

GLS/WH/

29th June 2000

Dr Helena Daly
27 Silver Pines
Brewery Road
Shillogren
Blackrock
Co Dublin
EIRE

Dear Helena

I enclose a short statement which I hope will answer the questions that you have asked. I think it is accurate and derived from records that I have available but I would not be prepared to defend it under oath in a court of law. I am also enclosing photocopies of two letters, one from the Blood Products Laboratory and the other from the Deputy Chief Medical Officer which you might find helpful. Let me know if I can provide any further information.

With best wishes,

Yours sincerely

GRO-C

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Consultant Haematologist

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Haematology Department, Level 8, Bristol Royal Infirmary

GLS/WH/

29th June 2000

Statement re Introduction of Heat Treated Clotting Factor Concentrates into the Bristol Haemophilia Centre

I confirm that I was the Director of the Bristol Haemophilia Centre based at the Bristol Royal Infirmary and Bristol Children's Hospital in 1984 and I remain in this post at the present time. I was not and never have been a Director of the Blood Transfusion Service at Bristol. It was always my policy to use plasma-derived products from English and Welsh donors which were fractionated at the NHS-managed blood products laboratory at Elstree, in preference to commercial products. (Scotland had its own blood transfusion and blood products service). My belief was that the NHS products carried less risk of infection, particularly hepatitis and HIV than commercially derived products from the USA. Allocation of these products was determined by the amount of plasma which was collected by each regional blood transfusion centre, and as the Bristol centre serving the south west regional health authority had a very good record for plasma collection our allocation was above average. Nevertheless it was not sufficient to cover our needs and therefore commercial blood products had to be purchased to make up the deficit. Priority for NHS products was given to children and adults who had previously received little treatment and were known to be hepatitis and HIV negative. I think that my decision was justified by the fact that the incidence of HIV infection amongst haemophiliacs in Bristol was lower than in many other parts of the country.

In late 1984 heat treated commercial products became available but not in sufficient supply to provide our needs. The first heat treated products were received in the Bristol Haemophilia Centre in December 1984. There was discussion amongst haemophilia centre directors and also by the Haemophilia Society although I do not have documentary proof available about whether heat treated commercial products were preferable to NHS products. The efficacy of heat treatment had not been fully established and it was believed by many physicians dealing with haemophilia that NHS concentrates although not heated were preferable.

Heat treated NHS Factor VIII became available in March 1985 although our quota was not sufficient to meet our needs. It was the policy to give heat treated NHS concentrates to children and mildly affected adults who had not received much treatment previously. We continued to use non heat treated NHS product and also heat treated commercial product.

In August 1985 all the NHS product was heat treated. We were asked to return all non heat treated product. We did not keep a large stock nor did any patients but all the patients were asked to return their non heat treated product and it was replaced. The non heat treated product was returned to Elstree. Our allocation was still not enough to meet our needs and therefore commercial heat treated product was used as well. In October 1985 the new NHS intermediate purity heat treated product VIIIY was introduced and from that time it became our major treatment product and commercial Factor VIII was gradually withdrawn.



NHS Factor IX has always been used in the Centre and the supply has always been adequate so that there has been no necessity to purchase commercial product. At the end of October 1985 heat treated Factor IX became available from Elstree, all non heat treated was withdrawn and patients were asked to return their non heat treated material.

GRO-C

Dr G L Scott, MD, FRCP
Consultant Haematologist
Director, Bristol Haemophilia Centre



BLOOD PRODUCTS LABORATORY

National Blood Transfusion Service

Director:
R. S. LANE, MD MRCP MRCPATH

Telephone : 01-953-6191

Dagger Lane,
Elstree,
Borehamwood,
Herts WD6 3BX.

Our Ref.: PI8HT/02

7th February, 1985

Dr. G. L. Scott,
Casualty Department,
Bristol Children's Hospital,
St. Michael's Hill,
Bristol,
BS2 8BJ

Dear Dr. Scott,

Supplies of Heated Factor VIII Concentrates - An Update

As you may have been informed by the Director of your Regional Transfusion Centre, stocks of the heated intermediate purity factor VIII concentrate will be distributed via Transfusion Centres, thereby guaranteeing satisfactory Regional allocation of resources. The first dispatches of concentrate should be possible in late February, and subsequently at monthly intervals.

Each consignment to an RTC will comprise individual packages identified for onward transmission to a designated haemophilia centre director. If you have not already written advising me of the names of patients you wish to treat with the heated NHS concentrate, I would be grateful if you could do so urgently. Without this information it will not be possible for BPL to make a sensible allocation of product within any region.

Several Haemophilia Centre Directors have enquired about the availability of heated factor IX concentrates. Acknowledging the thromboembolic potential of any prothrombin complex concentrate (heated or unheated), BPL are concerned that heated factor IX concentrate should be subjected to extended safety testing, including assessment in a dog model, prior to release for clinical use. This work is progressing and we confidently expect to be in a position to begin general issue of a heated factor IX concentrate during July.

Yours sincerely,

GRO-C

T. J. SNAPE
Head of Quality Control

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JH + 111
→ G.S.

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Dr G L Scott
Department of Haematology
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15 August 1985

Dear Dr Scott

HEAT TREATED FACTOR VIII

In the letter from the Haemophilia Reference Centre Directors to the British Medical Journal on the 22 June it was apparent that at certain Haemophilia Centres Factor VIII concentrate which had not been heat treated was still in use.

I am now writing to give you the latest information of the availability of heat-treated Factor VIII concentrate. The Blood Products Laboratory at Elstree has been heat-treating all their output of Factor VIII concentrate since April this year; whilst there was a period during which only limited supplies were made available, I am pleased to say that output has now been increased to the maximum level possible in the current BPL plant. Until the new BPL plant comes into production later next year, there will continue to be a need to obtain additional supplies of Factor VIII from commercial sources. I am understand that all commercial Factor VIII concentrate now imported into this country is also heat treated. There would thus appear to be no longer any need to use un-heat-treated Factor VIII concentrate.

Yours sincerely

GRO-C

E L HARRIS
Deputy Chief Medical Officer

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