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Independent statins review panel terms of reference

Independent panel established to review articles published in *The BMJ* by Abramson et al [1] and Malhotra [2]: Terms of reference

1. Background

In October 2013 *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. [1] Abramson et al set out to reanalyse data from the Cholesterol Treatment Trialists Collaboration. Their contention was that the benefits of statins in low risk people were less than has been claimed and the risks greater.

In their conclusion and in a summary box, they said that side effects of statins occur in 18-20% of people. This figure was repeated in another article published in the same week in *The BMJ* by Aseem Malhotra. [2] *The BMJ* and the authors of both articles have now been made aware that this is incorrect, and corrections have been published withdrawing these statements.

The corrections explain that, although the 18-20% figure was based on statements in the referenced observational study by Zhang et al --which said that "the rate of reported statin-related events to statins was nearly 18%," [3] the BMJ articles did not reflect necessary caveats and did not take sufficient account of the uncontrolled nature of Zhang et al's data.

The BMJ was alerted to the error by Rory Collins, professor of medicine and epidemiology in Oxford and head of the CTT collaboration whose data are reanalysed by Abramson et al. Professor Collins has called for the retraction of both articles.

As explained in an editorial, [4] *The BMJ*'s editor in chief Fiona Godlee has decided to pass the decision on whether to retract one or both of the articles to an independent panel, whose membership and terms of reference are given below.

References

1. Abramson JD, Rosenberg HD, Jewell N, Wright JM. Should people at low risk of cardiovascular disease take a statin? <u>BMJ 2013;347:f6123</u>.

2. Malhotra A. Saturated fat is not the major issue. BMJ 2013;347:f6340.

3. Zhang H, Plutzky J, Skentzos S, Morrison F, Mar P, Shubina M, et al. Discontinuation of statins in routine care settings. <u>Ann Intern Med2013;158:526-34.</u>

4. Godlee F. Adverse effects of statins. BMJ 2014; 348:g3306.

2. Membership of the panel

Chair:

lona Heath, former chair, Royal College of General Practitioners; former chair, The BMJ's ethics committee.

Members:

Stephen Evans, professor of pharmacoepidemiology, London School of Hygiene and Tropical Medicine

<u>Curt Furberg</u>, professor emeritus of public health sciences, Wake Forest University School of Medicine; former chair of steering committee and principal investigator, ALLHAT trial; member, editorial advisory board of *The BMJ*

Julia Hippisley-Cox, professor of epidemiology and general practice, University of Nottingham

Harlan Krumholz, Harold H. Hines Jr. professor of medicine (cardiology) and professor of investigative medicine and of public health (health policy), Yale School of Medicine

<u>Cynthia Mulrow</u>, senior deputy editor, Annals of Internal Medicine; adjunct professor of medicine, Texas University of Health Science Center; member, Institute of Medicine

Paul Wicks, vice president of innovation, Patients Like Me; member, editorial advisory board of The BMJ

3. Scope of the panel's work

To consider whether either or both articles should be retracted.

To review and comment on the process by which the articles were published.

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

To summarise its findings and make recommendations to *The BMJ*s editor in chief in a report that will be published on bmj.com.

4. Accountability and transparency

All submissions to the panel and all documents used by the panel will be placed in the public domain on bmj.com, either at the time of submission or as part of the panel's final report.

Panel members and all those submitting information to the panel will make full declarations of their interests, which will be published on bmj.com.

5. Timeframe

To complete review and deliver report by 31 July 2014

To comment on these terms of reference, please post a rapid response or email Jane Smith (jsmith@bmj.com). Consultation period ends Friday 23 May 2014.

See also:

<u>Rapid responses</u> to Fiona Godlee's <u>editorial</u> announcing the withdrawal of statements suggesting that adverse events occur in 18-20% of patients.

Access the <u>original submission of the article</u> Should people at low risk of cardiovascular disease take a statin? with links to updated versions of it, showing tracked changes, and peer review feedback.

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