

Lessons from the controversy over statins

Virginia Barbour states in her letter that, with respect to the submission to the Committee on Publication Ethics (COPE) in October, 2014, by a group of senior doctors and scientists, she had “recused myself because of a potential conflict of interest”. However, that is not strictly accurate; Barbour only recused herself in September, 2015, 8 months after she had adjudicated on the submission in January, 2015.

In that adjudication, Barbour had not addressed any of the specific concerns that had been raised about failures of editorial integrity at the British Medical Journal (BMJ), and had not reviewed any of the supporting material that was provided as links within the submission, so she was asked in February, 2015, to address these issues specifically.

Barbour was then also responsible for sharing the submission with the BMJ several months before recusing herself. In June, 2015, a response from the BMJ was addressed in a second substantive submission from the group of senior doctors and scientists, which reiterated their concerns and again asked that COPE address each of them specifically.

It was only in September, 2015, that Barbour stated that she was recusing herself because she had a potential conflict of interest. The nature of that competing interest was not made clear (and it is not disclosed in her letter), but what is clear is that Barbour did not recuse herself before having determined the outcome of COPE’s review. Indeed, conclusions from Barbour’s report are being used as the basis for asserting that COPE has conducted a properly independent review of the issues raised.¹

After Barbour did recuse herself, it took until April, 2016, before COPE eventually stated that it felt the BMJ

had taken steps to correct its mistakes. However, COPE still did not address any of the specific concerns raised about failures of editorial integrity at the BMJ or the adverse effect on public health of the misleading claims that the BMJ had published about side-effect rates with statins.

COPE was again asked to address these points specifically. However, it refused to do so and also refused to allow the matter to be considered by its Ombudsman, writing in July, 2016, that it regarded "this matter as closed as there is nothing further that we can usefully bring to this debate." Therefore, it is difficult to understand Barbour's other assertion that Richard Horton was incorrect in stating that COPE declined to act further.

In parallel with Barbour, the Editor of the BMJ has suggested in a letter² that Horton's Offline Comment was incorrect because he had not had access to the material submitted to COPE (including by the BMJ) and its responses. However, that is not correct: a detailed description of this sequence of events, along with links to the submissions to COPE and its responses, was made available at the Cholesterol Treatment Trialists' Collaboration website³ in June, 2016, and other related material was also provided to *The Lancet*.

Our *Lancet* Review⁴ provides a detailed explanation of the reasons why the available evidence from the randomised controlled trials provides a more reliable basis for assessing the safety and efficacy of statin therapy than does observational evidence from case reports or health-care databases. Its intention is to help ensure that doctors and their patients are properly informed about the safety and efficacy of statin therapy (and not, as stated by the BMJ's editor,⁵ to shut down debate).

As Barbour's letter demonstrates, Horton's proposal for a tribunal that could address such matters of public

health importance independently of the journals does need to be explored further. However, in the meantime, the failure of the BMJ to deal properly with the seriously misleading claims about the effects of statin therapy that it published, and then the failure of COPE to deal properly with editorial failures at the BMJ, is continuing to have an adverse impact on public health worldwide.

Along with several other scientists and doctors, we were cosignatories to the submission to COPE and coauthors of the recent *Lancet* Review of the safety and efficacy of statin therapy. The CTSU has received grant funding from the pharmaceutical industry for independent research; our approach to maintaining the independence of that research is described at https://www.ctsuo.ox.ac.uk/research/ctsuo-independent-research_27june14.pdf and to maintaining our own independence by not taking honoraria or consultancy payments from industry is described at https://www.ctsuo.ox.ac.uk/about/ctsuo_honoraria_25june14-1.pdf.

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- 1 Husten L. The Lancet versus BMJ: a dispatch from the statin wars. New York: MedPage Today. Sept 15, 2016. <http://www.medpagetoday.com/Cardiology/CardioBrief/60251> (accessed Oct 11, 2016).
- 2 Godlee F. Rapid response re COPE complaint. London: BMJ. Sept 14, 2016. <http://www.bmj.com/content/351/bmj.h3908/rr-8> (accessed Oct 3, 2016).
- 3 Renewed call to retract BMJ articles that mislead on statin effects. <https://www.cttcollaboration.org/news/renewed-call-to-retract-bmj-articles-that-mislead-on-statin-effects> (accessed Oct 3, 2016).
- 4 Collins R, Reith C, Emberson J, et al. Interpretation of the evidence for the efficacy and safety of statin therapy. *Lancet* 2016; published online Sept 8. [http://dx.doi.org/10.1016/S0140-6736\(16\)31357-5](http://dx.doi.org/10.1016/S0140-6736(16)31357-5).
- 5 Godlee F. Statins: we need an independent review. London: BMJ. Sept 15, 2016. <http://www.bmj.com/content/354/bmj.i4992> (accessed Oct 11, 2016).