Reviewer’s report

Title: Modified versus standard intention-to-treat reporting: Are there differences in methodological quality, sponsorship, and findings in randomized controlled trials? A cross-sectional study.

Version: 1 Date: 20 November 2010

Reviewer: Joel Lexchin

Reviewer’s report:

Thank you for the opportunity to read this manuscript. The authors have explored a new avenue of potential bias in the reporting of clinical trials. The manuscript is organized, well written and easy to follow. Overall, I don’t have any major concerns with it but there are some areas where I feel that improvements can be made.

Minor Essential Revisions

Background:
Perhaps this is not necessary for readers of this particular journal but the authors may want to briefly state why trials should be reporting using an ITT analysis.

Page 6 (Funding source):
The authors should provide more details, e.g., did they categorize the provision of drugs, equipment, etc. as industry funding?

Page 11 (Analysis of findings):
Was there any association between no ITT reporting and favourable results?

Page 13 (First two lines):
It should be noted that the rating used to assess methodological quality may not capture some elements that lead to bias, e.g., not reporting primary prespecified outcomes.

Page 13, Second paragraph:
The last two lines in this paragraph don’t read properly.

Page 14, Third paragraph:
I think that the authors mean “for-profit”, not “not-for-profit”.

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

In 2007 I was a consultant to a legal firm representing Apotex Inc with regard to the effect of promotion on sales. In 2007-2008 I was a consultant to the Canadian federal government in its defence against a law suit challenging the ban on direct-to-consumer advertising of prescription drugs.

In 2010 I was a consultant to a legal firm representing a plaintiff in a law suit against Allergan.