

**Malcolm Hooper, Emeritus Professor of Medicinal Chemistry  
2, Nursery Close, Sunderland, SR3 1PA**

Dr Stuart Spencer  
Executive Editor (Head of Fast Track Team)  
The Lancet  
32 Jamestown Road  
LONDON  
NW1 7BY

28<sup>th</sup> March 2011

Dear Dr Spencer

**COMPLAINT WITH REFERENCE TO FAILURE TO FULFIL ETHICAL DUTIES WITH REGARD TO  
THE PREPARATION AND PUBLICATION OF ARTICLES ON "PACE" TRIAL PUBLISHED ONLINE  
ON 18<sup>TH</sup> FEBURARY 2011**

I am writing to draw to your attention to a number of apparent failures to observe the relevant professional ethical codes in connection with the production and publication of the above article, and to seek an investigation of the matters set out in my attached report.

The report raises a number of questions concerning possible breaches of research and publication ethics in relation to the conduct, reporting, and publication of the above trial and the presentation and publication of the associated Comment.

In my opinion, the material presented in the attached report demonstrates that an in-depth, independent, evidence-based review by The Lancet editorial staff is indicated.

I ask that, in order to prevent iatrogenic harm to people with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), the article itself and the Comment be urgently retracted pending the outcome of such a review.

With specific reference to Elsevier Ethical Guidance policy, there would appear to be breaches of the **Ethical Duties of Authors** in relation to:

- **Reporting Standards:** *Authors of reports of original research should present an accurate account of the work performed as well as an objective discussion of its significance. Underlying data should be presented accurately in the paper. Fraudulent or knowingly inaccurate statements constitute unethical behaviour and are unacceptable. Review and professional publication articles should also be accurate and objective*
- **Fundamental Errors in Published Works:** *If the editor or the publisher learn from a third party that a published work contains a significant error, it is the obligation of the author to promptly retract or correct the paper or provide evidence to the editor of the correctness of the original paper*

- **Disclosure and Conflicts of Interest:** *All authors should disclose in their manuscript any financial or other substantive conflicts of interest that might be construed to influence the result or interpretation of their manuscript*
- **Ethics in Publishing: Instructions to Authors:** *Ethics and Procedures (General): Fundamental Principles: the paper should....be placed in the context of prior and existing research*

With specific regard to the review article **Ethical Duties of Reviewers**, I ask The Lancet to consider whether the relevant criteria have been met:

- **Standards of Objectivity:** *reviews should be conducted objectively*
- **Disclosure and Conflict of Interest:** *Reviewers should not consider manuscripts in which they have conflicts of interest resulting from competitive, collaborative, or other relationships or connections with any of the authors, companies or institutions connected to the paper.*

Several of the requisite criteria set out in the **Elsevier Publishing Ethics Resource Kit (PERK)** may have been violated. In particular, there would appear to be issues with regard to:

- **Research Error and Fraud (PERK 5):** *Fraud is publishing data or conclusions that were not generated by experiments or observations, but by data manipulation or invention. Changing the data measurements to conveniently fit the desired end result is fraud, but excluding inconvenient results is deliberate research error, which, in effect, is the same result – fraud*
- **Research Standards Violations (PERK 6):** *Research standards violations normally come to light when a referee sees that there was no informed consent on human subjects ...*
- **Undisclosed Conflicts of Interest (PERK 7):** *Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion*
- **Reviewer Bias (PERK 8):** *Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest, ... Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it to be appropriate. As in the case of authors, silence on the part of reviewers concerning potential conflicts may mean either that such conflicts exist that they have failed to disclose, or that conflicts do not exist. Reviewers must therefore also be asked to state explicitly whether conflicts do or do not exist.*

My appraisal of these documents in relation to the published PACE Trial article strongly suggests that the Elsevier policy on retraction/replacement of published articles is pertinent:

- **Article Retraction: Infringements of Professional Ethics Codes** would include the **Declaration of Helsinki**, which states: *Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.*
- **Article Replacement:** *Identification of false or inaccurate data that, if acted upon, would pose a serious health risk.*

I note that the Elsevier journals group, to which the Lancet belongs, appears to set high store by publishing ethics, acknowledging that: *The publication of an article in a peer-reviewed journal is an essential building block in the development of a coherent and respected network of knowledge. It is a direct reflection of the quality of the work of the authors and the institutions that support them.*

I further note that all Elsevier journals are members of the Committee on Publication Ethics (COPE) which provides resources to support the investigation of and response to possible breaches in research and publication ethics.

In so far as investigation of any failure of the editorial process may fall within the remit of The Lancet Ombudsman, I bring to your attention the fact that the present incumbent, Professor Charles Warlow, is conflicted since he has previously collaborated with one of the authors of the PACE article, Professor Michael Sharpe. This has been confirmed by a Lancet editor with whom contact has been made.

I am aware that this complaint cannot be investigated unless the corresponding author and the funding institutions are informed, with which I concur.

I request that your prompt response be sent to my home address, but in the meantime, given the over-riding public interest, I reserve the right to place this full complaint in the public domain within a reasonable time.

Yours sincerely,

Malcolm Hooper  
Emeritus Professor of Medicinal Chemistry  
University of Sunderland

cc. Erik Engstrom, CEO, Reed Elsevier, 1-3 Strand, London WC2 5JR

