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Dr Virginia Barbour
Chair of Council
Committee on Publication Ethics

Dear Dr Barbour

In light of your advice as Chair of the Committee on Publication Ethics (COPE), we are writing to draw your attention to our concerns about editorial actions at the British Medical Journal related to its handling of problems with the BMJ's 22 October 2013 papers by [Abramson](#)¹ et al and by [Malhotra](#)².

The BMJ's Editor (Dr Godlee) is running a "[Too Much Medicine](#)" campaign³ and has [indicated](#)⁴ that those papers are likely to have been published in the BMJ due to that campaign. However, debates as to what constitutes "over-medication" (and, indeed, what constitutes under-medication) should be conducted on the basis of objective and impartial presentation of the scientific evidence.

Both papers under-stated the beneficial effects of statins and greatly over-stated their side-effects (with one particularly glaring error already having to be withdrawn). It has been shown in [large-scale randomised-controlled trials](#)⁵ that effective use of statin therapy reduces the rates of vascular deaths, heart attacks, ischaemic strokes and revascularisation procedures (typically preventing about 60-120 such events per 1000 patients with vascular disease treated for 5 years), with rates of [side-effects](#)⁶ that are comparatively low (about 5-10 adverse events per 1000 during 5 years of treatment).

We are concerned that misrepresentations in the BMJ of the evidence on the safety and efficacy of statins have led to people stopping their statin therapy or not starting it. For example, in the recent [British Cardiovascular Society survey](#)⁷ of its members, 60% of the respondents reported that they had patients with clear indications for statin therapy who had stopped it due to the confusion caused by recent publications and related media coverage. Among patients who are at elevated risk of heart attacks and strokes in particular, this could be resulting in many heart attacks, strokes and vascular deaths that could have been avoided by the use of statin therapy.

Consequently, given the public health implications, we are seeking advice from COPE as to whether the BMJ's handling of this matter, as described below (with embedded links to supporting materials), has been consistent with COPE's Code of Conduct and Best Practice Guidelines for Journal Editors.

Publishing incorrect side-effect claims despite being advised they were misleading

In a section of their paper entitled “Myopathy”, [Abramson et al](#)⁸ misleadingly compared the 5-year excess with statin therapy of 0.5 per 1000 for [myopathy](#)⁹ (i.e. a severe muscle problem with a specific definition) in the randomised placebo-controlled trials with the excess of 53 per 1000 for muscle pain in the [NHANES observational study](#)¹⁰ (which did not assess myopathy but was instead based on reports of musculoskeletal pains of any severity and, crucially, had no “blinded” comparator group), and stated that the *“increase in muscle pain is 100 times greater than that reported in clinical trials”*.

In commenting on that claim prior to publication, [one peer reviewer \(Smeeth\)](#) stated¹¹: *“The results presented for myopathy are misleading [our emphasis]. NHANES focused on ascertaining symptoms from people exposed to statins. Muscle pain is incredibly common in the general population and is thus incredibly common among people both treated and not treated with statin. In the randomised Heart Protection Study, almost one third of people in both arms (i.e. including the placebo arm) complained of muscle pain and the effect estimate was 0.99 (95% CI 0.95 to 1.03).”*

Despite this clear warning, [a BMJ editor is recorded as saying](#)¹² in an editorial meeting: *“Smeeth’s review hints they may have overstated harms. Still it probably doesn’t matter too much [emphasis added]. If they have got it wrong people can say so in the RRs [Rapid Responses]”*. However, when [Cochrane Collaboration statin trial reviewers](#)¹³, and others, pointed out this error in Rapid Response letters, [the BMJ allowed Abramson et al to repeat their misleading claim](#)¹⁴ instead of correcting it.

It is of concern that an editor at the BMJ would suggest that it does not matter to publish misleading information, and raises questions about standards for which the Editor is responsible (in accordance with articles 1.1 and 8.1 in COPE’s code of conduct). Moreover, the BMJ has still not corrected this error (which is entirely distinct from the partially corrected error in both the Abramson et al and Malhotra papers that related to a paper by Zhang et al: see below).

We would invite your views as to whether this contravenes COPE’s Code of Conduct, including articles 1.1, 1.6, 1.8, 8.1 and 12 (*“Ensuring the integrity of the academic record: 12.1 Errors, inaccurate or misleading statements must be corrected promptly and with due prominence”*.)

Publishing a misleading “correction” of other incorrect side-effect claims

The papers by Abramson et al and by Malhotra both misrepresented the report of an observational study by [Zhang et al](#)¹⁵ by claiming that it showed that side-effects were caused by statins in 18-20% of patients who took them. However, the evidence in the Zhang paper does not support these alleged rates of side-effects, and Zhang and his co-authors did not conclude that it did so.

After a considerable delay, the Editor accepted that this had been an error, but she then drafted and published a “correction” on 15 May 2014 that was itself not correct.

In her [accompanying editorial](#)¹⁶, the Editor states *“The text of the correction, which includes a further interpretation of Zhang and colleagues data, has been peer reviewed”*. However, a peer reviewer (Smeeth) made it clear in [his advice \(provided on 9 May\)](#)¹⁷ that he did not agree with the proposed correction: *“undertaken a new misleading calculation to come up with a figure of 9%... interpreting this as being the people who had side effects caused by statins is plainly wrong [emphasis added].”*

The Editor did not accept the peer reviewer's advice, [saying](#)¹⁸: "... I sent the text of the correction to Zhang et al, and they have come back saying they are happy with the interpretation placed on their data in the correction, so I propose to leave the 9% figure as it stands". [The published correction states](#)¹⁹: "The correct interpretation of the data, as confirmed to The BMJ by Zhang et al [emphasis added], is as follows... 9% of the study population having possibly discontinued statin therapy as a consequence of statin related events rather than the 18% cited".

However, following publication of the correction and the Editor's accompanying editorial, [Zhang et al submitted a Rapid Response letter](#)²⁰ to the BMJ that was published on 28 May. That letter forcefully reiterates that "The goal of our study was never to establish the rate of adverse reactions caused by statins, which would be impossible using the tools we employed". In [subsequent correspondence](#)²¹, the senior author of the Zhang et al paper has written "when we read the BMJ correction as it was published [our emphasis], we wrote a letter in an attempt to further clarify any misconceptions".

We would invite your views as to whether the manner in which this process of peer review was conducted, and the manner in which the subsequent checking with the authors of the paper was conducted, contravenes COPE's Code of Conduct (including articles 1.6, 7.1, 8.1 and 17.1).

Publication of inaccurate editorial and media statements accompanying the published "correction"

In the same editorial (15 May 2014), the [BMJ's Editor stated](#)²² that "Abramson and colleagues' article was submitted and peer reviewed...The initial submission reported that Zhang and colleagues found that '18% of statin treated patients had discontinued therapy because of statin related events'. This was a misreading of Zhang and colleagues' data that was not picked up by the peer reviewers...". (This claim was repeated in the [BMJ's press release](#)²³ and on the [BBC Radio 4 Today programme](#).)²⁴

However, this account is inaccurate (and, indeed, the BMJ's editorial team had advised the Editor prior to publication that the peer reviewers had not seen the text containing this error: see below).

The Editor refers explicitly to the initial submission in her editorial when she asserts that the peer reviewers missed the misrepresentation of the Zhang paper. However, it is clear from the [materials posted on the BMJ's website](#)²⁵ that the paper by Zhang et al was not referred to in the [original draft](#)²⁶ of the paper by Abramson et al that had been peer reviewed (and so, of course, the peer reviewers could not have picked up the misrepresentation of the paper, which was added at a later stage).

This error is a matter of considerable concern, especially since the Editor had been asked specifically in letters that were sent to her on [31 March, 14 April and 25 April](#)²⁷ 2014 to check the peer reviewers' comments with regard to the misrepresentation of Zhang et al's paper in particular.

Furthermore, the Editor was informed by [the BMJ's analysis editor](#)²⁸ non 8 May (i.e. a week before the editorial was published) that the reviewers had not seen the revised draft of the paper by Abramson et al that referenced the Zhang paper: "the incorrect fact...seems to have been inserted at the final stage of editing... This has two implications, firstly that the peer reviewers did not scrutinise the 18% fact in particular and they may well have picked this out as erroneous... not re-reviewed externally".

This failure to provide an accurate account was then compounded by the delay in correcting the statement after one of the peer reviewers contacted the Editor about it, immediately following its publication, on 16 May 2014²⁹. A correction was only put on the BMJ website on 27 May³⁰, when most of the people who were going to read the editorial (including the media) had already done so and, consequently, would not have been made aware that it was inaccurate. [Note: The editorial was accessed over 24,000 times during May³¹, whereas the correction only 1600 times³² by the end of June.]

We would invite your views as to whether this conduct contravenes COPE's Code of Conduct, including article 8.1 ("*should take all reasonable steps to ensure the quality of the material they publish*") and article 12.1 ("*errors, inaccurate or misleading statements must be corrected promptly and with due prominence*").

Inappropriate use of Abramson to review the accompanying paper by Malhotra

The papers by Abramson et al and by Malhotra published on 22 October 2013 both misrepresented the paper by Zhang et al in the same way by mistakenly saying that it showed that side-effects were caused by statins in 18-20% of patients who took them. It eventually emerged that Malhotra's paper had been reviewed by Abramson himself, which would seem to be quite irregular.

The reviewers' comments for both papers had been sought repeatedly in letters sent during March and April 2014³³, but whereas the peer reviewers' comments for the paper by Abramson et al were made available on the BMJ's website when corrections for both papers were published on 15 May 2014, the peer reviewers' comments for the Malhotra paper were not.

The Editor was subsequently reminded on 21 May³⁴ that peer reviewers' comments for Malhotra's paper had not been made available, and her panel's Chair was reminded again on 30 May³⁵, but they were still not released. It was only when a further request was made on 3 July³⁶ that the reviewers' comments for the Malhotra paper were made available on 7 July, after a 3 month delay. The Editor stated that they had not previously been made publicly available due to a "*technical problem*"³⁷.

This explanation is somewhat surprising given the number of times that the Editor had been asked for these reviewers' comments and reminded that they had not been made available. However, it is understandable that there might well have been reluctance at the BMJ to make it publicly known that the only reviewer of this parallel paper to the one by Abramson et al was Abramson himself.

We would invite your views as to whether this conduct contravenes COPE's Code of Conduct, including article 7.1 which requires that Editors "*strive to ensure that peer review at their journal is fair, unbiased and timely*", as well as the Best Practice recommendation for Editors of "*ensuring that appropriate reviewers are selected for submissions (i.e. individuals who are able to judge the work and are free from disqualifying competing interests)*".

Questionable independence of the BMJ's review of published errors

In her editorial of 15 May 2014, the BMJ's Editor stated³⁸ that she would set up an "*independent panel ... whose members will include people with no 'dog in this fight'...*" to decide whether to retract the papers by Abramson et al and by Malhotra. Instead, however, not only did the Editor determine the terms of reference, but she also personally chose³⁹ all of the panel members.

In our view, these [terms of reference](#)⁴⁰ were unduly limited in their scope. Although the panel's report is written carefully, its conclusions as to what constitutes harmful misinformation are not easy to accept. The panel [stresses](#)⁴¹ that the two papers are "*Analysis and Observation pieces*" intended to "*provide a commentary*". However, since articles of this type are typically aimed at a wide range of practitioners and may well be taken up by the media, it is reasonable to expect that particular care would be taken to avoid publication of misleading or incorrect analysis. We would question whether the panel has been rigorous enough in dealing with the issues, including [its decision](#)⁴² not to consider the adverse impact of misleading claims on patient safety.

By any normal standards of judgment, none of the [review panel members](#)⁴³ could be considered to be independent of the BMJ. For example, the chair and the 6 other panel members are either current or past members of BMJ committees (e.g. Editorial Advisory Board, Hanging Committee, Primary Care Advisory Panel, Ethics Committee), and the panel secretary was previously the BMJ's Deputy Editor and had dealt with the paper by Abramson et al when it was originally submitted.

Nor were the members independent of the issue. At least 6 have published papers about statin side-effects: these included an undeclared [paper](#)⁴⁴ by the chair claiming statins cause cancer in the elderly and a [paper](#)⁴⁵ by another member claiming that statins cause an excess risk of cataract about as large as the reductions in vascular events (both published in the BMJ and both [refuted by the randomised trial evidence](#)⁴⁶), and another undeclared [paper](#)⁴⁷ by a panel member that made similar claims about the efficacy of statins to those made in the Abramson paper (as did the [paper](#)⁴⁸ by the panel's chair).

Moreover, at least one panel member (Furberg) had been paid for [litigation work related to statin therapy](#)^{49 50} which has not yet been declared, and he had also published an [undeclared paper](#)⁵¹ in the BMJ in September 2013 about clinical practice guidelines for statins and other treatments which involved [Abramson](#)⁵² as a collaborator (see below for an additional conflict of interest related to that paper).

This information was not fully disclosed by the BMJ in its widely publicised statements, including in the description of the panel members on its website. When the panel's report was published some more, but not all, of these potential conflicts of interest were declared. We would invite your views as to whether this conduct contravenes COPE's Code of Conduct (including articles 17. 1 and 17.2).

BMJ links to public statements in support of its own position

By virtue of its position, the BMJ is able to exert considerable influence over the manner and context in which events are presented. It has a clear responsibility to its readers and members of the public at large to present matters of significant public health concern in a balanced and objective manner.

The "Timeline of events" on the BMJ's website highlights a [letter](#)⁵³ signed by about 500 people, which called on the BMJ and its panel not to retract these articles, as supportive of the BMJ's approach. What is not made clear, however, is that a journalist (Jeanne Lenzer) who is [paid to work for the BMJ](#)⁵⁴ was involved in coordinating that letter and that [she had attempted to have it published](#)⁵⁵ in another medical journal without making her BMJ links known.

Nor has it been made clear that that journalist was a co-author of the [September 2013 BMJ paper](#)⁵⁶ (see above) about the development of guidelines for statin therapy (and other treatments), in which

Abramson himself is listed as a [collaborator](#)⁵⁷, with a member (Furberg) of the BMJ's review panel that was considering whether to retract the paper by Abramson et al.

We would invite your views as to whether this conduct contravenes COPE's Code of Conduct (including articles 17.1 and 17.2).

Inaccurate statements about materials posted with the review panel report

Both the review panel's report and the Editor's accompanying editorial state unequivocally that the BMJ has put all of the materials submitted to the panel on its website alongside the panel's report (as had been [stated](#)⁵⁸ would be done at the beginning of the process). In particular, the Editor [wrote](#)⁵⁹: "*As part of our commitment to transparency, all documents submitted to and produced by the panel are published online (thebmj.com/statins)*" [emphasis added].

Unfortunately, that statement is inaccurate.

Malhotra and others sent a letter on 19 June 2014 to NICE and the Secretary of State for Health (and the media) in which they made a number of claims about the safety of statins. It is clear that the BMJ considers that letter to be relevant since it refers to it in its "[Timeline of events](#)"⁶⁰ on the review panel section of its website. However, a detailed [submission to the review panel](#)⁶¹ describing serious errors in that letter, and their relevance to the panel's review, has not been put on the BMJ's website.

This omission has been drawn to the attention of the BMJ's Editor and the chair of her panel. They have, however, [refused](#)⁶² both to have the submission put with the report and to provide any reasons for not doing so, despite it having been [pointed out](#)⁶³ that this action is entirely inconsistent with their explicit statements that all of the submitted materials have been put on the website with the report.

Moreover, by drawing attention to the letter to NICE by Malhotra and his colleagues, the BMJ is propagating the misinformation that it contains despite the serious errors in it having been drawn to the attention of the Editor. [Note: The Lancet has now published a [peer-reviewed letter](#)⁶⁴, along with [supporting materials](#)⁶⁵, describing the extent of these errors and their significance for public health.]

In addition, the BMJ redacted other material that had been submitted to it, in what it put alongside the panel report, for what it asserts are [legal reasons](#)⁶⁶. In one particular case, the BMJ has redacted the following statement from the [letter submitted](#)⁶⁷ by Professor Eugene Braunwald, Distinguished Hersey Professor of Medicine at Harvard Medical School:

"I am deeply disturbed by these two papers, particularly the paper by Abramson et al. I believe very strongly in the "free speech rights" in the First Amendment of the Constitution of the United States and I do not support censorship of any kind, especially in science which often advances as a result of controversy. However, it is well understood that this amendment does not give anyone the right to falsely shout "Fire" in a crowded room."

The argument that redaction of this statement was made on legal grounds is untenable.

We would invite your views as to whether this conduct contravenes COPE's Code of Conduct (including articles 14.1, 15.1 and 17.1).

Request for COPE to investigate failures to comply with its Editorial Code of Conduct

This letter addresses issues of public health significance. We have set out our concerns about the manner in which the BMJ has dealt with this matter, both during the review process and following publication. We would now invite COPE's views on whether its Code of Conduct for Journal Editors has been contravened and, if so, what steps will be taken to rectify the situation.

Yours sincerely,



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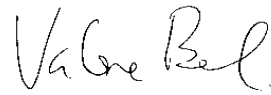
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Professor Robert Souhami, CBE FMedSci
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cc Baroness Ilora Finlay, President of the British Medical Association

Disclosure of interest: Some (but not all) of us have previously drawn attention to errors in the BMJ papers by Abramson et al and by Malhotra and the letter sent to NICE by Malhotra and colleagues, have been involved in the Cholesterol Treatment Trialists collaborative meta-analyses that were criticised in those articles and the letter, have received research grants from pharmaceutical companies that make statins, hold patents related to statins (e.g. genetic tests; poly-pill), and/or have received honoraria from pharmaceutical companies for giving advice or presentations.

Supporting materials attached

1. Abramson et al. Should people at low risk of cardiovascular disease take a statin? *BMJ* 22 October 2013
2. Malhotra. Saturated fat is not the major issue. *BMJ* 22 October 2013
3. Too much medicine campaign. *BMJ online* October 2014
4. Godlee. Re: recent articles on statins safety and efficacy. *Email correspondence* October 2013
5. Cholesterol Treatment Trialists' (CTT) Collaborators. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. *Lancet* 2012
6. Armitage. The safety of statins in clinical practice. *Lancet* 2007
7. BCS Statins and the media survey results. *British Cardiovascular Society* 2014
8. Abramson et al. Should people at low risk of cardiovascular disease take a statin? *BMJ* 22 October 2013
9. Armitage. The safety of statins in clinical practice. *Lancet* 2007
10. Buettner et al. Prevalence of Musculoskeletal Pain and Statin Use. *Journal of General Internal Medicine* 2008
11. Smeeth. Peer review comments on Abramson et al. *BMJ*
12. BMJ editor comment. *BMJ editorial meeting* August 2013
13. Huffman et al. Re: Should people at low risk of cardiovascular disease take a statin? *BMJ Rapid Response* October 2013
14. Abramson et al. Authors' reply to Huffman and colleagues. *BMJ letter* 26 February 2014
15. Zhang et al. Discontinuation of statins in routine care settings. *Annals of Internal Medicine* 2013
16. Godlee. Adverse effects of statins. *BMJ editorial* 15 May 2014
17. Smeeth. Peer reviewer response. *BMJ Statins Timeline* 31 May 2014
18. Godlee. Response to Liam Smeeth. *BMJ Statins Timeline* 31 May 2014
19. Abramson et al. Should people at low risk of cardiovascular disease take a statin? *BMJ correction* 15 May 2014
20. Zhang et al. Re: Adverse effects of statins. *BMJ Rapid response* 28 May 2014
21. Turchin. Re: Request for advice regarding BMJ misrepresentations of your paper on statin-related adverse effects. *Email correspondence* 16 September 2014
22. Godlee. Adverse effects of statins. *BMJ editorial* 15 May 2014

23. BMJ authors withdraw statements about adverse effects of statins. *BMJ press release 15 May 2014*
24. Collins, Godlee. *Transcript of the Today programme 15 May 2014*
25. Data supplement. Should people at low risk of cardiovascular disease take a statin? *BMJ 2013*
26. Abramson et al. Should people at low risk of cardiovascular disease take a statin? *BMJ original draft June 2013*
27. Collins. Letters to Godlee. *31 March, 14 April and 25 April 2014*
28. Macdonald. Decision on Abramson et al manuscript *email correspondence 9 Aug 2013*
29. Smeeth. Re: BMJ and statins *email correspondence to Rory Collins 16 May 2014*
30. Adverse effects of statins. *BMJ correction 27 May 2014*
31. Article usage metrics. *BMJ editorial 15 May 2014*
32. Article usage metrics. *BMJ correction 27 May 2014*
33. Collins. Letters to Godlee. *31 March, 14 April and 25 April 2014*
34. Collins to Godlee. Re: papers for the panel considering the retraction of papers misrepresenting the evidence of statin side effects. *Email correspondence 21 May 2014*
35. Collins to Heath. Re: papers for the panel considering the retraction of papers misrepresenting the evidence of statin side effects. *Email correspondence 30 May 2014*
36. Collins to Chalmers, Armitage, McPherson and Godlee. Re: Statins. *Email correspondence 3 July 2014*
37. Godlee to Chalmers, Collins, Armitage, McPherson. Re: Statins. *Email correspondence 7 July 2014*
38. Godlee. Adverse effects of statins. *BMJ editorial 15 May 2014*
39. Brendel. Online comment response regarding how the independent statins review panel was chosen. *BMJ Blog 2014*
40. Independent statins review panel terms of reference. *BMJ May 2014*
41. Report of the independent panel considering the retraction of two BMJ papers. *BMJ July 2014*
42. Report of the independent panel considering the retraction of two BMJ papers. *BMJ July 2014*
43. Independent statins review panel terms of reference. *BMJ May 2014*
44. Mangin, Sweeney and Heath. Preventative health care in elderly people needs rethinking. *BMJ 11 August 2007*

45. Hippisley-Cox. Unintended effects of statins in men and women in England and Wales: population based cohort study using the QResearch database. *BMJ* 2010
46. (1) CTT Collaboration. Lack of effect of lowering LDL cholesterol on cancer: Meta-analysis of individual data from 175,000 people in 27 randomised trials of statin therapy. *PLoS One* January 2012; (2) Kostis and Dobrzynski. Prevention of cataracts by statins: A Meta-analysis. 4 December 2013
47. Furberg. Is lower and lower better and better? A re-evaluation of the evidence from the Cholesterol Treatments Trialists' Collaboration meta-analysis for low-density lipoprotein lowering. *Journal of Clinical Lipidology* 2012
48. Mangin, Sweeney and Heath. Preventative health care in elderly people needs rethinking. *BMJ* 11 August 2007
49. Furberg. Quarterwatch team and funding sources. *ISMP Quarter Watch website*
50. Potential for conflict of interest in the evaluation of suspected adverse drug reactions, use of Cerivastatin and risk of Rhabdomyolysis. *JAMA* December 2004
51. Furberg et al. Ensuring the integrity of clinical practice guidelines: a tool for protecting patients. *BMJ* 17 September 2013
52. Furberg et al. Ensuring the integrity of clinical practice guidelines: a tool for protecting patients. *BMJ* 17 September 2013
53. Timeline of events. Articles and letters published supportive of BMJ approach. *BMJ online*
54. Lenzer. Online profile. *BMJ online*
55. Lenzer. Re: open letter in support of the BMJ. *Email correspondence* 2014
56. Lenzer. Ensuring the integrity of clinical practice guidelines: a tool for protecting patients. *BMJ* 17 September 2013
57. Abramson. Ensuring the integrity of clinical practice guidelines: a tool for protecting patients. *External guideline reviewer BMJ* 2013
58. Independent Statins review panel terms of reference. *BMJ* May 2014
59. Godlee. Statins and the BMJ. *BMJ* 7 August 2014
60. Timeline of events. An open letter to NICE about draft guidance on Statins is published. *BMJ* 11 June 2014
61. Armitage, Baigent and Collins. Letter to the Chair and Panel Members considering retraction of papers by Abramson et al and by Malhotra. 7 July 2014
62. Smith. Re: Letter to BMJ Panel. *Email correspondence* 12 August 2014
63. Collins. Re: Decision not to include materials submitted to the BMJ's panel with its report. *Email correspondence* 12 August 2014

64. Peer reviews of Lancet letter
65. Supporting information. Annotated version by Thompson and colleagues, and links on the CTSU (Oxford University) webpage
66. Submissions to the BMJ's panel. *BMJ*
67. Braunwald. Letter to the panel showing redactions made by BMJ



10 June 2015

Dr Virginia Barbour
Chair of Council
Committee on Publication Ethics

Dear Dr Barbour

Comments on the BMJ's response to COPE's investigation of potential breaches of its Code of Conduct by the BMJ

In light of your advice as Chair of the Committee on Publication Ethics (COPE), we wrote on 23 October 2014 to ask you to consider whether the BMJ's Editor had breached COPE's Code of Conduct for Journal Editors in her handling of problems with the BMJ's 22 October 2013 papers by Abramson et al and by Malhotra. As summarised below, the BMJ has not provided adequate responses to COPE with regard to the set of specific concerns that are described in our October 2014 letter (and supported by detailed background material).

Our letter raised issues of considerable public health significance. The safety of patients and the public depends on the ability to consider the value of particular treatments based on objective and impartial representations of the evidence. Instead, the BMJ has published claims about the effects of statins that they were advised in advance were incorrect (and still has not corrected them), has made statements about its processes for review that are contradicted by its own documents, and was selective about the information that it made public.

There is good evidence that people at high risk of heart attacks and strokes have stopped their statin therapy in the period after the BMJ's misrepresentations. The confusion caused by the Editor's failure to deal promptly and properly with this issue appears to have exacerbated this problem. The published results of extensive peer-reviewed research indicate that this reduction in the number of high-risk patients taking statin therapy will have resulted in many having heart attacks, strokes and vascular deaths that could have been avoided.

Given the potentially diversionary nature of the BMJ's response, we summarise below each of the specific examples of inappropriate editorial behaviour that we raised, the relevant part of the BMJ's response, and our conclusions as to breaches of COPE's Code of Conduct. The BMJ is widely read and influences patient care, so it is in the public interest that COPE does now make a clear statement about the BMJ's failure to act properly in the interests of public health.

1. Publishing incorrect side-effect claims despite being advised they were misleading

Issue raised: A peer reviewer of the paper by Abramson et al advised that "*The results presented for myopathy are misleading*", but a BMJ editor stated in an editorial meeting that "*it probably doesn't matter too much*" to publish those results even if they are wrong.

BMJ response: The BMJ justifies this course of action by claiming that the peer reviewers and the paper's authors disagreed, and by maintaining that the definition of myopathy is debatable (having taken advice on this point from the paper's authors alone). The BMJ now acknowledges that its processes should be improved.

Our comment: It is a serious concern that the BMJ still does not consider it to be necessary to 'fact-check' data relating to important public health issues before their publication. Moreover, despite the Cochrane Collaboration statin reviewers and other experts having pointed out this error in writing to the BMJ, the Editor has still not corrected it and, indeed, continues to dispute it is an error.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

2. Publishing a misleading "correction" of other incorrect side-effect claims

Issue raised: The BMJ published papers that misrepresented a study by Zhang et al, claiming incorrectly that it showed that statins cause side-effects in 18-20% of patients. After a 6 month delay, the Editor did accept that this was an error, but then published a 'correction' that the peer reviewer had advised the Editor was "*plain wrong*" in quoting a figure of 9% for statin adverse effects.

BMJ response: The Editor states that she amended the correction to address some of the peer reviewer's comment and decided to proceed with expeditious publication, rather than to seek further peer review, because she states that the authors of the original study (i.e. Zhang et al) had agreed with her correction.

Our comment: The Editor failed to address the peer reviewer's chief concerns. Moreover, the senior author of the Zhang paper has confirmed that "*the BMJ correction as it was published*" was misleading. In matters of such public health significance (particularly when correcting errors), it is surely appropriate for journal editors to make serious efforts to ensure accuracy (e.g. by seeking additional external advice).

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

3. Publication of inaccurate editorial and media statements accompanying the published "correction"

Issue raised: The Editor stated incorrectly in her 15 May editorial that the peer reviewers had missed the misrepresentation of Zhang et al's paper in the paper by Abramson et al. However, one week beforehand, the BMJ's Analysis editor had written specifically to advise the Editor that the peer reviewers had never been given an opportunity to review the draft of the paper by Abramson et al that referred to Zhang et al's report.

BMJ response: The Editor states that she did not appreciate this point in time to amend the editorial before publication, nor when she issued an accompanying press release, and nor when she repeated this incorrect statement on the BBC Radio 4 Today programme on the following day. She asserts that the correction was posted "*as soon as it was clear that it needed to be*".

Our comment: The Editor's response does not address the point that she had also been asked to check the reviewers' comments specifically relating to the misrepresentation of Zhang et al's paper on at least 3 separate occasions in the months before her editorial was published. Nor

does it explain why she failed to take account of such specific advice from the Analysis editor. Since the Editor was contacted about the error by a reviewer on the day after publication, it is unclear why she did not feel that a correction was 'needed' until 11 days later, and why, when it was eventually published, it was not given the due prominence necessary to ensure that the medical profession and public were not misled.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

4. Inappropriate use of Abramson to review the accompanying paper by Malhotra

Issue raised: Despite being asked repeatedly in writing during March, April and May 2014 to provide the reviewers comments for the accompanying paper by Malhotra (which repeated the misrepresentation of the Zhang et al paper), the Editor did not do so. Only when asked yet again to do so in July, did she make them available (i.e. after more than 3 months). It then became apparent that the only reviewer of Malhotra's paper was Abramson himself.

BMJ response: The BMJ now accepts that the use of Abramson as a reviewer was "not ideal" and that such an approach should be avoided in future. The explanation given for the delay in making the reviewer's comments available was that it was not easy for the BMJ to extract the comments from a pdf and to display the pdf and comments separately on its website.

Our comment: It is remarkable that the BMJ lacks the technical capacity to put a pdf on its website more quickly than it did. However, if that truly is the case, then the decision not to provide the reviewers' comments more rapidly in an alternative format raises concerns. In any case, it is clear that the peer review process was not unbiased.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

5. Questionable independence of the BMJ's review of published errors

Issue raised: The Editor has repeatedly described as "independent" the panel that she selected to consider retraction of the papers by Abramson et al and Malhotra, and stated that it would include people with "no dog in the fight". However, as described in detail in our submission (with supporting materials), this is clearly not correct. The Chair and members of the panel were not only not independent of the BMJ, but they were also not independent of the issue under review (i.e. the safety of statins).

BMJ response: The Editor's response characterises the issue of independence as relating only to whether the panel was independent of the BMJ, and rejects accusations of bias in the selection of panel members.

Our comment: The Editor's response appears disingenuous. All of the panel members had close links to the BMJ and its Editor and/or had published concerns about statin safety, so its decision could have been predicted by the Editor with some certainty. This represents a clear example of 'panel-stacking', which the BMJ has correctly criticised in the context of panels writing guidelines for drug treatment.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

6. BMJ links to public statements in support of its own position

Issue raised: The “Timeline of events” on the review panel section of the BMJ’s website highlights a letter that is presented as an independent call for the BMJ and its panel not to retract the articles. However, it was not independent of the BMJ. Instead it was coordinated by a journalist (Jeanne Lenzer) listed on the BMJ website as a paid contributor and who was also a co-author of a 2013 BMJ paper about statin therapy in collaboration with Curt Furberg (i.e. one of the panel members), and with Abramson (i.e. the author of one of the papers under review by the panel) acting as a contributor.

BMJ response: The BMJ stated that it was unaware of Lenzer’s involvement with this letter, and does not consider Furberg’s association with Lenzer and Abramson on a paper about statin guidelines to be a relevant conflict of interest.

Our comment: Again, the BMJ’s response appears disingenuous. These undeclared links between Furberg, Abramson and Lenzer, and with the BMJ, represent serious conflicts of interest. It is clear that the Editor’s assertions about the independence of this review process and her panel are misleading.

The BMJ would appear to have breached COPE’s Code of Conduct in this regard.

7. Inaccurate statements about materials posted with the review panel report

Issue raised: The Editor stated “As part of our commitment to transparency, all documents submitted to and produced by the panel are published” on the BMJ website alongside the panel report. This was an incorrect statement. Instead, a detailed submission relating to misleading information about statins in a letter sent to NICE by Malhotra (who is the author of one of the papers reviewed by the panel) was deliberately excluded. Requests for this submission to be included on the website were refused by the BMJ’s Editor. In addition, other submitted material had text redacted for “legal reasons”.

BMJ response: The BMJ response states that the submission was not posted on its website because the review panel did not consider it to be relevant to its deliberations. It asserted that it was merely following legal advice when it redacted other material.

Our comment: The fact remains that the excluded material was submitted to the panel, so it should either have been posted along with the other submitted material or the BMJ should have corrected its statement (which it refused to do). The Editor’s response that the excluded submission was not relevant to the panel’s review is contradicted by the BMJ itself, which refers explicitly to the letter to NICE from Malhotra in its “Timeline of events”.

With regard to the redaction of the following statement in the submission to the panel by Professor Eugene Braunwald of Harvard Medical School:

“I am deeply disturbed by these two papers, particularly the paper by Abramson et al. I believe very strongly in the “free speech rights” in the First Amendment of the Constitution of the United States and I do not support censorship of any kind, especially in science which often advances as a result of controversy. However, it is well understood that this amendment does not give anyone the right to falsely shout “Fire” in a crowded room.”

it may be uncomfortable reading for the BMJ's Editor, but the argument that its redaction is warranted on legal grounds is untenable.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

Conclusion: We would ask COPE now to decide whether the BMJ has contravened its Code of Conduct for Journal Editors and, if so, to act appropriately to rectify the situation – particularly in light of the adverse impact on public health of the confusion about statin safety caused by the BMJ's misrepresentation of the evidence and other failures of editorial integrity at the BMJ.

The BMJ has stated that it intends to publish its response and related material before COPE has completed its assessment. This would not appear to be consistent with COPE's processes.

Instead, our understanding is that it is COPE's role to consider the original complaint, the BMJ's response and any further information before making a judgement about breaches of its Code of Conduct. Equally, it is COPE's role (not the BMJ's) to make its conclusion public along with any material that is relevant to the complaint.

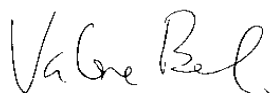
Yours sincerely



Professor Jane Armitage, FRCP FFPH
Professor of Clinical Trials and Epidemiology
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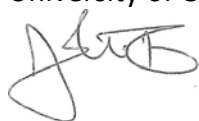
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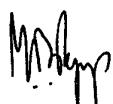
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Baroness Ilora Finlay, President of the British Medical Association