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## Ghosts In The Pharma Attic: Jon & Jeff Explain

By Ed Silverman // [June 12th, 2012](#) // 11:10 am

[34 Comments](#)



*For the past several years, the controversy over ghostwriting has festered with no clear resolution. Efforts to adopt policies have been met with a mix of indecision and partial measures. Meanwhile, various episodes have stained the research associated with various drugs and, in the process, placed academics, medical journals and drugmakers on the defensive. And so, we asked Jonathan Leo, a professor at the DeBusk College of Osteopathic Medicine at Lincoln Memorial University, and Jeff Lacasse, a professor at the College of Public Programs at Arizona State University, to help sort out several recent examples of both the ghostwriting problem at large and the attempted fixes...*

The medical community is currently trying to come to grips with the idea that much of the clinical trial literature has not been written by named authors, and, instead, has been written by medical writers employed by pharmaceutical companies who are not listed on the author byline. The success of virtually all of the blockbuster drugs has been tainted by charges of ghostwriting. To clean up the medical literature and stop ghostwriting, medical journals and universities are attempting to put policies in place to stop the practice. However, there is also a troubling trend by several groups in academic medicine that, on one hand, take a public stance that they oppose ghostwriting, but then on the other hand, turn around and develop policies that condone the practice of having invisible authors on papers. Under the traditional notion of ghostwriting it would seem impossible to do this. How does one ban ghostwriting but allow invisible authors? Simple: Change the definition of ghostwriting.

Some might say it is a minor point but in academic medicine there is currently an institutionalized loophole in place, that essentially says that anyone deserving of the term "author" should be listed on the byline, unless they are employed by a pharmaceutical company, in which case it is acceptable to mention them in the acknowledgement section. We do not think this is a good idea. For each segment below we discuss how various groups or organizations have approached this idea. We would appreciate any comments or thoughts on this.

### **International Committee of Medical Journal Editors**

Ironically, the most problematic policy in terms of allowing ghostwriting comes from the group with the most power to curb the practice. The ICMJE, a group of medical editors who have

developed policies related to the medical publishing process, has proposed three criteria for determining who should be given a byline as author on scientific papers. These criteria are: 1 – substantive 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. While these are now the traditional, oft-cited criteria for authorship, they do not address the contemporary concern of ghostwriting. In fact, although unintended, use of the ICMJE criteria may facilitate ghostwriting while creating the impression that medical journals have strict policies on authorship.

Consider this hypothetical situation: An industry-funded medical writer authors a paper in conjunction with academic researchers. The medical writer authors the first draft of the paper and makes many substantive edits, eventually writing 99 percent of the paper. Before the absolute “final” version is reached, the medical writer turns it over to the academic researchers, and never approves the final version; the medical writer is acknowledged for editorial assistance.

Thus, an inaccurate byline and a ghost author are created, but the authors followed the ICMJE rules to the letter — writer who does not approve the final manuscript cannot be an author. If accused of ghostwriting, all concerned can simply declare that they followed ICJME guidelines. We do not think that the above example follows the spirit of the guidelines as envisioned by the ICMJE but that is an example of exploiting a loophole in the policy. Merriam-Webster defines “[loophole](#)” as “an ambiguity or omission in the text through which the intent of a statute, contract, or obligation may be evaded.” Typically, when a loophole is discovered the authors of the policy seek to close it.



We are not the only ones pointing this out. In a 2011 [paper](#) in PLoS Medicine, a current ghostwriter, Alastair Matheson, published “How Industry Uses the ICMJE Guidelines to Manipulate Authorship – And How they Should be Revised.” In discussing the loophole in the ICMJE guidelines that allows industry authors to write the majority of the paper and then bow out at the last moment, he states:

“Provided academics make some contribution to design or data analysis, some revisions to a manuscript, and approve it, they are required to be named as authors. By contrast, industry may conduct most of the design, data collection and analysis, and all the writing, but if sign-off is ceded to the academic, it is disqualified from authorship. Unsurprisingly, the practice of ceding final sign-off to academic ‘authors’ is widespread in commercially driven publications.”

Matheson refers to this loophole as the “tool for the industry and that because of this error in logic, “industry and medical writers’ organizations are thus able to publicly condemn ghostwriting using comparable framings while the misattribution of authorship remains widespread.” It is no surprise that industry does this, but what will probably surprise many

academics is that, as we discuss below, universities do the same thing.

### **The University of Pennsylvania School of Medicine**

Several months ago, two professors at the University of Pennsylvania were accused of being involved with a ghostwritten paper published in 2001. The charges were the result of allegations by Dr. Jay Amsterdam that several professors allowed their names to be added to the authorship line of a [paper](#) examining the use of Paxil for the treatment of bipolar disorder. The paper did not mention any involvement of Scientific Therapeutics, a medical writing company. Amsterdam's complaint involved several accusations, only one of which was ghostwriting. The university has now announced that its own internal investigation has found that the professors were not guilty of any misconduct or violating any policy in place at the time the papers were written ([back story](#)). However, the charges, countercharges, the committee report, and several of the media articles go back and forth between charges of honorary authorship and ghostwriting as if they are the same exact thing.

Regardless of UPenn's past policy, what is of more concern is their new policy, which calls for simply acknowledging editorial assistance when medical writers were co-authors of the paper. According to the results of the recent investigation "...current Perelman School of Medicine policy and journal practice call for acknowledgment assistance." Thus UPenn is setting an institutional norm for authorship where it is appropriate for medical writers to simply be acknowledged at the end of the article, often in small print.

This is allowed despite the fact that it is well known that medical writers often write the vast majority of such articles, frequently the first drafts, and are paid employees of the pharmaceutical company with a product to sell. Medical researcher Peter C. Gøtzsche and colleagues note that such acknowledgments are a euphemism for... "XX from Company YY wrote the paper." It would be a simple matter to avoid all this by simply listing medical writers as authors, thus presenting authorship transparently ([the plan advocated by Alastair Matheson](#)), while we can think of only one reason not to do so: It obscures a conflict of interest.

### **University of Miami Miller School of Medicine**

In 2009, the University of Miami hired Charles Nemeroff to chair its psychiatry department. Nemeroff has been at center of numerous allegations about problematic authorship practices. Most recently, US Senator Charles Grassley [wrote the NIH](#) to ask why it gave Nemeroff a \$2 million research grant since he is under investigation by the Office of Inspector General. [Bernard Carroll](#) has in-depth discussion of the ghostwriting allegations. For a medical school to hire someone involved in ghostwriting as chairman of a major department, the message sent to the entire medical school faculty appears to be that ghostwriting is considered an acceptable practice. Some might even suggest that they value it.

### **Wikipedia**

For anyone who does a Google search on ghostwriting and follows the link to Wikipedia, they

will find the statement below. To us, this statement makes a mockery of the definition of authorship. The problematic part of this paragraph is that the author, probably a medical writer, can use medical journals as sources to support their idea that as long as the pharmaceutical company employee is listed in the acknowledgement section that this is somehow legitimate. It would be interesting to take this definition of ghostwriting to a University Faculty Committee and see if it could pass muster:

“Professional medical writers can write papers without being listed as authors of the paper and without being considered ghostwriters, provided their role is acknowledged. The [European Medical Writers Association](#) have published guidelines which aim to ensure professional medical writers carry out this role in an ethical and responsible manner. The use of properly acknowledged medical writers is accepted as legitimate by organizations such as the World Association of Medical Editors and the British Medical Journal.”

To publish a paper that demotes an author to the acknowledgement section, and elevates a minor contributor to the byline is an academic sleight of hand. Why not just call an author an author? For authorship standards to have integrity, the meaning of the word “author” has to mean something. The system of acknowledging medical writers seems Orwellian to us: It regulates ghostwriting by allowing ghostwriting.

### **Medical Publishing Insights and Practices (MPIP)**

Recently, eight pharmaceutical companies and several medical journals published a statement designed to increase the transparency of research. They had ten recommendations. The fifth recommendation says this: “Improve disclosure of authorship contributions and writing assistance, and continue education on best publication practices to end ghostwriting and ghost authorship” ([read here](#)). It is unclear from the document whether citing medical writers who make substantial contributions to the text should be listed on the byline or in the acknowledgement section. According to the lead author of the guidelines, who is also a senior editor at The Lancet, the medical writer should be cited in the acknowledgement section on the grounds that they would not meet the ICMJE guidelines.

### **The Journal Neurology**

Some journals have adopted policies stricter than the ICMJE guidelines. For instance, the journal Neurology has instituted a much more stringent policy. Rather than asking who is an author per ICMJE criteria, they ask, “Who influenced the content?” and require that any paid medical writer be included in the author byline, accompanied by full disclosure. In their authorship standards, they define a ghostwriter as “an undisclosed person (paid or unpaid) who has made an intellectual contribution in writing the submitted manuscript.” Basically, Neurology has formalized, for the medical literature, a pragmatic and intellectually sound definition of ghostwriting. To us, this demonstrates that it is possible, even simple, to address the issue of ghostwriting, if there is a desire to do so.

### **Should Study 329 be considered Ghostwritten?**

It is [generally acknowledged](#) in the medical literature that the most egregious example of ghostwriting is [Study 329](#). The study examined the use of Paxil in adolescents and concluded, “Paroxetine is generally well tolerated and effective for major depression in adolescents.” Several years after the paper was published, court proceedings revealed internal company documents admitting that the study found that Paxil was not any better than placebo on the pre-registered outcome measures, and that the company was concerned about how to manage the negative findings.

A [fascinating series of documents](#), all available on the web, reveal the steps involved in Study 329’s transformation from initial idea to final draft. Sally Laden, an employee of Scientific Therapeutics, was hired by GlaxoSmithKline, which makes Paxil, and wrote the first draft. After each draft was submitted, she incorporated suggestions from some of the listed authors into each subsequent draft. But, rather than be listed as one of the 22 academic co-authors listed on the byline, Laden was only acknowledged for editorial assistance. Sally Laden was also involved in the paper at the center of the allegations about ghostwriting at U Penn.

If one goes by the traditional idea that a ghostwritten paper has an invisible author, than Study 329 would be considered a good example of a ghostwritten by most people. Yet, according to the idea put forth by some segments of academia, that listing authors in the acknowledgement section is legitimate, this study should not be considered ghostwritten. Any new policy that is supposed to stop ghostwriting yet would legitimize Study 329 simply does not make sense.

Sally Laden was also involved in [another dust up](#) over ghostwriting in 2006, when Charles Nemeroff and his colleagues published a paper in the journal Neuropsychopharmacology. Their review article concluded that a useful treatment for depression was the vagus nerve stimulator manufactured by Cybertronics. The journal Science [discussed charges](#) that the article in question was ghostwritten because one of the main authors of the paper, Sally Laden, was not listed on the authorship byline. Laden was also paid by Cybertronics.

A [subsequent editorial](#) in 2007 in the Journal of the European Medical Writers Association (EMWA) by Karen Shashok and Adam Jacobs was very critical of the Science article and took a very dismissive tone with it. Jacobs has also taken this dismissive tone in the comments section of the [BMJ](#). In his editorial, he never argued about the facts behind the vagus nerve paper, Laden’s role or who her employer was. The major point of his editorial was that the paper should not be labeled as ghostwritten because Sally Laden was mentioned in the acknowledgement section. In his defense of Laden’s role he stated:

“In fact, Ms Laden’s role, and the fact that the authors maintained final control over the content, were reported in the Acknowledgements section in these words: ‘We thank Sally Laden for editorial support in developing early drafts of this manuscript. We maintained complete control over the direction and content of the paper. Preparation of this report was supported by an unrestricted grant from Cyberonics, Inc.’ ”

And just [last year](#) in a discussion about Study 329, Jacobs again used the “editorial assistance



argument.” In his words, “It’s also not accurate to describe this as a ghostwritten article, as I see that Sally Laden was acknowledged in the published version.”

We are certainly not calling for any kind of a ban on medical writers. Medical writers provide a valuable service and there is no reason they should not be used. However, rather than be hidden in the shadows we think that their skills and intelligence should be given the credit they deserve by being listed on the byline. Sally Laden is surely one of the most prolific authors in the scientific literature, yet a Pubmed search would not reveal this.

### The Acknowledgement Section

Some might say that listing authors in the acknowledgement section is full disclosure, but “editorial assistants” are not listed in medical databases such as Pubmed, are not listed in the abstract, they are not cited, and they are not called by the media to talk about the importance of a study. And, other than minimizing the company’s role in the study, there seems to be no good reason for not giving them their due credit. The acknowledgement section is traditionally seen as a spot to mention people who don’t rise to the level of “author” – for instance, colleagues who looked at the paper and made comments, a grammar guru who tweaked the composition, or Mom and Dad who provided the necessary motivation.

In a sense, the published paper also carries the endorsement of the university employing the named authors. Ghostwritten papers carry authorship bylines listing renowned professors from elite institutions, giving the papers great promotional value. Minimizing the role of the ghostwriter by re-defining authorship only benefits the pharmaceutical companies, who we know from their own internal documents, see the peer-reviewed literature primarily as a venue for promoting their products. Forest Pharmaceutical’s marketing plan for the antidepressant Lexapro states: “Bylined articles will allows us to fold Lexapro’s message into articles into depression, anxiety, and comorbidity developed by (or ghostwritten) for thought leaders.” Do universities and journals really want to promote this practice?

Calling for accurate bylines is not an earth shattering idea or very profound idea. There are numerous problems with conflicts of interest in medicine and accurate bylines are not the sole problem. But they are fairly simple step in the right direction. It just seems to be simple common sense. If readers can’t trust that the authorship line is accurate, then why should they trust the rest of the paper?

### Comments

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**as**

June 12th, 2012  
11:41 am

This is fascinating. Great post. We should probably remember that, scientifically, ghost-writing shouldn’t be a terribly big deal. In clinical research, it’s the data, not the prose, that matters. Good readers can look through good writing to spot bad data.

The much bigger related issues are publication bias and biases in study