From: Fiona Godlee [mailto:fgodlee@bmj.com]
Sent: 14 May 2014 17:22
To: Rory Collins
Cc: Emma Dickinson
Subject: Withdrawal of statements on adverse effects of statins - BMJ press release

Dear Rory. We have press released an editorial announcing the correction and withdrawal of the statements on adverse effects of statins in the two BMJ articles. See below. The editorial will be published online at midnight tonight and in this week's print journal which comes out on Friday. I am sharing this with you now as members of the press may contact you about it. If you need any further information, do contact me or Emma Dickinson in our press office. Best wishes. Fiona

Sent from my iPhone

Begin forwarded message:

From: Emma Dickinson <<u>edickinson@bmj.com</u>> Date: 14 May 2014 05:08:52 pm BST To: Fiona Godlee <<u>fgodlee@bmj.com</u>> Subject: Final press release to send to Rory Collins

BMJ Press Release Embargo 00:01 hours (UK time) Thursday 15 May 2014

BMJ authors withdraw statements about adverse effects of statins

Decision whether to retract articles will be made by an independent panel

Editorial: Adverse effects of statins

Authors of two articles published in The BMJ last year are withdrawing statements about the adverse effects of statins.

An editorial by Editor-in-Chief, Dr Fiona Godlee aims to alert readers, the media, and the public to the withdrawal of these statements "so that patients who could benefit from statins are not wrongly deterred from starting or continuing treatment because of exaggerated concerns over side effects."

Dr Godlee has also asked an independent expert panel to decide whether the articles should be retracted.

In October last year, The BMJ published an article by John Abramson and colleagues that questioned the evidence behind new proposals to extend the routine use of statins to people at low risk of cardiovascular disease.

The authors re-analysed data from the Cholesterol Treatment Trialists' (CTT) Collaboration. This showed no mortality benefit associated with treatment of people with a less than 20%

risk of developing cardiovascular disease over the next 10 years. This has not been challenged.

However, they also cited data from a separate uncontrolled observational study showing that statin side effects occur in 18-20% of patients. This was repeated in another article published in the same week in The BMJ by Aseem Malhotra – and is the statement the authors have now withdrawn.

The BMJ was alerted to the error by Rory Collins, professor of medicine and epidemiology at Oxford University and head of the CTT Collaboration whose data were re-analysed by Abramson and colleagues.

This error was due to a misreading of data from one observational study, and was not picked up by the peer reviewers or editors, explains Dr Godlee. "The BMJ and the authors of both these articles have now been made aware that this figure is incorrect, and corrections have been published withdrawing these statements."

She explains that writing, peer reviewing, and editing are human processes subject to error, "which is why we must be, and are, ready to correct things when they are found to be wrong."

Professor Collins has requested retraction of both articles, but Dr Godlee questions whether the error is sufficient for retraction, "given that the incorrect statements were in each case secondary to the article's primary focus."

Guidelines of the International Committee on Publication Ethics state that journals should consider retracting a publication if there is clear evidence that the findings are unreliable, either as a result of misconduct or honest error.

Dr Godlee has decided to pass this decision to an independent panel, chaired by Iona Heath, former chairwoman of the Royal College of General Practitioners and of The BMJ's ethics committee.

Full details of the panel and processes will be published shortly, and all submissions to the panel will be placed in the public domain on <u>bmj.com</u>. Dr Godlee has also committed to implementing the panel's recommendations in full.

Meanwhile, she says, "The BMJ will continue to debate the important questions raised in both these articles: whether the use of statins should be extended to a vastly wider population of people at low risk of cardiovascular disease; and the role of saturated fat in heart disease.

Contact:

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Embargoed link to full editorial: <u>http://press.psprings.co.uk/bmj/may/statins.pdf</u> Public link once embargo lifts: <u>http://www.bmj.com/cgi/doi/10.1136/bmj.g3306</u>

Link to Abramson article: http://press.psprings.co.uk/bmj/may/Abramson.pdf

Link to Malhotra article: http://press.psprings.co.uk/bmj/may/Malhotra.pdf



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