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THE ROYAL INFIRMARY OF EDINBURGH

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CAL/AT

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LOTHIAN HEALTH
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GM

Mr T Jones
General Manager
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EDINBURGH

Dear Trevor

NEW VARIANT CJD AND THE TREATMENT OF HAEMOPHILIA

Thank you for arranging for me to receive a copy of the letter from Sir David Carter of the 15th December. A number of issues are raised in his letter on which I would like to comment.

Whilst it is almost certainly true that there is a higher viral load for HIV, HBV and HCV in US derived plasma I am not aware of any reliable data indicating "higher transmission rates" for these viruses by the derived concentrates. The current viral inactivation steps used in the manufacture of licenced products are extremely effective against these three viruses. Even if there is a higher contamination rate in the starting plasma these viruses are effectively destroyed and the final products rendered non infectious. It is perhaps worth recalling that the transmission of hepatitis A has been almost exclusively a problem in plasma collected and fractionated in Europe. Furthermore, there was a large outbreak of hepatitis B caused by a coagulation factor concentrate manufactured in Europe recently. I would be interested to know how the Department of Health can "quantify risks" of HIV, HBV and HCV. Against this background I believe there is no evidence to demonstrate that US derived products are less safe from these viruses and that if the Department of Health has such data then it has a responsibility to present it. I, and my colleagues consider it is therefore appropriate to recommend the use of US derived plasma concentrates as opposed to those derived from UK plasma because nv CJD and BSE are almost exclusively UK conditions. As you are aware there is increasing evidence of the infectious agent for nv CJD being carried in the blood. I am therefore of the firm conviction that recombinant factor VIII is indisputably the treatment of choice for haemophilia A and if this is not available the evidence from the epidemiological and animal studies favours the use of US derived plasma concentrates.

Sir David states that "the Government is following SEAC's advice in this area", however Professor John Pattison, Chairman of SEAC, has explicitly stated that the Committee has not offered any advice in relation to the use of coagulation factor concentrates in the treatment of haemophilia. Furthermore, despite repeated requests, the Department of Health for England has not yet been able to indicate the terms of reference for the committee on the "risk assessment" on leukodepletion. Even if the Government decides to introduce leukodepletion this will take possibly up to a year to accomplish. Meanwhile people with haemophilia, if receiving UK derived plasma products, will not only potentially be exposed to the infectious agent for nv CJD in plasma already collected and processed into concentrate, but also from plasma that will be collected over the next year. If leukodepletion is introduced I wonder how good the evidence will be that the plasma is safe from transmitting nv CJD. Animal experimental evidence suggests that prion diseases may be transmissible by blood relatively early in infection and thus if nv CJD is transmissible then it is possible that blood donors may be more infectious now than in a year's time.

Whilst I agree that it would be prudent to wait for further studies, including the risk assessment on leukodepletion, before halting permanently the use of UK plasma derived concentrates, in the short term there are safer alternatives and it is my firm view that Health Boards should make these available to patients.

I note Sir David's concern not to "further increase alarm in the haemophilia community" and I would fully endorse this but from my perception people with haemophilia are increasingly alarmed and frustrated at the inability of purchasers and Government to respond quickly and appropriately to the threat of new potentially transmissible infectious agents.

Yours sincerely

GRO-C

Christopher A Ludlam
Director
Haemophilia and Thrombosis Centre

GRO-C

c.c. Haemophilia Directors in Scotland and Northern Ireland