

Merck accused of disguising its role in research

Drug company used ghost-writers for papers published on Vioxx trials.

Daniel Cressey

International drug giant Merck stands accused this week of manipulating research papers on one of its products published in medical journals.

Thousands of documents relating to Merck's withdrawn painkiller rofecoxib (Vioxx) were made available as part of a legal action. They were reviewed by medical researchers paid by the litigants in the trial, which ended in 2006, and seem to show Merck's extensive involvement in ghost-writing and 'guest authorship' of research and review papers. The results of the analysis are published this week in the *Journal of the American Medical Association (JAMA)*.

By omitting the names — or downgrading the involvement — of drug-industry writers, and adding the names of academics who were not substantially involved in a paper, the industry's role in research may be concealed. And doctors may be misled over the independence of the work.

"The idea of a company conducting a clinical trial, having its employees design the trial, analyse the data, write the paper, and then towards the very end recruit academic authors to put their name on the paper to give it that seal of supposed authenticity is very wrong," says Joseph Ross, a doctor at Mount Sinai School of Medicine, New York, and one of those behind the analysis (*J. S. Ross et al. JAMA* **299**, 1800–1812; 2008).

Ross and his colleagues closely scrutinized 250 documents released by Merck during the case relating to rofecoxib and say there are some strong suggestions of ghost-writing. For example, one of the Merck-held documents lists a number of clinical trials in which a Merck employee is to be author of the first draft of a manuscript. However, when these trials were published, in 16 of 20 of the articles an external academic is listed as first author.

Where Ross's team was able to identify manuscript drafts before and after leaving Merck, they found "scant documentary evidence" that authors subsequently named on studies were actually involved. A pattern of "inappropriately attributing authorship to academic authors and a failure to disclose relevant financial relations" emerges from the Merck documents, they say.

Another article based on documents from a separate court case reports "striking" disparities between mortality results for the drug in published papers and those contained in Merck's internal analyses (B. M. Psaty and R. A. Kronmal *JAMA* **299**, 1813–1817; 2008). Taken together, say two of *JAMA*'s editors, these papers show that Merck "apparently manipulated dozens of publications to promote one of its products".

Merck rejects the allegations of manipulation and misrepresentation and denies that the documents show any wrongdoing. Jim Fitzpatrick, a partner at Merck's external counsel Hughes Hubbard & Reed in New York, says, "These are allegations that were made by these particular authors who acted as experts for the plaintiffs in the Vioxx litigation, and during the course of that litigation Merck responded to all those allegations. Quite frankly, we think that a lot of the conclusions and statements in the articles are either outright incorrect or really misleading because they lack any context surrounding them."

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