

EDINBURGH AND SOUTH-EAST SCOTLAND REGIONAL BLOOD TRANSFUSION SERVICE

REGIONAL CENTRE
ROYAL INFIRMARY
EDINBURGH EH3 9HB

FEB/IMCK

4th July 1985.

Dr R J Perry
Director
Protein Fractionation Centre
21 Ellen's Glen Road
EDINBURGH
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Telephones	
PROTEIN FRACTIONATION	
Received: 25 JUL 1985	
File No: 2-46 H1 FVIII	
Refer to	Action: J.B.
DR. R. J. PERRY	
[Handwritten signatures]	

Dear Bob

Please find enclosed a photocopy of a letter and results from Arthur Bloom concerning five patients who received the latest batch of heat treated FVIII.

One of them had inhibitors and therefore did not give meaningful results in terms of a recovery. However, it is interesting that he had no clinical sequelae of any note.

Of the other four, none of them showed any clinically adverse affects, the results when plotted out gave a similar degree of scatter as those observed in study of our own three patients. However, I have plotted them out and taken the liberty of drawing a straight line from the 24 hour point to the origin doing a 'best fit'. My observation may not be the most accurate but I think is reasonably meaningful. Taking this line I get the following values;

██████████	T half, 12.5 hours - recovery 72% of expected.
██████████	T half, 11.5 hours - recovery 158% of that expected.
██████████	T half, 15 hours - recovery 167% of that expected.
██████████	T half, 27.5 hours - recovery 120% of that expected.

As Arthur says in his letter the 24 hour point on ██████████ is possibly erroneous and would affect the T half in particular.

It looks as if there may be a slight over estimate on the percentage recovery. The average is about 130%. This is certainly high but I don't think clinically significant.

1. The first part of the document is a letter from the Director of the National Security Agency to the Secretary of Defense. The letter is dated 10/10/50 and is addressed to the Secretary of Defense, Department of Defense, Washington, D.C. The letter is signed by the Director of the National Security Agency, George A. Black.

2. The second part of the document is a letter from the Secretary of Defense to the Director of the National Security Agency. The letter is dated 10/10/50 and is addressed to the Director of the National Security Agency, Department of Defense, Washington, D.C. The letter is signed by the Secretary of Defense, Louis A. Howe.

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I have replied to Arthur giving him my estimates from his points. I also note that you have written to him concerning the calcium enriched FVIII trials and have commented to him that if he does undertake them he need not feel obliged to do all the samples at all the times suggested in the protocol.

I am also enclosing a copy of Chris Prowse's summary, prepared at the end of May, of our three patients. I am not sure if you have had this before. You will note that in our cases the half life varies between 10 hours and 19 hours (from the best fitting line) and that the recoveries which I think are best expressed in Chris's term 'b/d' in his recovery summary vary between 88% and 110%.

All in all I think the seven patients give an excellent validation of the biological efficacy of the heat treated FVIII both in recovery and half life terms. Haemostatic evaluation can only come about by clinical observation of bleeding tendencies and all I can say is that so far I have had no intimation that the first generation heated treated product is any way clinically 'weaker' than the unheated treated products.

Kindest Regards

Yours sincerely



F.E. Boulton
Deputy Director

Encl.

