



Ghostwriting in Medical Literature

Minority Staff Report

111th Congress

**United States Senate Committee on Finance
Sen. Charles E. Grassley, Ranking Member**

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BACKGROUND

In 2005, the Senate Committee on Finance (Committee) initiated an inquiry into educational grants for continuing medical education (CME) programs. This inquiry began after reports that drug companies were using the grants to promote off-label uses of their drugs, *i.e.*, uses that had not been approved by the Food and Drug Administration. The findings of that inquiry were released in a Committee staff report in April 2007.¹ The Committee's inquiry revealed that the pharmaceutical industry spent more than a billion dollars a year to fund CME programs.

Since releasing that report, Ranking Member Charles Grassley expanded his inquiries into the financial relationships between drug and device companies and academic physicians and scientists. These financial relationships include payments to physicians and scientists for consulting services, speaking engagements, and research activities. Senator Grassley also examined the policies and reporting practices at over a dozen medical schools in the United States and found that the medical schools have not adequately monitored the outside income of their researchers and faculty. The National Institutes of Health (NIH) relies on an institution to report and manage its faculty members' conflicts of interest in order to maintain the integrity of federal funding for biomedical research. However, Senator Grassley found cases where there were vast disparities between the amounts of payments leading physicians and scientists received from drug companies and the amounts they reported to their institutions.

Senator Grassley's inquiries led to the introduction of the bipartisan Physician Payments Sunshine Act, which he co-authored with Senator Herb Kohl. This bill was incorporated into the recently passed health care reform legislation, the Patient Protection and Affordable Care Act,² which was signed into law by President Obama on March 23, 2010. Beginning in March 2013, drug, device, and biologics manufacturers will be required to report annually payments they made to physicians nationwide.

About two years ago, Senator Grassley inquired about an industry practice to get articles published in major medical journals touting the benefits of a company's product without public disclosure that the company initiated and paid for the development of the articles. Specifically, Senator Grassley wrote to Merck & Co., Inc. (Merck) and Scientific Therapeutics Information (STI), a medical publishing company, following the publication of a study in the *Journal of the American Medical Association (JAMA)*.³ In that study the authors examined Merck's manipulation of scientific literature through ghost writers to market the painkiller Vioxx. Notably, based on their review of court documents the authors of the *JAMA* article concluded that "review manuscripts were often prepared by unacknowledged authors and subsequently

¹ Committee Staff Report to the Chairman and Ranking Member, *Use of Educational Grants by Pharmaceutical Manufacturers*, S. Prt. 110-21, April 2007, available at <http://finance.senate.gov/newsroom/chairman/release/?id=af4af834-3fab-4293-be6d-ca7f1246484f>.

² Pub. L. No. 111-148, § 6002 (2010).

³ Merck removed Vioxx from the market in 2004 because of cardiovascular risks.

attributed authorship to academically affiliated investigators who often did not disclose industry financial support.”⁴

Medical ghostwriting is a practice where pharmaceutical or device companies hire medical education, marketing or communications companies to draft articles that are presented to prominent physicians and scientists to sign on as authors to increase the likelihood that the article will be published in important medical journals. Ghostwritten articles include articles that are drafted by pharmaceutical or device company employees who are not acknowledged in the final publication. The articles may be review articles, editorials or primary research papers, and they are typically presented to physicians and scientists affiliated with academic institutions. The physicians and scientists agree to sign on even if they may not be intimately familiar with the underlying data or relevant research or provided limited input on the article. Authors who make little to no contribution to a publication are also referred to as “guest” authors.

Senator Grassley is concerned about the lack of transparency that exists in medical ghostwriting. Not only are the articles typically initiated and paid for by a pharmaceutical or device company, but also more significantly, the final publications do not disclose the company’s role and financial support for the article. Ghostwritten articles can have a significant impact on, among other things, physician prescribing practices. When prominent physicians and scientists lend their names to an article, it raises the credibility of the findings and conclusions presented. This, in turn, can affect the pocketbook of the American taxpayer since Medicare and Medicaid pay billions of dollars for prescription drugs. In addition, manipulation of medical literature could lead physicians to prescribe drugs that are more costly or may even harm patients.

A prominent researcher and professor of medicine at a leading medical school informed Committee staff that in the late 1990s and early 2000s it was common practice for pharmaceutical companies to approach him and his colleagues with requests to review and sign on as primary authors to company studies. Specifically, a company would tell a physician or scientist at an academic institution that it completed a study and would like his or her interpretation and feedback on the results of that study. In return, the company would offer that physician or scientist lead authorship on the paper, which was written by someone other than the physician or scientist. The physician or scientist would not be paid for being the author of the paper, but he or she may receive compensation for the time and effort related to reviewing and commenting on the study results. The researcher who contacted Senator Grassley stated that while he was aware of colleagues accepting the companies’ offers, his own policy is “I won’t touch it if I wasn’t involved in the concept of the study.”

In December 2008, Senator Grassley also wrote to Wyeth⁵ about allegations that the company was engaging in the practice of ghostwriting. The Committee was provided with documents from recent lawsuits involving Wyeth’s hormone therapy products. The documents showed that Wyeth hired a medical communications and education company, DesignWrite Inc. (DesignWrite), to draft review articles regarding the breast cancer risk of hormone therapy

⁴ Joseph S. Ross, Kevin P. Hill, et al., “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib,” *JAMA*, 2008; 299 (15): 1800-1812.

⁵ Pfizer, Inc. acquired Wyeth on October 15, 2009.

products and then invited academic researchers to sign on as the primary authors. The documents also revealed information about the process. In one email dated March 24, 1999, DesignWrite's Vice President for Scientific Affairs described the company's role to Wyeth:

The first step is to choose the target journal best suited to the manuscript's content, thus avoiding the possibility of manuscript rejection. We will then analyze the data and write the manuscript, recruit a suitable well-recognized expert to lend his/her name as author of the document, and secure his/her approval of its content. After the client has reviewed and released the manuscript for submission, DesignWrite will see it through the necessary production stages-creating camera-ready figures and tables and the text according to the journal guidelines-and submit the package...to the appropriate journal editor. Any revisions requested by the journal will be handled by DesignWrite in conjunction with the client and the author. Should the journal reject the manuscript, DesignWrite will restyle it for submission to another journal within 10 working days. [Emphasis added] See Attachment 1.

Because medical schools and medical journals have a role in promoting greater transparency and accountability in the development and authorship of medical literature, Senator Grassley wrote to leading medical schools and journals and asked about their positions and policies on ghostwriting. Letters of inquiry were sent to the following medical schools:

- Columbia University College of Physicians and Surgeons (Columbia)
- Duke University School of Medicine (Duke)
- Harvard University School of Medicine (Harvard)
- Johns Hopkins University School of Medicine (Johns Hopkins Medicine)
- Stanford University School of Medicine (Stanford Medicine)
- University of California, San Francisco School of Medicine (UCSF)
- University of Pennsylvania School of Medicine (Penn Medicine)
- University of Washington School of Medicine (UW Medicine)
- Washington University in St. Louis School of Medicine (Washington University)
- Yale University School of Medicine (Yale)

Letters of inquiry were sent to the following medical journals:

- *American Journal of Medicine*
- *Annals of Internal Medicine*
- *Annual Review of Medicine*
- *Archives of Internal Medicine*
- *Nature Medicine*
- *PLoS Medicine*
- *The Journal of the American Medical Association (JAMA)*
- *The New England Journal of Medicine (NEJM)*

The following report presents the Committee staff's findings to date, based on (1) a review of documents provided to the Committee by the medical schools, the medical journals, DesignWrite, Merck, STI, and Wyeth; (2) a review of court documents and publications the staff collected online and through literature search; and (3) interviews with published academic researchers, physicians, and attorneys examining conflicts of interest and/or the practice of ghostwriting.

FINDINGS

A. Despite acknowledgment of medical writers for “editorial assistance,” the role of pharmaceutical companies in medical publications remains veiled or undisclosed

Senator Grassley wrote to Wyeth in December 2008 after receiving documents from recent lawsuits involving the company's hormone therapy products. In his letter, the Senator highlighted three publications as examples of articles that Wyeth had paid the medical communications firm, DesignWrite, to outline and draft for target authors.⁶ According to Wyeth, 44 review articles relating to the Premarin products were authored by outside academic experts with “publication support” from DesignWrite. DesignWrite's documents show that the company “initiated a comprehensive, peer-reviewed publication program in support of the PREMARIN Family of Products” in 1997. One goal of the communications plan was to “restore confidence” in the Premarin family of products.

In Wyeth's response to Senator Grassley, the company described the extent of the authors' involvement in the development and review of the three publications cited in the letter. The timing of the authors' input varied during the development of each article. In one case, input and involvement appeared to have been initiated with the first draft of the manuscript. In the other two cases, Wyeth stated that the authors were involved at an earlier stage in the manuscript's development, providing input on the outline of the drafts as well as the draft manuscripts themselves.

Nevertheless, as Senator Grassley pointed out in his letter to Wyeth, the final journal publications only acknowledged the medical writers for their “editorial assistance” or “assistance.” The articles did not disclose that Wyeth had initiated and paid DesignWrite for the development of the manuscripts and that the medical writers were hired and compensated by DesignWrite. Wyeth stated that DesignWrite was compensated for its work in getting manuscripts drafted and submitted for publication but payments were not allocated for individual articles.

⁶ John Eden, “Progestins and Breast Cancer,” *Am J Obstet Gynecol*, 2003; 188(5): 1123-1131; Lila E. Nachtigall, “Sex Hormone-Binding Globulin and Breast Cancer Risk,” *Prim Care Update OB/GYNs*, 1999; 6(3): 39-45; Trudy L. Bush, Maura Whiteman, and Jodi A. Flaws, “Hormone Replacement Therapy and Breast Cancer: A Qualitative Review,” *Obstet Gynecol*, 2001; 98(3): 498-508.

Wyeth's role did not end with underwriting the cost of manuscript development. It appears from documents in the Committee's possession that Wyeth also reviewed and provided input on the outlines and drafts of manuscripts prepared by the medical writers. However, that involvement also was not disclosed in the final publication. An article published in *PLoS Medicine* in February entitled, "Ghostwriting at Elite Academic Medical Centers in the United States,"⁷ illustrates the points at which a company may be involved in a journal article's development. A company may play a role in reviewing and approving an article at different stages of the article's development. The company may influence the outline, the draft before it is sent to a target author for review, the draft after the author provides comments or edits, or the medical writer's responses to reviewer comments on the article during the peer review process. Another point where the company may play a role is during final approval of the manuscript before the author submits it to the journal. According to an email from DesignWrite to an author dated November 17, 1999, it may be the company that gives an article the green light for submission. *See* Attachment 2.

Documents Merck submitted to the Committee also demonstrate the company's involvement in developing articles for journal publication. For example, STI's June 1999 proposal to Merck on secondary publications shows that STI proposed an outline, author and time frame for Merck's approval to proceed on a specific article. The rest of the timeline shows that the first draft was submitted to the company for review and comment before it was sent to the author for input. Subsequent drafts were also reviewed and approved by Merck before the articles were submitted for publication. *See* Attachment 3.

The editor-in-chief of the medical journal *PLoS Medicine* expressed her concern regarding medical ghostwriting in a statement that was filed in support of the Public Library of Science's motion to intervene and motion for access to discovery materials in the Prempro Products Liability Litigation. In that statement she said:

Medical ghostwriting is a particularly troubling form of manipulation. When they are appropriately acknowledged for their involvement, medical writers paid by drug companies...may have a legitimate role in helping shape papers for publication. However, when the medical writers' involvement is *hidden* they become ghostwriters, and hence they are unaccountable for their work. The fact that ghostwriters are paid for by drug companies, and that their role is by definition hidden, suggests that it is likely that they will write about a company's products in a biased way....When ghostwriters are used, readers are unaware that the company was ever involved in shaping the article's contents. Instead, the published article bears only the names of the academic physicians or scientists, who are often highly renowned and trusted in their fields. By keeping the company's role in the article hidden, the article has

⁷ Jeffrey R. Lacasse and Jonathan Leo, "Ghostwriting at Elite Academic Medical Centers in the United States," *PLoS Med*, 2010; 7(2): 1-4.

greater credibility in the eyes of the medical community, and thus greater opportunity for influencing the prescribing behavior of physicians.⁸

“Editorial assistance” may suggest to the reader and journal editors that there was involvement of a third party medical writer, hired by a pharmaceutical company through a medical educational, communications or marketing company, to develop publications in support of the pharmaceutical company’s products. However, published articles have not consistently acknowledged editorial assistance. For example, one of the Vioxx-related articles that Merck paid STI to help develop does not mention STI or the medical writer that assisted Merck and the author with the article.⁹

Furthermore, the term “editorial assistance” is poorly defined and does not shed light on the specific roles played by a pharmaceutical company or other commercial entities. Unless an article presents a company-funded study, there may be no mention of financial support from the pharmaceutical company. Companies compensate the medical educational, communications or marketing company for their work on the articles, but they do not always pay the authors of the articles. For example, Merck stated that there were four articles related to Vioxx that the company engaged STI to assist with production. Two of the authors declined compensation while the other two authors received an honorarium of \$1500.

Wyeth informed the Committee that it revised its publication policies in 2006 to include greater disclosure of the role that Wyeth and medical writers play in developing a Wyeth-funded publication. Specifically, Wyeth’s policy stated:

The Acknowledgements section of a publication should...also be used to acknowledge the project’s funding and Wyeth’s involvement in the analyses of the data or preparation of the publication.

* * *

When professional writing staff assist an author in interpreting data and/or producing a publication, the author should recognize their contributions appropriately in the resulting publication.

* * *

It is Wyeth’s expectations that authors and speakers will fully disclose all financial and material support for research related to the publication, disclose all potential conflicts of interest related to the publication, and affirm that they have read and approved the final publication.¹⁰

⁸ Declaration of Virginia Barbour in support of the Public Library of Science’s Motion to Intervene and Motion for Access to Discovery Materials, *In re Prempro Products Liability Litigation* (D. Ark. 2009), available at <http://www.plosmedicine.org/static/ghostwritingDeclaration.pdf>.

⁹ William R. Garnett, “Clinical Implications of Drug Interactions with Coxibs,” *Pharmacotherapy*, 2001; 21(10): 1223-1232.

¹⁰ “Policy on External Publications and Presentation,” Wyeth Pharmaceutical Policies, Policy 513, May 4, 2006.

The question, however, is how was this policy enforced and who ensured that the authors made the appropriate disclosures to the medical journals.

Since Pfizer acquired Wyeth last fall, Pfizer's policies are now in effect. On Pfizer's website is its policy on public disclosures of Pfizer-sponsored clinical studies, including a requirement that authors of study publications "acknowledge individuals who provide editorial support and disclose the funding source."¹¹ Pfizer's internal document on public disclosure and authorship also includes policies governing other manuscripts submitted to peer-reviewed medical and scientific journals, such as review articles, secondary articles, supplements, abstracts and book chapters. According to that document, if Pfizer pays an author or a healthcare institution for the development of a publication, Pfizer makes the payment directly to the author or institution. Furthermore, if Pfizer pays a third party for editorial/writing support and the medical journal does not specify how Pfizer support is to be acknowledged in the publication, Pfizer's policy provides acknowledgment language that should be submitted to the journal. For example, the acknowledgment/disclosure statement for editorial support would be: "Editorial/medical writing support was provided by <Name> at <Company/affiliation> and was funded by Pfizer Inc."

In addition, according to Pfizer's internal document, to ensure that authors are informed of Pfizer's policies on authorship and disclosure of Pfizer's support, the company sends each potential author a letter on its policies and asks the authors to acknowledge that they will adhere to the policies. If an author refuses to sign an acknowledgment, then the matter is referred to the legal department.

B. Some medical schools explicitly prohibit ghostwriting in their policies

Last November, Senator Grassley wrote to 10 leading medical schools asking whether or not the schools have written policies regarding ghostwritten articles as part of his continuing effort to shed light on the ties between the pharmaceutical industry and medical professionals. Based on a review of the responses, which were submitted in December 2009, the Committee staff found that:

- Six of the medical schools have policies that explicitly prohibit ghostwriting—Columbia, Johns Hopkins Medicine, Stanford Medicine, UCSF, UW Medicine, and Washington University.
- In addition to prohibiting ghostwriting, UW Medicine's policy prohibits guest (honorary, courtesy, prestige) and gift authorship. Yale's policy also prohibits gift authorship. Guest authorship is often granted to increase the credibility of the work or the likelihood of publication, even though the individuals do not meet the criteria required for authorship. Gift authorship is offered to individuals who do not contribute intellectually or

¹¹ Pfizer's policy on public disclosure and authorship of Pfizer-sponsored clinical trials is available at http://www.pfizer.com/research/research_clinical_trials/registration_disclosure_authorship.jsp.

substantially to the work as repayment or in exchange for another benefit or anticipated benefit.

- Three of the medical schools' policies—Harvard, Duke, and Yale—prohibit guest, honorary or courtesy authorship but not ghostwriting explicitly. Harvard, however, stated that it prohibits the practice of ghostwriting and is examining ways to strengthen its current prohibitions related to ghostwriting. Yale does not use the term guest or honorary but it prohibits faculty from adding as co-authors “highly respected individuals merely as an attempt to increase the likelihood of publication.” In addition, Yale stated that the university believes its current standards for authorship, which requires that the individual contribute in a meaningful way, effectively prohibit ghostwriting because “the purported authors have not made meaningful contributions to the content nor have they given attribution to the true authors.” The Dean of the School of Medicine also sent out an email in December 2009 to Yale medical faculty and students regarding ghostwriting. He wrote that the “practice is strictly contrary to the values and principles of academic medicine and is prohibited by existing Yale University policy.”
- Penn Medicine does not use the term “ghostwriting” in its authorship policies, but stated that it has policies against plagiarism and it considers ghostwriting to be the equivalent of plagiarism.

In addition, based on the responses submitted, six of the medical schools—Duke, Harvard, Johns Hopkins Medicine, UW Medicine, Washington, and Yale—appear to have adopted the same criteria for authorship that have been recommended by the International Committee of Medical Journal Editors (ICMJE).¹² In general, under the schools' policies, to qualify as an author, the individual must meet at least all three of the following:

- 1) contribute substantially/significantly to the conception, design, execution and/or data acquisition or interpretation of the underlying paper;
- 2) participate in the drafting, reviewing and/or revising of the manuscript for intellectual content; and
- 3) provide final approval of the manuscript to be published.

Authorship policies alone, however, do not address the lack of transparency in the role of a pharmaceutical or device company in the development of scientific articles. In addition to explicit policies regarding ghostwriting and/or guest, honorary or gift authorship, seven medical schools¹³ have policies requiring acknowledgment of individuals and/or entities that contribute to the publication but do not meet the criteria for authorship. These policies generally state that contributors should be disclosed or acknowledged in the final publication. Columbia's policy specifically states that “any articles or other materials written in conjunction with commercial entities must include full disclosure of the role of each author, as well as other contributions or participation by such commercial entities.”

¹² International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship*, available at http://www.icmje.org/ethical_1author.html.

¹³ Columbia, Duke, Harvard, Johns Hopkins Medicine, UW Medicine, Washington, and Yale.

While the responses from the 10 medical schools to Senator Grassley show that most expressly prohibit ghostwriting in their policies, a recent survey published in *PLoS Medicine* shows that a smaller percentage of the top 50 academic medical centers have such explicit policies. In February 2010, Drs. Jeffrey Lacasse and Jonathan Leo published a survey of academic medical center policies to determine the extent to which these policies explicitly prohibit ghostwriting.¹⁴ The authors found that ten of the academic medical centers explicitly prohibited ghostwriting. They also found that three centers have authorship policies that prohibit ghostwriting in practice but do not mention the term “ghostwriting” and thirteen authorship policies fail to ban all aspects of ghostwriting, mainly because the policies do not require that all qualified authors be listed.

C. Detection of ghostwriting by medical schools is limited

In their responses, all of the medical schools reported that they do not allow or condone ghostwriting. For example, some referred to the practice as “unacceptable,” a “violation of university policy,” “inconsistent with principles of sound research and scholarship,” and “contrary to the values and principles of academic medicine.” As discussed earlier in this report, some of the medical schools have policies that specifically prohibit ghostwriting and require acknowledgment of third parties that contribute to or assist with faculty publications. While it is important to have clear policies on authorship and acknowledgment of the contributions of non-authors, including the pharmaceutical or device company that financed development of the article, these policies require enforcement to be effective. However, like the disclosure of faculty financial conflicts of interest, the universities rely on a faculty honor system. Senator Grassley found from his inquiries that the system has its flaws when it comes to disclosure of financial interests.

UCSF also pointed out that ghostwriting is not as easily detected as plagiarism, where the original or aggrieved author would report the incident. Specifically, the university noted an incident in 2008 when UCSF received an allegation from an author that his work had been plagiarized by a UCSF faculty member. As a result of UCSF’s investigation into the matter, the university found that the article was ghostwritten and plagiarized by a medical writer. According to UCSF, an industry representative had presented the paper to the faculty member for review and signature. The UCSF faculty member reviewed the article, made minimal modifications and signed it without realizing that the ghost writer had plagiarized another author’s work. The faculty member wrote to the publisher and retracted his name from the article. The investigating committee at UCSF recommended that the university develop resources to educate everyone about the serious matter. UCSF stated that because the faculty member did not know that the article had been plagiarized, no sanctions were imposed for plagiarism.

Two other universities also reported allegations related to ghostwriting. Washington University described an allegation in December 2005 that a faculty member’s paper had been substantially influenced by a medical writer paid by industry. The medical writer was not acknowledged in the published article. The university investigated and concluded that the

¹⁴ Lacasse and Leo, *supra* note 7.

faculty member “liberally edited the draft and that the opinions were that of the faculty member.” However, the university also informed the faculty member that failure to acknowledge the contribution of the medical writer violated the spirit of university policy. The university has since updated its policy to explicitly prohibit ghostwriting.

UW Medicine also received an allegation in 2005 that a faculty member failed to disclose involvement of a third party that was paid by a drug company to develop and draft a manuscript. The university’s investigation concluded that the faculty member had made significant intellectual contribution to the work and had a role in writing and reviewing the manuscript. The university stated that such participation did not violate university policy, but “the incident was the motivating event for the UW SOM to adopt its Ghost Authorship Policy in 2007.”

Seven medical schools stated that they had not received any allegations of ghostwriting since 2004. Several of the schools added that faculty members are not required to report their publication activities to the university. However, they noted that some reporting may occur annually or periodically to department chairs, for example, when a faculty member is being considered for promotion or as part of an annual review or grant submission. Thus, allegations may be handled at the department level and never brought to the attention of the dean or other senior university administrators.

In addition, pharmaceutical companies usually pay the medical education, communications, or marketing companies or the medical writers for drafting the manuscript instead of the authors listed in the publication, so these payments do not appear in financial disclosure forms submitted by university faculty. As the documents from the Prempro litigation show and as Wyeth told Committee staff, authors are not typically paid for “authoring” the articles. Because the authors do not receive direct financial support from the company for the articles, they typically do not acknowledge any outside funding. Disclosures of financial support may occur when there is financial support for the underlying study, but in those cases there is still a lack of acknowledgment of a company’s role in developing a manuscript. At times, a company may offer authors an honorarium, but the author may refuse such money. For example, one expert stated in an email to STI, the medical communications company hired by Merck, that there was no expectation for an honorarium and “I really do not feel it is appropriate to be paid for this type of effort.” *See* Attachment 4.

Duke does not explicitly prohibit ghostwriting, but the medical school stated, “it is expected that a faculty member will maintain records that document his/her active participation in the design, conduct or analysis of research, and will not accept authorship on clinical studies where such active involvement cannot be demonstrated.” However, without department verification of records or information maintained by the faculty member, the institution would have to trust that the faculty member is compliant or rely on third party reports of potential misconduct. UW Medicine stated that department chairs are responsible for disseminating and enforcing the policies, but it is not clear what steps would be taken by the department chairs to ensure compliance. Columbia also believes that requiring “public disclosure of the contributions or participation of commercial entities to medical articles and papers is more effective than internal disclosure to Columbia alone.”

Johns Hopkins Medicine includes in its “Rules and Guidelines for Responsible Conduct of Research” a professional obligation for faculty, students, and fellows to inform superiors if they have reservations about the integrity of the work of a university colleague. Johns Hopkins’ guidelines also state that the institution “recognizes the risks to persons who report research or professional misconduct and has made every effort to protect them as well as those who might be accused in error” and the institution “will adhere to federal rules and guidelines regarding the protection of whistleblowers, as applicable.”

D. Strengthening journal authorship policies appears to have limited effect on ghostwriting and disclosure of industry financing of medical articles

Last summer, Senator Grassley wrote to leading medical journals regarding their position and policies on ghostwriting—*American Journal of Medicine*, *Annals of Internal Medicine*, *Annual Review of Medicine*, *Archives of Internal Medicine*, *JAMA*, *Nature Medicine*, *NEJM* and *PLoS Medicine*. Based on a review of authorship policies and journal responses, which were submitted in July 2009, as well as other information and materials obtained by the Committee, the staff found the following:

- All eight medical journals require that authors disclose potential conflicts of interest, competing interests and/or potential biases.
- *Annals of Internal Medicine*, *Archives of Internal Medicine*, and *JAMA* explicitly address ghostwriting and use the terms “ghostwriting” or “ghost authorship” in their policies and guidelines for authors. In addition, the *Archives of Internal Medicine* and *JAMA* follow the *AMA Manual of Style: A Guide for Authors and Editors*.¹⁵ This style guide explains ghost authorship and discusses the requirements of authorship and guidelines for ensuring that proper credit is given to individuals who contributed to the work, such as medical writers and others who participate substantially in the writing and editing of the manuscript.
- According to the documents provided to the Committee, the *Annals of Internal Medicine*, the *Archives of Internal Medicine*, and *JAMA* also require the public disclosure and acknowledgment of individuals who contribute to a publication, such as medical writers, industry employees, and/or other contributing non-authors. The *AMA Manual of Style* also notes that *JAMA* “discloses the affiliation and funding of individuals who contribute to manuscripts but who are not authors.” In addition, it notes that such disclosure is supported by the American Medical Writers Association and the European Medical Writers Association “as it is more helpful to editors, reviewers, and readers than are vague statements about writing or editorial assistance that gives no indication about financial relationships.”
- *JAMA* requires authors to sign statements certifying that “all persons who have made substantial contributions to the work reported in this manuscript (e.g., data collection,

¹⁵ *AMA Manual of Style: A Guide for Authors and Editors* (10th ed.), available at <http://www.amamanualofstyle.com>.

analysis, or writing or editing assistance) but who do not fulfill the authorship criteria are named with their specific contributions in an Acknowledgment in the manuscript.” The *Archives of Internal Medicine* has a similar form. See Attachment 5.

- The *Annals of Internal Medicine* requires authors to sign statements attesting that “all individuals who contributed to the manuscript have been appropriately acknowledged, and also that all contributors who are not authors are named in the Acknowledgment section.” See Attachment 5.
- The *NEJM* author disclosure form, which is the same form developed by ICMJE, asks if the author or the author’s institution was paid for preparing the manuscript, and if so, by whom and what was the nature of the compensation. However, it does not ask if someone else was paid to assist with the manuscript. The *Annals of Internal Medicine* disclosure form also asks if the author received payment for “involvement in the preparation” of the manuscript.
- *PLoS Medicine* follows the guidelines of ICMJE on authorship and stated that the involvement of any professional medical writer must be declared. Its policy also refers authors to the European Medical Writers Association (EMWA) guidelines, which recommend that medical writers and their funding source be acknowledged. Specifically, EMWA states, “Identifying the writer, either as an author or contributor or in the acknowledgements section, helps readers, reviewers, and journal editors to understand how the manuscript was developed, and recognizes the writer’s involvement. Identifying the writer’s funding source ensures transparency and makes readers aware of any potential conflicts of interest.”¹⁶
- *Nature Medicine* stated that it has an authorship policy that defines what it means to be an author and that the policy should prevent some authors’ willingness to appear on papers in which they did not contribute. The journal added, however, that it is not strictly a medical journal but rather a journal for and by basic researchers so “ghostwriting is not a problem significant enough to warrant an official position against it.” A *JAMA* survey presented at the International Congress on Peer Review and Biomedical Publication in 2009 found that the prevalence of ghost authorship was lowest in *Nature Medicine* compared to the other medical journals but it also found that the prevalence of honorary authorship was the highest in *Nature Medicine*.¹⁷
- *Annual Review of Medicine* stated that no ghostwriting is permitted and its approach for avoiding conflicts is through careful author selection. Topics are chosen by its editorial committee about 18 months in advance of publication, and the journal invites authors it considers best qualified to write the articles. *NEJM* also stated that most editorials and review articles are solicited by an *NEJM* editor.

¹⁶ Adam Jacobs and Elizabeth Wager, “European Medical Writers Association (EMWA) guidelines on the role of medical writers in peer-reviewed publications,” *Curr Med Res Opin*, 2005; 21(2): 317-321.

¹⁷ Joseph Wislar, Annette Flanagan et al., “Prevalence of Honorary and Ghost Authorship in 6 General Medical Journals, 2009,” Paper presented at the Sixth International Congress on Peer Review and Biomedical Publication, Vancouver, British Columbia, Canada, Sept. 10, 2009.

- The *American Journal of Medicine* stated that it rejects any manuscript that appears to be written by someone other than the authors of the article.
- *PLoS Medicine* stated that the journal has had a longstanding interest in documenting ghostwriting and its negative effects. In fact, *PLoS Medicine* has published several articles and opinion pieces on the subject over the last three years.

Despite efforts by journals in recent years to strengthen their authorship and publication requirements, a survey released last year found that the prevalence of ghostwriting has not changed much in the past decade. In 2009, *JAMA* presented an abstract on its survey of authors of 630 research articles, review articles and editorial/opinion articles that were published in six medical journals in 2008.¹⁸ The six journals were *Annals of Internal Medicine*, *JAMA*, *Lancet*, *Nature Medicine*, *NEJM*, and *PLoS Medicine*. *JAMA* found that 26 percent of the articles had honorary authors, 8 percent had ghost authors, and 2 percent had both. The survey also showed that these numbers did not differ significantly from a 1996 study, which found 19 percent honorary authorship, 11 percent ghost authorship, and 2 percent of both.¹⁹ In addition, *JAMA* reported that the prevalence of ghost authors was highest in *NEJM* (11 percent), lowest in *Nature Medicine* (2 percent), and “no significant differences were found between journals requiring author contribution disclosures and those that do not.” Thus, it appears that despite policies to ensure that all authors who contribute to a publication are identified and that the authors listed in fact contributed substantially to the publication, the prevalence of ghostwriting remains largely unchanged.

Nevertheless, clear and strong policies are needed not only to ensure that all listed authors meet the authorship criteria but also, more importantly, to ensure appropriate public disclosure of the roles of non-authors, in particular the role of a pharmaceutical or device company in initiating and paying for a manuscript. Although the *JAMA* survey did not find that the prevalence of ghostwriting has changed much, it did find a slight decrease. The challenge is educating authors of their responsibilities under the policies and ensuring compliance. Following up on red flags would also allow journals to prevent manuscripts without appropriate acknowledgments and disclosures from being published. For example, *MedPage Today* quoted Dr. Harold Sox, editor of the *Annals of Internal Medicine*, in April 2008, stating that, “Ideally, we’d be calling and saying, what exactly did they do,” but the journal didn’t have a policy on following up routinely.²⁰

In addition, an editor-in-chief of a medical specialty journal contacted Senator Grassley and said that his journal handles articles that it suspects were ghostwritten by questioning or editing the articles. He informed Committee staff that at least one third of the papers submitted to his journal were written by science writers hired by an agency and paid for by a pharmaceutical company. The editor added that in some cases, it was clear to him that the academic expert had limited input in the writing of the article and that while authors now

¹⁸ *Id.*

¹⁹ Annette Flanagan, Lisa A. Carey et al., “Prevalence of Articles with Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals, *JAMA*, 1998; 280(3): 222-224.

²⁰ John Gever, “Fewer Medical Journal Articles Planted by Phantom Authors,” *MedPage Today*, April 14, 2008.

acknowledge that they received editorial assistance, what is unclear is whether or not the academic expert evaluated the implications of what he was submitting for publication. That editor was also concerned that medical literature “has become inundated with repetitive promotional articles.”

E. National Institutes of Health does not have explicit policies on disclosure of industry financing of ghostwritten articles

In August 2009, Senator Grassley wrote to NIH to bring to the agency’s attention several NIH-funded researchers who were authors on what appeared to be ghostwritten articles paid for by the pharmaceutical industry and ask NIH about its policies on ghostwriting. NIH responded that it did not use the term “ghostwriting” in its policies. Instead, NIH stated that Federal regulations and policies related to Public Health Service supported research could be applicable to ghostwriting and noted that a case involving NIH-funded researchers may be appropriate for consideration as a case of plagiarism.

The NIH also stated that it “acknowledges the importance of journal policies and practices that promote transparency by disclosing investigators’ financial interests.” However, as discussed earlier in this report, if a company does not provide direct financial support to the author of an article, then the company’s role may not be captured in the author’s financial disclosures to the journal editors or in the published article. NIH distributes billions of dollars of extramural funds each year to support medical research that helps improve the health of the American people. Thus it is important that NIH allocates those public funds responsibly. NIH may want to consider requiring grantees to certify that they disclosed all potential conflicts of interest, not only financial interests. Furthermore, during his inquiries into NIH’s policies on financial conflicts, Senator Grassley found that NIH relies on the academic institution to document, manage and address its faculty members’ financial conflicts. The institutions, however, do not verify the disclosures, thus they cannot address conflicts that are not accurately reported to them.

CONCLUSIONS

Just as the Physician Payments Sunshine Act is intended to promote transparency in the financial relationships between healthcare companies and physicians that may influence medical behavior, Senator Grassley’s inquiry into ghostwriting is intended to shed light on interactions between the pharmaceutical industry and academic physicians and scientists. In the interest of transparency and accountability, all parties who contribute substantively or financially to a publication should be acknowledged. Only then can readers understand the context of a study and be aware of any commercial interests that initiated and influenced the results or recommendations presented in the publication.

The pharmaceutical company who pays a third party to develop articles that present the company’s products in a positive light stands to benefit from a manuscript that is published in a medical journal. As Wyeth’s own presentation slide states, “A scientific publication plan is as

vital as a carefully designed media plan in overall product marketing.”²¹ Academics who author the articles also benefit, even if they do not receive payment from the company for an article. Successful publications raise the authors’ visibility in their fields and may lead to promotions or more research funding opportunities. For physicians and scientists in academia, it’s “publish or perish”—a phrase that is commonly used to describe the pressure that faculty feel to publish frequently in order to further their careers.

It is encouraging that many of the medical schools and journals that responded to Senator Grassley’s inquiries have policies against ghostwriting. More significantly, it was welcome news to find that some of the schools and journals already require the disclosure or acknowledgment of individuals or entities involved in developing a manuscript. These relationships, however, should be disclosed regardless of whether or not a commercial entity specifically provided funding to the faculty or to an institution for work on the article. As stated in this report, a pharmaceutical or device company does not typically provide financial support to the faculty or institution for the articles, but instead to a third party who drafts the article for the faculty member to sign on as the author.

In addition, while acknowledging “editorial assistance” may provide a clue that the article was potentially ghostwritten, it does not give the reader any information about the roles of others, in particular the pharmaceutical or device company, that may have helped shape the publication. If a pharmaceutical or device company initiated, drafted, reviewed or paid for a manuscript, the final publication must disclose that information and include a detailed description of the company’s contribution to the article.

Drs. Lacasse and Leo stated that when academic medical centers do not prohibit their faculty from participating in ghostwriting, the centers:

enable the pharmaceutical company to covertly shape the medical literature in favor of commercial interests. When a pharmaceutical salesperson hands a clinician an article reprint, the name of the institution on the front page of the reprint serves as a stamp of approval. The article is not viewed as an advertisement, but as scientific research.²²

The Institute of Medicine (IOM) also recommended that academic medical centers adopt policies prohibiting ghostwriting. It raised concern about the practice, stating:

Such arrangements (which are essentially gifts) send the wrong message about the values of intellectual independence, professional ethics, accountability, and evidence-based medicine. In the context of research, they raise questions about the objectivity of research reports that other researchers as well as practitioners and developers of practice guidelines rely on.²³

Specifically, the IOM recommended:

²¹ Available on the Drug Industry Document Archive at <http://dida.library.ucsf.edu/pdf/atb37b10>.

²² Lacasse and Leo, *supra* note 7.

²³ Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice* (2009).

For all faculty, students, residents, and fellows and for all associated training sites, academic medical centers and teaching hospitals should adopt and implement policies that prohibit...educational presentations or scientific publications that are controlled by industry or that contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged.²⁴

In addition, Dr. Lisa Bero and Ms. Jenny White of UCSF recommended uniform standards for all journals so that companies will not be able to target journals that have weaker policies on authorship and conflicts of interest. Dr. Bero and Ms. White found in their review of journal policies regarding ghostwriting that while the journals had policies requiring disclosure of conflicts of interest, a majority did not address ghost authorship. They also noted that journals varied in their effectiveness in verifying full disclosure of conflicts of interest and authorship.²⁵

Once clear and strong policies regarding authorship and disclosures/acknowledgments are in place, the challenging task is ensuring compliance. Academic institutions rely on their faculty to report accurately and honestly. Unfortunately, Senator Grassley found several cases where medical faculty failed to report millions of dollars received from pharmaceutical companies on their financial disclosure forms.²⁶ Similarly, unless a journal looks out for signals or clues that an article may have been ghostwritten and follows up on what is disclosed to them by the authors, they must rely on the authors to report accurately and honestly. It is important that the academic institutions and medical journals educate authors on their policies and author responsibilities. It may be the case that faculty are not knowledgeable of the requirements and their failure to report is not an intention to withhold or deceive. The authors of one opinion piece published in *PLoS Medicine* in February 2009 believe that “existing guidelines already emphasize the need for appropriate disclosure of writing assistance” and suggested that “one of the most practical ways to tackle ghostwriting could be the mandatory use of a checklist that could help editors detect ghostwriting and help authors avoid ghostwriters.”²⁷ The checklist would include a question asking if the source of funding for a medical writer’s services is identified in the acknowledgments. The authors proposed that the checklist could be included in a journal’s instructions to authors.

According to a *MedPage Today* article, Dr. Adriane Fugh-Berman, a researcher at Georgetown University, proposed that journals could ask more questions of named authors to curb the practice of ghost authoring.²⁸ Dr. Fugh-Berman pointed out that the *American Family Physician*, for example, asks specific questions in its author conflicts of interest disclosure form about manuscript writing assistance and the involvement of a medical communications company

²⁴ *Id.*

²⁵ Lisa Bero and Jenny White, “Ghost Writing: How Some Journals Aided and Abetted the Marketing of a Drug, Paper presented at the Sixth International Congress on Peer Review and Biomedical Publication, Vancouver, British Columbia, Canada, Sept. 10, 2009.

²⁶ See <http://finance.senate.gov/newsroom/ranking/release/?id=67b016e1-58dd-4f7f-acia-05fce22393a1>; see also <http://finance.senate.gov/newsroom/ranking/release/?id=91aa840c-e86d-476d-a8fa-300220d602e0>.

²⁷ Peter C. Gotzche, Jerome P. Kassirer, Karen L. Woolley et al., “What Should Be Done to Tackle Ghostwriting in the Medical Literature?” *PLoS Med*, 2009; 6(2): 122-125.

²⁸ Gever, *supra* note 20.

or professional writers. If an author answers yes, the form asks who paid for the assistance. The form also asks authors whether or not “a pharmaceutical company, public relations firm or any commercial entity sponsor[ed] the substance or creation of [the] article directly or indirectly.” See Attachment 6.

PLoS Medicine also stated that before it accepts a paper for submission, the editors ask the authors if anyone prompted or paid them to write the article and the extent to which a professional writer contributed to the article. In addition, the journal pointed out that when individuals other than the authors inquire about the progress of the peer review of a study, it is a red flag and prompts the editors to immediately contact the author. Such follow-up may help capture third party contributions that were not initially disclosed.

In addition, the Centers for Medicare and Medicaid Services (CMS) allows its contractors to use peer-reviewed literature to determine if an off-label use of a drug or biologic is a medically accepted indication for purposes of coverage. CMS should consider requiring that the peer-reviewed articles follow strict authorship and disclosure/acknowledgment policies. Such policies might prevent coverage decisions based on the findings and recommendations of articles that do not have adequate disclosures that they were initiated and paid for by a pharmaceutical company.

Unknown

From: [REDACTED]
Sent: Wednesday, March 24, 1999 4:20 PM
To: [REDACTED]
Subject: Information regarding publication planning

Alice:

Here is our general approach to publication planning.

The first step is to choose the target journal best suited to the manuscript's content, thus avoiding the possibility of manuscript rejection. We will then analyze the data and write the manuscript, recruit a suitable well-recognized expert to lend his/her name as author of the document, and secure his/her approval of its content. After the client has reviewed and released the manuscript for submission, DesignWrite will see it through the necessary production stages-creating camera-ready figures and tables and the text according to the journal guidelines-and submit the package (manuscript, art, cover letter, and any required forms and checklists) to the appropriate journal editor. Any revisions requested by the journal will be handled by DesignWrite in conjunction with the client and the author. Should the journal reject the manuscript, DesignWrite will restyle it for submission to another journal within 10 working days.

From receipt of the internal summary report for a given study, a time frame of 1 to 2 months is estimated for manuscript development. The time frame between submission of draft and the client approval is subject to internal review. Subsequent revisions based on the client, author, or reviewer comments are typically addressed in 2 to 3 weeks. A period of 6 to 16 months is projected for actual publication once the manuscript has been accepted by the journal. This latter time frame is a function of individual journal policies.

Unknown

From: [REDACTED]
Sent: Wednesday, November 17, 1999 1:54 PM
To: [REDACTED] MD'
Cc: [REDACTED]
Subject: estrogen manuscript

Dear Dr. [REDACTED],

I hope all is well with you. I received word from Wyeth to go ahead and submit the manuscript for publication. It has been formatted for submission to the *American Journal of Obstetrics and Gynecology*, as we discussed. I will be sending you the appropriate number of copies on bond paper required for submission.

I am also drafting a submission letter for you, which I will email to you when complete so that you can print it out on your letterhead, sign it and include it with the submission packet. To complete the letter, I need three recommendations from you for suggested reviewers, as required by the journal. I will also indicate in the letter where you will need to provide any conflict of interest or disclosure statements.

I know you are out of town today, and look forward to speaking with you tomorrow so that we can proceed with manuscript submission by the end of the week.

Best Regards,

[REDACTED]
[REDACTED]
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DesignWrite, Inc.
189 Wall Street
Princeton, NJ 08540
tel: [REDACTED]
fax: [REDACTED]
[REDACTED]

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TIME AND EVENTS SCHEDULE (Article I)

The following is the proposed time and events schedule for completion and submission of this interesting article.

TIME	EVENT
June 3, 1999	Suggested outline, author and time and events schedule provided for approval
June 7, 1999	Approval provided to proceed
July 9, 1999	Draft I to sponsor for review and comment
July 16, 1999	Comments on Draft I to STI
July 23, 1999	Draft II to sponsor and primary author
July 30, 1999	Comments from sponsor and author to STI
August 13, 1999	Draft III to sponsor and author for final review and approval
August 20, 1999	Final approval provided to STI
August 27, 1999	Journal submission package to author for submission to Journal
4 th quarter 99 or 1 st quarter 2000	Estimated date for appearance in journal

Sent: Monday, August 14, 2000 9:07 AM
To: [REDACTED]
Subject: RE: ms

can you forward a copy of the final submitted manuscript, electronically if possible. thanks

> -----
> From: [REDACTED]
> Sent: Monday, August 14, 2000 8:28 AM
> To: [REDACTED]
> Cc: [REDACTED]; [REDACTED]; [REDACTED]; [REDACTED];
> [REDACTED]; File
> Subject: RE: ms
>
> Dear Dr [REDACTED]:
>
> We are pleased to learn that you submitted the ms to the Journal of Family
> Practice. Please contact me when you learn about the status of the paper
> from the journal. If the paper is accepted with revisions, we would be
> more
> than happy to provide our editorial services to assist you with the
> revisions. If the paper is rejected, we could style the ms for another
> journal.
>
> In regards to the honorarium, I have cancelled the check processing as you
> requested not to be paid for the development of this ms. Thank you again
> for all your efforts in this project. Please do not hesitate to contact
> me
> if you have any questions or require additional information.
>
> Regards,
> [REDACTED]
>
> [REDACTED]
> Associate Editor
> Scientific Therapeutics Information, Inc
> Tel: [REDACTED]
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> E-mail: [REDACTED]
>
>
> cc: 1514 (contributor)
>
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>
>
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> form.
> I have lined out the honorarium portion -- there was no expectation or
> offer of payment to do this article and I really do not feel it is
> appropriate to be paid for this type of effort.
>

> Thanks for your help.

>

> [REDACTED]

>

>

>

> [REDACTED] M.D., Ph.D.

> Professor and Director

> [REDACTED]

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