Witness Name: Dr Philip Paul Mortimer
Statement No.: WITN7105001
Exhibits:
Dated: 6th September 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF

DR PHILIP PAUL MORTIMER

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 8 July 2022.

I, Dr Philip Paul Mortimer, will say as follows: -

Section 1: Introduction

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

1. Philip P Mortimer. GRO-C . Date of birth GRO-C 1942. MD, BS, Dip Bact, Lond.

2. Please set out your employment history with dates if possible, including the various roles and responsibilities that you have held throughout your career.

2. House Officer posts: St Helier Carshalton, St Thomas's Lambeth, St Anne's Tottenham, St Stephen's Chelsea, hospitals
1969-73:Registrar then consultant virologist PHLS Colindale

1973-86. Director Virus Reference Lab Colindale 1986 with particular responsibility for HBV, HIV, HCV until retirement in 2004.

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, where possible, the dates of your membership and the nature of your involvement.**

3. Committees and their dates wholly as shown in Inquiry's documents, representing the PHLS as a medical virologist. Nil else.

Section 2: Previous statements and evidence

4. **The Inquiry understands that you provided a written statement to the Penrose Inquiry: PRSE0001857. Please confirm whether this statement is true and accurate to the best of your knowledge and belief. If there are any matters within the statement that you do not consider to be true and accurate, please explain what they are and how the inaccuracy occurred. Please also identify any evidence you gave to the Penrose Inquiry, other than this statement.**

4. This was a reply to a letter from Ms Lovell, not a formal statement, and was my only involvement with Penrose. I was never sent nor have seen the final report. The letter still represents my view.

5. **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 your evidence if it is available to you.**

5. None at all.

Section 3: The meeting of the Biologicals Sub-Committee of the Committee on the Safety of Medicines, held on 13 July 1983

The questions in this section relate to the meeting of the Biologicals Sub-Committee of the Committee on Safety of Medicines ("CSM(B)") held on 13 July 1983, at which you were present. On 6 July 1983, an internal DHSS memorandum (DHSC0003618_147) stated that the CSM(B) would be based on two papers: a paper prepared by the Chairman (DHSC0001209) and a paper written by Dr L. K. Fowler (DHSC0002229_059). Two documents recorded the discussions which took place on 13 July 1983: the minutes of the CSM(B) (ARCH0001710) and a summary of the main points discussed by the CSM(B) (DHSC0001208).

6. Why were you invited to attend this meeting and who invited you?

6. I was invited as the reference virologist for PHLS by DHSS or possibly Dr JWS Smith, the director of the PHLS, who was my boss.

7. Had you previously been involved in advising the DHSS regarding AIDS? If so, please describe the nature and extent of any earlier involvement you had had, or any earlier advice you had provided.

7. No.

8. As far as you can recall, did you receive and did you read the two papers prior to attending the CSM(B) on 13 July 1983 (DHSC0001209; and DHSC0002229_059)? What was your view of those documents at the time?

8. As regards 1209, my opinion was minuted, and, DHSC0002229_059, Dr Fowler in particular emphasised the uncertainties about the cause of AIDS. As regards the risk that more pre-AIDS haemophilia cases might arise we did not know what if any other aetiological factors predominantly made gay men (MSMs) ill. As a virologist I was aware that haemophilia patients and blood recipients were exposed to many viruses, known and unknown.

9. The Chairman's paper contains an "agenda" which appears to set out a number of "conclusions". It suggested you address the CSM(B) on the aetiology of AIDS (DHSC0001209, page 1).

a. Did you do so? If so, what information did you present to them?

9. I do not remember.

b. Did the Chairman discuss the aetiology of AIDS with you prior to your attendance at the meeting? If so, please set out your recollection of that discussion.

10. I don't remember. He was a busy senior with a similar professional background to me and very probably had similar views to mine, but I speculate.

c. Was what was set out on p. 1 of the "agenda" under the heading 'Aetiology' an accurate and fair description of your views on the aetiology of AIDS at that time?

11. Yes.

d. How, if at all, did your view of the aetiology of AIDS change after you had attended the CSM(B)? You may wish to refer to: ARCH0001710, page 2, para. 5.1.

12. It didn't change

10. The Chairman's paper stated: *"recipients of clotting factor concentrates are at risk. The degree of risk cannot yet be quantified"* (DHSC0001209, page 2). The minutes of the CSM(B) stated: *"patients who repeatedly receive blood clotting-factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small"* (ARCH0001710, page 2, para. 5.2). What evidence was presented to the CSM(B) which suggested the risk was *"small"*? Who presented that evidence and who, if anyone, challenged it?

13. "Small" because there were so very few known cases of AIDS worldwide in haemophilia patients, particularly in the UK. They might have had other causal factors. In retrospect we know that they were a younger group than others subsequently found to be HIV infected, and so immunologically more resistant to the cumulative damage due to HIV infection.

11. Please refer to the briefing paper by Dr L. K. Fowler (DHSC0002229_059):

a. The paper stated: *"transmission [of AIDS] would require donation during a period of viraemia. Chronic, asymptomatic viraemia would be unlikely and donors would tend not to donate while feeling unwell"* (DHSC0002229_059, page 2).

i. Did you agree with this statement at the time? Please explain your answer.

14. Probably not entirely, but I can't remember. I knew that HBV could be carried asymptomatically for years. Many knew that. Therefore, donors who were unrecognised carriers of an AIDS related virus could donate while they were asymptomatic.

ii. What discussion about the paper and in particular this statement took place during the CSM (B) meeting?

15. I can't remember.

b. Dr Fowler's paper stated: *"the most convincing hypothesis so far for the aetiology of AIDS is advanced by Sonnabend et al. (1983)"* (DHSC0002229_059, page 2). Please refer to: OXUH0002239_005:

i. At the time of the CSM(B), did you agree that the Sonnabend hypothesis was "the most convincing"? Please give reasons for your answer;

16. Dr Fowler was, I think, a renal transplant physician with much experience of AIDS - like illnesses in those patients. There had at the time been eleven such illnesses in haemophilia patients in the USA and two known of in the UK, compared with thousands of cases in MSMs, and so it was reasonable to think all of these eleven plus two patients might have had undisclosed homosexual behaviours.

ii. **Did you comment on the Sonnabend paper at the CSM(B)? If so, what comments did you make?**

17. My other reason I suspect, in retrospect, was that as a virologist I was aware of asymptomatic chronic viral infections such as NANB(=HCV) and the common herpes viruses any of which might have been involved in aetiology. So I respected Sonnabend paper's position.

18. Given the rarity of such known illnesses in haemophilia at the time it was sensible to search for a specific cause in the main risk group, MSMs, which is what was happening in Paris and at NIH, Bethesda, US.

iii. **What discussion about the Sonnabend thesis took place during the CSM(B) meeting? Did anyone endorse or challenge it?**

19. I can't remember any focus on the views of Sonnabed et al. article by me or by the committee, but Dr Fowler emphasised it and I shared the views of Sonnabend et al.

12. In regards to the possibility of replacing factor concentrates with cryoprecipitate:

a. **The minutes of the CSM(B) stated: *"this is not feasible in the UK on grounds of supply"* (ARCH0001710, page 2, para. 5.3). What did you understand this to mean? Who made this argument at the CSM(B)? What evidence, if any, did they cite in support?**

20. I don't remember this being discussed, but I do now know that making cryoprecipitate from individual or small numbers of plasmas was "fiddly" on a large scale, that BPL Elstree felt a shortage of plasma from which to prepare it, that they were reliant on England and Wales regional transfusion centres to supply them with enough plasma which not all may have done (or so BPL said) and I did know that cryoprecipitate was not going to meet all the needs of patients with severe haemophilia. Note I did not work as a clinician after 1971 when I became a senior house officer at St Stephens as a pathologist with a bacteriology/virology interest. I learnt as a student about haemophilia, gave cryoprecipitate at St Helier hospital in 1969 and learnt that many patients needed concentrated factor all or some of the time, often given by the family at home once they'd been taught. I subsequently became aware of BPL's role, its difficulties obtaining English plasma in sufficient quantity, and the necessity to resort to US manufactured concentrate. I never had a clinical role in deciding to give either cryoprecipitate or concentrate.

b. The Chairman's paper stated: *"the perceived level of risk does not justify serious consideration of this solution"* (DHSC0001209, page 3). Did you agree with this conclusion? Please explain your answer.

21. I think I almost certainly agreed. The work of BPL was not part of my expertise or indeed details of individuals' haemophilia treatment, but in retrospect it did become obvious that BPL lacked the capacity fully to respond to the advances in haemophilia treatment that had been made in the 1970s.

13. Please refer to: ARCH0001710, pages 2-3, para. 5.4. As regards the possibility of withdrawing US concentrates from the UK:

a. The minutes of the CSM(B) concluded this was *"not at present feasible on grounds of supply."* What did you understand this to mean? Who made this argument at the CSM(B)? What evidence, if any, did they cite in support?

22. It meant that the demand for concentrate, with use of which it was possible to transform the lives of moderate to severe haemophilia patients (the majority) could not be satisfied in England and Wales without importing US manufactured concentrate. It is unlikely, even if '' home-grown" supplies of concentrate had been adequate, that contamination would have been avoided once HIV entered the UK, perhaps as early as 1980.

b. The minutes stated: "*the perceived level of risk does not at present justify serious consideration of such a solution.*" Did you agree? Please explain your answer.

23. At the time I wasn't well enough informed about concentrates to have a useful view, but in any case, proof of a serious AIDS risk to haemophilia patients was still wanting.

c. The minutes continued: "*Efforts are however being made to secure UK independence of foreign suppliers of clotting factor concentrates.*" What did you understand this to mean? What efforts were being made and by whom?

24. I don't remember, but it implies that BPL and the corresponding Edinburgh outfit would be funded to expand their work making concentrates.

14. Please refer to: ARCH0001710, pages 3-4, para. 5.10. The minutes of the CSM(B) state: *"the PHLS, through its Communicable Disease Surveillance* Centre *is co-ordinating clinical observations on [AIDS]"*. To the best of your recollection, please explain:

a. What did "*coordinating clinical observations on*" AIDS involve?
b. Which institutions and individuals were the PHLS coordinating?

25. 14a and b. The work of PHLS Communicable Disease Surveillance Centre (CDSC) already involved collecting microbial infection data and could be expanded to ask STD clinics and AIDS clinical centres to report AIDS cases as well.

c. What was the nature and extent of your involvement?

26. This was not my role in the PHLS. At the time the PHLS was made up of some 40 clinical and public health diagnostic labs serving local NHS "customers" plus a central lab site at Colindale, North London. This site had three roles, the labs, but also the PHLS administration and director's office, and a surveillance centre for infectious diseases and data coordination headed by Dr Galbraith (CDSC). The labs were reference centres, mine the virology one doing R and D as well as more advanced diagnostics. So I was not involved in CDSC.

d. What findings did the PHLS make and when? To whom at the DHSS were the PHLS' findings reported?

27. Only Dr Galbraith, now dead, could have answered.

e. Who at the DHSS kept in touch with the PHLS in relation to this matter? How frequently did communication between the PHLS and the DHSS occur?

28. 14d and 14e. CDSC had been set up in part to improve liaison with DHSS as regards England and Wales (not Scotland). I assume Dr Galbraith, the CDSC director, often advised people at DHSS, but I don't know whom.

15. Please set out in as much detail as you can your recollection of the meeting which took place on 13 July 1983.

a. In particular, please set out what you can recall of any contributions made by Professor Bloom, Dr Fowler, Dr Galbraith, Dr Craske and Dr Gunson.

29. I don't have that level of recall. I already knew all of them except Dr Fowler so I was aware "where they came from", but I don't remember what they said.

b. Why, in your view, were the Chairman's *"brief possible conclusions"* substantially adopted at the meeting, with limited record of discussion and no record of dissent, despite the Chairman anticipating *"doubtless these will change radically"* (DHSC0001209, page 1)?

30. I had a high regard for the chair and respected his conclusions. I think the implication of his use of 'doubtless' was that a single infectious cause might be found, but there was as yet no evidence of it. Let me offer an analogy: multiple sclerosis is a quite common progressive debilitating illness of young to middle aged adults. A viral cause has been searched for decades, but only very recently has EBV been implicated as its cause and I for one remain sceptical about that. AIDS in 1983 was like MS before EBV was postulated as a cause.

c. Looking back now, what, if anything, could or should have been done differently?

31. Nothing, I regret to say. Only later did the number of AIDS haemophilia cases mount to the point at which their immune system was much more obviously the object of a specific infectious agent.

Section 4: Development, evaluation and implementation of HTLVI-III (HIV) screening tests for donors

32. By September 1985 we at PHLS Colindale had published in The Lancet a comparison of five anti-HIV kits, and DHSS had made available a 67 page report of that work. The Inquiry will note that the PHLS has since been wound up and with that probably the capacity to do as prompt and timely an independent evaluation nowadays.

16. Please explain your involvement in the evaluation of the HTLV-III screening tests. The following documents may assist you in answering this and the following questions (DHSC0000425; DHSC0000421 pages 1-2; DHSC0002287_017, pages 2-3; DHSC0000551; BART0000778;

DHSC0002311_016, PRSE0000718, PRSE0001069; PRSE0001857; PRSE0002628; PRSE0002734; and PRSE0004604). In particular:

a. Did you agree that an evaluation programme was necessary and if so why?

33. Yes. The world market for tests was going to be large and test accuracy was essential, but manufacturers might be tempted to offer kits that were underdeveloped. We wanted several kits to be reliably available to the UK market, but without compromising accuracy.

b. Did the evaluation take too long to get started?

34. No. We wanted the candidate kits to be in a consistent and completely developed form, and to include several kits both to make comparisons and to allow end users to choose the one that suited their local circumstances best.

c. Please set out your views of, and any concerns or frustrations you had about, the process that was undertaken and the time taken to complete it.

35. Ideally the panel of sera would have been larger, for instance including more sera expected to be negative, and sera from individuals only just infected with HIV; but a prompt result was needed both by potential users (the NBTS especially) and by manufacturers who were looking to scale up to meet unsatisfied demand.

17. In February 1985, Public Health Laboratories ("PHLS") was appointed to carry out the first steps of the evaluation of the HTLV-III screening test (DHSC0000425, page 1). To the best of your knowledge please answer the following:

a. Five tests were included in the initial evaluation in 1985 (PRSE0004604, page 2; PRSE0000718). What, if any, were the requirements for tests to be included in the evaluation?

36. Availability, and manufacturers' willingness to train and if necessary equip my technical colleagues to do the bench stage of the evaluation.

b. In DHSC0002277_034, it is stated by Dr Smithies that only kits where there is "*a certainty that they are in large scale commercial production*" were accepted for the evaluation. Which kits were not accepted for the evaluation on this basis (as of 3 September 1985)?

37. None as far as I knew.

c. Please describe (in broad terms) the process of evaluation which was undertaken in respect of the kits.

38. The kits were needed to be available in a form that allowed a few hours or possibly overnight as the maximum time to completion, and were to be applied to a panel of sera from which clear positive and negative results were required unless there was a known reason why the result might be uncertain e.g. a serum from a person very recently symptomatic.

18. In the minutes of the Expert Advisory Group on AIDS ("EAGA") Screening Test Subgroup, held on 10 June 1985, it was minuted that 'Production Pasteur' were marketing a kit (DHSC0000551, paragraph 4).

a. Was this kit included in the PHLS evaluation?

39. No.

b. If not, do you recall the reason why it was excluded?

40. I don't recall why not, but probably because it did not materialise. I don't recall a Pasteur product becoming available in the UK later on. In retrospect was it the one Dr Karpas, Cambridge, refers to?

19. In May 1985, the Department of Health and Social Security ("DHSS") expressed preference for evaluating a British test (DHSC0002311_016), stating *"It is therefore not desirable to be precise about the timetable for testing Abbott's test in isolation"*.

a. Was this opinion ever explicitly communicated to the PHLS during the initial stages of evaluation?

41. No.

b. Can you recall if this was a position you shared with the DHSS at the time? If so, why?

42. I shared the department's view.

c. Do you believe that this could have contributed to the overall delay of UK wide testing being rolled out?

43. It did mean that the Abbott kit as first offered in Spring 1985 was not immediately rolled out. In its initial form we expected there might be false positives because of its basic format and we wanted to be confident that Abbott would minimise that outcome. By the Summer I think they had. Any delay was minimal and to be set against an alternative of having a single, overseas, supplier who might have other priorities than maintaining a supply to the UK. While it was urgent it had to be universal and consistent throughout UK, and not compromise the blood supply to patients who needed to be transfused.

20. To the best of your knowledge, was the evaluation programme delayed, or did the evaluation programme take longer than it might otherwise have done, in order for the Wellcozyme HTLV-III test to be included? You may wish to consider: DHSC0000551, page 3

44. No. **DHSC0000551** reveals how urgent the introduction of anti-HIV testing was seen to be. I recall my lab was already familiar with the format (as an

RIA) that the Wellcozyme ELISA was based on. It was a kit that must have been available to us in June 1985 when I think our bench stage evaluation got underway. The evaluation's final report was published 19 October in the Lancet and was probably in the journal's hands by September which was when the DHSS's full version of 67 pages was made available; but I can't be absolutely certain of all this 37 years later.

21. In a letter from Dr Smithies, DHSS, to Dr Karpas, University of Cambridge Medical School, regarding the protocol for DHSS evaluation of HTLV-III screening kits, Dr Smithies mentions "*a carefully chosen panel of about 400 sera has been used to test for sensitivity and specificity under standard comparative conditions.*" (DHSC0002277_034).

a. How was the sera selected?

45. Sera were mainly from AIDS and pre AIDS patients, blood donors already probably self-selecting on the basis of leaflets and so expected to be anti-HIV negative, and some other sera that might be prone to give false positive results.

b. In which ways did the sera selection affect the results of the evaluation?

c. What were the standard comparative conditions for testing for sensitivity and specificity?

46. 21 b and c. by showing whether the kits gave clear positive and negative results. The same panel was applied to all the kits evaluated. A bigger panel would have been preferable but assembling it would have introduced delay.

d. Dr Smithies suggested that Dr Karpas approach you for help in providing a panel of sera. Did he do so and if so what was your response?

47. He didn't as far as I remember.

22. In as much detail as you are able to, please describe the second stage of the HTLV-III screening test evaluation. In particular, please explain:

a. What were the parameters for the tests that went through to the second stage?

b. Did you consider the parameters fair? How has your view changed over time, if at all?

You may wish to refer to: DHSC0000421, pages 1-2; DHSC0002287_017, pages 2-3; DHSC0000551; BART0000778; and DHSC0002311_016.

48. Although **DHSC0002287_017** refers to five more kits expected to become available, my recollection is that the market momentum was such that a second stage evaluation never actually took place at Colindale. I don't know how many further kits actually materialised but thereafter PHLS left NHS and NBTS directors to make their own choices based on their own technical preferences. My lab continued to offer reference facilities regarding screen reactive and ''doubtful" specimens-that was our routine role.

23. In your written evidence to the Penrose Inquiry you stated: "in hindsight it *might* have been possible to set up continuing UK wide screening with it [i.e. the Abbott kit] a few months before it actually began; but this is not certain and the gain would not have been great as other precautions, as mentioned above, were by then coming into play" (PRSE0001857, page 1). Please expand on this statement and explain:

49. My letter in answer to Ms. Lowell referred to the advice to donors to rigorously self-select.

a. In your view, what factors which contributed to the delay were avoidable, if any?

b. What you meant when you stated: "*the gain would not have been great as other precautions... were by then coming into play.*";

50. 23a and b. I thought that the Abbott test in its initial form might generate quite a lot of false positive results which from the NBTS point of view was very undesirable. They had then where possible to try to reassure donors about their status. There had even once been a traditional mantra that transfusion services had an equal responsibility to donors and to recipients. Otherwise the supply of donors, already more rigorously selected by the early 1980s, might ''dry up''.

c. **Was it your view that "*donor leaflets.... heat treatment of Factor VIII concentrates... [and] getting anti-HIV tests available in GUM clinics and other Health Service facilities*" were as effective as a UK wide screening programme would have been in that period?**

51. Yes, until accurate test kits were established and available to bulk users in the regional NBTS centres and to diagnostic labs UK wide.

24. **Professor R. S. Tedder told the Penrose Inquiry that: "*at the end of 1984 there was an understandable reluctance in the National Blood Service to institute screening in part of the service, even if only for a sero-prevalence survey and for a limited time, since this could be anticipated to draw in to donation individuals who were curious to know their own status ... For this reason, no attempt was made to introduce part screening for any purpose in the NBS until such time as the NHS had free access and confidential screening available in the GUM clinics*" (PRSE0001069, paragraph 5). In your view, was this attitude justified and, if so, why? How did these considerations affect the date on which routine anti-HTLV-III screening was introduced within the UK, if at all?**

52. Yes, a justified attitude till 1985. During 1985 donors were being made more and more aware of their responsibility to self-select.

25. **In your view, did any other factors - aside from the type of test and the evaluation programme - affect the date on which routine anti-HTLV-III screening was introduced within the UK? If so, please give details.**

53. No, except that the NBTS had collectively in numerous UK centres, I think over a dozen, to equip itself and train staff to start anti-HIV screening of donated blood.

Section 5: Surrogate Testing

Surrogate Testing NANBH

26. What was your opinion of surrogate testing as a potential method of donor screening for NANBH, and how did this change over time? Insofar as you are able to do so, please comment with reference to specific surrogate tests.

54. It was negative. Most NANB carriers were healthy. LFTs were known to be unreliable except when very definitely positive, and the latter could be due to all sorts of non-viral causes.

27. A report prepared by Dr H. H. Gunson in August 1987 set out the conclusions of a Council of Europe Working Group established to consider the introduction of routine surrogate testing for NANBH (NHBT0008816_002). The Working Group concluded it could not make a recommendation as to the introduction of surrogate testing in light of the following considerations:

a. The use of surrogate tests as a public health measure to reduce the incidence of NANBH remained controversial;
b. There was no guarantee that there would be a significant reduction of NANBH;
c. The introduction of surrogate testing could lead to a severe depletion of blood donors which could compromise the blood supply in some countries;
d. If surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT.

Were you aware of the Working Group's report? If so, did you agree with the conclusions reached by the Working Group? If not, why not?

55. 27a to d. I was unaware of the report but would have agreed with it.

28. The aforementioned report stated: "*if a stance is taken that blood should have maximum safety then the tests would be introduced*" (NHBT0008816_002, page 6, paragraph 8). In your view, did the decision not to introduce routine surrogate testing amount to a decision not to provide "*maximum safety*"?

56. Maximum safety was and remains incompatible with blood transfusion. Surrogate testing would have added little and compromised the service to cases with life threatening trauma, post-partum haemorrhage etc.

29. In October 1989, Dr Gunson, the Chairman of the Advisory Committee on Transfusion Transmitted Diseases ("ACTTD"), recommended: "*The routine introduction of non-specific tests should be deferred, unless this is necessary for the acquisition of product licences in the UK for fractionated plasma products*" (NHBT0000188_072, paragraph 7.5). Then, in November 1989, the ACVSB concluded that there was no case for using surrogate testing for non-A non-B Hepatitis (NHBT0005043, paragraph 29). As far as you can recall, why was this the view of the ACVSB and were you in agreement with it?

57. Yes, ACVSB were taking the only realistic view.

HIV

30. What was your opinion of surrogate testing as a potential method of donor screening for HIV, and how did this change over time? Insofar as you are able to do so, please comment with reference to specific surrogate tests.

58. In the UK in the 1980s syphilis was rare, and probably very rare in self-selecting blood donors. Screening for it was, rightly, subsequently

dropped. Other surrogate testing would be far less valuable than the further use of heat-treated concentrates which could transform the lifestyle of badly affected haemophilia patients.

31. **On 14 October 1983, at the first meeting of the Central Blood Laboratories Authority ("CBLA") Working Group on AIDS (CBLA0001754, page 2), the use of surrogate tests was discussed.**

    a. **It was generally agreed (see paragraph 3.1.2 of the minutes) that if investigation into surrogate tests was to be carried out, it would be preferable to investigate the use of anti-HBc screening rather than the TPHA test. Why was this?**

    59. Anti-HBc testing of donors would perhaps have been worth considering e.g.as a possible marker of past drug use or of being a man who had sex with men (MSM).

    b. **It was also agreed that other surrogate tests such as the detection of α-Thymosin α-interferon and β2-microglobulin were not yet suitable for large-scale screening, but may be of value in a study for examining blood samples of anti-HBc positives. Why were these tests unsuitable for large-scale screening?**

    60. It was too complicated and too non-specific.

Section 6: Donor selection/exclusion and self-deferral

32. **In your Statement to the Penrose Inquiry (PRSE0001857, page 1) you recorded that *"[o]ther than blood donation screening, there were by early 1985 three precautions to protect blood supplies in place or under urgent consideration. First, 'advice to donor' leaflets required recognised risk groups not to donate[...]"*. With regard to that statement, please describe, in as much detail as you are able to:**

    a. **Any involvement you had with the development of advice to donor leaflets and/or donor selection/self-deferral. You may be assisted by**

PRSE0004191, CBLA0001754, and NHBT0006906 in answering this question;

b. **Any views you can recall holding as to the effectiveness of the leaflets as a means of reducing risk;**

c. **Any views you can recall holding as to the effectiveness of other donor selection/self-deferral risk reduction approaches considered?**

61. 32a, b and c. Though I got to see drafts of leaflets which I could consider in the light of being a regular donor myself, as a lab worker I was not in a position to judge their overall impact at the very many donation collection points. I suspect most donors were already well informed and did self-select by the early 1980s, before anti-HIV screening was introduced.

33. **In the minutes of the first meeting of the Working Group on AIDS in Relation to Blood Transfusion on 14 October 1983 (CBLA0001754), you are recorded as being in attendance. At 3.1.1, the minutes record the discussion on *"The Leaflet 'AIDS and how it concerns blood donors'".***

a. **It was recorded that *"[...] the Group considered that a uniform system of distribution [of the AIDS leaflet] would be advantageous"* (CBLA0001754, page 2). With regard to that statement, did you view the concerns on divergent approaches to leaflet distributions as being dealt with appropriately?**

62. Though present on 14th October and I would have supported the proposal for uniformity and for a wider expression of the concern to have donors self-select this was not the main reason for me being at the meeting.

b. **It was noted that *"[w]ith respect to the content of the leaflet itself, it was considered that the important message as far as the blood donor was concerned, i.e. not to give blood if they were in a high risk group, should be highlighted in some way"* (CBLA0001754, page 2). With regard to that statement:**

i. **To what extent did you consider the leaflet succeeded in this aim?**

63. In retrospect the leaflet's text was so brief that I have the impression it was much more about maintaining an adequate supply of donations than anything else. There was an understandable fear that if donors thought they might be quizzed at NBTS collection points they would be the subject of embarrassing questions and so would stay away.

ii. Do you recall having any concerns with the leaflet's content and/or distribution at the time? You may find the leaflet itself of assistance in answering this question (BPLL0007247).

64. As a lab worker I wasn't in a position to judge the impact of a leaflet, and I can't recall discussion of it; but I would emphasize that at that time there was far more sqeamishness about any Government acknowledgement of homosexual practices and promiscuous heterosexual behaviour, common though they might be. The government and the public have come a long way in the intervening nearly forty years.

34. In the minutes of the meeting of the AIDS Group of Haemophilia Centre Directors on 17 June 1985 (HCDO0000523, page 4) it was recorded that *"[you] thought that heating blood products was likely to be safer than relying on donor selection".* With regard to that statement, please describe the concerns you can recall that you had with the safety of the donor selection process.

65. As I have said above, heat treatment, properly applied and assuming it didn't destroy factor VIII/IX in the concentrates, could have an absolute protective effect. Donor self-selection could not be absolute.

35. In an undated scientific report titled 'Blood Donor Screening by Wellcozyme' (NHBT0004468, page 2), jointly authored by you, it is stated that: *"[m]ore rigorous donor selection and self-deferral may also have a role in excluding infected donations".* The report refers to your Lancet article 'Mortimer PP, Parry JV, Mortimer JY, Which anti HTLV III LAV assays

for screening and confirmatory testing? Lancet ii, 873-877, (1985)' (PRSE0000718). Please explain:

a. Which areas of donor selection and self-deferral lacked sufficient rigour at the time.

b. What a more rigorous approach to donor selection and self-deferral would have included.

66. 35a and b. I think my intention in the report and article was to emphasise that the anti-HIV assays needed to be backed up by donor selection because of their possible lack of sensitivity and because of the short ''window'' period before antibody appeared. It soon became obvious that anti-HIV positivity strengthened rather than weakened over time infected.

36. Please consider the enclosed report on the European Economic Community ("EEC") Workshop on AIDS held at Institut Pasteur, 20-22 November, 1984 (CBLA0001928).

a. The report has an appendix dated 15 November 1984 which was authored by you. Were you also the author of the main report and did you attend the workshop in question?

67. While I must have written the appendix the main report includes content that I couldn't have been aware of so that it must have been a joint effort or by a single author who did have access to much relevant data. In retrospect it was an excellent document. I did attend the Paris workshop.

b. Page 5 of the report records the chief suggestions offered by American colleagues and/or emerging from the data and opinions at the meeting as including that *"[f]urther attempts must be made to warn homosexuals of their high risk and to emphasise again the possible protection offered by restricting severely the range of sexual contacts and by using barriers to prevent exchange of semen."* Did you agree with this position at the time? Was it your view that insufficient efforts had been made to warn homosexuals of their "*high risk*" status in the UK?

68. Yes, the US attendees were in the midst of an HIV epidemic of huge proportions in MSMs, which the UK wasn't yet. In 1984, the UK public was more coy about talking about the semen exchange involved in anal intercourse. (In 2022. it is still coy about the transmission of monkeypox virus by its main, the same, route). So I expect I advocated warning homosexual men more.

37. The conclusions in the report also state that *"Blood donations must, as soon as possible, be screened for anti HTLV 3. Until then much tougher weeding out of at risk donors is needed. To compensate, more (especially female) donors must be sought".* With regard to this comment, please describe the extent to which you agreed with this position at the time.

69. Yes, I would fully have agreed with that. Women, seen as more susceptible to anaemia, were, I think, not encouraged as much as men were to donate blood.

38. In the meeting of the Advisory Group on AIDS on 27 November 1984 (PRSE0004191), in which you are in attendance (see page 2), please could you assist so far as you are able to with the following:

a. At page 2, it was recorded that Dr Tedder and yourself *"reported from Pasteur meeting (Nov 20 - 22) that 2 groups have given Travenol Dry Heat VIII to seronegative patients. No sero conversions over about 6 months".* Can you recall whether the rest of the recommendations and conclusions, particularly with regard to donor selection, were passed on to the Advisory Group on AIDS or to others (and if so whom)?

70. No, but I hope we did.

b. At page 3, under the heading 'publicity and donor selection', it was stated that "*[m]uch criticism of new DHSS leaflet (SNBTS leaflet meets most of the points but need for redrafting of para 2 (sic)*".

i. What did you take these criticisms to be?

ii. **Was the criticism from the Advisory Group or from others?**

iii. **What input, if at all, did the Advisory Group have with the development of the donor leaflets produced by the DHSS?**

iv. **If they did have input, to what extent was that input or advice heeded by the DHSS or others?**

71. I can't recall the criticism and am unable to respond to the questions at 70b.

c. **At page 3, under the heading 'publicity and donor selection' it was noted *"No recommendation to increase questioning of donors or introduce physical".***

i. **What was the reason for this decision?**

72. This will be answered in part ii.

ii. **What was your reaction to this decision in light of the report containing recommendations from the EEC Workshop on AIDS held at Institut Pasteur, 20-22 November, 1984 (CBLA0001928, page 5)?**

73. I suspect the idea of interrogating and physically examining donors was anathema to NBTS. As a donor it would have put me off as involving time and shedding clothes, a good way of emptying every collection centre even if it had been equipped for it.

d. **At page 3, under the heading 'publicity and donor selection' it was noted *"No recommendation for a signed declaration." and "Further television publicity advocated"***

i. **What was the reason for these conclusions?**

74. This will be answered in part ii.

ii. What actions were taken in light of these decisions?

75. In retrospect the former might have been a good idea. The latter ought only to have been considered if the number of stalwart donors had begun to fall away.

39. In the first meeting of the Expert Advisory Group on AIDS ("EAGA") on 29 January 1985, at which you are recorded as in attendance, there is discussion of leaflets on AIDS by the Health Education Council and the DHSS/ National Blood Transfusion Service ("NHSBT") AIDS leaflet (PRSE0002734, page 5). With regard to these discussions,:

a. What about the blood donor leaflet made it *"insufficiently forceful"* with regard to persuading homosexuals not to donate?

76. In retrospect, I think the committee's attitude would have been that in 1984 homosexuality was commoner than was generally acknowledged.

b. What was your view at the time as to how best allow homosexual donors to *"withdraw unobtrusively from the system"*?

77. All homosexual donors had to do was to fail to turn up, but if they had previously gone collectively e.g. as a work group to a church or village hall some might have felt social pressure to go on attending although "closet" MSMs.

Section 7: Development, evaluation and implementation of HCV screening tests for donors

Please note, between 4 April 1989 and 9 February 1993, you attended 13 of the 15 meetings of the Advisory Committee on The Virological Safety of Blood. For ease of reference, the minutes of each of those 15 meetings are included in the schedule of documents below.

40. In April 1989, Dr Charles Rizza wrote to all UK Haemophilia Centre Directors noting that Ortho was making available to you their new test and asking for directors to help you in the study (GGCL0000033_001). Please describe your involvement in the evaluation(s) of the Ortho and any other NANB/HCV tests. You may also wish to consider: (DHSC0003532_062, page 5; NHBT0000014_048; NHBT0000079_087, page 2, NHBT0008073_002).

78. My recollection of Dr Rizza's letter and the NBTS centres' possible response to it is poor, but it was quite demanding of them and I suspect they didn't respond.

41. At the meeting of the Advisory Committee on the Virological Safety of Blood ("ACVSB") held on 22 May 1989, *"it was agreed NANB testing should not be introduced into the NBTS prior to the results of the UKBTS NANB trial"* (NHBT0005019, page 3).

79. Refers to **NHBT0005019** which considers the prospect of screening for NANB in the light of a possibly soon to be available HCV test following Chiron's discovery of part of the HCV genome.

a. Do you recall why this was the opinion at the time?

80. The reasons probably were the same as had informed the need for the anti-HIV assay evaluation.

b. In your view did this contribute to a delay in introducing testing?

81. No because I don't remember any evaluation similar to that for HIV took place.

42. At the 21st Meeting of the UK Haemophilia Centre Directors Organisation held on Monday 9 October 1989, you are recorded as "*willing to accept samples for HCV testing*" as "*the working party would be looking at HCV testing in haemophiliacs*" (HCDO0000015_035, page 10). You may also wish to refer to DHSC0000551, page 4. As to this:

a. Can you describe the ethical guidelines surrounding this process, having regard in particular to issues of patient selection, monitoring, patient consent and the notification protocol for patients found to be at risk of HCV transmission within such studies?

b. In studies such as the one listed above, did you have any professional expectation as to when patients who were found to have contracted HCV would be informed of the findings of the studies?

82. 42a and b. I would have regarded both as the responsibility of the directors of the haemophilia centres.

43. In the minutes of the ACVSB meeting held on 24 April 1990 (NHBT0000072_098, page 2) it is noted that you "*thought there had been an underlying feeling against screening because of the lack of confirmation [and] thought confirmatory testing would become available within a reasonable time and that the routine screening of blood donors could not be delayed for a long time*" (PRSE0001477).

a. Was it your view that the rollout of screening for Hepatitis C was being unnecessarily delayed within the National Blood Transfusion Service ("NBTS")?

83. No. I was concerned that the NBTS get on with it, but because of the current failure to appreciate the long-term morbidity associated with HCV carriage it didn't seem as urgent as for HIV.

b. What other factors delayed the rollout of screening?

84. The medical attitude to NANB was different to that towards HIV with its often much shorter interval to AIDS. For instance, many thousands of US soldiers had very probably been exposed to HBV and NANB through contaminated yellow fever vaccines in WW2 and had died decades later unaffected by it. So any short delay was not seen as so much of an issue.

Refer to H.Alter's 2019 Gordon Wilson Lecture **[RLIT0001170]**, the doyen of NANB studies.

44. **In the draft notes you wrote on the procedure for the introduction of an anti-HCV screening programme (NHBT0000049_002), you note that the pilot study raises issues that must be resolved before screening is introduced. Do you recall how these were subsequently addressed, including timescale?**

85. No. I don't recall having been involved in a 'pilot' study.

Section 8: Manufacture and use of blood products

Factor concentrates

45. **On 14 October 1983, you attended the first meeting of the CBLA Working group on AIDS in Relation to Blood Transfusion (CBLA0001754). As to this:**

a. **It was stated that the manufacture of factor concentrates from smaller plasma pools may have *"considerable advantages"* (CBLA0001754, page 3). To the best of your recollection, please explain what these advantages were;**
b. **What was your view as to the advantages and disadvantages of manufacturing factor concentrates from smaller pools of plasma at this time?**

86. 45a and b. The pools used to make concentrates varied between the UK state-funded centres (Elstree and Edinburgh), and US and other possible commercial sources. The latter were thought to use larger pools, up to 20,000 and even more. Obviously the risk of including viral contaminated plasma units increased with the size of pool.

Immunoglobulins

46. A letter by R. S. Lane, published in The Lancet on 22 October 1983 (PRSE0004375), stated that "*In a clinical trial of an intravenous HNIg developed in this laboratory for the maintenance therapy of hypogamma-globulinaemia all 12 patients developed hepatitis compatible with a non-A non-B viral origin.*" No patients in the matched control group receiving intramuscular HNIg had any evidence of hepatitis, and a reason suggested for this was "*a change in downstream processing of the fraction II for intravenous use*".

a. Were you aware of these findings, and if so, when did you become aware?

87. No.

b. What action was taken to reduce the risk of NANBH in intravenous immunoglobulin as a result of these findings?

88. I don't know.

c. Did you consider the findings relevant to discussions of the potential infectivity of immunoglobulins in respect of AIDS? If so, what action was taken as a result of this?

89. Once PHLS did know about this risk from i.v. immunoglobulin (intravenous immunoglobulin), which potentially might include a risk of exposure to HIV, and even a possible risk from i.m. immunoglobulins (intramuscular immunoglobulins) the organisation was I'm sure alarmed.

47. In the minutes of the eighth meeting of EAGA held on 15 January 1986, in which you were in attendance, there was significant discussion on the issue of the safety of immunoglobulin. It was stated, inter alia, *"Professor Weiss thought that despite Professor Zuckerman's reassurance, there was some cause for concern and he felt that until intravenous immunoglobulin*

could be manufactured from plasma from screened donors, it should not be administered" **(DHSC0000833, page 5). Please describe in as much detail as you can recall:**

a. Whether, in your view, there was a lack of serious consideration given to concerns raised by Dr Rubenstein that HTLV-III survived the manufacturing process of immunoglobulins (DHSC0000833, page 4);

90. i.m. immunoglobulin, properly prepared by the Cohn method had, I think, never been associated with viral transmission, nor over some two years' experience of being able to detect transmission of HIV.

b. Whether in your view, the EAGA's response to the conclusion of the CSM(B) was appropriate given the concerns raised by Dr Rubenstein and reiterated by Dr Weiss?

91. The concerns relate to intravenous immunoglobulin, a different product from intramuscular immunoglobulin.

c. What you understood *"panic measures"* (DHSC0000833, page 5) to mean, and whether you agreed with the position that such measures were not necessary?

92. i.m. immunoglobulins were in worldwide use and in England and Wales a particular concern of the PHLS. It would have been obliged to act to stop the widespread use wholly and straightaway which was what 'panic' implied.

d. Whether you were aware of any recipient of immunoglobulin seroconverting for HIV before or after that meeting. If so, please give details.

93. No.

48. In February 1986, you co-authored a report titled 'Batches of Blood Products Laboratory intramuscular immunoglobulin that have been tested

for anti HTLV III/LAV' (BPLL0009973). In that report, three batches of BPL intramuscular immunoglobulin were found to be positive for anti HTLV-III/LAV. You go on to comment that *"these results do not necessarily imply that any of the immunoglobulin preparations examined are an infection risk"* (BPLL0009973, page 2). Please describe:

a. **Why, given these results, you came to that conclusion;**
b. **With regard to the statement *"it is not surprising that unscreened blood donations collected before strict self-deferral mechanisms were in place might have produced immunoglobulin contaminated with anti HTLV III/LAV"* (BPLL0009973, page 2):**
i. **Why you considered that a lack of stringent self-deferral mechanisms was a key cause?**
ii. **At what stage you considered adequate self-deferral mechanisms to be in place;**
iii. **Why, if there were concerns as to the self-deferral mechanisms, more stringent manufacturing processes and operating procedures were not put in place to reduce infection risk.**

94. 48 a and b. I'm glad to clarify this. The choice by me of the word 'contaminated' is misleading. Some i.m. immunoglobulin specimens were found to contain antibody (that was their function) but it did not mean that they contained live HIV. Cohn method-based i.m. immunoglobulin is extracted from plasma donations so that a dose of human immunoglobulin containing a range of antibodies can be administered. If the source plasma pool contained even a single anti-HIV positive specimen that would probably be sufficient to make the product positive in a diagnostic anti-HIV assay. Though an undesirable outcome this did not indicate HIV infectivity. There was no evidence of this from anywhere.

c. **With regard to your suggested actions, why you recommended that "*all immunoglobulin should be made from screened blood donations and remaining stocks withdrawn*" was to be done "*as soon as practical*" (BPLL0009973, page 3) and not immediately, given the three infected batches;**

d. Why you considered that immunoglobulin only represented a "theoretical *hazard*" (BPLL0009973, page 3), as opposed to a real hazard given the results of your report;

e. The response to your recommendations and the extent to which they were acted upon. You may be assisted by DHSC0001428, which is a letter from N. S Galbraith to you dated 7 March 1986.

95. 48c, d and e. Worldwide immunoglobulin was being manufactured by a longstanding procedure and being distributed to very many clinics. I must have thought their Instant withdrawal, even UK wide, was scarcely feasible, and undesirable given the therapeutic value of i.m. immunoglobulin and the absence of evidence of harm in the shape of HIV infection.

96. Dr Galbraith's letter 7 March 86 to me refers to 'three suggestions', but I don't recall exactly what they were. From his answers I infer as to 2) that my wife Janet. a PHLS statistician, had suggested a study of i.m. immunoglobulin recipients, but she says it wasn't acted upon. As to 3)Dr Galbraith thought that use of i.m. immunoglobulin might be greatly restricted. That would have been his task to enforce and not mine. As to 4) Galbraith's suggestion is very interesting, but never, I think, acted upon.

49. On 11 March 1986, the EAGA discussed the possibility of withdrawing immunoglobulin preparations (DHSC0003714_043, page 3, paragraph 12). To the best of your recollection, please explain:

a. Whether *"outdated"* immunoglobulin was recalled from hospitals following this meeting;

97. I don't know.

b. Whether you considered that the potential for recall to cause *"public alarm"* was an appropriate factor to be taken into consideration in such discussions;

98. Yes.

c. Whether you agreed that *"no action should be taken to withdraw immunoglobulins made from untested material."*;

99. Yes.

d. Notwithstanding that the *"[t]he Blood Products Laboratory (BPL) Elstree was not subject to licensing legislation"* (DHSC0003714_043, page 3, paragraph 11), whether the response of the EAGA with regards to immunoglobulins was appropriate in light of (i) the concerns raised in the meeting and (ii) the findings of your February 1986 report (BPLL0009973)?

100. I don't know if BPL made i.v. immunoglobulins. In regards to i.m. immunoglobulin, I hope they switched to anti-HIV negative pools thereafter.

50. On 16 October 1995 you wrote to Dr A Rejman regarding IM Immunoglobulin and a proposal to require PCR screening of start plasma and to add a validated viral inactivation step in IM Immunoglobulin (DHSC0006205_034). With reference to that letter, please describe:

a. Whether, in light of your February 1986 report (BPLL0009973), the comment that the *"[...] Cohn ethanol fractionation method is absolutely safe when properly done"* (DHSC0006205_034, page 1) was an accurate depiction of the potential risks of infection through IM immunoglobulins;

101. Everyone, including me, thought so. Cohn's method was longstanding and had not been associated with illnesses that might have suggested viral transmission.

b. Evidence you had to suggest that a viral inactivation step, properly tested, would make the product unsafe;

102. It was speculation on my part. But it was right to suggest that an inactivation step might make the injected material irritant.

c. The extent to which, if at all, supply problems and cost implications influenced your advice to Dr Rejman.

103. Not at all.

Section 9: Autologous transfusion

51. On 29 January 1993, you wrote to the Second Secretary of the British High Commission of Singapore regarding 'directed' and autologous blood transfusions (NHBT0006906, page 2):

a. You stated: *"the view is that far from increasing the safety of the blood supply [directed transfusion] would detract from it because individuals known to a potential recipient might be unwilling to disclose information that would lead to their blood being rejected... For this reason our transfusion services neither seek nor accept directed transfusion."* Was this your view at this time? To the best of your recollection, was this view supported by data or research? If so, please provide details of the data or research;

104. Yes, though I didn't know of any supporting research.

b. You stated that, in contrast to some other countries, the UK had *"not so far made a large commitment to autologous transfusion."* What was your understanding as to why the UK transfusion service took a different approach to other countries in this regard?

105. I don't think the NHS used directed transfusion at all though private UK medicine may occasionally have done so. I didn't know about research and I think I guessed that directed transfusions were done almost exclusively in countries that had a very widespread HIV and/or hepatitis problem and a poorly developed transfusion service.

106. The UK did what other "First World" countries did.

52. On 27 October 1997, you attended a meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation ("MSBT"). at which an increasing interest in autologous transfusion was discussed in (SBTS0000522, page 10). What action, if any, did the MSBT take with regard to autologous transfusion following this meeting?

107. I think none.

53. On 5 May 1999, you attended a meeting of the UK Blood Transfusion Service/National Institute for Biological Standards and Control Standing Advisory Committee on Transfusion Transmitted Infections at which it was stated that *"autologous transfusion could be valuable if the arrangements were properly targeted and managed"* (NHBT0017405_001, page 6). What decisions or actions were taken in light of this discussion, if any?

108. Again I think none. The quote from the minutes may refer to leucodepletion in connection with HTLV1 virus in groups at increased risk of that infection.

Section 10: Variant Creutzfeldt-Jakob disease ("vCJD")

54. On 1 October 2001, you wrote to Dr Pat Troop enclosing a paper titled *"Blood use and vCJD: thinking about the unthinkable"* (NHBT0000700). On 22 October 2001, you proposed measures to reduce the risk of vCJD at a meeting of the MSBT (NHBT0008553_002). Please explain:

a. Why it was your view that further measures to reduce the risk of the transmission of vCJD by blood and blood products should be taken.

109. I think my letter to Dr Troop is adequate in itself and focussed on introducing the idea of haemovigilance into the UK which I think it did. Thankfully vCJD has not seemed to have become an epidemic in the UK.

b. **What was done in response to the concerns that you were raising in the paper and at the MSBT meeting.**

110. I think DHSS and NBTS did implement valuable haemovigilance measures, but the Inquiry should ask them. The concept of Haemovigilance was a french idea of encouraging clinicians to use donated blood more sparingly.

c. **Whether sufficient steps were taken in your view, to protect recipients of blood and blood products from vCJD.**

111. Given the lack of new cases in the UK so far, probably enough has been done, but we must remain mindful of vCJD.

<u>Section 12: Other issues</u>

55. **In Dr Abraham Karpas' written statements to the Inquiry, he made various assertions about you. The enclosed 'Supplementary schedule of documents', contains both of those statements and exhibits provided to the Inquiry by Dr Abraham Karpas. For ease of reference however, the extracts of those statements in which Dr Karpas makes assertions about you are below. So far as you are able to, please set out your response to those assertions.**

In Dr Karpas' first statement (WITN0684001) he states the following:

"[...] Unfortunately there was yet another 6-month delay in the introduction of HIV testing on top of the 'Lost Year' in the UK. That 6-months delay is entirely the responsibility of Dr Philip Mortimer, a Consultant Virologist who was head of the Public Health Laboratory Service (PHLS) Virus Reference Laboratory in Colindale. He was the only person who could decide when to start testing and which tests to evaluate for HIV infection. It appeared that due to his friendship with Weiss and Tedder he delayed the approval of the US Abbott test in

order to enable Wellcome Diagnostics to develop a British test with Weiss' so-called CBL-1 virus." (Page 7).

"[...] In the UK I learned that there was delay in the introduction of screening for HIV after reading an article in the New Scientist of 8 August 1985, titled 'Ministers Delay Launch of AIDS Test' (exhibited as W1TN0684014). Although the article does not mention the names of doctors Mortimer and Weiss, Mortimer was the person in charge at the PHLS Virus Reference Laboratory Colindale, which had been chosen to carry out the evaluation of proposed tests on behalf of the DHSS by the Expert Advisory Group on AIDS (EAGA.), an Expert committee of the UK Health Department. It was his responsibility to select the tests to approve for HIV and thus determine when the roll-out into the NHS could begin." (Page 7).

"[...] But in the UK on top of this there was a further 6-month delay in the introduction of HIV testing, directly the responsibility of Dr Mortimer and more remotely a failure of the DHSS in leaving such a significant decision affecting thousands of lives in the hands of a single person [...]" (Page 8).

"[...] Nevertheless Dr Weiss later shared the Queen's Award for Industry for helping Wellcome develop the test, though by delaying the introduction of the Abbott test by 6 months many more of the Queen's subjects will have become HIV infected, developed AIDS and died. It is possible Mortimer might have received a grant to his lab from Wellcome for his collaboration but I have no knowledge of the matter." (Page 8).

"Dr Mortimer is responsible for the following 6-month delay in the UK before screening for HIV was introduced, through allowing his friendship with Tedder and Weiss to influence the timely validation of tests." (Page 9).

In Dr Karpas' second statement (WITN0684019), he states:

"A further 6 months' delay occurred in the introduction of tests for HIV infection in the UK and was reported in the 8 August 1985 issue of the journal New Scientist in an article entitled "Ministers Delayed Launch of AIDS test". The first commercial test for HIV infection, developed by the American company Abbott laboratories, received FDA approval in March 1985 and was introduced in many countries, but not in the UK. Officially the reason was that it took Dr P Mortimer's virus laboratory 6 months to evaluate the Abbott test; but when my test was evaluated in that laboratory the results of the evaluation were returned to me in the post within a week. According to Abbott laboratories, as outlined in the New Scientist article, the delay was in order to allow time for Wellcome Diagnostic to complete the development of their own test with the so-called CBL-1 HIV which they were licensing from Weiss. When the Wellcome test was ready the Abbott test was also approved. It so happens I know that both Dr Weiss and Tedder were friends of Dr Mortimer; and Dr. Mortimer had sole responsibility for deciding which tests to approve and which not. The Wellcome test went into use nationally in September 1985 in the UK, 6 months after the Abbotts' test was licensed by the FDA and available for use. It was a gross defect in the government of the day to have placed such an important decision affecting life and death for thousands of people in the hands of a single individual." **(Pages 3-4).**

112. Dr Karpas's remarks about me are a mixture of errors and exaggerations. There are still some uncertainties about where early isolates of the virus that came to be known as HIV were made. First, I think this was by Barre-Sinoussi and Montagnier in Paris in 1983, then I understand by Gallo at NIH, USA, and by Weiss at the Chester Beatty lab in London. I didn't and don't know when Dr Karpas isolated HIV. As far as I was concerned, I had previously worked first with Dr Dane and then with Dr Tedder at the Middlesex Medical School on hepatitis A and B viruses, and Dr Tedder was our link with Professor Weiss.

113. Weiss and Tedder helped us at Colindale to set up an in-house ''competitive'' RIA in 1984 and we used it widely as a reference assay to support clinical diagnosis. My boss, Dr Pereira, who headed PHLS VRL, I think used the Weiss isolate in an immunofluorescence assay for anti-HIV. During 1985 commercial companies developed anti-HIV ELISA kits and the DHSS, the NBTS, STD colleagues and we at Colindale were all concerned about their sensitivity and specificity. We, as a reference lab, saw being able to check specificity of initially reactive specimens as one of our roles. DHSS were, I understood, concerned about continuity of supply in a ''thirsty'' world market to sustain UK blood donor screening and have accurate clinical testing. I was not the 'single' person deciding when UK-wide blood donor testing should be introduced. That was a DHSS/NBTS decision.

114. During 1984 we began in-house anti-HIV testing for our associated PHLS and other laboratories, and some STD clinics, using a competitive RIA. No ELISA assay was available until Abbott offered us one in Spring 1985, but other commercial ELISA ones followed within weeks so that we were able to begin evaluating them during the Summer.

115. Dr Karpas rightly says that due to my concern that the first Abbott kit shown to us in Spring 1985 might be prone to false positive reactions I didn't support its immediate introduction (in spite of a vague and improper offer by a representative concerning use of a Swiss villa), and meanwhile Abbott and other manufacturers continued to demonstrate their ELISA kits to us and no doubt others in UK. And meanwhile the DHSS decided to ask and I think specially to fund an evaluation of commercial kits at Colindale. This was underway in June, a 67 page report submitted to Mr Kennedy DHSS in August and made generally available by him in September 1985.

116. Dr Karpas rightly refers to my concerns about the initial Abbott "indirect" format product shown to me in Spring 1985. My main concerns included: (i) accuracy; (ii) worries about false positive reactions and how all the donors whose bloods might be found to be reactive were going to be dealt

with by NBTS; and (iii) continued availability and reliance on a single foreign supplier. I didn't therefore support its immediate introduction.

117. Note that Abbott were/are a powerful multinational company influential in Federal USA. The UK was not obliged to fall in with the FDA's opinion if we had concerns and before we could compare products' specificities.

118. Dr Karpas may be unaware of the source of PHLS funding. PHLS, and so my laboratory, was solely and fully funded by DHSS and never accepted funding from any other source. It didn't need to as it had been founded by Government in 1940 and had never had to look elsewhere for support. In particular, to my knowledge, Wellcome neither offered to PHLS nor was the company asked by PHLS, formally or informally, for any financial support or funding. Any implication by Dr Karpas of a conflict of interest is unfounded.

119. Dr Karpas writes that we evaluated his test (not mentioned in that DHSS prompted evaluation) in a week. I don't recall doing this or when or if we did it.

120. Dr Karpas says a friendship between me and Tedder and Weiss improperly influenced me. Tedder had long been a helpful colleague and was a friend. Weiss I did not know before 1984. It turned out we lived close and I did later once visit him and his wife. That was the nature of those acquaintances. They did not lead to improper influence or impropriety of any kind.

121. Dr Karpas thinks that by the element of delay in UK blood donor screening implied above I was solely responsible for the deaths of thousands and I strongly refute that. Almost all of the HIV infections of recipients of factor preparations had taken place before heat treatment was introduced, and of blood transfusions before donor self-selection was made rigorous.

56. Please provide any further comment that you wish to provide on matters that you consider may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and List of Issues.

122. I would like to make three general points:

123. i) Many of the events and related issues that are the subject of this inquiry were already considered in the Penrose Inquiry nearly a decade ago; but that dealt specially with Scotland and reported only to the Scottish Health minister of the time. This inquiry is by now focussed on events that happened 30 to 50 years ago and I am now 80 years old. I am conscious that after an interval of up to 50 years my memory is not precise and is influenced by hindsight. I have tried to answer the questions about those events frankly and as things seemed to me at the time when they occurred. When I have responded with the benefit of hindsight I say so.

124. ii) As a virologist I am very aware that haemophilia patients were exposed from time to time to a multitude of viruses in donated blood, cryoprecipitates and factor concentrates, and that other recipients were exposed to these viruses in donated blood, plasma, and possibly some intravenous immunoglobulin preparations. The present inquiry focuses on HIV, HBV and HCV, but blood may contain other infectious viruses that are known and unknown, old, new or recurrent, acute or persistent, trivial, non-trivial, serious, and even mortal. Examples are CMV, EBV, zoster and other herpes viruses, HTLV 1, B19, Dengue, Zika and other tropical viruses caught by UK holidaymakers and travellers, and just now coronaviruses. This is as well as HIV, HBV and HCV which are the focus of the inquiry. Those other viruses could not and cannot realistically all be screened for in blood donors, and this is one of the reasons why so very much effort was put into requiring donor self-selection. Ever since the end of WW1 blood transfusion in its many forms has had, and continues to have, great benefits. It can't yet be replaced, nor can it be made entirely safe.

125. iii) Finally, both HIV and HCV are RNA viruses and so are sensitive to heat treatment. Very sadly, though, most affected haemophilia patients had been exposed to untreated concentrates before effective heat treatment of these products was introduced. Thereafter this became an effective way of protecting them, arguably more important than the self-selection and screening of blood donors which very properly is being examined above.

Statement of Truth

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

Signed: GRO-C

Date: 13/09/2022

Exhibit Table

	UID	Date	Description
1.	**RLIT0001170**		THE GORDON WILSON LECTURE: THE HEPATITIS C

		01/01/2019	VIRUS: FROM HIPPOCRATES TO CURE by Harvey J. Alter, 2019.