

Guidelines on Professional Medical Writing



2005 ISMPP Inaugural Meeting
Princeton, NJ

The Issue...

Journal editors and others have raised concerns regarding the ethics of using professional medical writers to prepare manuscripts for publication.

Journal Editor's Position

Thanks to
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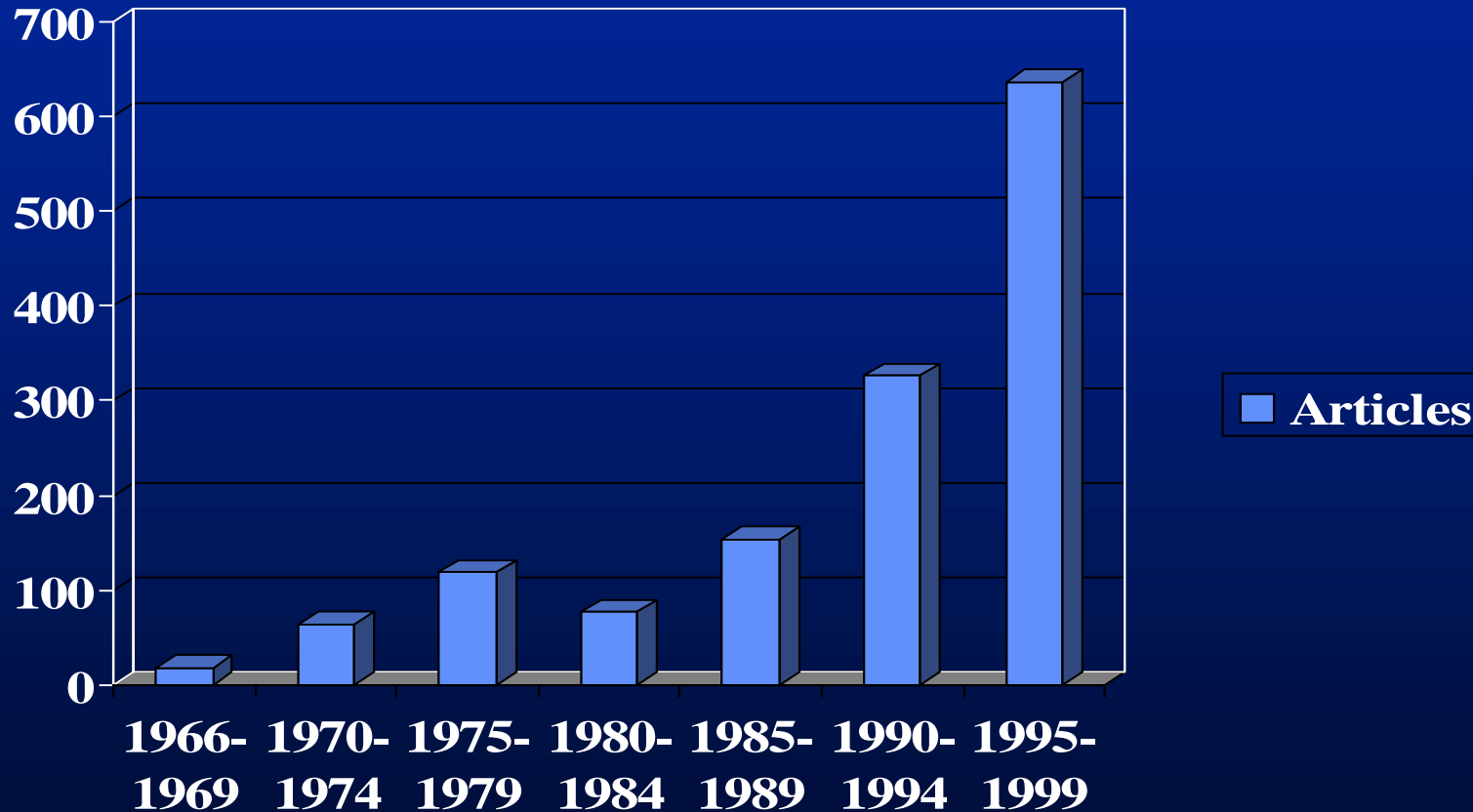
JAMA Policy Statement

Data Access and Responsibility.

For reports containing original data, at least 1 author who is independent of any commercial funder (eg, the principal investigator) should indicate that she or he "had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis." For industry sponsored studies, the data analysis should be conducted by statisticians at an academic center, rather than only by statisticians employed by the company sponsoring the research.

- ◆ Concerns about authorship
- ◆ What journal editors think about ghost authors
- ◆ What journal editors think about ghostwriters
- ◆ Recommendations

Articles on authorship, 1966-1999



MEDLINE, 1966-1999

Research on authorship

- ◆ Increase in numbers of authors
- ◆ Order of authorship
- ◆ Meaning of authorship
- ◆ Honorary (gift or guest authors)
- ◆ Ghost authors
- ◆ Roles and contributions of authors and others

Prevalence of ghost authors in medical journals

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.

- ◆ Survey of 1179 corresponding authors or articles published in 6 peer-reviewed journals in 1996
- ◆ 809 authors responded (69%)
- ◆ ghost author defined as an individual not listed as an author who made contributions that merited authorship or an unnamed individual who participated in writing the article

Prevalence of ghost authors

	N	Total	Research	Reviews	Editorials
Am J Cardiol	137	9%	9%	13%	14%
Am J Med	113	13%	10%	16%	0
Am J Ob Gyn	125	10%	10%	19%	7%
Ann Intern Med	104	15%	20%	10%	7%
JAMA	194	7%	10%	3%	5%
N Engl J Med	136	16%	26%	2%	7%
Total	809	11%	13%	10%	6%

Prevalence of ghost authors in medical journals

Flanagin A, Carey LA, Fontanarosa PB, et al. *JAMA*. 1998;280:222-224.

93 of 809 articles (11%) had ghost authors

- ◆ Of these 93 articles, 79 (85%) had no acknowledgment section

Survey of contributorship in Cochrane reviews

Mowatt G, Grimshaw JM, et al. Survey of contributorship in Cochrane reviews. Fourth International Congress on Peer Review in Biomedical Publication. Barcelona. Sept 14, 2001.

- ◆ Survey of primary contacts for 577 Cochrane reviews published in 1999
- ◆ 362 primary contacts of reviews responded (63%)
- ◆ Ghost author defined as person not listed as an author who had made a contribution that merited authorship or who had assisted in drafting the review
- ◆ 32 (9%) of reviews had ghost authors

Who is an author?

International Committee of Medical Journal Editors (ICMJE) or “Vancouver Group”
Criteria

Substantial contributions to:

1. Conception or design, or acquisition of data, or analysis or interpretation of data
2. Drafting the manuscript or revising it critically for important intellectual content
3. Final approval of the version to be published

Authors should meet conditions 1, 2, and 3.

Concerns about ICMJE authorship criteria

Studies show that

- ◆ many authors do not recognize or understand the criteria
- ◆ many authors do not think the criteria are practical
- ◆ many authors do not meet the criteria for authorship

Proposal to address authorship concerns

- ◆ Contributorship (Rennie et al. *JAMA*. 1997;278:579-585.)
- ◆ Each author is asked to identify how they have contributed to the work
- ◆ Two methods of identifying contributions
 - Ask authors to self-identify contributions (*Lancet*, *BMJ*)
 - Provide a checklist of various contributions (*Annals of Internal Medicine*, *JAMA*, *Radiology*)

JAMA Authorship Responsibility, Criteria, and Contributions

A. I certify that

- the manuscript represents valid work and that neither this manuscript nor one with substantially similar content under my authorship has been published or is being considered for publication elsewhere, except as described in an attachment; and
- if requested by the editors, I will provide the data or will cooperate fully in obtaining and providing the data on which the manuscript is based for examination by the editors or their assignees; and
- for papers with more than 1 author, I agree to allow the corresponding author to serve as the primary correspondent with the editorial office, to review the edited typescript and proof, and to make decisions regarding release of information in the manuscript to the media, federal agencies, or both; or, if I am the only author, I will be the corresponding author and agree to serve in the roles described above.

B. I have given final approval of the submitted manuscript.

C. I have participated sufficiently in the work to take public responsibility for (check 1 of 2 below)

part of the content.

the whole content.

I have made substantial contributions to the intellectual content of the paper as described below.

1. (check at least 1 of the 3 below)

- conception and design
- acquisition of data
- analysis and interpretation of data

2. (check at least 1 of 2 below)

- drafting of the manuscript
- critical revision of the manuscript for important intellectual content

3. (check at least 1 below)

- statistical analysis
- obtaining funding
- administrative, technical, or material support supervision
- no additional contributions
- other (specify)

Author Contributions:

Dr Jones participated in study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, obtaining funding, administrative, technical, or material support, and supervision of the study.

Dr Smith participated in critical revision of the manuscript for important intellectual content and provision of statistical expertise.

Mr Wells participated in study concept and design, analysis and interpretation of data, and critical revision of the manuscript for important intellectual content.

Who are the ghosts?

- ◆ Medical journals have been working to define, identify, and hopefully “flesh-out” ghost authors.
- ◆ Can we do the same with ghostwriters?

Definition

Main Entry: ghost Date: before 12th century

From *Merriam-Webster's Collegiate Dictionary* <http://www.m-w.com/cgi-bin/dictionary>

- 1 the seat of life or intelligence: **SOUL**
- 2 a disembodied soul; *especially*: the soul of a dead person believed to be an inhabitant of the unseen world or to appear to the living in bodily likeness
- 3 **SPIRIT, DEMON**
- 4 a faint shadowy trace; the least bit
- 5 a false image in a photographic negative or on a television screen caused especially by reflection
- 6 one who **ghostwrites**
- 7 a red blood cell that has lost its hemoglobin

Ghostwrite (verb)

From *Merriam-Webster's Collegiate Dictionary* <http://www.m-w.com/cgi-bin/dictionary>

- ◆ Etymology: back-formation from *ghostwriter*
Date: 1927
- ◆ *intransitive senses* : to write for and in the name of another
- ◆ *transitive senses* : to write (as a speech) for another who is the presumed author

Difference between ghost authors and ghostwriters

- ◆ Ghost authors should be listed in the byline; ghostwriters should not.
- ◆ If a ghostwriter has done enough to merit listing in the byline, then she is a ghost author.
- ◆ How are ghost authors and ghostwriters similar?
 - Neither is visible to editors, peer reviewers, readers, or those who may wish to hire the author or the writer
 - Neither gets credit
 - Neither is publicly accountable for their work

What do medical editors and publishing scholars think of ghostwriting?

- ◆ “Ghostwriting for scholarly publications raises serious ethical questions.”
 - Lois DeBakey, 1975
- ◆ “In a discipline in which the pursuit of truth is of primary importance, there is no place for any form of subterfuge, sham, or dissimulation. And how far is it from ghostwriting to ghost data?”
 - Lois DeBakey, 1975

What do medical editors and publishing scholars think of ghostwriting?

- ◆ Ghostwriting is what you do for a football player when it is painfully obvious from his every utterance on and off the field that he has little to say but still needs help to say it. The practice ought to have no place in scientific writing, yet it happens...” -David Sharp, *Lancet*, 1998
- ◆ “the ghost-writing arrangement goes against the spirit of author responsibility that editors have been struggling to introduce.” -David Sharp, *Lancet*, 1998

What do medical editors and publishing scholars think of ghostwriting?

-From Drummond Rennie, October 24, 2001

“Ghostwriting is crooked and foolish - crooked, because it is deliberately deceptive and foolish because it allows writers to let their work be taken by others.”

What do medical editors and publishing scholars think of ghostwriting?

- ◆ “The practice of buying editorials reflects the growing influence of the pharmaceutical industry on medical care...Indeed, the goal of public-relations firms that ghostwrite editorials and do other work for drug companies is to blur the distinction between primary [interests, such as patient’s welfare or the validity of research] and secondary interests [such as financial gain.]”
 - Troyen Brennan, *N Engl J Med*, 1994

Common problems encountered by editors when ghostwriting is involved

- ◆ Difficulty in review and consideration of a manuscript
- ◆ Difficulty identifying potential biases and conflicts, which need to be made available to readers
- ◆ Difficulty correcting published errors
- ◆ Loss of trust

What do some medical editors who recognize the work of professional writers think?

- ◆ We value the writing, not the ghosting.
- ◆ “Aside from the obvious need for better communications between communicators, we believe that, at the very least, medical writers and authors’ editors should be identified and given credit in an acknowledgment, just as a statistician or laboratory assistant might be named.”

Drummond Rennie and Annette Flanagin, *JAMA*, 1994

Anesthesiology Guide for Authors

- ◆ All persons or organizations involved in the work must be listed as authors or acknowledged. Manuscripts are received with the understanding that they have been written by the authors; ghostwritten papers are unacceptable.

Acknowledgment

- ◆ This is the place to give credit to all who contributed substantially to a manuscript but who do not merit authorship.
- ◆ This is the place to give credit to writers who are not authors.
- ◆ This is the place to make ghostwriters visible.

JAMA Acknowledgment Statement

I certify that all persons who have made substantial contributions to the work reported in this manuscript (eg, data collection, analysis, or writing or editing assistance) but who do not fulfill the authorship criteria are named along with their specific contributions in an Acknowledgment in the manuscript. I certify that all persons named in the Acknowledgment section have provided me with written permission to be named.

What have industry editors and writers told journals about ghostwriting?

- ◆ “In the best of worlds all authors would write their own papers, and write them well. Alas, the best of worlds eludes us...we should recognize that medical writers are here to stay and progress to the next step -guidelines to ensure that medical-writing services are used ethically.”

Leni Grossman, *The Lancet*, 1998

- ◆ “Instead of criticising the ghosts, journal editors and sponsoring companies should work together to draw up guidelines of acceptable practice.”

Elizabeth Wager, *The Lancet*, 1998

Recommendation

- ◆ Extend the idea of contributorship in journals beyond authors to include professional writers

The following contributions of medical writers should be disclosed

- ◆ assisting with drafting of the manuscript
- ◆ assisting with revision of the manuscript
- ◆ conducting or assisting with literature review or bibliographic searches
- ◆ creating or assisting with graphics and tables
- ◆ supervision or project management
- ◆ serving as liaison between sponsor and authors
- ◆ preparing manuscript and other materials for journal submission
- ◆ other contributions?

Conclusions

- ◆ Ghostwriting is unethical, writing is not.
- ◆ The key to maintaining the integrity of and trust in medical communication is disclosure
 - including disclosure of the specific contributions of professional writers.

The AMWA Position

Thanks to Cindy W. Hamilton, PharmD

Overview

- ◆ What guidelines are available for medical writers who want to take the ghost out of ghostwriting?
- ◆ What is AMWA's position statement?
- ◆ What can pharmaceutical companies do about the ghostwriting controversy?

What guidelines were used to prepare AMWA's position statement?

- ◆ Journals' instructions for authors
- ◆ Uniform requirements for manuscripts submitted to biomedical journals
- ◆ Good Publication Practice (GPP) for pharmaceutical companies

What guidelines were used to prepare AMWA's position statement? (cont'd)

- ◆ PhRMA Principles for the Conduct of Clinical Trials and Communication of Clinical Trial Results
- ◆ AMWA Position Statement on the Contributions of Medical Writers to Scientific Publications

What is AMWA's Code of Ethics?

- ◆ Preamble: AMWA “is an educational organization that promotes advances and challenges in biomedical communication by recommending principles of conduct for its members.”
- ◆ Principle 1 of 8: “Biomedical communicators should recognize and observe statutes and regulations pertaining to the materials they write, edit, or otherwise develop.”

What is AMWA's position statement?

- ◆ AMWA recognizes the valuable contributions of biomedical communicators to the publication team.
- ◆ Biomedical communicators who contribute substantially to the writing or editing of a manuscript should be acknowledged
 - with their permission and
 - with disclosure of any pertinent professional or financial relationships.
- ◆ In all aspects of the publication process, biomedical communicators should adhere to the AMWA code of ethics.

How should biomedical communicators use AMWA's position statement?

How should the biomedical communicator be acknowledged?

- ◆ We thank Susie Smith, a freelance writer who received payment from the sponsor, for assisting with the first draft and preparing the manuscript for submission.
- ◆ Acknowledgment: Tom Black, an author's editor, edited the manuscript and received payment from the sponsor for this work.

What about journals that don't allow acknowledgments?

How can pertinent professional or financial relationships be disclosed?

How can professional or financial relationships be disclosed?

Contributor

Financial Relationship

Authors

Investigator A

Research grant

Investigator B

Consultant

Acknowledged Contributors

Statistician

Full-time employee

Writer

Fee for writing and editorial services

The EMWA Position

The Problem

- ◆ Ghostwriting: where a professional medical writer prepares a manuscript on behalf of a named author, but the writer is not listed as an author.

The Process

- ◆ Using a Delphi consultation process, a group of medical writers established by EMWA set out to determine the current thinking on the problems of ghostwriting in medical publications and what should be done about them.

The Task Force

- ◆ Selected at EMWA's 2003 Annual Conference.
- ◆ Professional experience relevant to ghostwriting.
- ◆ Primarily freelance consultants or communication agencies to ensure minimum pharma. influence.

The Process

4-Round Delphi Consultation

- ◆ **Round 1**: provide initial ideas about ghostwriting, in 3 categories:
 1. What are the major issues
 2. What should be the objectives of the process, or how would we like ghostwriting to operate in an ideal world.
 3. What activities should be undertaken to reach objectives

The Process

4-Round Delphi Consultation

- ◆ **Round 2:** elaborate on Round 1 ideas
- ◆ **Round 3:** collation of ideas into statements on ghostwriting and rating of each on a scale from 0-10
- ◆ **Round 4:** Re-rate those items that had not achieved consensus (eg, standard deviation of <2)

Results

The idea that had the strongest support was that “skilled medical writers are an important resource and can improve the quality of scientific papers”.

Results

Benefits:

- ◆ Speeding the publication process
- ◆ Improving readability of papers (accessible to wider audience)
- ◆ Providing critical appraisal and assuring that reporting guidelines are met

Issue:

- ◆ Broaden appreciation of **journal editors** and **authors** of the value-add beyond merely improving grammar

Observations

Some journal editors are hostile to the concept of ghostwritten manuscripts, and we would like that hostility to disappear. However, we did not feel it necessary that journal editors should go so far as to actively encourage manuscripts written by medical writers.

Observations

Involvement of medical writers should be fully transparent. Need to define exactly how medical writers should be mentioned. Current authorship guidelines are inadequate to address this issue.

Observations

Unethical ghostwriting practices should be avoided.

While ghostwriting is widely perceived as unethical, we believe strongly that it is NOT intrinsically unethical.

Observations

While the term “ghostwriting” itself is an unfortunate term, merely changing the term would be of little use without also ensuring that high ethical standards were maintained.

Observations

Medical Writers should have a thorough understanding of publication ethics.

Next Steps

- ◆ Initiation of meetings with people who object to ghostwriting to explore their objections and how we might overcome them.
- ◆ Provide opportunities to discuss medical writing with all interested parties
- ◆ Educate medical writers about ethical ghostwriting standards
- ◆ Develop EMWA Position Statement

EMWA Guidelines

EMWA:

- ◆ Affirms that medical writers have a legitimate role in assisting named authors in developing manuscripts for peer-reviewed journals and material for presentation at peer-reviewed scientific meetings.
- ◆ Believes that such contributions and relevant information about funding should be openly acknowledged.
- ◆ Discourages use of the term “ghostwriter” to describe professional medical writers, as this term implies that there is something secretive about the involvement of the writer. Rather, the involvement of professional medical writers should always be transparent.

EMWA Guidelines

- ◆ Believes that properly trained medical writers can make a positive contribution to manuscript preparation. Such writers bring expertise about the requirements of journals and congresses and the ethics and conventions of peer-reviewed biomedical publications. They also offer skills in language, scientific communication, and data presentation. Such skills and knowledge enable professional writers to prepare drafts that are clearly written and follow the relevant guidelines. Involving medical writers may therefore raise the standard of publications and accelerate the writing and publication process.

EMWA Guidelines

- ◆ Encourages medical writers to ensure that publications are developed in a responsible and ethical manner, as specified in the guidelines that accompany the position statement; eg,
 - keeping up-to-date with relevant guidelines (eg, CONSORT, ICMJE, GPP) and journal or conference requirements for financial disclosures or statements about competing interests
 - advising colleagues and customers about these

EMWA Guidelines

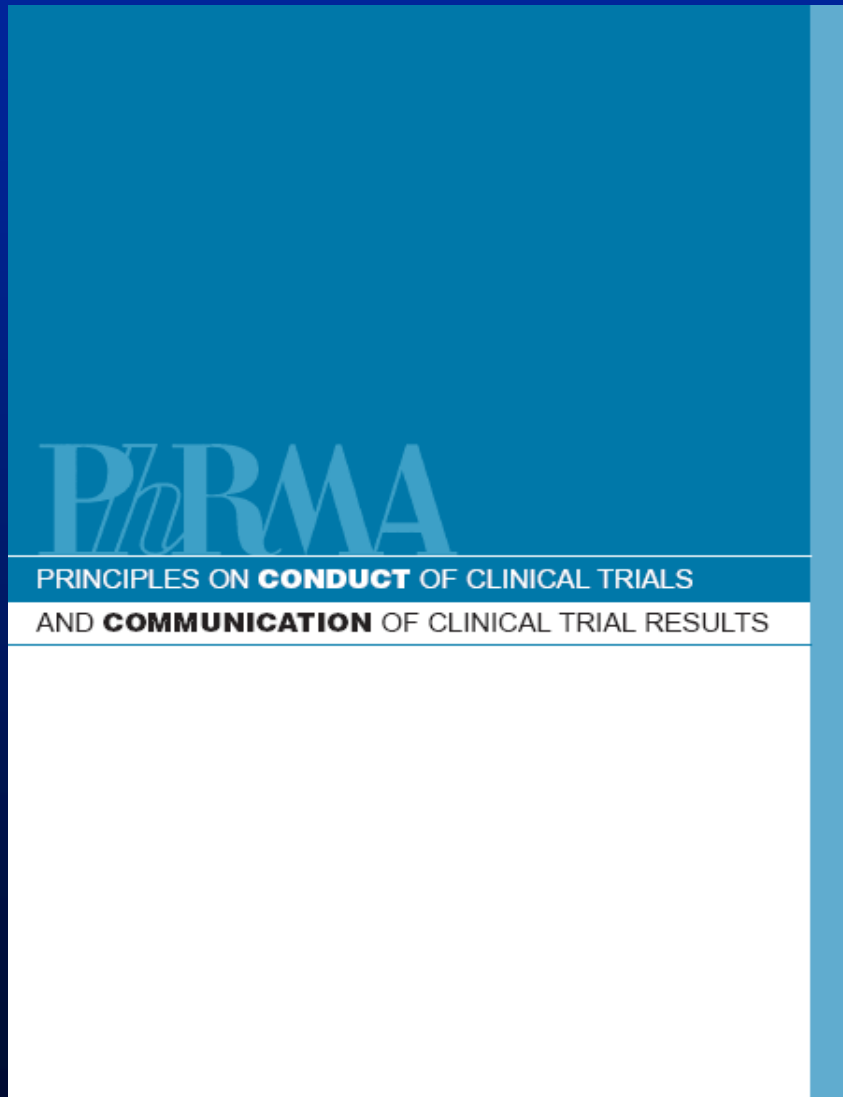
- involving the named author(s) early in the publication process
- refusing requests to develop publications without sufficient involvement of the named author(s)
- making their best efforts to ensure that publications are accurate, balanced, and scientifically valid, acknowledging the limitations of their expertise and seeking guidance where needed
- taking particular care to present results relating to the sponsor's product in a fair and balanced fashion

EMWA Guidelines

- endeavoring to ensure that the named author(s) has access to the necessary data and adequate time to contribute to a publication
- endeavoring to ensure that all named authors approve the final version before submission to a journal or conference
- refusing requests to develop publications in an unethical or irresponsible manner

The Pharmaceutical Industry Position

What are the PhRMA Principles?



- ◆ Release date: June 2002
- ◆ Issue 4 of 4
 - Disclosure of clinical trial results
 - Authorship consistent with ICMJE

PhRMA Principles (cont'd)

- ◆ “Companies sometimes employ staff to help analyze and interpret data, and to produce manuscripts and presentations. Such personnel must act in conjunction with the investigator-author.”
- ◆ “Their contributions should be recognized appropriately in resulting publications – either as a named author, a contributor, or in acknowledgments depending on the level of their contribution.”

Do pharmaceutical companies have any innovative solutions to the ghostwriting controversy?

What did the survey show?

Question	Number of yes/total responses (%)
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Does your company have a publication policy?

7/10 (70)

If yes, does the policy address ghostwriting?

5/9 (56)

What did the survey show (cont'd)?

Does your company comply with the following?	Number of yes/total responses (%)
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Uniform Requirements	6/10 (60)
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Good Publication Practice for Pharmaceutical Companies	5/9 (56)
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PhRMA “Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results”	6/10 (60)
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What does Amgen do about the ghostwriting controversy?

- ◆ Avoid the word “ghostwriting”
- ◆ Make medical writers and editors part of the team
- ◆ Use the acknowledgment section of the manuscript to acknowledge the people who write the following:
 - Clinical study report
 - Manuscript

What does J&J do about the ghostwriting policy?

- ◆ Publication policy
 - Dissemination of results, whether positive or negative
 - No ghost authoring
 - Author(s) identification before writing begins
 - Author involvement throughout manuscript preparation
 - Close cooperation between author(s) and writer
 - Author(s) responsible for contents

What does Merck do about the ghostwriting controversy?

- ◆ Guidelines for Publication of Clinical Trials and Related Works: Authorship and Accountability
 - Anyone who provides substantial effort or has a major impact in study design, data analysis and interpretation, or in manuscript preparation or revision should receive appropriate recognition (as an author, contributor, or in acknowledgments) ...
 - Conversely, individuals who do not contribute ... do not warrant named authorship.
 - Subject to journal policy, we will list ... all investigators at the end of a manuscript. The lead author is generally responsible for defending the content and the integrity of the manuscript...

Conclusions

- ◆ How can we solve the ghostwriting controversy?
 - Become familiar with existing guidelines
 - Develop a publication policy
 - Publicize your publication policy

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Sources of Information

- ◆ AMWA Position Statement on the Contributions of Biomedical Communicators to Scientific Publications www.amwa.org
- ◆ International Committee of Medical Journal Editors and Uniform Requirements www.icmje.org
- ◆ JAMA's Instructions for Authors http://jama.ama-assn.org/ifora_current.dtl
- ◆ Good Publication Practice for Pharmaceutical Companies <http://www.gpp-guidelines.org/>

Sources of Information

- ◆ Peer Review Congress Web site
<http://www.jama-peer.org>
- ◆ PhRMA Principles <http://www.phrma.org/publications/policy/2002-06-24.430.pdf>
- ◆ Merck Guidelines for Publication of Clinical Trials and Related Works
www.merck.com/about/cr/policies_performance/pdf/clinical_trial_publication_guidelines.pdf
- ◆ Jacobs A. The involvement of professional medical writers in medical publications: results of a Delphi study. *Curr Med Res Opin* 2005;21(2):311-6
- ◆ 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(2):317-21

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