Reviewer's report

Title: A cross-sectional analysis of HIV & hepatitis C clinical trials 2007-2010: The relationship between industry sponsorship and randomized study design

Version: 1 Date: 7 September 2013

Reviewer: Joel Lexchin

Reviewer's report:

Major Compulsory Revisions

This is another in a series of studies that looks at whether industry involvement in clinical trials produces bias results. As the authors note most previous research has looked at published trials whereas this one utilizes a clinical trial registry and removes the influence of publication. The use of the registry is both one of the strengths and weaknesses of this study. The authors are interested in whether there is a difference in randomization but because they are only looking at the registry they cannot tell how randomization was described and it is possible that there was a systematic difference between how industry sponsored studies defined randomization compared to non-industry sponsored studies. The authors also used the sponsorship field to determine industry involvement but that also means that other relationships between the trial and industry were not examined, e.g., the presence of authors who either worked for industry or authors who had other types of relationships with industry. Both of these issues need to be addressed by the authors.

Minor Essential Revisions

Presumably the authors focused on the question of randomization because the use of a RTC design would be more likely to yield less biased results but the authors should state that explicitly.

Lines 116-118:

Even journals that support the ICMJE policy are willing to publish non-registered trials - see JAMA 2009;302:977-84.

Lines 269-271:

The authors should refer to the recent Cochrane review by Lundh et al that looked at the results and outcomes of studies funded by industry compared to those with other sources of funding. The conclusion was that the industry bias associated with favorable results and conclusions may be mediated by factors other than traditional measures of the risk of bias (e.g. lack of concealment of allocation, blinding and drop-out) and sample size.

Level of interest: An article whose findings are important to those with closely
related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.