

## Survey Results

# Pharma-Sponsored Medical Ghostwriting

What the Ghosts Have to Say About It

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PMN88-02

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This article is part of the September 2009 issue of *Pharma Marketing News*.

For other articles in this issue, see:

<http://www.news.pharma-mkting.com/PMNissueSep09archive.htm>

*Published by:*

**VirSci Corporation**

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Newtown, PA 18940

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The *New York Times* recently reported that "a growing body of evidence suggests that doctors at some of the nation's top medical schools have been attaching their names and lending their reputations to scientific papers that were drafted by ghostwriters working for drug companies—articles that were carefully calibrated to help the manufacturers sell more products." What inspired the article was a letter sent to National Institutes of Health by Senator Charles E. Grassley urging NIH "to crack down on the practice" (see "Sen Grassley puts pressure on NIH to crack down on ghostwriters"; <http://bit.ly/2Aswrl>).

The *Wall Street Journal* concurs: "Many of the articles that appear in scientific journals under the bylines of prominent academics are actually written by ghostwriters [people other than the listed authors who do some or all of the writing] in the pay of drug companies" (see Figure 1, below and "At Medical Journals, Writers Paid by Industry Play Big Role"; <http://bit.ly/n5N4M>). "These seemingly objective articles, which doctors around the world use to guide their care of patients, are often part of a marketing campaign by companies to promote a product or play up the condition it treats."

#### How Rampant is Pharma-Sponsored Ghostwriting?

Meanwhile, at the recent International Congress on Peer Review and Biomedical Publication, editors of the *Journal of the American Medical Association* (Joseph Wislar, Annette Flanagan, Phil Fontanarosa, and Catherine D. DeAngelis), reported results of a study that found that six of the top medical journals published a significant number of articles in 2008 that were written by ghostwriters financed by drug companies.

"Among authors of 630 articles who responded anonymously to an online questionnaire created for the study, 7.8 percent acknowledged contributions to their articles by people whose work should have qualified them to be named as authors on the papers but who were not listed," reported the *NY Times* (<http://bit.ly/2oamxN>; see Table 1 for results from individual journals).

Journal	% "Ghost" Articles
NEJM	10.9%
JAMA	7.9%
Lancet	7.6%
PLoS Medicine	7.6%
Annals of Internal Medicine	4.9%
Nature Medicine	2%

Table 1. Medical Journal Ghost Articles. Source: JAMA

Journals unwittingly aided the off-label marketing of gabapentin (Neurontin) through lax policies on ghostwriting and disclosure of financial conflicts, researchers said at the Congress on Peer Review.

#### Pharma's New Marketing Partner: Medical Journals

Pharma blogger Rich Meyer commented on his DTC Marketing Blog that "Medical journal articles sponsored by drug companies are part of marketing. That is a fact of a capitalist business that has to market to medical professionals. 'Ghostwriting' has been around for over 20 years and is standard industry practice for the drug industries. I personally see nothing wrong with ghostwriting as long as it is made clear at the beginning of the article who wrote it and who endorses the content." (see "Ghostwriting: What is right and wrong"; <http://bit.ly/yBLj9>).

Ghostwriting in and of itself may not be objectionable, but when sponsored by pharmaceutical companies that distribute medical journal articles on off-label indications to physicians, it becomes a huge marketing compliance and ethics concern.

In 2008, the FDA relaxed its regulations concerning the distribution of medical journal reprints by pharma reps. According to FDA's guidance on "Good Reprint Practices for the Distribution of Medical Journal Articles ... on Unapproved New Uses of Approved Drugs..." (see <http://bit.ly/1HMW7H>), drug and device makers can provide doctors with copies of medical journal articles that discuss product uses that have not been vetted or approved by the FDA.

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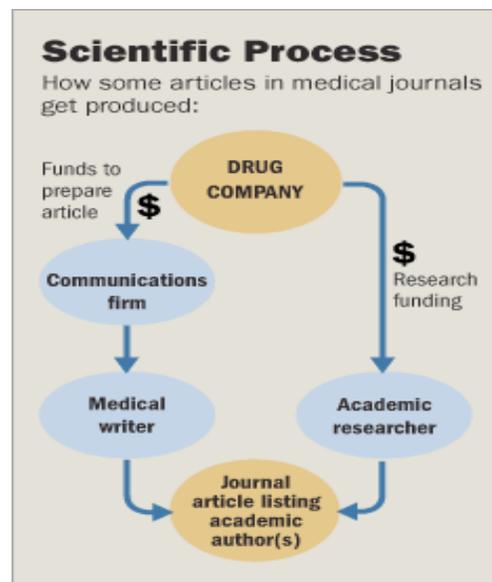


Figure 1. Source: WSJ, <http://bit.ly/n5N4M>

### Survey Results

To determine readers' views on the issues raised by the above research and revelations reported in the media, *Pharma Marketing News* hosted the online "Pharma-Sponsored Medical Article Ghost Writing Survey," which collected 83 responses. The survey specifically asked respondents to what degree they agreed or disagreed with the following statements:

**STATEMENT 1.** Medical journal articles sponsored and ghostwritten by drug companies are a legitimate part of marketing to physicians.

**STATEMENT 2.** Drug companies provide ghost-writing services primarily because academic researchers are busy and some may not be skilled writers. I.e., it's NOT a marketing tactic.

**STATEMENT 3.** There is nothing wrong with ghost-writing as long as it is made clear at the beginning of the article who wrote it and who endorses the content.

**STATEMENT 4.** Medical journal articles sponsored and ghostwritten by drug companies are often biased (eg, emphasize the benefits of a drug and de-emphasize the risks).

**STATEMENT 5.** Pharma-sponsored ghostwritten medical journal articles are ethically suspect when physicians are paid by the pharma company to add their names as authors even though they have not made a substantive contribution.

**STATEMENT 6.** Physicians would never sign on as an author of a ghostwritten article that they did not review thoroughly.

**STATEMENT 7.** Medical schools should prohibit their faculty, trainees and students from being authors or co-authors of articles written by employees of commercial entities if the author's name or school title is used without substantive contribution.

**STATEMENT 8.** The federal government should revise research grant terms to prohibit grantees from being authors or co-authors of articles written by employees of commercial entities if the author's name or grant title is used without substantive contribution.

**STATEMENT 9.** Most physicians do not care that medical journal articles are ghostwritten.

The survey collected responses between August 21, 2009 and August 31, 2009. The remainder of this article presents the results of this survey plus selected comments from respondents. The survey has been re-opened for additional comments (see <http://bit.ly/2BYB2b>).

### Defining Ghostwriting

Medical journals depend upon professional medical writers who are paid to assist physician authors to write articles for publication. These individuals may be referred to as "guest authors," a term used to designate an individual who does not meet authorship criteria as an author and is therefore not listed as an author.

*"If professional medical writers ceased to exist, so would a lot of medical journals, because the quantity of publications would decrease dramatically,"* said an anonymous survey respondent. *"Medical journals editors cannot deny this."*

Many survey respondents pointed out the distinction between "guest authors" and "ghostwriters." Caitlin Rothermel, MA, MPHc, a Medical Writer/Consultant ([www.MedLitera.com](http://www.MedLitera.com)), said:

*"Please, please consider your words carefully. If a medical writer drafts an article, and all steps are conducted in an up front manner (ie, they are acknowledged for writing assistance), it is not 'ghostwriting.' If the term ghostwriting continues to be broadly applied to all forms of medical writing assistance, the concepts will become synonymous, and it will be increasingly more difficult to discuss the integrity of the profession."*

In other words, guest authors become "ghosts" when there is no disclosure of their contribution to the publication.

Other comments relating to distinguishing between ghost authors and professional medical writers include:

*"I wish you wouldn't refer to it as ghostwriting! We are professional medical writers who assist in the preparation of manuscripts. We don't make up the study protocol or the data -- we assemble the information given to us and prepare a cohesive manuscript."* – Anonymous, medical education communications company.

"Most of the discussion on this topic fails to address several aspects of this complex situation," said Kathryn Nelson Emily, ELS (<http://bit.ly/2mvlwU>), of KMN Communications, LLC. Emily quoted from a letter written by professional medical writers Tom Lang and Art Gertel to Senator Grassley:

*"[It is important] to distinguish between ghost authors and professional medical writers (=ghost writers' who are acknowledged). Whereas ghost authors meet the criteria for authorship but their contribution to the work is unacknowledged in the author list,*

*Continues...*

*professional medical writers 1) work under the direction and supervision of a named author and 2) do not meet the criteria for authorship. They do not develop content, they help present content. They may edit, rewrite, or write drafts of the work, but at most, their contribution to content is limited to what might be provided by a peer reviewer: that is, suggestions as to how to improve the accuracy, completeness, and clarity of the work.*

The key qualifier in the above comments is “acknowledged for writing assistance.” Obviously, if a writer is not acknowledged, that person is a “ghost” and that is what the survey had as its focus. Hopefully, survey respondents clearly understood the meaning of ghostwriting and answered the questions accordingly.

### About the Respondents

A large portion (39%) of respondents were involved in medical communications in one way or another (ie, as medical writers, CME providers, marketing professionals, or employed at medical communications companies). Other affiliations are shown in Figure 2. About 36% of respondents worked in organizations that are involved in medical ghostwriting, whereas 59% are not involved in such an organization. Sixty-nine percent (69%) are very or somewhat supportive of the pharmaceutical industry, whereas 14% are very or somewhat unsupportive.

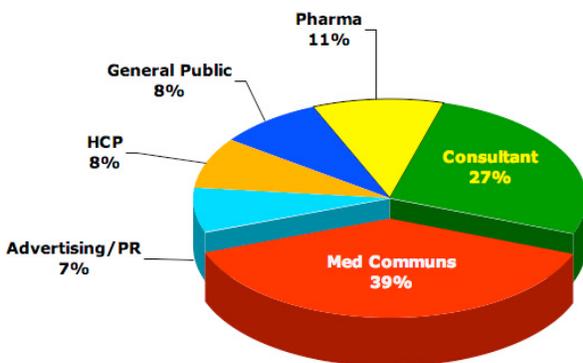


Figure 2. Affiliations of Survey Respondents.

### Part of Marketing?

Are ghostwritten articles a legitimate part of pharmaceutical marketing? Respondents were divided on this issue: 42% agreed that medical journal articles sponsored and ghostwritten by drug companies are a legitimate part of marketing to physicians, whereas 49% disagreed (see Figure 3, pg 5). Those who strongly disagreed, however, greatly outnumbered those who strongly agreed (35% vs. 14%, respectively). Looking only at respondents who admit to being part of an organization involved in ghost-

writing, 60% agreed that ghostwriting was a legitimate part of pharma marketing (33% agreed somewhat, 27% agreed strongly).

### It's a Service

As one respondent quipped, “Writing is not what most physicians are good at.” This is a legitimate concern to pharmaceutical companies, which often supply services to their physician consultants. “Ghost authorship is unethical and objectionable, but professional medical writing is necessary and desirable,” said Lang and Gertel in their letter to Grassley. “Necessary, because the primary reason for not publishing research is the principal investigator's lack of time to write the article; desirable, because a skilled writer, working with information provided by the authors, can usually prepare a draft manuscript faster, better, and less expensively than can the authors.”

A majority (54%) of survey respondents agreed (somewhat or strongly) that drug companies provide ghostwriting services primarily because academic researchers are busy and some may not be skilled writers (see Figure 3, pg 5). Seventy-seven percent (77%) of medical communications respondents agreed (50% strongly and 27% somewhat).

An anonymous medical writer admitted to being a ghostwriter in exchange for pizza while a college student:

*“I got into medical writing when asked by a colleague to help him with a review article on which he'd been working. He couldn't put words on paper to save his life, and it showed. I knocked his work into coherence and I've been writing on behalf of similarly inept fellow physicians ever since. Indeed, I started 'fixing' fellow students' papers in every sort of academic area while I was in college, typing their godawful papers for pizza money. There came a point at which I could no longer stand the strain of doing nothing more than transcribing their errors of grammar, orthography, and thought verbatim. None of 'em minded at all, any more than most doctors mind having their own work bashed into publishable form by medical writers with the time, talent, and experience the average physician simply does not have. Think 'division of labor economy' and the sense of this comes instantly to the fore. I have NEVER worked with an author who did not input substantive thought for each manuscript from first to last, uniformly at levels of perspicacity and consequentiality exceeding that of almost all of the peer reviewers whose comments I have had to help address. These doctors do not want publishing credits in their curricula vitae that do not reflect well upon their reputations, and anyone who thinks otherwise is an idiot.”*

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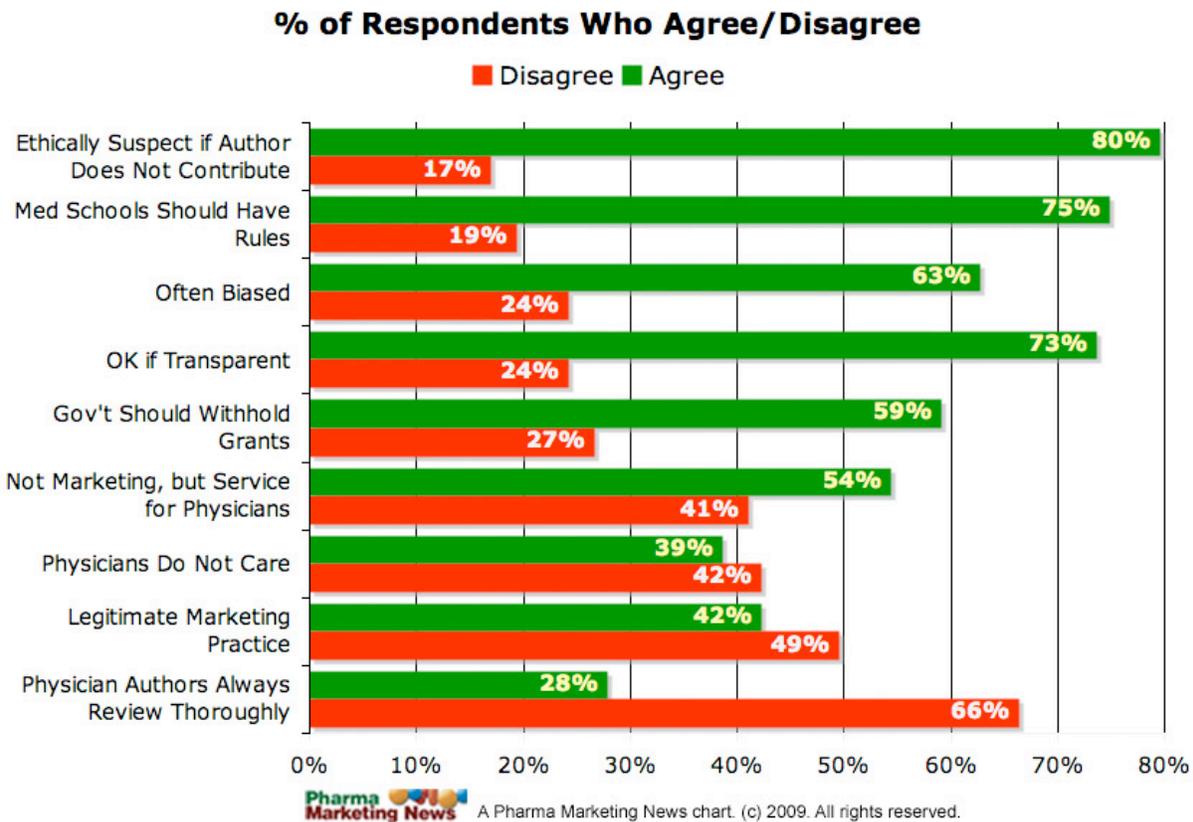


Figure 3. Survey Results. All respondents.

### Pharma Sponsorship Leads to Bias

A very strong majority of respondents (63%) agree somewhat (27%) or strongly (36%) that medical journal articles sponsored and ghostwritten by drug companies are often biased, whereas only 24% disagree. Among ghostwriter respondents, only 41% agree (33% agree somewhat vs. 7% who agree strongly).

*"Since you invited me to comment further," said Emily. "I would like to emphasize my concern that the controversy over this issue may result in the baby being thrown out with the dirty bathwater. The 'dirty bathwater' that needs to be thrown out is the bias that can be introduced when pharmaceutical companies or other vested interests pay for scientific or medical articles to be written. The problem of ghostwriting is only a small part of the problem of bias, because financial support from vested interests always can cause bias to creep in, no matter whether an author writes the entire manuscript from scratch or uses a draft produced by an unacknowledged medical writer. The 'baby' that needs to be saved is the contribution of professional medical writers, whose expertise in presentation often vastly*

*improves the understandability and even the objectivity and overall scientific value of a manuscript.*

*"As most scientific journals have already recognized, the solution to the problem of bias is not elimination of payments by vested interests, but full disclosure of payments. Likewise, discouraging the contribution of medical writers does not solve the problem, even when they are paid by commercial interests, but their contributions should be fully disclosed. It is time to recognize that the old 'ivory tower' concept of authorship no longer applies. Just as most scientific endeavor today is a matter of teamwork, so, too, is authorship of a scientific or medical paper. Professional medical writers should be valued, acknowledged members of the team.*

*"Articles submitted for publication to medical journals undergo a theoretically rigorous peer-review process. It is the journal's responsibility to uncover bias. If journal editors and reviewers are unable to find bias, it speaks either to the quality of the article, regardless of who wrote or sponsored it, or the reviewers'*

*Continues...*

*functional illiteracy. Pharma companies are for-profit entities whose primary goal is to sell product. To expect otherwise is simply naive. It is the responsibility of the journals, reviewers, physicians, and readers to detect bias. Moreover, the senators and others continue to falsely persist in believing that communication can be objective. Every text, even scientific texts, always already try to convince a reader of something."*

Jacqueline Limpens, a medical writer and author of Laika's MedLibLog Blog (<http://bit.ly/1arMu2>), said *"Clinical studies financed by the pharmaceutical industry are already biased (towards more positive results). Ghostwriting only leads to more bias. Co-authoring is no problem (or justified) as long as there is substantive contribution, and the ties with the industry are clear."*

An anonymous respondent and medical writer who claimed to work for a company involved in medical ghostwriting suggested that drug companies tend to select writers who favor the industry to begin with: *"Pharma companies generally only work with those authors who are sympathetic to the pharma companies views. But they are also bound by the ABPI [Association of the British Pharmaceutical Industry] code to be balanced, which may on occasion sway the content of a piece further away from being promotional than [if the] authors [were] actually ... left to their own devices."*

### Is Disclosure Enough?

Some experts – like Rich Meyer – contend that concealment is the real problem and that full disclosure of who helped write the article is enough to prevent bias from influencing the reader. Many survey respondents agreed: 73% agreed (43% strongly agreed) that there is nothing wrong with "ghostwriting" an article (ie, an article written by someone other than the listed author or authors) as long as it is made clear at the beginning of the article who wrote it and who endorses the content.

*"Most medical writers do not consider themselves 'ghostwriters' and do not engage in 'ghostwriting',"* commented an anonymous "ghostwriter." *"The term ghostwriting implies a lack of disclosure; when fully disclosed, medical writing assistance is not, by AMA publication guidelines, ghostwriting."*

*"Biases occur in all publishing,"* said another anonymous medical writer survey respondent, *"bias in favour of ones own work, research area, institution, friends etc and against competing theories, research groups etc. Therefore the issue with ghostwritten articles is not that they are biased in favour of drug companies who support them, but that they should clearly acknowledge the support and*

*bias so that these biases may be kept in mind when reading them. It is concealment of ghostwriting that is the real issue, not ghostwriting per se."*

But, in the realm of medical publishing, is full disclosure enough? At least one physician and former hired-gun Key Opinion Leader for pharma thinks not (see "Confession of a KOL: The Perverse Effect of Conflict of Interest Disclosure"; box, below).

"Full disclosure" and "transparency" are terms used so often these days they are becoming meaningless. A case in point is the brouhaha regarding Elsevier's publication of "fake" medical journals in Australia, which is seemingly a hotbed for pharmaceutical marketing excess.

It has been said that Elsevier "colluded with Merck to produce a fake journal, the Australasian Journal of Bone and Joint Medicine (AJBJM), to promote rofecoxib and other Merck products." That's how critics described it in correspondence to The Lancet—a real medical journal published by Elsevier. The authors call for Elsevier to either divest itself of either its medical publishing or pharmaceutical services division.

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### Confession of a KOL: The Perverse Effect of Conflict of Interest Disclosure

"I was also wrong about disclosure," said James Stein, MD at a University of Wisconsin conflict of interest seminar. Dr. Stein, a cardiologist, was proud to list all his drug company affiliations on his CV in the 90's and admitted he liked the money he got from being on their advisory boards and speakers' bureaus.

"I really felt that if I stood up in front of a crowd and said these are my disclosures, look how honest I am, that I was really managing conflict of interest. The literature tells me it [has] the opposite effect. Although its laudable to disclose your relationships [with drug companies] ... it actually has the perverse effect. The recipient of your information becomes more trusting. Also, professionals who disclose become more biased. That's the perverse effect of disclosure."

The good doctor drew chuckles from the audience when he said "The solution isn't disclosure. If you are doing something that's wrong or unethical, don't disclose it. Just don't do it!"

Elsevier admitted it should not have called these publications "journals," but was silent on whether or not it "colluded" with Merck. It just says, in effect, such a lack of "disclosure" will not happen again: "We have done a full internal review of all our publishing practices and are finalising a set of revised guidelines to ensure that this type of misrepresentation and lack of disclosure is not repeated," Elsevier said in reply to the letter to The Lancet.

"It should be noted that Excerpta Medica is very clear and transparent in stating that its mission is to help pharmaceutical companies publish and market their research. This is a legitimate and important function, assisting in the dissemination of advancements in pharmaceutical research that aid medical professionals every day."

I empathize with a publisher that wishes to help its advertising clients promote their products within their publications, even to the point of publishing sponsored articles. I do that myself in *Pharma Marketing News*. That's all well and good for trade publications. But mixing up marketing and editorial content in the medical field is another thing altogether.

If medical publishers don't take steps more drastic than issuing guidelines about transparency, they will come under increasing scrutiny from regulators similar to that leveled against the for-profit CME industry (for more about that, see "Waning Pharma Support of CME"; PMN Reprint #87-03; <http://bit.ly/VjKlK>).

### A Question of Ethics

An overwhelming majority (80%) of survey respondents agreed (54% strongly agreed) that pharmaceutical sponsored ghostwritten medical journal articles are ethically suspect when physicians are paid by the pharmaceutical company to add their names as authors even though they have not made a substantive contribution.

*"The majority of faculty/authors with whom I have worked for the past 20 years (which is in the 100s) ... have a high level of integrity and feel that their participation as faculty/author puts their own professional reputations at stake,"* commented an anonymous medical "ghostwriter." *"Therefore they tend to: a) seek work with groups/writers whom they trust to be ethical, providing few editorial comments to these trusted groups because information is ethically presented from the onset; b) refuse to work with less trusted groups/writers; c) if aligned with a group/writer with whom they have little faith, faculty/authors tend to contribute substantial edits, throw many fits, or if material is compromised, ask that their name(s) be removed from material."*

It's possible to interpret "substantive contribution" to mean editing and throwing "fits." But as far as I am concerned, if you edit, you're an editor and not an author. Even physicians who are "godawful" writers should be able to write a draft version of the article that can be polished up by a real editor.

A majority (66%) of survey respondents, however, disagreed with this statement: Physicians would never sign on as an author of a ghostwritten article that they did not review thoroughly. That is, these respondents believe some physicians do lend their names to papers that they have not reviewed thoroughly.

*"Many of these answers would depend on how 'substantive contribution' is defined,"* noted one anonymous ghostwriter survey respondent. *"The physician can contribute much to the design and actual performance of the study but not so much to the actual writing up of the data and should still be included as an author because of his overall contribution to the study. The primary acknowledgment that a researcher has contributed to a research study is by getting named as an author on the eventual publication. Of course, they would have to review the paper carefully and make revisions as needed (and ideally contribute to its development) to assure that the results are being presented fairly."*

It's easy to imagine a physician claiming author status even though he or she did not review the article thoroughly. As noted by the commentator just cited, a physician may have been part of the research being written about, but not involved in writing the article. There's nothing unethical about that.

It is certainly unethical, however, for a physician to put his or her name on an article if the physician played no role whatsoever in the research being written about. Professional medical writers hired by pharmaceutical companies to "ghostwrite" the article may not know or care if all the individuals listed as authors were involved in the research or not.

*"What is important is that the named 'author' actually contribute to the paper — any MD who sells his name w/o making a substantive contribution to a paper is essentially a prostitute,"* said an anonymous respondent. *"Moreover it should be considered fraudulent by law. But using his name while a medical writer does much of the writing/editing is fine — as long as the MD participates in the outline, the content, the review and final editing/approval. Between the writer and the MD, there should be sufficient honor to ensure an unbiased article, even if a drug*

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*co. is paying the tab — I can verify this with years of personal experience. It is the MDs who 'sell' their names and do nothing who are the worst culprits — worse than the drug companies who 'purchase' the names."*

*"The problem isn't ghost writers, it's ghost authors who let their names be attached to a paper without actually meeting the criteria for authorship," said an anonymous consultant/ghostwriter respondent.*

*"Whether or not money changes hands is less important than whether the named author actually contributed to the paper or not. Ghost writers are providing services that researchers are seldom in a position to do well on their own--think statistical analysis or preparation of charts & figures that almost always involve outside experts who may or may not be named."*

It is not known how frequently physicians merely "sell" their names to pharma companies who ghostwrite the articles. According to at least one survey respondent, it happens very rarely:

*"What is being called 'ghostwriting' is really 'ghost-authoring,' where a physician merely reviews and adds their name to a prepared article. In my 15 years as a professional medical writer, this is a rare practice and not one that I have personally experienced.*

*"The professional medical writer acts as a consultant to the pharmaceutical company, just like the physician/author who runs clinical trials for the company. The professional medical writer's job is to assist the author turn the clinical trial results into a publishable article.*

*"Remember, physicians who research new drugs for pharmaceutical companies also teach medical students and treat patients. Writing is an extremely time-intensive activity and takes certain skills that the average physician does not possess. When I write an article for a physician, it is under the direction of the physician.*

*"I have NEVER--in 15 years--worked with a physician who allowed me to put words into their mouth, so to speak. In the articles that I provide service for, I always add my name in the acknowledgements, and the funding source, ie, the pharmaceutical company, is also identified. The reader can draw whatever conclusions they see fit from those disclosures."*

#### **How Should Bad Practices Be Eliminated?**

Aside from "[Bringing] on the handcuffs and indictments" as suggested by one survey respondent, how should unethical ghostwriting practices be eliminated? The survey offered two choices for respondents to consider:

The first choice was inspired by Iowa Republican Sen. Charles Grassley who wrote a letter to the NIH in August signaling that he was "running out of patience with the practice of ghostwriting," according to a report in the *NY Times* (see "Ghosts in the Journals"; August 19, 2009).

The federal government should revise research grant terms to prohibit grantees from being authors or co-authors of articles written by employees of commercial entities if the author's name or grant title is used without substantive contribution. Putting pressure on the NIH is significant claimed the Times "because the N.I.H., a federal agency in Bethesda, Md., underwrites much of the country's medical research. Many of the nation's top doctors depend on federal grants to support their work, and attaching fresh conditions to those grants could be a powerful lever for enforcing new ethical guidelines on universities."

Surprisingly, 59% of respondents agreed (45% strongly agreed) that the federal government should revise research grant terms to prohibit grantees from being authors or co-authors of articles written by employees of commercial entities if the author's name or grant title is used without substantive contribution.

But the NIH told the Times that the responsibility for policing ghostwriting falls upon institutions that employ the researchers. Perhaps these institutions – ie, medical schools – should police their faculty. This option was more popular with survey respondents, 75% of whom agreed (52% strongly agreed) that medical schools should prohibit their faculty, trainees and students from being authors or co-authors of articles written by employees of commercial entities if the author's name or school title is used without substantive contribution.

#### **Do Physicians Care?**

When all is said and done, do physicians really care whether the article was written by the authors or by paid ghostwriters? Survey respondents were divided about that. While 42% agreed that physicians probably do not care, 39% disagreed and thought that physicians do care.

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