Haunting Prose
Ghostwriting and Transparency in Pharmaceutical and Medical Device Publications

The last several years have seen increasing government and media focus on what both term a lack of transparency in some medical publications authored or financed by pharmaceutical or medical device companies. A target of heavy criticism is medical ghostwriting, which occurs whenever a medical writer makes substantial contributions to a publication but is not identified or acknowledged by the author. Ghostwriting includes retaining professional medical writing or marketing companies to draft articles that are provided to prominent physicians and scientists who sign on as authors, sometimes increasing the likelihood that the article will be published in significant medical journals. Ghostwritten articles may also include publications drafted by pharmaceutical company employees who are not acknowledged in the final publication. Interpreted broadly, the term may also include a company’s funding the research underpinning and the development of a publication proclaiming the merits of its product without public disclosure of the company’s role and financial support for the research and the resulting article.

Ghostwriting also has gained increasingly significant attention in a series of high-profile cases brought against major pharmaceutical companies. The lengthy and thorough discovery conducted in such litigation often reaches publications and publication practices related to the product in issue. In some instances, discovery has led to the production of documents that support a conclusion that ghostwriters have been employed by a pharmaceutical company without contemporaneous disclosure of the company’s involvement with the publications. Plaintiffs’ counsel have been able to use such information as powerful ammunition in presenting their cases.

As these cases garner public attention, the media has levied sharp criticism at publication practices that allow the use of ghostwriting. One writer puts the issue into sharp focus: Because physicians rely upon medical publications, “the concern about ghostwriting is that doctors might change their prescribing habits after reading certain articles, unaware they were commissioned by a drug company.” In the wake of these cases and the resulting media attention, United States Senator Charles Grassley issued a Minority Staff Report, Ghostwriting in Medical Literature (June 24, 2010), which details inquiries into pharmaceutical and medical device company practices regarding initiation and development of articles for publication in medical journals. Senator Grassley describes the practice of ghostwriting in such publications as prevalent. Within the report and in letters to the National Institutes of Health (NIH), Senator Grassley urged governing bodies to adopt strict requirements prohibiting ghostwriting in medical publications. In fact, the NIH has recently finalized new rules regarding investigator conflicts of interests which add “paid authorship” to the list of financial interests that must be reported. In finalizing this amendment, the NIH noted that it was “particularly concerned about situations in which investigators may have accepted payment from private entities, in return for allowing their names to be used as authors on publications for which they had very limited input.” As described by the NIH, “by including ‘paid authorship’ in the definition of ‘significant financial interest’ […] the NIH is sending a clear message to institutions and investigators alike that we support the principles of transparency and accountability in research and that institutions and investigators engaging in such activity may be subject to more rigorous disclosure and reporting.” The NIH has expressly stated that it does not condone ghostwriting, and may, in appropriate circumstances, consider the practice plagiarism.

In light of the increased attention focused on publication transparency, any pharmaceutical or device company should familiarize itself with and follow industry recognized guidelines regulating publication disclosures. As detailed below, numerous professional bodies and the OIG have developed clear requirements for authorship, contributor, and funding disclosures in publications ranging from articles to posters.

Industry Guidelines

Following the increased media and government attention, leading industry organizations developed or revised guidelines for appropriate publication disclosures. While each organization may add some unique provisions regarding disclosure, an overview of the most cited guidelines provides significant insight into the best practices in the industry.

International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) has promulgated extensive and well-cited uniform requirements for medical publications. For many
professional organizations, journals, and academic institutions, these requirements are the touchstone for authorship disclosure standards. Under the ICMJE requirements, an “author” of a medical publication must: (1) take responsibility for at least one component of the work, and should be able to identify who is responsible for each other component, and (2) make substantive intellectual contributions. Moreover, authorship credit should be based on: (1) substantial contributions to conception, design, execution, and/or data acquisition/interpretation; (2) participation in drafting, reviewing, and/or revising intellectual content; and (3) providing final approval. Significantly, all persons who qualify as “authors” must be disclosed as authors in the final publication.10 Other persons who do not qualify as “authors” but who provided assistance with the publication should be identified as “contributors” in the final publication acknowledgements.11 Contributors would include those providing purely technical help, writing assistance, or general support.12

Additionally, all participants in the publication process must disclose all relationships that could be viewed as potential conflicts of interest. Authors must identify individuals who provide assistance and disclose the funding source for the assistance. Authors should describe the role of the study sponsor, if any, in study design, collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication.

**Pharmaceutical Research and Manufacturers of America**

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a trade group representing the country’s leading pharmaceutical research and biotechnology companies. PhRMA has issued authorship guidelines and disclosure requirements within its “Principles on Conduct of Clinical Trials & Communication of Clinical Trial Results.” These principles apply to all “publications” which are defined to include “a paper in a peer-reviewed journal, abstract submission with a poster or oral presentation at a scientific meeting, or making results public by some other means.”13 Within these guidelines, PhRMA expressly adopts the ICMJE requirements for “authorship” credit and requires that all contributors to publications be recognized.

**Counsel of Science Editors**

The Counsel of Science Editors is self-defined as an organization of “editorial professionals dedicated to the responsible and effective communication of science.”14 In 2009, the organization issued its White Paper on Promoting Integrity in Scientific Journal Publications, which adopts the ICMJE definition of author, and emphasizes the need for all publication contributors (whether or not “authors”) to be disclosed. Additionally, authors and contributors are expected to designate their functional role along “with the individuals’ institutional affiliations if relevant.”15 Individuals who have made less substantial contributions should be identified in the “Acknowledgments” sections of publications. The White Paper expressly states that “guest authorship, honorary or gift authorship, ghost authorship, and anonymous authorship” is inappropriate.16 Moreover, it is “inappropriate” for pharmaceutical, device, or equipment firms to offer guest or “courtesy” authorship. All ghost authorship is forbidden. “Ghost authorship” is defined as any substantial contribution to the writing of a manuscript by an individual whose role is not disclosed in the manuscript.17 Unattributed contributions to data analysis may also constitute ghost authorship.

**International Society for Medical Publication Professionals**

The International Society for Medical Publication Professionals, issued a revised set of publication guidelines in 2009 titled Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP2).18 The GPP2 provides extensive and detailed publication guidance regarding:

- Roles of authors, sponsors, and other contributors;
- Reimbursement and honoraria;
- How to establish a publication steering committee;
- Role of professional medical writers; and
- Recommendations for publication planning and documentation.

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By its terms, the GPP2 applies peer-reviewed journal articles and presentations at scientific congresses, including abstracts and posters. As with other guidelines, the GPP2 defines “author” by reference to the ICMJE requirements. Unlike the ICMJE, however, the GPP2 makes significant policy and procedure recommendations to be followed by medical companies. It is specifically recommended that companies adopt a written description of the company’s obligations for good publication and that all authors be provided copies. All contributors should be acknowledged within the article or presentation. Disclosures should be made in articles, abstracts, and posters and included in oral presentations whether or not requested by the journal or Congress. The GPP2 provides sample language for various types of contributions.
and financial disclosures to be included in all publications. Examples:

- “The authors would like to thank D, YZ Pharmaceuticals, for overall management of the trial and E, WX Medical Writing, for drafting the manuscript.”
- “In collaboration with A and B, XY Pharmaceuticals designed the study, analyzed, and interpreted the data, and edited contributions are made. The GPP2 makes an important distinction by noting that professional medical writers are not ghostwriters — as long as transparency exists.

-European Medical Writers Association-

The European Medical Writers Association (EMWA) has issued *Guidelines on the Role of Medical Writers in Developing Peer-Reviewed Publications* that encourages pharmaceutical and device companies to follow the GPP2. While the EMWA acknowledges that medical writers can be appropriately hired by sponsoring companies for publications, their contribution and relationship to the company should be accurately acknowledged as an author, contributor, or in the acknowledgements section. The EMWA states that authors should be involved at the earliest possible stage, specifically stating that “[i]t is unethical to invite investigators to be authors if they have seen only a pre-final version of a paper.” Furthermore, the GPP2 asserts that “[v]ague acknowledgements of the medical writer’s role, such as ‘providing editorial assistance’ should be avoided” to ensure clarity about contributor relationships to the work. The EMWA provides suggested wording: “We thank Dr. Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.”

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-U.S. Food and Drug Administration (FDA)-

In 2009, the FDA issued “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices.” As described by the FDA:

This guidance is intended to describe the Food and Drug Administration’s (FDA or Agency)
current thinking regarding ‘Good Reprint Practices’ with regard to the distribution by a drug or medical device manufacturer (or representative) of medical journal articles and scientific or medical reference publications (referred to generally as medical and scientific information) that discuss unapproved new uses for approved drugs, or approved or cleared medical devices marketed in the United States to healthcare professionals and healthcare entities.  

Under the guidelines, any reprints must disclose the manufacturer’s interest in the drug or device; any author known as having a financial interest or who is receiving compensation from the manufacturer, including amount; and any person known to the company used these articles to promote off-label use of one of its pharmaceutical products. This practice, along with other acts, was alleged to have been in violation of the federal Anti-Kickback Statute. The company entered into a $520 million dollar settlement agreement which included a five-year CIA with the OIG. This CIA appears to be the first CIA to expressly prohibit ghostwriting. The CIA also requires the company to develop written policies regarding publication authorship disclosures and to take part in a monitoring program for all publication materials. The written policies require compliance with ICMJE authorship and contributor disclosure guidelines. All authors must enter into written agreements stating the exact fees paid and all compliance obligations. Moreover, authors are required to disclose in “manuscripts, journal submissions, and elsewhere as appropriate under the Anti-kickback Statute Violation

As demonstrated, the OIG has given every indication that medical publications used by pharmaceutical and device companies for marketing will be subject to increased scrutiny under the Anti-kickback Statute (AKS) and other federal laws. The AKS contains a criminal prohibition against remuneration (in any form) made to purposefully induce or reward the referral of goods or services that may be paid for, in whole or in part, by a federal healthcare program. The AKS also prohibits remuneration in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering goods or services payable by a federal healthcare program. The statute’s language and reach is broad, as the OIG has noted: “[…] we believe that many marketing and advertising activities may involve at least technical violations of the statute.”

Certainly, on its face, pharmaceutical and device manufacturer programs that employ ghostwritten publications for the purpose of marketing a product, and that include payment to prominent scientists and medical professionals as nominal “authors” in order to generate increased publicity and attention (thus inducing referrals and purchases), appear to be a high-risk transaction under the AKS.

Numerous OIG statements and publications confirm this conclusion. For example, then Chief Counsel to the Inspector

Office of Inspector General (OIG) Attention

Traditionally, the OIG has not focused on the practice of ghostwriting and, prior to last year, was not known to incorporate authorship disclosure requirements into Corporate Integrity Agreements (CIA), which are often negotiated in settlement of federal investigations and false claims cases. However, a shift has occurred, and the practice of ghostwriting has captured the OIG’s attention. A false claims act suit was filed against a major pharmaceutical company accusing it of hiring doctors to serve as authors for professional articles ghostwritten by the company. The OIG alleged that the company did or required,” any potential conflicts of interest, including all financial relationships with the company.

Additionally, on March 10, 2011, the OIG presented a program at the Third Annual Summit on Disclosure, Transparency, and Aggregate Spend which repeatedly raised the issue of ghostwriting and medical publication transparency. In the presentation, the OIG emphasized the “broad scope of transparency and disclosure requirements” to “ensure that contracts with consultants and authors require disclosure.” Under the “Trends and Predictions” section, the OIG predicts “continued enforcement actions against drug and device companies” and “large numbers of FCA matters […] including against device manufacturers.”

The presentation closed by recommending that companies “assess transparency and disclosure in […] publication activities.”
General, Lewis Morris, provided testimony to a committee of the House of Representatives in which he sharply criticized the use of ghostwriting to promote off-label uses of pharmaceuticals:

In these schemes, manufacturers pay physicians to “write” advocacy articles about off-label uses of products that are, in fact, written by the manufacturer. This practice is particularly insidious, because the publication of such articles in certain medical compendia may be sufficient to qualify the off-label use for reimbursement under some State Medicaid programs.³⁹

Similarly, within its Compliance Program Guidance for Pharmaceutical Manufacturers, the OIG identifies “several common or problematic relationships between manu-

facturers and physicians.”⁴⁰ In summarizing these suspect relationships, the OIG emphasizes “in particular, the use of health care professionals for marketing purposes — including, for example, ghost-written papers or speeches — implicates the anti-kickback statutes.”⁴¹ Moreover, “while full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk.”⁴² The OIG cautions that at a minimum, manufacturers should construct and review arrangements to ensure that: (i) The arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment. The OIG also recommends structuring the agreement to fit within the personal services safe harbor.

Obviously, determining whether a particular arrangement violates the AKS is a fact-intensive inquiry. Some arrangements, however, appear considerably more risky than others. Of particular note is the industry practice of creating “whitepapers” that are nothing more than internally created articles touting the benefits of a product or drug and intentionally designed for marketing purposes. If healthcare professionals are paid to be nominal authors on these whitepapers, providing little or no scholarly input or editing, they clearly fall into the suspect categories identified by the OIG. In such situations, there is no legitimate need for service, no legitimate services are provided (other than lending a name), and thus no fair market value can be assessed. It is arguable that the remunerative arrangement is made merely to indirectly induce others to purchase or recommend the purchase of the associated product.

Moreover, such a transaction likely would not fall within the AKS personal services safe harbor because agreements would rarely exceed the one-year minimum requirement imposed by the exception, nor would they be for “fair market value” of a necessary “service” as required. Even if the medical professional does provide editing or other professional service to development of the whitepaper, it may not insulate the arrangement under the AKS. The OIG has specifically observed that “under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g. physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business).”⁴³ By their very nature, marketing materials are designed to induce business.

Accordingly, remunerating healthcare providers or other medical professionals who have the ability to influence business for the manufacturer for authorship services related to pharmaceutical or medical device marketing materials is a high risk practice under the AKS. Caution should be taken to design these types of contracts to meet as many of the personal service safe harbor criteria as possible. Moreover, any services provided by the healthcare professional should be for documented legitimate needs and must be accurately disclosed within the publication per ICMJE guidelines. Inaccurate or incomplete disclosures, particularly attributing authorship credit to healthcare providers that do not meet ICMJE “author” guidelines, creates an air of impropriety that could support the conclusion that the healthcare provider is being paid to promote the product addressed in the publication. Even with proper disclosure, if the documented purpose of the publication (or even a documented purpose) is for marketing and promotional purposes, remu-

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would constitute ghostwriting. Accordingly, any written policy should specify that, where the company hires technical support to help analyze and interpret data or prepare manuscripts and presentations, those contracted service providers should work under the direction of the authors. Technical writers should be recognized in resulting publications, either as a named author, a contributor, or in the acknowledgments, as appropriate to reflect their contribution.

Moreover, all authors and contributors to any publication should be accurately and fully disclosed in accordance with ICMJE guidelines. Any funding or support provided by a pharmaceutical or device company should be accurately and fully described in any publication, including articles, manuscripts, abstracts, marketing whitepapers, or materials for presentations and promotions. Consideration should be given to adopting the OIG policies imposed upon the pharmaceutical company in the CIA addressing publication disclosures. Chief among these practices is the adoption of written policies regarding publication authorship disclosures. All authors should be required to enter into written agreements stating the exact fees paid and the precise services provided. All authors, including healthcare providers, should be provided copies of the company's publications policies and should be required to confirm their compliance with such policies.44

In addition, companies should consider establishing a monitoring program for all published materials that includes a cross-check procedure immediately before final publication to assure that all financial conflicts of interest have been disclosed, "authors" have performed authorship functions, and all other contributors have been appropriately acknowledged. The company should consider involving the compliance department in the review of all whitepapers or other marketing materials "authored" by healthcare providers to assure that no unintentional violation of the AKS or other federal law occurs.

With government oversight agencies providing every indication that the issue of publication transparency is of increasing interest and importance, pharmaceutical and medical device companies must act now to avoid serious challenges in the future. Adopting industry best publication practices combined with a formal oversight program will provide significant protection against otherwise high-risk transactions.

1. See Sen. Charles Grassley, Minority Staff Report: Ghostwriting in Medical Literature (June 24, 2010).
2. Id.
3. Id.
7. Letter from Director Francis Collins (NIH) to Paul Thacker (Investigator Project of Government Oversight) (Feb. 17, 2011).
8. Id.
10. Id.
11. Id.
12. Id.
13. Pharmaceutical Research and Manufacturers of America, "Principles on Conduct of Clinical Trials & Communication of Clinical Trial Results," (July 2011).
16. Id.
17. Id.
19. Id.
21. Id.
22. Id.
24. Id.
25. Id.
28. Id. at ¶B.3(t).
29. Id. at ¶K.3 & ¶N.
30. Id.
31. Id.
33. Id. at 15.
34. Id. at 16.
35. Id. at 19.
36. 42 U.S.C. §1320a-7(b).
37. Id.; OIG Compliance Program Guidance for Pharmaceutical Manufacturers at 23734.
39. Testimony of Lewis Morris before the House Oversight and Government Reform Committee (February 9, 2007).
41. Id. at 23738.
42. Id.
43. OIG Compliance Program Guidance, F.R. Doc. 03-10934 at 23737.
44. Some pharmaceutical companies have recently implemented disclosure practices closely tracking these requirements. For example, one major pharmaceutical company has issued a Public Disclosure and Authorship statement on its website which requires authors to acknowledge individuals who provide editorial support and disclose all funding sources. The policy expressly adopts ICMJE and PhRMA guidelines for authorship credit. Where Pfizer hires technical support to assist in analysis, interpretation of data, or to prepare manuscripts and presentations, they must work at the direction of the author. “Technical writers must be recognized” in the publication as author, contributor, or in acknowledgments, as appropriate. Id. These policies cover clinical studies, manuscripts, and abstracts. All authors receive a letter agreement regarding the disclosure policies and must sign an acknowledgement regarding the policy.