MRC Pace trial

This is the letter which was sent by Professor Malcolm Hooper,on the 7th October, to The Rt Hon Dr Vince Cable MP, Secretary of State with responsibility for the Medical Research Council(MRC), relating to the failure of the MRC to respond to his formal complaint on the PACE Clinical Trial, which he first lodged on the 11th February 2010. May be reposted.

The Rt Hon Dr Vince Cable MP
Secretary of State
Department for Business, Innovation and Skills 1, Victoria Street London SW1H 0ET

7th October 2010

By Special Delivery

Dear Dr Cable,

re: Complaint about the MRC PACE Trial on "CFS/ME"

Mindful of your record of commitment to and concern about the serious plight of people with the neuroimmune disorder myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), I ask that in your position as Secretary of State responsible for the Medical Research Council (MRC), you will respond promptly and fully to this letter.

Having received no response from the Medical Research Council to our concerns about the PACE Trial that purports to be studying this disorder, on 11th February 2010 I lodged a detailed complaint with the Minister then responsible for the MRC, The Rt Hon The Lord Drayson, enclosing a bound copy of my 442 page fully referenced report "Magical Medicine: how to make a disease disappear" setting out the evidence that forms the basis of my complaint.

He replied by letter dated 8th March 2010 (his reference being 2010/0013270POLD), advising that I should raise the matter formally with Dr Morven Roberts of the MRC Clinical Trials Unit, which I duly did by letter dated 30th March 2010, with which I enclosed a further bound copy of my report.

I specifically asked Dr Roberts for an informed and considered response and not the standard and dismissive pro forma MRC letter that has been sent to numerous people who have already written to the MRC expressing their concerns about the inappropriateness of the PACE Trial, the false beliefs of the small but influential group of psychiatrists upon which it is predicated, and its very real potential for iatrogenic harm.

My letter and the accompanying report were sent by Special Delivery and were received by the MRC on 1st April 2010, for which the Royal Mail provided a signed receipt.

I did not receive the courtesy of an acknowledgement, so six weeks later, on 18th June 2010, my research assistant telephoned the MRC and asked to speak to Dr Morven Roberts. When my assistant explained that the enquiry related to my formal complaint about the PACE Trial, she was

informed that there was no-one of the name of Dr Morven Roberts in the Clinical Trials Unit and was met with a total refusal to discuss the matter, the MRC employee saying: "I think I'm going to have to put the phone down", which she rudely did. The episode was a quite extraordinary response to a simple and polite request to speak to Dr Morven Roberts in relation to a complaint about an MRC trial.

The following day, Dr Morven Roberts sent me an email (incorrectly addressed to Professor "Cooper") in which she wrote: "I understand you have recently tried to contact me in regard to your complaint lodged with me as Clinical Trials Manager about the PACE Trial. I can let you know that the MRC are working through the large document you have sent and will respond in due course. Morven".

Despite it being over six months since I lodged my complaint and four months since Dr Morven Roberts assured me I would receive a response, I have heard nothing from the MRC. I am sure you will agree that such a delay in such an important matter is unacceptable.

On 5th October 2010, my research assistant telephoned your Department, quoting the reference number on Lord Drayson's letter of 8th March 2010, to seek your personal commitment to pursue this issue as a matter of urgency, only to be informed that there is no record of my complaint as Lord Drayson's reply to me has been lost and that I must start my complaint all over again. She was informed that someone from your office would ring her back that same day; you may not be surprised to know that no-one bothered to do so.

Reasons why this complaint is now urgent

The MRC PACE Trial intentionally used the Principal Investigators' (PIs') own entry criteria for "CFS" (the 1991 Oxford criteria), yet these criteria lack diagnostic specificity, have been shown to have no predictive validity, and select a widely heterogeneous patient population which may or may not include people with true ME/CFS. It is virtually unheard of for studies to use criteria that have been superseded; indeed, one of the PIs himself, Professor Michael Sharpe – who was lead author of the Oxford criteria -- stated in 1997 that they "have been superseded by international consensus" (Occup Med 1997:47:4:217-227).

Of equal concern is the fact that the PIs and other psychiatrists involved with the PACE Trial continue to regard ME/CFS as a behavioural disorder and refuse to engage with the extensive biomedical and scientific evidence that identifies damage, deficits and dysfunction in major bodily systems of patients with ME/CFS, particularly in the neurological, immune, endocrine and cardiovascular systems. For over two decades they have asserted that ME does not exist (and that it is merely an "aberrant belief" that one has a disorder called ME); they equate it with chronic "fatigue", a completely different disorder classified by the WHO as a psychiatric disorder in ICD-10 at F48.0, whilst ME/CFS is classified as a neurological disorder at ICD-10 G93.3.

The potentially harmful results of the PACE Trial for those with ME/CFS are particularly important in the light of the findings of the strong association between ME/CFS and a retrovirus (XMRV) of the same family as HIV/AIDS. The findings of that paper, published one year ago in the journal with the highest impact factor of any scientific journal worldwide (Science 2009:326:585), have been

confirmed and strengthened by further research published in August 2010 in the Proceedings of the National Academy of Sciences (PNAS 10.1073/pnas.1006901107) showing polytropic murine leukaemia virus-related viral sequences (MLV) to be present in the blood of 86.5% of patients studied.

The over-riding international concern is that when the PACE Trial results are eventually published, they will deliver what has long been known to be the PIs' intention and primary objective, ie. the results will confirm the PIs' favoured intervention of "cognitive restructuring" (which incorporates graded aerobic exercise) as the intervention of choice. This is an intervention that is specifically designed to disabuse ME/CFS sufferers of their (correct) perception that they suffer from a serious, multi-system neuroimmune disease.

The cognitive modification is directive, not supportive, ie. it is not offered as adjunctive psychological support for those dealing with a life-wrecking illness because the PACE Trial Manuals claim that it is curative: the chief PI, Professor Peter White, claims that "a full recovery is possible" (Psychother Psychosom 2007:76(3):171-176); the participants' CBT Manual informs people that the PACE Trial therapies are curative, and it is asserted that "many people have successfully overcome their CFS/ME" with such behavioural interventions ("Information for relatives, partners and friends", page 123).

To recommend behavioural modification strategies for those suffering from such devastating organic illness would be inhumane and inexcusable: if such an intervention were to be imposed on those with other neurological diseases (such as motor neurone disease or multiple sclerosis) to force them to change their correct perception that they suffer from a serious organic disorder, it would be roundly condemned as unethical.

You may already be aware that a world expert on both HIV/AIDS and ME/CFS is on record as stating:

"I hope you are not saying that (ME)CFS patients are not as ill as HIV patients.I split my clinical time between the two illnesses, and I can tell you that if I had to choose between the two illnesses I would rather have HIV" (Nancy Klimas, one of the world's foremost AIDS and ME/CFS physicians; Professor of Medicine and Immunology, University of Miami; New York Times, 15th October 2009). In addition, in a radio interview on 19th September 2010, she stated: "…there is a chronic inflammation, neuro-inflammation, and it upsets the whole balance of your systems…the patients become terribly ill…. The immune system is really cranked up; it's a tremendous amount of inflammation. I think that if doctors could get this in their heads that it's sort of like lupus or one of these really inflammatory disorders…it is that level of inflammation. There's a tremendous amount of inflammatory stuff going on, and there's a lot of inflammation in the brain itself" (http://www.litemiami.com/spotlite/index.aspx).

This is important, because the incremental aerobic exercise recommended by the PACE Trial Principal Investigators is contra-indicated in cases of inflamed and damaged tissues and inevitably results in post-exertional relapse with malaise, which is the cardinal symptom of ME/CFS.

Furthermore, in a lecture on 24th April 2010, Anthony Komaroff, Professor of Medicine at Harvard and another world expert on ME/CFS, said on record in answer to the question whether or not he would consider ME/CFS a neurological illness: "…there is now abundant evidence of measurable

abnormalities in the central nervous system and the autonomic nervous system in people with this illness. That makes it neurological…That's why I think it makes sense…to call it Myalgic Encephalomyelitis…because I think those two words adequately classify or describe an underlying biology that tests have shown to be the case" (http://www.masscfids.org/news-a-events/2/221).

As the evidence for retroviral involvement in ME/CFS becomes impossible to dismiss, it becomes paramount to prevent the potentially damaging PACE Trial results from being applied nationally to anyone with the label "CFS/ME" who, given the indisputable heterogeneity of the PACE Trial cohort, may have either chronic tiredness for which psychological interventions may be appropriate or a multi-system neuroimmune disorder for which behavioural modification is contra-indicated.

I trust you will appreciate the gravity and urgency of the current situation that adversely affects an estimated 240,000 people in the UK (for comparison, the Multiple Sclerosis Society estimates that there are 83,000 sufferers in the UK) and that your own involvement will be both prompt and efficacious. The situation is particularly pressing now that people with ME/CFS are embroiled with new legislation that many fear – and some have already found – is threatening to remove state benefits they currently receive that are vital to support their severely sick and damaged lives.

It is completely unacceptable that Dr Roberts and the MRC can be permitted simply to ignore this complaint (which has received worldwide academic attention, comment and support) in order to protect the unsustainable beliefs of a handful of psychiatrists who work for the medical and permanent health insurance industry and the scandalous waste of over £5 million, especially given that the effects of the interventions on over 3,000 patients were already known to be at best ineffective and at worst to be actively harmful in 50% of cases (for references, see "Magical Medicine" -- the copy that was sent to Lord Drayson should still be in your Department but I will provide a further copy if necessary).

I ask that you give this matter your urgent attention; that you will intervene to expedite the promised response from Dr Morven Roberts and that you personally will supervise and approve her response.

Yours sincerely,

Malcolm Hooper

cc. Dr Morven Roberts, Clinical Trials Unit, MRC, 20 Park Crescent, London W1B 1AL