POLICY CHANGE NOW CAMPAIGN: PHASE III

You don't need to have participated in previous campaigns or be a UK resident to take part. This campaign runs for a fortnight 20th January -3rd February.

Task: Send each email to the corresponding UK health official.

STEP ONE

Send the following to Andrew Lansley, Secretary of State for Health, at both of the following email addresses: **lansleya@parliament.uk** and **dhmail@dh.gsi.gov.uk**

Dear Rt Hon. Andrew Lansley,

Thank you for your response to emails sent by ME sufferers as part of the patient driven Policy Change Now campaign. The main issues raised were the continued lack of funding for biomedical research; the state of UK based XMRV research; and the recent life time blood ban.

You stated that *"The stark differences in prevalence of apparent infection seen globally.. are unlikely to be solely the result of different methodologies."* On what evidence has this assertion been made? Sample preparation and assay development have been key issues for the US Blood Working Group precisely because of the extreme likelihood that differing methodologies are the cause of these discrepancies.

Also you stated that *"Officials are assured that detection of the XMRV genome based on amplification of the number of copies present (PCR) is widely regarded as the best and most sensitive method available for this purpose."* From whom has the government received this assurance? Scientists in this field widely regard PCR to be an inadequate means of screening blood for XMRV. *"Negative PCR is not a stand-alone assay for detection of this virus in clinical samples."* Eminent retrovirologist and HIV researcher, Dr Frank Ruscetti (first to isolate HTVL, the earliest human retrovirus known) 1st International XMRV Workshop. This seeming lack of awareness of the facts is worrying and leaves patients to doubt government claims that *"the international published evidence has been fully considered."* I note, and commend, your assurance that the unpublished English donor study was a prelude to further extensive studies, but I am concerned that the application of an antibody test is not considered an essential part of this future research. You stated that *"Further research to develop and apply a test for an antibody to XMRV is being considered"* Can you now confirm whether this research is to go ahead?

The publication *Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome1* gives details on the most accurate

XMRV detection methods, as used by the scientists responsible for the *Science* study. An extract:*"we further detail the multiple detection methods we used in order to observe XMRV infection in our CFS cohort. Our results indicate that PCR from DNA of unstimulated peripheral blood mononuclear cells is the least sensitive method for detection of XMRV in subjects' blood. We advocate the use of more than one type of assay in order to determine the frequency of XMRV infection in patient cohorts in future studies of the relevance of XMRV to human disease."*

Will a UK study which attempts to replicate these techniques now be funded? The claim that recent UK studies, published simultaneously in *Retrovirology,* have found flaws in the previous studies is not accurate. They in no way undermine the conclusions of the *Science* or *PNAS* study as neither relied solely on PCR.

"*The positive studies, which cannot be explained away by PCR experiments, are those which have used multiple methods to show that XMRV is a live replicating gamma retrovirus in human blood and tissue samples using the gold standard methods of viral isolation and antibody testing, in addition to PCR.*

Most significantly, the recent Retrovirology publications failed to address the most important pieces of scientific evidence of human infection in the previous XMRV studies, including the fact that XMRV positive patients produce human antibodies to gamma retroviruses, XMRV integrates into human tissues, and infectious virus has been cultured from the blood of hundreds of patients with a diagnosis of Chronic Fatigue Syndrome and M.E" WPI Press Release.2

As it appears, those responsible for advising the British government believe these studies have definitively proved XMRV does not cause ME/CFS, cannot infect humans, and is not an infectious virus but a laboratory contaminant. Can you please clarify the current government stance on XMRV and its potential role in human disease in light of these recent UK publications? Are further studies still to be funded and the blood screened with more effective tests?

While there is at present no accepted causal role for XMRV in human disease, I cannot agree that *"the international published evidence does not currently support concerns about a risk to the safety of the blood supply."* This statement is concerning as it appears to completely disregard every study that has successfully detected XMRV in healthy blood donors and controls, and suggests that the UK is basing its strategy on its own studies alone. I understand that the government does not wish to cause public panic over this newly discovered human retrovirus at a time when no causal role for XMRV in human disease has been proven and current testing techniques are unable to screen XMRV from the blood supply, but patients and their families are already extremely concerned by this pathogen and its spread.

I feel the following question, which was left unanswered by your representative, is an important one; can you please address this? *Will the*

Medical Research Council provide guidance on 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?

I understand and appreciate the way scientific studies are generally funded by the MRC, and that it is not usual practice to ring fence funds for expenditure on particular topics, but is the situation with ME/CFS not an unprecedented one that requires assertive action? There is an acute need for research into this disease, largely due to the remarkable lack of funding to date. No significant disbursement has ever gone into funding biomedical research into ME and yet this debilitating disease afflicts an estimated 250,000 people in the UK. More than 70,000 are so ill that they are bed bound and require round-the-clock care. It is the leading cause of long term absence from school and the cost to the nation was estimated by *Action for ME* to be £3.5 billion a year in 2003 and £6.4 billion a year in 2006. What will the cost be today? Can the government afford not to ensure biomedical ME research is funded?

I am pleased that in your last message, received in November, you stated that the *"MRC is now preparing to take forward the recommendations resulting from the work of the MRC Expert Group on CFS/ME and issues and priorities discussed at a CFS/ME Research Prioritisation Meeting in June 2010."* This clearly indicates to sufferers that a new approach will now be taken. Can you please give details on the progress the MRC has now made or a time frame for when we can expect results? Will the DOH or MRC now keep patients and patient groups fully informed of all actions taken and progress made in this area? A simple mailing list akin to the NIH ME/CFS Working Group LISTERV would be most helpful and greatly appreciated.

Thank you for contacting NHSBT and clearing up the confusion over why ME patients have acquired a life time blood ban. You've made it clear that while JPAC initiated the review, after concerns over XMRV were raised, the blood ban is for donor safety alone and that NHSBT was wrong to state otherwise and also incorrect in stating that Fibromyalgia sufferers were included in the ban. However, I am disappointed that you failed to clarify the specific reasons for the blood ban as requested. Am I to understand that no new evidence of a risk to patient health has been uncovered? And if this is the case, why wasn't the risk to ME donor health acted on sooner?

Thank you for confirming that NHSBT has issued a further notice to all staff alerting them of the blood ban. However, the reliance on current health questions in screening out ME sufferers remains a cause for concern. People in the UK with a diagnosis of ME or CFS are routinely told by the medical profession that they do not have a serious medical condition, are refused hospital investigations, and the tests which are available to them on the NHS rarely show abnormalities. They are also unlikely to disclose their condition unless asked directly due to the unfavourable reactions and disbelief they often receive from medical staff. Is the introduction of a direct question being considered? And if not, what checks have lead officials to believe this is not necessary?

Finally, I'd like to request that the Department of Health send a representative to the 6th Annual Invest in ME International Biomedical Conference due to be held in Westminster on the 20th of May 2011. The conference provides a unique opportunity to confer with leading experts, review the latest research, and instigate scientific collaboration. The Department of Health has been invited to send a representative every year but failed to do so, I hope that this year will be different and the department will make use of the opportunity to further understanding and research in the UK.

Yours Sincerely,

1. *http://www.ncbi.nlm.nih.gov/pubmed/21178474*

2. http://www.wpinstitute.org/news/docs/WPI_XMRV_010111.pdf

STEP TWO

Send the following to Dame Sally Davies, Chief Medical Officer for the Department of Health, at **CMOweb@dh.gsi.gov.uk**

Dear Dame Sally Davies,

I was disappointed by the inadequate response made by your representative to the email sent by many concerned ME sufferers. The email was sent as part of the patient driven Policy Change Now campaign and raised valid concerns over the continued lack of funding for biomedical research; the state of UK based XMRV research; and the recent life time blood ban.

While your representative replied with a short standard email, that had already been received in response to previous emails and provided no further information, sufferers did receive a more helpful reply on behalf of Andrew Lansley. The response stated that *"The stark differences in prevalence of apparent infection seen globally.. are unlikely to be solely the result of different methodologies."* On what evidence has this assertion been made? Sample preparation and assay development have been key issues for the US Blood Working Group precisely because of the extreme likelihood that differing methodologies are the cause of these discrepancies.

It was also stated that *"Officials are assured that detection of the XMRV genome based on amplification of the number of copies present (PCR) is widely regarded as the best and most sensitive method available for this purpose."* From whom has the government received this assertion? Has this assurance come from the MRC? Scientists in this field widely regard PCR to be an inadequate means of screening blood for XMRV. *"Negative PCR is not a stand-alone assay for detection of this virus in clinical samples."* Eminent retrovirologist and HIV researcher, Dr Frank Ruscetti (first to isolate HTVL, the earliest human retrovirus known) 1st International XMRV Workshop. This seeming lack of awareness of the facts is worrying and leaves patients to doubt government claims that *"the international published evidence has been fully considered."*

Patients were assured that the unpublished English donor study was a prelude to further extensive studies and told that *"Further research to develop and apply a test for an antibody to XMRV is being considered"* I am concerned that the application of an antibody test is not considered an essential part of this future research. Can you now confirm whether this research is to go ahead?

The publication *Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome1* gives details on the most accurate XMRV detection methods, as used by the scientists responsible for the *Science* study. An extract: *"we further detail the multiple detection methods we used in order to observe XMRV infection in our CFS cohort. Our results indicate that PCR from DNA of unstimulated peripheral blood mononuclear cells is the least sensitive method for detection of XMRV in subjects' blood. We advocate the use of more than one type of assay in order to determine the frequency of XMRV infection in patient cohorts in future studies of the relevance of XMRV to human disease."*

Will a UK study which attempts to replicate these techniques now be funded? The claim that recent UK studies, published simultaneously in *Retrovirology,* have found flaws in the previous studies is not accurate. They in no way undermine the conclusions of the *Science* or *PNAS* study as neither relied solely on PCR.

"*The positive studies, which cannot be explained away by PCR experiments, are those which have used multiple methods to show that XMRV is a live replicating gamma retrovirus in human blood and tissue samples using the gold standard methods of viral isolation and antibody testing, in addition to PCR.*

Most significantly, the recent Retrovirology publications failed to address the most important pieces of scientific evidence of human infection in the previous XMRV studies, including the fact that XMRV positive patients produce human antibodies to gamma retroviruses, XMRV integrates into human tissues, and infectious virus has been cultured from the blood of hundreds of patients with a diagnosis of Chronic Fatigue Syndrome and M.E" WPI Press Release.2

As it appears, the UK scientists responsible for these studies believe they have definitively proved XMRV does not cause ME/CFS, cannot infect humans, and is not an infectious virus but a laboratory contaminant. Can you please clarify the current government stance on XMRV and its potential role in human disease in light of these recent UK publications? Are further studies still to be funded and the blood screened with more effective tests?

While there is at present no accepted causal role for XMRV in human disease, I cannot agree with the statement made that *"the international published evidence does not currently support concerns about a risk to the safety of the blood supply."* This statement is concerning as it appears to completely disregard every study that has successfully detected XMRV in healthy blood donors and controls, and suggests that the UK is basing its

strategy on its own studies alone. I understand that the government does not wish to cause public panic over this newly discovered human retrovirus at a time when no causal role for XMRV in human disease has been proven and current testing techniques are unable to screen XMRV from the blood supply, but patients and their families are already extremely concerned by this pathogen and its spread.

I feel the following question, which was left unanswered by your representative, is an important one; can you please address this? *Will the Medical Research Council provide guidance on 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?*

The ring fencing of funds for biomedical research was also queried. I understand and appreciate the way scientific studies are generally funded by the MRC, and that it is not usual practice to ring fence funds for expenditure on particular topics, but is the situation with ME/CFS not an unprecedented one that requires assertive action? There is an acute need for research into this disease, largely due to the remarkable lack of funding to date. No significant disbursement has ever gone into funding biomedical research into ME and yet this debilitating disease afflicts an estimated 250,000 people in the UK. More than 70,000 are so ill that they are bed bound and require round-the-clock care. It is the leading cause of long term absence from school and the cost to the nation was estimated by *Action for ME* to be £3.5 billion a year in 2003 and £6.4 billion a year in 2006. What will the cost be today?

I was pleased to hear in November that the *"MRC is now preparing to take forward the recommendations resulting from the work of the MRC Expert Group on CFS/ME and issues and priorities discussed at a CFS/ME Research Prioritisation Meeting in June 2010."* Can you please give details on the progress the MRC has now made or a time frame for when we can expect results? Will the DOH or MRC now keep patients and patient groups fully informed of all actions taken and progress made in this area? A simple mailing list akin to the NIH ME/CFS Working Group LISTERV would be most helpful and greatly appreciated.

I am disappointed that the specific reasons for the blood ban have yet to be clarified. Am I to understand that no new evidence of a risk to patient health has been uncovered? And if this is the case, why wasn't the risk to ME donor health acted on sooner? The reliance on current health questions in screening out ME sufferers, who consider themselves well enough to donate, is a cause for concern. There are several reasons why these questions are inadequate in identifying an ME/CFS diagnosis. Patients are routinely told by the medical profession that they do not have a serious medical condition, are rarely sent for hospital investigations, and the tests the NHS do provide rarely show abnormalities. Sufferers are unlikely to disclose their condition unless asked directly due to the unfavourable reactions and disbelief they often receive from medical staff. Is the introduction of a direct question something that is currently being considered? And if not, what checks have lead officials to believe this is not necessary?

Finally, I'd like to request that you attend the 6th Annual Invest in ME International Biomedical Conference due to be held in Westminster on the 20th of May 2011, or send a suitable representative. The conference provides a unique opportunity to confer with leading experts, review the latest research, and instigate scientific collaboration. The Chief Medical Officer has been invited every year but failed to attend; a representative has only ever attended once and for a single morning session. I hope that this year will be different and you will make full use of the opportunity to further understanding and research in the UK.

Yours Sincerely,

1. *http://www.ncbi.nlm.nih.gov/pubmed/21178474*

2. *http://www.wpinstitute.org/news/docs/WPI_XMRV_010111.pdf*

STEP THREE

Send the following to Sir John Savill, Chief Executive of the Medical Research Council, at the following address (which contains his personal assistant's name) **Linda.Willmott@headoffice.mrc.ac.uk**

Dear Sir John Savill,

I was disappointed by the inadequate response made by your representative to the email sent by many concerned ME sufferers. The email was sent as part of the patient driven Policy Change Now campaign and raised valid concerns over the continued lack of funding for biomedical research; the state of UK based XMRV research; and the recent life time blood ban.

While the reply sent on your behalf provided no further information, sufferers did receive a more helpful reply on behalf of Andrew Lansley. The response stated that *"The stark differences in prevalence of apparent infection seen globally.. are unlikely to be solely the result of different methodologies."* On what evidence has this assertion been made? Sample preparation and assay development have been key issues for the US Blood Working Group precisely because of the extreme likelihood that differing methodologies are the cause of these discrepancies.

It was also stated that *"Officials are assured that detection of the XMRV genome based on amplification of the number of copies present (PCR) is widely regarded as the best and most sensitive method available for this purpose."* From whom has the government received this assertion? Has this assurance come from the MRC? Scientists in this field widely regard PCR to be an inadequate means of screening blood for XMRV. *"Negative PCR is not a stand-alone assay for detection of this virus in clinical samples."* Eminent retrovirologist and HIV researcher, Dr Frank Ruscetti (first to isolate HTVL, the earliest human retrovirus known) 1st International XMRV Workshop. This seeming lack of awareness of the facts is worrying and leaves patients to

doubt government claims that *"the international published evidence has been fully considered."*

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As it appears, the UK scientists responsible for these studies believe they have proved XMRV does not cause ME/CFS, cannot infect humans, and is not an infectious virus but a laboratory contaminant. Can you please clarify the MRC's current position on XMRV and its potential role in human disease in light of these recent UK publications? Are further studies still to be funded and the blood screened with more effective tests?

While there is at present no accepted causal role for XMRV in human disease, I cannot agree with the statement made that *"the international published evidence does not currently support concerns about a risk to the*

safety of the blood supply." This statement is concerning as it appears to completely disregard every study that has successfully detected XMRV in healthy blood donors and controls, and suggests that the UK is basing its strategy on its own studies alone.

I feel the following question, which was left unanswered by your representative, is an important one; can you please address this? *Will the Medical Research Council provide guidance on 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?*

The ring fencing of funds for biomedical research was also queried. I understand and appreciate the way scientific studies are generally funded by the MRC, and that it is not usual practice to ring fence funds for expenditure on particular topics, but is the situation with ME/CFS not an unprecedented one that requires assertive action? There is an acute need for research into this disease, largely due to the remarkable lack of funding to date. No significant disbursement has ever gone into funding biomedical research into ME and yet this debilitating disease afflicts an estimated 250,000 people in the UK. More than 70,000 are so ill that they are bed bound and require round-the-clock care. It is the leading cause of long term absence from school and the cost to the nation was estimated by *Action for ME* to be £3.5 billion a year in 2003 and £6.4 billion a year in 2006. What will the cost be today?

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I am disappointed that the specific reasons for the blood ban have yet to be clarified. Am I to understand that no new evidence of a risk to patient health has been uncovered? And if this is the case, why wasn't the risk to ME donor health recognised and acted on sooner? The reliance on current health questions in screening out ME sufferers, who consider themselves well enough to donate, is a cause for concern. There are several reasons why these questions are inadequate in identifying an ME/CFS diagnosis. Patients are routinely told by the medical profession that they do not have a serious medical condition, are rarely sent for hospital investigations, and the tests the NHS do provide rarely show abnormalities. Sufferers are unlikely to disclose their condition unless asked directly due to the unfavourable reactions and disbelief they often receive from medical staff. Given this, and the risk to donor health, will the introduction of a direct question be considered? And if not, what checks have lead officials to believe this is not necessary?

Finally, I'd like to request that a MRC representative attend the 6th Annual Invest in ME International Biomedical Conference due to be held in Westminster on the 20th of May 2011. The conference provides a unique opportunity to confer with leading experts, review the latest research, and instigate scientific collaboration. I hope that the MRC will make the most of this opportunity to further understanding and research of ME.

Yours Sincerely,

1. *http://www.ncbi.nlm.nih.gov/pubmed/21178474*

2. *http://www.wpinstitute.org/news/docs/WPI_XMRV_010111.pdf*

STEP FOUR

Send an email to **ukpolicychange@gmail.com** entitled **Phase III**, no text in the body of the email is required. This step is important as it reveals the number of emails sent, a number which will then be used to inform the government of the level of public concern there is for this issue.

We are not asking people to Bc: or Bcc: ukpolicychange@gmail.com, as in previous campaigns this has lead to emails being caught in spam filters.

The campaign event page can be found here, please invite your friends to join! http://www.facebook.com/event.php?eid=148723758515587&ref=mf

THANK YOU for taking part

the Action Now Team.