

# Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools



## COI Toolkit on Ghostwriting and Name-lending

### I. Introduction

Medical ghostwriting and name-lending undermine the credibility and integrity of medical research and publishing by fraudulently hiding the true identity of authors. A general definition of ghostwriting is “to write for and in the name of another.”<sup>1</sup> In the medical arena, for example, someone directly or indirectly employed by a pharmaceutical or medical device company writes a paper but gives credit for the authorship to prominent physicians in the field who sign-on as “authors.” The identity of the true author is not disclosed, thus the term *ghostwriter*.

The person who allows his or her name to be used as the author is often described as a “guest author” or “honorary author,” but a more appropriate label for this activity is name-lending, as aptly described in the United Kingdom. However, the person “lending” his or her name to the ghostwritten article is usually paid a handsome fee. The name-lender rarely has access to the trial data for independent analysis and is only included after key decisions have been made by the pharmaceutical or device company regarding how the data is to be represented.<sup>2</sup>

Ghostwriting and name-lending contribute to carefully planned industry strategies to market their products under the guise of objective, unbiased scientific data. Faculty who participate in these practices abrogate their responsibility to uphold ethical standards for academic and professional conduct. For example, the following unsealed corporate marketing documents confirmed how manufacturer Wyeth used ghostwritten articles for marketing of the hormone combination drug PremPro: “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.”<sup>3</sup> Wyeth was able to publish more than 50 ghostwritten papers in peer-reviewed journals, aimed to either minimize the perceived risks of breast cancer or to claim unsupported cardiovascular benefits associated with the now-discredited hormone-replacement-therapy (HRT).

Many other examples of ghostwriting and name-lending have recently been exposed in connection with the drugs Paxil, Zoloft, Lexapro, Vioxx, Neurontin and others. Despite attempts by medical journals to assure

# Ghostwriting and Name-lending

that the listed authors are the bona fide sources of the scientific research or opinions presented, ghostwriting persists. The editors of PLoS Medicine describe how industry succeeded in having ghostwritten articles published in their own journal, as well as among many other leading medical journals.<sup>4</sup>

## II. The Persistence and Impact of Ghostwriting and Name-Lending

Despite authorship standards first published by the International Committee of Medical Journal Editors (ICMJE) in the 1980's,<sup>5</sup> ghostwriting and name-lending persist. A survey of corresponding authors at major medical journals showed “evidence of honorary and ghost authorship in 21 percent of articles” published in 2008, although not defined to include only industry related authorship. The “prevalence of ghost authorship was 11.9 percent in research articles, 6.0 percent in reviews, and 5.3 percent in editorials.”<sup>6</sup> According to an analysis of policies at 50 leading academic medical centers in 2009-10, 13 (26 percent) prohibited ghostwriting explicitly or in practice and 13 (26 percent) did not ban all aspects of ghostwriting, especially failing to require that all authors be listed.<sup>7</sup>

According to ICMJE standards, authors are defined as those who make substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; draft the article or revise it critically for important intellectual content; and, provide final approval of the version to be published. While professional medical writers can play a legitimate and useful role in improving the communication of important medical research to the public and to the profession, any such contributions must be recognized properly and openly in the manuscript. The initiative to use professional medical writers should come from the investigators, who should directly and exclusively supervise the drafting and revision of any scientific or editorial manuscript for publication and accept personal responsibility for the final product.

Name-lending is analogous to students buying term papers off the Internet, but more egregious.<sup>8</sup> Whereas students pay for fraudulently authored papers that they submit as their own work, name-lending faculty are actually paid to take credit for the work and hide the real source. Traditional university policies on plagiarism may not be well suited to deal with this kind of academic dishonesty since the real author is in collusion with the name-lending author and will not file a complaint.<sup>9</sup>

Ethical principles are violated when industry uses a prestigious author to lend credibility and authority to research and conclusions in which, as one ghostwriter put it, “advertising masquerades as unbiased health information.”<sup>10</sup> Furthermore, readers are deprived of information that would lead them to be otherwise more skeptical of the paper.

Ghostwriting and name-lending jeopardize the scientific foundations of medicine and threaten the quality of care. Patients can be hurt and even die when new products are rapidly and widely adopted due to promotional

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*“Editors, reviewers, and readers must know who participated in writing a manuscript. When submitting a paper, the corresponding author must ensure that all authors are listed and anyone who has contributed to the paper is identified.”*

*— Howard Bauchner, MD.  
Editor-in-chief, Journal of the  
American Medical Association*

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strategies that lead practicing physicians to act on what they perceive to be the scientific work of well-respected experts in the field. In some instances a troubling counter-reaction may also occur if readers of the literature, unable to distinguish which articles are ghostwritten and which are legitimate scholarship, choose to approach all medical literature with caution, or even cynicism, and delay or fail to adopt new treatments or clinical practices that could be helpful to their patients. Since ghostwriting also occurs with self-study continuing medical education (CME), it may also disguise industry influence, as well as undermine trust in legitimate programs in this sphere of learning.

### III. Policy Considerations

While primary responsibility for ferreting out ghostwriting lies with the medical journals, medical schools and AMCs should focus on name-lending. Their faculty sustain this practice when they allow themselves to be used by industry in this manner.

Medical schools and AMCs should unambiguously condemn name-lending as a violation of professional ethics. Just as important, institutions should create mechanisms to assure compliance with this standard and delineate and enforce penalties for violation. Since faculty are meant to be role models for students, the penalty for faculty who engage in name-lending should be at least equal to the penalty applied to students who buy term papers off the Internet and submit them as their own work. This should include public acknowledgement of the ghostwritten article and the possibility of suspension or dismissal for willful violation. In addition, any manufacturer found to have engaged in conduct that played a role in enticing a faculty member to engage in name lending should face institutional consequences as well.

To strengthen compliance, as well as prevent inadvertent name-lending by naïve faculty, academic medical institutions should consider promulgating a checklist that must be completed by a faculty member who is submitting a manuscript for publication (including clinical guidelines and self-study CME materials) or is allowing a manuscript to be submitted by another person on which the faculty member is listed as an author. The checklist could include the following questions:

1. Have you met the ICMJE conditions for authorship (substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; and, final approval of the version to be published)?
2. Has any person other than the authors listed provided research or writing for this manuscript?
3. Have you received any financial payment, directly or indirectly, in exchange for allowing yourself to be credited as an author?

*“It’s time for the medical profession to discontinue any further practice of ghostwriting or name-lending. It diminishes the integrity of the clinical research process and leads to worse patient care.”*

*— Joseph S. Ross, MD, M.H.S.,  
Assistant Professor of Medicine,  
Yale School of Medicine.*

The answers to these questions should be submitted to the department or division chair or in the case of a department chair, to the dean. If the answer to the second or third questions is yes or the answer to the first question is no, then the department or division chair or dean should interview the faculty member to assure that name-lending is not occurring.

Allegations of name-lending should be handled in the same manner as allegations of plagiarism and academic dishonesty by the appropriate medical school or university procedures.

#### IV. Model Policies

##### EAST TENNESSEE STATE UNIVERSITY QUILLEN COLLEGE OF MEDICINE

###### *Ghostwriting*

- a. ETSU faculty, staff, students, and trainees are prohibited from having publications or professional presentations of any kind, oral or written, ghostwritten by any party, industry or otherwise.
- b. This does not apply to transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts.

##### COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS AND SURGEONS

###### *Conflict of Interest Policy on Education and Clinical Care for P&S Faculty and Researchers*

.... P&S Faculty and Researchers adherence to these policies for limiting potential or perceived conflicts helps to avoid conflicts of interest. Annual disclosure in itself does not constitute avoidance or management of conflicts of interest. Failure to comply with mandatory policies will prompt formal review by the CUMC COI Review Committee on Education and Clinical Care, with recommendations to the Dean, and may lead to sanctions up to and including non-renewal of appointment.

###### *Ghost Authorship and Ghost Writing:*

Contributions to medical literature made by or through commercial entities should be transparent with respect to authorship and the contribution of authors. P&S Faculty and Researchers, trainees, and students are prohibited from authoring or co-authoring articles written by employees of commercial entities, or their agents, where their name or Columbia title is used without their substantive contribution. If commercial employees are co-authors, they should be acknowledged as such. 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. P&S Faculty and Researchers authors who collaborate with commercial entities must maintain editorial independence at all times. P&S Faculty and Researchers who are or become aware that a published

*“We must make name-lending as unacceptable as plagiarism.”*

*— Adriane Fugh-Berman, MD,  
Associate Professor, Georgetown  
University Medical Center.*

paper on which he/she is an author contains contributions from an un-credited source who is employed by or through a commercial entity, should notify, in writing, the relevant journal editors to correct misstatements or omissions regarding those responsible for writing, co-authoring, or otherwise responsible for the paper. Comparable corrections and notifications, as appropriate, should be made in the Faculty or Researcher's CV, dossier for promotion and other academic documentation.

## IX. References

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<http://tinyurl.com/AmcModelCoiPolicy>

The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.