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## The Haunting of Medical Literature

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### Abstract

*Ghostwriting*, or using the names of academic researchers to validate studies commissioned by pharmaceutical companies, has become a growing concern within medical literature. Omission from authorship of the names of individuals making considerable contributions to a paper is one of the most significant aspects of ghostwriting. Policy prohibiting medical ghostwriting is lacking, and it is nearly impossible to prevent the practice without strict and thorough guidelines. More strict guidelines banning ghostwriting, denying government funds to organizations without such policies, and development of databases to track offending authors and organizations could decrease the impact of ghostwriting in medical literature.

### Background

Clinical evidence has come to be revered as the standard of truth in medical practice. Pharmacists turn to clinical literature to make sound recommendations for patient drug therapy. It is often assumed that the integrity and validity of a published paper is ensured by referring to literature in esteemed, peer-reviewed journals. However, ethical considerations and conflicts of interest in authorship are slipping through quality assurance systems employed by these journals and threatening the foundation of medicine. *Ghostwriting*, or using the names of academic researchers to validate studies commissioned by pharmaceutical companies, has become a growing concern within medical literature.<sup>1</sup> Also concerning may be the use of *publication planning*, a form of systematically populating medical literature on the corporate scale. Publication planning is conducted by a team of people employed by a pharmaceutical manufacturer in an attempt to control every possible aspect of public information available about a drug of interest.<sup>2</sup> Publication plans include strategies for conducting explicit trials that yield desired results combined with the carefully timed release of information to specific target audiences. In some cases, the planning team may be more responsible for manuscripts submitted to medical journals than the respected author(s) appearing on the page.

### Contributing Factors

The first factor contributing to medical ghostwriting is the definition of authorship. The correct protocol for listing authors is complicated by historical methods of listing authors alphabetically or listing the head of department as lead author as a sign of respect.<sup>3</sup> Currently, the International Committee of Medical Journal Editors defines authorship as fulfilling all of the following criteria for authorship: substantial contribution to conception and design, acquisition of data, or analysis and interpretation of data, drafting the article and/or revising it critically for important intellectual content, and final approval of the version to be published.<sup>4</sup> Omission of the names of individuals making consider-

able contributions to a paper from authorship is one of the most significant aspects of ghostwriting. More importantly, with the title of author comes a responsibility to ensure that the paper's content, intent and findings are based on the results of the study and scientific principle and not skewed by financial or political gain.<sup>5</sup> Authors list disclosure statements to inform the reader of existing conflicts of interest; however, the term "conflict of interest" is difficult to define. These conflicts typically include employment, grants and other financial support, but the lines become blurred when referring to patent rights, personal relationships or political ties. When the true authors are excluded from publications, they cannot be held responsible for the integrity of their work.

Policy prohibiting medical ghostwriting is lacking. In an evaluation of 50 of the top academic medical centers in the United States, 52 percent had no published policy regarding authorship or ghostwriting.<sup>1</sup> Without a policy in place, it is nearly impossible to stop this type of unethical misconduct. While the responsibility of honesty and disclosure lies with the author, there are few tools available for editors to police authorship validity.<sup>5</sup> A mere 8.8 percent of journals have a policy for verifying author claims and conflicts of interest.<sup>6</sup>

### A Case of Ghostwriting

An example of ghostwriting that is thought to significantly impact the medical literature was when a pharmaceutical manufacturer attempted to prove that their drug could be used as an antidepressant in adolescents.<sup>7</sup> This study's results were published in the *Journal of the American Academy of Child and Adolescent Psychiatry* and listed 22 authors. The idea for the study came from the primary author and was accepted and conducted by the pharmaceutical manufacturer. However, the result of this study and similar studies showed no efficacy for the drug in adolescents compared to placebo. The manufacturer worried that the lack of efficacy in pediatrics would possibly make the medical community question the efficacy of the drug in general. Therefore, the manufacturer decided only to publish the positive findings from the study. A medical publishing company was hired to draft the positive information and prepare it for publication.

A synopsis of the clinical report was provided to the ghostwriter in the medical publishing group who used this shortened report to write the first draft of the manuscript. The ghostwriter also was found to have contributed to the article by developing and implementing a publication plan, responding to peer-reviews, and providing the primary author with drafts and cover letters.

Research looking into the communication between the listed authors and employees at the medical publishing company showed that many of the 22 listed authors had little to no involvement with the article. The ghostwriter was actually the primary writer of the article drafts, even though not listed as such. Also, it was shown that the second and third authors made only minor edits to the article throughout the process. Many of the authors were shown to have only made small edits to one of the drafts, having only assisted in running the study, or having made no recognizable contribution at all.<sup>7</sup>

A major issue with the first draft was that there were noticeable differences between it and the final clinical report, even though this was the source used to write the first draft. In the clinical report it is stated that only two primary outcomes were measured. In the first draft, eight primary outcomes were mentioned; four of these outcomes showed increased efficacy of the drug over placebo, which contradicts the findings of the study. Also, the line between the primary and secondary outcomes was blurred. After peer review, the article was edited again to include only the original two primary outcomes, but the information was presented in such a way that one of the outcomes appeared to be positive and reinforced the idea of efficacy for the drug. The side effects of the medication were inconsistent with the original report as well, and the seriousness of some listed side effects was not expressed.<sup>7</sup>

The results of this study being published include many clinicians believing the drug to be an effective and highly tolerable medication for adolescents. In 207 articles published since 2008, this study was mentioned and used as evidence that the drug is effective for use in adolescents. Only 31 of these articles correctly presented the information from the original study and showed slight skepticism over the results of the publication.<sup>7</sup>

### Possible Solutions

Strict definitions of authorship need to be included in the policies of both medical journals and academic medical centers. It is not enough to condemn ghostwriting; the term needs to be extensively defined to be enforceable.<sup>1</sup> This strategy can further be amplified by government funding denying grants to institutions that lack these stringent ethical policies. Enforcement of these policies could be further reinforced by journals requiring listed article authors to sign a statement guaranteeing the integrity of their article and holding them accountable if dishonesty is suspected.<sup>8</sup> If violation of these policies is proven, offenders could be punished by revoking government funding, refusing to publish subsequent works by the author, and enforcing legal responsibility for falsifying documents.<sup>1</sup> These exclusions could be made possible by compiling an online database for easy access to a list of an author or institution's ethical infractions.<sup>8</sup>

### Discussion

Ghostwriting will not be stopped until all levels of medical publishing commit to higher standards for literary ethics. Practitioners have a right to be informed of these conflicts of interest in literature so they can make their own decisions about the clinical validity of the evidence they are reading. Ghostwriting and publication planning allow publication of biased or incomplete information that may be harmful to patients who begin therapy with a medication with side effects and risks that are not fully disclosed. Many patients now may be suffering from severe adverse effects of medications because the dangers were not known and the treatment was marketed as being safe and effective. Ghostwriting is an emerging problem in medical writing that not only has ethical implications, but also affects patients and their wellbeing. The quality of medical care provided to patients is only as strong as the integrity of the literature that backs it.

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