

What conflict of interest?

“If in doubt, disclose” — Committee on Publication Ethics¹

Under full glare of the media spotlight in February this year, the editor of *The Lancet*, Richard Horton, partially retracted an article published 6 years before.^{2,3} This act was triggered by allegations of research misconduct in the study, taken to *The Lancet* by a *Sunday Times* journalist.⁴ The *Lancet*'s investigations⁵ and the events that ensued involved the article's authors (doctors at London's Royal Free and University College Medical School), the institution's ethics committee, the General Medical Council, the British Parliament, and even the Prime Minister, Tony Blair.

Why the fuss? In 1998, this research report implied a link between autism, bowel disease and the combined measles–mumps–rubella (MMR) vaccine.³ A storm of controversy erupted, and MMR vaccination rates in England fell from 92% of children reaching the age of two in 1996/97 to 82% in 2002/03.⁶ Confirmed cases of measles rose from 112 in 1996 to 442 in 2003. When the allegations of misconduct were probed this year, it was found that, at the time the article was submitted and published, its lead author and senior investigator, Dr Andrew Wakefield, had not disclosed that he had been commissioned by the Legal Aid Board (for the sum of £55,000) to determine if there was evidence to support legal action by parents of children allegedly harmed by the MMR vaccine. Some of these children were also in Wakefield's *Lancet* study. This led to a partial retraction of the article by 10 of its original 13 authors, but not by Wakefield.⁷ Richard Horton remarked, “If we had known the conflict of interest Dr Wakefield had in this work I think that would have strongly affected the peer reviewers about [its] credibility. . . in my judgement, it would have been rejected”.²

The Medical Journal of Australia has not had such sensational experiences (yet!). Conflict of interest in publication was first raised in a position statement by the International Committee of Medical Journal Editors, published in 1993.⁸ Our first conflict of interest statement appeared in the late 1990s, but declaring conflict of interest was deemed by many then to be optional — an exercise in political correctness.

So, except in extreme situations, does conflict of interest really matter? Unfortunately it does. It is a principle long enshrined in the conduct of scientific research.⁹ Moreover, we can no longer ignore the growing body of evidence that conflict of interest can bias research outcomes. Systematic reviews have shown that results of sponsored studies are more likely to favour the sponsor when it is a pharmaceutical company,¹⁰ and industry-sponsored studies are not only associated with pro-industry conclusions, but with restrictions on publication and data sharing.¹¹ As more research is funded by non-academic sources, we cannot ignore the potential for bias to affect its outcomes.¹² Neither can we ignore an increasingly educated, involved 21st-century Western society that is calling for greater accountability in health research.

MJA disclosure statement for authors and reviewers

(A) Authors are asked to indicate Yes or No to questions about affiliations with manufacturers of products mentioned in the article or of competing products:

- Ownership of stock or stock options or other financial instruments of companies whose products are mentioned in the article or who manufacture competing products (does not include mutual fund ownership)
- Ongoing paid consultancy with company or a competitor (actual or within the last 2 years)
- Employment with company or competitor (actual or within the last 2 years)
- Honorarium or other compensation for writing the article or for participating in the development of the article
- Honorarium or other compensation for conducting research related to material contained in the article
- Speaker fees and/or educational grants
- Travel assistance to attend meetings.

(B) Authors are asked to provide details where the answer to any of the above questions is “yes”.

(C) Authors are asked to declare any other (non-financial) competing interests.

What conflict of interest is not

- Conflict of interest is not always present, and may be potential rather than actual. Such dual interests are better termed “competing” rather than “conflicting” interests (eg, commitment to a patient’s welfare and to a research project).
- Having a conflict of interest is, in itself, not wrong, and may be unavoidable. Disclosing competing interests should not be seen as an admission of wrongdoing, but as promoting transparency in the public record.

What conflict of interest is

- “Financial or personal relationships that inappropriately influence (bias) . . . actions [of an author (or the author’s institution), reviewer, or editor] . . . The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment”.¹³
- Anything, be it personal, financial, academic, religious, or political, “which, when revealed later, would make a reasonable reader feel misled or deceived”.¹

Current MJA policy

Authors

- All authors are required to provide a disclosure statement (Box).
- Funding sources are to be acknowledged, together with any role they played in study design, data collection, data analysis, interpretation of the data, their reporting and publication.
- A study may not be published if its sponsor asserts the right to control publication.¹³
- We publish competing interests statements for all research, viewpoint and review articles, and, where such interests are declared to exist, for editorials and letters to the Editor.

Reviewers

Peer review is a useful but imperfect tool that we can refine by seeking to clarify potential biases:

- We do not ask those from the same institution(s) as the author(s) to review an article.
- We now ask all reviewers to provide a disclosure statement similar to the one authors provide (Box).
- Reviewers who disclose competing interests are not necessarily disqualified. Their reviews will be carefully considered by the editors, bearing their potential biases in mind, and in conjunction with comments from other reviewers.

Editors

- Editors commission articles, assess submitted articles, and ultimately decide their fate. Thus, MJA editors with competing

interests relating to an article will exclude themselves from taking primary responsibility for it.

Conclusion

Our aim is not to exclude anyone with a potential conflict of interest from publishing or reviewing — to do so would disqualify virtually everyone (including editors). Conflicts of interest may occasionally be too extreme to allow publication of the article or involvement of someone in the decision-making process. However, our ultimate goal in advocating disclosure is to promote transparency, reduce bias, and maintain public trust in what we publish. Let the reader to be the judge!

Mabel Chew

Deputy Editor

The Medical Journal of Australia, Sydney, NSW
 medjaust@ampco.com.au

- 1 Committee on Publication Ethics. Guidelines on good publication practice. Available at: www.publicationethics.org.uk/cope2003/pdf2003/2003pdf15.pdf (accessed Jun 2004).
- 2 BBC News. Journal regrets running MMR study. 20 February, 2004. Available at: news.bbc.co.uk/1/hi/health/3508167.stm (accessed Jun 2004).
- 3 Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 1998; 351: 637-641.
- 4 Deer B. Revealed: MMR research scandal. *The Sunday Times (London)* 2004 22 Feb. Available at: www.timesonline.co.uk/article/0<10009-1012410,00.html (accessed Jun 2004).
- 5 Horton R. A statement by the editors of The Lancet. *Lancet* 2004; 363: 820-821.
- 6 Health Protection Agency. Epidemiological data — measles. Available at: www.hpa.org.uk/infections/topics_az/measles/data.htm (accessed Jun 2004).
- 7 Murch SH, Anthony A, Casson DH, et al. Retraction of an interpretation. *Lancet* 2004; 363: 750.
- 8 The International Committee of Medical Journal Editors. Position statement: conflict of interest. *Med J Aust* 1993; 159: 57.
- 9 Institute of Medicine, National Academy of Sciences. The Responsible Conduct of Research in the Health Sciences. Washington: Institute Of Medicine, 1989. Available at: <http://books.nap.edu/books/0309062373/html/index.html> (accessed Jun 2004).
- 10 Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 2003; 326: 1167-1170.
- 11 Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA* 2003; 289: 454-465.
- 12 Davidoff F, DeAngelis CD, Drazen JM, et al. Sponsorship, authorship, and accountability. *N Engl J Med* 2001; 345: 825-826.
- 13 International Committee of Medical Journal Editors. Uniform Requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Updated November 2003. Available at: www.icmje.org/index.html (accessed Jun 2004). □