
Ghostwriting

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Introduction

One of the hidden secrets of the medical literature is that the named authors on a paper's byline, particularly in the case of clinical trials, are not necessarily the individuals who wrote the paper. It is not uncommon for pharmaceutical companies, or medical product manufacturers, to write their own papers and then find university professors to agree to be the named authors of the paper. The company employees are then invisible to the readers. Presumably, the suggestion that a certain medication or medical product is safe and efficacious will carry more weight if it comes from a supposedly unbiased source a key opinion leader (KOL), rather than a company representative (Leo, Lacasse, & Cimino, 2011).

Definition

Medical ghostwriting is the practice of pharmaceutical companies secretly authoring journal articles published under the byline of academic researchers. This allows pharmaceutical companies to use the peer-reviewed literature as a venue for promoting their products. Much has been learned about ghostwriting from the release of internal pharmaceutical company documents. For instance, in their marketing plan for Lexapro, Forest Pharmaceuticals succinctly summarizes their use of the peer-reviewed literature for marketing purposes: "Bylined articles will allow us to fold Lexapro's message into articles into depression, anxiety, and comorbidity developed by (or ghostwritten) for thought leaders." Alleged ghost authors haunt the clinical trial literature of virtually all the recent blockbuster drugs,

including medications such as Vioxx, Avandia, Paxil, Zoloft, Zyprexa, hormone replacement therapy, and fen-phen (McHenry, 2010). Recently, a public dialogue on ghostwriting has emerged, with public advocacy organizations and some medical journal editors, practicing physicians and bioethicists voicing their perspectives and calling for reform.

Keywords

ICMJE authorship guidelines; Study 329; Paxil; medical writer; honorary authorship

Traditional Debates

It is generally acknowledged in the medical literature that the most egregious example of ghostwriting is Study 329 which was published in the *Journal of the American Academy of Child and Adolescent Psychiatry*. The study examined the use of Paxil in adolescents and concluded, "Paroxetine is generally well tolerated and effective for major depression in adolescents." Several years after the paper was published, court proceedings revealed internal company documents admitting that the study found that Paxil was not any better than placebo on the preregistered outcome measures and that the company was primarily concerned about how to manage the negative findings.

A series of documents, all available on the web, reveal the steps involved in Study 329's transformation from an initial idea to a final draft. Sally Laden, an employee of Scientific Therapeutics, was hired by GlaxoSmithKline, which makes Paxil, and wrote the first draft. After each draft was submitted, she incorporated suggestions from some of the listed authors into each subsequent draft. But, rather than be listed as one of the 22 academic coauthors listed on the byline, Laden was only acknowledged for editorial assistance (Jureidini, McHenry, & Mansfield, 2008).

Study 329 was prominently featured in the recent Department of Justice's report on GlaxoSmithKline's illegal marketing practices

(Department of Justice [DOJ], 2012). The report resulted in GSK being fined three billion dollars. While the DOJ treats GSK as the sole author of Study 329, only two of the named authors were actually GSK employees. All of the other named authors were affiliated with universities. In their complaint about Paxil and the role of Study 329, the DOJ did not mince words: “The United States argues that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misrepresented that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy.” They also note that the article, “. . . misstated Paxil’s efficacy and safety for children and adolescents” (Basken, 2012).

Charges of ghostwriting have also surrounded several scientific papers that reported positive findings regarding the use of Vioxx, a medication pulled from the market in 2004 due to safety concerns. In response to questions about a paper in the *Annals of Internal Medicine*, Jeffrey Lisse, the lead author, stated, “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” (McHenry, 2010).

In 1997, an employee of GSK wrote an internal company memorandum discussing two letters to the editor about Paxil. The memo stated, “We’ve written two draft letters to the editor regarding the Lilly discontinuation supplement.” The memo goes on to discuss the fact that the references are the same for both letters and suggests that, “. . . complete duplication will look fishy if we decide to submit both. At the very least we can’t have the references appear in the same order” (McHenry, 2010).

Critical Debates

A recent case of alleged ghostwriting involves the textbook “Recognition and Treatment of Psychiatric Disorders,” published by the American

Psychiatric Press (APP) in 1998. The named authors are Charles Nemeroff, current chairman of psychiatry at the University of Miami, and Alan Schatzberg, former chairman of psychiatry at Stanford and former president of the American Psychiatric Association. Documents recently released as part of discovery in a lawsuit against GlaxoSmithKline have led to allegations that the textbook involved ghost authors employed by the manufacturer of Paxil. The APP’s trade journal, *Psychiatric Times*, defended the textbook’s use of medical writers and declared that they stand behind the authorship line because Drs. Nemeroff and Schatzberg signed off on the final copy. James Scully, medical director for the APA, stated: “The book was reviewed for any potential bias (among other things) by eight independent reviewers, and there was no undue influence on the content from industry or any other outside source” (Moran, 2011). The idea that it is acceptable for papers to have misleading bylines, as long as the paper is reviewed by outside experts, is debatable (Leo & Lacasse, 2012).

The International Committee of Medical Journal Editors (ICMJE), a group of medical editors who have developed policies related to the medical publishing process, has proposed three criteria for determining who should be given a byline as author on scientific papers. These criteria are “(1) substantive contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published.” While these are now the traditional, oft-cited criteria for authorship, they do not address the contemporary concern of ghostwriting. Consider this hypothetical situation: An industry-funded medical writer authors a paper in conjunction with academic researchers. The medical writer authors the first draft of the paper and makes many substantive edits, eventually writing 99 % of the paper. Before the absolute “final” version is reached, the medical writer turns it over to the academic researchers and never approves the final version; the medical writer is acknowledged for editorial

assistance. Although the byline is not an accurate representation of who contributed to the article, the paper meets the ICMJE guidelines. Several groups, including some medical writers, have pointed out that this is a loophole in the ICMJE guidelines (Matheson, 2011).

As ghost authoring gains more notice, some journals have adopted policies stricter than the ICMJE guidelines. For instance, the journal *Neurology* has instituted a much more stringent policy. Rather than asking who is an author per ICMJE criteria, they ask, “Who influenced the content?” and require that any paid medical writer be included in the author byline, accompanied by full disclosure. In their authorship standards, they define a ghostwriter as “an undisclosed person (paid or unpaid) who has made an intellectual contribution in writing the submitted manuscript”.

The concepts of ghostwriting and honorary authorship are often confused in the medical literature, but importantly, are different concepts. Honorary authorship involves an undeserving person being listed on the byline, whereas ghostwriting involves a deserving person not getting credit. The two do not necessarily go together. It is possible for the contributions of named authors on a paper to warrant authorship, but if someone else deserving of authorship credit did not appear in the byline, the paper has still been ghostwritten. The extent of the named authors’ involvement in the paper is immaterial in determining whether the paper was ghostwritten; the extent of involvement of unnamed authors is of key importance.

The Purpose of the Acknowledgement Section

Traditionally, the acknowledgement section of a paper is reserved for people who do not rise to the level of the byline – laboratory assistants or copyeditors, for instance. Several groups in medicine including the European Medical Writers Association (EMWA) endorse the practice of thanking medical writers for providing “editorial assistance” in the acknowledgment section of the paper instead of listing them on the authorship byline. Recently, eight pharmaceutical

companies and several medical journals formed a committee titled, Medical Publishing Insights and Practices (MPIP) and published a statement in *Mayo Clinic Proceedings* on how to close the credibility gap in industry-sponsored clinical trials. They had ten recommendations, one of which was to: “Improve disclosure of authorship contributions and writing assistance, and continue education on best publication practices to end ghostwriting and ghost authorship.” It is unclear from their document whether the committee believes that medical writers who make substantial contributions to the text should be listed on the byline or in the acknowledgement section. In e-mail correspondence with the lead author, who is a senior editor at *Lancet*, it was confirmed that the committee believes that it is acceptable to leave medical writers off the byline and to instead mention them in the acknowledgement section.

However, there are others who do not sanction the practice of moving writers from the byline to the acknowledgement section. As one example, in a report from the Senate Committee on Finance titled, “Ghostwriting in the Medical Literature,” Senator Charles Grassley stated, “Despite its acknowledgement of medical writers for ‘editorial assistance,’ the role of pharmaceutical companies in medical publications remains veiled or undisclosed.” Others have pointed out that “editorial assistants” are not listed in PubMed, are not listed in the abstract, are not cited, and are not called by the media to talk about the importance of a study. Therefore, there is one, and only one, criterion to determine whether a scientific paper has been ghostwritten: If a deserving author has been left off the byline, then the paper should be considered ghostwritten (Leo et al., 2011).

Consequences to Ghostwriting

A recent article in the *Chronicle of Higher Education* titled “Academic Researchers Escape Scrutiny in Glaxo Fraud Settlement” pointed out that none of the academic authors of Study 329 have faced any scrutiny from their universities or other journals. In fact, shortly after the DOJ report was released, two of the named authors of Study 329 had articles published in *Psychiatric*

Times, the main trade journal for the psychiatry profession. One of Study 329 authors published an article giving advice to new psychiatry residents, and a second 329 author had a review article on the use of antidepressants in children, which concluded that the SSRIs do not contribute to an increase risk of suicidality. In addition, the journal that published Study 329, *The Journal of the American Academy of Child and Adolescent Psychiatry*, has never retracted the paper.

Jay Amsterdam, a professor of psychiatry at the University of Pennsylvania, recently charged several colleagues with ghostwriting. A committee at Penn exonerated the professors primarily based on the fact that in 2001, when the study was published, ghostwriting was considered acceptable. In their words, “While current Perelman School of Medicine policy and journal practice call for acknowledgement of the assistance of a medical writer, the committee concluded that guidelines in place in 2001 did not.” It is interesting that under Penn’s new policy, it is acceptable for medical writers who write the majority of the paper to simply be listed in the acknowledgement section; this is how Study 329 was handled, and Study 329 is widely accepted as an example of ghostwriting in the medical literature. The Office of Research Integrity, which reports to the Secretary of Health and Human Services, is still investigating the complaint (Leo & Lacasse, 2012).

As of 2010, only about a third of US medical schools had a policy in place concerning ghostwriting (Lacasse & Leo, 2010). It is expected that over the next several years, an increasing number of medical schools will implement policies that ban ghostwriting.

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Global Justice

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Introduction

The interdisciplinary field of Global Justice Research originates in Political Philosophy, with Thomas Pogge (2002, 2010) being the founding