

Documents relating to a complaint about *The BMJ* made to COPE by Jane Armitage, Rory Collins et al, October 2014 - April 2016

Introduction

In October 2014, a letter of complaint was sent to the Committee on Publication Ethics (COPE) about *The BMJ*'s handling of two papers that were critical of plans to extend the use of statins to people at low risk of cardiovascular disease.[1] [2]

The complaint took 18 months to resolve, with COPE concluding in April 2016 that *The BMJ* had acted appropriately.

It was always our aim to ensure that the complaint and associated documentation would be made public, whatever the outcome.[3] We initially asked COPE to publish the documents but have now understood that this is not their policy. Prompted by misreporting of the outcome of the complaint in the *Lancet* [4] we made available the documents below, in chronological order. (Note that we did not initially have permission to include the documents numbered 1 and 8 in this series, so a [previous version of this document](#) published in September 2016 contained summaries only.)

References

1. Abramson JD, Rosenberg HG, Jewell N, Wright JM. Should people at low risk of cardiovascular disease take a statin? *BMJ* 2013;347:f6123.
2. Malhotra A. Saturated fat is not the major issue. *BMJ* 2013;347:f6340.
3. Parish E, Bloom T, Godlee F. Statins for people at low risk. *BMJ* 2015;351:h3908.
4. Horton R. Offline: Lessons from the controversy over statins. *Lancet* 2016;388 (No 10049):1040, 10 September 2016.

[Updated 29 November 2016]

1. Letter of complaint from Armitage et al, October 2014

A letter dated 23 October 2014 asked COPE to consider whether the Editor in Chief of *The BMJ* had breached its code of conduct for editors of medical journals. The letter sought to draw COPE's attention to editorial actions at *The BMJ* relating to its handling of two articles published in 2013:

23 October 2014

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](#) et al and by [Malhotra](#).

The BMJ's Editor (Dr Godlee) is running a "[Too Much Medicine](#)" campaign and has [indicated](#) 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](#) 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](#) 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](#) 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](#) misleadingly compared the 5-year excess with statin therapy of 0.5 per 1000 for [myopathy](#) (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](#) (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 \(Smeeth\)](#) stated: “*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](#) 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](#), and others, pointed out this error in Rapid Response letters, [the BMJ allowed Abramson et al to repeat their misleading claim](#) 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](#) 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](#), 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 \(provided on 9 May\)](#) 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](#): *“ 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](#): *“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](#) 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](#), 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](#) 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](#) and on the [BBC Radio 4 Today programme](#).)

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](#) that the paper by Zhang et al was not referred to in the [original draft](#) 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](#) 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](#) on 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 2014](#). A correction was only put on the BMJ website on [27 May](#), 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 May](#), whereas the correction only [1600 times](#) 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 2014](#), 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 May](#) that peer reviewers' comments for Malhotra's paper had not been made available, and her panel's Chair was reminded again on [30 May](#), but they were still not released. It was only when [a further request was made on 3 July](#) 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”*.

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 stated](#) 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 chose](#) all of the panel members.

In our view, these [terms of reference](#) 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](#) 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](#) not to consider the adverse impact of misleading claims on patient safety.

By any normal standards of judgment, none of the [review panel members](#) 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](#) by the chair claiming statins cause cancer in the elderly and a [paper](#) 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](#)), and another undeclared [paper](#) by a panel member that made similar claims about the efficacy of statins to those made in the Abramson paper (as did the [paper](#) by the panel's chair).

Moreover, at least one panel member (Furberg) had been paid for [litigation work related to statin therapy](#) which has not yet been declared, and he had also published an [undeclared paper](#) in the BMJ in September 2013 about clinical practice guidelines for statins and other treatments which involved [Abramson](#) 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](#) 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](#) was involved in coordinating that letter and that [she had attempted to have it published](#) 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](#) (see above) about the development of guidelines for statin therapy (and other treatments), in which Abramson himself is listed as a [collaborator](#), 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](#) would be done at the beginning of the process). In particular, the Editor [wrote](#): "[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](#)" on the review panel section of its website. However, a detailed [submission to the review panel](#) 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](#) both to have the submission put with the report and to provide any reasons for not doing so, despite it having been [pointed out](#) 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](#), along with [supporting materials](#), 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](#). In one particular case, the BMJ has redacted the following statement from the [letter submitted](#) 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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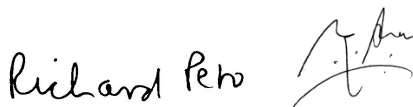
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cc Baroness Ilora Finlay, President of the British Medical Association

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.

2. COPE report on complaint on BMJ Statin papers, dated 12 January 2015

Process and timeline

August 2014: phone conversation with Virginia Barbour (VB) and Professors Collins and Baigent

October 2014: Letter from Professor Armitage and colleagues received at COPE

November 2014: Discussed at Officers' t-conference November and agreed VB would review and report back to Officers

VB investigated and prepared report

December 2014: Report discussed at Officers' t-conference

January 2015: Report sent to Professor Armitage and colleagues with copy to Dr Fiona Godlee.

VB review

Review of correspondence received at COPE

Review of BMJ enquiry – published report

<http://www.bmj.com/about-bmj/independent-statin-review-panel>

Review of Papers and correspondence published in BMJ – last reviewed 1 December 2014 <http://www.bmj.com/content/349/bmj.g5688/rapid-responses>

Review of other recent related articles published in academic journals and lay press, eg Armitage, Collins and Baigent

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)61765-7/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61765-7/fulltext)

Background

Professor Armitage and colleagues have asked us to consider the actions of the BMJ in relation to the peer review of these papers, the process and the outcome of the review commissioned by the journal. In addition we were contacted by Dr Simpson of the British Cardiovascular Society.

Specifically (from Professor Armitage and colleagues' letter)

“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.”

It is important to note, as I have done to Professor Collins earlier, that we are not a statutory or regulatory body but a voluntary membership organization. These are the [terms](#) under which we can consider complaints about our members. Specifically, we cannot get involved in individual editorial decisions. In addition, we do not investigate individual cases but aim to facilitate a dialogue between the parties. Finally, it is not appropriate for COPE to make a specific recommendation on the specific medical issues raised here, regardless of any public health implications.

The approach that we take therefore and the way in which we have considered this case and others, is what would have been our advice had this case been brought to a COPE forum. Specifically, we encourage an open debate (in our terms we say that “To facilitate an open dialogue, we believe that correspondence relating to concerns should be open, and we will copy all parties on correspondence from COPE (unless there are legal or other compelling reasons for confidentiality) and expect that all parties will do the same.”) and therefore we will also send this report to Dr Fiona Godlee, Editor of the BMJ.

Summary of issues

It appears that there are three issues here.

1. Was the review process pre publication appropriate for the papers?
2. Was the post publication process appropriate, including the handling by the panel and its recommendations?
3. Has the literature been corrected: is there anything further that could or should be done in this debate now?

For the first two issues, when I spoke with Professors Collins I advised him if he had not already done so and/or remained unhappy about the handling of these papers he should to contact the journal’s publisher directly. It appears that this has not happened directly but we note that Baroness Ilora Finlay, President of the British Medical Association was cc’ed in letters to us.

Review of the above questions:

1. *Was the review process pre publication appropriate for the papers?*

Professor Armitage and colleagues lay out a number of issues that occurred during the review of the paper. These have been extensively documented and discussed, including in the report from the review panel. Consideration of this is therefore folded into the discussion below.

2. *Was the post publication process appropriate, including the handling by the panel and its recommendations?*

Was the review panel completely independent? It is worth pointing out that it is highly unusual for a journal to even consider setting up a panel to review its processes. Generally speaking journals consider these issues internally only. Notwithstanding that, the panel’s composition, its deliberations, and conclusions were apparently all made public. If there are documents or other relevant information that have not been made public as Professor Armitage and colleagues claim we would agree that they should be. **We recommend the journal review the allegations by Professor Armitage and colleagues and add any missing material.**

The panel had the following terms of reference:

a) ToR1. To consider whether either or both articles should be retracted
The panel found that neither paper met the COPE criteria for retraction.

We understand that there are differences of opinion in these matters, but in the end the decision to retract papers does lie with the Editor. The Editor did seek advice from a separate review panel and this panel agreed with the Editor's decision on retraction. The panel made separate recommendations about the corrections (see ToR3)

b) ToR 2 To review and comment on the process by which the articles were published.

The panel said: "The panel has made a number of suggestions aimed at improving the editorial process and was concerned about the late inclusion of an unscrutinised reference on a short timescale. However, the panel concedes that the peer review and editorial processes must rely on goodwill to a very considerable extent and can never be completely foolproof – especially in view of the time pressures under which authors, peer reviewers and editors are working."

Our understanding from notes published in the journal that the Editor has accepted the recommendations of the panel. However, it would appear that it would be appropriate for the journal to now explain how these recommendations have been acted on. **We suggest that the journal and the publisher should work jointly to do this and make public the results of this, and specifically address the alleged breaches of the COPE Code of Conduct and what has been done to address these.**

c) ToR 3 To review and comment on how criticisms and complaints against the articles were raised, and how the journal responded.

The panel concluded "The BMJ editorial staff should implement a significant event audit in relation to the need for the correction. The aim of the audit would be to try and identify what would need to have been in place to ensure that the correction was made in a more timely fashion."

We suggest that the journal and the publisher should work jointly to do this if not already undertaken and make public the results of this.

3. *Has the literature been corrected: is there anything further that could or should be done in this debate now?*

Without having an opinion on one or other side of the debate on the use of statins and their side effects, it is clear that this is a topic on which there is a considerable range of opinion and no purpose is served by censoring either side of the debate. There has been much discussion in previous COPE forums of the need for post publication criticisms to be aired in the journal that it was originally published in and we note that the BMJ repeatedly offered Professor Collins and colleagues the opportunity to respond, but they declined. We think that it is unfortunate that the most important issue here, ie

having a full response in in the BMJ of the specific issues of concern to Professor Collins and colleagues in the Abrahamson and Malhotra papers has not yet happened and we feel this needs to be rectified as soon as possible, notwithstanding other comments published in newspapers and other journals. **We therefore strongly recommend that a response by Professor Collins and colleagues on the substantive scientific issues they dispute is submitted and published in the BMJ itself as soon as possible.**

Finally, we note that Professor Armitage and colleagues allege that in a number of instances authors of comments and other material post publication did not have competing interests fully declared. **The journal should review these comments and ensure that all competing interests are declared appropriately.**

In conclusion and in order for the debate on this important issue to be as clear as possible and hopefully to allow the discussion about these particular papers to finalized, **we urge the BMJ, its publisher and Professors Collins, Armitage and colleagues to work together to make public a follow on from this debate which addresses the various unresolved issues:**

- the outcome of the review of the peer review process that the BMJ has undertaken,
- the publishing of any further submissions to the review panel;
- a response to alleged breaches of the COPE Code of Conducts and the journal's response to these;
- the publication of a response by Prof Collins and colleagues in the BMJ itself on the substantive issues of the incidence of side effects statins.

3. BMJ response to points raised in the complaint to COPE, sent 11 May 2015

In this document, we aim to respond point-by-point to the concerns raised by Professors Armitage, Collins and colleagues in their complaint to COPE dated 23 October 2014.

In each response, we use the section heading used in the letter of 23 October, then attempt to disambiguate the various complaints being made. We note the section(s) of the [COPE code of conduct](#) to which the section refers and provide our response to each alleged breach of the relevant section.

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

We understand this complaint to be that an editor said in an editorial meeting, in the light of reviewer Smeeth's comments, that it didn't matter if the numbers (complaining of muscle pain in statin vs control groups) were wrong as this could be highlighted in the Rapid Responses to the article online, as follows

- A. that there are low editorial standards at The BMJ, with the editors failing to protect the academic record, as detailed in point C.
- B. that this error persists and has not been corrected.

Response: the issue has been raised in rapid responses, making the distinction between myopathy, myalgia and myositis, all of which appear under a heading “Myopathy”. Abramson responded on 20 December saying the argument is ‘semantic’. In our view, the complaint in part concerns the use of a short heading (Myopathy) to cover multiple conditions that are then enumerated individually in the text (myopathy, muscle pain, musculoskeletal disorders overall and injuries). The Heath panel also commented on this issue, saying “The panel thought that including three different definitions of muscle problems, widely ranging in severity, all under a heading of the more serious myopathy, might lead to the reader to conflate these. However, as Abramson et al point out in their submission to the panel (SP23), myopathy and myalgia can be conflated in the opposite direction by referring to severe problems as if they included milder ones and this can also lead to misinterpretation.”.

[The Editor has again discussed this issue with Abramson, a copy of whose response can be read \(attached\).](#)

- C. This section refers to items in the [COPE Code of Conduct](#) as follows:

1.1. Editors should be accountable for everything published in their journals.

Response: The Editor in Chief and her staff do indeed hold themselves accountable for all the content published in the journal

- D. **1.6. [This means the editors should] maintain the integrity of the academic record;**

Response: In areas of disagreement between one reviewer and an author, or indeed between one reviewer and another, we believe an editor can reasonably decide to let the point be debated post-publication. In this case, there seems to be continuing debate on precisely how best to represent this issue.

- E. **1.8. [This means the editors should] always be willing to publish corrections, clarifications, retractions and apologies when needed.**

Response: We believe *The BMJ* has shown itself very willing to correct and clarify all the issues raised around the publication of these articles. It seems from our detailed analysis (below) that one point may have been missed from the private concerns that were sent to the journal by Professor Collins in letters to the editor marked “not for publication” or mentioned in conversation or via third parties. We apologise wholeheartedly for all such omissions. We would once again urge Professor Collins and colleagues, as COPE has urged, to make any remaining criticisms or concerns public in the pages of the journal. We do not feel a retraction was required on this occasion, and this conclusion was supported by the Heath panel.

- F. **8.1. Editors should take all reasonable steps to ensure the quality of the material they publish, recognising that journals and sections within journals will have different aims and standards.**

Response: The Heath panel concluded that the journal’s processes were broadly

appropriate, as did our internal review [published alongside this response]. We did however note a number of areas where we could improve our processes to make them even more robust and rigorous, and we have put this into practice. We will continue to review our processes and improve them where we can.

G. **12.1. Errors, inaccurate or misleading statements must be corrected promptly and with due prominence.**

Response: We believe errors and inaccuracies have indeed been corrected with due prominence. Although there was an interval of several months between publication of the Abramson article and its correction, discussion around the article was ongoing on the journal's website during this period. In general the pace of corrections and retractions is regrettably slow (see [Steen RG:J Med Ethics 2011;37:249-253 doi:10.1136/jme.2010.040923](#))

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

In essence, we read this complaint as follows. That in drafting a correction, the editor chose not to listen adequately to reviewer Smeeth on the subject of how to present the number of people complaining of side effects and also did not take adequate account of the views of Zhang *et al.* who felt moved thereafter to submit a further Rapid Response in clarification.

- A. In complaining about this process of reviewing the correction and deciding what it should say, the complaint refers to items in the COPE Code of Conduct as follows:

1.6. [This means the editors should] maintain the integrity of the academic record;

7.1 Editors should strive to ensure that peer review at their journal is fair, unbiased and timely.

Response: Once again we had a disagreement between parties and had to decide how to proceed. On this occasion, the authors of the Zhang *et al.* study said the correction was fine as drafted but reviewer Smeeth felt it was not. The Editor made a decision to publish in a timely way with minor amendments to address Smeeths concern but without final resolution on this point; and to encourage further public discussion of this issue. The correspondence about the correction, between Fiona Godlee and the authors of Zhang *et al.* [included below], and Fiona Godlee and Liam Smeeth [also included below], is provided with this document.

- B. **8.1. Editors should take all reasonable steps to ensure the quality of the material they publish, recognising that journals and sections within journals will have different aims and standards.**

Response: Every effort was indeed made to ensure the quality of the articles and the correction, and where our critical event audit identified how processes could be improved we have amended them.

- C. **17.1 Editors should have systems for managing their own conflicts of interest as well as those of their staff, authors, reviewers and editorial board members**

Response: We are unsure of the relevance of this section of the code to the issue of the handling of the correction. In relation to the correction we believe we consulted the appropriate parties and asked the panel to consider its suitability. In terms of the editor's own conflicts of interest, she highlighted in [the editorial announcing the convening of the Heath panel](#) "as the editor responsible for publishing the articles, I have a vested interest in not retracting them unless the case for doing so is completely clear. So I have decided that the right thing to do is to pass this decision to an independent panel." We therefore feel that the issues of conflict of interest have been adequately handled with regard to the correction and the question of retraction.

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

We read this complaint as being that the [Editorial](#) said that a statement about side effects was missed by peer reviewers when in fact this statement was inserted by the authors after review, in a version of the article that was not re-reviewed. Specifically, we interpret the complaint as being that the editor knew this but that she published an editorial saying something she knew to be untrue, repeated this statement to the media, and took 11 days to correct it, in breach of the following COPE guidelines:

- A. **8.1. Editors should take all reasonable steps to ensure the quality of the material they publish, recognising that journals and sections within journals will have different aims and standards.**

12.1. Errors, inaccurate or misleading statements must be corrected promptly and with due prominence.

Response: Professors Armitage, Collins and colleagues [highlight notes on the manuscript tracking system from the Analysis editor](#) noting that the error was introduced in the revised article that was not peer reviewed. Although this note was made before publication of the Editorial, unfortunately the Editor-in-Chief did not appreciate this point in time to amend the editorial before publication, nor at the point at which she issued the press release and discussed the matter with Professor Collins on the Today programme. This issue was corrected subsequently in less than two weeks, as soon as it was clear that it needed to be.

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

This complaint concerns the delay in making the review of Malhotra paper available, when the reviews of the Abramson paper were made available much earlier.

- A. There is an implication that this was a deliberate delay due to reluctance on the part of the journal, and a disbelief in the description of a 'technical problem'.

Response: When presenting peer review reports for articles, it is the journal's preference to present the comments separate from the article. However, the peer review of the Malhotra article was provided as comments within a PDF, which could not be easily displayed. It was therefore necessary to prepare a version of his comments that could be seen in the context in which they were provided but read easily and reliably by users of The BMJ's website. This is what is now provided as a Data Supplement to the article at http://www.bmj.com/content/bmj/suppl/2014/07/07/bmj.f6340.DC1/See_peer_review_for_this_article.pdf. As this is a non-standard presentation it took us some time. We reject the suggestion that we were deliberately delaying posting

of the reports.

- B. The complaint is that use of Abramson to review Malhotra's article is in breach of the following COPE guidelines:

7.1 Editors should strive to ensure that peer review at their journal is fair, unbiased and timely.

Response: While it is not ideal with hindsight to have had Abramson review the article by Malhotra, it is not unusual to have two authors of related articles review each others work. In the light of our critical event audit we are making every effort to ensure that in future in such cases we seek a wider range of opinions; [see the document detailing our audit.](#)

Best practice for editors {Described by COPE as "more aspirational and [were] developed in response to requests from editors for guidance} **would include: 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)**

Response: As above, we would agree that best practice would include avoiding such reviewer-author pairs.

5. "Questionable independence of The BMJ's review of published errors

- A. We see the essence of this complaint as being that the Heath panel wasn't in fact independent of the journal, and that its Terms of Reference come from the Editor. **Response:** We appreciate the concern that the panel was not entirely independent of all connections with the journal. We would note, however, that there is no guidance or best practice on appointing such a panel, as it is an unprecedented move. Our aim in appointing the panel was to have it act in lieu of an ombudsman. The panel was given access to all information and asked to evaluate all issues. It acted completely independent of input from the editorial team, and reached its own conclusions.

- B. That the panel was not sufficiently rigorous in considering the harm caused.

Response: In our view the panel was extremely rigorous. In fact, the independent retractionwatch website noted ["This is the most detailed justification for a journal's decision not to retract a paper that we've seen in a long time, perhaps ever."](#) But the panel was not tasked with considering whether or not statins should be prescribed and for whom.

- C. That the panel members are biased on the issues at hand and members did not declare all relevant papers and COIs, related to litigation and to collaboration with Abramson.

- a. an undeclared paper by the chair (Heath) claiming statins cause cancer in the elderly. **Response:** We read this paper differently, as saying people on statins don't die of cardiovascular events but do die of cancers, suggesting that there is little life-saving effect of statins, but not that the statins are a cause of cancer. It says ""The most likely reason [for the observed phenomenon] is substitution of cause of death."

- b. A paper by panel member Hippisley-Cox on statins and their side-effects (about cataracts, inter alia) is not specifically declared.

Response: This article is, we believe, declared in the [panel's materials.](#)

thus: “In 2010 we published an observational study in the BMJ to quantify unintended effects of statins which is referenced in the Abramson paper⁸” - 8. Hippisley-Cox J, Coupland C. Unintended effects of statins in men and women in England and Wales: population based cohort study using the QResearch database. BMJ 2010;340:c2197.

- c. Two other undeclared papers by a panel member that made similar claims about the efficacy of statins to those made in the Abramson paper.

Response: This concerns articles by panel member Furberg, who conflicts of interest declaration states “Publication of a large number of studies of statin and other lipid studies” but does not enumerate them.

- d. Undeclared litigation work by panel member Furberg.

Response: *Professor Furberg declares that he has done no litigation work in the past decade related to the safety statins. Professor Furberg also asked the journal to note that he has been a co-author and collaborator with the Oxford group on multiple articles in the past 7 years, and might therefore be expected to be biased in their favour, but he aims for balance.*

- e. This is in breach of COPE guidelines:

17.1 Editors should have systems for managing their own conflicts of interest as well as those of their staff, authors, reviewers and editorial board members

Response: *The BMJ does indeed have such systems, and declares conflicts of interest for staff (listed for [editors](#) on their profile pages), authors (on each paper), reviewers (on each review) and editorial board members (listed for [board members](#) on their profile pages) .*

17.2. Journals should have a declared process for handling submissions from the editors, employees or members of the editorial board to ensure unbiased review

Response: *The BMJ does indeed have such systems, and if we have missed any we will correct them (please see below). But we are unsure of the relevance of this guideline in the context of the panel.*

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

- A. The timeline published with the panel’s report links to a [supporting letter with 500 signatories](#) without pointing out that journalist Jeanne Lenzer coordinated it and we pay her for some work.

Response: The Editor was not aware of Lenzer’s role in coordinating the letter and certainly did not commission or pay her to do so. Lenzer was at the time a freelance journalist known to do some work for the BMJ and declares that she helped coordinate the open letter after she was approached by a group of concerned physicians.

- B. That Lenzer had attempted to publish this letter elsewhere without declaring that she sometimes works for The BMJ.

Response: As noted above, Lenzer was not acting for the journal in this regard.

- C. That Lenzer published a 2013 paper listing Abramson as a collaborator and with a member of the panel as a co-author.

Response: As Lenzer was not involved in the work of the panel, her work with a panel member and with Abramson does not appear to be relevant. Her co-author was panel member Furberg. As noted above (point 5Cc) his conflicts of interest

declaration states “Publication of a large number of studies of statin and other lipid studies” but does not enumerate them in detail. However, our understanding is that in fact Furberg had no interaction with Abramson in his role as an external reviewer of this paper.

- D. This is in breach of COPE guidelines:

17.1 Editors should have systems for managing their own conflicts of interest as well as those of their staff, authors, reviewers and editorial board members

Response: This issue is primarily addressed above (point 5Cd). We note that as panel member Furberg is a member of The BMJ’s editorial advisory board, he has a [generic conflicts of interest statement](#) in addition to the one prepared specifically for the Heath panel.

17.2. Journals should have a declared process for handling submissions from the editors, employees or members of the editorial board to ensure unbiased review

Response: As noted above we do have such systems but are unsure of the relevance here, as the Lenzer submission reported by Professors Armitage, Collins and colleagues was not submitted to *The BMJ*.

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

Both the panel report and the accompanying editorial say that all relevant material is published, but it is not.

- A. A submission to the panel about a letter by Malhotra and others to NICE was not posted.

Response: As we understand it, Professor Collins wrote privately to the panel to ask about this issue and the panel declined to respond in private, preferring to discuss all these issues openly. Now that this matter is being made public, the panel have advised the journal that they did not consider the letter to NICE and Professor Collins complaint about it relevant to their work.

- B. The claim to have redacted things for legal reasons is untenable - and one piece of redacted claim is reiterated.

Response: The journal takes legal advice when it believes content might be defamatory or otherwise in breach of good practice. It did so on this occasion, and redacted those parts of statements that were highlighted by counsel as problematic. We continue to decline to publish this statement on legal advice.

- C. This is in breach of COPE guidelines:

14.1. Editors should encourage and be willing to consider cogent criticisms of work published in their journal.

Response: We believe we have shown the journal to be very willing to consider and respond to cogent criticisms. We do, however, also have to take legal advice and respond to it.

15.1 Editors should respond promptly to complaints and should ensure there is a way for dissatisfied complainants to take complaints further. This mechanism should be made clear in the journal and should include information on how to refer unresolved matters to COPE.

Response: The journal has responded promptly and on numerous occasions to these complaints. We also make plain how to take matters further, and note that this complaint is via COPE.

17.1 Editors should have systems for managing their own conflicts of interest as well as those of their staff, authors, reviewers and editorial board members.

Response: We believe we have responded on this point, above, and are unsure how it applies to this specific concern.

4. Letter from John Abramson and colleagues, in response to the letter of complaint from Armitage *et al*, sent to *The BMJ* 20 March 2015 and included with the response to COPE, 11 May 2015

We would like to thank Prof. Collins *et al* for the opportunity to respond to their ethics complaint regarding our BMJ article of October 2014.¹ First Prof. Collins *et al* state that in the section of our paper titled “Myopathy,” we “misleadingly compared” the rates of myopathy (as defined by CTT) to the rates of musculoskeletal symptoms reported in the NHANES observational study, “which did not assess myopathy” and which “had no ‘blinded’ comparator group.” Second, Prof. Collins *et al* raise concern about our having failed to respond to an “error” in our original manuscript that had been pointed out by a peer reviewer: that the frequency of musculoskeletal symptoms reported in the manuscript was “misleading” because only musculoskeletal symptoms among statin users were ascertained, without taking into account the fact that “muscle pain is incredibly common in the general population.” And finally, Prof. Collins *et al* state that in response to Cochrane Collaboration statin trial reviewers’ Rapid Response, which expressed concern about our use of the term “myopathy,” the BMJ allowed us “to repeat our misleading claim.”

None of these statements about the article as published in the BMJ or our response to the Cochrane Collaboration statin trial reviewers is correct.

Addressing the first issue, Prof Collins *et al* wrote in their complaint that, under the heading of “Myopathy,” we had “misleadingly compared” the rate of statin-associated myopathy reported in the CTT meta-analyses “(i.e. a severe muscle problem with a specific definition)” to the rate of more common statin-associated musculoskeletal symptoms based on the NHANES survey as reported by Buettner *et al*² “(which did not assess myopathy)”.

Notwithstanding the opinion of Prof. Collins *et al* about what the definition of myopathy should be, there is not one universally accepted definition. We relied upon the approach taken by Fernandez *et al* in the Cleveland Clinic Journal of Medicine, titled “Statin myopathy: A common dilemma not reflected in clinical trials,”³ cited as footnote 11 in our Rapid Response of 20 December 2013. This article acknowledges that “little consensus exists on how to define the adverse muscle effects of statins, which may contribute to the

¹ Abramson J, Rosenberg H, Jewell N, Wright JM, Should people at low risk of cardiovascular disease take a statin? *BMJ* 2013;347:f6123 doi: 10.1136/bmj.f6123 (Published 22 October 2013, Correction May 15, 2014)

² Buettner C, Davis RB, Leveille SB, *et al*, Prevalence of Musculoskeletal Pain and Statin Use, *J Gen Intern Med*, 2008; 23:1182–6

³ Fernandez G, Spatz ES, Jablecki C, Phillips PS, Statin myopathy: A common dilemma not reflected in clinical trials, *Cleveland Clinic Journal of Medicine*, 2011;78:393-403

under-diagnosis of this complication.” The authors define three categories of statin-induced myopathy: myalgia (muscle symptoms without elevation of CK enzyme), myositis (elevated CK with or without muscle symptoms), and rhabdomyolysis (muscle symptoms with CK level ≥ 10 times the upper limit of normal). These authors’ broad definition of myopathy is clear in the following excerpt:

Another reason [statin-induced myopathy is so uncommon in clinical trials] is that these trials were designed to assess the efficacy of statins and were not sensitive to adverse effects like muscle pain. When they looked at myopathy, they focused on rhabdomyolysis—the most severe form—rather than on myalgia, fatigue, or other minor muscle complaints.

This broader definition of “myopathy” is consistent with that presented in the 2002 American College of Cardiology/American Heart Association/National Heart, Lung, and Blood’s “Clinical Advisory on the Use and Safety of Statins.”⁴ Focusing specifically on the use of the term “myopathy,” this document states that because the terminology describing muscle toxicity was inconsistent, it would provide more specific definitions. “Myopathy” was then defined as “a general term referring to any disease of muscles.” Under the general heading of myopathy, the document identified three subcategories of muscle problems:

- Myalgia—muscle ache or weakness without creatine kinase (CK) elevation.
- Myositis—muscle symptoms with increased CK levels.
- Rhabdomyolysis—muscle symptoms with marked CK elevation (typically substantially greater than 10 times the upper limit of normal [ULN]) and with creatinine elevation (usually with brown urine and urinary myoglobin).

The Canadian Working Group on statin adverse events and intolerance also chose to adopt the broad definition of myopathy as a collective term encompassing all forms muscle disease:⁵

The term does not necessarily connote symptoms or any degree of CK elevation. For example, several myopathies may present with normal CK levels, including steroid myopathy, critical-illness myopathy, pediatric dermatomyositis, myotonic dystrophy type 2, and the periodic paralyses. Indeed, biopsy evidence suggests that even some statin induced myopathic changes may be present in the context of normal CK levels.

On the other hand, the CTT as well as the National Lipid Association and the FDA, have chosen to define myopathy as having muscle symptoms *and* CK levels > 10 times the upper limit of normal. This measure of a statin-induced muscle problem is limited to significant muscle inflammation, a small subset of the broader category of statin-related muscle problems. Which of the two definitions is most relevant is a matter of opinion, but use of one definition or the other is neither factually wrong nor misleading.

⁴ Pasternak RC, Smith SC, Bairey-Merz CN, et al., ACC/AHA/NHLBI Clinical Advisory on the Use and Safety of Statins, *Circulation* 2002;106:1024-1028.

⁵ Mancini GBJM, Baker S, Bergeron J, et al., Diagnosis, Prevention, and Management of Statin Adverse Effects and Intolerance: Proceedings of a Canadian Working Group Consensus Conference, *Canadian Journal of Cardiology*, 2011; 27: 635–662.

The external panel appointed by The BMJ to determine whether retraction of our article was warranted, wrote this about our use of term “myopathy”:

The panel thought that including three different definitions of muscle problems, widely ranging in severity, all under a heading of the more serious myopathy, might lead to the reader to conflate these. However, as Abramson et al point out in their submission to the panel (SP23), myopathy and myalgia can be conflated in the opposite direction by referring to severe problems as if they included milder ones and this can also lead to misinterpretation.

The frivolous nature of the ethics complaint by Prof. Collins et al about our reporting multiple types of statin-related muscle symptoms under the single heading of “Myopathy” is made clear in Prof. Collins’ citation of a 2014 article in his request for retraction of our BMJ article:⁶

These carefully conducted randomised trials and meta-analyses of trials (along with meta-analyses of relevant observational studies; for example, Macedo et al; BMC Medicine 2014)...

Four out of five of the authors of the article by Macedo et al are members of the Cochrane Heart Group.⁷ Under the heading titled “Myopathy,” this article includes multiple definitions of muscle problems associated with statin use: an increased odds ratio of myopathy with no definition, a significant decrease in grip strength associated with statin therapy in both men and women,⁸ CTT’s finding of increased risk of myopathy (without definition), and the results of an observational study showing that the prevalence rate of any myopathic event (which used the ACC/AHA/NHLBI definition described above⁹) associated with statin initiation is approximately 250 such events per 10,000 person years. Although not stated in the article by Macedo et al, 95% of the myopathic events reported in this last study were either myalgia or myositis,¹⁰ not meeting the CTT’s criteria for myopathy.

In retrospect, had we stated explicitly that we were using the broader definition in the “Myopathy” section of our paper, this confusion would have been avoided. But our comparison of the rates of myopathy as defined by CTT (symptoms plus CK levels > 10 times normal) to the absolute increase in the number of statin-users vs. non-users experiencing musculoskeletal symptoms would not have changed. However, it should be noted that neither the 2012 nor 2015 CTT meta-analyses state that their definition of “myopathy” is limited to people with muscle symptoms plus enzyme elevations (this definition is relegated to a footnote). Although we think the CTT’s approach minimizes the

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<http://journals.bmj.com/site/bmj/statins/SP15%20Note%20from%20Rory%20Collins%20for%20the%20panel%20considering%20the%20retraction%20of%20Abramson%20and%20Malhotra%20papers.pdf>

Accessed April 12, 2015

⁷ Unintended effects of statins from observational studies in the general population: systematic review and meta-analysis, *BMC Medicine*, 2014;12:51. <http://www.biomedcentral.com/1741-7015/12/51> Accessed April 12, 2015.

⁸ Ashfield TA, Syddall HE, Martin HJ, et al, Grip strength and cardiovascular drug use in older people: findings from the Hertfordshire Cohort Study. *Age Ageing* 2010, 39:185–191.

⁹ Nichols GA, Koro CE: Does statin therapy initiation increase the risk for myopathy? An observational study of 32,225 diabetic and nondiabetic patients. *Clin Ther*, 2007, 29:1761–1770.

¹⁰ *Ibid*.

frequency with which people treated with statins experience muscle symptoms, we do not feel that this warrants a letter of complaint about the Lancet's CTT publications to the Committee on Publication Ethics.

Addressing the second issue, Prof Collins et al state that we failed to respond to a peer reviewer's comment that the results from the NHANES study in our manuscript were misleading because (in essence) we presented uncontrolled data on the rate of musculoskeletal symptoms reported by statin users in the NHANES survey. Had this data been uncontrolled, Prof. Collins et al would have been correct that it was meaningless because musculoskeletal symptoms are so common in the general population. However, in order to determine the "muscle effects" of statins, Buettner et al¹¹ used the NHANES database to compare the prevalence of any musculoskeletal pain in statin users and non-users among a sample of 3,580 adults ≥ 40 years of age.

In response to the peer reviewer's comment, we wrote to BMJ editors:

The NHANES data [were] not simply the incidence of muscle pain in statin-takers, but the difference in prevalence of muscle pain between statin takers and non-statin takers, so this should be an accurate reflection of the effect [of] statins on the prevalence of muscle pain. This was clarified in the updated manuscript.

Based on the reviewer's comment, we revised the language in the published article to clarify that the NHANES data did not simply reflect the background incidence of muscle pain in statin users, but rather the authors compared the prevalence of muscle symptoms in statin users and non-users.

Finally, the ethics complaint by Prof. Collins' et al states that when Cochrane Collaboration statin trial reviewers pointed out our "error" conflating myopathy (per the definition adopted by CTT) with the broader category of statin-related muscle problems (described above) in Rapid Response letters, "the BMJ allowed Abramson et al to repeat their misleading claim instead of correcting it."

The Cochrane reviewers letter stated:¹²

They also conflate muscle pain (myalgias), an important side effect of statins, with myopathy, a rare and more serious problem, both of which warrant ongoing study.

We responded:¹³

This is a semantic criticism, with which we disagree. From a practical point of view, statin induced myopathy includes: myalgia (muscle symptoms without raised creatine kinase), myositis (raised creatine kinase, with or without muscle symptoms), and rhabdomyolysis (creatine kinase >10 times the upper limit of

¹¹ Buettner et al, *op.cit.*

¹² *BMJ* 2014;348:g1520

¹³ *BMJ* 2014;348:g1523

normal).¹⁴ Furthermore, histopathological findings of myopathy occur in patients with or without muscle symptoms and normal creatine kinase levels.^{15 16 17}

Ironically, two of the three Cochrane reviewers who submitted the Rapid Response in question were co-authors on the paper by Macedo et al , whose section titled “Myopathy” didn’t only conflate myalgias with myopathy, but also failed to inform readers which definition pertained to which findings.

The external panel appointed to adjudicate Prof. Collins’ request for retraction of our BMJ article did not find fault with either the editors’ selection of Rapid Responses sent to us, or with our replies:

Rapid responses

Assessment

The journal received several rapid responses that raised substantive criticisms and discussion of the Analysis article. The editors’ selections of rapid response letters that were directed to John Abramson for further response and discussion were appropriate. Editors’ decision-making about those selections and their follow-up was executed in a timely manner. John Abramson and colleagues responded to the selected letters promptly.

In conclusion, we do believe there is an important ethical issue raised by our article and The BMJ’s editorial decisions related to our article. The unrelenting harassment we have been subjected to by Prof. Collins—in the media, in the demand for retraction of our paper that was unanimously rejected by the external panel (with Prof. Collins having been unwilling to make public the concerns he expressed to The BMJ about our paper prior to the panel’s decision), and now through a letter of complaint to the Committee on Publication Ethics about The BMJ’s handling of our article—is creating an atmosphere in which responsible scientific discourse is being strongly discouraged. Specifically, these ongoing tactics are inimical to improving our understanding of the benefits and risks of statins. If this process is allowed to continue or be repeated, a great disservice will be done to the public.

John Abramson, Harriet Rosenberg, Nicholas Jewell, J M Wright

(John Abramson and Nicholas Jewell serve as experts in litigation, including cases involving statins)

¹⁴ Fernandez G, Spatz ES, Jablecki C, Phillips PS, Statin myopathy: A common dilemma not reflected in clinical trials, *Cleveland Clinic Journal of Medicine*, 2011 ; 78:393403

¹⁵ Draeger A, Monastyrskaya K, Mohaupt M, et al, Statin therapy induces ultrastructural damage in skeletal muscle in patients without myalgia, *Journal of Pathology*, 2006 ; 210: 94–102.

¹⁶ Association between statin-associated myopathy and skeletal muscle damage, *Canadian Medical Association Journal*, 2009 ; 181(12):E11E18.

¹⁷ Phillips PS, Haas RH, Bannykh S, et al, Statin Associated Myopathy with Normal Creatinine Kinase Levels, *Annals of Internal Medicine*, 2002 ; 137:581585

5. Response to COPE from Tim Brooks, CEO of BMJ sent to The BMJ 4 May 2015 and included with the response to COPE, 11 May 2015

In its response to a complaint from Professor Sir Rory Collins, the Committee on Publication Ethics (COPE) invited both *The BMJ*'s editor Dr Fiona Godlee and 'the publisher' to respond. After discussion we determined that the 'publisher' response was probably best coming from me. Dr Godlee reports to me, and as CEO I have a fiduciary responsibility to the board of BMJ, as well as to our owner, the British Medical Association (BMA).

(It should be noted that – as stated every week in *The BMJ* - the BMA cedes complete editorial independence to the Editor-in-Chief. The Association's assurance of quality control stems from BMA Council's sole authority to appoint and remove the Editor-in-Chief).

The issue is whether taking statins is on balance a good thing or a bad thing for people who are at lower risk of heart disease. (There is little if any dispute that statins are good for people at elevated risk). Prof Collins believes they are a good thing. Others – including John Abramson, the author of the original piece that triggered Prof Collins's complaint – don't agree. The issue is important, because the work of Prof Collins's unit, the Clinical Trial Service Unit at Oxford University, and others has directly informed new UK and US guidelines that greatly extend the universe of adults for whom statins are recommended as routine medication.

Professor Collins's original complaint to *The BMJ*, in October 2013, has proliferated and ramified through correspondence and investigation such that the files are centimeters thick. It would take the kind of obsessive who read the entire report of the Warren Commission into Kennedy's assassination, to plough through it all.

Also published here – and slightly more digestible – are the journal's responses to the points raised by Professor Collins in his complaint to COPE and by COPE in its response to Collins. As 'publisher', I am going to stand back from the detail and make some fairly basic observations.

The BMJ made some mistakes in the editing process as a result of which author errors, relating to statistics about reported side effects from statins were not picked up. *The BMJ* and the authors of the two articles concerned have corrected them. As with all organisations committed to self-improvement, *The BMJ* has sought to learn from those mistakes and tighten or create procedures to avert their recurrence. I am satisfied it has done so, and thus has benefited from this episode. This does not mean the journal will not make mistakes in the future. It is edited by humans. What is important is how you deal with the mistakes you make. To be clear: The BMJ has done nothing wrong in publishing these papers as part of a scientific debate. The panel found that the error did not compromise the principal arguments made in either of them.

From the outset, Dr Godlee has invited Prof Collins to state his views in writing in *The BMJ*. He has yet to do so: despite stating it at great length, in a series of letters marked

‘not for publication’. Rather than take up this invitation, in fact, he had recourse to *The Guardian*, in March last year, to attack *The BMJ* for publishing the original pieces.

As a result of the article in *The Guardian*, the BBC’s Today programme followed up the story, on March 22nd last year, with a live interview of both parties. In this interview, Prof Collins said that when he first complained to Dr Godlee, she ‘fobbed me off’. I reproduce here that first email exchange, so that you can judge for yourself whether this is right. Note that Dr Godlee’s reply was made on the very same day that she received the initial complaint:

On 30 Oct 2013, at 05:34 pm, Rory Collins wrote: Dear Fiona It seems that you and the BMJ have decided to take a stand against the widespread use of statins to protect people from suffering heart attacks and strokes. I can guess at some of the reasons, but I would very much welcome an opportunity to discuss this with you since I do think that there is a danger that mis-representation of the evidence in the BMJ could cause a lot of harm, which I know is not your intention. Might it be possible for me to drop by your offices sometime soon when I am in London to discuss my concerns — as well as, of course, yours? Best wishes,

On 30 Oct 2013, at 18:27, Fiona Godlee wrote: Dear Rory. Very happy to meet. Julia will be able to suggest some dates. As for the BMJ’s position on statins, I don’t think we have one. The article by Abrahams [*sic*] and co was submitted and peer reviewed and published in the usual way. I guess they might have chosen the journal because of our too much medicine campaign. If there is anything factually incorrect or misleading in it, I would urge you to send a rapid response which we would almost certainly want to publish as a letter. In fact I do hope you will do this anyway as readers will want to know what members of the CTT collaboration make of these authors’ analysis. If you have any difficulties submitting a rapid response, our letters editor Sharon Davies can help and is copied in. All best wishes, Fiona

Prof Collins insisted that correction of editing errors was insufficient, and that the only remedy was for *The BMJ* to retract the offending articles. Retraction of papers in a scientific journal, as many readers will understand, is a very rare event. Normally it occurs only if the underlying research is shown to be entirely unreliable, either as a result of fraud or profound error, or if the research reported is unethical or plagiarised. . Otherwise scientific publishing relies upon the process of publication and counter-publication to drive thinking forward in the area under inquiry.

Dr Godlee – determined throughout this process to ensure that right was done to all concerned, including of course the original, complained-of authors – took the unprecedented step of establishing an independent panel of experts to assess Prof Collins’s complaint and to judge whether indeed the original articles should be retracted. She undertook in advance to abide by their decisions. – and has done so.

In his own submission to that panel, [Prof Collins wrote](#) that Abramson and the other authors concerned seemed to have a ‘deliberate intent to mislead the medical profession and the public despite the potential for harm to patients’: an astonishing allegation. The panel concluded that there was nothing in the articles to suggest the authors acted malevolently or fraudulently.

Prof Collins’s response to the establishment of this panel was to speak to *The Guardian* again. He dismissed the idea that the panel was independent, and called for the General Medical Council or the Department of Health to investigate instead. The panel, for the

record, included, among others, the Senior Deputy Editor of the *Annals of Internal Medicine*, (one of *The BMJ*'s main competitors), a professor of cardiology and of public health at Yale; and a professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine. By accusing *The BMJ* of investigating itself, Prof Collins appeared to characterise the panel members as Dr Godlee's poodles. I don't know what they made of that.

The panel reported that it had no contact with *The BMJ* about its deliberations. The panel's findings were published in full by *The BMJ*, along with all the accompanying documentation, and all of that can be found [online](#). The panel made a number of recommendations to the journal for improving procedures, but *unanimously* rejected Collins's view that the articles should be retracted, and noted with concern that he did not use the pages of the journal, as repeatedly offered, to make his counter-arguments.

RetractionWatch – an independent website/pressure group which works to keep scientific publishing honest – [commented](#) on the publication of the panel's work: 'This is the most detailed justification for a journal's decision not to retract a paper that we've seen in a long time, perhaps ever'.

Two further things I would like to note. In his submission to the panel, Collins detailed the grants received by his unit to fund research over the past 20 years (until one year ago) [*Editor's note: this refers to the time of writing, May 2015*]. Merck (which makes many hundreds of millions of dollars every year from cholesterol-lowering drugs) has funded the Unit's work to the tune of £179,700,000 over the past 20 years. The next biggest funder has been Schering-Plough – which was acquired by Merck in 2009 – at £40m. That combined total is equivalent to a run rate of £900,000 per month every month for 20 years; in today's money that amount is almost certainly more than £1m per month, on average. After Merck/Schering, the next biggest funder in Collins's declaration was the Medical Research Council at £13,700,000 over the 20-year period. That money does not of course go into Prof Collins's pocket: it is to fund the research; but he is right to declare such funding as a potential conflict of interest.

Trials included in the Cholesterol Treatment Trialist's Collaboration (CTTC) were, as Abramson noted, funded by statin manufacturers (a fact acknowledged by Prof Collins and the CTTC). Abramson for his part correctly declared as conflict of interest that he and one of his co-authors serve as experts for plaintiff's lawyers in drug industry litigation (including statins).

Abramson, author of the original article that triggered the complaint, is a lecturer in health policy at Harvard Medical School; somebody whose views on mass medication in principle merit respect just as Prof Collins views do. The possibility for differing views on this, as on every scientific subject, was exemplified by a [letter to *The BMJ*](#) from Klim McPherson, Visiting Professor of Public Health Epidemiology at Oxford University – in other words a colleague of Prof Collins. He described the NICE guidance on statins, which is based directly on Prof Collins's work, as 'foolhardy'. He subsequently told a *BMJ* journalist 'It is quite obvious to me that muscular myopathy is much more common than Rory [Collins] believes and that it's quite disabling'. [[BMJ 2014;349:g5007](#)].

I have no idea whether Collins or McPherson is closer to the truth on this point. The truth in science – as in every field of human enquiry - is generally speaking beyond our grasp. We advance towards it haltingly, through debate and discussion, through trial and – yes – error, enduring reverses and encountering blind alleys, as we ascend towards this summit of righteous knowledge; only to discover that the ascent is of a convex slope, and what we thought of as the peak, is merely a foothill on the journey. As Voltaire said: ‘Doubt is not a pleasant state; but certainty is a ridiculous one’.

The BMJ, through this process of patiently and openly dealing with Prof Collins’s complaints, has opened up its internal workings to a degree that is possibly unmatched, and certainly not exceeded, by any other scientific journal. This has made it a better journal. I am proud of the work of Dr Godlee and her team, and I stand by that work, and by them. I trust that this is the end of this matter – although not, of course, the end of the debate on the role of statins in prescribing habits.

6. Email correspondence between Fiona Godlee and Liam Smeeth, May 2014

On 11 May 2014, at 18:18, Fiona Godlee <fgodlee@bmj.com> wrote:

Many thanks Liam. I will strengthen the comment about the uncontrolled nature of the data and the equal rates in active and placebo arms in the RCTs. 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. Many thanks again for your help. Best wishes, Fi

On 9 May 2014, at 17:05, Liam Smeeth <Liam.Smeeth@lshtm.ac.uk> wrote:

Dear Fiona

two comments.

1. While they have apologised, they have also undertaken a new misleading calculation to come up with a figure of 9%.

As I said in my referee's report:

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). Serious rhabdomyolysis was rare: 5 cases in the 10,269 allocated to simvastatin and 3 cases in the 10,267 allocated to placebo.

This means that in any observational study of statin use, a large number of people (likely to be something like one third) will get muscle pain that they would have got without statins. A varying proportion of this muscle pain (that is nothing to do with statins) will be blamed on statins, and a varying proportion of people will then stop

their statins because of wrongly blaming them for muscle pain. Even if the 9% is the correct number, interpreting this as being the people who had side effects caused by statins is plainly wrong.

7. Email correspondence between Fiona Godlee and Alexander Turchin, co-author of Zhang et al, May 2014

From: Turchin, Alexander,M.D.,M.S. <ATURCHIN@partners.org>
Date: 10 May 2014 at 22:13
Subject: RE: Request from The BMJ relating to your paper on discontinuation of statins
To: Fiona Godlee <fgodlee@bmj.com>
Cc: Helen Macdonald <HMacdonald@bmj.com>, Huabing Zhang <huabingzhang@yahoo.com>, "Plutzky, Jorge,M.D." <jplutzky@rics.bwh.harvard.edu>

Dear Dr. Godlee,

We have reviewed the original BMJ paper by Abramson et al. and the proposed correction. We agree that the correction appropriately characterizes our study's findings with respect to the statin-related events.

Thank you for the opportunity to provide our input,

Alex

From: Fiona Godlee [fgodlee@bmj.com]
Sent: Friday, May 09, 2014 8:35 AM
To: Turchin, Alexander,M.D.,M.S.; Plutzky, Jorge,M.D.
Cc: Helen Macdonald

Subject: Request from The BMJ relating to your paper on discontinuation of statins

Dear Dr Plutzky, Dr Turchin, Dr Zhang (with apologies, as I don't seem to be able to find Dr Zhang's email address)

I am editor in chief of The BMJ and I am writing to ask for your help in responding to a complaint we have received about an article we published last year.

<http://www.bmj.com/content/347/bmj.f6123>

The BMJ paper, by Abramson et al, references the study you published in April last year in Annals of Internal Medicine on the discontinuation of statins

<http://annals.org/article.aspx?articleid=1671715>

The complaint, from Rory Collins in Oxford, is that the paper misrepresents your findings and in so doing, overstates the evidence on the rates of adverse events from statins.

We are working on a correction that we hope will do full justice to the issues involved.

I would be very grateful if you could look at the Abramson et al paper and give me your views on the way it characterises your findings in relation to statin related events.

The draft correction is included below, on which I would welcome your comments

I very much appreciate your help with this matter and would be especially grateful if you could get back to me early next week if at all possible.

All best wishes, Fiona Godlee

Dr Fiona Godlee FRCP
Editor in Chief
The BMJ (bmj.com)
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Correction to Abramson et al (Draft FG May 9)

In our article, we stated that side effects of statins occur in about 18-20% of patients. We withdraw this statement. Although it was based on statements in the referenced paper by Zhang et al that "the rate of reported statin related events to statins was nearly 18%," our article did not reflect necessary caveats and did not take sufficient account of the uncontrolled nature of the study. Zhang et al observed that the rate of statin related events found in their study (18%) was "substantially higher than the 5% to 10% usually described in randomized, placebo controlled, clinical trials." Two caveats must be considered: As Zhang et al point out, the rate of Statin related events reported in their observational study was uncontrolled, and therefore may be inflated because events attributed to statins might have occurred in a placebo group as well. In addition, although Zhang et al do not make this point, the 5-10% rate quoted by Zhang et al as having been observed in randomised trials was, in many cases, similar in both active and placebo groups.

The exact rate of statin related adverse events in people at low risk of cardiovascular disease remains uncertain. As discussed by Zhang et al, observational studies report rates of [add rates]. Meanwhile, clinical trials may underestimate the frequency of statin related adverse events due to patient selection, exclusion of older patients and those with comorbid conditions, underrepresentation of women, and selection bias created by willingness to participate in a clinical trial. Access to the full data from the trials of statins would help to determine the comparative rates of serious adverse events in

statin and control groups, but probably would not help to determine the frequency of less than serious statin related adverse events.

Also in our article, we mistakenly said that Zhang et al found that "18% of statin treated patients had discontinued therapy (at least temporarily) because of statin related events." Based on review of structured EMR categories and automated review of unstructured narratives from follow up visits of 107 835 patients over 8 years, Zhang et al found that "Of all study patients, 18 778 (17.4%) had a statin related event documented during the study." Further, among those who experienced a statin related event, 59.2% had statin therapy discontinued at least temporarily. However, because of possible miscategorization due to the limited options in the EMR listed as reasons for discontinuation of statin therapy, the authors of the study concluded that "as many as 87%" of these discontinuations could have been due to statin related events. This equates to up to 9% of the study population having possibly discontinued statin therapy as a consequence of drug related adverse events, rather than the 18% we cited.

We note that the primary finding in our article—that CTT data fail to show reduction in overall risk of mortality by statin therapy for people with <20% risk of CVD over the next 10 years—was not challenged in the process of communication about this correction.

8. Second letter from Armitage, Collins et al to COPE, 10 June 2015

In a letter dated 10 June 2015 the complainants expressed the view that The BMJ's response to COPE was inadequate:



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.

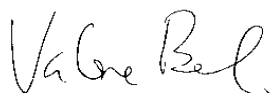
Yours sincerely



Professor Jane Armitage, FRCP FFPH
Professor of Clinical Trials and Epidemiology
University of Oxford, Oxford, UK



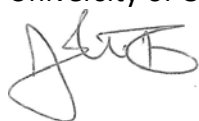
Professor Colin Baigent, FRCP FFPH
Professor of Epidemiology
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Professor Dame Valerie Beral, FRS FMedSci
Professor of Epidemiology
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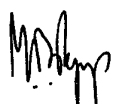
Professor Sir Rory Collins, FRS FMedSci
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Professor John Danesh, FMed Sci FRCP
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Professor Sir Richard Peto, FRS FMedSci
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Professor Neil Poulter, FMedSci FRCP
Professor of Preventive Cardiovascular Medicine
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Professor Peter Sandercock, FMedSci DM
Professor of Medical Neurology
University of Edinburgh, Edinburgh, UK



Professor Robert Souhami, CBE FMedSci
Emeritus Professor of Medicine
University College, London, UK



Professor Sir Nicholas Wald, FRS FMedSci
Professor of Environmental and Preventive Medicine
Queen Mary University of London, London, UK

cc Mr Jay Lippincott, Chairman of BMJ Publishing Group
Baroness Ilora Finlay, President of the British Medical Association

9. COPE response to Armitage, Baigent and Collins - 15th April 2016

Nuffield Department of Population Health
Richard Doll Building
Old Road Campus
Headington
Oxford OX3 7LF

15 April 2016

Dear Professors Armitage, Baigent and Collins

We are writing in response to the concerns raised to the attention of COPE regarding the publications in the BMJ by Abramson and Malhotra. The concerns and the journal's response have been reviewed by three of the COPE Trustees. Trustees with a potential conflict of interest were not included in the decision-making process.

We would like to first of all reiterate COPE's remit and the scope of our review of this case (<http://publicationethics.org/contact-us#complaints>). COPE is a membership organization and not a regulatory authority; COPE membership by journals and publishers is voluntary.

COPE's goals are the education of our members and the promotion of a better understanding of publication ethics overall. We provide a number of resources to our members, one of these is the COPE Code of Conduct which also includes best practices as an aspirational guide on steps journals can take to enhance their workflows. COPE guidelines are just that and not mandates, failure to implement all of the goals outlined under the best practice guidelines does not in itself imply deviation from ethical publishing practices.

COPE does not complete regular audits of member journals to verify compliance with the Code of Conduct, however we do consider complaints against members and follow up on those as necessary. We encourage self-audit at journal level and have developed a self-audit tool which we make available to our members. This is intended to assist them in identifying aspects of their practices that may require improvement and to promote transparency in their processes.

In situations where concerns are identified about a journal's process, either through an internal audit or a complaint, the key consideration is to ensure the journal is able to address the original issue in a reasonable manner and implement any necessary procedural changes to prevent the situation arising again. The fact that an error or a procedural gap is identified does not demand sanctions, and as noted above COPE does not have regulatory powers.

Upon review of the information available, we understand that the BMJ completed a self-audit of their processes related to the peer review of the articles and the handling of the concerns raised upon publication. The journal took steps to correct the articles and implemented procedural changes to address issues identified through their internal audit.

publicationethics.org

We believe that the journal took extraordinary steps to follow up on the concerns raised by convening an independent panel, whose findings they have since reported publicly at <http://www.bmj.com/about-bmj/independent-statins-review-panel>.

We recognize that different journals will have different processes in place and differing resources available to follow up on concerns raised to their attention, and thus that some level of flexibility is necessary on how journals develop and implement practices to address ethical challenges they face. In light of this, the main principle for addressing such challenges is to be as transparent as possible; we consider that the BMJ acted as per this principle by posting information on their internal audit publicly.

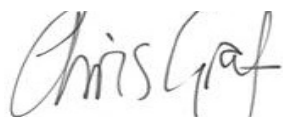
COPE also has a Code of Conduct for publishers which indicates that publishers should foster editorial independence. The documentation supplied by the publisher supports that they acted in line with this expectation.

In consideration of the above and upon review of the information available, we believe that the BMJ acted appropriately by completing an internal investigation and audit to a high standard, and promoted transparency by making information on the process publicly available.

While we appreciate that our response will not fully satisfy your original request, we believe that the journal acted with due diligence and in line with the expectations under the COPE Code of Conduct. We appreciate that differences in opinion may remain that COPE is unable to resolve in the context of this review. It is clear there are differing opinions on the science, however, those differences are best resolved by open dialogue in the scientific literature.

Thank you for raising this matter to the attention of COPE and we apologize for the time it has taken to conclude this case.

With best wishes,



Chris Graf, co-Vice-chair



Geri Pearson, co-Vice-chair



Charon Pierson, COPE Secretary