

Witness Name: Professor Christine Ann Lee

Statement No: WITN0644001

Exhibits: WITN0644001/1-15

Dated: May 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 5 April 2019.

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 enclosed (**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	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

	Hospital, Roehampton, London	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	The Director was not able to work again for health reasons.

	and Haemostasis Unit, Royal Free Hospital, London	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 - 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.

Section 2: Criticism by Della Hirsch

Response to Question 4 – “Mrs Hirsch claims in her statement that she was only informed by you of Nick’s test result nearly three weeks later. Please comment on this”

6. The hepatitis C virus (HCV) was identified in 1989. Previously it was known as non-A, non-B hepatitis. A diagnosis of hepatitis C was made by exclusion of hepatitis A and hepatitis B and with abnormal liver transferases (transaminases). In 1990, we were able to test for antibody to HCV. This test

was developed in the virology laboratory together with expertise from the liver unit at the Royal Free Hospital. At this time the NHS did not have a licensed test and the National Blood Transfusion Service were awaiting further verification of testing kits, but they began testing in 1991.

7. I did not conduct the review of NH on 5 June 1990 which provided the sample for the June 1990 test result. I believe that this review was conducted by Dr Goldman.
8. We sent the results of these tests to respective patients/parents and their GPs. A letter to NH's parents confirming the June 1990 results was sent on 9 July 1990. The letter was in my name because I had the responsibility for organising the testing with the laboratory and reviewing the results. The letter was explanatory giving full information as far as we knew it at the time.
9. Patients/parents had been party to discussions about non-A non-B hepatitis at each review appointment since 1985. What was new at this time was that because the virus HCV had been identified in 1989 we could now measure anti-HCV with an in-house testing kit in order to show past infection. An invitation was extended for patients/parents to attend the Haemophilia Centre before the next six monthly review (or opportunistically if this was before the review, as they came in regularly to collect medications) if they wished to discuss these results.
10. The three-week delay in receipt of the letter documenting the results is likely to have been due to the large number of test results to be collated, carefully checked names against the relevant results and mailed. I sent letters of this nature to 88 patients on 9 July 1990 alone, and another 40 between August and November 1990.

Response to Question 5 – “Ms Hirsch claims that you failed to explain what the HCV diagnosis would mean to Nick or his parents, nor how Nick came to be exposed. Please comment on this”

11. NH would have been infected with HCV when he received his first dose of NHS plasma derived large pool factor VIII concentrate. There was 100%

transmission rate for non-A non-B hepatitis from this NHS concentrate made from British plasma. It is also possible that he acquired it from NHS cryoprecipitate – although this is a single donor product and therefore less likely. Both of these treatments were administered at Great Ormond Street Hospital (GOSH) and therefore I was unable to provide any details of the patient's exposure as I did not have copies of NH's records from GOSH.

12. I understand that Dr Goldman conducted the majority of NH's reviews at this time. Having reviewed NH's medical records, the following entries appear to be of relevance to this question:

- a. Review with Dr Goldman on 17 April 1991 (**WITN0644001/2**) – *"Mrs Hirsch came to discuss hepatitis C".*
- b. Review with Dr Goldman on 15 May 1991 (**WITN0644001/3**) – *"Mr & Mrs Hirsch requested appointment to discuss Hep C – very distressed by report in Sunday Times re carcinoma of liver associated with hep C. Interview videotaped. Discussed CT scan as further way of monitoring progress and interferon as possible treatment. No evidence to suggest immediate cause for concern but he will be followed very closely..."*
- c. Review with Dr Goldman on 24 July 1991 (**WITN0644001/3**) – *"Reference to hepatitis was clearly not wanted by the parents & this was not pressed. Nicholas said he vaguely remembered discussing it last year."*
- d. Letter from Dr Goldman to GP following 24 July 1991 review (**WITN0644001/4**) – *"Most haemophiliacs treated with concentrate in the past have been infected with the Hepatitis C virus. Mr and Mrs Hirsch had been separately to discuss Hepatitis C since Nicholas is now known to be anti-HCV positive. They discussed the prognosis and implications of the test in some detail in May and made it clear that they did not wish the subject raised at the time of the review."*
- e. Note by Dr Goldman on 3 March 1992 (**WITN0644001/5**) – *"Hep C discussed with Ms Hirsch. On their return from a business trip to India they will bring Nicholas in to discuss hep C himself."*

- f. "To whom it may concern" letter provided to Mrs DRH by Dr Goldman on 6 May 1992 (**WITN0644001/6**) – *"Unfortunately, Nicholas has also been infected with the hepatitis C virus which was present in blood products before heat treatment became available."*
 - g. Review with Dr Telfer on 12 May 1992 (**WITN0644001/7**) – *"Nicholas has good understanding of hep C and his condition."*
 - h. Review with Dr Goldman on 28 October 1993 (**WITN0644001/8**) – *"Discussed hepatitis A, B & C."*
 - i. Letter from myself to GP on 25 March 1996 (**WITN0644001/9**) – *"I note that he has chronic hepatitis C (genotype 1) and he was probably infected in 1980 with first clotting factor concentrates."*
 - j. Letter from myself to GP on 20 November 1996 (**WITN0644001/10**) – *"I saw Nicholas Hirsch on 19th November for a review of his haemophilia, although the predominant area of discussion was around hepatitis C infection. [...] We do not know precisely when he was infected but, it is likely to be approaching 20 years ago."*
13. It was always my practice to discuss hepatitis at reviews. The knowledge about hepatitis was evolving and we were fortunate to work together with hepatologists in the world renowned liver unit at the Royal Free established by Dame Sheila Sherlock to provide the most up to date diagnosis and treatment for our patients.

Response to Question 6 – *"Mrs Hirsch claims that you advised Nick by letter that he had been exposed to Variant Creutzfeldt-Jakob disease but failed to provide any further explanation about his exposure. Please comment on this."*

14. It should be noted that by this point in time, NH was no longer a minor therefore communication was with the patient and not his parents. Knowledge of variant

Creutzfeld-Jacob disease (vCJD) was also still very limited and was evolving at this time.

15. The response to the problem of vCJD was co-ordinated by the United Kingdom Doctors' Haemophilia Organisation (UKHCDO) in collaboration with the Haemophilia Society. Due to the uncertainty of vCJD transmissibility by plasma products, it was recommended that a product be recalled where a donor subsequently diagnosed with vCJD had contributed to the plasma pool.
16. We informed our patients as soon as we received communication about the recall from the Bio Products Laboratory (BPL), the UK fractionators. The fax from BPL to us was dated 30 November 1997 (as exhibited to Mrs DRH's statement as WITN0282028), and my letter to NH was sent three days later on 2 December 1997 (as exhibited to Mrs DRH's statement as WITN0282027).
17. BPL had explained in their fax to us that they had initiated a product recall as a precautionary measure following a post-donation disclosure by a donor which meant that the donor did not meet the current health requirements for vCJD.
18. Although BPL's fax stated that the advice from the Lothian Ethical committee was that patients *"should not be informed that the product that they have received has been recalled for this reason"*, I did not agree with this. I therefore included BPL's explanation in quote marks within my letters to the relevant patients. I also explained as much further information as we knew at that time.
19. For all patients there was an offer of a consultation in the Haemophilia Centre to further discuss the issues. Some patients/parents took this opportunity.
20. Having reviewed NH's medical records, the following entries also appear to be relevant to this question:
 - a. Note by Christine Harrington (Nurse Consultant) on 2 December 1997 (WITN0644001/11) – *"Mrs Hirsch rang me. Insisted that a letter re: CJD should not be sent to Nicholas. She had consulted her G.P. who felt it was 'an appalling way to give information'. She feels strongly that Nicholas does not need to know. I explained that since he is aged 21 we should be*

informing Nicholas in his own right. After some discussion we agreed that a letter could be sent with general issues re CJD & asking him to make an appointment to discuss. I stated that I would need to OK this with Dr Pasi as acting Centre Director. She agreed to phone me back at 5 ish on my bleep. I agreed with her that it was preferable to discuss this issue with Nicholas in person in the centre. She has not raised with subject with Nicholas."

- b. Note by Christine Harrington on 3 December 1997 (**WITN0644001/11**) – *"Nicholas attended to pick up home treatment. Dr David Perry & I saw him to discuss CJD & lack of evidence of transmission via blood or blood products. Informed him that he had received recalled batch 8Y FHB4419 in 1995. His main concern was Hep C & the possibility of starting combination therapy. Given letter with info from the consultant staff."*
- c. Further note by Christine Harrington on 3 December 1997 (**WITN0644001/11**) – *"Mrs Hirsch rang me. Very angry & upset that Nicholas was told. Wanted to know whose decision this was. I stated that the decision to inform all patients had been taken by the three consultant staff."* The three consultant staff that Christine refers to would be myself, Dr Perry and Dr Pasi.
- d. Review by myself on 27 January 1998 (**WITN0644001/12**) – *"Reviewed CJD issues. No concerns"*.
- e. Review by myself on 5 October 1999 (**WITN0664001/13**) – *"'Freaked out' by receiving concentrate derived by nvCJD donor in Nov 97."* The words "freaked out" are my quotation of NH's own words.
- f. Letter from myself to GP on 11 October 1999 (**WITN0644001/14**) – *"He was also freaked out that he had received concentrate that had been derived from a new variant CJD donor and was told in November 1997."* As above, the words "freaked out" were NH's words, and I included them here to explain how NH had described his feelings to me.

g. Review by myself on 6 February 2001 (WITN0644001/15) – “Discussion about nvCJD”.

Statement of Truth

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

Signed

GRO-C

Dated

10 May 2019