Use of ghostwriters, guest authors appears frequent for studies involving rofecoxib

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An examination of medical articles about rofecoxib (a nonsteroidal anti-inflammatory drug) and court documents from litigation related to this product indicates that company employees or other unacknowledged authors were frequently involved in writing clinical trial articles and review articles, but that primary authorship was often attributed to academically affiliated investigators who may have had little to do with the study, or who did not always disclose financial support from the sponsor of the study, according to an article in the April 16 issue of JAMA.

Authorship in biomedical publication provides recognition while establishing accountability and responsibility. Guest authorship has been defined as the designation of an individual who does not meet authorship criteria, according to background information in the article. 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.

“Recent litigation related to rofecoxib provided a unique opportunity to examine guest authorship and ghostwriting, practices that have been suspected in biomedical publication but for which there is little documentation,” the authors write.

Joseph S. Ross, M.D., M.H.S., of Mount Sinai School of Medicine, New York, and colleagues conducted a case-study review of court documents, in combination with a review of the relevant medical literature, to

describe the practice of guest authorship and ghostwriting related to rofecoxib. The researchers used court documents, created predominantly between 1996 and 2004, originally obtained during litigation related to rofecoxib against Merck & Co. Inc. In addition, publicly available articles related to rofecoxib were identified via MEDLINE. Approximately 250 documents were relevant for the review.

When publishing their own clinical trials (designed, conducted, and sponsored by Merck), documents were found describing Merck scientists often working to prepare manuscripts and subsequently recruiting external, academically affiliated investigators to collaborate on the manuscript as guest authors. “Recruited authors were frequently placed in the first and second positions of the authorship list. For the publication of scientific review papers, documents were found describing Merck marketing employees developing plans for manuscripts, contracting with medical publishing companies to ghostwrite manuscripts, and recruiting external, academically affiliated investigators to be authors,” the researchers write. Documents indicated that medical publishing companies provided near complete drafts of review manuscripts to authors for editing, in addition to managing submissions and revisions.

Documents were also found describing Merck compensating investigators with honorarium for agreeing to serve as authors on review manuscripts ghostwritten on their behalf by medical publishing companies. “Among 96 relevant published articles, we found that 92 percent (22 of 24) of clinical trial articles published a disclosure of Merck’s financial support, but only 50 percent (36 of 72) of review articles published either a disclosure of Merck sponsorship or a disclosure of whether the author had received any financial compensation from the company.”

“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," the authors write. "We are hopeful that our findings encourage discussion of ways in which to improve the integrity of research. The medical profession and the pharmaceutical industry should agree that collaborations must be conducted with the highest standards. We suggest that academic researchers consistently provide to the journals the author contributions for all manuscripts, including original research, meta-analyses, reviews, and commentaries, and disclose relationships and support from all industry sources, regardless of the journal's requirements."

"Authors who 'sign-off' on or 'edit' original manuscripts or reviews written explicitly by pharmaceutical industry employees or by medical publishing companies should offer full authorship disclosure, such as, 'drafting of the manuscript was done by representatives from XYZ, Inc.; the authors were responsible for critical revisions of the manuscript for important intellectual content.' A coordinated oversight strategy involving academic physicians, journal editors, and industry representatives is necessary to discourage both guest authorship and ghostwriting and improve the integrity of the biomedical authorship system," the authors conclude.

Source: JAMA and Archives Journals