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# CJD INCIDENTS PANEL

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CONFIDENTIAL

21st January 2011

Dear Marc

**SNBTS: Positive PMCA result**

I am writing in response to your request for advice on this matter to be considered at yesterday's Panel meeting when Dr Pat Hewitt presented the summary paper dated 15th January 2011 on your behalf. I appreciate the circumstances, but it was unfortunate that this serious and complex set of issues could only be referred to the Panel three days before the meeting.

You have asked the Panel to advise on the management of four donors (and former recipients of their blood) whose blood samples were included among 250 negative controls used in testing the adaptation of the Protein Misfolding Cyclic Amplification assay to peripheral blood. One, unexpected, positive result was found among the 250 controls. The amplicon from the PMCA assay was injected into humanised transgenic mice in April 2010. Although the mouse study will not be complete until 2012, four of the five mice who have died of inter-current illness showed evidence of $PrP^{TSE}$ accumulation in their spleens. It has been possible to deduce that one of a group of four donors donated the blood from which the sample in question was taken. SNBTS is of the view that there is sufficient evidence to justify taking precautionary measures in respect of the four donors, including a request to take further blood samples for repeat testing, at this juncture.

The Panel is of the view that further information is needed from other experts, including the CJD Resource Centre Oversight Committee, about the meaning and interpretation of the test results before advice can be given on the management of the four blood donors. In particular, information is needed about the significance of the observation that the product amplified from PL45 was protease sensitive whereas the product accumulating in the transgenic mice is protease resistant. I am aware that the decision about when to inform the donors about such a sensitive and newsworthy situation may be taken out of your hands and that this may need to be done quickly. The Panel is available to assist with the messages which could be conveyed to both the donors and the media as well as to provide substantive advice on the management of the four donors once more information is available and there has been sufficient time to consider it – possibly at a special meeting.

Ivan GRO-A
GRO-A
assay

The Panel was at pains to focus on the issues in relation to the management of the four donors so as to make the best use of the short time available. However, I have been asked to convey the Panel's concern about certain ethical and governance aspects of the study described in your paper which have given rise to a situation which could have been avoided. As always, the Panel's greatest concern is about the anxiety likely to be caused to the individuals and their families involved, as well as others, when the matter becomes public knowledge. I trust that a local Scottish group will be set up which brings together appropriate agencies to manage all aspects of the situation.

Yours sincerely,

GRO-C

Mr David Pryer
Chairman, CJD Incidents Panel

cc Mr Mark Noterman, Department of Health
Dr Andrew Riley, Scottish Government



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