorsing a universal policy around the practice of medical and scientific writing and publishing, these organizations can be instrumental in ensuring that academic researchers, the pharmaceutical industry, and the

publishing community are following the same set of standards to ensure that ethical boundaries are not being crossed.

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