Reviewer's report

Title: Sponsor's influence on conduct and reporting of industry trials: a comparison of protocols and published papers

Version: 1 Date: 28 February 2012

Reviewer: Joel Lexchin

Reviewer's report:

This paper adds another element in examining the influence of sponsorship on clinical trials, in this case by looking at whether sponsorship leads to influence on the conduct and reporting of clinical trials. While the findings from the authors are limited to what happens at Lancet, if there are problems at a high-impact journal then in all likelihood the problems are even more severe at other journals without the resources and prestige of Lancet. Therefore, despite the authors noting that their results are not necessarily generalizable I view the results of this present study as very important.

The methodology of the study is well described and appropriate for the issue that the authors chose to investigate and the writing is for the most part clear and easy to follow although there are some instances where the wording could be clearer. Most of my comments are of a relatively minor nature.

Major Compulsory Revisions

Page 6, second paragraph:

Why were these 7 trials published in Lancet if Lancet didn’t have the full protocols. My understanding is that Lancet does not publish trials in the absence of having the protocols.

Page 8, first paragraph:

I’m not sure what the authors mean by “disagreements” - who disagreed or where were the disagreements found?

Page 10, Discussion:

If Lancet had the protocols then what are the implications for the editorial process at Lancet that the contents of the publications differed from what was in the protocols?

Page 12, last paragraph:

Fewer industry sponsored trials being published could have negative financial implications for journals due to lower sales of reprints. The authors should discuss this point.
Page 13, last paragraph:
Not only should journals require these elements but they should be put on a publicly available web site.

Minor Essential Revisions

Page 6, first paragraph:
When the authors say that two protocols were similar to other included trials is one implication that these were instances of duplicate publication?

Page 6, last paragraph:
When the authors say “In 35 trials (51%), it was not described how the clinical data were processed” do they mean that the trials didn’t describe who did the processing?

Page 7, third paragraph:
When the authors say “in 2 (3%) via membership in the Data and Safety Monitoring Board” do they mean that in 2 trials the sponsor had access via the DSMB?

Page 9, second paragraph:
What statements are the authors referring to when they say “overriding statements”?

Page 10, second line:
Delete “about” at the start of this line.

Tables 1 and 2:
The heading for these tables should say whether the data comes from the protocols or the publications.

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:
I have been working with one of the authors on a Cochrane review. I declare that I have no other competing interests.