

Exorcizing the Ghosts (and Other Authorship Issues That Go Bump in the Night)

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Introduction

This Member Briefing describes the types of practices that constitute ghostwriting and other authorship practices that have been challenged as potentially unethical or illegal.

On July 1, 2009, Senator Charles Grassley (R-IA), who is the ranking member of the U.S. Senate Finance Committee overseeing Medicare and other federally funded programs, wrote a letter to eight leading medical journals to ascertain their policies and policing of “medical ghostwriting.”¹ Ghostwriting, which has been criticized as threatening to confuse the reporting of medical research with the marketing efforts of drug and device manufactures, encompasses a variety of authorship practices impacting the healthcare industry and implicates issues of transparency and ethics (including research misconduct concerns, kickbacks, and conflicts of interest).

These practices can extend to published manuscripts in journals and presentations at scholarly meetings, and have even been implicated in the production of a journal that appeared to serve as a marketing platform for a major pharmaceutical concern.² The practice is not limited to the scientific literature. A report recently outlined the ghostwriting (by a British American Tobacco author) of an advertising report on the effectiveness of

¹ Senator Charles Grassley, Press Release, Grassley asks top medical journals about ghostwriting, July 2, 2009, available at http://grassley.senate.gov/news/Article.cfm?custome1_dataPageID_1502=21624# (last accessed Nov. 9, 2009).

² Bob Grant, *Merck published fake journal*, The Scientist: NewsBlog, Apr. 30, 2009, 04:27 PM GMT, available at www.the-scientist.com/blog/print/55671 (last accessed Nov. 9 2009).

advertising bans on tobacco purportedly authored by Professor J.J. Boddewyn.³ Recently, Wyeth was found to have employed ghostwriters to write articles favorable of hormone-replacement therapy drugs (and assuaging fears about their side effects); these articles were sent to physicians to “put their spin” on them and serve as authors.⁴ Wyeth’s hired writers maintain that physicians had “editorial control” and that the articles were still subject to peer-review at the journal level. Bioethicists are concerned that failure to disclose drug company involvement in articles such as these permits “seeding” of the medical literature with manuscripts supporting the use of their drugs.⁵

What Is Ghostwriting: Definitions and Guidelines

There are two basic flavors of ghostwriting. One is additive and involves the inclusion of an author who should not be listed as an author—this author has not met the qualifications of authorship and may be an “honorary” or “guest” author.⁶ The other is subtractive and involves an individual who should be listed as an author given his or her involvement in the manuscript but is not included in the authorship listing.⁷

An article published in 1998 in the *Journal of the American Medical Association (JAMA)* evaluated 809 published articles in both high-impact and smaller-circulation journals, looking for evidence of both honorary/gift authorship and/or ghostwriting.⁸ This study found that 19% of these articles demonstrated indicia of honorary authorship, 11% indicated the possibility of ghost authorship, and 2% of the evaluated articles showed indicia of both honorary and ghost authorship.⁹ The study further suggested that there was no significant

³ R. M. Davis, *British American Tobacco ghost-wrote reports on tobacco advertising bans by the International Advertising Association and J J Boddewyn*, 17 *TOB. CONTROL* 211 (2008).

⁴ Jef Feeley and Sophia Pearson, *Wyeth used ghostwritten Prempro articles, files show (Update3)*, Bloomberg.com, Aug. 5, 2009, available at www.bloomberg.com/apps/news?pid=newsarchive&sid=abGoyhK2PAes (last accessed Nov. 9, 2009).

⁵ *Id.* (The article cites Carl Elliott, a bioethicist at the University of Minnesota: “Companies can play down the side-effects of their drugs, exaggerate the prevalence of the illnesses their drugs treat, and the messages will all be laundered so that there appears to be no connection to the sponsor whatsoever.”)

⁶ Joseph S. Ross, Kevin P. Hill, David S. Egilman, and Harlan M. Krumholtz, *Guest authorship and Ghostwriting in Publications Related to Rofecoxib: A case study of industry documents from rofecoxib litigation*. 299(15) *JAMA* 1800-1812, 1800 (2008) (“Guest authorship has been defined as the designation of an individual who does not meet authorship criteria as an author.”)

⁷ *Id.* (“Ghostwriting has been defined as the failure to designate an individual (as an author) who has made a substantial contribution to the research or writing of a manuscript.”)

⁸ Annette Flanagan, Lisa A. Carey, Phil B. Fontanarosa, Stephanie G. Philips, Brian P. Pace, George D. Lundberg, and Drummond Rennie, *Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals*, 280(3) *JAMA* 222 (1998).

⁹ *Id.* at 223.

difference between high-impact journals and smaller-circulation journals concerning these issues.¹⁰ These results were mirrored in a 2002 report by Mowatt et al. studying honorary and ghost authorship in Cochrane Review articles.¹¹ In the Mowatt study, 39% of articles had indicia of honorary authorship, 9% indicated possible ghost authors, and 2% suggested that both honorary and ghost authors were involved with the manuscript.¹²

Following the Cochrane Reviews study, Gøtzsche et al. sought to estimate the amount of ghost authorship associated with industry-initiated randomized trials.¹³ This study compared protocols for industry-sponsored trials to the manuscripts that resulted from these studies.¹⁴ The study found a high prevalence of ghost authors (75%, or up to 91% if someone who qualified as an author was listed in the acknowledgments section), especially regarding statisticians involved in the publications.¹⁵ This study suggested that the omission of statisticians from authorship listings was of particular concern, as “multicenter trials are often complex and generate large datasets.”¹⁶

An even more recent study suggests that ghostwriting may be declining, while honorary/guest authorship remains at about the same level as previous studies have indicated.¹⁷ At the 2009 International Congress on Peer Review and Biomedical Publication, Dr. Joe Wislar reported that a recent survey of corresponding authors suggested about an 8% incidence of ghost authorship (it was about 12% in 1996).¹⁸

¹⁰ *Id.* at 222.

¹¹ Graham Mowatt, Liz Shirran, Jeremy M. Grimshaw, Drummond Rennie, Annette Flanagan, Veronica Yank, Graeme MacLennan, Peter C. Gøtzsche, and Lisa A Bero, *Prevalence of Honorary and Ghost Authorship in Cochrane Reviews*, 287 JAMA 2769 (2002). (The Cochrane Review is an electronic review of healthcare interventions; articles are reviewed by an editorial staff prior to publication. This study used the survey instrument developed in the study conducted by Flanagan et al. as a guide for design of the survey instrument used in this study.)

¹² *Id.*

¹³ Peter C Gøtzsche, Asbjørn Hróbjartsson, Helle Krough Johansen, Mette T Haahr, Douglas G Altman, and An-wen Chan, *Ghost authorship in industry-initiated randomized trials*, 4(1) PLOS MED. 0047 (2007).

¹⁴ *Id.*

¹⁵ *Id.* at 0048. (“We defined ghost authorship as present if an individual who wrote the trial protocol, or performed the statistical analyses, or wrote the manuscript did not appear among the authors, or members of a study group or writing committee, or in an acknowledgment.”)

¹⁶ *Id.* at 0049.

¹⁷ Shelley Wood, *Ghost authorship on the wane, but guest authorship still common*, Sep. 11, 2009, available at www.theheart.org/article/1001867.do (last accessed Nov. 9. 2009).

¹⁸ *Id.*

A number of organizations offer guidance and recommendations regarding authorship. These include the International Committee of Medical Journal Editors (ICMJE), World Association of Medical Editors (WAME), and the European Medical Writers Association (EMWA).

ICMJE publishes its guidance as the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication.”¹⁹ The Uniform Requirements are followed by a number of international journals,²⁰ including the *American Journal of Medicine*, the *Annals of Internal Medicine*, *Archives of Internal Medicine*, *PLoS Medicine*, *JAMA*, and the *New England Journal of Medicine* (NEJM); six of the eight journals contacted by Grassley’s office. “Authorship,” the ICMJE states, “means both accountability and independence.”²¹ The ICMJE is concerned not only with ghost authorship but also sponsor control and influence over the design, execution, and reporting of data.²² The guidance recommends that authors be able to access all data, including data detrimental to the sponsor, and have control regarding data publication.²³ ICMJE recommends that all individuals who meet authorship criteria be listed as an author.. Authorship credit is recommended according to three criteria:

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published. Authors should meet conditions 1, 2, and 3.²⁴

ICMJE also recommends that all authors be publicly responsible for the data that they are responsible for as presented in the manuscript.²⁵ Individuals such as technicians,

¹⁹ ICMJE, *Uniform Requirements for Manuscripts*, available at www.icmje.org/urm_main.html (last accessed Nov. 9 2009).

²⁰ See www.icmje.org/journals.html.

²¹ ICMJE, *Sponsorship, Authorship, and Accountability*, available at www.icmje.org/update_sponsor.html (last accessed Nov. 9, 2009).

²² See also Frank Davidoff, Catherine D, DeAngelis, Jeffrey M. Drazen, John Hoey, Liselotte Højgaard, Richard Horton, Sheldon Kotzin, M. Gary Nicholls, Magne Nylenna, A John PM Overbeke, Harold C. Sox, Martin B. Van Der Weyden, and Michael S Wilkes, *Sponsorship, Authorship, and Accountability*, 345 *NEW ENG. J. MED.* 825 (2001).

²³ ICMJE, *Sponsorship, Authorship, and Accountability*, available at www.icmje.org/update_sponsor.html (last accessed Nov. 9, 2009). The ICMJE is particularly concerned with the use of clinical trials as vehicles for marketing drugs or devices: “Patients participate in clinical trials largely for altruistic reasons—that is, to advance the standard of care. In light of that truth, the use of clinical trials primarily for marketing, in our view, makes a mockery of clinical investigation and is a misuse of a powerful tool.”

²⁴ *Id.* (II. A. 1. Byline Authors).

department chairs, and writers should be listed in the Acknowledgements section if those individuals do not qualify as authors.²⁶

Concerned with the influence of commercial interests in not only medical literature but also marketing and educational forums, **WAME** supports disclosure of ghostwriters, along with their affiliation and listing the funding source for their work.²⁷ This would presumably acknowledge medical writers and dissuade biased ghostwriting. For undisclosed ghostwriting that is later identified, WAME has suggested informing readers, institutions, companies, and the general public as to the ghostwritten character of the manuscript.²⁸

EMWA has attempted to formulate guidelines for medical writers in the practice of their craft.²⁹ Medical writers may or may not be employed by sponsors; some may be freelance writers.³⁰ EMWA suggests a straightforward acknowledgment disclosing the contribution of the medical writer and disclosing on whose behalf the medical writer was writing.³¹ Jacobs and Wagner³² suggest eight key ethical guidelines for medical writers to consider when preparing manuscripts on behalf of other parties. Ultimately these guidelines speak to the

²⁵ *Id.* (II. A. 1. Byline Authors).

²⁶ *Id.* (II. A. 2. Contributors Listed in Acknowledgements).

²⁷ The World Association of Medical Editors, *Ghost writing initiated by commercial companies*, 20 J. GEN. INTERNAL MED. 549 (2005).

²⁸ *Id.* (“Several actions are possible: 1) publish a notice that a manuscript has been ghostwritten, along with the names of the responsible companies and the submitting author; 2) alert the authors’ academic institutions, identifying the commercial companies; 3) provide specific names if contacted by the popular media or government organizations; and 4) share their experiences on the WAME listserv and within other forums.”)

²⁹ Adam Jacobs and Elizabeth Wagner, *European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications*, 21(2) CURRENT MEDICAL RESEARCH AND OPINION 317-321 (2005).

³⁰ *Id.* at 318. (These writers dislike the terminology “ghostwriting” to describe their profession. “The use of writers who have not participated in research to help the named authors to develop publications is sometimes referred to as ‘ghostwriting’. This term implies that the writer is invisible because their work is not acknowledged or because it is purposely concealed. Similarly, the practice of omitting deserving individuals from authorship lists is sometimes termed ‘ghost authorship’. We have avoided using these terms in these guidelines, partly because we believe that medical writers can have a legitimate role in developing papers and we therefore want to avoid these slightly pejorative terms, and also because we feel they are misleading if the writer’s contribution is properly acknowledged.”)

³¹ *Id.* at 319.

³² *Id.* at 320. (“Medical writers should be aware of any guidelines that apply to the publication they are producing . . . medical writers should also advise customers and colleagues about the conventions of peer-reviewed publications . . . must strive to ensure that the publications they develop are accurate and scientifically valid . . . should ask for guidance from the named author(s) for any parts of the paper that are beyond [the medical writer’s] expertise . . . that results are presented in a responsible and balanced fashion . . . should draw attention to any limitations of the study in the discussion section . . . [for review articles] should ensure that search criteria are stated . . . and [if aware of contrary data or literature] the writer should attempt to ensure that this research is cited.”)

reliability of the data presented in the manuscript and the adherence to ethical experimental and/or writing practices.

Some journals are attempting to define authorship with specificity regarding submissions to their publications. A recent example is the authorship definition used by *Pharmacotherapy*: “Authors need to have contributed to the data’s acquisition in some way (e.g., design of experiment or interpretation of data), contributed to the writing and/or revision of the manuscript in some meaningful way, and approve of the final document.”³³

Honorary or Guest Authorship

Honorary or guest authorship usually is associated with the concept that an author is listed as an honor to his or her position (usually senior) in a department or section. In some instances the authors may wish to add the honorary author’s name to add gravitas to the paper or to improve publication chances.³⁴ Honorary authorship also may be bestowed upon less auspicious grounds, as when the honorary author expects to be listed on the paper, sometimes regardless of the attitudes of the other authors.³⁵ In some circumstances, the honorary author may have been involved with an aspect of manuscript preparation, but not satisfy all three criteria for authorship as directed by ICMJE recommendations.³⁶ It is part and parcel of the question of honorary authorship what level of involvement—intellectual³⁷ or physical³⁸—is actually required to achieve authorship status.

Assignment of Writing

“Assignment” of authorship occurs when a researcher (often a prominent figure in the field) assigns writing of a paper or presentation to a junior faculty member or resident. The

³³ Richard T. Scheife, *The Ghost in the Machine*, 29(4) PHARMACOTHERAPY 363-364, 364 (2009).

³⁴ V. Ramana Feeser and Jeremy R. Simon, *The ethical assignment of authorship in scientific publications: Issues and guidelines*, 15 ACADEMIC EMERGENCY MED. 963, 964 (2008).

³⁵ *Id.* at 964.

³⁶ Graham Mowatt, Liz Shirran, Jeremy M. Grimshaw, Drummond Rennie, Annette Flanagan, Veronica Yank, Graeme MacLennan, Peter C. Gøtzsche, and Lisa A Bero, *Prevalence of Honorary and Ghost Authorship in Cochrane Reviews*, 287 JAMA 2769, 2771 (2002). (In the Cochrane Review study the authors note that the “main reason for authors being classified as honorary authors were that they had not participated in drafting or revising the review or had not approved it for submission to the editorial base of [the Cochrane Collaborative Review Groups].”)

³⁷ Such as conceptualizing experiments, familiarity with literature, or contributions to the manuscript.

³⁸ Such as conducting experiments, presenting findings, drafting and editing manuscripts, or crunching statistics.

assignment may often include topic, scope, and suggested resources.³⁹ This sort of arrangement may be classified as “collaboration” by those in the relevant research community.⁴⁰ This practice is distinct from ghostwriting in that the author whose name will be associated with the work is in effect commissioning the work, directing its development, and presumably reviewing the work for content and tone prior to publication and presentation. Although authorship assignment is not usually associated with flaws in the data, there may be issues regarding excluding junior authors from authorship.⁴¹

Academic Ghost Authorship: An Example

In 2004 Dr. Adriane Fugh-Berman of the Georgetown University School of Medicine, a noted expert in the area of herbs and dietary supplements,⁴² was approached to author a review paper describing the interactions of warfarin (an anticoagulant) and herbs. She described this “invitation to authorship” experience in an article published in the *Journal of General Internal Medicine*.⁴³

Briefly, Dr. Fugh-Berman was asked by a medical education company if she would serve as author on a paper. The paper was being funded by a pharmaceutical company that did not manufacture warfarin.⁴⁴ Dr. Fugh-Berman asked why the company was interested in the topic.⁴⁵ A few months later a draft version of the article was sent to Dr. Fugh-Berman for her edits. In response to her query she was also informed that the pharmaceutical company funding the paper was “keen to set the scene for new anticoagulants that are not subject to the numerous limitations of warfarin.”⁴⁶ Dr. Fugh-Berman declined authorship. The medical educational company moved on and found another author. This paper was submitted to the *Journal of General Internal Medicine*. Dr. Fugh-Berman was asked to

³⁹ Alan J. Wein, *To the editor*, 25 NEUROLOGY AND URODYNAMICS 297 (2006).

⁴⁰ Jerry G. Blaivas, *Reply*, 25 NEUROLOGY AND URODYNAMICS 297 (2006).

⁴¹ P. Riis, *Scientific dishonesty: European reflections*, 54 J. CLIN. PATHOL. 4, 5 (2001). (“Transgressions at the level of the scientists themselves involve unfair relations between scientists; for instance, unrightful access to original ideas and observations, and unrightful authorship or exclusion of potential authors, as young ‘water carriers.’ In this last type of dishonesty, the scientific data are mostly reliable, but the balance between the researchers involved is incorrect because some of those who did the research have been excluded.”)

⁴² For example: Adriane Fugh-Berman, *Herbs and Dietary Supplements in the Prevention and Treatment of Cardiovascular Disease*, 3(1) PREV. CARDIOL. 24-32 (2000).

⁴³ Adriane Fugh-Berman, *The Corporate Coauthor*, 20 J. GEN. INTERNAL MED. 546-548 (2005).

⁴⁴ *Id.* at 546.

⁴⁵ The proposed paper was tentatively entitled, “Interactions between dietary supplements and warfarin: the hazards of self-administration.”

⁴⁶ Adriane Fugh-Berman, *The Corporate Coauthor*, 20 J. GEN. INTERNAL MED. 546-548, 547 (2005).

review the paper. Upon recognizing the paper, she informed the journal of her history with the manuscript.⁴⁷

The journal addressed the experience in an editorial,⁴⁸ which appeared in the same issue as Dr. Fugh-Berman's account of her invitation to author the paper,⁴⁹ and a statement by WAME on ghost authorship.⁵⁰ The journal stated that it "had no problem with the manuscript being commissioned by a pharmaceutical manufacturer or that someone from a medical education company had performed a literature review and written the draft manuscript."⁵¹ The issues were that the actual authorship of the paper was not disclosed either in the authorship listing or acknowledgments,⁵² and that the funding source was not properly described.⁵³ The *Journal of General Internal Medicine* established editorial policies aimed at identifying all authors on papers⁵⁴ and cites to the WAME policies for authorship and conflict of interest in response to this incident.⁵⁵

The issue with ghostwriting is that hidden author(s) can sometimes evince a possible hidden agenda. If an actual author is not identified or disclosed, there are two possible issues: (1) an individual is not recognized for the work they contributed to the article, and (2) that individual's potential conflicts of interest are not readily discernable.⁵⁶

⁴⁷ *Id.*

⁴⁸ William M. Tierney and Martha S. Gerrity, *Editorial: Scientific Discourse, Corporate Ghostwriting, Journal Policy, and Public Trust*, 20(6) J. GEN. INTERNAL MED. 550-551.

⁴⁹ Adriane Fugh-Berman, *The Corporate Coauthor*, 20 J. GEN. INTERNAL MED. 546-548 (2005).

⁵⁰ The World Association of Medical Editors, *Ghost writing initiated by commercial companies*, 20 J. GEN. INTERNAL MED. 549 (2005).

⁵¹ William M. Tierney and Martha S. Gerrity, *Editorial: Scientific Discourse, Corporate Ghostwriting, Journal Policy, and Public Trust*, 20(6) J. GEN. INTERNAL MED. 550-551, 550 (2005).

⁵² *Id.* at 550. ("First, the contribution of the manuscript's original author(s) was not recognized by coauthorship or a note in the Acknowledgments, some indication that the person or persons employed by the medical education company were taking direct responsibility for the work.")

⁵³ *Id.* ("Second, the financial relationship between the original author(s) and the pharmaceutical company was not acknowledged. Would exposing such a relationship automatically result in rejection of such a manuscript? No, but it would have resulted in closer scrutiny for potential bias in favor of the company's products (currently on the market or in development).")

⁵⁴ *Id.* at 551. ("[E]veryone who had input into the writing of a manuscript, including generating data from reviewing published articles, must be specifically named either as a coauthor or in the Acknowledgments.")

⁵⁵ *Id.*

⁵⁶ Richard T. Scheife, 29(4) *The Ghost in the Machine*, PHARMACOTHERAPY 363-364, 364 (2009) ("'Ghost' authorship is defined as a person or entity contributing substantially to the creation of a manuscript . . . but who is not acknowledged as an author. This situation most often arises when a commercial entity (e.g., a medical education company acting on behalf of a pharmaceutical manufacturer) actually creates the first or subsequent drafts of a manuscript. The ethical breach here is that an actual author is missing from the list of authors. The remedy is to reveal all 'real' authors to the readers, as well as their affiliations.") Examples of medical writing/pharmaceutical collaboration included Wyeth and DesignWrite (hormone therapy) and Merck and Scientific Therapeutics Information (VIOXX) (see Senator Charles Grassley, Press Release, Grassley

Grassley's Request

Grassley's request on ghostwriting policy was sent to eight high-impact American journals, including: the *American Journal of Medicine*, *Annals of Internal Medicine*, *Annual Review of Medicine*, *Archives of Internal Medicine*, *Nature Medicine*; *PLoS Medicine*, *JAMA*, and *NEJM*.⁵⁷ The concerns are that lack of authorship transparency could lead to advertising being presented as dispassionate medical manuscripts, influencing physicians, patients, and ultimately payors, regarding drugs or medical devices, based on these manuscripts.⁵⁸ To better understand the parameters of the issues, Grassley asked each of the journals five questions:

(1) What is the journal's position regarding the practice of ghostwriting; (2) Does the journal have written policies regarding ghostwritten articles? If so, please provide a copy of those policies; (3) Is an author who submits an article for publication required to disclose to the journal the direct or indirect involvement of any drug or device company or other third party in the development and/or writing of the article?; (4) What are the journal's policies or practices regarding public disclosure of the involvement of any drug or device company or other third party in the development and/or writing of a journal article, in particular when the listed authors are not affiliated with the company or third party?; and (5) Since 2004, has the journal taken action against any author for failing to disclose the involvement of a third party in the development and/or drafting of a manuscript? If so, please provide details.⁵⁹

Reviewing the named journals' web pages for current authorship policy, most addressed the issue of honorary or guest authorship.⁶⁰ Direct policies regarding individuals not listed as authors are not so readily discernable. Some journals do require that the corresponding author acknowledge that all those listed have contributed to the work being published (avoiding the issue of guest authorship), and also that all those who did contribute meaningfully to the work have indeed been listed (avoiding ghost authorship).

asks top medical journals about ghostwriting, July 2, 2009, available at http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=21624# (last accessed Nov. 9, 2009).

⁵⁷ Senator Charles Grassley, Press Release, Grassley asks top medical journals about ghostwriting, July 2, 2009, available at http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=21624# (last accessed Nov. 9, 2009).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *The American Journal of Medicine, Guide for Authors/Manuscripts*, available at www.elsevier.com/wps/find/journaldescription.cws_home/525049/authorinstructions (last accessed Nov. 9, 2009), requires that conflicts of interest be disclosed for authors and has a policy against guest authorship ("Each author must have participated in the writing of the manuscript, and have seen and approved the submitted version. Further, each author should have been involved in the conception and design of the study, or the analysis of the data."). Questions regarding authorship are directed via email to the editors..

An example is the *Annals of Internal Medicine*, whose instructions for authors clearly state:

Acknowledge only persons who have contributed to the scientific content or provided technical support. Authors should obtain written permission from anyone they wish to list in the Acknowledgments section. The corresponding author must also affirm that he or she has listed everyone who contributed significantly to the work in the Acknowledgments.⁶¹

The *Annals of Internal Medicine* also specifically addresses ghostwriting:

Medical writers and industry employees can be legitimate contributors, and their roles, affiliations, and potential conflicts of interest should be described when submitting manuscripts . . . These writers should be acknowledged on the byline or in the Acknowledgments section in accord with the degree to which they contributed

⁶¹ *The Annals of Internal Medicine*, available at www.annals.org/site/misc/ifora.xhtml (last accessed Nov. 9, 2009) has specific authorship requirements; those who do not meet all authorship criteria are to be listed in the acknowledgments section (see www.annals.org/site/misc/ifora.xhtml#criteria-and-policy, (last accessed Nov. 9, 2009)); *The Annual Review of Medicine*, part of the *Annual Reviews* family, links to a twenty-five-page author handbook (www.annualreviews.org/authors/pdf/blue_book_apr_07_online.pdf (last accessed Nov. 9, 2009)), which contains a statement upfront to disclose any potential conflicts of interest for “any member of your authorship team,” which could presumably encompass unlisted authors who contribute substantially to the work; *The Archives of Internal Medicine* addresses guest authorship (all authorship criteria must be met to be included as an author) and also addresses the issue of sponsor input to the preparation, revision, and approval of the manuscript (see <http://archinte.ama-assn.org/misc/ifora.dtl#EditorialPoliciesforAuthors> (last accessed Nov. 9, 2009)); *Nature Medicine* (a publication of the *Nature* group) does not require a signed letter of submission from all authors. It does require a “contributions” statement, in which the contribution of each author is delineated. Data also should be available for reanalysis and should be representative of the experimental results (see www.nature.com/authors/editorial_policies/authorship.html (last accessed Nov. 9, 2009)); *PLoS* is an open-access peer-reviewed medical literature source. Reviewing the authorship for *PLoS Biology*, author status criteria specifies that the involvement of a medical writer be declared (“The involvement of any professional medical writer in publication must be declared.”) Authors are directed to the European Medical Writers Association (www.emwa.org/Mum/EMWAGuidelines.pdf) for guidance regarding medical writers. The disclosure of competing interests that might influence the work also is requested (see www.plosbiology.org/static/policies.action#status (last accessed Nov. 9, 2009)); JAMA has extensive authorship requirements, and also requires a breakdown of each author’s contribution to the work. Those who have contributed through writing the manuscript, if not qualified as an author, are directed to be listed in the Acknowledgments section of the paper (“All other persons who have made substantial contributions to the work reported in this manuscript (e.g., data collection, analysis, or writing or editing assistance) but who do not fulfill the authorship criteria should be named with their specific contributions in an Acknowledgment in the manuscript.”) *JAMA* requires extensive disclosure of potential conflicts of interest, as well as the role of the sponsor in designing the study, interpreting data, and/or manuscript preparation, (see <http://jama.ama-assn.org/misc/ifora.dtl#AuthorshipCriteriaandContributionsandAuthorshipForm> (last accessed Nov. 9, 2009)); NEJM has published criteria for authorship (<http://authors.nejm.org/Help/acHelp.asp>, Journal Policies) including a statement that those who qualify as authors should not be left out of authorship listings (Jeffrey M. Drazen, and Gregory D. Curfman, *On Authors and Contributors*, 347(1) *NEW ENG. J. MED.* 55 (2002). “By extension of this reasoning, it is logical that those who meet the criteria for authorship not be excluded as authors.”) The role of sponsors in the research and research reporting process was addressed in an editorial published in 2001 (Frank Davidoff, et al., *Sponsorship, Authorship, and Accountability*, 345(11) *NEW ENG. J. MED.* 825-826 (2001)).

to the work reported in the manuscript. *The editors consider failure to acknowledge these contributors ghostwriting, which is contrary to Annals' editorial policy.*⁶²

One of the influences of selecting who will be listed as an author may be that the journal limits the number of authors listed on the article. The NEJM, for example, used to limit the number of authors on the title page of an original article to twelve.⁶³ In 2002, to facilitate listing all qualified authors, NEJM adopted new editorial policies that did not limit the number of authors that could be listed on a paper; it also directed that contributors who did not qualify as authors “be listed in an appendix.”⁶⁴

According to a report published in *The New York Times* online, “[n]one of the editors reported taking action against an author for ghostwriting.”⁶⁵

Conflicts of Interest

One of the issues involved with ghost authorship and Grassley's investigation of the practice is the conflict-of-interest (COI) question. COI is the potential for bias to influence the design, conduct, or reporting of a trial. COI is usually thought of in terms of financial relationships—that sponsorship and the provision of funding will potentially influence the study towards favoring the sponsor's position. However, other factors may bias (favorably or unfavorably) experimental design, data collection, data interpretation, data dissemination, and publication decisions—these can include personal relationships, personal intellectual investment in the science or medicine, or academic competition.⁶⁶ The hidden nature of the ghost author—presumably associated with favoring positive outcomes for the industry sponsor or supporting negative outcomes for competitors—may mask potential COI issues with the manuscript.

⁶² *Annals of Internal Medicine*, “Authorship: Criteria and Policy,” (emphasis added), available at www.annals.org/site/misc/ifora.xhtml#criteria-and-policy, (last accessed Nov. 9, 2009).

⁶³ Jeffrey M. Drazen and Gregory D. Curfman, *Editorial: On Authors and Contributors*, 347 *NEW. ENG. J. MED.* 55 (2002).

⁶⁴ *Id.*

⁶⁵ Natasha Singer and Duff Wilson, *Medical Editors Push for Ghostwriting Crackdown*, Sep. 7, 2009, available at www.nytimes.com/2009/09/18/business/18ghost.html?hpw (last accessed Nov., 9, 2009).

⁶⁶ ICMJE, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Conflicts of Interest*, available at www.icmje.org/ethical_4conflicts.html (last accessed Nov., 2009).

Authors are usually asked to disclose potential COIs and identify funding source(s).⁶⁷ That is not to discount that sponsors “have a legitimate interest in the publication of the research they fund.”⁶⁸ The concern is the potential for “cherry picking” favorable data and using authors as vehicles for the credibility of studies. The increased transparency of industry-academic collaborations, especially regarding manuscript preparation and publication, would assist in identifying and disclosing potential COI issues.

VIOXX: The Case Study in Ghost Authorship

Inflammation is associated with enzymes known as Cox-1 and Cox-2.⁶⁹ Nonsteroidal anti-inflammatory agents (NSAIDs)⁷⁰ are believed to interact with these enzymes and reduce inflammation. One of the now familiar NSAID side effects is gastrointestinal side effects related to the NSAID interacting with Cox-1 and interfering with prostaglandin production.⁷¹ In an effort to alleviate gastrointestinal side effects, the Cox-2 (cyclooxygenase 2) inhibitors were developed. These drugs included rofecoxib (Vioxx, manufactured by Merck), valdecoxib (Bextra, manufactured by Pfizer), and celecoxib (Celebrex, also manufactured by Pfizer).

In 2001, an abstract was published in JAMA that warned of potential adverse cardiovascular events associated with the use of Cox-2 inhibitors.⁷² Subsequently an article appeared in the journal *Circulation* that downplayed the potential seriousness of cardiovascular events associated with rofecoxib, commonly known by its brand name Vioxx.⁷³

⁶⁷ Id.

⁶⁸ Adam Jacobs and Elizabeth Wagner, *European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications*, 21(2) CURRENT MED. RESEARCH AND OPINION 317-321, 318 (2005).

⁶⁹ Carol and Richard Eustice, About.com, June 15, 2006, <http://arthritis.about.com/od/cox2inhibitors/g/cox.htm> (last accessed Nov. 9, 2009).

⁷⁰ One estimate indicates that 30 million Americans a day use a NSAID. R Morgan Griffin, *Pain Relief: How NSAIDs Work*, WebMD, www.webmd.com/rheumatoid-arthritis/features/how-anti-inflammatory-drugs-work (last accessed Nov. 9, 2009).

⁷¹ Id.

⁷² D. Mukherjee, S.E. Nissen, and E.J. Topol, *Risk of cardiovascular events associated with selective COX-2 inhibitors*. 286(8) JAMA 954-9 (2001).

⁷³ Marvin A. Konstam, Matthew R. Weir, Alise Reicin, Deborah Shapiro, Rhoda S Sperling, Eliav Barr, and Barry J Gertz, *Cardiovascular thrombotic events in controlled, clinical trials of rofecoxib*, 104 CIRCULATION 2280, 2287 (2001). (“As noted, our analysis provides no evidence that rofecoxib was associated with excess [cardiovascular] events compared with placebo, nor was their evidence of an increased risk of such events relative to the non-naproxen NSAIDs that were studied.”)

The *Circulation* article identified that the first and second authors of the paper, Drs. Konstam and Weir, were paid consultants of Merck and Pharmacia, and that Dr. Konstam was a paid consultant to Pfizer.⁷⁴ In addition, the fact that five of the listed authors⁷⁵ were Merck employees was likewise disclosed, along with the fact that these authors received income and had stock interests in the company.

Later studies questioned the results published in the *Circulation* article. In contrast to the conclusions presented in the *Circulation* article, these other studies supported the possibility that rofecoxib was associated with increased adverse cardiovascular events.⁷⁶ By 2004, there was increasing evidence that rofecoxib was associated with cardiovascular events. Merck announced a voluntary worldwide withdrawal of rofecoxib from the market based on confirmed cardiovascular events occurring in the Adenomatous Polyp Prevention on VIOXX (APPROVe) trial.⁷⁷ Litigation ensued, including both American and Australian courts. During the course of this litigation, the allegation surfaced that the *Circulation* paper had been ghostwritten by Merck and that Dr. Marvin Konstam, the first author, had not made the contributions necessary to be considered an author.⁷⁸ Merck settled the lawsuits concerning Vioxx for \$4.85 billion. The settlement also included release of internal Merck documents to plaintiffs.⁷⁹

The ghostwriting issue and the rofecoxib literature were examined in a 2008 paper published in *JAMA*.⁸⁰ The *JAMA* paper authors, consultants on behalf of the rofecoxib

⁷⁴ *Id.* at 2280.

⁷⁵ Drs. Recin, Shapiro, Sperling, Barr, and Gertz.

⁷⁶ David J. Kerr, Janet A. Dunn, Michael J. Langman, Justine L. Smith, Rachel S.J. Modgley, Andrew Stanley, Joanne C. Stokes, Patrick Julier, Claire Iveson, Ravi Duvvuri, and Christopher C. McConkey, for the VICTOR Trial Group, *Rofecoxib and Cardiovascular Adverse Events in Adjuvant Treatment of Colorectal Cancer*, 357 NEW ENG. J. MED. 360 (2007), (“However, our findings suggest an increased risk of a cardiovascular thrombotic event in patients randomly assigned to receive rofecoxib (as compared with those randomly assigned to receive placebo) as adjuvant treatment for the prevention of colorectal cancer”)

⁷⁷ Merck Dear Customer Letter Announcing Worldwide Voluntary Withdrawal of VIOXX, available at www.pbm.va.gov/vioxx/direct%20purchasers.pdf (last accessed Nov. 9, 2009).

⁷⁸ Alice Dembner, *Drug firm paid MDs for bylines*, BOSTON GLOBE, Apr. 16, 2008, available at www.boston.com/business/healthcare/articles/2008/04/16/journal_drug_firm_paid_mds_for_bylines?mode=PF (last accessed Nov. 9, 2009).

⁷⁹ Stephanie Saul, *Ghostwriters Used in Vioxx Studies, Article Says*, N.Y. TIMES, Apr. 15, 2008, available at www.nytimes.com/2008/04/15/business/15cnd-vioxx.html?ex=1365998400&en=2a73513738d4f1a2&ei=5124 (last accessed Nov. 9, 2009).

⁸⁰ Joseph S. Ross, Kevin P. Hill, David S. Egilman, and Harlan M. Krumholtz, *Guest authorship and ghostwriting in publications related to rofecoxib: A case study of industry documents from rofecoxib litigation*, 299(15) JAMA 1800 (2008).

plaintiffs,⁸¹ concluded that the sponsor would produce a prepared manuscript and then recruit academic investigators to fill the authorship positions.⁸² In response to the *JAMA* article and similar articles, Merck issued a press release in which it countered that outside authors were “intimately involved in the studies.”⁸³

Regardless of the litigation outcomes and legitimacy of the studies in the rofecoxib literature, the concern was that rofecoxib was prescribed to patients without adequate information on cardiovascular risks. The ghostwriting issue was so poignant because if the literature could be so manipulated, it failed to serve as neutral grounds of information and dissemination of medical data. Likewise, if data is good, but then suspect because ghostwriting is implicated, this could also disserve the medical literature. The case points to the potential power of having the right article in the right journal with the right names on it.

Conclusions

The issue with sponsor-directed medical ghostwriting is that the purported author is giving their name to the thoughts and ideas of another entity, oftentimes an entity with a financial interest in the topic. The seeding of the medical literature with articles supporting specific pharmaceutical products may induce physicians to prescribe those drugs, patients to request those drugs, and in turn result in payments for those drugs by insurance companies or federally funded programs. It is this translation of veiled marketing into the

⁸¹ *Id.* at 1801.

⁸² *Id.* at 1806. (“This case-study review of industry documents related to rofecoxib demonstrates that Merck used a systematic strategy to facilitate the publication of guest authored and ghost written medical literature. Articles related to rofecoxib were frequently authored by Merck employees but attributed first authorship to external, academically affiliated investigators who did not always disclose financial support from Merck, although financial support of the study was nearly always provided. Similarly, review articles related to rofecoxib were frequently prepared by unacknowledged authors employed by medical publishing companies and attributed authorship to investigators who often did not disclose financial support from Merck.”).

⁸³ Merck responds to the Journal of the American Medical Association Articles, Press Release, Apr. 15, 2008, available at www.merck.com/newsroom/press_releases/corporate/2008_0415.html (last accessed Nov. 9, 2009). See also Stephanie Saul, *Ghostwriters Used in Vioxx Studies, Article Says*, N.Y. TIMES, Apr. 15, 2008, available at www.nytimes.com/2008/04/15/business/15cnd-vioxx.html?ex=1365998400&en=2a73513738d4f1a2&ei=5124 (last accessed Nov. 9, 2009) (“Merck . . . acknowledged that it sometimes hires outside medical writers to draft research reports before handing them over to doctors whose names eventually appear on the publication. But the company disputed the article’s conclusion that the authors do little of the actual research or analysis. And at least one of the doctors whose published research was questioned in Wednesday’s article, Dr. Steven H. Ferris, a New York University psychiatry professor, said the notion that the article bearing his name was ghostwritten was ‘simply false.’ He said it was ‘egregious’ that Dr. Ross and his colleagues had done no research besides mining the Merck documents and reading published medical journal articles.”)

disbursement of federal money that has attracted the attention of politicians and policy makers, such as Grassley.

There is an argument to be made that legitimate ghostwriting—the technical preparation of an article in accordance with the listed authors’ directions—has a place. Busy academic physicians may be pressed for time to conduct full literature searches to accompany their own cases,⁸⁴ or the physician may lack the writing skills necessary to compose his or her own manuscripts. In these cases, acknowledgements may serve both to recognize the technical writer’s skill as well as support that the paper reflects the intents and opinions of the listed authors.⁸⁵ Many academic institutions have scientific writing departments to assist in the preparation and submission of articles; likewise, most journals will assist in the editorial process. However, these individuals do not direct the content or expression of data.

The general gist of evolving authorship zeitgeist is that the authors listed on a work have contributed substantially both to data and manuscript preparation, that the authors can point to what contributions they made to the work (and that those who contributed are either listed as an author or in the acknowledgments), and that the authors share co-responsibility for the work.⁸⁶ Detailed contribution information, such as “Author X contributed to the design of the study, reviewed data, and assisted in the writing and review of the manuscript” may help in defining authorship and informing readers as to the relative contributions of those listed as authors.⁸⁷ This also may bring to light when authors have not fulfilled authorship criteria and should be listed in the Acknowledgment section.⁸⁸

⁸⁴ Frank Place, *Ghost Writing*. 22(4) BULL. MED. LIBR. ASSOC. 209-13, 211-212 (1934).

⁸⁵ *Id.* at 212. (“The more proficient and self-effacing the ghost is, the greater the reason for crediting him with his part in compiling the paper. His proficiency will consist of his ability to assemble the material and to prepare it so that it will express the employer’s ideas, style and intent most accurately and effectively. Indeed it is usually the case that the doctor who is best able to write is the most free in giving credit for such assistance . . . The ghost or paid literary worker, has been, and will be, a necessary help to busy physicians in preparing papers and other literary material. Instead of being condemned for mistakes in the past the ghost is to be encouraged, and authors are well-advised in acknowledging assistance rendered by him.”)

⁸⁶ P Riis. *Scientific dishonest: European reflections*. 54 J Clin Pathol 4, 6 (2001).

⁸⁷ See, e.g., V. Ramana Feeser and Jeremy R. Simon, *The ethical assignment of authorship in scientific publications: Issues and guidelines*. 15 ACADEMIC EMERGENCY MED. 963, 966 (2008), which contains suggestions for this format.

⁸⁸ See the reminder in Joseph S. Ross, Kevin P. Hill, David S. Egilman, and Harlan M. Krumholtz, *Guest authorship and ghostwriting in publications related to rofecoxib: A case study of industry documents from rofecoxib litigation*, 299(15) JAMA 1800 (2008) (“Participating only in minor editing does not meet authorship criteria of the [ICMJE].”)

Some have even suggested scoring tools that weight contributions and attempt to create algorithms for determining authorship and authorship order.⁸⁹

The most obvious answer to industry-driven manuscripts is the acknowledgment of professional writers in either the authorship listing or acknowledgments section, along with attribution of their affiliations to medical education writing companies *and* the sponsoring entity. This allows for reviewers and editors to quickly query and potentially identify possible bias. ICMJE recommendations and journal requirements should be consulted before and during manuscript preparation. At least one editor-in-chief has noted, “Each must obey his own conscience at the least, editors and publishers should insist that, everyone that materially contributes to a paper be listed as an author, and that each author signs an affidavit to that effect.”⁹⁰ In effect, authorship becomes a net of certain weave; those who should not be listed as authors slip through the holes, and all those who should be listed as authors remain captured in the net. It is in having a consensus over the gauge of the weave that the issues arise.

Increased journal vigilance regarding authorship criteria also would possibly aid adherence to authorship guidelines and requirements. Professional societies and organizations also may assist in establishing ethical writing and authorship rules. For example, the SAEM Ethics Committee Society for Academic Emergency Medicine has established guidance for professionalism in emergency medicine that includes “honesty in data collection, reporting of research results, collaboration, and authorship credit.”⁹¹ At least one journal is considering banning authors associated with ghostwriting from future contributions.⁹² Without adequately defining authorship criteria and its enforcement, and the provision of meaningful penalties for unethical authorship practices, it is difficult to imagine how ghostwriting will be effectively deterred.

⁸⁹ V. Ramana Feeser and Jeremy R Simon, *The ethical assignment of authorship in scientific publications: Issues and guidelines*, 15 ACADEMIC EMERGENCY MED. 963, 967-968 (2008).

⁹⁰ Jerry G. Blaivas. *Ghost unwriting*, 23 NEUROLOGY AND URODYNAMICS 287 (2004) (While this statement is directed toward ghostwriting, it finds perfectly adequate application to honorary authorship. The fair and accurate identification of actual authors goes to the heart of each question.)

⁹¹ V. Ramana Feeser and Jeremy R Simon, *The ethical assignment of authorship in scientific publications: Issues and guidelines*, 15 ACADEMIC EMERGENCY MED. 963, 963 (2008).

⁹² Natasha Singer and Duff Wilson, *Medical Editors Push for Ghostwriting Crackdown*, Sep. 7, 2009, available at www.nytimes.com/2009/09/18/business/18ghost.html?hpw (last accessed Nov., 9, 2009). (“In an interview last month, Dr. Cynthia E. Dunbar, the editor in chief of Blood, said that, in the future, the journal would consider a ban of several years for authors caught lying about ghostwriting, in addition to retracting their ghosted articles.”)

The pharmaceutical industry itself has recently endorsed policies to improve authorship accuracy and disclosures. The Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors announced revised principles in April 2009.⁹³ These include adopting the ICMJE guidelines regarding the authorship definition and describing “the role of sponsors in designing the study, collecting and interpreting data, and writing the report.”⁹⁴ PhRMA recently published updated guidance regarding clinical trial reporting.⁹⁵ The guidelines specify that persons who qualify as authors should be listed,⁹⁶ and that persons who do not qualify as authors—but who provided writing assistance—should be listed in the Acknowledgments.⁹⁷ While appearing to address the ghostwriting issue,⁹⁸ two concerns regarding this PhRMA guidance have already emerged. One is that the guidance is not mandatory,⁹⁹ and the other that the use of medical education companies in the preparation of manuscripts is not adequately covered by the new PhRMA recommendations.¹⁰⁰ Regardless, the pharmaceutical companies’ acknowledgment of the perception of their published data¹⁰¹ and an apparent acknowledgment that negative data

⁹³ PhRMA, Revised Clinical Trial Principles Reinforce PhRMA’s Commitment to Transparency and Strengthen Authorship Standards, Press Release, Apr. 20, 2009, available at www.phrma.org/news_room/press_releases/revised_clinical_trial_principles_reinforce_phrma%92s_commitment_to_transparency/ (last accessed Nov. 9, 2009).

⁹⁴ *Id.*

⁹⁵ PhRMA, *Principles on Conduct of Clinical Trials/Communication of Clinical Trial Results*, available at www.phrma.org/clinical_trials/, (last accessed Nov. 9, 2009). These guidelines were effective as of October 1, 2009.

⁹⁶ *Id.* at 21.

⁹⁷ *Id.* at 22.

⁹⁸ *Id.* at 15. (“Authors should identify individuals who provide writing or other assistance and disclose the funding source for this assistance. Authors should describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication. If the sponsor had no such involvement, the authors should so state.”)

⁹⁹ *New Pharma Guidelines: No Ghostwriting, More Public Info*, <http://blogs.wsj.com/health/2009/09/30/new-pharma-guidelines-no-ghostwriting-more-public-info/tab/print/> (Sep. 30, 2009, 4:46PM ET). (“The guidelines are purely voluntary . . . Jeffrey K. Francer, PhRMA’s assistant general counsel, told the Health Blog that the trade group could get into antitrust trouble for making the rules mandatory.”)

¹⁰⁰ Shelley Wood, *New “principles” on authorship and COI from PhRMA get mixed response*, www.theheart.org/article/1010093.do (last accessed Nov. 9, 2009). (According to the report published by theheart.org, Dr. Steven Nissen of the Cleveland Clinic stated: “Accordingly, a company could develop a manuscript through a medical education and communication company (MECC) and give it to a physician to submit as an author. If the participation of the MECC is revealed, such activity would not violate the PhRMA guidelines; however, it would still be unethical.”)

¹⁰¹ *New Pharma Guidelines: No Ghostwriting, More Public Info*, <http://blogs.wsj.com/health/2009/09/30/new-pharma-guidelines-no-ghostwriting-more-public-info/tab/print/> (September 30, 2009, 4:46PM ET).

should be available at least in summary form¹⁰² may indicate a move toward more ethical writing practices from industry.

In a letter published in December 2004, Dr. David Healy brings up an interesting point: “That the key problem with ghostwriting is not the medical writing itself but the issue of transparency.”¹⁰³ One ghost was caught through inadvertent transparency—a reviewer considering a manuscript on his computer was provided with the ability to see “tracked changes” in the manuscript; upon looking at the comments, the influence of a pharmaceutical company was revealed by their commentaries in the paper.¹⁰⁴ At least one journal sometimes mines metadata for evidence of unlisted authors; interestingly, certain submissions apparently try to remove author identification information.¹⁰⁵

Increasing transparency for those who have contributed significantly to the work, such as industry writers or statisticians, would benefit the final consumers of the medical literature, by revealing who contributed to the paper and giving credit where it is due. The adoption of more standardized norms for authorship and the dissemination of those standards would help to eliminate ghost authorship, and address the concerns Grassley has raised in his effort to elucidate the current influence of ghostwriting upon the medical literature.

¹⁰² PhRMA, *Principles on Conduct of Clinical Trials/Communication of Clinical Trial Results* at 20, available at www.phrma.org/clinical_trials/, (last accessed Nov. 9, 2009). (This provision is not retroactive, and certain results may be withheld for intellectual property reasons. see *New Pharma Guidelines: No Ghostwriting, More Public Info*, <http://blogs.wsj.com/health/2009/09/30/new-pharma-guidelines-no-ghostwriting-more-public-info/tab/print/> (Sep. 30, 2009, 4:46PM ET)).

¹⁰³ David T. Healy, *Figure for ghost written articles was misquoted*, 329 *BMJ* 1345 (2004).

¹⁰⁴ Steinar Madsen, “Track changes” tracks ghost writers, 330 *BMJ* 1332 (2005). (“As we all know, the problem with ghosts is that it is very difficult to prove their existence. This was a rare example of ghost tracking.”)

¹⁰⁵ Brendan Borrell, *Using forensics to reveal medical ghostwriting*, *REUTERS HEALTH*, Sep. 11, 2009, available at www.reuters.com/article/healthNews/idUSTRE58A3BC20090911 (last accessed Nov. 9, 2009). (The journal, *Journal of Managed Care Pharmacy*, has a stringent requirement for authorship disclosure: individuals who “contribute more than 1% to the manuscript [must be] disclosed, and those that contribute more than 25% [to the] manuscript must be a listed author.” The editor-in-chief of the journal has even listed someone identified as an author against the wishes of that author. As for efforts to cleanse the metadata of author identifiers, Curtiss stated, “Now people are savvy about it . . . we are getting manuscripts where they have purposely removed data from the identification box.”)

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“This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought”—*from a declaration of the American Bar Association*