Witness Name: Dr Diana Samson
Statement No.: WITN4673001
Exhibits: N/A
Dated: 10 December 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DIANA SAMSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 4 November 2020

I, Dr Diana Samson, will say as follows: -

Section 1: Introduction

1) I sincerely wish to assist the Inquiry as far as I am able. I have answered the questions to the best of my ability, but I am afraid I have no clear recollection of events of over 30 years ago. I left the NHS over 20 years ago and kept no documents. I cannot guarantee that my memory is accurate.

1. Please set out your name, address, date of birth and professional qualifications.

2) Name: Diana Maureen Samson
Address: My address is known to the Inquiry
Date of Birth: GRO-C 1944
Professional Qualifications: BSc, MB. BS, MD, FRCP, FRCPath

2. **Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.**

3) **1968 – 1972** Junior posts in medicine, pathology and haematology

4) **1973 – 1976** MRC Clinical Research Fellow, MRC Clinical Research Centre, Harrow and Honorary Senior Registrar, Northwick Park Hospital and St. Mary's Hospital. This was a training post in haematology including diagnostic and clinical work, during which time I worked at Northwick Park Hospital and St. Mary's Hospital and also spent 6 months at the North London Blood Transfusion Centre. My position as Clinical Research Fellow meant I also had dedicated time to pursue original research.

5) **1977 – 1983** Consultant Haematologist, Northwick Park Hospital and MRC Clinical Research Centre, Harrow. Post jointly funded by MRC and NHS. My responsibilities to the NHS were to share in responsibility for the clinical and diagnostic work of the NHS haematology department, and my responsibility to the MRC was to pursue original research at the Clinical Research Centre

6) **1983 – 1998** Senior Lecturer in Haematology, Charing Cross and Westminster Medical School, subsequently Imperial College School of Medicine, and Honorary Consultant Haematologist, Riverside District Health Authority, subsequently Hammersmith Hospitals NHS Trust. My responsibility to the Medical School was to contribute to teaching of medical students and to take part in original research. My responsibilities to the NHS at Charing Cross Hospital were to share in responsibility for the clinical and diagnostic work of the department. I had a particular responsibility for care of patients with haematological malignancies and jointly developed and ran the bone marrow transplant unit. From 1995-6 when the Charing Cross Hospital Bone Marrow Transplant Unit moved to the Hammersmith Hospital, and I moved with it, my NHS responsibilities were only to take part in the clinical service for patients with haematological malignancies and those undergoing bone marrow transplantation.

7) I ceased NHS work in the summer of 1997 and retired from my post in April 1998.

8) From **1998 – 2003** I worked part-time in teaching and research at Imperial college School of Medicine.

9) **2004 – 2008** I was Medical Director of the Joint Accreditation Committee of the European Group for Blood and Marrow Transplantation, working on centre accreditation, quality control and harmonisation of standards between Europe and North America.

10) The remainder of my working life was spent in freelance writing and editing. In particular, I contributed to various guidelines on the management of multiple myeloma and related disorders.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

11) No relevant committees etc, apart from attending meetings of the UKHCDO.

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.

12) No

Section 2: Decisions and actions of the Centre

6. In relation to your work as a haematologist at Northwick Park Hospital, please:

a. Describe your role and responsibilities and how they changed over time;

b. Provide an account of the Centre's history, its establishment and its activities during this time.

c. Describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of treatment with blood or blood products;

d. Identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of treatment with blood or blood products, and their roles and responsibilities during the time that you worked there.

13) My senior colleague Dr I Chanarin was already in post when I joined and continued in post after I left. I shared the work of the department with him, with responsibility for the haematology laboratory service and for the care of patients with haematological disorders. Over time I assumed particular responsibility for patients with haematological malignancies and set up a service for bone marrow transplantation.

14) I do not remember being specifically responsible for patients with haemophilia and allied disorders and have no memory of seeing any individual patient. However I see from the records provided to me that I wrote to Dr Spooner soon after I took up my post to say that I would be looking after the patients with haemophilia and I completed the return for 1976 (records HCDO0000075_003; HCDO0000075_004). I attended the UKHCDO Annual meeting in 1977 (record PRSE0001002); I also attended the meeting in 1981 but the minutes state that I was representing Dr Chanarin who was the Director (CBLA0001464). From this I infer that we shared responsibility for relevant matters.

15) There was no physical entity designated "Haemophilia Centre" and no dedicated staff. There were very few patients with haemophilia and allied

disorders treated at Northwick Park Hospital and I have no recollection of any specific patients or relevant events during the time I worked there as consultant haematologist. We were a very small centre treating only a few patients. The return for 1976 shows only 3 patients were treated. The series of letter between myself and Dr Brozovic and others show that a patient transferred from Lewisham Hospital in 1980 (BPLL0002094). I do not remember any other new patients being referred but there may have been. However, I think the total number of patients must have been less than 10, probably less than 5. Unfortunately no Annual Returns are available for dates between 1977 and 1982 so I cannot be sure.

16) I do not think we would have had any written protocols. For such a small number of patients management would have been decided on an individual basis and would have been guided by current knowledge and expertise as transmitted to us via the UKHCDO meetings and by reading the literature.

17) I left Northwick Park in the summer of 1983 to go on maternity leave before taking up my new post at Charing Cross and Westminster Medical School. HIV was not identified in UK patients at the time I left NPH (June 1983). Hepatitis B was a known risk but was not common and I do not remember whether we specifically looked for this on a regular basis. Hepatitis C had not yet been identified and non-A non-B hepatitis was not then known to have serious consequences. I do not recall any patients with hepatitis.

18) I do not remember that there were other senior colleagues involved in relevant work at this time. My junior colleague Dr Cecil Reid was appointed to a consultant post at Northwick Park Hospital at some point, but I am uncertain whether this was before or after I left.

5. **In relation to your work as a haematologist at Charing Cross and Westminster Medical School, please:**

a. **Describe your role and responsibilities and how they changed over time;**

19) I worked at Charing Cross Hospital (CXH) from the autumn of 1983 until I moved to Hammersmith Hospital around the end of 1995. While at Charing Cross Hospital I shared with my senior colleagues the responsibilities of the department including managing the haematology laboratories, the blood transfusion service and the care of patients. My main responsibility was the care of patients with haematological malignancies and those undergoing bone marrow transplantation (BMT). I jointly established and ran the BMT unit until the unit moved to the Hammersmith Hospital around the end of 1995 when I also moved to the Hammersmith Hospital.

20) I do not remember being specifically responsible for patients with haemophilia, and have no memory of seeing any individual patient. Roles and responsibilities within the department including looking after haemophilia patients and acting as haemophilia centre director would be assigned by the Head of Department.

21) Regarding the role of HCD, I note from the records provided to me that:

The minutes of the UKHCDO in Oct 1983 show that my colleague Dr Catherine Haworth was the director at Charing Cross, and Dr M Desai attended in her place. (PRSE0004440).

The minutes of the UKHCDO in Oct 1984 show that I attended the meeting but do not indicate whether I attended as Director or in place of someone else. (PRSE0003659)

The minutes of the UKHCDO in Oct 1985 (PRSE0001638) show that Dr Haworth again attended the meeting but do not state that I gave my apologies or that she was attending in my place, suggesting she was attending as Director.

b. Provide an account of the Centre's history, its establishment and its activities during this time.

22) Charing Cross was a very small centre treating only a few patients. There was no physical entity designated "Haemophilia Centre". We did not have a dedicated specific treatment area or any dedicated staff. Unfortunately, no Annual Returns are available for the period I worked at Charing Cross so I cannot be sure how many patients were treated. However, I believe the total number of patients must have been less than 10.

23) I do not myself remember seeing any individual patient. I have some memory of a few individual patients who were treated by colleagues, but there were not many. By 1985 – 86 when the problem of HIV and potential other infectious agents was clear, several patients, including newly diagnosed patients, were transferred to the care of the Haemophilia Centre at St Thomas' Hospital, because it was felt they required more expert care and support than we could give at Charing Cross.

24) I do not think we would have had any written protocols during the early 1980s. Management would have been decided on an individual basis and would have been guided by current knowledge and expertise as transmitted to us via the UKHCDO meetings and by reading the literature. We would also have sought advice from colleagues at the Royal Free Hospital Haemophilia Centre which was our Reference centre. Dr Lee who worked at the Royal Free also spent 1 day a week at Charing Cross from 1984 and though I do not remember exactly what her role was she would have been able to give advice.

c. Describe your work insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of treatment with blood or blood products;

25) As noted, I do not recall any personal involvement with haemophilia patients. I do have some recollection of individual patients who were under the care of colleagues.

d. Identify senior colleagues involved in the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of treatment with blood or blood products, and their roles and responsibilities during the time that you worked there.

26) The following were my senior colleagues at different times and may have been involved in caring for patients with haemophilia and allied disorders.

Head of Dept Prof AJ Barrett, until 1989, replaced by Prof Brian Durie, until 1992, then post vacant until merger with RPMS in 1994 when Prof John Goldman became Head of Department.

Senior Lecturer Dr Minou Foadi

Senior Lecturer Dr Catherine Haworth, until 1993, subsequently Dr Donald McCarthy and then Dr Edward Kanfer

Later joined by Associate Specialists Dr Diana Hagger and Dr Faiza Nadir, I do not remember the date they took up this role.

6. Approximately how many patients with bleeding disorders were under the care of a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School when you began your work there and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

27) Northwick Park Hospital less than 10, probably less than 5

28) Charing Cross Hospital less than 10 in 1983 and fewer than this after 1985-6 when we began referring patients to St Thomas' Hospital

29) These figures are the best estimate according to my memory. I have asked for copies of the UKHCDO Annual Returns which would be able to answer this

question accurately, but I am told the only year for which they are available is 1976, as above these indicated 3 patients treated at Northwick Park hospital.

7. **To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:**

30) My replies below relate to both Northwick Park and Charing Cross.

a. **How, and on what basis, were decisions made about the selection and purchase of blood products?**

31) I do not recall. However, the current recommendations of the UKHCDO would have been followed. DDAVP, cryoprecipitate and Factor concentrate would have been used in different circumstances. Unfortunately, as no copies of the Annual Returns are available after 1976, I cannot be sure what exact products were used and how much of each type of product

b. **What were the reasons or considerations that led to the choice of one product over another?**

32) These would have included severity of bleeding disorder, practical considerations e.g. home therapy, and patient choice.

c. **What role did commercial and/or financial considerations play?**

33) I do not think there would have been any financial consideration given the small number of patients involved.

d. What, if any, involvement did you have?

34) I do not recall any such involvement.

8. What particular products were used for treating patients at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School, over what period of time and for which categories of patients?

35) At Northwick Park Hospital the annual return for 1976 shows the use of both cryoprecipitate and NHS Factor VIII concentrate, for 3 patients with Haemophilia A. I was no longer working at Northwick Park Hospital when heat-treated concentrate became available. The records provided to me indicate that another patient transferring his care to Northwick Park Hospital in 1980 was receiving NHS Factor VIII concentrate (BPLL0002094)

36) I do not know if commercial concentrate was ever used.

37) At Charing Cross Hospital from 1983 onwards I know both cryoprecipitate and Factor VIII concentrate were used because I remember they were used in one specific patient, but I do not know how much and for what type of patient, as no Annual Returns are available. I am aware of at least 2 patients who were on home treatment with concentrate prior to my arrival at Charing Cross and I imagine, but cannot be sure, that as they were children they would have received NHS concentrate. I do not know if commercial concentrate was ever used.

9. What was the relationship between a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School, and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the decisions and actions of those institutions?

38) I am not aware of any such relationship at either hospital.

10. If the responsibility for the selection and purchase of blood products lay with an organisation other than a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School, please specify which organisation and provide as much information as you can about its decision-making.

39) I am not aware that any other organisation was involved.

11. How were decisions taken at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School as to which products to use for individual patients? What involvement did you have in such decisions? To what extent, if at all, were patients offered a choice as to which products to use?

40) a. and b. Management would have been decided on an individual basis and would have been guided by current knowledge and expertise as transmitted to us via the UKHCDO meetings and by reading the literature. I cannot remember being personally involved in such a decision in any individual patient.

12. What alternative treatments to factor concentrates were available a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School in the 1970s and 1980s for people with bleeding disorders?

41) Both DDAVP and cryoprecipitate were available.

13. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

42) DDAVP might allow avoidance of the use of blood products but was only suitable for mildly affected patients with haemophilia A or those with von Willebrands disease. Cryoprecipitate was not really suitable for home treatment. At Northwick Park I do not remember what was used in which

patients but from the annual return in 1976 both cryoprecipitate and concentrate were used. Regarding Charing Cross Hospital, from my recollection of one individual patient I am aware that after the problem of HIV became apparent in around 1984, DDAVP would be used in preference to any blood product for untreated patients with mild – moderate Haemophilia A and von Willebrands disease and then if necessary cryoprecipitate.

14. What was the policy and approach at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders?

43) I do not recall any specific policy at either hospital. Cryoprecipitate was certainly used at both hospitals but I do not recall the specific policy for when they should be used. It would have been difficult to use cryoprecipitate for home treatment.

a. Did that policy and approach change over time and if so, how?

44) Yes: after 1983-4 every effort would be made not to use any blood product at all if bleeding could be controlled with DDAVP.

b. How, if at all, was the policy and approach informed by discussions had with external parties?

45) It would have been informed by discussions with, and guidance received from UKHCDO.

15. What was the policy and approach at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School in relation to home treatment? Did the policy and approach change over time and if so, how?

46) I am unable to recall any specific policy. There was one patient at Northwick Park who was on home treatment when his care was transferred to Northwick Park, and two, or possibly more, patients at Charing Cross Hospital who were

already on home treatment when I started working there. There may have been more but I do not remember.

16. **What was the policy and approach at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School in relation to prophylactic treatment? Did the policy and approach change over time and if so, how?**

47) I do not remember.

17. **What was the policy and approach a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so, how?**

48) I do not remember.

18. **To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School?**

49) I do not remember.

19. **What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School in consequence of the use of blood products?**

50) I do not recall any such infections.

20. **Please see the enclosed correspondence between yourself, Dr Lane, Dr Brozovic and Dr Whitmore [BPLL0002094]. The letters discuss arrangements for the reallocation of Factor VIII concentrate for a patient transferring from Lewisham Hospital to Northwick Park Hospital in 1980. With regard to this document, please answer the following questions:**

a. **Please explain the processes, individuals, organisations and issues involved in the transfer of patients to a haemophilia centre in a new region.**

b. **In a letter to you from Dr Brozovic dated 20 August 1980 (p5 of BPLL002094], Dr Brozovic states that he 'cannot foresee any difficulties in supplying you with factor VIII concentrates.' Without speaking to any patient in particular, please outline what difficulties in concentrate supply could arise in the process of a patient transferring into the care of a haemophilia centre in a different region.**

51) These letters refer to a purely administrative matter, regarding arrangements for the supply of NHS Factor VIII concentrate to an individual Haemophilia Centre. Centres received supplies of concentrate according to their need, which were distributed via the Regional Blood Transfusion Centres. This particular patient was transferring their care from Lewisham Hospital, served by the South Thames Blood Transfusion Centre, to Northwick Park Hospital, served by the North London Blood Transfusion Centre.

52) The allocation of concentrate therefore needed to move from one Transfusion Centre to the other, and the BPL therefore needed to adjust the relative amounts sent to each Transfusion Centre. The letters are making sure everyone is aware of the change and agreeable to it. Regarding possible difficulties I suppose it is theoretically possible that the staff at either Lewisham Hospital or South London Blood Transfusion Centre could object to their allocation being reduced, but I cannot imagine this would happen as it is an allocation for a specific patient.

21. **Please see the enclosed minutes from a meeting of Directors of Haemophilia, Associate Haemophilia and Blood Transfusion Centres 4, 5 and 6 dated 23 September 1977 [CBLA0000657]. The minutes record that you were present at this meeting. Several clinicians reported that they had purchased commercial concentrate to supplement shortfalls in availability of NHS products. In some cases, this was due to the increase in home**

treatment of patients. Did you experience a shortfall at Northwick Park Hospital? Did you have to purchase commercial concentrate to address this issue in your capacity as director at Northwick Park Hospital? Please comment on how, if at all, the shortage was resolved, and any effects the shortfall of NHS products and use of commercial concentrates may have had on the treatment and health of your patients.

53) I do not recall the discussion at the meeting, but I do not think we would have experienced any shortfall in availability given that in 1976 only 3 patients were treated at Northwick Park.

Section 3: Knowledge of, and response to, risk

Please answer the following questions, if appropriate, in relation to a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School. Where a question does not relate to one or either of these institutions, please indicate this in your answer.

General

22. When you began work as a consultant haematologist at the Centre, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

54) At the time I worked at Northwick Park, it was known that both hepatitis B and non-A non-B hepatitis could be transmitted by blood products. UK blood donors were already screened for hepatitis B, and at that time it was not appreciated that non-A non-B hepatitis could lead to chronic liver disease. I think we felt that blood products were very safe.

55) This all changed after I moved to Charing Cross Hospital when in 1984 it became evident that HIV could be transmitted by blood products, particularly products prepared from pooled plasma, and subsequently that commercial

products were associated with a higher risk than NHS products. The sources of my knowledge were information received from UKHCDO meetings, together with published articles in journals such as the BMJ, the Lancet, and the New England Journal of Medicine. Of course the internet did not exist and communication was slow. I believe that the UKHCDO meeting in 1984 (PRSE 000 3659) was the first meeting at which the role of HTLV3 in AIDS in haemophiliacs was discussed, and I think I would not have known about it before that meeting.

23. What advisory and decision-making structures were in place, or were put in place, at the Centre to consider and assess the risks of infection associated with the use of blood and/or blood products?

56) I do not recall any such structures being put in place. Relevant information would have been discussed at the weekly departmental meetings of senior medical staff.

24. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products, and (ii) the use of NHS blood products?

57) It was known by 1980 that the risk of hepatitis B was greater with commercial concentrate than with NHS blood product, as discussed at the minutes of a meeting of the UKHCDO on 30 September 1980 [PRSE0003946].

58) I think we would therefore have suspected that the risk of other infections would be greater with commercial concentrate, and it is my memory that the risk of HIV was demonstrated to be greater in commercially supplied products around the end of 1984 after serological testing became available.

Hepatitis

25. When you began work at the Centre, what was your knowledge and understanding of the risks of the transmission of hepatitis (including

hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products? What were the sources of your knowledge? How did that knowledge and understanding develop over time?

59) At the time I worked at Northwick Park, and when I began work at Charing Cross, it was known that both hepatitis B and non-A non-B hepatitis could be transmitted by blood products. UK blood donors were already screened for hepatitis B, and at that time it was not appreciated that non-A non-B hepatitis could lead to chronic liver disease. Knowledge regarding the risks of non-A non-B hepatitis grew slowly during the 1980s and I cannot say with any certainty when I became aware that there was a significant risk of serious liver disease.

26. What, if any, further enquiries and/or investigations did you and/or the Centre carry out or cause to be carried out in respect of the risks of the transmission of hepatitis? What information was obtained as a result?

60) I do not recall any such enquiries or investigations.

27. What, if any, actions did you and/or the Centre take to reduce the risk to patients of being infected with hepatitis (of any kind)?

61) As I remember, we would, wherever possible

- avoid the use of blood products
- use cryoprecipitate in preference to concentrate
- use heat treated concentrate (after this became available)
- choose NHS over commercial concentrate

28. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

62) See above answer to Q. 25

HIV and AIDS

29. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products during your time working at the Centre? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

63) I did not know in 1983 that HIV could be transmitted by blood and blood products. I became aware of this sometime during 1984.

30. How and when did you first become aware that there might be an association between AIDS and the use of blood products?

64) Sometime during 1984, certainly it was discussed at the UKHCDO meeting in 1984 (PRSE0003659)

31. What, if any, enquiries and/or investigations did you and/or the Centre carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?

65) I remember that at Charing Cross Hospital there were two children on home treatment who were tested and found to be HIV positive. I was not personally involved in their care. I do not remember if any other patients were tested, but I am not aware of any other patients who were HIV positive.

32. At a meeting of the UKHCDO dated 13 September 1982 at which you were present [CBLA0001619], Dr Craske stated that there was a remote possibility that commercial blood products had been involved in cases of HTLV-III in the United States, including three cases in haemophiliacs. Dr Craske instructed Haemophilia Centre Directors to report any cases in their patients. Did you ever make such a report to Dr Craske regarding patients at your Centre? As far as you are able to recall, how soon after this meeting did you become aware that HIV could be transmitted by blood and/or blood

products, and that this had occurred in the UK? If you are able to give precise dates, please do so.

66) I do not remember attending the meeting nor receiving the minutes but I have looked at the record which has been provided to me. I note Dr Craske mentioned that three cases of AIDS had been reported in haemophiliacs in the US, but he did not mention the HTLV-III virus which had not yet been identified. It was not yet clear that HIV could be transmitted by blood products and there was still uncertainty about the cause of AIDS.

67) In 1982 I was working at Northwick Park Hospital. We had not had any cases of AIDS.

33. What, if any, actions did you and/or the Centre take to reduce the risk to your patients of being infected with HIV?

68) See Q 29. above

34. Did the Centre continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? Why?

69) I am aware that the 2 patients at Charing Cross Hospital who were already HIV-positive continued to receive concentrate. I do not know what type of concentrate and whether this changed. I do not recall whether there were any other patients receiving concentrate, and if so, what decision was taken in these patients.

Response to risk

35. Did you or your colleagues at the Centre take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

70) I do not recall any specific steps. Information would have been given on an individual basis by the doctor caring for the patient.

36. When did the Centre begin to use heat treated factor products and for which categories of patients?

71) I do not recall but I think we would have used whatever products were recommended by UKHCDO therefore probably in 1985.

37. Do you consider that heat-treated products should have been made available earlier? If not, why?

72) I do not have sufficient expertise to comment.

38. Did you or your colleagues at the Centre revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, how was it determined which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

73) I do not remember.

39. Do you consider that your decisions and actions, and those of the Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

74) My memory is not sufficiently accurate to be able to comment.

40. Looking back now, what decisions or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

75) I cannot identify any such decisions. As a small centre we were very dependent on advice from UKHCDO.

41. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

76) I do not have sufficient knowledge or expertise to comment.

42. Do you consider that greater efforts could and/or should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

77) I do not have sufficient knowledge or expertise to comment.

43. The enclosed letter [CBLA0001975] from Peter Kernoff dated 7 January 1985 outlines the agenda for an upcoming meeting of Directors of Haemophilia Centres supplied by NBTS Edgware. The letter states that the meeting will aim to reach a uniform policy regarding the use of heat- treated concentrates.

a. If you have the minutes arising from the meeting, please provide a copy. If not, please explain as far as you are able to recall, the discussions that took place in this meeting.

78) I do not have a copy of the minutes. I do not know if I attended the meeting and I do not recall the discussion.

b. To your knowledge, was a policy reached in the meeting? If so, please explain what the policy decision was. Please explain how it was implemented. If a policy was not reached, please explain why.

79) I do not recall.

44. Please consider the enclosed appendix to a report from April 1988 titled 'AIDS/HIV: The Cost of the Service in Riverside DHA' [DHSC0004477_113][1]. In a breakdown of haematology costs at Charing Cross (p44), the report states that 3% of blood was considered 'at risk', but that you believed that this figure was at 4%. Please explain why you believed that the figure was in fact 4%, rather than that stated by the report, whether this difference was material, and the significance of this figure.

80) This part of the document relates to laboratory testing of blood samples by the haematology department. There was a large HIV/AIDS service in Riverside which generated diagnostic work for the laboratories. The phrase "blood considered at risk" means there was a risk of infection for staff handling the samples, leading to a different way of handling which was more expensive. It has nothing to do with the treatment of patients with blood products and as such is not relevant to the inquiry.

45. The same report [p.44 of DHSC0004477_113] recorded that you had discussed the implications of rising demand as a result of HIV on the cost of human albumin. Please outline your understanding of why there was a cost increase, your involvement in these cost discussions outside of this meeting, and whether, to your knowledge, adequate funding was available to meet this cost increase.

81) I believe this means that there was a cost increase to the hospital because more albumin was required to treat patients with AIDS who were under the care

[1] This document only comprises the appendix of this report. The full report may be made available if you feel it would assist you in answering these questions.

of the HIV/AIDS service. This is not relevant to the terms of the Inquiry.

46. At a meeting of the UKHCDO on 27 September 1984 at which you were present [PRSE0003659], Dr Craske asked Haemophilia Centre Directors to 'give special attention to work on HTLV-3'. Please explain in practical terms what was meant by this request. Did you/the Centre take any steps to fulfil this request? If so, what were the results of these efforts? If not, why not?

82) I do not recall the discussion. I imagine Dr Craske wished to draw attention to the risk of HIV in haemophiliacs and make sure that we all kept up to date with information provided by the HCDO. I know that some patients at Charing Cross were subsequently tested for HIV (see 33).

Section 4: Treatment of patients at the Centre

Please answer the following questions in relation to a) Northwick Park Hospital and b) Charing Cross and Westminster Medical School. Where a question does not relate to one/either of these institutions, please indicate this in your answer.

Provision of information to patients

47. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients at the Centre with a bleeding disorder about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates) prior to such treatment commencing? Please detail whether, and if so, how this changed over time.

83) I have no specific recollection. Information would have been given on an individual basis by the doctor caring for the patient.

48. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients about alternatives to treatment with factor concentrates? Please detail whether, and if so, how this changed over time.

84) I have no specific recollection. Information would have been given on an individual basis by the doctor caring for the patient.

49. What information did you provide or cause to be provided (or was, to your knowledge, provided by others) to patients before they began home treatment/home therapy?

85) I do not remember any patients who started on home therapy during the time I worked at either hospital.

50. Please see the enclosed minutes of a meeting of the UKHCDO on 30 September 1980 [PRSE0003946]. At pp.5-6, there is a discussion regarding the inadequate supplies of NHS concentrate. Professor Stewart commented that "Centres at present only bought commercially that amount of material which was required as a dire necessity by the Centre". To the best of your recollection, was this an accurate portrayal of the situation? Dr Swinburne is reported as saying that despite increased factor VIII usage, some patients remained undertreated. Was this ever your experience at either Northwick Park Hospital or Charing Cross Hospital?

86) I do not recollect any such cases.

HIV

51. When did you first discuss AIDS or HIV (HTLV-III) with any of your patients?

87) I do not recall looking after any patients with haemophilia at, or after, the time the risk of HIV became evident, so I did not discuss AIDS with any of my patients.

52. Please describe how and when you learned that patients under your care/the care of the Centre had been infected with HIV.

88) I remember that there were 2 children with haemophilia who were tested for HIV and found to be positive, I believe that this would have been in late 1984 or early 1985. I myself did not see these patients.

89) I have no recollection of any other patients who were infected, nor of those who might have been tested.

53. What, if any, arrangements were made at the Centre for pre-test counselling?

90) This would have been done by the doctor caring for the patient.

54. How and when and by whom were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by phone? Were they seen individually or in groups? What, if any, involvement did you have in this process?

91) This would have been done by the doctor caring for the patient.

55. What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret?

92) I do not know. I was not personally involved in any such case.

56. What was the Centre's/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were the tests carried out?

93) I do not recall.

57. What, if any, information or advice was provided by you or colleagues at the Centre to partners or family members of people who were at risk of infection with HIV or were infected with HIV?

94) I do not recall.

58. What, if any, arrangements were made at the Centre for post-test counselling?

95) I do not recall.

59. How many patients at the Centre were infected with HIV? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

96) I have already mentioned the 2 children with severe haemophilia A who were infected with HIV. As far as I recall no other patients were infected.

60. Was work undertaken at the Centre to establish the time period during which patients seroconverted? If so, please describe what work was done and what, if any, conclusions were reached.

97) No

Hepatitis B

61. Were patients infected with hepatitis B informed of their infection and if so, how? What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management? What, if any, involvement did you have in this process?

98) I do not recall that any patients were infected.

62. How many patients at the Centre were infected with hepatitis B?

99) I do not remember any such patients, at either hospital.

NANB Hepatitis/Hepatitis C

63. Were patients infected with NANB hepatitis informed of their infection and if so, how and by whom? What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management? What, if any, involvement did you have in this process?

100) I do not remember any such patients, at either hospital

64. When did the Centre begin testing patients for hepatitis C? How, when and by whom were patients informed of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What, if any, involvement did you have in this process?

101) I do not recall when testing began and whether any haemophilia patients were tested. Those at greatest risk, including the two HIV positive patients, had already been referred elsewhere.

65. What information was provided to patients infected with hepatitis C about their infection, its significance, prognosis, treatment options and management?

102) I do not recall any such patients.

66. When a test for HCV became available, what, if any, steps were taken by the Centre and/or by you to ensure that all patients who had received blood products were traced and invited to be tested?

103) I do not recall.

67. How many patients at the Centre were infected with hepatitis C?

104) I am not aware of any who were tested during the time they were treated at Charing Cross.

Delay/public health/other information

68. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

105) I believe results would have been communicated promptly as this would be good medical practice.

69. To what extent, if at all, did you/your colleagues take into account the public health implications of HIV, AIDS, hepatitis B, NANB hepatitis and hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?

106) I cannot make any specific comment.

70. What information was provided to patients about the risks of other infections?

107) I do not recall if any such information was routinely given.

71. What information was provided to patients about the risks of infecting others?

108) This would have been discussed with the patient, or in the case of children, their parents, by the doctor caring for them.

Consent

72. How often were blood samples taken from patients attending the Centre and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so, how and where?

109) I am not able to remember.

73. Were patients under your care or under the care of your colleagues at the Centre treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and if so, how and where?

110) No patients were treated without consent as far as I am aware. I am not able to remember how consent was obtained and recorded.

74. Were patients under your care tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing? Was their consent recorded and if so, how and where?

111) No patients were tested without consent as far as I am aware. It was hospital policy at Charing Cross that no patient whatever the diagnosis should be tested for HIV without giving their consent. However, I do not remember how consent was obtained and recorded.

PUPS

75. Please detail all decisions and actions taken at the Centre by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

112) I do not remember any PUPS at Northwick Park Hospital.

113) I remember only one such patient at Charing Cross Hospital, who had severe von Willebrand's disease, and who was treated with DDAVP and cryoprecipitate.

114) This patient and subsequently other new patients were referred to St Thomas Hospital Haemophilia Centre for further management.

Research

76. Please list all research studies that you were involved with during your time as a consultant at the Centre. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:

a. Describe the purpose of the research.

b. Explain steps that were taken to obtain approval for the research.

c. Explain what your involvement was.

d. **Identify what other organisations or bodies were involved in the research.**
e. **State how the research was funded and from whom the funds came.**
f. **State the number of patients involved.**
g. **Provide details of steps taken to inform patients of their involvement and to seek their informed consent.**
h. **Provide details of any publications relating to the research.**

Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

115) N/A

77. **Were patients involved in research studies without their express consent? If so, how and why did this occur?**

116) N/A

78. **Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express consent? If so, what data was used and how and why did this occur?**

117) I do not recall any such use, apart from the HCDO Annual Returns where data was anonymised.

79. **Was patient data (anonymised, de-identified or otherwise) shared with third parties without their express consent? If so, how, and why did this occur, and what information was provided to whom?**

118) As per 78 above.

80. **At a meeting of the UK Haemophilia Centre Directors on 24 October 1977, it was noted that in relation to the provision of further information to the**

National Register, some clinicians expressed concern about the potential misuse of confidential patient data [p19 of PRSE0001002]. Did you share this concern? As far as you can recall, was the risk associated with including patient data in the National Register theoretical, or were you aware of any instances where confidential data was used inappropriately? If so, please explain what occurred.

119) I have no recollection of this discussion. I am not aware of any inappropriate use of such data.

81. Please see the enclosed memo dated 19 April 1991 [BPLL0005964]. The memo concerns products issued from PFL provided to haemophilia centres "mostly without charge" in return for the provision of clinical data. Your name is included on p4. As far as you are able to recall, please explain the arrangement referred to [p1 of BPLL0005964], including:

120) This memo concerns practical arrangements for obtaining so-called "minor blood products", that is, products which were not often used but which were previously manufactured by the PFL and would in future be manufactured by the BPL. These could be requested by telephoning the PFL. I note that the memo is circulated to haematologists who had used antithrombin III (ATIII), Factor VII concentrate, and Factor XI concentrate.

a. how much product was given to your Centre;

121) I do not recall

b. whether the product was provided free of charge;

122) Yes

c. what types of products were provided;

123) I used ATIII for one patient in 1983 while at Northwick Park and I believe I used Factor VII concentrate for one patient while at Charing Cross. I note that my colleagues Dr Hagger and Dr Haworth are also listed as users of ATIII at Charing Cross, but I do not have any information about this.

d. what, if any, information or clinical data was sent by you, to whom, and for what purpose; and

124) For the patient receiving ATIII at NPH I believe that I provided data to BPL on antithrombin III levels post transfusion, and data on liver function tests. These data were to provide BPL with information on efficacy and risk.

e. whether patient consent was obtained for the sharing of this data.

125) I do not recall specifically but that would have been my normal practice.

82. Please consider the enclosed Clinical Efficacy report [BPLL0016048_002]. To your knowledge, please confirm whether this relates to the same matter discussed in question 81. If this is the case, please explain any further information within your knowledge which may not have been addressed by question 81. If the two matters are not related, please explain the arrangement referred to on p29 of this report, including:

a. how much product was given to your Centre;
b. whether the product was discounted and to what extent;
c. what types of products were provided;
d. what, if any, information or clinical data was sent by you, to whom, and for what purpose; and
e. whether patient consent was obtained for the sharing of this data.

126) Yes this document relates to the matter discussed in Q 81, but specifically relates to antithrombin III and not the other minor products, and concerns efficacy and safety rather than practical arrangements for issue of the product. See answers to Q 81.

83. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference.

127) I am not quite sure if this is relevant to the Inquiry's Terms of Reference but I published a case report of the treatment of the patient mentioned in item 81.

D Samson, Y Stirling, L Woolf, D Howarth, M J Seghatchian, R de Chazal. Management of planned pregnancy in a patient with congenital antithrombin III deficiency Br J Haematology 1984 vol 56 pp 243-9.

84. The Inquiry is aware that for several years, you were involved in some capacity as a member of the Medical Research Council until your resignation in 1983 or 1984 [p84 of MRCO0000071]. Please confirm your role at the Medical Research Council, the dates you occupied that position, and explain what this role entailed.

128) This refers simply to my position as Consultant Haematologist at the MRC Clinical Research Centre (1977-1983). My role was to carry out clinical research. At the time I worked there my research was looking into the mechanisms of anaemia in different situations, including rheumatoid arthritis.

Treatment of patients who had been infected with HIV and/or Hepatitis

85. How was the care and treatment of patients with HIV/AIDS managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

129) As mentioned above, the 2 children with HIV were transferred to the Haemophilia Centre at St Thomas' Hospital. I do not remember any other patients with HIV, but if there were any such patients I believe they would also have been transferred to St Thomas' or possibly the Royal Free Hospital. This

was so that they could benefit from the expertise and support available at a larger Centre.

b. What treatment options were offered over the years to those infected with HIV?

130) N/A see 85 above

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

131) N/A see 85 above

86. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

132) N/A see 85 above

87. How was the care and treatment of patients with hepatitis B managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

133) I do not recall any such patients. If there were any they would have been referred to the consultant hepatologist for further management.

88. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis B?

134) See 87.

89. How was the care and treatment of patients with NANB hepatitis managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

135) I do not recall any such patients. If there were any they would have been referred to the consultant hepatologist for further management.

90. How was the care and treatment of patients with hepatitis C managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?
b. What treatment options were offered over the years?
c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

136) see 89.

91. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis C?

137) see 89.

92. What arrangements were made for the care and treatment of children infected with HIV or hepatitis? How did those arrangements differ (if at all) from the arrangements made for adults?

138) see 85a.

93. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

139) I do not remember

94. Did the Centre receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?

140) Not as I recall.

95. What, if any, difficulties did you/the Centre encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

141) None as I recall.

96. What, if any, involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

142) None as I recall.

Records

97. What was the Centre's policy with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis?

143) I do not remember that there were any patients with HIV or hepatitis who died while under the care of either hospital.

98. What were the retention policies of the Centre's in regards to medical records during the time you were practising there?

144) Patient records would be treated in the same way as for all hospital patients, and were the responsibility of the relevant Medical Records Department. I am assuming that the policies of each hospital were in line with National Guidance.

99. Did you maintain separate files for some or all patients? If so, why; where were those files located; and where are those files now?

145) No, none, only normal hospital records.

100. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the Centre? If so, why, what information and where is that information held now?

146) No, none.

101. Do you still hold records or information about any of your patients? If so, explain why and identify the records or information that you still hold.

147) No, none.

Section 5: UKHCDO

102. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups).

148) I attended meetings of UKHCDO over the years. I was never involved in any working parties, committees or groups.

103. During the period that you were involved with UKHCDO, please outline:

a. **The purpose, functions and responsibilities of UKHCDO, as you understood them.**
b. **The structure, composition and role of its various committees or working groups.**
c. **The relationships between UKHCDO and pharmaceutical companies.**
d. **How decisions were taken by UKHCDO.**
e. **How information or advice was disseminated by UKHCDO and to whom.**
f. **Any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to:**
    - **the importation, purchase and selection of blood products;**
    - **the manufacture of blood products;**
    - **self-sufficiency;**
    - **alternative treatments to factor products for patients with bleeding disorders;**
    - **the risks of infection associated with the use of blood products;**
    - **the sharing of information about such risks with patients and/or their families;**
    - **obtaining consent from patients for the testing and storage of their blood, for treatment and for research;**
    - **heat treatment;**
    - **other measures to reduce risk;**
    - **vCJD exposure; and**
    - **treatments for HIV and hepatitis C.**

149) My understanding was that the UKHCDO existed to promote good practice in the treatment of bleeding disorders, also that it was one of their roles to act for the Department of Health in relation to this. I attended meetings as a non-specialist seeking information about current knowledge and about best practice.

I am not sure how the various committees and working groups were established. I have no knowledge of any relationships with pharmaceutical companies. I was not involved in the development of any policies.

104. Please consider the enclosed minutes of a meeting of the UKHCDO which took place on 9 October 1981, at which you were present [CBLA0001464]. The minutes record that the Department of Health requested that Haemophilia Centre Directors keep accurate records of the purchase and use of commercial factor VIII concentrates, and that the annual returns submitted by Haemophilia Centre Directors were not 'sufficiently rapid or complete'. Please comment on whether or not you agree with this assessment of the data collected through annual returns. If this is your view, please explain why. Following this meeting, what steps, if any, were taken to improve the accuracy of data collection on the usage and purchase of factor VIII concentrates and to ensure this information was provided sufficiently promptly to the Department of Health?

150) I do not recall the discussion. I am not sure how the data collection centre would know whether the returns were accurate or complete. I do not remember now how the data collections forms changed and evolved over the years.

105. The minutes from this meeting [CBLA0001464] also record a discussion around arrangements for the regional purchase and distribution of blood products. Professor Bloom stated that Haemophilia Centre Directors should undertake to provide the Department of Health with data as required, and that organised Regional services purchasing of factor VIII might help with this. Did the Department of Health ever make such a request? If so, please explain what type of information was required, with what frequency and, as far as you are aware, the purposes for which that information was used.

151) I do not recall.

106. Please consider the enclosed letter [HCDO0000075_003] from you to Rosemary Spooner dated 3 June 1977 and the enclosed forms [HCDO0000075_004] for patients treated at Northwick Park Hospital during 1976. As far as you are aware, why had these forms not been previously completed, as you stated in your letter? From that point forward, did you provide details of patients under your care to Oxford Haemophilia Centre?

152) I had just taken up my post at Northwick Park. I imagine the request for the 1976 data had been sent to Dr Chanarin some time earlier in 1977 and he kept it to one side for me to complete when I arrived. I am sure that I would have filled in any return forms subsequently addressed to me.

Section 6: Pharmaceutical companies/medical research/clinical trials

107. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.

153) I provided independent advice at different times to the Ethical Committee at Glaxo (1970s) and to Trial Review Committees at Chugai Pharma (1990s). I am not aware that these companies were involved in the production of blood products, certainly the studies I was involved with did not involve blood products.

108. Have you ever received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

154) No.

109. Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of

blood products? If so, please provide details of your involvement and of any financial or other remuneration you received.

155) See above 107/108.

110. Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

156) No.

111. Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

157) No.

112. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

158) No.

113. What regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

159) I do not recall what guidelines would have been in place. If there were any I am sure I would have followed them.

114. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

160) No.

115. Have you ever provided a pharmaceutical company with results from medical research studies that you have undertaken? If so, please provide details.

161) No, other than results that were within the public domain – presented at meetings or published. These studies would be in relation to clinical trials in haematological malignancies and transplantation, and not relevant to the Inquiry.

116. If you did receive funding from pharmaceutical companies for medical research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

162) The department at Charing Cross received support in the context of clinical trials including for example funding for trial coordinators. Such funds were always administered via the Medical School and/or NHS Trust.

117. The minutes of a meeting of the UKHCDO dated 9 October 1981, which you attended, record a discussion about the transfer of responsibility for purchasing, holding and distribution of blood products.

a. **Firstly, there was a discussion about transferring responsibility to the Blood Transfusion Centres [p9 of CBLA0001464]. It was recorded that the Haemophilia Centre Directors were troubled by this suggestion, and it was noted that it had been decided that these responsibilities should remain with the Haemophilia Centre Directors. As far as you can recall, why were the Haemophilia Reference Centre Directors concerned about this prospect? Why had the decision been taken not to agree to the transfer of responsibility?**

b. **A further proposal was made about transferring the manufacture of factor concentrates to the pharmaceutical industry. It was unanimously agreed that the Department of Health and Social**

Security should not do so. Did you share this view? As far as you are able to recall, please explain the reasoning for the proposal raised by Dr Chanarin and why this was considered undesirable by the UKHCDO.

163) I do not remember this discussion and am unable to comment.

Section 8: The financial support schemes

118. What, if any, involvement did you have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, EIBSS) which were set up to provide financial support to people who had been infected?

164) None as I recall.

119. To what extent, during your time at the Centre, did staff (including you) inform patients about the different trusts or funds?

165) I do not recall any such patients, i.e. patients treated at the centre. The patients who became HIV positive had already been transferred to larger haemophilia centres.

120. Did the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

166) I do not recall.

121. What kind of information did the Centre provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

167) See 119 above

122. Did the Centre, or any of their staff, act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

168) See 119 above

123. Was the Centre or any of its staff involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

169) No.

124. Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your patients in relation to the trusts or funds, do you consider that the trusts and funds were well run? Do you consider that they achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

170) I have had no relevant experience.

125. The Inquiry understands that you were involved in the Scheme of Payments for Those Infected with HIV through NHS Blood or Tissue. In answering this question, you may wish to consider the enclosed documents relating to a patient under your care who may have benefitted from this scheme [NHBT0090113_014 & DHSC0006212_131]. Without referring to any particular patient, please explain:

a. How this scheme functioned and your involvement with it;

171) I had no involvement with the scheme. This particular patient was not a patient with a bleeding disorder and was not under my care but under the care of the oncologists (see q 131 below). In this case I acted only in my role as one of the

consultants responsible for the blood transfusion laboratory and I passed on the letter to the clinician in charge of the patient.

b. How many patients under your care at any of the institutions at which you have worked received assistance from this scheme;

172) None, to my knowledge, at least while still under the care of Charing Cross Hospital.

c. Your opinion regarding the functioning of this scheme: for instance, how it was run, whether it achieved its aims, and any shortcomings in its operation.

173) I am not able to comment.

Section 7: vCJD

126. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?

174) Not while I was still working at Charing Cross Hospital. I moved to the Hammersmith Hospital in 1995/6.

127. Did you have any involvement in decisions as to what information to provide to patients about vCJD?

175) No.

If so please answer the following questions:

a. What steps were put in place at either of the institutions at which you have worked for informing patients about possible exposure to vCJD?

b. **What steps were taken to tell patients of possible exposure to vCJD?**
c. **What steps were taken to provide information to patients about the risks of vCJD?**
d. **What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?**

176) N/A re all of the above

128. What measures were put in place at either of the institutions at which you have worked from a public health perspective, in relation to the care and treatment of patients?

177) I do not recall.

Section 9: Look-back

129. The enclosed letter from Dr Hewitt to you dated 20 February 1990 [NHBT0090113_028] concerns a look-back exercise conducted on a patient under your care at Charing Cross Hospital. With regard to this patient and/or similar exercises conducted on other patients under your care, please answer the following questions[2]:

a. **To your knowledge, what was the procedure for conducting a look-back exercise on a patient?**

178) My understanding is as follows. If the National Blood Transfusion Service identified that a donor posed an infection risk, they would identify the numbers of the units of blood or blood products that donor had donated, and contact all the haematologists responsible for the transfusion laboratories in the hospitals

[2] In answering these questions, you may find it helpful to refer to the following documents between you and Dr Dewitt dated 9 February 1990 [NHBT0090113_029] and 29 August 1990 [NHBT0090113_017] which relate to the HIV look-back exercise conducted on this patient.

that had received the products. The haematologists would then identify from local records which patients had received the products and contact the relevant clinician. The patients would then be counselled and tested by that clinician.

b. What was your involvement in the look-back exercise in NHBT0090113_028 and similar cases? What were the results and what steps were taken to inform the patients?

179) This case and the one discussed under Q 130 were the only cases in which I was involved as far as I can recall. Neither was related to a patient with a bleeding disorder.

180) I was informed by Dr Begent that the patient had been found by the clinician now looking after her in Birmingham to be HIV positive and that it appeared likely she had been infected by a previous blood transfusion she received while undergoing surgery at Charing Cross Hospital. I then identified from the records in the transfusion laboratory what were the donation numbers of the units she had received and informed Dr Hewitt at NBTS. The purpose of informing NBTS would be so that they could trace the donors and take appropriate steps to determine whether any of them were HIV positive and if so whether any other patients had been potentially infected.

c. In the enclosed letter from Dr Begent to you dated 17 January 1990 [NHBT0090113_030] Dr Begent asks whether anything further should be done regarding this patient who was found HIV-positive, such as contacting the blood donors. As far as you can recall, were any further steps taken in relation to this patient, for what reason, and with what result?

181) See b above. Note that my letter to Dr Hewitt was after I received the letter from Dr Begent (dated 9th Feb 1990, NHBT 00090113_029), it was not earlier. There were subsequently 2 follow-up letters to me from Dr Hewitt (NHBT 00090113_017 and NHBT 00090113_014) regarding their investigations of the case. They were not able to identify a donor who could have been the source

of the infection. Regarding the patient herself, she remained under the care of Dr Blackledge in Birmingham and I have no further information about her.

130. Please consider the enclosed letter from Dr Macdonald to yourself dated 19 May 1997 [NHBT0099180_230] regarding a hepatitis C look-back exercise in a patient previously under your care. Dr Hewitt offered you the opportunity to contact the patient yourself. As far as you can recall, did you contact the patient? In answering this question, you may find it useful to consider the enclosed documents [NHBT0099180_223 & NHBT0099180_226] which also refer to your involvement in this matter.

182) I remember this patient who was a bone marrow transplant recipient who had been under my care for several years and who was still followed up by myself and my colleague Dr Ed Kanfer at the bone marrow transplant unit at Hammersmith Hospital where we had moved in 1995-96. I am fairly sure that I contacted him myself to arrange for him to come and see us for counselling and testing. However in the summer of 1997 I became unwell and had to take an extended period of sick leave, so my memory is unclear as to whether I saw him myself or whether he was seen by Dr Kanfer. However I note that document [NHBT0099180_226] indicates he was counselled and tested by Dr Kanfer.

Section 11: Other Issues

131. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

183) None

132. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

184) None

Statement of Truth

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

Signed GRO-C

Dated 10th Dec 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
N/A	N/A	N/A