

Witness Name: Professor Christine Ann Lee

Statement No: WITN0644183

Exhibits: WITN0644184 - 186

Dated: February 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHRISTINE ANN LEE IN RESPONSE TO WITNESS W5653

I provide this statement in response to a Rule 13 notification dated 25 March 2022.

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) DSc (Med) (1996) FRCP (1990) FRCPATH (1994) FRCOG (2010). A copy of my CV is exhibited at **WITN0644001_001**.
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	Senior Registrar to Professor PT Flute, Department of Haematology, St	This appointment was under government scheme HM (69)6, known as The Women Doctors' Retention Scheme, which enabled female doctors with family

(part-time)	George's Hospital Medical School. This included appointments at St James Hospital, Balham, Royal Marsden Hospital Sutton and South London Blood Transfusion Centre.	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	Consultant	Particular care for patients infected with

1987 - December 2005	Haematologist Haemophilia Centre and Haemostasis Unit, Royal Free Hospital, London.	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 Free Hospital, London	The Director was not able to work again for health reasons. Overnight I had to take responsibility for the 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	Emeritus Professor of	The title Professor of Haemophilia within

- present	Haemophilia, University College London	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 gave oral evidence to this Inquiry on 20 November 2020 and provided a comprehensive written statement beforehand. This statement addresses specific criticisms made by witness W5653 in relation to my treatment of her ex-husband, witness W5654. I have had the opportunity of reviewing witness W5654's records from the Royal Free Hospital and have exhibited to this statement those records that are relevant to the matters under consideration as **WITN0644184** (correspondence) and **WITN0644185** (clinical notes).

Section 2: Background information regarding witness W5654

7. Witness W5654 was diagnosed with mild haemophilia in 1960 at the West Herts Hospital. This type of haemophilia does not result in spontaneous bleeding but usually only in response to trauma or surgical intervention.
8. In January 1974, witness W5654's care was transferred to the Haemophilia Centre at the Royal Free Hospital under the care of the late Katharine Dormandy. I was not working there at the time. Because he had mild haemophilia, he was not a frequent attender.
9. On 30.11.82, witness W5654 was treated with FVIII (Armour) at GRO-B during a surgical repair of severed tendons and nerves in his right hand. This would have been when he was infected with HIV and exposed to HCV, which he subsequently cleared. The HIV virus was first identified in around June 1984 and testing was carried out in around October 1984. The HCV virus was only identified in 1989 and the PCR test became available in the mid-1990s. In witness W5654, he was first tested for HCV antibodies on 26.06.91 and was negative. His PCR test for HCV was negative on 02.01.97.
10. It appears that AIDS was first discussed with witness W5654 when he attended the Haemophilia Centre on 17.06.85 and was seen by Dr Elizabeth Miller, Senior Registrar in Haemophilia when he was told he was HLTV III positive (later HIV). The records suggest that he was also informed about non-A non-B hepatitis (later HCV) at that time.
11. In 1988 it was possible to treat some patients with haemophilia with Zidovudine (AZT) and these patients were treated by Dr Seng Lim who reported the findings in a paper – Lim S.G, Lee C.A, Kernoff P.B.A, 'Zidovudine Treatment for HIV-positive haemophiliacs' *Clin lab Haematol* 1990 12 167-378. Patients were also treated in the context of the MRC Concorde trial comparing Zidovudine to placebo and this ran from October 1988 to October 1991 and was reported, 'Concorde: MRC/ANRS randomised double-blind controlled trial of immediate and deferred zidovudine in symptom-free HIV infection', *Lancet* 1994; (i): 871-881. The novel treatment, zidovudine, was discussed in a structured group to define, evaluate and rank the many treatment dilemmas inherent in participating in this drug trial, reported in Lee C.A., Miller R. and Goldman E. 'Treatment Dilemmas for HIV Infected Haemophiliacs' *AIDS Care* 1989 1: 153-158. Witness W5654 was able to access this novel treatment and was regularly reviewed by Dr Lim in the Haemophilia Centre from 1988 onwards. The records show that discussions were held in relation to this trial on multiple occasions between 1988 and 1994.

12. The first time I saw witness W5654 in the Haemophilia Centre was on 30.06.89. The last review I had with him was on 30.01.01 (the corresponding letter has been dated 31.01.12 in error, it should be dated 31.01.01).

Section 3: Criticism by witness W5653

Paragraph 7 – Witness W5653 states that witness W5654 was not informed that he had also been infected with HCV until sometime in 1994. It is alleged that I informed witness W5654 of his HCV diagnosis casually, as an incidental infection as though it was something that witness W5654 should have been aware of.

13. As outlined above, HCV was first identified in 1989 and the PCR test only became available in the mid-1990s. Whilst witness W5654 acquired HCV, his antibody tests and PCR on 02.01.97 were negative. He never had abnormal transaminases nor any signs of liver damage.
14. It is not correct that witness W5654 was not informed that he had been infected with HCV until 1994. According to the records:
- a. On 17.06.85, witness W5654 was told by Dr Miller that he probably acquired non-A, non-B hepatitis in 1982.
 - b. On 20.09.91, I discussed HCV with witness W5654 and that his ALT result was normal.
15. It is also possible that between those two appointments and from 1991-1994 there were discussions with other healthcare providers in relation to his HCV diagnosis. As stated above, the PCR test for HCV only became available in the mid-1990s and the knowledge around this virus was evolving.

Paragraph 8 – Witness W5653 states that no information was given to help manage the infections.

16. It is evident from the records that witness W5654 was repeatedly advised by a number of healthcare practitioners at the Haemophilia Centre about his infections and how these could be managed from 1985 onwards.
17. It is clear that during an appointment with Dr Peter Kernoff on 18.11.86, a discussion was held in relation to the significance of his HIV infection. He was offered further counselling with Riva Miller.

Paragraph 9 – W5653 states that witness W5654 was not pre-warned of any risk before he had FVIII concentrate and that he should have been told that he had become infected with HIV and HCV much sooner.

18. Witness W5654 acquired the infections when he was treated at the **GRO-B** **GRO-B** not whilst he was at the Royal Free. In any event, I was not treating witness W5654 at the time he became infected. In 1982, neither virus had yet been identified.

Paragraph 14 – Witness W5653 states that I refused to put witness W5654 on recombinant treatment for his HCV.

19. In 1996, the UKHCDO had recommended the use of recombinant FVIII in published guidelines (UKHCDO Executive Committee Guidelines on therapeutic products to treat haemophilia and other hereditary coagulation disorders – *Haemophilia* 1997; 3: 63-77). Although funding became available in 1998 to treat children with haemophilia with recombinant FVIII, this did not extend to adult patients until 2003-2006.
20. I tried hard for recombinant treatment to be available for adults including;
- a. A letter to the Chief Executive of the Royal Free Hospital (cited in the Independent article dated 08.03.20, entitled '*Money or their lives*' where I wrote about my discomfort about prescribing plasma-derived concentrate which we knew had the potential to transmit life-threatening viruses to children **[WITN0644102]**;
 - b. A memorandum sent directly to the Chief Medical Officer on 01.02.96 advocating the use of recombinant FVIII and emphasising that plasma-derived products continued to transmit viruses **[DHSC0003540_061]**.
21. Thus I did not refuse to treat witness W5654 with recombinant FVIII, I was not allowed to.

Paragraph 21 – Witness W5653 states that when she told me of her intention to start a family with witness W5654, I said 'Why would you want to have a child with a man who is HIV positive? You need to use a donor's sperm' and that I later said 'Sorry, we are still learning'.

22. The approach to the counselling of HIV positive men who wished to have children was described in a paper co-authored by Dr Eleanor Goldman, Riva Miller and myself – 'Counselling HIV positive men who wish to have children' *BMJ* 1992; 304: 829-830

[WITN0644186]. Although I would have talked with witness **W5654** and his wife about starting a family in line with this approach, any counselling was primarily given by the family therapists, Dr Goldman and Riva Miller.

23. The notes record that I saw witness W5654 with his then girlfriend, witness W5653, on 15.03.91. We had a long discussion about their relationship/marriage. I would not have used the words suggested at paragraph 21 of witness W5653's statement.
24. On 06.12.93 there was a discussion with Dr Telfer about sperm washing and sexual transmission of HIV.
25. On 21.03.94 at a review with Dr Telfer, witness W5654 requested counselling about having a family with his wife. An appointment was arranged with the family therapists, Dr Goldman and Riva Miller.

Other issues

26. In relation to paragraphs 10-13 of witness W5653's statement and the issues concerning vCJD, I wish to make a few comments.
27. The issues relating to vCJD are recorded in the paper by Millar CM and Makris M – 'Dealing with uncertain risk of variant Creutzfeldt-Jacob disease transmission by coagulation replacement products' *BJH* 2012; 158: 442-52 **[WITN0644098]**.
28. There were two recalls of FVIII between 1995 and 1997. This is because a blood donor who had contributed to a plasma pool had subsequently died of vCJD. I felt very strongly that patients should be told about this but the advice from the DOH at the time was that patients would 'not benefit from this knowledge and the uncertainty created by informing such patients could cause unjustified worry and carry a permanent blight on their lives'. However, many haemophilia physicians, in common with me, directly informed their patients at the time. Witness W5653 acknowledges that I had expressed dissatisfaction during a BBC interview.
29. I attach copies of the correspondence with witness W5654 in relation to vCJD. This shows that:
 - a. On 02.12.97, a letter was sent to witness W5654 regarding the two recent recalls of BPL Factor VIII batches on the basis that a donor had not met the current health requirements for vCJD.

- b. On 31.10.00, witness W5654 attended the Haemophilia Centre with his wife, witness W5653. It was noted that he had been treated with Replenate and that this had been contributed to by a blood donor with vCJD. Witness W5653 wanted more information as to who the blood donor was; I agreed to write to BPL on witness W5654's behalf.
- c. On 15.11.00, witness W5653 sent me an email seeking further details regarding the vCJD donor. I forwarded witness W5653's email to the National Blood Authority on 24.11.00.
- d. The National Blood Authority responded on 05.12.00 and this correspondence was forwarded to witness W5654 on 07.12.00.
- e. On 30.01.01, there was a further discussion regarding vCJD when witness W5654 attended the Haemophilia Centre with his wife to discuss his notes. Witness W5654 was informed that he did not have an implicated batch.
- f. Further letters regarding vCJD were sent to witness W5654 on 20.09.04 and 08.10.04.

Statement of Truth

I believe the facts 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 February 17th 2023