Does Extensive Financial Support Create Author Bias? 
The Juvéderm Injectable Gel Study

TO THE EDITOR:
It was with great interest that I read the Juvéderm injectable gel study by Pinsky et al1 published in the January/February 2008 issue of Aesthetic Surgery Journal. As a plastic surgeon who desires to offer safe and effective injectable filling agents to my patients, the article appeared timely and pertinent. However, as I was reading the article, the proprietary wording of the discussion section and the extensive financial link of the authors to Allergan became quite clear. The study was also funded by Allergan.

It certainly makes sense from a business perspective for Allergan to financially support this research. There is multibillion dollar competition in the worldwide filler market, and each company desires supporting documentation published in peer-reviewed journals to use in marketing. Marketing to physicians is easier when favorable results are published in peer-reviewed journals like Aesthetic Surgery Journal.

In this paper, financial disclosures were provided. The lead author, a plastic surgeon member of our societies, is a stock holder of Allergan. The second and third authors are employees of Allergan. The fourth author both holds Allergan stock and is a former employee of the company. The study was financially supported by Allergan. There is not one author on this paper that does not have a financial link to Allergan or a financial disclosure to make. Is it possible that all these authors were completely unbiased at interpreting the data? Isn’t there a conflict of interest here? Were the authors compensated for conducting the study? Did Allergan play a role in designing and controlling the results of this study?

Recently, the influence of pharmaceutical companies and ethical conflicts created with their extensive financial support of product research has been discussed in both prominent national media and the medical literature. A Wall Street Journal article published on April 16, 2008, revealed the publishing ethics practices of Merck & Co. During litigation stemming from the recall of Vioxx, internal documents from Merck suggested that the pharmaceutical company was extensively funding Vioxx clinical studies for publication and was intimately involved in designing, controlling, and reporting research studies. Evidence even suggested that many papers published on Vioxx were ghostwritten by Merck, and that academic physicians or well respected clinicians may have been brought in as principal authors. The article emphasized that the research was controlled primarily by Merck, rather than the listed academically affiliated lead author.

In an editorial published in the JAMA, editors associated with review of the Merck-sponsored articles suggested that the funding of clinical research—and the control that pharmaceutical companies play in study design, analysis, and selection of authors—undermines the value of scientific clinical research. They also indicated that “medical journals, academic scientists, and pharmaceutical companies all bear part of the blame for practices which undermine the integrity of medical research.” They suggested that “all parties shore up standards and increase vigilance to end such conduct.”

Because the value of a scientific paper is largely based on the objectivity of the authors and the strict adherence to the scientific method, it is hard to believe that the multiple financial links between the sponsoring company and the authors have not affected this study. It would have been a better service to the readership if authors had published an objective, unbiased study conducted by investigators, not all of whom were financially linked to Allergan.

The tone of the discussion section supports authorship bias and read in some parts like advertising copy. The authors claim the superiority of Juvéderm longevity compared to published studies for Restylane and Perlane. The comparative studies quoted by the authors were conducted by different investigators, in different countries, with differences in study protocol. It is not accurate to claim increased longevity of the Juvéderm products until investigators who are not employees or financially linked to Allergan conduct a comparative study between Juvéderm and Restylane/Perlane in the same subjects. Were the 3 Allergan employees associated with this study involved in writing the Discussion section of this paper?

We as plastic surgeons are exposed to the marketing of pharmaceutical companies, especially in the realm of dermal fillers. This is a multibillion dollar business with a
great deal of money at stake. It appears that pharmaceutical companies marketing dermal fillers, including Allergan and Medicis, sponsor research to publish in our society journals. This is a form of marketing to physicians. Each company wishes to make claims of superiority of their competitor. We must be astute in reading the articles, and not give too much value to results published by authors who have extensive financial links to the sponsoring pharmaceutical company and who may not be objective.

With the topic of pharmaceutical company manipulation of clinical research so timely, this problem may benefit from more consideration at the journal editorial level. Personally, I do not believe that just providing author financial disclosures is enough. Peer review to question the meaning of disclosures and verify that a broad enough authorship and unbiased research is published may be useful. Although many journals maintain financial disclosure confidentiality in the review process to reduce influencing editorial decisions, this policy may allow articles with financially linked authorship bias to escape editorial review. The reader is to question the value of disclosures. If a published article has extensive financial disclosures and conflicts which may be noted by readers, as does the Juvéderm study, the marketing value of publication will still be significant to the pharmaceutical company. Some readers of the journal may only read the abstract or skim the article and not notice or appreciate the undermining influence of the disclosures. Furthermore, physicians outside our specialty who are marketed with the results of the study likely do not have access to the financial disclosures.

As busy clinicians, plastic surgeons often find it difficult to keep up with the reading from our many sources, and will appreciate any assistance that journal peer review can provide in eliminating articles with ethical conflicts based on financial disclosures.

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DISCLOSURES

The author has no disclosures with respect to the manufacturers of products mentioned in this article.

REFERENCES


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1090-820X/534.00
doi:10.1016/j.asj.2008.08.001