

**SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE**

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JDC/EP

22nd March 1985

Dr C A Ludlam  
Consultant Haematologist  
Department of Haematology  
Royal Infirmary  
EDINBURGH

Dear Chris

Heat Treated Factor VIII

I was most distressed and surprised to read your letter of the 19th March to Frank Boulton for you indicated at the meeting in the SHHD on 7th March that you were "ready to undertake the much needed clinical studies tomorrow". As you know I have every sympathy with the issue you have raised and hold identical views as yourself on the need for proper compensation arrangements. You will have gathered from the last meeting of the Haemophilia/BTS Directors that I have, over the years, been engaged in much discussion on the matter.

During the meeting on the 7th March I detected for the first time that the climate may now be changing and subsequent investigations have consolidated that view, for the DHSS are now involved. As a consequence I dispatched a letter to the Secretary of the CSA and this has already been lodged in SHHD for their urgent consideration. In the present serious circumstances I believe you should have a copy of this letter but would be grateful if you would treat it as confidential. I send it to you to provide some evidence of the good faith of the SNBTS.

Your decision to hold back your much needed co-operation at this time is likely to have a quite major impact on the medium term supplies of factor VIII for the SHS. Until the arrival of your letter we were utterly relying on this collaboration in terms of our production schedules for 1985/1986 and, moreover, we were assuming that the second generation product would be shown to be biologically and clinically acceptable. As things stand at the moment we envisage that by June/July 1985 the supplies of the first generation product (68°C for 2 hours Dry Heat) will be exhausted - production was stopped in February 1985.

I write, therefore, to request that in the light of the extremely difficult position the SNBTS is now in and the evidence that the compensation issue is being tackled, you reconsider your position and agree to proceed with the requested clinical studies as soon as possible and without referring the matter to the Ethics Committee. There can be no doubt that if this work is not completed by the end of April 1985 then all of us will have to make some major policy decisions, with regard to the immediate dismantling of the batch dedication programme and the planning for supplies beyond June/July 1985.

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Dr C A Ludlam

22nd March 1985

I do hope you will feel able to help.

Kindest regards,

Yours sincerely

John D Cash

Copy to:

Dr Perry

Sc D McIntyre