Witness Name: Christopher Ludlam
Statement No.: WITN3428019
Exhibits: WITN3428020
Dated: 14 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTOPHER LUDLAM

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 7 October 2019.

I, Christopher Ludlam, will say as follows: -

Section 1: Introduction

1) My full name is Christopher Armstrong Ludlam. My date of birth is GRO-C 1946. My address is known to the Inquiry. My professional qualifications are B.Sc, M.B.,Ch.B, MRCP, MRCPath, Ph.D, FRCP, FRCPath.

2) I have set out the positions I have held as a haematologist in the curriculum vitae held by the Inquiry (WITN3428002).

3) All past and present memberships of committees and groups relevant to the Inquiry's Terms of Reference are set out in my curriculum vitae (WITN3428002).

Section 2: Responses to criticism of W0196

4) I am distressed to learn of Mr GRO-B 's experiences that he has recorded in his statement. Although I have not had access to his medical case records, I have tried to respond to his specific criticisms, and I have provided a little extra background documentation which I hope is helpful.

Mr GRO-B records attending the December 1984 meeting (paragraph 15) and states in paragraph 16 that 'We were told that there was a chance that we had contracted HIV from one rogue batch of factor VIII. This was not true; there was way more than one infected batch. They said they didn't know who did and didn't have it, but this was also not true'

5) In paragraph 15 of his statement Mr GRO-B sets out an invitation by telephone to a meeting at the Royal Infirmary of Edinburgh when he was aged 14. The meeting referred to was held in the Royal Infirmary in December 1984, when I believe Mr GRO-B was probably aged 16 (or possibly 17) years. Invitation to the meeting was by letter. It is likely that he attended the meeting along with at least one parent.

6) Paragraph 16 (not 15 as indicated in the rule 9 request) relates to the meeting. Mr GRO-B indicates that there were "100 odd people there". I think this is an over-estimate. My recollection is that there about 50 or so people present. The meeting was chaired by Dr Forbes (Glasgow Haemophilia Centre) and I was present along with Dr McClelland (SNBTS). The meeting was to explain that some people with haemophilia in Scotland had been identified as having been exposed to the virus that caused AIDS. I told the meeting that some people in Edinburgh were found to be positive for the antibody to the virus and that it appeared to us at that time that many had become exposed as a result of receiving a batch of SNBTS concentrate in the spring of that year.

7) At that time we were uncertain of the total number of those who were anti-HTLVIII positive as investigations were still underway. We thought it possible there was more than a single source of HTLVIII. Mr GRO-B is therefore correct in understanding that there was likely to have been more than a single source of factor VIII containing HTLVIII.

8) We clearly stated at the meeting that we knew some individuals were anti-HTLVIII positive but we did not have the complete picture about everyone's status as investigations were continuing. I have provided the Inquiry with a witness statement given to the Penrose Inquiry with an informal minute of that meeting (PRSE0002471).

Mr GRO-B indicates in paragraph 16 (not 15 as indicated in the Rule 9 request) that 'they didn't know who did and didn't have it (HIV), but this was not true'

9) I have responded to paragraphs 15 and 16 above.

Mr GRO-B states in paragraph 20 that he was told about his infection with hepatitis C "in general conversation during a regular meeting". The Rule 9 request characterises this as being 'in a flippant manner"

10) Mr GRO-B records in paragraph 15 of his statement that he knew he had non-A non-B hepatitis. It seems likely that he was informed about the diagnosis of hepatitis C at one of his regular attendances at the Haemophilia Centre. It is very likely that it would have been explained that the virus causing non-A non-B hepatitis had been identified as hepatitis C. I cannot properly comment on this meeting without review of the notes. I am sorry Mr GRO-B remembers the episode with 'bitter devastation.' I would have tried to offer him some reassurance about hepatitis C and respond to his concerns. I would certainly not intend to be 'dismissive' about a diagnosis of Hepatitis C in anyone and I do not believe I was.

Mr GRO-B states in paragraph 21 (not 20 as set out in the Rule 9 request) that "very little information was provided".

11) The routine when explaining a Hepatitis C infection was to offer an appointment to see Dr Hayes (hepatologist). Whilst I gave my patients the diagnosis and explained what it meant, as well as providing the hepatitis C information sheet we had prepared for patients, Dr Hayes was the consultant who treated the Hepatitis C and would provide much more information (WITN3428020).

12) Hepatitis C is only rarely transmitted sexually and therefore I would have recommended that the chance of him infecting his partner with hepatitis C during unprotected sexual intercourse was very small while trying for a family. It is not clear from paragraph 21 of Mr GRO-B 's statement whether the changing advice he comments on was changing in one meeting or over a series of meetings.

Mr GRO-B in paragraph 67 refers to a holiday he took with his parents during 1981 or 1982. He describes being told 'not to take Factor VIII in England because it's "poison" and also relates his memory of being treated for a bleed at hospital.

13) I think Mr GRO-B is referring to the written information I gave to all patients on a small piece of paper to keep with their Haemophilia Card in the early 1980s. At the time there was concern about the cause or causes of non-A non-B hepatitis which

would have been explained to all patients and it is clear from his statement that he was aware of the situation. This requested that if the patient presented to a Haemophilia Centre needing treatment he should be given, if possible, NHS factor VIII concentrate or cryoprecipitate. This was because the majority of Edinburgh patients had only received SNBTS NHS concentrate, unlike in England where many had also been treated with commercial concentrates. This request was to reduce the risk of Edinburgh patients being exposed to a different donor source (by commercial concentrates) which might contain a different spectrum of potential infectious agents.

14) Mr GRO-B reports having 'one shot of factor VIII in Chichester'. He does not record his understanding of what type of factor VIII he received. I did not refer to the English treatment as being "poison".

Mr GRO-B in paragraph 68 refers to a shortage of factor VIII in the late 1990s and early 2000s and states that he was told he was "being put back onto the old Edinburgh factor" and that "they couldn't guarantee that it was free from infection."

15) By the late 1990s many patients in Scotland were receiving recombinant factor VIII as a result of early agreement to provide these new products in Scotland from 1996 onwards (in contrast to the much later introduction in England). Unfortunately in 1999 one of the principal commercial manufacturers of recombinant factor VIII ceased temporarily manufacturing and releasing recombinant factor VIII. This created a major world shortage of recombinant factor VIII. As a consequence there was a major shortage of recombinant factor VIII in Scotland and insufficient supply to maintain all patients on this type of product.

16) I have produced documents relating to this shortage of recombinant factor VIII which includes a letter from the Director of National Services Division of the Scottish NHS Common Services Agency to Health Board Chief Executives about the shortage, UKHCDO guidance and letters that would be sent to patients. (reference numbers to be provided)

17) The alternative to recombinant was plasma derived factor VIII concentrate either from SNBTS or a commercial source. By this time SNBTS had developed and manufactured a plasma derived concentrate which was virally inactivated with a proven safety record for HIV and HCV. It had been used as the standard treatment for patients in Scotland prior to the introduction of recombinant factor VIII. It was considered to be as safe as

any available plasma-derived concentrate. In the absence of adequate supplies of recombinant factor VIII, some patients were offered the SNBTS concentrate for home therapy. When a patient developed a bleed if they did not wish to receive the SNBTS concentrate they could attend the Haemophilia Centre and received recombinant concentrate, if available, as treatment.

18) I do not know who is alleged to have told Mr GRO-B that it could not be guaranteed to be free from infection but as set out above it was considered to be safe from HIV and hepatitis C.

Mr GRO-B states in paragraph 68 that he was asked to sign a form indicating he would not sue the Edinburgh Haemophilia Centre if he contracted HIV or other infections during his treatment and as a result of refusing to do so he was told he could not take any of the "other factor" home.

19) As explained above patients were offered SNBTS factor VIII concentrate for home therapy or to come to the Haemophilia Centre with a bleed and receive recombinant concentrate if available.

20) As a result of the introduction of recombinant factor VIII, SNBTS production of plasma derived concentrate had been reduced as less was required. As a result of the shortage of recombinant factor VIII SNBTS responded by increasing the availability of plasma-derived concentrate.

21) I do not recall patients being asked to sign a consent form at this time in relation to the use of plasma-derived factor VIII concentrate. It is likely that Mr GRO-B will have been invited to agree to the use of a newly developed heat-treated concentrate in 1987 as it was issued in Scotland under a clinical trial arrangement.

Mr GRO-B gave evidence on 11 July, as a result of which a further Rule 9 request was made. The transcript of evidence begins on page 55 of that day's transcript. The Rule 9 request refers to pages 27 and 30 of the transcript containing criticism but that pagination is based on a version which was sent to me in a reduced format, I have referred to the pagination on the published transcripts.

At page 81 it is recorded that Mr GRO-B gave evidence to the effect that he thought I had records in my house and was "adamant he's got two sets of records."

22) All Mr GRO-B 's clinical records, so far as I am aware, are at the Royal Infirmary. I do not have any notes at my house and I did not keep copies of patient notes or records at home. Any investigations carried out were recorded in a patient's records. There may have been some investigations which gave unreliable results and were not entered into his record, e.g. first-generation anti-hepatitis C antibody results.

Mr GRO-B describes an episode when he claims I "sneaked" him back to the Royal Infirmary of Edinburgh after a synovectomy at the Princess Margaret Rose Hospital.

23) I do not have any recollection of the incident Mr GRO-B describes of an operation at Princess Margaret Rose Hospital. Without sight of his case notes I think it likely that following his operation he required regular (probably three times daily) injections of factor VIII concentrate. There may have been a difficulty in him being given these infusions at night at the orthopaedic hospital and this was the reason for his transfer back to the Royal Infirmary.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 14/11/20

Table of exhibits:

Date	Notes/ Description	Exhibit number
2001	Correspondence relating to the shortage of Recombinant Factor VIII	WITN3428020