

## Medical Journal Editors to Crackdown on Ghostwriting\_NYT

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This month PLoS editors called for a zero tolerance policy: calling upon journals to identify and retract ghostwritten articles and banish their authors from publishing in their journal.

The New York Times reports (below) that:

"In medical journal circles, the exorcism of industry-financed editorial assistance even has its own name: ghostbusting."

Medical journal editors are FINALLY determined to do something meaningful to prevent company-crafted, ghostwritten articles from infiltrating their journals under the "authorship" of prominent academics who are engaging in research misconduct for cash. Those ghosted articles have corrupted the practice of medicine, leading to the use of ineffective, harmful therapies, and have largely undermined the integrity of the scientific literature.

Despite a continuing stream of revelations in U.S. courtrooms where company documents confirm the planting of promotional articles that masquerade as science, "leading medical journals have continued to rely largely on an honor system of disclosure to detect such potential bias, asking authors to voluntarily report any industry ties or contributors to their manuscripts." Journal editors, afraid of losing corporate ads and reprint income, have been duplicitous in turning a blind eye to the corruption.

The editors of PLoS Medicine--Virginia Barbour, Jocalyn Clark, Susan Jones, Larry Peiperl, Emma Veitch, and Gavin Yamey--have taken up the clarion call that Dr. Richard Smith, longtime editor of the British Medical Journal, had been championing without success. This month PLoS editors called for a zero tolerance policy : calling upon journals to identify and retract ghostwritten articles and banish their authors from publishing in their journal.

"Any papers where this breach is substantiated should be immediately retracted," the editors wrote. "Authors found to have not declared such interest should be banned from any subsequent publication in the journal and their misconduct reported to their institutions."

The power of persuasion, however, does not lie with the editors of PLoS--it lies with Congress.

The Times reports, "As Washington tries to revamp the health care system, concerns about ghostwriting are taking on new urgency. One of the underlying assumptions of the health care overhaul effort is that money can be saved and medical care improved by relying more heavily on research showing which drugs and procedures are the most effective. But experts fear that the process could be corrupted if research articles are skewed by the hidden influence of drug or medical device makers."

Senator Charles E. Grassley, the former chair of the Senate Finance Committee, which has taken a leading role in the health overhaul effort, is hot on the trail of ghostwriting. In July, Mr. Grassley sent letters to eight leading medical journals asking about their ghostwriting policies. He also asked whether in the last five years, the journals had taken action against any author who had failed to report the involvement of a third party in the development of a manuscript.

None of the editors reported taking action against an author for ghostwriting. Their replies to the senator, obtained by The New York Times, varied from assurances of editorial diligence to the equivalent of "don't ask, don't tell." One editor in chief, for example, wrote that because his journal prohibited ghostwriting, the publication did not have a specific policy on the practice. Journals without explicit ghostwriting rules can expect to hear more from the senator...

Shame on medical journals and academia for demonstrating their inability / unwillingness to take action against the polluters of Medicine: not until the threat of Congressional tightening of the purse strings did journal editors consider cleansing the scientific literature of fraudulent articles.

Contact: Vera Sharav

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Medical Editors Push for Ghostwriting Crackdown

By NATASHA SINGER and DUFF WILSON

The scientific integrity of medical research has been clouded in recent years by articles that were drafted by drug company-sponsored ghostwriters and then passed off as the work of independent academic authors.

Yet the leading medical journals have continued to rely largely on an honor system of disclosure to detect such potential bias, asking authors to voluntarily report any industry ties or contributors to their manuscripts.

But now, in light of recently released evidence that some drug makers have gone to great lengths to turn scientific articles into marketing vehicles for their products, some influential medical editors are cracking down on industry-financed ghostwriting. And they are getting help from some members of Congress.

These editors are demanding that journals impose tougher disclosure policies for academic authors and that the journals enforce their own rules by actively investigating the provenance of manuscripts and by punishing authors who play down extensive contributions by ghostwriters.

In medical journal circles, the exorcism of industry-financed editorial assistance even has its own name: ghostbusting.

In an editorial last week calling for a zero tolerance policy, the editors of the medical journal PLoS Medicine, from the Public Library of Science, called for journals to identify and retract ghostwritten articles and banish their authors.

“Any papers where this breach is substantiated should be immediately retracted,” the editors wrote. “Authors found to have not declared such interest should be banned from any subsequent publication in the journal and their misconduct reported to their institutions.”

In the past, researchers have raised allegations of ghostwriting in articles about quality-of-life drugs like antidepressants, painkillers and diet pills. But the situation has become more serious this year after a few editors said they had discovered ghostwriting in manuscripts about life-and-death products like cancer and hematology drugs.

As Washington tries to revamp the health care system, concerns about ghostwriting are taking on new urgency. One of the underlying assumptions of the health care overhaul effort is that money can be saved and medical care improved by relying more heavily on research showing which drugs and procedures are the most effective. But experts fear that the process could be corrupted if research articles are skewed by the hidden influence of drug or medical device makers.

One senator on the trail of ghostwriting is Charles E. Grassley, a Republican of Iowa and a member of the Senate Finance Committee, which has taken a leading role in the health overhaul effort.

In July, Mr. Grassley wrote letters asking eight leading medical journals about their ghostwriting policies. He also asked whether, since 2004, the journals had taken action against any author who had failed to report the involvement of a third party in the development of a manuscript.

None of the editors reported taking action against an author for ghostwriting. Their replies to the senator, obtained by The New York Times, varied from assurances of editorial diligence to the equivalent of "don't ask, don't tell." One editor in chief, for example, wrote that because his journal prohibited ghostwriting, the publication did not have a specific policy on the practice.

Journals without explicit ghostwriting rules can expect to hear more from the senator.

"Objective research is really at the heart of public trust in medicine," Mr. Grassley wrote in an e-mail message to a reporter last Friday.

Allegations of ghostwriting first surfaced several years ago in the promotion of the diet drug combination fen-phen, which was taken off the market because of safety concerns in 1997, and the painkiller Vioxx, withdrawn in 2004. And last month, documents made public in litigation against the pharmaceutical giant Wyeth showed that the company had paid a medical writing firm to draft articles, published through 2005, favorable to its Premarin family of hormone drugs even as evidence mounted that certain hormone drugs could increase the risk of breast cancer.

Some researchers say industry ghostwriting is widespread and continuing. Even with disclosure policies already in effect at many publications, unnamed authors played a role in more than 40 articles published last year at six major medical journals, according to a study made public last week. That study, conducted by an editorial team at The Journal of the American Medical Association, or JAMA, defined ghostwriting broadly as any uncredited significant contribution to research or writing, regardless of whether it was financed by industry.

Over the last few years, international associations of medical journal editors have developed stricter disclosure criteria for authors of and contributors to scientific manuscripts. The International Committee of Medical Journal Editors, for example, defines an author as a person who makes a substantial contribution to developing a study or analyzing its results and in drafting a manuscript, and who approves the final version of an article. Authors should identify other contributors to an article and their financing sources, according to the group.

Drug companies say they are about to put these publication principles into effect for clinical trials.

"The pharmaceutical industry is moving in lock step with the editors of medical journals," Jeffrey K. Francer, assistant general counsel of the Pharmaceutical Research and Manufacturers of America, an industry trade group for drug makers, said in an interview last week. The new standards are to take effect in October, he said.

But even though disclosure policies are already in place at many journals, the new JAMA study found a ghostwriting rate of more than 7 percent at JAMA and PLoS Medicine, and nearly 11 percent at the New England Journal of Medicine. Joseph S. Wislar, who led the study, said in an interview last week that The New England Journal of Medicine may have had a higher rate because the journal did not require lead authors to list all other contributors.

Editors of The New England Journal of Medicine said that they were puzzled by and skeptical of the JAMA data, but confirmed that the publication left such disclosures to the discretion of authors.

Experts who study disclosure said authorship policies might be inadequate in part because they asked for incomplete information, but also because they typically had no teeth.

“Requiring someone to write a retraction or barring them from publishing in academic journals for some period of time — that would be an effective deterrent,” said George Loewenstein, a professor of economics and psychology at Carnegie Mellon University in Pittsburgh who has conducted research on the effect of conflict-of-interest disclosures in medicine.

A few editors said they were already taking tougher stances after discovering their disclosure policies had allowed authors to acknowledge writers financed by drug companies without explaining that the paid writers played primary roles in creating the manuscripts.

The problem of incomplete disclosure is particularly worrisome for opinion pieces like review articles, in which an author brings a personal perspective to a wide body of research, according to an editorial in *The Oncologist*.

“These articles are likely to influence the direction of new investigation as well as the practice of oncology,” wrote Dr. Bruce A. Chabner, the clinical director of the cancer center at Massachusetts General Hospital and the editor in chief of *The Oncologist*. “It is critical that such articles represent the unbiased views of the authors, and not those of a ghostwriter or a drug’s sponsor.”

The *Oncologist* plans to continue publishing clinical trials sponsored by drug companies, Dr. Chabner wrote. But the journal no longer accepts opinion pieces that involve writers with ties to companies that have a commercial interest in an article’s content — nor will its editors correspond with hired writers who are not named as the authors of manuscripts.

Mr. Francer, of the Pharmaceutical Research and Manufacturers of America, said such measures could be detrimental because they could “chill research and chill support for research.”

But the trend may be too far along to deter.

In January, editors at *Blood*, the journal of the American Society of Hematology, discovered that an unsolicited manuscript submitted by a prominent researcher involved significant contributions from a pharmaceutical company employee named in the acknowledgments — a major role in the manuscript that should have qualified the employee to be listed as an author of the paper. Further detective work quickly turned up two other ghostwritten

manuscripts.

Editors decided to make their discoveries public in an editorial titled "Ghostbusting" at Blood, in which they wrote that the journal would henceforth reject opinion pieces that had industry ties.

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.

But, said Dr. Dunbar, who is a hematologist at the National Institutes of Health in Bethesda, "I hope we don't have to do that."

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