On Guest authors and Ghostwriters

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The legal disputes following the withdrawal from the market of two drugs for the treatment of pain (the COX-2 inhibitors rofecoxib and valdecoxib) have led to another critical examination of the paper publishing process. I have written in February about the drug company Pfizer trying to obtain confidential peer review documents from the journals JAMA and NEJM. Courts in Chicago and Boston have denied such requests.

An article and accompanying editorial in this week's JAMA look at guest authorship and ghostwriting in publications related to rofecoxib (better known as Vioxx, produced by Merck). Guest authorship was defined as an author that does not meet authorship criteria. The Uniform Requirements for Manuscripts to Biomedical Journals from the International Committee of Medical Journal Editors (ICMJE) define authorship as follows:

Authorship credit should be based on 1) substantial contributions to conception and design, or 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.

Ghostwriting was defined as the failure to designate an individual that made significant contributions to the research or writing of a manuscript.

The JAMA article did a systematic analysis of the court documents obtained during litigation related to rofecoxib. Guest authorship was identified in 16% of research articles and 26% of review articles; ghostwriting was identified in 13% of research articles and 10% of review articles. The editorial in the same issue is called Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence and dicusses this article as well an another article called Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment in the same issue. The editorial proposes that drastic action is necessary and includes a list of 11 measures.

Criteria for authorship and disclosure of financial interests are clearly defined not only by the ICMJE, but also by the World Association of Medical Editors (WAME) and by most journals. And the European Medical Writers Association

(EMWA) has published guidelines on the role of medical writers in peer-reviewed publications. As medical writers usually don't fulfill the authorship criteria defined above (with the possible exception of review articles), they should rather be acknowledged. The EMWA guidelines propose the following wording:

We thank Dr Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.

The rules are clear and it is also clear that there will be violations of these rules. Guest authorship and ghostwriting are probably common practices, not only in publications supported by drug companies. Typical examples would be the inclusion of the department head that did little more than to provide financial support or the exclusion of the technician that did critical experiments but is not acknowledged. Cases of suspected guest authorship or ghostwriting should be taken seriously and the papers in JAMA will ignite a renewed discussion on these topics.

For different views on this topic, look at Exit ghost by Juan Carlos Lopez over at Spoonful of Medicine and Cut it out. Cut it out now. by Derek Lowe at In the Pipeline.