Scientists May Have Put Their Names on Papers Written by Drug Companies

By LILA GUTERMAN

Academic scientists appear to have put their names on papers that are actually ghostwritten by for-profit companies and then published in medical journals, a new study indicates. Some of the scientists accused of doing so deny any wrongdoing, but journal editors are already outlining measures to prevent future breaches of academic integrity.

In the April 16 issue of The Journal of the American Medical Association, four scientists published the results of a search of court documents. The documents are about to the anti-inflammatory drug Vioxx, which has been withdrawn from the market and has been the subject of hundreds of lawsuits because of concerns about its safety.

The search revealed mentions of many articles that were published under academic researchers' names but appear to have been written by others. Those others worked for Merck & Company, which is the developer of Vioxx, or for medical-publishing companies.

In an editorial accompanying the article, Catherine D. DeAngelis and Phil B. Fontanarosa, editor in chief and executive deputy editor of JAMA, respectively, call researchers' guest authorship "unprofessional and demeaning to the medical profession and to scientific research."

The JAMA researchers, led by Joseph S. Ross, an instructor of geriatrics at Mount Sinai School of Medicine, searched a database of millions of documents provided by Merck for two Vioxx-product-liability cases. (All four of the JAMA researchers had been paid as consultants to the plaintiffs in the cases.)

The researchers examined 96 articles that had been discussed in internal Merck documents before they were published. They found that papers reporting the results of clinical trials or reviewing data from multiple studies sometimes appeared to have been written by employees of Merck or of publishing companies, and that academic names were added only later.

In one instance, an e-mail message from Scientific Therapeutics Information, a medical-publishing company, to Merck lists eight manuscripts the publisher was preparing, "intended" external authors, and the journals the manuscripts would be sent to. Dr. Ross and his colleagues identified seven published review papers that matched the list of eight, all with just one author listed. And, in each case, that author was from academe.

The Chronicle attempted to contact the seven authors. Two responded, and both denied lending their names to a ghostwritten article.

One of them, A. Mark Fendrick, a professor of internal medicine at the University of Michigan at Ann Arbor, said he had worked with the medical-publishing company to develop the outline but had done the writing himself.

The other, Noor M. Gajraj, a doctor at Sherman Pain Care, in Texas, who used to be on the faculty of the University of Texas Southwestern Medical Center, said in an e-mail message: "The article was written solely by myself, certainly without any help by a medical-publishing company."

Authorship and Participation

In another example, the JAMA authors compare the draft and published versions of a paper about a clinical trial. The draft lists only Merck authors along with "External author?" as first author. The published paper has three external authors: one from the University of California at San Diego, one from New York University, and one from a contract research organization.

But Steven H. Fries, one of the external authors of the paper and a professor of psychiatry at New York University, said the JAMA article was "totally wrong." The three external authors helped design, analyze, and run the trial, he said, as well as edit the manuscript. His role was to serve on a paid committee of three scientists who analyzed patient data from different doctors, to make sure the patients received proper diagnoses.

http://chronicle.com/weekly/v54/i33/33a01201.htm
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The researcher from San Diego, Leon J. Thal, who died last year, helped design the study, Mr. Ferris said, and the scientist from the research organization, Louis Kirby, ran one of the sites that enrolled patients.

The other two members of Mr. Ferris's committee were not named as authors, nor were the leaders of the other research sites. "You could argue the fine points of who gets selected and who doesn't," said Mr. Ferris. "The basic question is, Is there justification for these people's inclusion based on participation in a substantive way in the study itself and in the preparation of the manuscript? Both of those requirements were met here. This was not guest authorship."

Dr. Ross, however, called these explanations "hard to believe" in light of the documents he turned up. He added that he did not intend to impugn any single researcher or even Merck. "This is a widespread practice," he said. "These just happen to be people whose behavior we had witness to because of the litigation documents. The point is that physicians in the scientific community need to come together and agree this is wrong. This is not how science is conducted."

In their editorial about the two Vioxx-document studies, Dr. DeAngelis and Dr. Fontanarosa call for "drastic action." "Ensuring, maintaining, and strengthening the integrity of medical science," the two editors conclude, "must be a priority for everyone."