

EDITORIALS

How to Ensure Our Readers' Trust: The Proper Attribution of Authors and Contributors

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ONE OF THE GREATEST ASSETS MEDICINE POSSESSES is the public's trust. Similarly, a critical asset a medical journal must maintain is the trust of its readers. The peer-reviewed journals strive to provide accurate and unbiased information that forms the basis for how medicine is practiced. The recent controversy in which the pharmaceutical giant Merck allegedly concealed the true authorship of articles, hiring outside consultants or ghost writers and naming prestigious authorities as guest authors,^{1,2} prompts us to review and restate our standards for the proper attribution of authors and contributors.

The answer, we believe, is transparency in the medical literature. This is an ethical responsibility that extends to authorship, because not only is authorship integral to establishing credit, but it also assures accountability and responsibility.³ Unfortunately, authors listed in the byline do not always fulfill the criteria for authorship. Conversely, there may be others who are responsible for the information generated, but are not being acknowledged properly for their role in the preparation of the manuscript.⁴⁻⁷ Let's dissect the confusion, the debate, and the deception.

An author, as presently defined by the International Committee of Medical Journal Editors (ICMJE), is someone who has made "substantive intellectual contributions to the reported study, including the conception and design, or acquisition of data, or analysis and interpretation of data" and "drafting the article or revising the intellectual content."⁸ Each author should have "participated sufficiently in the work to take public responsibility for appropriate portions of the content."⁸ As important as the collection of data or general supervision of the research group are, these activities alone do not justify authorship. Journals are increasingly requiring that one author ("guarantor") be identified as the participant who takes responsibility for the integrity of the work as a whole, from inception to published article.

In the social sciences, *author* implies that you wrote the article; in medical and many other science journals,

however, *author* means that you made a substantial intellectual contribution to the manuscript (with the actual writing considered something of a technical exercise). As the complexity of scientific trials has increased, the accepted principles of authorship have become more difficult for participants to understand. Accordingly, Rennie and associates suggested a complementary model that would elicit the actual responsibility of each author in the study.³ This attribution of responsibility complements but does not replace the ICMJE criteria for defining the criteria of authorship. The ICMJE more recently stipulated that additional valued contributors who do not meet the criteria for authorship should be listed in an acknowledgment section. Examples of those who might be acknowledged include a person who provided purely technical rather than conceptual help with study design, data collection, data analysis, or with manuscript preparation. With authors and contributors clearly defined and appropriately cited in the article, no place exists for interested nonauthors or noncontributors.

Statisticians frequently meet the requirement for authorship based on the ICMJE criteria, yet fail to be listed.⁹ This diminishes the accountability of the listed authors and contributors. The ICMJE does not give explicit instruction on the role of statisticians, although they are clearly involved in data analysis (or study design) and contribute to the manuscript. Particularly in randomized and multicenter trials, which are often complex and generate large data sets, statisticians are key interpreters of the research and therefore may warrant authorship.^{9,10} Omission of the study's or project's statistician(s), as either an author or contributor, deprives readers of being informed the role of a responsible participant in the research.

Guest authorship is authorship based on an expectation that inclusion of a particular, usually prestigious, name will improve the chances that the study will be published or will increase the perceived status of the publication, although the author in question does not meet the criteria for authorship.¹¹ Gift (Honorary, Invited Guest) authorship is authorship based solely on the basis of a tenuous affiliation with a study, for example bestowing "authorship" on the basis of an individual's position as head of a department, or as a favor to a colleague or mentor to whom

Accepted for publication Jun 9, 2008.

From the Editorial Offices of the AMERICAN JOURNAL OF OPHTHALMOLOGY, ARCHIVES OF OPHTHALMOLOGY, and OPHTHALMOLOGY.

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one feel indebted, or in an attempt to make the manuscript appear to be more academic.¹²

Ghost authorship by a medical writer is more complex. Ghost authorship occurs when an individual who contributed substantially to a manuscript is not named in the byline or acknowledgments. A common example of ghost authorship is the undisclosed contributions of medical writers to the draft of a manuscript. Pharmaceutical companies, academic institutions, and even journals differ in their sanctioning of this so-called medical writer syndrome.¹³ The ICMJE guidelines as well as other guidelines from pharmaceutical company and medical writers groups emphasize the need to acknowledge the role of medical writers as either authors or as contributors.^{14–17} It may be argued that the act of drafting a manuscript always involves an element of interpretation, yet the medical writer is not in a position to fulfill another important principle of authorship, that is, to take public responsibility for the study. Some so-called made-to-order drug studies conducted by contract research organizations analyze data in-house and have professional writers pen the manuscripts (because the physicians are practitioners who have not previously written scientific manuscripts); occasionally, an academic is asked to serve as the author of those manuscripts. The resulting articles affect the conclusions found in the medical literature and at times are used in promoting drugs or devices to doctors.¹⁸ This double iteration of the guest-ghost authorship is an increasing practice called the nonwriting author-nonauthor writer syndrome, which is frequently used in drug trial reports, editorials, and review articles.¹⁹ Medical writers may be instructed to insert biased phrases or selected information favorable to the company product.¹⁹ The nonwriting author (guest) may or may not be involved in the research at all, but is selected to enhance the prestige of the manuscript.^{13,20}

In less complex studies published in past decades, reports were written by a study's principal investigator.¹⁹ In reality, many good scientists are mediocre writers or communicators. To cope with the challenges of the complex multicenter studies now conducted, medical writers often are used to produce a clearer and more readable manuscript. This process can benefit the scientific community when used responsibly.^{13,18} Professional medical writers often are involved in either writing protocols or in preparing manuscripts for publication, but the writers should work under appropriate direction of the academics rather than at the direction of industry.^{11,21} A concern with a ghost-authored article is that the readers are deceived into assuming that the manuscript was written by an unbiased academic source instead of by a possible marketing-related source. Not listing the so-called ghosts limits desired transparency, especially with regard to disguising possible conflicts of interest or bias, and it undermines the scientific integrity of medical journals. Phar-

maceutical companies fund most clinical trials and control an immense quantity of research data. Because a substantial percentage of medical journal articles are ghost-managed, this allows the pharmaceutical industry to exert considerable influence (bias) on the medical literature, converting research into a vehicle for marketing, sometimes in innovative ways.^{9,18,21}

The frequency of these various authorship indiscretions is difficult to determine and to detect; most articles that have been identified as ghostwritten were revealed as such only by investigative work after publication.^{22–24} A high percentage of medical writers attest to ghost writing without proper attribution,²⁵ and 11% of younger scientists reported inappropriately assigning author credit at least once in the last three years.²⁶ A survey by Flanagan and associates of three major journals in medicine revealed that 19% of articles had evidence of honorary authors, 11% had evidence of ghost authors, and 2% had evidence of both. The prevalence of articles with honorary authors was greater among review articles than research articles.²⁷ Among National Institutes of Health investigators, 15% reported altering the design or interpretation of research at the request of the sponsor and 10% admitted to inappropriate assignment of guest or gift authorship.²⁶ Some medical schools are willing to enter into agreements that permit the sponsors to draft the manuscript and also to limit the academic investigator's ability to revise it.²⁸

ICMJE authorship criteria in fact are widely misunderstood and, because 62% of a sample of 66 British academics disagree with at least one aspect of the perceived strict ICMJE criteria,⁴ this topic seems both complex and evolving. Each journal presently may differ in its definition of author vs contributor (and the ICMJE and most journals do not define the terms definitively). There is clear misuse of medical writers, guest authors, and honorary authors, and although it is easy to criticize sponsors and ghost writers, researchers have permitted these irregularities.

In the wake of the Merck-Vioxx controversy, we endorse the 11-point agenda recommended by the JAMA editors.¹ Consistent with that, we will strive toward the following related policies for our own journals to achieve more transparency and more comprehensively to disclose all the major individuals who participated in the research and the manuscript preparation. These actions are in accordance with ICMJE, the medical writers associations, and the pharmaceutical company guidelines:

1. Academics should attest in the cover letter that they control the wording of the final manuscript, and sponsors should provide the guarantor of the manuscript all the study data.
2. All involved in the manuscript or study should be cited clearly, either as authors in the byline or as contributors in the acknowledgment section, along with their affiliations and financial disclosures.

3. Authors should fulfill the specific criteria of the ICMJE; the order of the authors should follow ethical principles. All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who may be acknowledged include: individuals who contributed cases, purely technical help, or medical writing assistance; or a department chair who provides financial support or other support. Other investigators may be listed, including their specific role in the study (participating investigator, scientific advisor, data monitor). All persons listed as contributors must give written permission to be acknowledged because the listing suggests an endorsement of the data or its interpretation.
4. Statisticians frequently reach the level of authorship but at the minimum should be listed as contributors.
5. Guest authors and gift (honorary) authors who have not actually been involved in the design, conduct, or supervision of the research will not be included as authors or contributors.
6. Pharmaceutical companies should submit their own studies with their own company authors and with the appropriate disclosure, rather than employing the deception of guest authorship; the manuscript will be subjected to scrutiny as are all manuscripts.
7. Although we encourage researchers to write their own manuscripts, when it is absolutely necessary to have the assistance of a medical writer, the medical writer should be under the direction of the academic participants rather than industry-controlled and should be acknowledged as either an author or as a contributor, along with their specific role in the manuscript, their affiliation, and their financial disclosure.

THE AUTHORS INDICATE NO FINANCIAL SUPPORT OR FINANCIAL CONFLICT OF INTEREST. ALL OF THE AUTHORS WERE involved in design and conduct of study; data collection; analysis and interpretation of data; and preparation and review of the manuscript.

REFERENCES

1. DeAngelis CD, Fontanarosa PB. Impugning the integrity of medical science: the adverse effects of industry influence. *JAMA* 2008;299:1833–1835.
2. Ross JS, Hill KP, Egilman DS, Krumholz HM. Guest authorship and ghostwriting in publications related to Rofecoxib: a case study of industry documents from Rofecoxib litigation. *JAMA* 2008;299:1800–1812.
3. Rennie D, Yank V, Emmanuel L. When authorship fails: a proposal to make contributors accountable. *JAMA* 1997;278:579–585.
4. Bhopal R, Rankin J, McColl E, et al. The vexed question of authorship: views of researchers in a British medical faculty. *BMJ* 1997;314:1009–1012.
5. Goodman NW. Survey of fulfillment of criteria for authorship in published medical research. *BMJ* 1994;309:1482.
6. Shapiro DW, Wenger NS, Shapiro MF. The contributions of authors of multiauthored biomedical research papers. *JAMA* 1994;271:438–442.
7. Mowatt G, Shirran L, Grimshaw JM, et al. Prevalence of honorary and ghost authorship in Cochrane Reviews. *JAMA* 2002;287:2769–2771.
8. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. 2006. Available: <http://www.icmje.org>. Accessed: February 24, 2008.
9. Gøtzsche PC, Hróbjartsson A, Johansen HK, et al. Ghost authorship in industry-initiated randomized trials. *PLoS Med* 2007;e19.
10. Chan A-W, Hróbjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. *JAMA* 2004;291:2457–2465.
11. Cullen DJ. Ghostwriting in scientific anesthesia journals. *Anesthesiology* 1997;87:195–196.
12. Claxton LD. Scientific authorship Part 2. History, recurring issues, practices, and guidelines. *Mutat Res* 2005;589:31–45.
13. Moffatt B, Elliott C. Ghost marketing: pharmaceutical companies and ghostwritten journal articles. *Perspect Biol Med* 2007;50:18–31.
14. The World Association of Medical Editors. Ghost writing initiated by commercial companies. *J Gen Intern Med* 2005;20:549.
15. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21:317–322.
16. Wager E. Authors, ghosts, damned lies, and statisticians. *PLoS Med* 2007;4:e34.
17. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin* 2003;19:149–154.
18. Sismondo S. Ghost management: how much of the medical literature is shaped behind the scenes by the pharmaceutical industry? *PLoS Med* 2007;4:e286.
19. Bodenheimer T. Uneasy alliance—clinical investigators and the pharmaceutical industry [Health Policy Report]. *N Engl J Med* 2000;342:1539–1544.
20. Elliott C. Pharma goes to the laundry: public relations and the business of medical education. *Hastings Cent Rep* 2004;34:18–23.
21. Laine C, Mulrow CD. Exorcising ghosts and unwelcome guests. *Ann Intern Med* 2005;143:611–612.
22. Ngai S, Gold JL, Gill SS, Rochon PA. Haunted manuscripts: ghost authorship in the medical literature. *Account Res* 2005;12:103–114.
23. Woolley KL, Ely JA, Woolley MJ, et al. Declaration of medical writing assistance in international peer-reviewed publications. *JAMA* 2006;296:932–934.

24. Healy DT. Transparency and trust: figure for ghost written articles was misquoted. *BMJ* 2004;329:1345.
25. Mathews AW. Ghost story: at medical journals, writers paid by industry play big role. *Wall Street Journal*, December 13, 2005:A1.
26. Martinson BC, Anderson MS, de Vries R. Scientists behaving badly. *Nature* 2005;435:737–738.
27. Flanagin A, Carey LA, Fontanarosa PB, et al. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *JAMA* 1998;280:222–224.
28. Mello MM, Clarridge BR, Studdert DM. Academic medical centers' standards for clinical-trial agreements with industry. *N Engl J Med* 2005;352:2202–2210.