

**Impugning the Integrity of Medical Science  
The Adverse Effects of Industry Influence  
Editorial**

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**THESE AUTHORS NOTE:**

“The profession of medicine, in every aspect—clinical, education, and research—has been inundated with profound influence from the pharmaceutical and medical device industries. This has occurred because physicians have allowed it to happen, and it is time to stop.”

Two articles in this issue of JAMA provide a glimpse of drug company Merck’s “misrepresentation of research data and its manipulation of clinical research articles and clinical reviews; such information and articles influence the education and clinical practice of physicians and other health professionals.”

“The direct influence of for-profit companies on education and clinical practice has been well documented, so this Editorial deals primarily with clinical research.”

Merck apparently manipulated dozens of publications to promote its Cox-2 inhibitor pain drug Vioxx. The manipulation included study results, authors, editors, and reviewers, and it only became public because of litigation involving Vioxx.

Clinical trial articles and review articles related to Vioxx were frequently “written by unacknowledged authors who were employees of for-profit information industries, and often attributed first (or primary) authorship to academically affiliated investigators who either had little to do with the study or review or who did not disclose financial support from the company.”

It is clear that some of the authors played little direct roles in the study or review, yet still allowed themselves to be named as authors. “Individuals, particularly physicians, who allow themselves to be used in this way, especially for financial gain, manifest a behavior that is unprofessional and demeaning to the medical profession and to scientific research.”

Merck may have misrepresented the risk-benefit profile of Vioxx in clinical trials involving patients with Alzheimer disease or dementia by purposely minimizing evidence of significantly increased mortality risk among patients assigned to receive Vioxx. Eight of the 11 authors named in the published article were Merck employees.

“Journal editors also bear some of the responsibility for enabling companies to manipulate publications. Some editors may allow articles and supplements to be published without requiring complete disclosure of individual financial support, and without requiring clear and complete disclosure of industry support of and direct involvement with research articles or reviews.”

In another Merck study, there was “no disclosure that the manuscript had been written by Scientific Therapeutics Information Inc, a company specializing in the development of scientific literature, ie, writing papers for a price.”

It appears that professional “ghost writers” are the actual writer of medical journal articles rather than the listed principal investigator, who may have become involved in the project after it was already completed.

Additionally, disclosing relationships with for-profit companies and identifying who actually writes articles for publication does little to stop unethical relationships or relationships in which the [drug company] sponsor has inappropriate influence over the data or control over the manuscript.

Problems with drug company sponsored studies include data analysis misrepresentation and selective reporting.

“Another source that may contribute to the manipulation of research studies involves peer reviewers who have relationships with industry. Such reviewers may provide biased reviews that favor products of companies with which they have strong financial relationships, may fail to disclose their conflicts of interest to journal editors, or may even provide for-profit companies with confidential information obtained during the peer review process.”

“Manipulation of studies and misrepresentation of study results could not occur without the cooperation (active and tacit) of clinical researchers, other authors, journal editors, peer reviewers, and the FDA.”

“In addition to clinical research, clinical practice and medical education also are greatly influenced by for-profit companies. Drastic action is essential, and cooperation of everyone involved in medical research, medical editing, medical education, and clinical practice is required for meaningful change to occur.”

These authors demand that:

- 1) "Journal editors must seriously consider funding sources and authors' disclosed financial conflicts of interest and financial relationships when deciding whether to publish a study or review."
- 2) "For-profit [drug] companies that sponsor biomedical research studies should not be solely or primarily involved in collecting and monitoring of data, in conducting the data analysis, and in preparing the manuscript reporting study results."
- 3) "All journals must require a statistical analysis of clinical trial data conducted by a statistician who is not an employee of a for-profit [drug] company."
- 4) "Professional organizations and providers of continuing medical education courses should not condone or tolerate for-profit companies having any input into the content of educational materials or providing funding or sponsorship for medical education programs."
- 5) "Individual physicians must be free of financial influences of pharmaceutical and medical device companies including serving on speaker's bureaus or accepting gifts."