



Industry involvement in preparation of articles

(MARCH 2005)

TO THE EDITOR: For a number of years, I have looked to the *Cleveland Clinic Journal of Medicine* as a useful source of peer-reviewed articles describing advances in internal medicine.

However, the recent editorial decision to prohibit publication of articles authored by private-sector researchers¹ seems so ill-founded that I now doubt the future scientific value of this journal.

The editorial states that the new authorship policy is driven by two concerns: an increase in the volume of manuscripts having industry involvement, and more importantly, a determination to keep the *Journal* as free from bias as possible.

It is a truism that the body of medical knowledge is growing exponentially, and the resulting volume of scientific literature poses a challenge for physicians (as well as editors) to efficiently navigate. As Moses et al² have recently observed, the complexity of the modern scientific enterprise has created an increasing interdependency between academic medical centers, which have historically led basic and clinical research, and the private sector. For evidence, one need look no further than the outskirts of many medical school campuses, which are often dotted with private-sector research facilities where private-sector and academic scientists collaborate. While some basic scientists look to these for access to technologies and other support unavailable within their institutions, many of their clinical colleagues work directly with commercial sponsors by participating in clinical research. By definition, this research necessarily involves interventions or diagnostic assessments that clinical investigators consider sufficiently beneficial to their patients to merit investigation.

Since breakthrough interventions are evaluated in this manner, it is not surprising that these activities routinely attract leading clinical investigators. In some therapeutic areas, academic-industry relationships are the rule rather than the exception. Several years ago, editors at the *New England Journal of Medicine* lamented that they were almost unable to find an expert academic psychiatrist without industry links who could review a clinical trial involving antidepressants.³ Both academia and the private sector bring expertise to scientific research. Removal of private-sector researchers from publication endeavors

not only creates the false impression that medical research is exclusively the domain of academia, but also deprives your readership of contributions from those with particular scientific expertise in cutting-edge clinical research.

Striving for freedom from bias is fundamental to any scientific journal's integrity, but restricting authorship is an overly simplistic approach inadequate to meet that goal. As a researcher who has been employed by the private sector for several years, I routinely declare my affiliation in my publications (but make an extraordinary exception here). The relationship is transparent. Academically based authors are held to a different standard. Currently, most journals require academic authors only to indicate whether they have consulted, received research grants, or hold equity in companies having potential commercial interests related to their article. This approach assumes that authors are compliant and, to the extent that such relationships influence academic authors, that there is no particular bias towards any particular commercial interest. There is no differentiation between authors who have served as occasional consultants from those who rely on such relationships for their professional and personal livelihood. Hence, the reader is left with uncertainty about the potential biases of the academic co-authors. While it may seem paradoxical, categorically removing industry co-authors from *Journal* reviews will provide your readership with even less of a context with which to gauge potential conflicts of interest.

My belief is that a twofold solution is needed. The *Journal* should revert to reviewing articles based on scientific merit rather than authorship affiliation. If the *Journal* is committed to reducing bias, it would do well to impose greater disclosure and transparency on prospective authors. The path forward is neither easy nor without controversy. A particularly provocative approach has been proposed by Joseph Alpert, MD,⁴ who recently suggested that authors stipulate the monetary value of their individual private-sector relationships. Such a strategy would then leave it to readers to assess the potential bias of the authors.

For the present, the new editorial course not only limits the value of the *Journal* as a source of contemporary scientific news, but provides your readers with the comforting but mistaken belief that published articles will be free from bias.

NAME WITHHELD BY AUTHOR'S REQUEST



■ REFERENCES

1. Mandell BF. New CCJM policy: no manufacturer involvement in the preparation of articles (From the Editor). *Cleve Clin J Med* 2005; 72:169.
2. Moses H, Thier SO, Matheson DHM. Why have academic medical centers survived? *JAMA* 2005; 293:1495–1500.
3. Angell M. Is academic medicine for sale? *N Engl J Med* 2000; 342:1516–1518.
4. Alpert JS. Doctors and the drug industry: how can we handle potential conflicts of interest? *Am J Med* 2005; 118:99–100.

IN REPLY: We have received many notes and e-mails about our new policy on authorship. Most have been supportive, but we believe it is important for our readers to have access to a thoughtful counter viewpoint, and my response.

As I stated in my editorial,¹ we realize we may lose some papers with this policy and perhaps be less timely in publishing information on new therapies. However, particularly because the papers we publish are review articles, we feel that the independence and transparency of our authors' relationship are of paramount importance to our readers. In original research papers, the data speak for themselves, and hopefully, the authors exercise their interpretive bias only in the discussion section. In review articles, in contrast, the entire article reflects the authors' interpretive opinion. Thus, it is especially important that reviews of new therapies not be perceived as marketing. Our readers have infrequently, but appropriately, questioned some authors' objectivity in the past.

I am not implying that there are nefarious motives in every paper from a private-sector researcher or drafted by a medical education company. We and others² have noted an increase in submissions produced by medical education companies at the behest of pharmaceutical companies, with an academician's name appended as author. It is often difficult to determine, even with diligent peer review, how responsible that academician has been for nuance of content. Although some such papers may be of excellent quality, and the coauthors diligent in vetting the paper for any bias, readers will always be justifiably concerned about the independence of these papers.

At the least, we believe authors must clearly state their total independence in what they write—which we pragmatically translate into a policy that the submitted manuscript not be ghostwritten or ghost-edited by a nonindependent party.

The author of this letter says our policy will deprive readers of “cutting-edge clinical research.” But cutting-edge papers remain mostly the purview of research

journals. We will continue to publish clinically relevant reviews focused on the application of new drugs and other innovations, with responsible objectivity of the authors as they express their own opinions (and biases) as to the utility of innovative therapies.

As to the call for more complete and transparent disclosure from all authors, new continuing medical education guidelines emphasize that an actual financial amount of relationship is not as relevant as disclosure of any relationship: \$2,000/year of speaking fees may have different impact on different authors. We will thus continue to pursue an understanding of any and all relationships that the authors have with relevant private-sector enterprises, including medical education companies.

To some readers, our policy does not go far enough. I agree with our correspondent that we should not exclude an academic author with any tie to the private sector. But we must do our best to exclude authors who are under pressures to express information in a certain way, or worse, have the information expressed in a way that implies a subliminal message that they did not intend. From my former experience in the private sector (acting director of clinical research at a pharmaceutical company), I fully appreciate the wealth of basic pharmacologic and clinical research knowledge contained within the private sector. I also appreciate the pressures brought to bear directly on industry investigators, and the more subtle pressure on industry-supported “opinion leaders.”

We at the *Journal* will continue to strive to reduce and disclose potential for bias in all of our papers and to increase transparency of authorship and author relationships. We will not be able to do this perfectly. We will continue to review submissions, as the correspondent suggests, primarily for scientific (and clinical) merit. This will continue to include peer reviews from investigators who have participated in “competing” studies when appropriate.

I appreciate all of the thoughtful communications sent to me on this topic.

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Editor-in-Chief

■ REFERENCES

1. Mandell BF. New CCJM policy: no manufacturer involvement in the preparation of articles (From the Editor). *Cleve Clin J Med* 2005; 72:169.
2. Fugh-Berman A. The corporate coauthor [Perspective]. *J Gen Intern Med* 2005; 20:e-pub.