Professor Howard Thomas Rule 9 - List of Questions

Section 1: Introduction

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

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. Please include:
    a. a description of your role and responsibilities in relation to (i) clinical work with patients, and (ii) research at the Royal Free Hospital;
    b. a description of your role and responsibilities as a Professor of Medicine and Consultant Hepatologist at St Mary's Hospital, Paddington;
    c. a full and up to date bibliography of your publications.

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.

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 the 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 that you provided, save for those that are already provided to you with this request.

5. The Inquiry understands that you took up a role as a Lecturer at the Royal Free Hospital School of Medicine in 1974, progressing to Senior Lecturer, Senior Research Fellow and thereafter to the role of Professor. Please provide, in outline

introductory terms (you are asked to give a detailed account on more particular points in subsequent questions):

a. A narrative chronology of your developing research focus over the course of your career, explaining your contribution to each topic area (insofar as relevant to the Inquiry's Terms of Reference), and any major findings or conclusions that were drawn from this work; and

b. The extent to which your work at the Royal Free was clinical, the nature of your engagement with patients, and the broad nature of their illnesses. If this changed or developed over time, please explain how and why.

6. The Inquiry understands that you took up a Chair at St Mary's Paddington in 1987 and subsequently at Imperial College until your retirement in 2011. Please provide, in outline introductory terms (you are asked to give a detailed account on more particular points in subsequent questions):

a. A narrative chronology of your developing research focus over the course of your career, explaining your contribution to each topic area (insofar as relevant to the Inquiry's Terms of Reference), and any major findings or conclusions that were drawn from this work; and

b. The extent to which your work at St Mary's was clinical, the nature of your engagement with patients, and the broad nature of their illnesses. If this changed or developed over time, please explain how and why.

Section 2: Your research about hepatitis

7. The Inquiry understands that you have conducted research or clinical trials and/or published articles in relation to topics that are relevant to the Inquiry's Terms of Reference. Please identify the relevant research and answer the questions listed at (i) to (viii).

(i) describe the purpose of your research, explaining the existing state of knowledge in the field about the topic, and identifying the contribution that this piece of research was intended to make;

(ii) identify the conclusions of your research, including any guidance provided or findings made;

(iii) if applicable, explain how the conclusions you drew or guidance you proposed following a particular study or trial altered practice going forward;

(iv) set out whether you now consider that your findings or conclusions were accurate, and if not, why not, and whether you subsequently reached any different views;

(v) explain what your involvement in the research was and identify what other organisations or bodies were involved in the research;

(vi) explain the steps that were taken to obtain approval for the research;

(vii) state how the research was funded and from whom the funds came; and

(viii) where the research was a clinical trial, state the number of patients involved and provide details of the steps taken to inform patients of their involvement and seek their informed consent.

8. On the whole, what do you understand to be the ethical principles that should guide research? Did you apply those principles to the research studies referred to above in your answer to question 7, and if so how? If not, why not?

9. In any of the studies that you have discussed in your answer to question 7 above, were patients involved in research studies without their express consent? If so, how and why did this occur?

10. In any of the studies that you have discussed in your answer to question 7 above, 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?

11. In any of the studies that you have discussed in your answer to question 7 above, was patient data (anonymised, de-identified or otherwise) shared with third parties? If so how and why did this occur and what information was provided to whom?

Section 3: Knowledge of, and response to, risk

General

12. When you started work at the Royal Free, what was your knowledge and understanding of the risks of the transmission of hepatitis (in all forms) from blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

13. What if any enquiries and/or investigations did the Department in which you worked and/or you carry out or cause to be carried out in respect of the risks of transmission of hepatitis? What information was obtained as a result?

14. What if any actions did the Department or you take to reduce the risk to patients of being infected with hepatitis (of any kind)?

15. 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?

Response to Risk

16. Did you or the Department at which you worked take any steps to ensure that patients and/or the public were informed and educated about the risks of hepatitis? If so, what steps?

17. Do you consider that your decisions and actions and those of the Department 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.

18. 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 from blood or blood products? What, if anything, do you consider could or should have been done differently by these others?

Section 4: Treatment of Patients at the Royal Free Hospital

19. Explain how your approach to the clinical diagnosis of your own patients at the Royal Free developed as a result of your research and understanding of different types of Hepatitis, referring as appropriate to the research discussed in your answer to question 7 above.

20. In your evidence to the Archer Inquiry you stated that Professor Kernoff "used to invite me to see occasional patients" [ARCH0000011]. In relation to the Royal Free Haemophilia Centre:
    a. What was your involvement in the care and treatment of patients who had a bleeding disorder?
    b. When did Professor Kernoff ask you to see patients? What were the circumstances that gave rise to your attendance?
    c. Did you ever request to see patients and/or for patients to be referred to the liver clinic?

21. What discussions, if any, did you have with Professor Kernoff or his colleagues about the risks of the transmission of infections through blood and blood products? Specifically:
    a. If you had such discussions, when did they take place and how did they arise?
    b. What were your views about the risks of the transmission of infections through blood and blood products?
    c. What views did Professor Kernoff express about the risks of the transmission of infections through blood and blood products?

22. The Inquiry understands that serum samples were stored and frozen by Professor Kernoff throughout his tenure as Director of the Haemophilia Centre. Were patients told that samples of serum were being stored? What, if anything, were they told about why the samples were being stored? Was their informed consent sought and/or obtained prior to such samples being taken?

23. At a meeting of the UKHCDO Hepatitis Working Party on 20 February 1980, you and Dr Kernoff described a "prospective study" that you had undertaken with patients

who had not previously received factor concentrate [HCDO0000550]. Were the patients aware that they were part of a "prospective study"? What were they told before they were given factor concentrates for the first time? Was there a clinical need for the use of factor concentrate or would an alternative treatment have been available to them? Did the patients give their informed consent to participating in this trial?

24. In a chapter you wrote with Prof Kernoff and Dr Bamber in Unresolved Problems in Haemophilia, it was noted that "… evidence suggests that infusion of large pool Factor VIII concentrate, whether of NHS or commercial origin, is a major cause of liver function test abnormalities". It went on to note that it seemed probable that transfusion transmitted viral hepatitis was responsible for liver function test abnormalities in the majority of patients. Further, that 42% of the patient group biopsied were found to have chronic active hepatitis and "although the prognosis of this lesion following NANB hepatitis is unknown, it should be noted that a similar lesion associated with chronic hepatitis B virus infection is progressive and, in a proportion of patients, ultimately results in the development of cirrhosis and its attendant complications" [DHSC0003621_042].
    a. Did this accurately represent your and/or Prof Kernoff's views in 1980?
    b. When did you come to the view that NANB was "potentially serious"?
    c. The chapter discusses patients who had undergone liver biopsy. Who undertook the biopsies? What were patients told about why they were undergoing the biopsy? Were they aware that they were part of a research study? Did they give informed consent to participate in the study? The attached letter from E. Goldman to Dr Aronstam dated 7 February 1980 [TREL0000146_044] may be of assistance.
    d. In light of these findings, what if anything did Prof Kernoff do in relation to the treatment of haemophilia patients? Specifically, what steps, if any did he take in relation to the types of products that were used and/or the quantity of products that were used?

25. Insofar as you are aware of the following matters please answer:
    a. Were patients infected with hepatitis B always informed of their infection and if so how?
    b. What information was provided to patients infected with hepatitis B about the

infection, its significance, prognosis, treatment options and management?

c. Were patients infected with NANB hepatitis always informed of their infection, and, if so, how?

d. What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management?

e. Were the results of testing for 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.

26. At a meeting of the UK Working Party on Transfusion Associated Hepatitis on 27 September 1983, there was a discussion about the involvement of concentrate in cases of AIDS (see [PRSE0001299], [PRSE0003121] and [PRSE0002278]). You stated that "30% of Royal Free haemophiliacs have raised T8 values whereas only a few have lowered T4 values. Recipients of low-purity factor VIII show the ratio abnormality, whereas high-purity factor VIII and factor IX recipients do not show abnormal ratios". How did you come to have this information? Who had tested the Royal Free patients to assess their T8 and T4 values? Were the patients told that their T8 and T4 values were being tested and the reason for those tests? Did they give their informed consent to those tests? Were patients informed of the results of these tests? Were they informed of the different results for those who had received low purity and high purity factor products?

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

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

Consent

29. Were patients under the care of the Haemophilia Centre tested for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was the approach to obtaining consent for testing?

Care and treatment

30. 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?
    d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis B?

31. 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?

Section 5: Treatment of Patients at St Mary's Paddington

32. Were you involved in the provision of hepatology care to any haemophilia patients referred to St Mary's from other Haemophilia Centres? Were you involved in the provision of hepatology care to any patients otherwise infected with hepatitis (of any type) through blood or blood products? If so please address the following:
    a. What information was provided to patients infected with hepatitis C about the infection, its significance, prognosis, treatment options and management?
    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?
    d. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis C?
    e. What arrangements were made for the care and treatment of children infected with hepatitis (of all types)? How did those arrangements differ (if at all) from the arrangements made for adults?
    f. What if any arrangements were made to provide patients infected with

hepatitis through blood or blood products with counselling, psychological support, social work support and/or other support?

g. What (if any) difficulties did you/the Department encounter in obtaining sufficient funding for the treatment of people who had been infected with hepatitis C?

Section 6: Safety of blood products

33. Please outline any interactions and dealings you had with the blood services, whether on a regional or national level, and/or with BPL during the time that you worked at the Royal Free and/or St Mary's.

34. What if any discussions or meetings or interactions did you have with any blood service (regionally or nationally) and/or BPL in relation to:

    a. the risk of infection with hepatitis from blood products;

    b. the risk of infection with HIV/AIDS from blood products;

    c. the steps to be taken to reduce the risk of infection?

35. Please explain the work you undertook in the early 1980s on the development of a radioimmunoassay test for hepatitis ([DHSC0003877_037]; [DHSC0003877_038] and [NHBT0000068_049]). What interactions did you have with (a) BPL, (b) other pharmaceutical companies and (c) the DHSS with regard to this development? Please set out a chronological account of the development of the test and any interactions with these bodies. (DHSC0002223_098, IPSN0000252_002 and RLIT0000183 may also be of assistance).

36. Please provide a chronological account of your work in relation to diagnostic assays for non-A non-B hepatitis, from the early 1980s to the establishment of a test for Hepatitis C. ([PRSE0003460], [CBLA0001788] and [NHBT0000187_044] may be of assistance).

37. What if any involvement did you have with any decisions or actions taken by any blood service (regional or national) and/or BPL in response to the risks arising from blood and blood products? In particular, please address what the aims and objectives were of the Working Party on Post-Transfusion Hepatitis, the issues

discussed and the recommendations that were made ([CBLA0001575], [CBLA0001625] and [BPLL0009204_005] may be of assistance).

38. In 1987 the Transfusion Associated Hepatitis Working Party discussed an anti-HBc/ALT screening trial (see [PRSE0000450] and [PRSE0002099]). Please explain the background to this discussion, what your involvement in the trial was and what your views of the trial were.

39. In Reviews in Medical Virology journal in 1991, you wrote a debate style piece titled "Blood Transfusion Services should have begun screening for Hepatitis C when an antibody assay first became available" [NHBT0088770]. You wrote in favour of the proposition. Was this also your own personal view? If not, please explain why it was not. If it was your view, please explain the basis for your view that anti-HCV screening ought to have been introduced earlier than it was, and explain your understanding of the reasons for any delay. In particular, please set out (to the extent that such matters are within your own knowledge):
    a. In your view, when screening / testing for NANB hepatitis should have been introduced across the UK;
    b. What were the competing arguments for and against the earliest possible introduction of testing;
    c. What decisions and actions were taken, and by whom, in relation to the testing of blood donations. Highlight in particular any decisions with which you disagreed;
    d. The extent to which the screening of blood donations and blood products was regulated, and, if not, whether in your view there should have been different or better regulation;
    e. Any efforts that you made to bring about the introduction of anti-HCV screening at an earlier date, whether by private correspondence, research, or publically-facing advocacy, and provide copies of any evidence to support this.

Section 7: UKHCDO

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

Section 8: Pharmaceutical companies and medical research / trials

41. Have you ever:
    a. provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?
    b. 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?
    c. sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?

42. 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 to comply with them?

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

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

45. 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?

Section 9: Involvement with the financial support schemes

46. Please set out the positions you have held at the Skipton Fund and the Caxton Foundation including with any committees, working parties or groups relevant to the Inquiry's Terms of Reference, and describe how you came to be appointed to those positions.

47. Please describe your role and responsibilities in the above positions.

48. What induction, training and information did you receive from the Skipton Fund and the Caxton Foundation as to their functions, aims and objectives?

49. How much time did you devote to the positions you held at the Skipton Fund and the Caxton Foundation? Please describe how your time was generally spent when discharging your role as Director of the Skipton Fund and Trustee/Director of the Caxton Foundation.

Section 10: Establishment of the Skipton Fund and the Caxton Foundation

50. What did you understand the aims and objectives of the Skipton Fund to be? What principles or philosophy underpinned its establishment?

51. Please describe your involvement with and/or recollection of the circumstances in which the Caxton Foundation was established.

52. What did you understand the aims and objectives of the Caxton Foundation to be? What principles or philosophy underpinned its establishment?

53. Please set out how the Skipton Fund and the Caxton Foundation were regulated.

54. What involvement (to your knowledge) did the Department of Health[1] or any other Government department have in the setting up of the Skipton Fund and the Caxton Foundation? In answering this question please address the following matters:
    a. Were you involved in any consultation by the Department of Health or any other Government department about the establishment of the Skipton Fund and the Caxton Foundation, their functions, aims and objectives?
    b. If so, please describe that process and set out the contribution you made to the consultation.
    c. Was there any discussion as to why the Government chose to distribute monies via the AHOs rather than directly? What, if anything, were said to be the risks and benefits of this scheme?

[1] Department of Health is the term used here to encompass all relevant health departments and their predecessors: see the Terms of Reference, footnote 3.

d. Was there any discussion as to why the Government chose to exclude those who contracted HBV from the schemes?
e. Was there any discussion about the discrepancies in the treatment of (i) those 'infected' with HIV and/or HCV and (ii) those 'affected' by these conditions (e.g. spouses, widows/widowers and dependants)?

55. Please describe your role on the Macfarlane Trust/Caxton Foundation Liaison Committee. You are referred to minutes of a meeting held on Friday 31 August 2012 [CAXT0000068_008] enclosed.

Section 11: Structure and Operation of the Caxton Foundation and Skipton Fund

Appointments of Trustees/Directors

56. Please provide a detailed description of the appointment process for the Skipton Fund and the Caxton Foundation and the exact composition of the board.

57. What was the process for electing/re-electing trustees/directors at the Skipton Fund and the Caxton Foundation? In particular, what involvement did (a) the Department of Health (or any other Government department) and (b) any other organisation or person have in this process? Did these matters change over time?

58. How, if at all, were positions advertised?

59. Were there sufficient applicants of sufficient quality or did you struggle to appoint trustees/directors?

60. How many trustees/directors were appointed by the Government, how many by the Haemophilia Society and how many were 'user' trustees during your tenure at the Skipton Fund and the Caxton Foundation?

61. How long did each trustee/director serve on the board? Could a trustee/director be re-elected? If so, how many times?

62. Were trustees/directors remunerated for their work? Please include details of any policies on this, including policies for allowances/expenses.

63. Was there an overlap of trustees/directors between the AHOs? Please explain how this worked.

Structure of the Caxton Foundation and Skipton Fund

64. Please explain the extent to which the AHOs shared premises, staff and resources. What impact did this have on data sharing and confidentiality and how were such issues managed? How were documents and information stored by the Skipton Fund and the Caxton Foundation? Was information shared across the AHOs? If so, were registrants aware of this?

65. Why did the Caxton Foundation act as employer for all five AHOs?

66. Please set out your recollection of the relationship between the different AHOs.

67. Please describe the working relationship between the trustees/directors and the senior management of the Skipton Fund and the Caxton Foundation. Were you aware of any difficulties? If so, what were they, how did they impact on the running of the Skipton Fund and of the Caxton Foundation and how, if at all, were they resolved?

Relationship with Government

68. To what extent were the Skipton Fund and the Caxton Foundation independent from Government? How much oversight did the Department of Health (or any other Government department) have over the Skipton Fund and the Caxton Foundation? In particular, did the Department of Health have any involvement with and/or give any direction/guidance to the Skipton Fund and the Caxton Foundation (and if so, what?) as to:
    a. the composition of their boards;
    b. the content of any policies adopted by them;
    c. how they should discharge their responsibilities to beneficiaries;
    d. the kinds of applications they should grant; and/or
    e. the quantum of the grants/payments they should make?

69. Did you, or others within the Skipton Fund and the Caxton Foundation, raise any concerns and issues with the Department of Health about the funding, structure, organisation or running of the Skipton Fund and the Caxton Foundation, or about the

involvement of the Department of Health, or about any other matter? If so, please explain what concerns and issues were raised. What was the response of the Department to those matters being raised?

70. What steps (if any) were taken by the Skipton Fund/Caxton Foundation in order to provide new treatment options to those who had been infected with HCV as a result of contaminated blood from the NHS? What was the response of the Department of Health?

71. What if any contact did the Skipton Fund and the Caxton Foundation have with the Department of Work and Pensions ('DWP')/its predecessors in relation to welfare benefits? In particular:
    a. Were you aware of any beneficiaries having their benefits stopped as a result of the assistance they received from the AHOs?
    b. Did the Skipton Fund and/or the Caxton Foundation take any steps to prevent this happening? If so, what? If not, why not?
    c. Did the Skipton Fund and/or the Caxton Foundation raise this issue with the DWP/its predecessors and if so what was the response?

72. Please describe the working relationship between (i) the Skipton Fund and the Department of Health and (ii) the Caxton Foundation and the Department of Health. Was there a particular point of contact? If so, who was that? Were you aware of any difficulties? If so, what were they, how did they impact on the running of the Skipton Fund and/or the Caxton Foundation and how, if at all, were they resolved?

Section 12: Funding/finances of the Caxton Foundation and Skipton Fund

73. Please set out the process by which the Skipton Fund and the Caxton Foundation received funding from the Government. Did this change over the time you were involved? If so, how? Were there problems with this process? If so, what were they and what were the consequences?

74. What do you know about how the Government set the budget for the Skipton Fund and the Caxton Foundation? What input did you, the Skipton Fund or the Caxton Foundation (as appropriate) have in this process? What input do you consider you should have had in this process on behalf of the Caxton Foundation and Skipton

Fund? Did the Government take account of any representations made by the Caxton Foundation and Skipton Fund?

75. What information, if any, did the Skipton Fund and the Caxton Foundation have about the beneficiary population and what was required to meet their needs? Where did this information come from? Was this information provided to the Government? If so, how and when? If not, why not?

76. Please set out as far as you can recall how much funding was provided at various times for the Skipton Fund and the Caxton Foundation. Please explain on what basis funding was allocated to each organisation.

77. Do you consider that the funding provided to the Skipton Fund and the Caxton Foundation by the Government was adequate? Please explain your answer.

78. What opportunities or procedures were there for the Skipton Fund and the Caxton Foundation to seek additional monies and/or apply for top up monies from the Government as the financial year progressed? Was this ever done? If so, provide details. In particular, were requests for additional funds throughout the financial year ever rejected? If so, please explain why.

79. Were there annual or other regular reviews between the Department of Health and the Skipton Fund and/or the Caxton Foundation? If so, please provide details including the following:
    a. Did the reviews take the form of meetings? If so:
        i. Who set the agenda for the meeting?
        ii. Who would attend the meetings?
        iii. Were any Trustees/Directors who did not attend able to contribute to the position to be put forward by the Skipton Fund and/or the Caxton Foundation and, if so, how?
        iv. What was discussed at the meetings?
        v. Were formal minutes, or any other written record, taken at the meetings? If so, by whom and who would be provided with copies?
    b. If the reviews were conducted without meetings taking place, please provide full details of the process.

80. Did the Skipton Fund and the Caxton Foundation have ad hoc meetings with the Department of Health? If so:

    a. How were these meetings arranged? Could the Skipton Fund and the Caxton Foundation call for such meetings?
    b. Who set the agenda for these meetings?
    c. Please describe any such meetings you know took place, including dates where possible.
    d. Who would attend these meetings?
    e. Were the Trustees/Directors who did not attend able to contribute to the position to be put forward by the Skipton Fund and the Caxton Foundation and, if so, how?
    f. Were formal minutes, or any other written record, taken at the meetings? If so, by whom and who would be provided with copies?

81. Did you, or others within the Skipton Fund and the Caxton Foundation, raise any concerns with the Department of Health about the substantial reduction in discretionary support proposed in a consultation launched by it in January 2016? Please refer to the annual financial report of the Caxton Foundation for the year ending 31 March 2016 [CAXT0000002_056], enclosed, pages 9-11.

82. Please specify any other streams or sources of funding/income other than that provided by the Government to the Skipton Fund and/or the Caxton Foundation during your tenure? Where relevant, where did this come from, how much was it, and how was it managed/spent by the Skipton Fund and/or the Caxton Foundation?

Financial management/governance

83. Were budgets/budget forecasts made by the Caxton Foundation prior to the start of the financial year? If so, how were the needs of the beneficiary population forecast? If not, why not?

84. What was the impact on the Caxton Foundation of spikes in applications and the amounts of funding being applied for?

85. What was the impact on the Caxton Foundation of spikes in beneficiary registrations and the amounts of funding being applied for?

86. Was the Caxton Foundation underfunded in your view? If so, what was the impact on the Caxton Foundation?

87. To what extent, if at all, did funding constraints impact on potential policy amendments in relation to the Caxton Foundation and/or the manner and timing of announcements of additional support? Please refer to the meeting minutes of 2 August 2012 [CAXT0000109_082], enclosed, heading "27.12: National Welfare Committee".

88. Please explain the comment in the minutes of the Caxton Foundation meeting held on 17 November 2011 that the Caxton Foundation should "spend as much money as they could, within reason, to show that there is unmet need amongst the community"; see [CAXT0000108_070], heading "43.11: Meeting with Mrs Ann Milton – Debrief, Report and Follow-up", enclosed.

89. Who decided on the level of reserves that the Caxton Foundation should maintain? Were you involved in those decisions? What was the justification for the level of reserves?

90. Did the level of reserves impede or otherwise have an impact on the Caxton Foundation's negotiations with the Government for increased funding?

91. What steps, if any, did the Skipton Fund and/or the Caxton Foundation take to cut operational costs so as to maximise the monies available for beneficiaries?

92. What steps, if any, did the Skipton Fund and/or the Caxton Foundation take to ensure that the salaries they paid their staff were proportionate and/or commensurate with the charitable sector?

93. What consideration, if any, was given to the impact on beneficiaries of reductions in benefits or other forms of income support from outside the AHOs? To what extent, if at all, was this raised with the Department of Health in relation to funding for the Skipton Fund and/or the Caxton Foundation?

Section 13: Identifying beneficiaries for the Caxton Foundation and Skipton Fund

94. Whose responsibility was it to identify potential beneficiaries for the Skipton Fund and the Caxton Foundation?

95. How were potential beneficiaries of the Skipton Fund and the Caxton Foundation identified?

96. What, if any, steps were taken by the Skipton Fund and the Caxton Foundation to advertise their existence and/or raise awareness of their work?

97. What, if any, steps were taken by the Department of Health, the UK Government and/or the Devolved Administrations to advertise the existence and/or raise awareness of the work of the Skipton Fund and/or the Caxton Foundation?

98. What steps were taken to contact the over 2000 potential beneficiaries who received a Stage 1 payment from the Skipton Fund but who had not yet applied to the Caxton Foundation? What impact did this have on funding and payments to beneficiaries? Please refer to the meeting minutes of 1 November 2012 [CAXT0000109_105], heading "41.12: Regular Payment Scheme", enclosed.

99. Do you consider that more should have been done (and, if so, what and by whom) to reach people who might be eligible for assistance?

Section 14: Eligibility for the Skipton Fund and the Caxton Foundation

100. Who set the eligibility requirements (i.e. what an applicant had to show in order to be accepted as eligible) for the Skipton Fund and the Caxton Foundation?

101. To what extent were written policies of the Skipton Fund and/or the Caxton Foundation publicly available or otherwise accessible to applicants? If so:
    a. Where or how could individuals access it?
    b. Did the Government have a view as to the publication of policies about the eligibility criteria? If so, what was it?

102. Were you, in your role, consulted about the eligibility requirements or otherwise involved in formulating them? If so, please provide details.

103. Please describe any significant changes to the eligibility requirements during your tenure, including the role of periodic reviews and the process followed.

104. Please describe any significant discrepancies or differences in the eligibility requirements between the different AHOs during your tenure? In particular:
    a. What were they and were they justified in your view?
    b. If not, did you raise this with anyone, and if so, who and when?
    c. What was the response, if any?

105. Please explain the rationale of the Caxton Foundation in disregarding means-tested benefits (such as DLA, child benefit and carer's allowance) when assessing household income (in line with Macfarlane Trust practice). Please refer to the meeting minutes of 1 November 2012 [CAXT0000109_105], heading "41.12: Regular Payment Scheme", enclosed.

106. In what circumstances was a medical opinion required to determine eligibility, in particular in relation to Skipton Fund eligibility? If so, from whom and what issues was it expected to address? How were applicants alerted to the requirements for medical evidence?

107. Who set the procedural requirements an applicant needed to satisfy before being accepted as eligible as a beneficiary for the Skipton Fund and the Caxton Foundation?

108. In relation to the Skipton Fund, what were the procedural requirements for establishing eligibility? In particular, did they change over time and, if so, how? In answering this question please address the following:
    a. Was there a burden of proof on the applicant and, if so, what was the standard and how did it operate?
    b. What kind of evidence or information did an applicant have to provide?
    c. Was there a requirement for an applicant to have evidence of receipt of blood/blood products in their medical records (even in circumstances where the NHS had lost/destroyed the relevant medical records or they were otherwise unavailable through no fault of the applicant)? If so, why?

d. What other documentary evidence was required?
e. How were the requirements for evidence and any policies on the burden and standard of proof brought to the attention of applicants before they made their applications?

109. To what extent were these procedural requirements publicly available in written form or otherwise accessible to applicants? If so, where and how could they be accessed? If not, why not?

110. To your knowledge, were there discrepancies or differences in the procedural requirements applied by the different AHOs? If so, what were they and were these justified in your view? If not, did you raise this with anyone and, if so, who and when? What was the response?

111. Were the eligibility requirements (both substantive and procedural) kept under review by the board of the Skipton Fund? If so, how often and in what frequency? If not, why not?

112. Were you aware of any concerns about or dissatisfaction with either the substantive or the procedural eligibility requirements for the Skipton Fund and the Caxton Foundation? If so, what were these and what did you/the board do in response?

113. Please explain your view regarding the exclusion of individuals who naturally cleared HCV from the Skipton Fund.

Section 15: Decisions on substantive applications

The process

114. Please explain who made decisions on applications for the Skipton Fund and the Caxton Foundation and how this changed over the time you were involved. In particular please explain:
    a. The decision-making role (if any) of staff in determining applications.
    b. Which committees were formed for the determination of applications, how they were formed, who was chosen (and why), how often they met, who they reported to and the process adopted for determining applications.

c. Which (if any) decisions on individual applications were made at board level and why.

115. Please describe the use of written and unwritten policies for the determination of applications by (i) the Skipton Fund and (ii) the Caxton Foundation:
    a. Who developed these? Were they publicly available? If so, where were they available?
    b. Was any expert (medical or other) advice sought to inform those policies? If so, what advice? Please give examples.
    c. Were the views of the beneficiary community taken into account when setting the policies? If so, how was this achieved? Please give examples.
    d. Please describe the policies.

116. In relation to applicants for grants:
    a. Please describe the core requirements.
    b. What was the burden and standard of proof?
    c. Were the procedural requirements reviewed? If so, by whom and how often? What were the outcomes of those reviews?
    d. Were you aware of beneficiaries who were unable to satisfy the procedural requirements such as providing supporting documentation? What if any adjustments or provision were made for determining such applications?

117. Did you, as a clinician, have any special role in any of the above? If so, please give details.

118. What proportion of applications were granted (wholly or in part) and what proportion were refused?

119. Were reasons for refusing an application provided to an unsuccessful applicant?

120. Was there a procedure in place to consider applications made on an urgent basis? If so, what was that procedure? If not, why not?

121. What was the procedure in place to consider retrospective applications? How did these procedures change over time? How did this impact beneficiaries?

122. What practical support or assistance was given to applicants to help them in making applications?

123. Please set out the number of beneficiaries/applicants assisted by (i) the Skipton Fund and (ii) the Caxton Foundation during your tenure at each AHO.

124. There is a report of a meeting you had with Mr Fish in the Skipton Fund meeting minutes of 26 March 2012. It states: "When borderline claims are received in the future, the lessons learned from Professor Thomas would be applied" [SKIP0000030_011], enclosed. Can you set out your recollection of that meeting and what this comment may refer to.

Skipton Fund

125. To your knowledge, how were the eligibility criteria for being provided with a stage 1 and/or stage 2 payment set?

126. In individual cases, who was authorised to determine whether an applicant was eligible for a stage 1 and/or stage 2 payment?

127. What supporting evidence was typically required for a successful application?

128. What was the proportion of applications that were granted?

129. Please explain the model prepared by you in relation to stage 2 applications, described in the minutes of the Skipton Fund board meeting held on 11 March 2013 [SKIP0000030_085], enclosed. Did you consider the model satisfactory for the purpose of making these assessments? Please explain your reasons.

Caxton Foundation

130. Did the success or otherwise of an application depend on the number of applications made per year or was each application considered on its merits, irrespective of the overall demand on the fund?

131. What was the percentage of applications that were successful per year?

132. Why and when did the Caxton Foundation introduce a regular payment scheme to support beneficiaries on lower incomes? How was this publicised?

133. Did the Caxton Foundation consider the amount of money previously given to an applicant when determining each application? If so, why?

134. Why did the Caxton Foundation have to reduce its support to beneficiaries in 2014? What was the level of reduction? What caused this? How was the decision made? What if any representations were made to the Government to increase funding? What was the response?

135. Please explain how, if at all, Skipton Fund payments impacted the assessment of need for Caxton Foundation grant applications.

Non-financial Support

136. What if any non-financial support was available to eligible beneficiaries of the Skipton Fund and the Caxton Foundation? Was the availability of non-financial support made known to the potential beneficiaries, and if so how?

Section 16: Complaints and appeals

137. Please describe the process (if any) for seeking a review of, or appealing against, or complaining about, a determination that an applicant did not meet the eligibility criteria for (i) the Skipton Fund and (ii) the Caxton Foundation. Relevant matters include:
    a. Any right to give evidence or make representations in person;
    b. Whether a representative was permitted to accompany the applicant;
    c. The standard of review or appeal applied;
    d. The criteria for members of review or appeal panels, including whether the original decision-maker was permitted to be present or make the decision;
    e. The extent to which written reasons were provided;
    f. Any time limits or fees for the bringing of a review or appeal; and

In relation to each of the above, any differences in the treatment of 'infected' individuals and 'affected' individuals (e.g. spouses, widows/widowers and dependants).

138. In relation to the Caxton Foundation, was there an appeal procedure? If so, what was it and how did it operate? Who determined the appeal and were they the same staff who made the original decision? Relevant matters include:
    a. Any right to give evidence or make representations in person;
    b. Whether a representative was permitted to accompany the applicant;
    c. The standard of review or appeal applied;
    d. The criteria for members of review or appeal panels, including whether the original decision-maker was permitted to be present or make the decision;
    e. The extent to which written reasons were provided; and
    f. Any time limits or fees for the bringing of a review or appeal.

139. In relation to the Skipton Fund, please explain:
    a. The lack of any right to give evidence or make representations in person, which limited the appeal procedure to the provision of further information;
    b. The standard of review or appeal applied;
    c. The criteria for members of review or appeal panels, including whether the original decision-maker was permitted to be present or make the decision;
    d. The extent to which written reasons were provided; and
    e. Any time limits or fees for the bringing of a review or appeal.

140. In relation to both the Caxton Foundation and the Skipton Fund:
    a. How common was it for decisions to be appealed?
    b. How many appeals were you aware of being launched during your tenure?
    c. How frequently did appeals succeed?

141. How common was it for the Skipton Fund and the Caxton Foundation to receive complaints? How many complaints were you aware of being made? How frequently were complaints upheld? Please describe any procedures that were followed.

142. What information was provided to beneficiaries of (i) the Skipton Fund and (ii) the Caxton Foundation about appeal and complaints procedures?

Section 17: Engagement with the beneficiary community

143. What steps did the Skipton Fund and the Caxton Foundation take to engage with and understand their beneficiary community?

144. In relation to groups and meetings involving the beneficiary community set up by or involving the Skipton Fund and/or the Caxton Foundation, please specify:
    a. What was the purpose of the groups/meetings?
    b. How often did they take place?
    c. Who set the agenda?
    d. Who attended the meetings and how were the beneficiaries selected for these meetings?
    e. What impact, if any, did these have on the way the Skipton Fund and/or the Caxton Foundation operated?
    f. Were there any problems encountered in the running of the group/meeting and how were they handled?

145. What was the relationship between the senior management/board of the Skipton Fund and the Caxton Foundation and the beneficiary community? Could this have been improved in your view? What steps did you take to improve the relationships?

Section 18: Relationships with other organisations

146. To your knowledge, what involvement or interactions did the Skipton Fund and the Caxton Foundation have with the Haemophilia Society?

147. Please describe the working relationship between (i) the Skipton Fund and the Haemophilia Society and (ii) the Caxton Foundation and the Haemophilia Society. Were you aware of any difficulties? If so, what were they, how did they impact on the running of the Skipton Fund and the Caxton Foundation and how, if at all, were they resolved?

148. During your tenure with the Skipton Fund and the Caxton Foundation, were there any directors/trustees who were also trustees of the Haemophilia Society? If so, please give details. Did this have an impact on the relationship between these organisations? Please give details.

149. What involvement or interactions did the Skipton Fund and the Caxton Foundation have with the UK Haemophilia Centre Directors Organisation?

150. Please describe the working relationship between (i) the Skipton Fund and the UK Haemophilia Centre Directors Organisation ('UKHCDO') and (ii) the Caxton Foundation and UKHCDO. Were you aware of any difficulties? If so, what were they, how did they impact on the running of the Skipton Fund and/or the Caxton Foundation and how, if at all, were they resolved?

151. Please list any particular clinicians you were in regular contact with during your work with the Skipton Fund and the Caxton Foundation.

Section 19: Reform of the Skipton Fund and the Caxton Foundation

152. Please provide details of any consultation or reform process you were involved in, in respect of the Skipton Fund and the Caxton Foundation.

153. What was your view of the changes made to the Skipton Fund and the Caxton Foundation as a result of the Archer Inquiry?

154. What concerns, if any, did you or the Skipton Fund and the Caxton Foundation have about the 2016/2017 reforms?

155. Did the Department of Health address the issues raised in the joint response sent by the AHOs in response to the January 2016 consultation document and, if so, how and when?

156. Did you raise any objection to the changes suggested or request additional time to consider the impact? If so, what was the response?

Section 20: Winding up of the AHOs and the Devolved Schemes

157. Do you consider that the Skipton Fund and the Caxton Foundation were well run? Do you consider that they achieved their aims and objectives? Were there difficulties or

shortcomings in the way in which the Skipton Fund and the Caxton Foundation operated or in their dealings with beneficiaries and applicants for assistance?

158. Please describe your involvement in the consultation with the Department of Health or any other Government department about the winding up of any AHOs? Please describe the contribution you made. You are referred to, by way of example, the minutes of the Skipton Fund board meeting held on 8 March 2016 [SKIP0000030_061], enclosed.

159. Please explain whether you considered the proposals made by the Department of Health in the period leading up to and during the transition from the AHOs to the Devolved Schemes[2] were better for infected and affected persons than the services and support provided by the AHOs. If so, why? If not, why not?

160. Regarding the transfer to the new Devolved Schemes:
    a. Please describe how information was shared between the Skipton Fund and the Caxton Foundation, on the one hand, and the Devolved Schemes?
    b. What information was provided to beneficiaries and in what format?
    c. Were you aware of any problems with the transfer arrangements?

161. Please provide any details of any involvement you have had with the NHS Business Services Authority following the dissolution of the AHOs, in particular in relation to the EIBSS.

162. Please describe your role in the Department of Health Reference Group.

163. Please explain your role in the Infected Blood IA expert group and your involvement with the Department of Health in developing what was to become the Special Category Mechanism ('SCM'). You are referred to the email chain with the Department of Health and other experts in March 2016 [DHSC0046882_001; DHSC0046882_002; DHSC0046882_003; DHSC0046882_004], enclosed. Who were the other clinicians involved in this?

164. Further in relation to the SCM:

[2] The term "Devolved Schemes" refers collectively to the England Infected Blood Support Scheme ("EIBSS"), the Scottish Infected Blood Support Scheme ("SIBBS"), the Infected Blood Payment Scheme for Northern Ireland ("Northern Ireland Scheme") and the Wales Infected Blood Support Scheme ("WIBSS").

a. Please describe the difficulties that were faced when compiling the eligibility criteria from a medical and/or ethical perspective.
b. To what extent was there agreement between the experts involved with the final eligibility criteria? Please explain your answer.
c. How relevant to the eligibility criteria was the total funding available?
d. Were any medical conditions that you or other experts believed should have been included in the eligibility criteria excluded? If so, why?

165. You are referred to in the minutes of the meeting held on 10 August 2016 [CAXT0000094_135], enclosed. In relation to mental health conditions:
    a. Were you involved with the Department of Health's work on whether mental health conditions should be included in the criteria? If so, please describe your involvement.
    b. Was there a mental health practitioner involved in the Department of Health Reference Group? If so, please provide details.
    c. Why was it considered to be problematic to have mental health conditions in the criteria?

166. Please explain your role in advising on and designing the individual assessment process of those infected with HCV or those co-infected with HCV and HIV through NHS supplied blood or blood products.

167. In relation to individual assessment:
    a. Please explain the difference between soft and hard evidence.
    b. Which of these types of evidence would typically take precedence, if at all? Please explain why.

168. Do you consider that the EIBSS is well run? Do you consider that it achieves its aims and objectives? Are there difficulties or shortcomings in the way in which the EIBSS operates or in its dealings with beneficiaries and applicants for assistance?

Section 21: Look back

169. The Inquiry understands that you were a member of the Ad Hoc Working Party drawn together to address the establishment of the look back programme:

a. Explain your role in the 'look back' exercises of the mid-1990s, both in terms of devising such a scheme and executing it clinically;
b. Provide, if you are able to do so, estimates of the number of individuals who were referred to you as HCV-positive following a 'look back' exercise;
c. Provide your overall views of the efficacy and consequences of the 'look back' exercise;
d. Explain why, as far as you are able to, why no comprehensive "look back" testing programme has been introduced whereby all people at risk (those receiving a transfusion or blood products between 1970 and 1991) are traced and advised to seek a test. Please include the following in your answer:
    i. What was meant by the "work involved in doing so would be disproportionate to the benefit?" [NHBT0009715]. Was this a view you agreed with?
    ii. On 13 October 1995 there appears to have been further discussion about extending the look back exercise [DHSC0003533_107]. What was the rationale for not extending the look back exercise? Did you agree with the decision?
    iii. At paragraph 11 of the press statement by Dr Metters dated 11 January 1995 [NHBT0005856], Dr Metters states that "there is no need for those who received blood transfusions to take any immediate action." A similar point was made in the attached document entitled 'Questions and Answers' [DHSC0003524_007]. In those circumstances, how was it envisaged that people would know that they should request a test?
    iv. Was there any further discussion about this issue at any point in time? If not, why not. If so, please explain what was discussed, when and what the outcome of those discussions was.

e. In a Memo from Dr Rejman to Dr Metters dated 24 May 1995 it is recorded that you had provided a paper to him referring to 40,000 transfusion associated cases [DHSC0003595_044]. This was further addressed at a meeting on 25 May 1995 [DHSC0002557_097]. How did you arrive at that figure? What explanation did you give for it to Dr Rejman? What was his response? What impact did the discussion with Dr Rejman have on your

subsequent advice to the Working Party?

You may find the following documents of assistance: NHBT0005851_002, DHSC0003555_155, NHBT0009715, PRSE0001024, DHSC0003595_030 and PRSE0000450.

170. What was your involvement in undertaking research arising from the HCV look back programme? Why did you consider that it was important for research to be undertaken? What was the research that you wished to complete and how was this facilitated? What were patients identified by the look back programme told about this research work? (DHSC0002556_039 and MODE0004454_001 may be of assistance).

171. In 2002 you provided a comment for a press release on the Department of Health "Hepatitis C strategy to improve effectiveness of prevention, diagnosis and treatment" [HSOC0000369]. Please explain:
    a. What was your involvement in the establishment of the strategy?
    b. Why was the strategy produced and why was it produced at this point in time?
    c. What were the aims and objectives of the strategy?
    d. What were the practical actions that arose from the strategy? Specifically, were any steps planned to identify individuals who had been infected with Hepatitis C through blood and blood products?
    e. In your view, were the aims and objectives of the strategy achieved? If so, please explain how. If not, please explain why not.

172. 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.

173. 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.