Witness Name: Professor Christine Ann Lee

Statement No: WITN0644104

Exhibits: WITN0644105-123

Dated: 26 January 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTINE ANN LEE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 26 May 2020 in relation to the witness statement Witness 1791 GRO-B

I, Professor Christine Ann Lee, will say as follows:

Section 1: Introduction

1. My name is Christine Ann Lee and my address is GRO-C GRO-C. My date of birth is GRO-C 1943. I hold the following professional qualifications – MA (Oxon) 1969 BM BCh (1969) MD (London) 1989, DSc (Med) (1996) FRCP (1990) FRCPath (1994) FRCOG (2010). A copy of my CV is exhibited **[Exhibit WITN0644105]**.

2. I have held the following positions as a haematologist for the following organisations and set out below my roles and responsibilities in each of these positions:

Dates	Position	Roles and responsibilities
September 1974 - June 1976	Registrar to Dr J Fielding, Department of Haematology, St Mary's Hospital	Laboratory and clinical; responsible in a district general hospital for the general haematology service. Six-month on call for emergency out of

		hours haematology including blood transfusion.
November 1976 - December 1982 (part-time)	Senior Registrar to Professor PT Flute, Department of Haematology, St George's Hospital Medical School. This included appointments at St James Hospital, Balham, Royal Marsden Hospital Sutton and South London Blood Transfusion Centre.	This appointment was under government scheme HM (69)6, known as The Women Doctors' Retention Scheme, which enabled female doctors with family commitments to work part time. Provision of haematology service and preparation for Membership of Royal College of Pathologists qualifying examination, achieved June 1982. During this time I provided some care for the small number of patients with haemophilia who attended St George's Hospital.
January 1983 - October 1984	Research Senior Registrar to Dr PBA Kernoff and Dr HC Thomas, Royal Free Hospital	Action Research Fellowship to study non-A non-B hepatitis in haemophilic patients. This work contributed to the dissertation for MD University of London awarded in 1989, entitled "The Natural History, Prevention and Treatment of Viral Hepatitis in Haemophilic patients."
November 1984 - November 1987	Senior Lecturer in Haematology, Charing Cross and Westminster Medical School and Honorary Consultant Haematologist, Queen Mary University Hospital, Roehampton, London	Single handed consultant haematologist responsible for the clinical and laboratory haematology service in the busy district general hospital, Queen Mary's University Hospital, Roehampton, part of Charing Cross and Westminster Medical School. I was also Senior

		Lecturer and provided regular teaching to undergraduate medical students.
September 1985 - November 1987	AIDS counsellor Richmond, Twickenham and Roehampton Health District	Responsibility for provision of HIV testing service using the newly developed test. Responsibility for providing education about HIV/AIDS to every secondary school within the borough of Richmond upon Thames.
April 1986 - November 1987	Honorary Consultant in Haematology Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, 2 sessions (1 day) per week.	There was no patient contact and these sessions were to prepare research for publication.
November 1987 - December 2005	Consultant Haematologist Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London.	Particular care for patients infected with HIV and hepatitis. Together with the director, Dr Peter Kernoff, I provided comprehensive care for people with haemophilia – the largest haemophilia centre in the UK with a patient population equivalent to the whole of Scotland and Northern Ireland. There was also provision of care for patients within the Royal Free Hospital who developed bleeding or thrombotic problems. There was a large anticoagulant clinic.
April 1991 - April 1992	Acting Director Haemophilia Centre and Haemostasis Unit, Royal	The Director was not able to work again for health reasons. Overnight I had to take responsibility for the

	Free Hospital, London	whole Unit as acting Director.
April 1992 - December 2005	Director Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London	As Director I was responsible for service delivery and management of a staff of 70 including physicians, nurses, physiotherapists, laboratory scientists and counsellors. Although I was an NHS employee, I also conducted research. Relevant to this enquiry, 4 of 18 MD or PhD theses I supervised were about hepatitis: (1) Dr Paul Telfer 1991-4 MD University of Oxford 'HCV infection in haemophilic patients'; (2) Dr Helen Devereux 1992-6 PhD University of London 'The molecular biology of HCV infection in haemophilia'; (3) Dr Thynn Thynn Yee 1998-2001 MD University of London 'The side effects of therapy for haemophilia'; (4) Dr Esteban Herrero 1998-2001 PhD University of London 'The molecular basis of HIV and HCV interactions'.
January 2006 - present	Emeritus Professor of Haemophilia, University College London	The title Professor of Haemophilia within University of London was an honorary title awarded in 1997 for my work in haemophilia. There was international peer review of my contribution. It was the first professorship in haemophilia in the UK.

April 2007 - April 2010	Honorary Consultant Haematology, Oxford Haemophilia and Thrombosis Centre	Responsibility for women with bleeding disorders.

3. Since May 2010, I have retired from clinical practice.

4. I hold and have held membership of the following committees or groups relevant to the terms of reference:
   a. April 2001 – December 2005: Member of UK Haemophilia Centre Doctors Organisation
   b. 1996-2003: Chair of International Haemophilia Training Centres Committee, World Federation Haemophilia
   c. 1993-2005: Member of Medical Advisory Panel, Haemophilia Society of UK
   d. 1996-2000: World Federation of Haemophilia Executive with special responsibility for WFH/WHO relationship.

5. I also gave evidence as an independent expert witness at the Tribunal of Inquiry into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters, which was chaired by Her Honour Judge Alison Lindsay in Ireland. The resulting report was published in 2002 and is available online.

6. I was the Founding Editor in 1995 and Chief Editor until 2013 of the journal *Haemophilia*, published by Wiley Blackwell.

Section 2: Background information regarding GRO-B

7. I make this statement on the basis of the medical records for GRO-B which have been disclosed to me by the Royal Free Hospital. The records are voluminous hence I have appended to this statement only those records which relate to the care I provided and which are relevant to the concerns that have been raised.

8. GRO-B and GRO-B were transferred to the care of Royal Free Hospital's Haemophilia Centre ('the Centre') from GRO-B on 9 July 1984 **[Exhibit WITN0644106]**. At GRO-B was diagnosed with severe haemophilia A and was on home treatment; he had received NHS Factor VIII concentrate and a commercial Factor VIII concentrate manufactured by Armour. The early records indicate that GRO-B had been diagnosed with hepatitis at the age of 5 although it is not known whether this was hepatitis B or non-A non-B hepatitis **[Exhibit WITN0644107]**. When tested at the Royal Free, GRO-B was found to have antibody to HBV and was HB surface antigen negative (i.e. he was not a carrier of HBV). It is not recorded when GRO-B became infected with non-A, non-B hepatitis but it would have been following the first treatment with Factor VIII concentrate at GRO-B It is also not clear when GRO-B became infected with HIV as there was no test until 1985 but it is likely that GRO-B contracted HIV before his transfer to the Royal Free in July 1984. GRO-B was informed of his HIV diagnosis by Dr GRO-B after he tested positive in 1985 (I was not working at the Royal Free Hospital at that time).

9. On 29 March 1988, GRO-B was seen in the Centre for a six-monthly review with Dr Jackson (Specialist Registrar) and it was noted that he had a rash over his arms and hands **[Exhibit WITN0644108]**. His impression was that there were no clinical signs of AIDS. I made a handwritten note in the records, *'what about the skin problem'* as seborrheic dermatitis is an early feature of HIV which the Registrar would not be expected to know.

10. I first encountered GRO-B in October 1988 in relation to the AZT trial for HIV infected patients. A letter about the trial was sent to him on 6 October 1988 followed up by a telephone call during which I explained what the trial would involve **[Exhibit WITN0644109 - WITN0644110]**. This letter was sent to all patients infected with HIV. The plan was for him to discuss this trial further with Research Fellow, Dr Lim. GRO-B did not participate in the AZT trial at the time.

11. The first time I saw GRO-B in the Haemophilia Centre was on 20 January 1993 **[Exhibit WITN0644111]**. We discussed his hepatitis and HIV infections at some length. In my

letter to GRO-B's GP dated 25 January 1993 **[Exhibit WITN0644112]** in relation to the consultation, I summarised matters as follows:

"He has had natural infection with hepatitis B in the past and has a good antibody level. He is hepatitis C positive but, his liver function tests are not abnormal. I discussed in detail with him, the implications of this and the fact that we would not give therapy if the liver tests were normal and it is possible he has cleared the virus.
He came to the Royal Free from GRO-B *in 1984 when he was already HIV seropositive. We do not know exactly when he seroconverted but, it is probable that he has been positive for over 10 years.*
I had a long discussion with him about therapy for HIV disease and explained that we introduce antiviral treatment with zidovudine and prophylactic treatment at a CD4 count of 0.2. The last count we have on his is in August 1991 and I explained that it was possible that as a result of this follow-up, we may have arrived at a time to start treatment."

12. I continued to see GRO-B periodically until March 2005. Copies of the entries I made in his records and the relevant correspondence is attached **[Exhibit WITN0644113]**. I deal with how we treated each of his infections in turn below.

13. HCV: Antibody to HCV was first detected by a second-generation test on 8 August 1991 and GRO-B remained consistently antibody positive. The antigen of HCV was detected by the branched-chain DNA (bDNA) assay on 21 January 1997 (reported as 0.5 x 10^6 genome equivalents). This was an early test and had limitations with high kit-to-kit variability and was unreliable. It was replaced by quantitative competitive PCR (polymerase chain reaction) based assays. Negative PCR tests were recorded on 30 September 1997, 15 December 1999, 20 November 2011, 23 July 2004 and 10 June 2005. His transaminases were normal throughout. For these reasons, the test result of 21 January 1997 is thought to be erroneous. GRO-B was considered a natural clearer of HCV. In July 2004, I completed an application form for GRO-B as he was applying for a payment under the Skipton Fund (the Hepatitis C ex-gratia payment scheme) **[Exhibit WITN0644114]**. On this form I stated that GRO-B had antibody to HCV, was PCR negative, had not had interferon treatment and was a natural clearer. GRO-B therefore did not

qualify for the payment at the time although I understand he later obtained this after I retired.

14. HIV: It is likely that GRO-B was tested for HIV in early 1985 but I was not working at the Royal Free at that time. Initially GRO-B had asymptomatic HIV infection. The HIV infection was monitored by measuring the CD4 (previously T4) lymphocyte count (normal range 0.6-1.7 x 10^9 per litre) or the CD4/CD8 (previously T4/T8) ratio (normal range 1.2-3.5). Treatment was recommended when the CD4 count fell to 0.2 x 10^9 per litre. A graph is attached **[Exhibit WITN0644115]**. which shows GRO-B's CD4 count between 1986 and 2005. There was a decline in the CD4 count from 0.74 x 10^9 per litre on 10 July 1986 to 0.31 x 10^9 per litre on 15 December 1999. The graph shows that GRO-B's condition was regularly monitored when he attended at the Royal Free. Unfortunately, GRO-B did not attend the Centre as regularly as was recommended, and he failed to attend the joint HIV clinics on 21 March 2000, 20 February 2001, 24 April 2001 and 14 August 2001 and therefore the CD4 count could not be measured on these dates. By the time GRO-B attended and was seen at the combined HIV clinic by Dr Margaret Johnson and me, a fungal infection was noted – this suggested immunodeficiency and was confirmed by the CD4 count of 0.020 x 10^9 per litre, reported 21 November 2001. It was recommended that GRO-B start antiretroviral therapy. On 26 November 2001, GRO-B was seen by Dr Yee and referred directly to the HIV Centre because he had developed oral candida. On 30 November 2001, GRO-B consented to the MaxCmin2 trial of antiretroviral therapy with Dr Johnson (attach consent p.71). Septrin prophylaxis was also given. It can be seen from the attached graph that the CD4 count increased following therapy indicating improvement of the profound immunodeficiency.

Section 3: Criticism by GRO-B

Response to Question 4.1 – *'At paragraph 14 of his statement, the witness states that there was a systemic issue where the moment he questioned the doctors, they became very defensive or made up lies. The witness states that it is now more apparent you and other clinicians were lying to the patients, and that he believes you were deliberately dismissive in order to deter the patients from asking more questions. Please comment on this'*

15. It is difficult to respond to this criticism without specific examples and I cannot speak for other clinicians but I vehemently deny that I ever lied to GRO-B or any of my other patients. I always answer questions that my patients pose honestly and to the best of my ability. This is evidenced in GRO-B's records. By way of example, my letter to GRO-B's GP dated 25 January 1993 refers to my having a long discussion with him about his disease **[Exhibit WITN0644112]**.

16. At the Centre, we spent a long time with our patients. Review appointments typically lasted about half an hour with the doctor (often the counsellor would sit in). The patient would then see the nurse specialist for about 20 minutes to discuss treatment and have blood taken. If necessary, the patient would also see the welfare rights officer, Mrs Elizabeth Boyd, who was situated in the Centre. The patient would then collect their home treatment. There would therefore be ample opportunity to address any questions the patient might have to any member of the comprehensive care team.

Response to Question 4.2 – 'At paragraph 15 of his statement, the witness states that when you were explaining his prognosis, you became very frustrated when he did not understand. The witness also states that you delivered the prognosis, that he had '6 years to live if [he] was lucky, without compassion. Please comment on this'.

17. I believe the first time I may have discussed GRO-B's prognosis was during a review appointment on 20 January 1993 **[Exhibit WITN0644111]**. Prior to this he had been seen by a number of my colleagues and the records indicate that hepatitis C and HIV was discussed. In relation to his hepatitis C, I would have explained the possibility of this clearing naturally, which it eventually did. In relation to HIV, it is likely that I would have used a linear depiction of the fall of CD4 count to illustrate when treatment for HIV would be advisable (i.e. when the CD4 count reached 0.2 x 10^9 per litre). I strongly refute the suggestion that I would have told GRO-B that he had 6 years to live. I was never this prescriptive with my patients.

Response to Question 4.3 – 'At paragraph 17 of his statement, in reference to his infection the witness states "they" insisted it was a "terrible accident" and that nobody could have foreseen it, nor was to blame. He states his attitude continued up until about three years ago. Please comment on this'.

18. I do not recall making this comment to GRO-B To the extent that it is suggested I was implicated in any "cover up", such suggestion is emphatically rejected.

Response to Question 4.4 – 'At paragraph 23 of his statement, the witness states that in December 1997 you sent him a letter stating there was no evidence that CJD could be transmitted by blood products. This is letter is exhibited at WITN1791005. Please comment on this.'

19. On 3 December 1997, the consultants at the Centre sent a letter to GRO-B in relation to vCJD **[Exhibit WITN0644116]**. At that time, we knew that 17 blood donors had donated blood prior to being diagnosed with vCJD. This was before it was known that vCJD could be transmitted by blood transfusion. The uncertainty of vCJD transmissibility by plasma products led to the recommendation by the Committee for Propriety Medicinal Products (CPMP) that a product be recalled where a donor subsequently diagnosed with vCJD had contributed to the plasma pool (termed 'an implicated batch'). There had been a recall of two BPL Factor VIII products as a precaution as it had been found that a donor did not met the current health requirements for vCJD. This letter was sent informing all patients what we knew at the time and whether they had been exposed or not. GRO-B was informed that he had not been treated with the implicated batches **[Exhibit WITN0644117]**.

20. When I saw GRO-B in the Centre on 4 August 1998 for a review **[Exhibit WITN0644113 16-17]**, we discussed the fact that from the Autumn, Factor VIII concentrate would be made from imported American plasma. BPL started to import American plasma from 1998 to avoid using British donor plasma which was perceived to be more potentially 'at risk' for transmission of vCJD.

21. On 20 September 2004, the Centre sent letters to GRO-B and his GP in relation to vCJD and plasma products **[Exhibit WITN0644118]**.

Response to Question 4.5 – 'At paragraph 27 of his statement, the witness states that from day one the way the hospital spoke to him was like he was their lab rat. He states they were only interested in using him for tests and research. Please comment on this.'

22. It is most unfortunate that GRO-B's perception of how he was treated by the hospital is described in these terms. From my perspective as one of his treating doctors at the hospital and whose first encounter with him was in 1988 in relation to the AZT trial, his description is entirely unjust. The Inquiry will understand that voluntary participation in clinical trials was often the way for patients to access state of the art treatment and to provide treatment which sometimes would not be available on the NHS. From the records, it appears that GRO-B was involved in/invited to participate in the trials listed below.

23. In 1988, GRO-B was invited to participate in an AZT trial. A letter about the trial was sent to him on 6 October 1988 followed up by a telephone call during which I explained what the trial would involve **[Exhibit WITN0644109 - WITN0644110]** The Inquiry is invited to read both of those documents and the terms in which they are expressed. GRO-B would have also been invited to attend a meeting to discuss the implications of participating in the trial face to face, to provide him with more information or allay any particular concerns he may have. He did not wish to participate. The role of structured meetings for discussing treatment options in relation to the AZT trial was subsequently written up in a published article – "*Treatment Dilemmas for HIV Infected Haemophiliacs*" – Lee et al - *AIDS Care* 1989; 1: 153-8 **[Exhibit WITN0644119]** GRO-B was invited to a meeting to discuss the results of the AZT trial on 29 March 1993 **[Exhibit WITN0644120]**. GRO-B did not participate in the trial as he did not want treatment at that time.

24. On 17 January 1995, there was an invitation to participate in a study to test effectiveness and safety of Monoclate-P during and after surgery **[Exhibit WITN0644121]**. His participation (as the letter makes plain) was entirely voluntary. Monoclate was a high purity plasma derived concentrate and one purpose of the trial was to show efficacy for surgery. The operation carried out on GRO-B was for excision of a

pilonidal sinus abscess on 17 January 1995. He was able to have the highest purity plasma derived Factor VIII concentrate by continuous infusion. Participation on a 'named patient' basis gave him access to the safest and most effective treatment at that time.

25. In November 2001, there was an invitation to participate in MaxCmin2 trial for treatment of HIV **[Exhibit WITN0644122]**. The letter makes clear why he was invited to participate and the potential benefits that he might obtain. Once again participation was entirely voluntary. As a consequence of his participation in the trial GRO-B was provided state of the art therapy under the guidance of HIV consultant, Professor Margaret Johnson. GRO-B s HIV infection was improved as a result of this treatment.

26. On 12 February 2004, there was an invitation to participate in the ESCHoL study **[Exhibit WITN0644123]**. In this case the benefits of voluntary participation were not so much to GRO-B himself but to the wider haemophiliac community. It was a large European study dependent on treatment records, bleeding history and demographic data. Consent was required but the data were accessed from patient notes. As with all other trials in which he was invited to participate, participation was voluntary. The records suggest that GRO-B did not volunteer or participate in this trial.

Statement of Truth

I believe the facts statement in this witness statement are true. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Signed GRO-C

Dated 26th January 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
18.04.2019	Professor CL's CV	**WITN0644105**
09.07.1984	Referral letter from GRO-B to the Royal Free Hospital	**WITN0644106**
23.07.1984	Clinical notes from Royal Free Hospital Haemophilia Centre	**WITN0644107**
29.03.1988	Clinical notes from Royal Free Hospital Haemophilia Centre	**WITN0644108**
06.10.1988	Letter from Dr Lim and Dr Lee to GRO-B	**WITN0644109**
25.11.1988	Clinical notes from Royal Free Hospital Haemophilia Centre	**WITN0644110**
20.01.1993	Clinical notes from Royal Free Hospital Haemophilia Centre	**WITN0644111**
25.01.1993	Letter from Dr Lee to GRO-B	**WITN0644112**
Various	Clinical notes and letters from Royal Free Hospital Haemophilia Centre	**WITN0644113**
July 2004	Skipton Fund application form	**WITN0644114**
29.11.2020	Graph depicting GRO-B s CD4	**WITN0644115**
03.12.1997	Letter from the Royal Free Hospital to GRO-B	**WITN0644116**
Undated	Patient vCJD exposure assessment form.	**WITN0644117**
20.09.2004	Letters from the Royal Free Hospital to GRO-B and his GP	**WITN0644118**
1989	"*Treatment Dilemmas for HIV Infected Haemophiliacs*" – Lee et al - *AIDS Care* 1989; 1: 153-8	**WITN0644119**
29.03.1993	Letter from Dr Telfer to GRO-B	**WITN0644120**
17.01.1995	Patient informed consent statement to participate in a Monoclate-P study	**WITN0644121**
30.11.2001	Invitation and consent form to participate in the	**WITN0644122**

	MaxCmin2 trial	
12.02.2004	Invitation to participate in the ESCHoL study	**WITN0644123**