

11 CARSICK VIEW ROAD  
SHEFFIELD  
S10 3LZ

Professor John A Eisman  
Editor-in-Chief  
Journal of Bone and Mineral Research  
3209 Guess Road, Suite 201  
Durham  
NC 27705, USA

1 May 2006

**Re: Procter and Gamble publications misconduct**

Dear Professor Eisman

Procter and Gamble last week provided to me the raw data underlying both abstracts, several draft publications and all statistical reports written in my name, including the key data underlying the Eastell 2003 paper in JBMR (2003;18-6:1051-1056). It is regrettable that JBMR did not itself press Procter and Gamble to do so.

Unfortunately you have again not replied to questions that would allow me to make a confident submission of the science to JBMR. I and others have carefully reread the unusual editorial correspondence from JBMR over two years. There is a general feeling that JBMR have not acted appropriately and have not helped the matter. I attach some of this unanswered correspondence and concerns for the record.

The data now obtained shows convincing evidence of incorrect analysis/scientific fraud apart from the ethical issues relating to withholding of data by a sponsor. It is for example clear that a) there is no plateau in the response curve for NTX as repeatedly asserted in the opaque statistics we encountered. It is for example clear that b) all graphs had been drawn with scales which encompassed less than 60% of the data as I had suspected. It is the case for example c) that in one abstract (Blumsohn et al., JBMR 2003: Relationship of Early Changes...The HIP study) and in the associated draft publications it was stated that:

*"there was little further improvement in fracture benefit below a decrease of 30-35% for NTX" and "Consistent with findings from the VERT trial, a non-linear function was more appropriate than a linear function for modeling the relationship between early changes in NTX and vertebral fracture risk over 3-years (5mg Risedronate, p=0.008). There was little further improvement in fracture benefit below a decrease of 30 to 35% for NTX."....In conclusion, .....there may be a level of bone resorption reduction below which there is no further fracture benefit. Key Message: The relationship between early changes in NTX and longer term fracture risk for 5mg Risedronate is non-linear (p=0.008), consistent with findings from the VERT trial."*

Nothing could have been further from the truth. In this subset of the data there was not a single incident vertebral fracture in any of the patients with NTX responses greater than 64%, comprising 37% of this cohort (all would have been outwith the scale of the plots as constructed). These are simple facts. There are many other discordances. The report by Professor Martin Bland was correct since the subset of randomization and event codes from the three key registration trials assessed by him (which P&G claim I stole from them) have been confirmed as correct. You declined to access this report.

Procter and Gamble agreed that the correct study findings should be published. After careful consideration I have decided not to submit this to JBMR given the absence of trust. I will instead submit the main manuscript relating to the science and some aspects of the research process to JAMA and/or the Lancet in the first instance.

You stated that it is not the job of a Journal to "investigate". I agree that a Journal is not an investigatory body, but editors do carry responsibilities. The Journal should for example have tried to ensure that any contemplation of obvious ethical principles are carried out in a plausible manner (addressing the correct question for example) and is not guided by those accused of misconduct or of cover-up.

More importantly, many aspects of this problem were directly editorial. For example, there is abundant evidence that the first author and at least one other academic author of Eastell et al 2003 (J. Bone Miner Res. 2003;18(6):1051-1056) did not have unfiltered access to any relevant raw data before, during or after submission of this paper, or when it was previously submitted to the Lancet. Published declarations to the journal were false. Professor Eastell has stated as much in response to the General Medical Council, in correspondence and in conversation with colleagues. He himself attempted to access this data from P&G but stated that it was not provided. This was repeatedly rationalized (as late as December 2005) on the odd basis that PHrMA guidelines specify that "*there should be no access to data for investigators*" (Appendices). Statements regarding conflicts of interest in this paper were also obviously untrue. Delmas and Garnero clearly have conflicts of interest, and one author (RH) who declared no conflict was receiving 100% salary funding from Procter and Gamble. Given that this paper carried the same statistical problems these are relevant conflicts. With all due respect, these are editorial matters.

Pending your explanation as to how I can reference material relating to the research process (per your previous statements that JBMR will not review any material related to these editorial matters because of the unspecified legal issues) I also wish to submit a fully explanatory letter of withdrawal to JBMR. It is perfectly right that the company can respond to properly written and referenced communication. These references may have to be to online documents or documents on file, and would quote directly in detail from these documents. Your response regarding this and other communications would be appreciated.

Yours Sincerely



Dr Aubrey Blumsohn

**Enclosures on following pages**

-----  
From: Aubrey Blumsohn <[blumsohn@btinternet.com](mailto:blumsohn@btinternet.com)>  
To: "Adrienne Lea" <[adrienne@jbmr.org](mailto:adrienne@jbmr.org)>, 'John Eisman'  
<[j.eisman@garvan.org.au](mailto:j.eisman@garvan.org.au)>, "'Lorenzo, Joseph'" <[JLorenzo@nso2.uchc.edu](mailto:JLorenzo@nso2.uchc.edu)>  
CC: [allEmaillist@thejabberwock.org](mailto:allEmaillist@thejabberwock.org)  
-----

Date: Friday, April 7, 2006 1:07:09 PM  
Subject: From Drs. Eisman and Lorenzo  
Attachments: <none>  
MessageID: <[15310523541.20060407130709@btinternet.com](mailto:15310523541.20060407130709@btinternet.com)>  
-----

Dear Professor Eisman

Thank you very much for this response. It bears no relation to my concerns (reproduced yet again below). You mentioned "significant legal issues" (which would influence what I write), yet refuse to tell me what these are. You have failed to let me know as Editor how you (or reviewers) will examine such submissions if you are unwilling to examine referenced material. You have failed as Editor to answer questions about conflicts of interest involving yourself, JBMR or ASBMR.

This really is not plausible.

Aubrey Blumsohn

==== Previous letter =====  
Dear Professor Eisman

Thank you. I did not say this.  
I simply explained why there will be a delay.

Again, I would appreciate it if you would answer the three questions I asked on 1 March, and the one from my last letter. I will repeat these for your convenience:

"I would appreciate some explanation as to

a) the nature of the "significant legal issues" you mention, and

b) an assessment as to the conflicts of interest which you feel you and the society might have in this matter and

c) I would also appreciate an explanation as to how you would propose to examine any repeat statement of concern if you are unwilling to examine materials sent to you.



01 March 2006

Professor John A Eisman  
Editor-in-Chief  
Journal of Bone and Mineral Research  
c/o Managing Editor: Amber Williams  
3209 Guess Road, Suite 201  
Durham  
NC 27705, USA

Dear Professor Eisman

Thank you for your letter. I had asked for space in your journal to withdraw my commitment to these two abstracts about Actonel, and to discuss procedural problems and misleading declarations by authors. I would not make this request if I were not convinced that the issues are serious. I have provided you materials germane to the editorial issue at hand. Editors cannot in my view simply refuse to look at evidence of editorial problems on the basis of unspecified "significant legal issues". The company has admitted that data in the abstracts is incorrect, and it is also clear that the 2003 paper has significant problems.

In your last communication you asked (indeed insisted) that you and your legal advisers would choose the phraseology I must use. Your selected phrasing does not allow any mention of the reasons for these concerns. You ask me to sign this content-free letter as if it were written by me, and then suggest allowing rebuttal by the pharmaceutical sponsor. This is inappropriate. I cannot imagine what readers would make of such a withdrawal or any "rebuttal" from the company. Do you wish to prevent the publication of this correction or prevent your readership learning the reasons for it?

Since I know the journal as a valuable, professional resource, I assume your policy is driven by fear of legal action involving the journal, or conflicts of interest involving the

ASBMR, JBMR or editorial staff. I do understand the dilemma this creates for you and I regret that you might perceive me as being, in any way, the agent of such difficulties.

You previously said that you would assess the evidence only with the consent of the pharmaceutical sponsor, and that you would ask for such consent. I have never come across a situation where a party accused of improper conduct can end the matter simply by refusing to consent to have its actions examined. Nevertheless, since you have not mentioned this again, I presume that consent was refused.

I find the situation that has evolved increasingly incredible. I will of course be submitting a proper letter to you as Editor with content which I will ask you not to remove this time. The pharmaceutical company may of course respond to such a letter as would be usual. I cannot understand why you would respond any differently to a repeat letter but I will certainly try.

In the meantime, I would appreciate some explanation as to a) the nature of the "significant legal issues" you mention, and b) an assessment as to the conflicts of interest which you feel you and the society might have in this matter and c) I would also appreciate an explanation as to how you would propose to examine any repeat statement of concern if you are unwilling to examine materials sent to you.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'A. Blumsohn', with a long horizontal flourish extending to the right.

Dr Aubrey Blumsohn MBBCh, BSc(hons), MSc, PhD, MRCPATH  
Senior Lecturer in Metabolic Bone Disease  
Honorary Consultant in Metabolic Bone Disease  
University of Sheffield and Sheffield Teaching Hospitals

-----  
From: Aubrey Blumsohn <[blums@btinternet.com](mailto:blums@btinternet.com)>  
To: Adrienne Lea <[adrienne@jbmr.org](mailto:adrienne@jbmr.org)>, Amber Williams <[amber@jbmr.org](mailto:amber@jbmr.org)>, [heather@jbmr.org](mailto:heather@jbmr.org)  
CC: [journal@jbmr.org](mailto:journal@jbmr.org)

Date: Sunday, September 11, 2005 7:15:02 AM  
Subject: JBMR Probity  
Attachments: 1.eml, 2.eml, 3.eml, 4.eml, 5.eml, 6.eml, 7.eml, 8.eml, 9.eml, 10.eml, 11.eml, 12.eml, 13.eml, 14.eml, 15.eml  
MessageID: <[1811585879.20050911071502@btinternet.com](mailto:1811585879.20050911071502@btinternet.com)>  
-----

Dear Professor Eisman

I must say, I am disappointed in JBMR. I don't know your email address and I have thus addressed to the various Editorial staff who have at various points responded on your behalf.

I wrote first on 24 Nov 2004 raising general concerns about probity of particular publications in JBMR.

I wrote again on 24 Dec 2004, and had a response "I would have to forward your query on to the editor-in-chief to get his view on this".

There was no further promised response for 5 months.

I Emailed and sent a formal letter on 20 May 2005 providing specific details of the publications concerned, and an indication of the problem.

This was acknowledged by the editorial office. "Your letter raises some very important concerns and we are following up with ASBMR staff and the Editor in Chief in order to get a proper response for you."

On 6 June I received correspondence about a promised conference call to discuss the matter.

There was a trail of correspondence with repeated enquiries as to why there was delayed or no response to the planned date for the promised telephone call. The last correspondence was on 13 July:

"Dear Dr. Blumsohn: I just wanted to let you know I am still awaiting word from Dr. Lorenzo's assistant about his available times; I will call her tomorrow if I do not hear from her, and will be back in touch with you. Thanks- Adrienne"

I then heard absolutely nothing.

This trail of correspondence is attached in reverse order.

I am aware that there is some intense politics involved, that you know some of those involved, and there is a suggestion from Markus Seibel that you have had some knowledge of this from third parties. You may have been provided with information to suggest that you should not get back to me.

I can assure you that there is a substantial problem here. Even if you believed what you had been told, I believe that this is inappropriate editorial practice which encourages publication malpractice.

I would appreciate your comment on the procedure.

Kind Regards

Aubrey Blumsohn

--  
/\=====

	Dr Aubrey Blumsohn
	Senior Lecturer in Metabolic Bone Disease
	Bone Metabolism Laboratory
	Human Nutrition Unit
	Division of Clinical Sciences (NGHT)
	Clinical Sciences Centre
	Northern General Hospital, Herries Road
	Sheffield S5 7AU, England
	Email: <a href="mailto:ablumsohn@sheffield.ac.uk">ablumsohn@sheffield.ac.uk</a>
	Tel: 114-2715963(office)
	Sec: Gill Vaughan Tel: 0114 271 5380

\/\=====

-----

6-7 Park Place  
Leeds  
LS1 2RU  
www.rlb-law.com  
Direct Dial +44 (0)113 261 5515

Tel +44 (0)113 234 1220  
Fax +44 (0)113 234 1573  
DX 14086 Leeds Park Square  
info@rlb-law.com  
kate.williams@rlb-law.com

**COPY LETTER**

# RadcliffesLeBasseur

Messrs McKay Law  
Solicitors  
41 St Paul's Street  
LEEDS  
LS1 2JG

9 June 2005

Our Ref: CJW2/MD/900100.8703

Your Ref: SM DO

L 250363 v1

Dear Sirs

**Re: Our Clients - Professor R Eastell**

We act for the Medical Protection Society on behalf of its member Professor Eastell. We have been passed a copy of your letter to Professor Eastell dated 25<sup>th</sup> May, asking for certain raw data underlying certain abstracts, which you identify.

As you say, your client has asked for this information before. But it is not information to which Professor Eastell has access. It belongs to the pharmaceutical companies. As your client knows, Professor Eastell has already requested the data from the Pharmaceutical companies. (Professor Eastell explained this in a letter to your client dated 13<sup>th</sup> December 2004, a copy of which is enclosed). Therefore Professor Eastell regrets that he is unable to help.

Yours faithfully,

**RadcliffesLeBasseur**

**COPY**



**Division of Clinical Sciences (North)  
Academic Unit of Bone Metabolism**

*R Eastell, Professor of Bone Metabolism*

*Research Dean, School of Medicine & Biomedical Sciences*

Northern General Hospy

Herries R

Sheffield S5 7

Tel: (0114) 271 4

Fax: (0114) 261 1

Email: r.eastell@sheffield.a

Web: www.shef.ac.uk/

**RE/GKH**

**13<sup>th</sup> December 2004**

Dr Aubrey Blumsohn  
Senior Lecturer in Metabolic Bone Disease  
Clinical Sciences Centre  
Northern General Hospital  
Sheffield S5 7AU

Dear Aubrey

Re: letter of 8<sup>th</sup> November 2004

Thank you for your letter about the manuscript I have been preparing with Professor Pierre Delmas and Dr Ian Barton. I note from your letter that you would like to be a co-author of this work. I also note that you disagree with the approach we have taken to data analysis. You will realise that when we submit the manuscript to a journal that you will need to sign an authorship agreement form stating that you are in full agreement with the work. If you wish to be a coauthor then you need to work towards a resolution of the issues we described in our letter. We have listened carefully to your concerns, and we feel that we have addressed all of these. We have now prepared several drafts of the manuscript and would like to submit this shortly. Please reassure us that you are prepared to work with us constructively on this manuscript in a timely way. We would like you to respond to this letter within the next month and if you still wish to be a coauthor then we will send you the manuscript for your comments. We would appreciate you giving us your comments in a clear and constructive fashion within a month of us sending you the manuscript.

continued...

- 2 -

You mention the issue of probity and from your previous e-mails I understand that your major concern is that you have not had access to the original data. I have checked with Aventis and with other pharmaceutical companies in the field of osteoporosis for their guidelines to publication. They state that they take the approach described in the PhRMA guidelines and that in these guidelines there is not access to the data (other than those from your centre) for investigators. I think that the approach we have taken for this manuscript of working closely with the statisticians to identify the best approach to analyse the data is an example of best practice, particularly the visit that Ian Barton paid you to go through the data analysis in detail and actually conduct the data analysis during the visit.

Please let us know whether you still wish to be co-author on this manuscript,

Yours sincerely



Richard Eastell  
Professor of Bone Metabolism