The Penrose Inquiry

SUPPLEMENTARY STATEMENT IN RELATION TO FACTOR VIII BATCH 023110090 from DR D B L McClelland

The Inquiry has requested the SNBTS to provide a written statement explaining step by step how the SNBTS came to identify the "implicated batch" and the evidence relied on in doing so. The Inquiry has also sought clarification as to what evidence was considered by which individuals before the document entitled "Actions surrounding FVIII Batch 023110090" was prepared.

Response:

The following statement summarises the documents included in the list of references and relates to the actions in which I was personally involved during the period when it was first recognised that HTLVIII seroconversion had occurred in patients with haemophilia who were believed to have received only factor VIII manufactured by the SNBTS. In relation to the document entitled "Actions surrounding FVIII Batch 023110090", I supplied the relevant papers in my possession (1, 16, 25, 26 and 27). I was not involved in reviewing other information for this document.

On November 20th 1984 I wrote a memorandum to Dr Perry and Dr Cash in which I described the events in which I was involved relating to Factor VIII batch 023110090 (3-009) (1). This was my contemporaneous summary of events to that date, and I do not have further recollections that allow me to add further information.

Dr Christopher Ludlam telephoned me at home on the evening of Friday October 26th to let me know that there were six of his patients who had been found to have developed antibodies to HTLVIII on initial testing. I do not recall if these patients had had earlier samples tested with negative results although my memorandum implies that the antibodies had become detectable in samples from patients who had previously had negative tests (seroconversion). Dr Ludlam thought that in three of these patients, the seroconversion was probably attributable to treatment with SNBTS factor VIII. The following morning I telephoned Dr Cash to give him this information. I noted that neither of us had felt that the information available justified a product recall. I do not recall the discussion or the arguments that were considered for and against withdrawal of the batch.

On either 29th or 30th October, I was off sick. In my absence, Dr Ludlam informed Dr Frank Boulton that three of the patients had received the same batch of SNBTS Factor VIII, but that all of them had also received a number of other batches. Dr Boulton telephoned me at home with this information and called Dr Cash to inform him. The conclusion again was that there were not yet grounds for a batch recall. Again, I do not recall the discussion or the arguments that were considered for and against withdrawal of the batch.

On November 1st, I contacted Dr Cuthbertson at PFC to report seroconversion in 3 Edinburgh patients with haemophilia (13) and a recall was initiated by PFC the next day (13).

At 10 pm on Friday November 2nd, Dr Ludlam telephoned me at home to inform me that he had received information from Dr Richard Tedder (whose laboratory was undertaking the HTLVIII antibody testing). Dr Tedder had reported that he had found HTLVIII antibody in samples from sixteen of Dr Ludlam's patients. "An initial look at these data indicated that either fifteen or sixteen of these patients had received the above batch" (30090) (1). I do not recall if this conclusion had been drawn by Dr Tedder, Dr Ludlam, or both.

The following morning (Saturday November 3rd) between 0930 and 1130, Dr Boulton and I telephoned each of the SNBTS Regional Centres and the Northern Ireland BTS to inform them of the situation (1). My memo states that we "informed a senior member of staff", but I do not recall which individuals we spoke to. I also contacted the PFC Duty Officer to inform them of the actions that had been taken. Again, I do not recall who I spoke to.

Dr Perry wrote to me on November 26th 1984 (13) summarising his understanding of the actions taken to that date. He states that on November 1st, I had contacted Dr Bruce Cuthbertson, who was deputising for Dr Perry, to inform him that there was evidence of HTLVIII seroconversion in Edinburgh haemophilia patients, and that a formal recall of the batch was initiated by PFC on Friday November 2nd. I have to say that I do not recall either of these events, although SEBTS must have been notified by PFC of the recall.

On November 15th I had a meeting with Dr Perry and Dr Ludlam to review the information available about the sixteen patients and the batches that they had received. On the same day I wrote to Dr Cash (16) to inform him of the outcome of this meeting. My letter stated "... there are, so far 16 patients in whom seroconversion is known to have occurred during 1984 and who have received exclusively PFC factor VIII, ... Initial analysis by Dr Ludlam and Dr Tedder showed that one batch of product had been received by all but one of the 16 patients and therefore was highly suspect. This batch (023110090) has been withdrawn"

The remainder of this letter deals with the actions taken about "... the other batches used over the relevant period in the attempt to determine if any of them should also be considered for withdrawal ..."

"Using his own records (confirmed where appropriate by BTS records) Dr Ludlam prepared lists of all recipients of the implicated batch, all the batches received by the 16 patients who were (sic) seroconverted and all the batches used in his patients during the relevant period" I have no knowledge of the dates at which any of these patients became HTLVIII antibody positive, and have never at any time seen any of the clinical records of these patients.

Four of the 33 batches (787, 784, 733 and 791) were no longer available for issue, so the question of their withdrawal did not arise. Twenty of the 33 batches had been received by 8 or fewer of the 16 patients. Batch 023110090 had been received by 15 out of 16. Two other batches (0030 and 0170) had been received by 14 of the 16 patients. The records of the patients who had received these batches were examined to identify instances in which either batch had been received at a time when it could have caused infection, i.e. before the date at which the patient was first found to have HTLVIII antibody. There were 5 patients of the 14 recipients of batch 0030 in whom infection could be excluded on date alone, and 8 of 14 in the case of batch 0170 in whom infection could be excluded on date alone. On this basis it was concluded that these batches "should not be considered anymore suspect than the other batches listed".

I do not know if further analyses along these lines were undertaken. I have no recollection of being involved in a further exercise. My letter also noted that there was one patient of the sixteen who did not receive batch 3-0090, and who was being retested to exclude an error in identification. I do not know the outcome of any further investigation of this patient.

My letter finally summarises the conclusions reached by Drs Perry, Ludlam and myself at that meeting, namely

"1 On the basis of this investigation ...the initial view is correct, namely that the single batch 023110090 is probably responsible for seroconversion

2 No other recent batches stand out as being distinctively strongly implicated

3 There is no obvious basis on which we could advise a selective withdrawal of one or more other batches

4 There may be a need for further confirmatory examination of the patient exposure to selected earlier batches although stocks are exhausted"

On November 20th, 1984 I wrote a memo summarising the events in which I had been involved related to this episode. (1)

On November 27th, 1984 I wrote to two experts who I knew were able to perform testing for HTLVIII antibody to enquire if they would be prepared to test samples of donations that had gone into batch 023110090. These were Dr Philip Mortimer of the Public Health Laboratory Service in Colindale hospital, London (25) and Dr Richard Tedder of the Department of Virology at the Central Middlesex hospital in London (26). Dr Tedder wrote declining this invitation on December 20 1984 (27). I have not located a reply from Dr Mortimer, but I am not aware that his laboratory tested any of these samples in response to my request.

Dr DBL McClelland 15th June 2011

Reference List:

As for Dr Perry's Supplementary Statement in Relation to factor VIII Batch 023110090, submitted to the Inquiry on 15 June 2011 (SNBTS reference 2011-00092).