

## **POLICY CHANGE NOW CAMPAIGN: PHASE II**

Emails sent to UK health officials, November 2010

### **Email to Andrew Lansley:**

Rt Hon. Andrew Lansley,

Thank you for taking the time to respond to recent requests from ME sufferers for the government to fund biomedical ME research. I'm pleased you recognise the need for biomedical research in this area and in particular research into the causative factors of ME but feel you have failed to adequately address our concerns.

The recent MRC CFS/ME prioritisation meeting in June 2010, did indeed identify biomedical research topics worthy of prioritisation. However, this is not a new development. Biomedical ME research has been recognised as a high priority for many years. Key issues highlighted in The Gibson enquiry report, published 2006, included the need for: the development of a diagnostic test, research into causes (an underlying theme in each of the hearings), biomedical research, the MRC to commission British versions of international studies (that have identified clear areas for further research), and the MRC to fund an ME programme similar to the AIDS programme (previously funded by the MRC). In 2003 the MRC CFS/ME research strategy consultation recommended key ways forward which included the need for an increase in research funding, for funding to be properly directed and for a shift from psychological to biological and medical research.

Despite this long standing recognition of the need for biomedical ME research, research grant applications in this area continue to be refused and their rejection put down to them failing to meet the MRC's high standards. Between April 2003 and November 2006 alone the MRC turned down 10 biomedical applications relating to ME, stating that they were not of a high enough scientific standard. These included applications under the headings of pathophysiology, genetics, biomarkers, immunology and neuroimaging. Biomedical applications known to have been rejected include those by Professor Jill Belch (herself a Principal Fellow of the MRC) and Dr Vance Spence of Dundee, as well as Dr Jonathan Kerr of St Georges, London.

The following quote further highlights this bias: *"In the UK all ME research is privately funded.. We have no government funding at all for biomedical research.. They say we can't get good grant applications but the scientists they're turning down with good grants applications are the very scientists they're funding with other grants applications (which are also very good). Johnathan Kerr particularly gave me his scores (it's out of ten) nine, nine, three. Guess who gave him the three? And so he'd lost it, not because it's not good quality science but because somebody has said this isn't what I agree with. There's an ideological and political dimension to this."* Professor Malcolm

Hooper, 5th Invest in ME International ME/CFS Conference 2010, plenary session.

Parliament officially recognised ME as a physical illness in a Private Members Bill, *The ME Sufferers Bill*, back in 1988. In 2010 sufferers are still waiting for any significant biomedical ME research to be funded. As Secretary of State for Health will you now ensure that funding for biomedical ME research is ring fenced given the continued bias against support for this type of research? And if not, how else do you propose to tackle this issue and correct the bias?

You also kindly responded to requests for research into the human retrovirus XMRV and its link to ME and accepted that there is a need for further research on the prevalence of XMRV in the UK. However, I feel it is important to recognise that the US research you mentioned has now gone beyond the original study undertaken by the American National Cancer Institute, Cleveland Clinic and the Whittemore Peterson Institute published in the eminent journal *Science*. A follow-up paper, by the US Food and Drug Administration and National Institute for Health, published in *PNAS* August 2010, found sequences of murine leukemia viruses in 85 percent of patients and up to 7 percent of controls. Both lead authors, Dr Harvey Alter (discoverer of the hepatitis C virus) and Dr Shyh-Ching Lo, stated that it confirmed the *Science* paper's results. You chose to refer to an unpublished study that failed to detect XMRV in 540 English blood donors but failed to acknowledge the recent study which successfully detected XMRV in 80 percent of the 50 UK ME sufferers tested (data presented at the NJCFSA Conference, October 2010). Evidence of ongoing viral infection in ME sufferers within the UK has also been shown in research funded by ME Research UK and The Young ME Sufferers (Tymes) Trust, published in the Archives of Paediatrics and Adolescent Medicine, which found abnormalities in the white blood cells of all the children with ME tested.

There are now around 60 people in the UK who have tested positive for XMRV and a further 250 waiting to receive blood test results (via participation in a US research study). Will the Department of Health and/or the NHS confirm whether those infected with XMRV should be following the same universal safety precautions as those infected with the other known human retroviruses, HTLV and HIV?

UK government funded XMRV studies have so far failed to detect XMRV in any of the patients or controls tested, suggesting that the testing methods being used may not be adequate. Will a new UK XMRV study be commissioned, as soon as the US blood working group standardises testing methods, in order to properly assess its prevalence in both ME sufferers and the general population?

In the light of the strong evidence of a retroviral link to ME, sufferers remain confused by the reasons given for the recent blood ban and the assertion that this is now necessary to protect donor health. This confusion has been compounded by contradictory information from NHS Blood and Transplant (NHSBT):

*“The reasoning behind the introduction of the deferral of donors who are suffering from ME/ Fibromyalgia is two fold. Firstly the protection of the donors health.. Secondly there is a theory of a post viral cause and we are following the lead of the USA in researching the possibility of spread of such viruses via blood transfusion. Hence the second reason is for the protection of the recipient.”* Response to email inquiry, 26th October 2010.

Is the second reason given in this response from NHSBT incorrect? If you maintain that the blood ban is entirely due to new concerns for donor health and is not to ensure recipient safety, what new evidence has come to light to initiate this change in policy?

Also, since the implementation of the blood ban on the 1st of November it has become clear that the blood services are failing to fully implement it. As recently as last week the person on duty at a donation venue admitted to not knowing anything about ME or CFS affecting a person’s ability to donate, the donor form also failed to mention ME or CFS. This is particularly worrying due to the number of individuals who have fully or partially recovered from ME. Currently, it seems the only people who are aware of this blood ban are those active in campaigning for ME and/or those who follow ME news and research closely. This is not the case for the vast majority of people who are healthy enough to consider donating blood. What steps have been taken to ensure donors, who have had a diagnosis of ME, do not continue to give blood? What, if any, action will be taken when cases of the blood ban not being enforced are reported to NHS Blood and Transplant?

Yours sincerely,

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**Email to Sir John Savill:**

Sir John Savill,

Thank you for taking the time to respond to recent requests from ME sufferers for the MRC to fund biomedical ME research. I’m pleased you recognise the need for biomedical research in this area and in particular research into the causative factors of ME but feel you have failed to adequately address our concerns.

The recent MRC CFS/ME prioritisation meeting in June 2010, did indeed identify biomedical research topics worthy of prioritisation. However, this is not a new development. Biomedical ME research has been recognised as a high priority for many years. Key issues highlighted in The Gibson enquiry report, published 2006, included the need for: the development of a diagnostic test, research into causes (an underlying theme in each of the hearings), biomedical research, the MRC to commission British versions of international studies (that have identified clear areas for further research), and the MRC to fund an ME programme similar to the AIDS programme (previously funded by the MRC). In 2003 the MRC CFS/ME research strategy consultation

recommended key ways forward which included the need for an increase in research funding, for funding to be properly directed and for a shift from psychological to biological and medical research.

Despite this long standing recognition of the need for biomedical ME research, research grant applications in this area continue to be refused and their rejection put down to them failing to meet the MRC's high standards. Between April 2003 and November 2006 alone the MRC turned down 10 biomedical applications relating to ME, stating that they were not of a high enough scientific standard. These included applications under the headings of pathophysiology, genetics, biomarkers, immunology and neuroimaging. Biomedical applications known to have been rejected include those by Professor Jill Belch (herself a Principal Fellow of the MRC) and Dr Vance Spence of Dundee, as well as Dr Jonathan Kerr of St Georges, London.

The following quote further highlights this bias: *"In the UK all ME research is privately funded.. We have no government funding at all for biomedical research.. They say we can't get good grant applications but the scientists they're turning down with good grants applications are the very scientists they're funding with other grants applications (which are also very good). Johnathan Kerr particularly gave me his scores (it's out of ten) nine, nine, three. Guess who gave him the three? And so he'd lost it, not because it's not good quality science but because somebody has said this isn't what I agree with. There's an ideological and political dimension to this."* Professor Malcolm Hooper, 5th Invest in ME International ME/CFS Conference 2010, plenary session.

Parliament officially recognised ME as a physical illness in a Private Members Bill, *The ME Sufferers Bill*, back in 1988. In 2010, despite the fact that ME has been a priority for the MRC for a number of years, sufferers are still waiting for any significant biomedical ME research to be funded. I am pleased to hear you say that the MRC is actively looking for ways to ensure the expert group's recommendations are taken forward, but after decades of waiting do not feel reassured by this statement. What steps is the MRC planning to take to tackle this issue and correct the bias against biomedical ME research? Will funding for biomedical ME research now be ring fenced? And if not, how else do you propose to tackle this issue and correct the bias?

You also kindly responded to requests for research into the human retrovirus XMRV and its link to ME. I feel it is important to recognise that XMRV research has now gone beyond the original study undertaken by the American National Cancer Institute, Cleveland Clinic and the Whittemore Peterson Institute published in the eminent journal *Science*. A follow-up paper, by the US Food and Drug Administration and National Institute for Health, published in *PNAS* August 2010, found sequences of murine leukemia viruses in 85 percent of patients and up to 7 percent of controls. Both lead authors, Dr Harvey Alter (discoverer of the hepatitis C virus) and Dr Shyh-Ching Lo, stated that it confirmed the *Science* paper's results. Another recent study successfully detected XMRV in 80 percent of the 50 UK ME sufferers tested (data presented at the NJCFSA Conference, October 2010). There are now

around 60 people in the UK who have tested positive for XMRV and a further 250 waiting to receive blood test results (via participation in a US research study). Despite this all UK government funded XMRV studies have so far failed to detect XMRV in any of the patients or controls tested, suggesting that the testing methods being used may not be adequate. Will a new UK XMRV study be commissioned, as soon as the US blood working group standardises testing methods, in order to properly assess its prevalence in both ME sufferers and the general population?

Yours sincerely,

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**Email to Dame Sally Davies:**

Dame Sally Davies,

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Parliament officially recognised ME as a physical illness in a Private Members Bill, *The ME Sufferers Bill*, back in 1988. In 2010 sufferers are still waiting for any significant biomedical ME research to be funded. As Chief Medical Officer of the Medical Research Council will you now ensure that funding for biomedical ME research is ring fenced given the continued bias against support for this type of research? And if not, how else do you propose to tackle this issue and correct the bias?

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