Witness Name: Professor Christine Ann Lee

Statement No: WITN0644003

Exhibits: WITN0644001/1, WITN0644003/1, WITN0644003/2, WITN0644003/3

Dated: 26 November 2019

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 14 May 2019 in relation to the witness statement of 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 (**WITN0644001/1**).

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. This statement is prepared in response to Mr GRO-B's witness statement number WITN1005001. I have been provided with copies of GRO-B's medical records from the Royal Free Hospital.

7. To assist the Inquiry, I set out below some relevant background information in relation to treatment of haemophilic and HIV patients at the Royal Free Hospital as well as the challenges we faced with HIV, Hepatitis C and vCJD disease during the relevant period.

Section 2: Background information about the Centre

8. I first worked at the Royal Free Hospital's Haemophilia Centre ("the Centre") between January 1983 and October 1984. I conducted epidemiological research as a Lecturer in Haematology, and was a Research Fellow under the supervision of Dr Peter Kernoff and Professor Howard Thomas, supported by an "Action Research for the Crippled Child" grant. I was not clinically responsible for patients at this time. I then returned to the Centre as a Consultant Haematologist in November 1987.

9. There was a team approach towards the treatment and care of haemophilic patients at the Centre. As at 1987, the team consisted of Dr Peter Kernoff (Director of the Centre), myself, Dr Goldman (clinical assistant), Riva Miller (counsellor), specialist nurses and a senior haematology registrar. Medical care was provided in a comprehensive care setting, with overall responsibility being held by Dr Kernoff.

10. My role was to provide clinical care for the emerging HIV illness in the 110 haemophilic patients who had been identified in the Centre with HIV infection, and patients with liver disease. HIV clinics were held every Monday.

11. Our team also worked closely with the hepatologists and held joint liver clinics with them.

12. Out-patient reviews for patients under the care of the Centre took place every 6 months and patients collected their Factor VIII concentrate every 3 months. Patients could, and did, attend the Centre at any time, however, if there were active problems. There was also the opportunity for patients to seek telephone advice from the nurse specialists. At each out-patient review appointment, blood samples would be taken by the nurses to check full blood count and liver function as well as whether there were any inhibitors to Factor VIII concentrate.

13. As a team we held regular meetings at the Centre to discuss our patients including the following:

    a. A weekly retrospective meeting to ensure that everyone was informed and updated about the patients who had been seen at the Centre in the previous

week. These would be attended by the clinical team (doctors, nurses and counsellors).

b. A weekly prospective meeting to discuss patients who were due to be seen at the Centre in the coming week. These would be attended by the clinical team as well as by the laboratory team as it was anticipated that specialised blood tests would be required.

c. A weekly HIV clinical case conference held by Dr Stuart Clark and Dr Margaret Johnson (Consultant in HIV medicine from 1989 onwards) which I attended. These conferences were attended by doctors and nurses from the Haemophilia Centre, counsellors, virologists and pharmacists. This was because learning about this disease was an ongoing process as initially so little was known of the progression.

14. We also attended monthly meetings at UCL and Middlesex to discuss what was happening with the treatment of patients infected with HIV generally in the London area.

Section 3: The history of HIV and Haemophilia

15. Dr Peter Kernoff was appointed as Director of the Centre in 1978, succeeding Dr Katharine Dormandy who died in 1978. He had worked at the Oxford Haemophilia Centre where the problem of hepatitis was (being) recognised. From the time of his appointment, he set up a system of storing blood samples from patients taken at each clinic appointment when they were treated with clotting factor concentrate. Patients were informed that samples were being taken and stored but consent was not formally requested; in 1978 this was the usual practice. The reason for collecting the specimens was that it was expected there would be a test for non-A non-B hepatitis (although this was not established until 1991). The samples enabled a vast amount of epidemiological work to be recorded and published in relation to hepatitis and HIV in haemophilic patients to assist the understanding and learning about these diseases.

16. HIV was a major challenge for all involved in care of haemophilia patients, particularly in the early 1980s when so little was known about it. The HTLV-III virus was first identified in Summer 1984, and a test was subsequently developed by Professor

Richard Tedder, Consultant Virologist at University College London during that year. At that time, there were approximately 500 patients at the Centre who had haemophilia, and it was important that we knew who of those 500 were infected with the HTLV- 111 virus in order to monitor and manage their clinical care and provide counselling and treatment when it became available.

17. I provided the relevant samples to Professor Tedder at the end of October 1984, before undertaking a new consultant post at Queen Mary's University Hospital Roehampton between November 1984 and October 1987. When the accepted HIV test became available, it was possible at a later date to test the stored samples in order to ascertain the date of seroconversion (period during which the body starts to produce detectable levels of HIV antibodies). I believe this was done much later and it was in an attempt to understand the evolution of AIDS. This was a unique possibility in these patients because the date of acquiring the infection could be pinpointed as the patients were in regular clinical follow up. This provided vital information for the care of the haemophilic patients as well as those in the wider community. This information was reported anonymously nationally and internationally and provided unique insight into the disease process.

Section 4: Criticism by Mr GRO-B

18. I note that it is stated by the Inquiry within the Rule 9 request letter that GRO-B was under my care at the Royal Free Hospital between 1980 and 1990. This is not correct. He would have been under the care of the team at the Royal Free Hospital Haemophilia Centre but his care would not have been assigned to any specific consultant.

19. I was not seeing patients at the Royal Free Hospital prior to November 1987. From the disclosed medical records it is apparent that I saw GRO-B in clinic between June 1988 and October 1990.

Response to Question 1 – GRO-B states he strongly believes that he was not asked whether he wanted to have his blood tested for HIV (at the time known as HTLV-III). Please comment on this.

20. From the disclosed medical records it appears that GRO-B was tested for HIV prior to me commencing my post at the Royal Free. The testing for HIV was retrospective on stored samples. This would have been after 1984. In common with all of the patients tested at this time, GRO-B was not asked whether he wanted his blood tested for the HIV virus. In the early days, we were still trying to understand what was going on in order to help our patients. There was of course a responsibility for staff, particularly those in the laboratory and family members to know even though universal precautions were applied. By the time I first saw GRO-B on 22 June 1988, he was aware that he was HIV positive although he did not want to know what his T4 lymphocyte count (now referred to as CD4 count, white blood cells that fight infection) was.

Response to Question 2 – GRO-B ***claims you were conducting research on patients, including himself, without informed consent. He states he was not told of this for some time. Please comment on this.***

21. The research that I led whilst at the Royal Free was wholly epidemiological, which meant that it involved comparing groups of patients who were alike. We monitored the clinical situation and laboratory tests in a cohort of 110 haemophilic patients infected with HIV. For hepatitis, groups of patients were compared along with the laboratory tests and there was some correlation with the concentrate used to treat patients. In particular, we showed that irrespective of the origin of source plasma, non-A non-B hepatitis occurred after a first infusion of concentrate. All of my research samples were anonymised and at this time informed consent was not required. None of the research was using the patient or the patient's blood samples experimentally.

22. We were in a unique position to study the natural history of HIV in a closely monitored cohort of patients. This provided invaluable information for the care of patients not only at the Royal Free Hospital but also worldwide. Natural history would allow identification as to when samples became infected and could then be traced to their origin, as well as continuing to monitor abnormal blood tests i.e. LFTs.

Response to Question 3 – GRO-B claims that the relationship between you and him grew "hostile". Please comment on this.

23. These events took place nearly 30 years ago, however, I do remember clearly that the relationship between GRO-B and all members of the team at the Centre had become difficult as a result of his manner and attitude.

24. My recollection is that GRO-B was self-infusing his treatments at home, and that he was using much greater amounts of Factor VIII treatment than other patients in the Centre. There are numerous references to this within GRO-B s medical records. We were under scrutiny for the amount of Factor VIII treatment that was being used and had been asked to identify user outliers. I believe that GRO-B was questioned about his overuse of Factor VIII treatment and his verbal behaviour towards members of staff at the Centre became unacceptable as a result of this. He subsequently transferred his care to St Thomas' Hospital.

Response to Question 4 – GRO-B claims the UK Haemophilia Doctors Organisation was incredibly slow to realise the risk of using blood clotting factors and that you stated the chance of infection was 1 in 1000. Please comment on this.

25. I did not become a member of the UK Haemophilia Centre Doctors' Organisation (UKHCDO Committee) until 1991.

26. In 1983, I was commissioned by the UK Haemophilia Society to write about the human immunodeficiency condition for "Hemofact" which was published on 11 May 1984. A copy of that publication is attached as **WITN0644003/1**. This was because I was knowledgeable about the condition as a result of my work in the Centre.

27. At that time, HIV had not yet been identified so the incidence rate of the virus was estimated by taking the number of haemophiliac patients who had reported AIDS (2 patients) and dividing that by the number of haemophilic patients who had been treated with clotting factor concentrate the previous year (2000 patients). This therefore gave the estimate of 1 in 1000. The data was obtained from Oxford (where national

data was being held) and it was a correct statement of fact at that time based on our knowledge.

Response to Question 5 – GRO-B ***claims you tried to make him go on a trial of AZT, with recommended doses that may have hastened many people's deaths. Please comment on this.***

28. In 1988, we had the opportunity of providing AZT (azidothymidine also known as Zidovudine (ZDV)) to patients with haemophilia in the context of the Medical Research Council Concorde Trial. This was a randomised double-blind controlled trial of use of immediate and deferred AZT in patients with symptom-free HIV infection.

29. I first discussed the trial with GRO-B at a clinic appointment on 4 October 1988. He said that he wanted to think about matters. He was given a patient information sheet about the trial.

30. We invited all patients who were infected (together with their families/friends/partners) to an evening meeting with the comprehensive care team in order to explain the trial and the details known about AZT. The team included myself, Dr Goldman, Dr Seng Lim (MRC Research Fellow, now Professor of Medicine at the University of Singapore), Riva Miller (psychologist), pharmacists and nurse specialists. There was an opportunity for discussion with, and questions from, patients and their relatives. The meeting enabled us to understand what patients were concerned about and was an opportunity for us to provide explanations where we could do so.

31. Attendance at the meeting was voluntary, as was participation in the trial. GRO-B did not participate in the trial.

32. A detailed anonymised report of the meeting was published in the journal, Aids Care in 1989, entitled "*Treatment Dilemmas for HIV Infected Haemophiliacs*" (**WITN0644003/2**).

33. I do not accept that I have ever tried to "make" any patient participate in a trial of AZT or of any other trial. There were no other treatment options at this time save for

prophylactic treatment which was only able to slow the disease process. The doses we were recommending were smaller than those being recommended at St Mary's Hospital. We were in the forefront of being able to provide this treatment which, it was hoped, would be the definitive treatment for AIDS. Although AZT was unlicensed, the AZT trial had been approved by the MRC as well as local and regional Ethics Committees.

34. The benefits of AZT were subsequently published in 1990 in an article entitled, "*Zidovudine treatment for anti-HIV positive haemophiliacs*" (**WITN0644003/3**).

Response to Question 6 – GRO-B ***claims that at a group patient meeting, he expressed anger that he and other patients had been infected and all that could be offered was a trial of unlicensed, highly toxic medicine. He claims you replied expressing words to the effect of "Think yourself lucky you don't live in America, you get free treatment here in the UK which you wouldn't get there". Please comment on this.***

35. I do not recall my exact words of 30 years ago, but it would not be in line with my usual practice to cause offence or appear insensitive through my remarks or explanations.

36. It would have been correct to state that AZT required payment in America, whereas there was the opportunity of free AZT treatment in the UK.

Statement of Truth

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

Signed GRO-C

Dated November 26th 2019.

Table of exhibits:

Date	Notes/ Description	Exhibit number
18.04.2019	Professor CL's CV	WITN0644001/1
11.05.1984	AIDS factsheet entitled *"Haemofact"*	WITN0644003/1
1989	Article published in Aids Care entitled *"Treatment Dilemmas for HIV Infected Haemophiliacs"*	WITN0644003/2
05.04.1990	Article entitled *"Zidovudine treatment for anti-HIV positive haemophiliacs"*	WITN0644003/3