

Exorcising ghostwriting...

Ghostwriting could potentially have serious repercussions for science and should therefore be treated as research misconduct

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Ghostwriting is when someone substantially contributes to a manuscript, but is not mentioned in the byline or in the acknowledgements. At its extreme, ghostwriting is used by companies that pay professional writers to produce an article that supports the product of that company, while authorship is attributed to academic scientists. This practice conceals the involvement of the company and can affect perception of the effectiveness and safety of a product. Pharmaceutical and communication companies in particular have constructed a vast and profitable ghostwriting industry. In 2001, an estimated 100 or more communications companies advertised their services for supplying and improving manuscripts (Barbour, 2010; Landow, 2002).

Ghostwriting in biomedical research carries a substantial risk for public health

Ghostwriting in biomedical research carries a substantial risk for public health. Ghostwritten articles might influence physicians to prescribe more expensive treatments that are less effective, or even risky (Singer & Wilson, 2009). Moreover, US and European medical professors are reported to have been included as guest authors of ghostwritten papers—some of them even listing these papers on their curriculum vitae—which suggests that promotions or grants could be awarded on the basis of false authorship (Lacasse & Leo, 2010).

It is difficult to determine the extent of ghostwriting owing to both secrecy and a lack of research. Flanagan *et al* (1998) found that of 809 articles published in

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peer-reviewed medical journals, for 156 (19%) there was evidence that guest authors had not substantially contributed to the article, 93 (11%) included ghost authors, and for 13 articles (2%) there was evidence of both. Highly publicized concerns about ghostwriting first appeared over the fenfluramine/phentermine diet drugs, which were withdrawn in 1997 owing to safety concerns, and rofecoxib, which was withdrawn in 2004 (Singer & Wilson, 2009). In 2008, during rofecoxib-related litigation, court documents obtained from the pharmaceutical company Merck revealed that unacknowledged authors had written clinical trial and review manuscripts, and first authorship was often attributed to academic investigators who were offered fees and did not always declare financial support received from industry (Ross *et al*, 2008). In 16 of the 20 clinical-trial reports analysed, Merck employees were listed as authors on manuscript drafts, but the published study listed an academic as the lead author. Merck also hired companies to write 72 review articles, 50 of which listed only academic scientists as authors.

Göttsche *et al* (2007) analysed reports of industry-initiated clinical trials that were approved between 1994 and 1995 by Danish ethics committees. They found evidence of ghostwriting in 31 of 44 cases. Documents released by a US federal court in 2009 showed that the pharmaceutical

company Wyeth had paid a medical-writing company to draft articles as part of a well-planned campaign to support its menopausal hormone therapy products. These articles used ghostwriters and guest authors, despite increasing evidence that some of the drugs increased the risk of breast cancer (Barbour, 2010; Singer & Wilson, 2009; PLoS Medicine Editors, 2009). *PLoS Medicine* revealed that Wyeth used ghostwritten articles to downplay the associated risks of breast cancer, support unproven cardiovascular 'benefits', and encourage unverified, off-label use such as for prevention of Parkinson disease and dementia (Fugh-Berman, 2010). So far, research and lawsuits have shown that drug companies have used ghostwriting to market at least 10 drugs (Lacasse & Leo, 2010). The issue of ghostwriting is likely to impinge on other areas in the life sciences in which substantial economic interests are at stake, such as plant and agricultural research and biotechnology companies.

In fact, ghostwriting is a common phenomenon. Many politicians and celebrities use ghostwriters to write or edit speeches, write opinion articles for newspapers and even their own memoirs. However, ghostwriting in the medical literature poses a risk because it could influence opinion about drugs and treatments both in academic circles and among politicians. A recent story in the *New York Times* illustrates the influence pharmaceutical companies wield over US Congress; during the health-care debate, 22 Republicans and 20 Democrats cited pro-biotechnology articles that were ghostwritten by lobbyists working for Genentech. Genentech, in fact, produced separate position papers in support of the health-care reform bill and provisions designed to be



included in the Congressional Record (Pear, 2009). The bill included a provision to give the US Food and Drug Administration (FDA) the right to approve generic equivalents of costly biotechnology drugs, a position supported by Genentech and other makers of brand-name drugs. Senators and representatives argued that it was essential for research on 'biosimilar' products to continue, in order to counter fierce competition from overseas.

Genentech was also in the news last year because it benefited from changes in Medicare policies that allow physicians to reimburse the use of Lucentis to treat macular regeneration. The drug costs US\$2,000 per dose, and many doctors actually advocate the use of Avastin—another drug made by Genentech—which costs US\$50–60 per dose.

However, there is no clear definition of ghostwriting. Should company researchers who examine a piece of evidence or supply figures and tables for a manuscript not be mentioned in the final publication (Gøtzsche *et al*, 2009)? There are also instances of professional writers merely providing a first draft of a paper for the sake of expediency; a busy academic might not have to write the article from scratch. In these instances, the intellectual effort predominantly comes from the academic, and the writer simply provides editorial support. Should this kind of contribution from medical-writing companies be considered as ghostwriting?

...in my opinion, ghostwriting violates the integrity and ethical principles of scientific research

Ghostwriting often occurs in tandem with guest authorship—also called honorary authorship—which is the naming of authors whose contributions are so meagre that they do not deserve a place on the byline (Gøtzsche *et al*, 2009). There are similar problems with genetic studies written on the basis of large data sets. When author X has ethical permission to study a set of patients whose DNA is included in a much larger study done by author Y, both X and Y eventually put their names on the paper. Although the work respects the original ethical stipulations, Y does not have a right to use these samples, other than within a collaborative study.

The question is whether a person whose only input is to supply samples for a study should be included as an author. Although some traditional researchers disapprove of this practice, there is often no way of publishing studies based on thousands of samples without including all who have participated in some way. More generally, large sequencing projects and genome-wide association studies have created an authorship problem; long lists of authors make it almost impossible to determine who has contributed what. For example, many studies by the Wellcome Trust Case-Control Consortium include as authors all researchers who have included material for the controls, even if they have contributed nothing else.

Following the most rigorous criteria for authorship—for instance those by the International Committee of Medical Journal Editors (ICMJE)—and recognizing that nobody likes being mentioned only in the acknowledgements, I propose that authorship should be determined on the basis of criteria indicative of both personal effort and accountability. Acquisition of funding, collection of data or general supervision of the research group alone do not constitute authorship (ICMJE, 2008). Colleagues who have only provided samples should receive an acknowledgement to avoid possible charges of unethical guest authorship.

Some argue that ghostwriting is a form of plagiarism, as it attributes authorship for the work to others, although the apparent ‘victim’—the company—is basically inviting the scientist to ‘steal’ its work and publish it as their own (Krimsky, 2007; Anekwe, 2010). However, the ghost is not plagiarizing anyone, and guest authors are not plagiarizing the ghost. It might also be argued that there are circumstances in which different authorship contributions make little difference to the outcome. What, then, about the argument that ghostwriting makes no difference, and that weeding it out is a waste of time and limited resources? After all, it is the data and analysis that matters, not the name on the top of the article. However, in my opinion, ghostwriting violates the integrity and ethical principles of scientific research.

Some countries and organizations have recognized and begun to tackle the problem of ghostwriting and guest authorship. Danish law, for instance, regards misappropriation of authorship as research misconduct (Danish Ministry of Science, Technology and Innovation, 2005). In

Table 1 | Ghostwriting policies of editors’ and medical writers’ associations

Association	‘Ghostwriting’ mentioned on website	Specific policy
International Committee of Medical Journal Editors (ICMJE)	No	No*
World Association of Medical Editors (WAME)	Yes	Yes
Committee on Publication Ethics (COPE)	Yes	Yes
American Medical Writers Association (AMWA)	Yes	Yes
Eastern Mediterranean Association of Medical Editors (EMAME)	Yes	No
Council of Science Editors (CSE)	Yes	Yes
European Association of Science Editors (EASE)	No	No
International Society for Medical Publication Professionals (ISMPP)	Yes	Yes
European Medical Writers Association (EMWA)	Yes	Yes

*ICMJE has a policy on contributors (http://www.icmje.org/ethical_1author.html)

regard to ghostwriting, the law on scientific dishonesty, which came into force in 2009, includes the definition of dishonesty as “false credit given to the author or authors, misrepresentation of title or workplace”.

...it is surprising that funding agencies have not enacted policies to avoid ghostwriting

In 2009, the Institute of Medicine recommended that US academic medical centres enact comprehensive policies to ban ghostwriting, a process often referred to as ‘ghostbusting’ (Singer & Wilson, 2009; Fugh-Berman, 2010), to 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” (Institute of Medicine, 2009).

Journals and editors’ associations also increasingly require author contribution and competing interest statements to name all those involved in writing an article (Table 1). In 2005, the World Association of Medical Editors (WAME) developed specific policies on ghostwriting, calling it dishonest and sanctionable (WAME, 2005).

Lacasse & Leo (2010) found that 10 of the top-50-ranked medical research centres in the USA explicitly prohibit ghostwriting, seven included some definition of ghostwriting in their policy and three prohibited ghostwriting without defining the term. However, 13 did not ban all aspects of

ghostwriting, most notably by not requiring that all qualified authors are listed.

Some websites, such as that of Washington University in St Louis, USA, contain explicit warnings on ghost and honorary authorship, emphasizing that even incorrectly acknowledging contributions to published research violates its authorship policies, and might be referred to the Research Integrity Officer as research misconduct (www.wustl.edu/policies/authorship). A 2009 survey of 10 leading medical schools in the USA found that six schools explicitly forbid ghostwriting. Some schools, such as Washington University, have also adopted the recommendations of the ICMJE.

Whether professional medical writers qualify as authors remains debatable (Götzsche *et al*, 2009; Wager, 2007; Jacobs & Wager, 2005). The Danish Committees on Scientific Dishonesty state that although professional writers seldom meet ICMJE criteria—as they are not involved in study design, data gathering or interpretation—their contribution must be acknowledged as a potential conflict of interest (The Danish Committees on Scientific Dishonesty, 2003). The European Medical Writers Association states that professional writers are usually not eligible for authorship, although their role should be acknowledged (Jacobs & Wager, 2005). Conversely, Peter Götzsche, Director of the Nordic Cochrane Centre, suggests that editors should insist that medical writers be authors, because it is inconceivable

Table 2 | Recommendations to alleviate ghostwriting

Source	Target	Proposal
Lacasse & Leo (2010)	Academic centres	Deans to ban ghostwriting Define ghostwriting as misconduct Monitor literature for clues Disciplinary action (FFP)
PLoS Medicine Editors (2009)	Editors	Warning about ghostwriting as unethical and punishable in AI Statements upon submission about involvement by companies Immediate retraction, ban from future publication and notification to centres
PLoS Medicine Debate (Götzsche <i>et al</i> , 2009)	Editors	Ghostwriting is scientific misconduct (AI) Identification of companies when a case comes to light Beware of manuscripts about drugs or medical devices
	Editors' bodies	Develop policies recommending that ghostwriting be deemed misconduct
	Journals and PubMed	Use the term 'misappropriated authorship' and not 'erratum' to properly document the inappropriate behaviour that needs to be termed misconduct
	Researchers	Research into the practice to learn frequency and impact

AI, authors' instructions; FFP, fabrication, falsification and plagiarism.

they could write papers without judgement and understanding of data (Götzsche *et al*, 2009). Simply put, if an author is not a person who writes, what is an author?

Governments, in turn, should not support institutions that allow ghostwriting by omission and which have no specific authorship policies

Editors of journals such as *The Oncologist*, which no longer accepts opinion pieces by writers who are linked to companies that are commercially interested in the content (Singer & Wilson, 2009), are hardening their stance after realizing that guidelines allow authors to acknowledge industry-financed writers without clarifying their role in manuscript generation. Some editors propose compulsory checklists to identify and avoid ghostwriting (Götzsche *et al*, 2009). The journal *Blood* recommends defining the interaction between professional writers and listed authors using the GATE criteria: guarantee—are the authors guarantors of the work?; advice—did the authors advise the writer?; transparency—is the writer acknowledged?; and expertise—did the author have sufficient expertise to draft the article? (Dunbar & Tallman, 2009; Daskalopoulou & Mikhailidis, 2005). Some journals are adopting clear and visible positions. The *International Journal of Clinical Practice* has an explicit ghostwriting policy

stating that ghost and guest authorship and failure to acknowledge significant contributions are unacceptable and suspected cases will be investigated according to the guidelines by the Committee on Publication Ethics (COPE; http://www.blackwellpublishing.com/ijcp_enhanced/policy.asp). Despite these efforts, a *JAMA* study of 630 research, review and editorial/opinion articles from six top medical journals in 2008, found that one-quarter of articles had honorary authors, 8% had ghost authors and 2% had both, and that these numbers had changed little since 1996 (Wislar *et al*, 2009).

Responses in industry have included the adoption of ICMJE authorship guidelines by the Pharmaceutical Research and Manufacturers of America (2009), who suggested that these should be applied industry-wide and state the effect of the sponsor on the study design, data collection and writing. Similarly, the Association of the British Pharmaceutical Industry does not support ghostwriting practices (<http://www.abpi.org.uk/media-centre/newsreleases/2005/Pages/130405.aspx>). The industry-run International Publication Planning Association (TIPPA) has taken a more active role, by encouraging good publication practices throughout the industry.

Given these efforts, it is surprising that funding agencies have not enacted policies to avoid ghostwriting. Regrettably, the National Institutes of Health (NIH) in particular, given its importance for

medical research, is missing this opportunity. The US Public Health Service, of which the NIH is a part, is the only federal agency with specific regulations regarding the statement of financial conflicts of interest (FCOI) in research and, to my knowledge, no public funders in other countries have specific rules on FCOI or ghostwriting. Although the NIH cannot direct policies for all research in the USA, it could address the issue in its disclosure policies, which would act as a benchmark for other agencies.

The revised NIH regulations would move the responsibility for determining whether the financial interests of investigators are related to NIH-supported research from investigators to institutions, and would also lower disclosure thresholds from ten to five thousand dollars (Rockey & Collins, 2010). However, explicit policies on the disclosure of industry-financed ghostwritten articles are not being contemplated. This seems to conflict with NIH director Francis Collins' recent comment that "people would allow their names to be used on articles they did not write, that were written for them, particularly by companies that have something to gain by the way the data is presented [...] if we want to have the integrity of science preserved, that's not the way to do it" (C-SPAN, 2009).

Recent disclosures by the Project on Government Oversight (POGO), an independent, non-profit organization, show that the NIH has provided millions of dollars to medical investigators who employ ghostwriters funded by pharmaceutical companies. One example involved two academics supported by the NIH who were listed as authors of a physicians' handbook, part of which were written by Scientific Therapeutics Information, a marketing company employed by GlaxoSmithKline (GSK) to support Paxil (paroxetine), an anti-depressant. The published handbook recognized "editorial assistance" from the marketing company and an "unrestricted educational grant" from GSK (<http://pogoblog.typepad.com/pogo/2010/12/ghostbusters-at-pogo.html>).

In December 2010, POGO sent a letter to Collins urging him to ban ghostwriting in NIH-based academic centres, in order to strengthen scientific integrity (<http://www.pogo.org/pogo-files/letters/public-health/ph-iis-20101129.html>). Collins replied that "[although] the NIH extramural policy governing NIH grantees does not use the term ghostwriting, Federal regulations and

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policies relating to Public Health Service (PHS)-supported research could be applicable to ghostwriting, depending on the specific circumstances of a particular case. For example, a case of ghostwriting involving NIH-funded researchers may be appropriate for consideration as a case of plagiarism ... or fabrication” and that “[such] a case would be handled by the Office of Research Integrity ... [if] ORI makes a finding of research misconduct, the NIH may take appropriate enforcement action(s).” He added that the “NIH believes that ghostwriting should be addressed when scientific articles citing extramural federal funding are submitted to journals for publication” and that “NIH is considering how best to address the issue of ghostwriting in the development and authorship of medical literature arising from federal research funding” (<http://pogoarchives.org/m/ph/nih-response-to-pogo-on-ghostwriting-20110217.pdf>).

WAME, COPE, the Institute of Medicine and some journal editors and independent authors recommend specific policies to regulate ghostwriting (Table 2; Titus & Bosch, 2010). However, only enforceable policies are useful. This requires an unambiguous definition of ghostwriting. In addition, journals—not only in clinical medicine, but also in other life sciences—should not accept meaningless acknowledgement of nonspecific editorial or technical assistance. Institutions that lack policies on authorship and ghostwriting should adopt existing models, such as that of Washington University. Ideally, such policies should emphasize the requirement for full transparency about the role of pharmaceutical and other firms in the genesis of the article.

Governments, in turn, should not support institutions that allow ghostwriting by omission and which have no specific authorship policies. Research funders should support greater transparency, disclosure and responsibility by making grant decisions contingent on adherence to authorship guidelines that explicitly ban ghostwriting. The UK Medical Research Council subscribes to ICMJE guidance on appropriate

authorship but ignores ghostwriting; so does the Wellcome Trust, whose statement that “honorary authorship is unacceptable” is not enough. Supranational funders, notably the European Commission (EC), through its Framework Research Programmes, and the European Science Foundation (ESF), should do similarly. The ESF has recently published a European Code of Conduct for Research Integrity (ESF, 2010; Bosch, 2010) which, although calling ghost authorship unacceptable, goes no further. Both the EC and the ESF are well-positioned to appoint independent experts to investigate ghostwriting allegations. Initially, the EC could request its advisory European Group on Ethics to generate recommendations.

Similarly, national bodies such as the UK Department of Health—which sets out good practice in the conduct of clinical trials to define the roles and responsibilities of investigators and trial sponsors—ignore authorship and ghostwriting. These bodies should include explicit statements on authorship in good-practice guidelines, and indicate that ghostwriting will be prosecuted.

The NIH could lead the discussion and guarantee that its grant recipients adhere to a higher level of transparency and accountability. This could be achieved by requiring all NIH-funded institutions to explicitly recognize, make public and enforce a prohibition of ghostwriting, by rules or amendments to the report. In particular, the Management and Reporting of FCOI section of the NIH Proposed Rule report (HHS, 2010) should include such stipulations. In addition, as suggested by US Senator Charles Grassley, the new NIH FCOI regulations should consider requiring that articles based on NIH-funded research are only published in journals that enforce ghostwriting policies (Grassley, 2010). Other health agencies using taxpayer money, such as the FDA, should do the same.

In the current climate, prevention is preferable to and more feasible than punishment

The UK Research Integrity Office, as part of the wider European Network of Research Integrity Offices, should define ghostwriting and class it as research misconduct. Similarly, the UK General Medical Council and equivalent bodies should formulate explicit guidance on what constitutes

honest authorship. As ghostwriting might affect areas other than clinical medicine, journals, institutions and organizations that specialize in basic research in the life sciences and translational medicine should join efforts to prevent and monitor the practice.

Moreover, bodies such as the US Office of Research Integrity should create and enforce regulatory policies on ghostwriting and consider it as research misconduct, following the Danish lead. In view of the importance of authorship to career progression, I would further argue that all transgressions of authorship, such as changing, omitting or adding names to bylines and misappropriation of authorship in general, are also research misconduct.

Given the amount of litigation involving the drug industry in recent years, it is surprising that no company has been sued for ghostwriting, as high-visibility lawsuits could rapidly terminate the practice. In the USA, lawyers could contend that ghostwriting violates the False Claims Act (FCA) and companies submitting a new drug application to the FDA in slanted, ghost-authored studies are likely to state a risk–benefit estimate that is not supported by evidence. In addition, products determined to be unsafe and ineffective for any indication do not qualify for Medicare or Medicaid reimbursement, and any federal money spent might have been falsely obtained according to the FCA (Morrissey, 2010).

Finally, to better protect public health, industry insiders with knowledge of ghostwriting should be urged to come forward. Whistleblowers should be aware that they can be rewarded under successful lawsuits brought by the FCA. However, additional protection would be needed to protect whistleblowers, using strategies to help them remain anonymous. In the current climate, prevention is preferable to and more feasible than punishment. Self-regulation, especially by commercially interested parties is unlikely to be effective, but rigorous public policies could successfully regulate this problem.

CONFLICT OF INTEREST

The author declares that he has no conflict of interest.

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