PARLIAMENTARY QUESTION 466 1989/90

Chronology

Notice paper despatched by fax to DoH on Wednesday 29 November 1989:
"The Lord Winstanley - To ask Her Majesty's Government what was the nature and result of the clinical trials into stocks of Factor VIII and Factor IX made by the Blood Products Laboratory at Elstree from unscreened blood donations which was referred to in the answer to Lord Winstanley's question on 18th December 1986 (HL Deb. Col. 345)."

Request for information faxed to CBLA at 17.10 hours on 4 December 1989 with a request for information by midday on 5 December.

Reply from BPL made by fax 11.31 a.m. 5 December 1989.

> Comment: The request from DoH to CBLA was passed to me for answer. The request coincided with a period when my own files were with solicitors as part of the information disclosure procedure involved in HIV litigation. For access to information I was dependent upon Dr. Snape's office. General file documents were provided by Dr. Snape on the evening of 4 December, before he departed for an official visit to Stockholm on 5 December. These files formed the basis of the response made to DoH. This was all that was possible in the time available.

Events and Documents

April 1985:	Heat treated factor 8Y commenced clinical evaluation.
1 September 1985:	8Y became the only available factor VIII product from BPL.
October 1985:	Heat treated factor 9A commenced re-issue for use (see attached Figure A showing the utilisation of BPL factor IX up to 1988).
14 October 1985:	NBTS introduced HIV testing for plasma.
June 1986:	CSM published recommendations on the testing of plasma and products for hepatitis antigen and HIV antibody.
1 June 1986:	BPL fractionated products only from HIV antibody tested plasma. The conversion date for PFL fractionation was slightly delayed but there was no exchange of material between PFL and BPL.
13 June 1986:	CSM recommendations on the status of plasma for fractionation particularly concerned with products other than factor VIII, factor IX and immunoglobulins.
25 June 1986:	CSM recommendations brought to the attention of the Quality Control Department.
16 July 1986:	Response to Dr. Rotblat (CSM) drawing attention to the stockpile of untested NBTS plasma at BPL.
29 July 1986:	Parliamentary Question and answer on the current practices in the UK for factor VIII and factor IX manufacture and plasma status (attached).
1 August 1986:	Status report on BPL products provided to Dr. Smithies, Medicines Division, DHSS (copy attached).

7 August 1986: Internal memorandum from T.J. Snape to me and CBLA reporting meeting with Dr. Smithies and Dr. Moore for discussions on above letter of 1 August (attached).

1 August 1986: Request from Dr. E.L. Harris for all BPL products to be tested at NIBSC for HIV antibody as part of the normal release procedure.

18 December 1986: Parliamentary question from Lord Winstanley and written reply (copy attached with documents referred to on 18 December 1989).

23 December 1986: Following the last PQ, Dr. Smithies requested information about the current status of BPL products setting out the general policy that routine issues would continue to be made from products manufactured from screened donations and setting out the exceptions. (Copy of letter attached.)

8 January 1987: Letter RSL to Dr. Smithies summarising the present position (attached).

29 January 1987: Letter from Dr. Smithies to Dr. Snape, endorsing BPL's proposals for the issue of remaining stocks of products derived from unscreened donations - precise stock positions were despatched to DHSS on 16 February 1987. (Copy letter attached.)

2 February 1989: Letter to Dr. Pickles updating the position with products prepared from unscreened donations issued in accordance with the above letter from Dr. Smithies (attached).

29 November 1989: Parliamentary Question from the Lord Winstanley (attached)

Comment: This is the PQ to which the current concern attaches.

5 December 1989: Draft reply from BPL to the above PQ (attached).

6 December 1989: Further correspondence between DoH and BPL on products from unscreened donations and reply 3 January 1990 (copies attached).

18 December 1989: Parliamentary Question from the Lord Winstanley and attached documents (page 3 of these attachments from Dr. Pickles draws attention to the earlier Parliamentary Question and Answer of 1986: note Dr. Pickles' view of the DoH response - "Last time we gave a weasle reply").

31 January 1989: Current letter from Dr. Pickles, drawing attention to the provision of incorrect information.

Analysis

The issues of BPL factor VIII and factor IX were all on routine issue as heat treated products prior to the commencement of testing of donor plasma for HIV antibody by NBTS in October 1985. In 1986, CSM directives threatened the viability of the FFP stockpile at BPL. However, by June 1986, all fractionation was from screened plasma (50 tonnes of unscreened FFP remains for fractionation for Ministry of Defence).

Parliamentary Question in July 1986 made specific enquiries about the issue of BPL products from unscreened plasma. The Parliamentary Answer was specific and it set out the general objective for all routinely issued BPL products to be prepared from screened plasma by the end of 1986.

It was clear at BPL that certain "orphan" products would be caught by the above requirement, and on 23 December 1986 (copy attached) we set out our position to DoH; after discussion, this received full endorsement from Dr. Smithies for DoH.

BPL practice since then has followed the lines of the proposal set out above and orphan products have been replaced with new material from screened plasma at the earliest practicable moment. The products concerned are heat treated coagulation products which have an intact record of safety against virus transmission; certain specific immunoglobulins for intramuscular use which, on a worldwide basis, have not transmitted HIV or other viruses; special pasteurised albumin products which are also unknown to transmit viruses. In addition, the special coagulation products were issued only to informed clinicians.

By the date of the latest Parliamentary Question, 18 December 1989, all stocks of issuable blood products which might be contaminated with AIDS had been destroyed.

Concerning the Parliamentary Question of 29 November 1989: the PQ, the DoH questions and my answers are set out below.

> Question: The Lord Winstanley - To ask Her Majesty's Government what was the nature and result of the clinical trials into stocks of Factor VIII and Factor IX made by the Blood Products Laboratory at Elstree from unscreened blood donations which was referred to in the answer to Lord Winstanley's question on 18th December 1986 (HL Deb. Col. 345). [29th November]
>
> Action:
>
> i) nature and result of clinical trials of F8 and F9:
>
> Administration of heat treated F8 and F9 prepared from unscreened blood donations was terminated at the end of December 1986. Administration of these products in patients showed no example of sero-conversion to HIV-1 or biochemical evidence of transmission of virus associated with non-A non-B hepatitis: the trial and its subsequent follow-up demonstrated the efficacy of dried heat treatment at 80°C for 72 hours used for all BPL manufactured F8 and F9 issued to NHS patients.
>
> ii) whether any stocks of product from unscreened plasma are still held:
>
> The answer is no.
>
> iii) are they being used in <u>any</u> circumstances?
>
> No.

iv) if not, when were they last used; were they used to exhaustion, still within clinical trial?

The products referred to ceased to be used at the end of December 1986; residual material was withdrawn from use and from stocks.

v) in other circumstances?

None.

You will see under question (iv) that I indicated that the products referred to ceased to be used at the end of 1986, although this specific information was not sought in the PQ itself. Within the time available, this was the best information I could transmit: you will appreciate that in the latter half of 1986, batch records were in a transitional state depending on source plasma type. Subsequently, it was brought to my attention that factor IX batches 9A 3411 and 9A 3361 continued issue into the beginning of 1987. 9A 3411 commenced issue on the 15th December with the last issue on the 5th February 1987: 9A 3361 was a special issue batch of low potency supplied with a covering advice note to clinicians - first issue was 22.10.86 with last issue 22.4.87. This information about factor IX surfaced as a result of enquiries in connection with the HIV litigation process but, in response to Dr. Pickles' request of 6 December 1989, I had no reason but to report the facts in my letter of 3rd January.

The matter raised in Dr. Pickles' latest letter about rabies immunoglobulin is a red herring. For obvious reasons, this product is only manufactured to replace a batch becoming outdated. The last batch from unscreened plasma is on record as becoming outdated in 1990. However, it was replaced in November 1989. 1285 vials of the unscreened batch were withdrawn, although not destroyed at the time of the first correspondence with Dr. Pickles. However, there was no possibility of this material being issued, which is a point that Dr. Pickles seems unable to accept. In the past, because rabies immunoglobulin is life-saving, we have preserved material that is about to out-date and we have despatched it, free of charge, to third world countries where rabies is endemic and where clinical trials into active and passive immunisation have been taking place - the fate of this latest batch, therefore, represents a political sacrifice.

I reiterate that our heated factors VIII and IX are currently regarded as the gold standard for safety against virus transmission; intramuscular immunoglobulin has not transmitted virus nor has pasteurised albumin.

I also point out forcibly that I consider the personal criticisms made in Dr. Pickles' letter to be unsupported and defamatory in the professional sense. I would draw to your attention the fact that you, Mr. Crowley and Dr. Snape received your copies of the correspondence three days ahead of my own letter, which represents the broadcasting of Dr. Pickles defamatory views in a manner which I could not immediately defend.

Finally, I have always taken the answers to Parliamentary Questions in a most serious and responsible manner. Dr. Pickles' comments alluding to the DoH's "weasle replies" might suggest a more cynical approach by civil servants to the politicians and one which I am sure Dr. Pickles would not wish to have drawn to their attention.

R.S. LANE,
6 February 1990.