



14 April 2014

Dr Fiona Godlee
Editor, BMJ
BMJ Publishing Group
Tavistock Square
London WC1H 9JR

Dear Fiona

NOT FOR PUBLICATION

Thank you for responding so rapidly to my letter of 31 March, but unfortunately the key points that I raised have not been addressed properly either by the letters from Abramson et al and Malhotra or by your response of 1 April.

I can assure you that this issue is not at all personal. As indicated previously, it seems highly likely that the misleading claims that have been reported by the BMJ about side-effect rates with statins will lead to large numbers of unnecessary heart attacks, strokes and premature deaths because patients at elevated risk will be dissuaded from taking statins. My concern is with the BMJ's failure to correct promptly and prominently such a serious mistake when it has major public health implications.

As I explained to you when we met, the evidence cited by Abramson et al and Malhotra does not support their claims that statins cause side-effects in 18-20% of patients. For the sake of clarity, a "statin-related adverse event" (which is what was studied in the paper by Zhang et al that is being cited) is not necessarily caused by, or a side-effect of, a statin. Consequently, it is a serious misrepresentation of the evidence for Abramson et al and Malhotra to state that it is. As was the case with the claims of a link between the MMR vaccine and autism, the most serious problem with these papers is the magnitude of the effect for which the claim is made that a causal link has been demonstrated – and the BMJ has now compounded the problem by reiterating this misleading claim in the recent letters by Abramson et al and Malhotra, despite the error having been pointed out explicitly.

In section 12 ("*Ensuring the integrity of the academic record*") of the COPE guidelines for Journal Editors, it states: "*12.1. Errors, inaccurate or misleading statements must be corrected promptly and with due prominence.*" When I met with you on 2 December, I explained my concerns about these two papers, and very specifically highlighted the problem with their claims about the magnitude of the rate of side-effects with statins. But, although you wrote in your email of 2 December that you took seriously the concerns that I had raised and would discuss with your colleagues what the BMJ should do, the BMJ has done nothing to correct the record. Indeed, as noted above, when this issue was raised again explicitly in a letter to the journal, Abramson et al were allowed to reiterate this unjustifiable claim. So, instead of correcting a seriously misleading statement when it is pointed out both verbally in a meeting set up to discuss these concerns and in writing, the BMJ has instead repeated it.

It would seem that this situation is explicitly covered by the COPE guidelines on retractions which state that *“Journal editors should consider retracting a publication if: they have clear evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or honest error (e.g. miscalculation or experimental error)”*. As indicated above, the finding by Abramson et al and by Malhotra of a side-effect rate of 18-20% is clearly unreliable (and this is reinforced by meta-analyses of relevant observational studies and randomised trials which refute those claims). Moreover, the adverse public health impact of this misrepresentation of the evidence is likely to be substantial (and, as I've indicated previously, far greater than that of the MMR vaccine and autism claims). Given that this is the case, please would you explain why the BMJ is still refusing to correct these misleading statements prominently and to retract these papers in accordance with the COPE guidelines?

When I first wrote to you about the problems with these two papers, you indicated that their quality had been assured by the BMJ's peer-review process. Given your public commitment to transparency, I had anticipated that you would want to demonstrate that the BMJ's peer review process was sufficiently rigorous and unbiased (which seems not to have been the case given the egregious nature of these errors). Again, this would appear to be covered by the COPE guidelines (for example, sections 7 and 8 on peer review). The identities of the reviewers is not relevant, but I again ask that you make available their anonymised comments, as well as those of the editors, for both papers so that it might be possible to understand how these errors of judgement could have occurred.

My previous letter was rather long and, as a consequence, you may well have missed the request in its postscript (since you have not responded to it). Please would you let me have the details of all conflicts of interest for Abramson et al and Malhotra, including the amounts of any payments that they have received for any statin-related work? This is information that should quite properly be in the public domain. In a spirit of reciprocity, I have attached the details of all grants from industry to CTSU for our research covering the past 20 years and more, along with CTSU's policy on honoraria and other payments from industry (which involves us not taking such payments, directly or indirectly, personally or to the institution, except for reimbursement of travel and accommodation to take part in relevant scientific meetings).

I do hope that it will be possible to move forward constructively with the BMJ to have these papers and their misleading claims withdrawn in the interests of public health. If you think that it might be helpful for us to speak about these points or any other issues then I would, of course, be delighted to do so either by phone or face-to-face in Oxford or London. In which case, please do let me know when would be convenient.

Yours sincerely



Rory Collins

Enclosed: Grants and CTSU policy