Witness Name: Peter Wormald
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INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF PETER WORMALD

Contents

I, Peter John Wormald, will say as follows: -

Preface

0.1. I am a retired career Civil Servant. From late 1978 to late 1981 I was the Under Secretary (Grade 3) in the Department of Health and Social Security ("DHSS") with responsibility, inter alia, for Blood Transfusion Services ("BTS").

0.2. I am providing the statement in response to requests from the Inquiry dated 4 November 2021 and 6 September 2022.

Structure of this Statement

0.3. For the Inquiry's convenience I have structured this Statement in the same way as the Questions put to me on behalf of the Inquiry in the request dated 4 November 2021.

0.4. I have appended a list of acronyms, for ease of reference, though much of the time they are spelt out in the text.

Opening Comments

0.5. I would like to begin my witness statement by making a few brief comments.

0.6. That part of my career in which I was responsible for matters of potential interest to the Inquiry lasted only 3 years and was some 40 years ago. At the time I had many other responsibilities. I was involved in very few of them on a day-to-day basis. I was not so involved with the BTS. Day to day work was devolved to a Branch headed by Mr John Harley (Assistant Secretary, Grade 5). My role as the Under Secretary (Grade 3) was general oversight plus personal involvement in particular issues as necessary. This involvement became considerable following the Medicines Division inspection of the Blood Products Laboratory ("BPL") in 1979.

0.7. After 40 years I have little memory of the detail even of those BTS issues with which I was closely involved. I have therefore relied heavily on documents, some provided by the Inquiry's support team and some by the Government lawyers who have assisted me in the preparation of this statement. There have been several hundred pages of these and I have reviewed them personally. Even so there have been gaps where, in spite of dedicated research, documents have not been found which would have put into context documents which I have, or in some cases would have explained what happened following a decision of which I have a record and no more.

0.8. My evidence contains a mixture of actual recollection, recollection triggered by documents, reconstruction based on documents and in some cases surmise. I have also, on occasion, quoted documents to which I cannot add, in the belief that they may assist the Inquiry. I have not attempted to indicate in every case into which of the first 3 categories individual pieces of evidence fall (some are a mix), but I have tried to indicate what is surmise and what is material which I have merely quoted.

0.9. I and my team of administrative staff worked closely with professional colleagues, most notably in the case of the BTS with medical and scientific colleagues. Not all of them were members of the Department. Many decisions were shared decisions, reached after careful consultation. We administrators tried to learn enough about the professional aspects of the work to understand the import of the professional advice which we received, and to do our jobs effectively, but we could never attain to the levels of expertise of a professional. Some issues, usually ones without substantial political or financial implications, were dealt with entirely by professionals. There are some questions which I have been asked on behalf of the Inquiry which I do not have sufficient knowledge or expertise to answer reliably, if at all. I have not risked misleading the Inquiry by attempting to do so.

Section 1: Introduction

1.1. My name is Peter John Wormald. I was born in 1936. My date of birth and address are known to the Inquiry.

Employment History

1.2. I joined the civil service in 1958, with a BA and MA in Jurisprudence. I remained in the Civil Service until I retired in 1996. I worked in the Ministry of Health (later the Department of Health and Social Security (DHSS)) from 1958 to 1990, apart from a two-year secondment to the Treasury.

1.3. The following paragraphs outline my employment history, in the Department of Health/Department of Health and Social Security unless otherwise stated:-

a) 1958 – 63: various training posts, culminating in a position as the Private Secretary to the Permanent Secretary;

b) 1963 – 1965: Principal (now Grade 7): administrative posts dealing with capital developments and financial allocations for a variety of health authorities, plus some specialist subject responsibilities which for about a year included blood transfusion services;

c) As regards the BTS in that year, I worked partly in support of Dr (later Sir) William Maycock, the Director of BPL who was then the Chief Medical Officer's Consultant Advisor on Blood Services. I had no involvement with professional medical matters or with the activities of the Regional Transfusion Directors, but I had some involvement with Regional Donor Organisers;

d) 1965 – 67: I was seconded to HM Treasury, dealing with Civil Service manpower issues;

e) 1967 – 70: Secretary to the Management Side of the negotiating body for pay and conditions of NHS manual staff;

f) 1970 – 74: Assistant Secretary (now Grade 5): development of corporate planning systems, successively for the Department and the NHS.

g) 1974 – 78: Regional Division conducting the Department's relationships with certain Regional Health Authorities and London Postgraduate

Teaching Hospitals. For the only BTS issue of substance with which I can remember dealing, see my answer to 35.2 below. Otherwise, I acted only as an intermediary between other parts of the Department and Regional Health Authorities.

h) 1978 – 81: Under-Secretary (now Grade 3): in charge of the Department's General Health Service Division (HS2). This had a wide range of responsibilities, carried out in conjunction with professional (mainly medical) colleagues. The BTS was one of my responsibilities. For the nature of my involvement see para 0.6 above;

i) 1981 – 90 (as Grade 3 and Grade 2): responsible for various industrial relations and associated administrative and policy matters, first as a Divisional head and then as Director of Operations (Personnel) on the NHS Management Board. I have not been able to ascertain the exact dates of my move to HS2 or from HS2 to Personnel, but I believe that the move to HS2 would have been in the autumn of 1978;

j) 1990 – 96: following transfer to the Office of Population Censuses and Surveys (now part of the Office for National Statistics): Head of Department and Registrar General for England and Wales.

1.4. I have not been a member (past or present) of or involved with any committees, associations, parties, societies, groups or organisations relevant to the Inquiry's Terms of Reference.

1.5. I do not have any business or private interests relevant to the Inquiry's Terms of Reference, nor have I had in the past.

1.6. I have not provided evidence 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.

Section 2: Self-Sufficiency and Related Issues

General Questions

2.1. I have been asked to supply a chronological account of my involvement in and knowledge of the DHSS's attempts to secure self-sufficiency in blood and blood products throughout my time in the DHSS.

2.2. As set out above, in my time in DHSS I held posts which involved some responsibility for blood and blood products only for a period of about a year between 1963 and 1965 and from 1978 – 1981. In general, I can provide evidence about these periods only.

2.3. My understanding is that during 1978 – 1981, England and Wales were able to collect sufficient blood from donors to satisfy the NHS's need for whole blood. Concern about self-sufficiency related to the supply of plasma needed for blood products.

2.4. I did have some peripheral involvement in BTS issues earlier in the 1970s when I was in Regional Division, but with the exception of the 1977 correspondence described at 35.2 below, neither the issues being dealt with nor my involvement with them were such as to inform me about issues of national self-sufficiency in blood and blood products.

2.5. I have addressed the question of a chronology of the DHSS's actions during the latter part of 1978 - 1981, to the extent that I am in a position to speak of it, by reference to the Inquiry's more detailed questions, below.

Q7: Government Policy on Self-Sufficiency

3.1. I have been asked what, during my time working within the Department, I understood the Government's policy on self-sufficiency to be.

3.2. I do not recall "self-sufficiency" being discussed in the 1960s, and I have not been shown any documents on policy in this area at that time. I do not believe that I had any direct involvement in the area. As far as I remember now, my assumption was that BPL had the capacity to satisfy demand for blood products, given sufficient raw materials. Whilst I do not think I received any

briefings on the subject, no one was saying otherwise, and as a relatively junior officer new to the subject, I would not have thought it appropriate for me to question the matter. The key problem at the time was obtaining enough blood (exclusively from voluntary donors) for BTS, including BPL needs. Much importance was attached to the voluntary donor principle, not just for financial reasons but because blood from paid donors was considered to carry a greater risk of infection, specifically hepatitis. I learnt this orally from Dr (later Sir) William Maycock who, as set out above, was the Director of the BPL and the CMO's Consultant Adviser on blood services. Note that the reference would be to hepatitis infection from transfusions rather than from blood products; and that this was before infection risk had become a significant element in discussions. It is possible that Dr Maycock had received information about the risk from prison donors in the USA.

3.3. By 1978, when I returned to the scene, it had been agreed between English and Scottish Departmental officials (in 1973 in the context of a Joint Steering Committee set up to achieve commonality of approach between BPL and the new Edinburgh (Liberton) Fractionation Centre) that the UK should aim for self-sufficiency in blood and blood products. This objective had received Ministerial backing. In 1975 the then MS(H), Dr David Owen, had authorised a special allocation of £500,000 with a view to achieving self-sufficiency in home produced Factor VIII by mid-1977. But although the production target had been met it had not resulted in self-sufficiency because of rising demand. To the best of my knowledge no detailed planning had been done since then as to the production levels which would be needed to attain "full" self-sufficiency, or how BPL (or the other fractionation laboratories) might increase production to achieve them; nor had the resources required been estimated nor any budgetary provision made. I am not in a position to review the documentary records of events before 1978 but I surmise that no such work had been done because the focus was on the "stop gap" developments referred to in paragraph 3.4 below (as potentially giving an early boost to production) and on the preparation of proposals for a phased BPL development programme, also referred to in the next paragraph. Assuming the latter was agreed in principle, much preparatory work would have to be done before detailed planning could

begin, including determining the required production levels, on which advice received from the "Trends" Working Party in December 1977 needed to be re-appraised - see paragraph 3.6 below. Both streams of work ("stop gap" and redevelopment) later had to take into account the report of the Medicines Inspectors on their inspection of BPL in 1979. All this inevitably made for longer lead times than were compatible with significant investment during 1978. It also imposed a considerable abnormal workload on the available staff, particularly BPL management.

3.4. This is not to say that nothing had been done. It may help if I summarise what had been done by the end of 1978. As background, in the early 1970s, the Ministry of Health had contributed to the cost of building a fractionation centre at Edinburgh (Liberton) with the intention that it should at some stage fractionate some plasma from England. This had not yet happened because no more plasma had been available in England than BPL could handle. But the possibility was still there. As to more recent action, in 1977 the then Director of BPL (Sir William Maycock) had, with DHSS encouragement, planned some "stop gap" works at BPL which were designed to produce a significant increase in BPL capacity pending full redevelopment, and also to improve safety. These were submitted to DHSS in December 1977 and approved in June 1978. (In the event the Medicines Division inspection of BPL began before implementation of "stop gap" had begun, and "stop gap" was significantly amended in the light of the Inspectors' findings.) "Stop gap" did not, however, claim to be enough to bring about self-sufficiency, with or without a contribution from Liberton. It was widely recognised by people in the NBTS and in the Department that there would need to be major addition to the BPL fractionation capability, whether at Elstree or elsewhere. Through 1978 work was in hand at BPL, again with DHSS encouragement given in 1977, to develop proposals for a phased BPL redevelopment programme, which were eventually submitted to the Department in May 1979. The scale of this redevelopment had not, however, yet been determined. This would depend on updated forecasts of future demands for blood products and the contribution, if any, which was to be made to English and Welsh needs by other fractionation plants, particularly Liberton.

3.5. However, despite these unknowns, during 1978 DHSS had also made a commitment to purchase the Elstree site from the Lister Institute, a step which furthered the potential development of BPL on the site (albeit that in the short to medium term it made further demands on the senior management team at BPL, which extended into 1979).

3.6. Work had also been done (by the "Trends" Working Party established in 1977) to estimate future demands for blood products, but this was already regarded as outdated. I see that I was copied into a minute dated 30 November 1978 from Mr Dutton to Dr Waiter **[DHSC0000184]**. This referred to a paper which Mr Harley was preparing on future demands on the NBTS and the implications of meeting them. It referred back to the "Trends" Working Party's estimates, but noted that these were already being challenged.

Q8: Meaning of Self-Sufficiency

4.1. I have been asked (the Inquiry's Question 8) what my understanding of the meaning of "self-sufficiency" was, as used by officials and Ministers within the DHSS. I think the term was mostly treated as self-explanatory, and may have meant slightly different things to different people. My own interpretation was that the domestic supply, from domestic raw materials, should suffice for all clinical demands, the assumption being that clinicians, while still free to exercise their clinical freedom, would not want to use imported blood products if high quality, low risk domestic products were available. I do not recall any consideration of whether there were patients or conditions that could be better treated by imported products. I understand that those clinicians who preferred to use imported rather than domestic products did so because they were more conveniently packaged. I do not believe that the lack of a formal definition of self-sufficiency was of any practical significance. The important requirement for planning was to have the best available forecasts from experts of future demands from clinicians, allowing for possible developments in clinical practice. In any case a formal definition which set out the purposes which self-sufficiency was to serve would have had to be reviewed whenever there was a significant

change in clinical practice. It could well have been contentious, and have given rise to accusations of denying clinicians their clinical freedom.

4.2. I have been asked (last sentence of the Inquiry's Question 7) if the policy on self-sufficiency changed during my time in the Department. I can only answer for the period 1978 -1981. There were a number of issues which needed to be more precisely articulated for the purposes of detailed planning of domestic capability. Quite a lot of work was done on this between the presentation of the Medicine's Inspectors' report on BPL in late 1979 and when I left Division HS2 in late 1981. I would not regard any of what happened as a change of basic policy, although the policy was certainly developed, and stood to be developed further after I left. I note that progress in 1979 was much affected by the Medicines Division inspection of BPL, the findings of which were recognised as potentially significant.

4.3. As to what work was done in the period leading up to the Medicine Inspectors' report, in May 1979 Dr Lane, who had succeeded Sir William Maycock as Director of BPL, produced a full redevelopment plan for BPL, which was discussed by the Scientific and Technical Committee ("STC") the following month. At about the same time a member of the STC, Mr Smart (Director of Glaxo holdings and a member of the Scientific and Technical Committee for the Central Blood Laboratories), produced a paper for the STC focussing on the financial aspects of redevelopment. Further consideration of these papers was put on hold pending receipt of and decisions on the Medicines Inspectors' report. And in July 1979 an ad hoc group of RTDs was set up to advise on the implications of estimates of future demand for blood products put forward in the "Trends" Working Party report in 1977, and to look again at the key estimates. Dr Lane produced a detailed discussion paper for this group, covering both "stop gap" and longer term redevelopment.

4.4. Question 7 also asked what the sources of my understanding of the Government's policy on self-sufficiency were. I do not recall, nor can I now trace, any general introductory briefing. I received briefings, oral and written, from administrative and medical colleagues in the DHSS, mainly as required by business in which I was to be involved. Some such business was awaiting me when I joined, so I was quickly off the mark.

Q9: Reasons for pursuing Self-Sufficiency

5.1. I have been asked about the reasons, to the best of my knowledge, why self-sufficiency was pursued as a policy. The reasons for the policy were that imported products were very expensive and in general were considered to carry much higher risk of cross-infections, particularly hepatitis.

5.2. There was also a WHO recommendation that countries should aim to be self-sufficient in blood and blood products. This was at least partly to prevent wealthier countries depriving less wealthy countries of scarce resources.

5.3. I do not believe that these reasons, or their relative importance, changed during the period in which I was active in this policy area, though it would be fair to say that the relative importance attached to cost and safety varied between individuals.

Q10: Risks with use of pooled plasma blood products

6.1. I have been asked about my understanding of the risks associated with the use of pooled plasma blood products in the late 1970s and early 1980s, and how that understanding changed. I have been asked to consider:-

a) Risks of Non-A, Non-B Hepatitis and Hepatitis B;

b) Domestic blood products as opposed to imported products;

c) Blood products versus cryoprecipitate, and the place of cryoprecipitate in treatment;

d) Blood products versus other forms of treatment for bleeding disorders for patients;

e) Differences in the degree of haemophilia (mild, moderate and severe), and whether that had implications for the risks and benefits of using blood products.

6.2. So far as I can now recall, I had no detailed knowledge of these matters, such knowledge not being necessary to carry out my role.

Q11: Role of cryoprecipitate

7.1. I have been asked what view, to the best of my recollection, did (i) I, and (ii) my colleagues within the Department have of the role, if any, for cryoprecipitate within the UK as part of the approach to providing domestic products to treat bleeding disorders; and did my view, or those of my colleagues, in respect of cryoprecipitate change at all in the period in which I was active in this area.

7.2. I had no views on the matter, which was essentially for clinicians. Mr Dutton did minute Dr Waiter on 30 November 1978 raising the possibility of phasing out cryoprecipitate – see 41.1 below. As I recall it, this was because use had been declining. I think that demand did in fact recover, although such changes would have been after I left this post. The more pertinent question, however, was whether RTCs should continue production or whether production should move to BPL, as being a more efficient way of using plasma. I do not know whether this change was ever made. This is not a question in which I can recall being involved.

Q12: Colleagues

8.1. I have been asked to identify the colleagues involved in decisions about blood and blood products whilst I was at the DHSS. Focussing as I must on the period from 1978 – 1981, the senior medical officers involved were Dr E L Harris (Deputy Chief Medical Officer), Dr R Oliver (Senior Principal Medical Officer) and Dr Sheila Waiter (Senior Medical Officer), replaced in September 1979 by Dr Diana Walford (Senior Medical Officer, subsequently holding more senior roles). On the administrative side my immediate superior, Mr T E Nodder (Deputy Secretary) was involved from time to time, but mainly delegated to me. Mr J Harley (Grade 5 in my command) was a key player and I in turn delegated much of the day-to-day work in this area to him. A further key player was Mr Dutton, who worked in Mr Harley's branch.

8.2. Any others involved should be apparent from the documents.

Q13 / 14: Progress in the achievement of Self-Sufficiency

9.1. I have been asked how successful the Government's efforts to achieve self-sufficiency were, and whether it was achieved in the 1970s and 1980s. I have seen varying figures for the use and production of Factor VIII in the late 1970s, but it is clear that use by clinicians had risen to between 45 and 50m i.u. per annum, whereas BPL production was of the order of 15m i.u., to which can be added about the same amount, but falling, of cryoprecipitate produced by RTCs; and NHS expenditure on commercial Factor VIII was rising towards £2m. It is clear that self-sufficiency was a long way off.

9.2. Short term developments ("stop-gap") approved in June 1978 were planned to increase BPL production to 28m i.u. This likewise gave no prospect of self-sufficiency, which would have to await long term development of BPL. This was still being planned when I left the policy area in late 1981. After that I lost touch.

Management and Redevelopment of the Blood Products Laboratory (BPL)

Q15: Medicines Inspectorate Report

10.1. The Inquiry has asked a series of questions about BPL in 1979, after the Medicines Inspection.

10.2. The Inquiry has noted that in April 1979, the Medicines Inspectorate carried out an inspection of the BPL and produced a highly critical report in September 1979, the conclusions of which are at **[DHSC0001812]**. Among other comments, the Inspectorate recorded that, were BPL a commercial operation, *"we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level."*

10.3. I have been asked, first, when I became aware of this report. I have been shown a minute from Mr Harley dated 9 July 1979, addressed to Mr J Brown but copied to me **[DHSC0002193_072]**. This refers to a recent meeting of the Scientific and Technical Committee for the Central Blood Laboratories, at which Dr Holgate *"gave an account of the inspection being carried out"* and *"indicated what he expected the trend of their report to be."* Mr Harley asked for information about how long it would take for the final report to be available,

noting the link to funding for "stop-gap". Together with documents such as my minute of 6 July 1979 **[WITN6934002]**, this suggests that the fact of the inspection and the possibility of difficult issues arising out of it was being brought to my attention (with others), as information emerged.

10.4. As might be expected, when a copy of the formal letter of notification of the Medicines Division's "Conclusions and Recommendations" and its report were sent by Mr Brown to Mr Harley on 10 September 1979 **[WITN6934003]**, the documents were copied to me, amongst others.

10.5. I have been asked about my role in responding to the report and dealing with the issues which it raised. My role, along with Medical colleagues, was to ensure that everything which needed to be done had been identified and was being tackled; and to involve myself personally when issues or circumstances required it. In the event I was quite heavily involved in a number of issues, as will be evident by later parts of this statement.

10.6. As to whether the findings of the report were a surprise to me, I knew that BPL was antiquated and in some respects sub-optimal, in addition to having insufficient capacity to meet current demands. But I knew this in only general terms (having not been involved in any detailed issues relating to BPL previously), and so I was surprised to learn how serious its problems were. My main feeling, though, was not "isn't this awful?" but "what are we going to do about this?"

10.7. I have been asked about the reactions to the report of colleagues in the Department and of Ministers. I cannot recollect colleagues' reactions, which probably varied according to how familiar they were with BPL.

10.8. Ministers were formally briefed, by Ministerial submission, on the report in December 1979 when recommendations were put to them – see my reply to Q19 below. I do not know what, if anything, they had been told about the report before this, nor can I recall any reaction from any Minister.

10.9. The Secretary of State, Mr Patrick Jenkin, had, however, been made aware earlier that there were issues. On 18 June 1979, shortly after he was appointed following the May 1979 General Election, Dr Harris had a meeting with him at which the proposed redevelopment of BPL was discussed. The note of this

meeting is not available, and I do not know whether Dr Harris said anything about the still on-going Medicines Division inspection, of which he (Dr Harris) was certainly aware. The only available written record is a minute of 9 July from Mr Vaughan of Finance Division to Mr Harley, which records that the Secretary of State had asked that the Government Accountancy Service be involved in the consideration of the options for BPL redevelopment **[WITN6934004]**.

Q16: Implications of Medicines Inspectors' Report for "Stop Gap"

11.1. Turning back to my actions after the anticipated findings had been informally made known, on 6 July 1979 I had written to Mr Harley on the subject of the "stop-gap" developments **[DHSC0020820_012]**. This minute was written in the context of a review by Finance Division of bids across the whole Department for resources for centrally funded services, presumably for the financial years 1980-81 and following. It would be for each Division to make its own bids and the cases for them, which would then be considered by the Finance Division, and eventually the top of the office and Ministers as necessary. "Stop gap" was one of these bids. It had already been approved, in June 1978, but there was now the possibility that the forthcoming Medicines Division report would necessitate some further early work to improve standards. If no additional resources could be allocated, or found from savings elsewhere, I feared that improvements might have to be funded within "stop gap" at the expense of some of the planned increases in capacity. We were in difficulty in that we did not know what additional work might be necessary, but I wanted to register a bid at once because it would be much more difficult to get the case for early additional resources accepted after the current review had been completed. And I was very anxious to avoid reducing capacity, if at all possible. In my minute to Mr Harley, I noted that the two Central Laboratory committees took the view that 'stop gap' was compatible with whatever work was required as a result of the Medicines Division report and should continue. I wrote that:

"I am afraid that cannot be the end of the story. Central funds are very pressed indeed, as you will know from Mr Hulme's [Head of Finance Division] recent

minute, and we cannot be certain that more money will be available in the short term for the Central Laboratories. I see no escape from examining the extent to which "stop gap" might be adjusted to help cope with the Medicines Commission findings. And we could find that we have to choose between increased capacity and improvement in existing standards. (I realise that "stop gap" already includes some of each.).

I have already asked you to consult colleagues about the relative priority of our various centrally funded projects – BPL, BGRL, PHLS, Porton - and to consider whether the PHLS project could be replaced by something less ambitious. Such choices may be forced upon us."

After Mr Harley's consultations I could have had to make a decision of my own about what relative priority I thought should be given as between the projects sponsored by HS2. Some of these were in the essential / inescapable category, e.g. a move of the BGRL to Oxford. Others had very strong high level support, e.g. the Secretary of State was anxious to see considerable expansion of Porton Down's genetic engineering work into the industrial field. So I might not have been able to give top priority to "stop gap". But I find it hard to believe that I would not have ranked it, or at least its main components, very highly. However, I have not been shown further documents on this issue. Priority, of course, is about timing as well as intrinsic importance, and there was the possibility that "stop gap" would slip in time (as indeed happened) because of the need to adapt it to the Medicines Inspectors' recommendations. Other projects were also liable to slippage. I was not involved in, and would not have knowledge of, bids from other Divisions and would not have been in a position to rank BPL against any such bids.

11.2. There is further context provided for this Minute from a further one that I wrote on the same day to Mr Nodder **[WITN6934002]**. This provides further details of <u>all</u> the bids for Centrally Financed Services that were being made at the time by the Division (HS2). It is apparent that the bids outstripped available resources.

11.3. Please note that it has not been possible to locate Mr Hulme's minute of 20 June 1979, to which I was responding, and which must have given further details of the financial situation.

11.4. With reference to my minute to Mr Harley I have been asked to expand on what I envisaged as the "trade-off" between increasing capacity and improving standards. I was not envisaging any particular trade-off, but merely noting that we would have difficulty getting additional funds, and without them BPL would not be able to respond effectively to the Medicines Inspectors' Report and to increase output as well. The latter was desirable to meet increasing demand which could otherwise only be met, if at all, by the greater use of commercial products.

11.5. By 30 August 1979, an ad-hoc Building Sub-Committee of the BPL Joint Management Committee had been set up under the chairmanship of Mr Harley **[WITN6934005]**, to manage a project relating to the freeze-drying facilities and workshop upgrading at BPL. Mr Harley was also pressing for details of exactly what work was needed to maintain production at BPL **[DHSC0001887]**. He wrote in a handwritten minute of 10 September 1979 to Mr Dutton, copied to me: *"What we need, in order to plan and argue the case for the expenditure needed to maintain production at the present level, is a detailed itemised list showing all short-term improvements in priority order, with the costs of each….."*

Q17: Possible Private Sector Involvement

12.1. I have been asked why it was agreed to explore the possibility of private sector involvement. This possibility was not new. In 1978 and early 1979 (i.e. before the May 1979 General Election) several firms had approached the Department, and in one case Ministers, about the possibility of establishing a fractionation facility in the UK, and their interest in supplying the NHS, possibly in collaboration with the Central laboratories, BPL in particular. Since the Election it was a general thrust of Government policy to move work from the public to the private sector if the latter could do it more efficiently, or to bring in expert private sector management for public services. Also, a private sector arrangement might include industry putting up capital to provide a new facility

or facilities, and thus to enable them to be brought on stream more quickly. It was officials' duty to explore such possibilities for blood products. In the submission of 21 December 1979 about the follow up to the Medicines Inspectors' report on the BPL, Ministers were accordingly asked to agree (and did so) to "*further exploration of the possibilities of rebuilding [BPL] either within the NHS or in collaboration with industry.*"

12.2. As the Inquiry has noted in its Q17, on 10 October 1979, I chaired a meeting to discuss *"problems in connection with BGRL (Blood Groups Reference Laboratory) and BPL"* **[DHSC0002325_036]**. This discussed, amongst other things, a minute from Dr Walford dated 19 September 1979 **[DHSC0003618_023]**. The minute and the meeting considered the possibility of private sector involvement in UK blood products production. Ministers' desire to transfer functions out of the public sector where this would increase efficiency were noted; so too were Mr Smart's views that BPL should do its own fractionation. *"It was likely that shortage of money might circumscribe what could be done within the NHS but the possibility of seeking money from commerce to build a new BPL might be worth considering although the revenue consequentials might be considerable*." The note of the meeting continues:

"It was agreed that undertakings to move towards national or NHS self-sufficiency in blood products did not preclude industrial participation in the purely technical process of fractionating plasma. Dr Tovey explained that WHO concerns that nations should become self-sufficient in blood products on the basis of unpaid voluntary donations stemmed from their concern that rich nations should not deplete the protein reserves of poor nations and the recognition that paid donors tended to carry a greater hepatitis risk."

12.3. Views on the practicability of inviting two commercial firms to interest themselves in fractionation differed. Dr Oliver highlighted the time (3 – 5 years) to bring new capacity on stream, however it was done, and emphasised that much would have to be done (over and above "stop gap") to the existing BPL in the meantime.

12.4. The note of the meeting records that:

"It was agreed that Mr Harley should continue with his options paper but in practise there appeared to be only two courses to put to Ministers:

(i) to spend the minimum necessary to upgrade BPL while at the same time rebuilding and expanding the laboratory within the NHS using NHS capital if available or seeking alternatives sources of funds if not;

(ii) to spend the absolute minimum on BPL to satisfy the Medicines Inspectors and to seek an agreement with industry to fraction NHS plasma on a mutually acceptable basis safeguarding the interests of existing BPL staff as far as possible.

It was agreed that the first practical step was to find out as soon as possible what facilities industry was able to offer and on what terms."

12.5. In this connection I should like to draw to the Inquiry's attention an adjournment debate in the House of Commons on 15 December 1980, 3 weeks after the House had been informed that the private sector option had been ruled out. In the course of a 15-minute speech the Parliamentary Under Secretary of State for Health and Social Security, Sir George Young, said "*Given the likely cost of redeveloping the laboratory, and given that a manufacturing plant of this kind is rather different from the general run of NHS activities, it was only right that we should examine a number of options concerning the longer term development of BPL. These included the possibility of some form of collaboration with industry". And later "in considering a development of this size we had to look thoroughly at all of the available options. It would have been irresponsible not to do so*." **[NHBT0006435_007]**.

12.6. I have been asked what my own views on this topic were, at the time. My personal views about the likelihood of securing a private sector arrangement appealing to that sector on terms that were also acceptable to the Government, the NHS and the public were irrelevant, but I think that most officials recognised that there were many potential problems, some of which might not be easy to resolve.

12.7. The Inquiry has asked whether there was focus on private sector involvement which "may have been to the detriment of other considerations". However, there was no "focus on private sector involvement" in the sense that this was

the Department's top priority, or that work was confined to it. Indeed it was important that work should continue on developing and analysing possible public sector solutions in order than an informed choice could be made. This was made explicit in the submission of 21 December 1979 (see Q19 below), which asked Ministers "*to agree to further exploration of the possibilities of rebuilding either within the NHS or in collaboration with industry*". This was on the basis that we should tell interested parties that "*at the same time as we are looking at the possibility of building a new NHS laboratory at Elstree we are actively exploring whether the involvement of industry would have economic benefits.*" I did not think at the time that this approach need delay matters, but even if I had it would have been necessary to follow it, given Government policy as noted above. It would have been much more difficult to get agreement to a public sector solution if possibilities for private sector involvement had not been examined and found to be not feasible or less appropriate.

12.8. In this connection I should like to quote again from Sir George Young's speech. Having given some detail of the work programme in connection with BPL redevelopment he said *"Much of this work has been going on for some time. I would not have the House think that we had held it up while we had our discussions with industry, but there is still work to be done before we can commission plans for the longer term redevelopment of the laboratory. We are getting on with that work urgently, but I am not in a position to tell the House tonight when we shall be ready to start planning the necessary changes to the laboratory itself – I emphasise that I am talking about changes quite apart from the £1.25 million that is already being spent on upgrading – or how long it will be before we could start building. It will be evident, however, that it will unavoidably be several years before the redevelopment is completed, and that this would be the case even if we could provide tomorrow the necessary capital funds."*

12.9. Given the comprehensive nature of its account of then current events and the Government's approach, I refer the Inquiry to the full text of Sir George Young's speech at **[NHBT0006435_007]**.

Q18: My Minute of 11 October 1979 to Dr Harris

13.1. On 11 October 1979, I sent a minute to Dr Harris, copied to others, concerning the future production of blood products in the UK **[DHSC0003743_193]**. I dealt with two main issues. First, what long term options we should present to Ministers, and second, what reply, if any, we could send to Medicines Division at that stage.

13.2. As to the second, I did not think we could send a full substantive reply until we had some basic decisions from Ministers.

13.3. As to the first, I said that there was a basic core choice between replacing BPL as an NHS enterprise of sufficient size to achieve self-sufficiency and moving over to commercial supply, there being no likelihood of finding a mixed system which might appeal to the private sector. I continued:

"…Given that we have not so far been able to mount any challenge to the Medicines Division Report on BPL (has this now become impossible?) we shall, as I see it, have to put to Ministers a basic choice between keeping the BPL going with such improvements as we can afford until such time as money can be found to replace it – but without commitment as to timing- and committing themselves now to replacing it within a definite period, say 5 years. We shall have to tell them that the first will not be acceptable to the Medicines Inspectorate and will make it difficult if not impossible to get their acceptance of any interim improvements as adequate. The decision, in effect, to override the Inspectors would have to be defended publicly, which would be inherently awkward and, I imagine, potentially damaging to the standing of the Inspectorate." I have been asked a number of questions about this excerpt.

13.4. I have been asked whether I am aware of any other decision in which the DHSS in effect overrode the decision of the Medicines Inspectors. The answer to this is that I have never known anything about any other Medicines Division report. Lest there be any misunderstanding, I was not suggesting that we should override the Inspectorate as a matter of deliberate policy. I was saying that we should warn Ministers that this was how a failure to commit to rebuilding BPL within a definite timescale would be seen. In the event it proved possible to

take short term action falling short of the recommended upgrading without this being seen in the way I feared.

13.5. I have been asked to explain the economic and financial constraints at the time. I have set out my recollection, but the Inquiry might be assisted by hearing from those with direct involvement in public and NHS finances at the time, or from an expert. Government policy at the time was to keep public expenditure under strict control. Monies made available for the NHS for the financial year 1979/80 would have already been allocated to health authorities and a number of centrally financed services including BPL. There may have been a small centrally held contingency reserve. BPL's allocations for 1979/80 included a modest amount for upgrading works, but were not sufficient to effect any major improvements, even supposing that they could have been planned and implemented during the year. There could have been no reasonable expectation that more money would be made available in-year.

13.6. Money for later years would have to be competed for within the totals for the NHS agreed in the Public Expenditure Survey (PES). In order to compete successfully it would be necessary to get Ministerial agreement to a long term policy for the BPL, i.e., (i) whether to keep it as part of the NHS, with or without private sector involvement in its management, or to contract out the production of blood products to the private sector, and (ii) if the former, whether to commit to major redevelopment of BPL within a defined period or to decide to keep it going with only modest improvements until the financial position became easier. This was basically a decision about the priority to be given to it, vis à vis other NHS developments.

13.7. I have been asked whether I envisaged a challenge to the Inspectorate Report. It was open to any organisation reported on by the Medicines Inspectors to challenge the Report. For BPL this would have been a major undertaking, requiring expert advice. I do not remember any proposal that the Report should be challenged. In so far as I have any recollection it is that people thought the Inspectors' criticisms were valid, but some were surprised at how severe they were. I was certainly not minded to challenge the Report, but merely trying to get on record agreement to rule out any challenge.

Ultimately, the December 1979 Submission to Ministers said (para 6) that it was accepted within the Department and by outside advisers that the basis of the inspection was sound.

Q19: Ministerial Submission, December 1979

14.1. On 17 October Mr Harley produced a "first shot" at a paper for Ministers, which he sent to me and others **[WITN6934006]**. Other versions followed taking account of comments received. Before dealing with the submission itself I should like to describe two important events which happened in the meantime.

14.2. On 29 October 1979, Mr Harley had replied to Mr Firstbrook at the Medicines Inspectorate (replying formally to the letter of 10 September 1979) **[CBLA0001018]**. He noted that both the Joint Management Committee and the Scientific and Technical Committees had recommended that the report be accepted. The DHSS proposed to seek Ministerial decisions, since the acceptance of that advice *"would imply both short-term improvements and the planning and building of a new manufacturing facility, funds for which are not currently budgetted".* He listed seven short-term measures that had been agreed and were being implemented; these were "important measures recommended by the Inspectors".

14.3. A meeting was held on 6 November 1979, at which Finance Division agreed that "*to satisfy the Medicines Inspectorate's short-term concern about BPL, additional capital funds would be made available in 1980-81 to enable minimum essential remedial measures to be put in hand*" **[DHSC0002305_015]**. A minute from Finance Division following the meeting (Mr Brechin, 13 November) also recorded their agreement that, with regard to the rebuilding of BPL that would be needed to satisfy the Inspectorate, the submission to Ministers "*should go forward on the basis that the necessary funds for rebuilding will be found, if need be, from DHSS PES provision*". Realistically that was unlikely before 1982 – 83. A further minute from Mr Harley dated 10 December 1979 **[WITN6934007]** suggested that a sum in the region of £0.6m for interim works would have to be found in 1980/81.

14.4. After several redrafts the submission to Ministers, agreed at Deputy Secretary level, went from Dr Harris on 21 December 1979 **[DHSC0002307_049 and DHSC0002307_050]**. I have been referred to my minute of 17 December **[DHSC0002305_009]**, to which was attached the previous draft. A parallel submission had been sent from Medicines Division on 18 December **[WITN6934008]**.

14.5. I have been asked a series of questions about the 21 December submission.

14.6. I have been asked to explain, insofar as I am able, the financial commitments that would have been involved in rebuilding BPL as an NHS unit, and the effect that this would have been likely to have on other aspects of the Department's budget.

14.7. Paragraph 12 of the Submission stated that a "preliminary estimate" of the cost of building a new factory on the Elstree site was about £18 million (more at current prices) spread over 3 or 4 years, with subsequent revenue costs of some £2million annually. But *"no confidence can yet be attached to this estimate"* and more work was said to be needed.

14.8. Paragraph 13 noted that the Government Accountancy Service had concluded that there was insufficient information as yet for a detailed evaluation, but the option of building so as to attain self-sufficiency would be well worth pursuing.

14.9. Paragraph 14 noted that the cost was too great for the present Centrally Funded Services programme and, unless some non-Exchequer source could be found, the money would have to come from adjustments to other NHS programmes, i.e. allocations to health authorities. This was underpinned by the comments on an earlier draft from Mr Brechin **[WITN6934009]** who had commented: *"Funding a £18 - £25m plant would cause considerable problems; it is on a very much larger scale than the CFS is used to. As fall-back the money could be found within our PES at some cost in developments etc forgone elsewhere."*

14.10. I would add that a start could not have been made until 1981 at the earliest, allowing for planning, design and tendering. The money (and in due course the additional running costs) would, in the normal course of events, have to be found within the sums authorised by the Treasury and Ministers for the NHS as a whole.

14.11. It was therefore inevitable that major expenditure on BPL would be at a cost to services elsewhere. It was possible that some of the money could be found by savings elsewhere in the Centrally Financed Services, but most of it would come from reducing allocations to Health Authorities. In the event it was all found in the latter way – see paragraph 26.1 below. It is impossible to be specific about what the impact was. It depends on how individual Authorities reacted to receiving smaller allocations than they would otherwise have had, and that would vary. I would expect that most of it came from curtailing or postponing other planned developments rather than by cutting existing services. These would range from small local developments to more substantial ones postponed by RHAs. The Department would not usually be told, even after the event, except in the most general terms.

14.12. Against that savings were ultimately expected from reducing the use of commercial concentrates as discussed below, but those savings would take time to achieve. And the savings would accrue on revenue account, whereas the initial reductions would be to capital.

14.13. In relation to such potential savings, I have been asked to comment on the confidence that I had at the time in Mr Smart's estimate that all capital expenditure would be paid back within 15 months (paragraph 14 of the submission). I refer to the following documents:-

a) A handwritten Note **[DHSC0002195_056]** dated 12 September 1979 from Mr Baylis, a Senior Accountant, to Mr Harley, commenting on the financial assumptions made by Mr Smart and the additional information needed to evaluate costs fully. This was a long list, including information on such topics as the additional costs of additional plasma collection that would be incurred by RTCs. That said, Mr Baylis commented that subject to such additional information, it was a "worthwhile project".

b) Further evaluation was contained in a minute from Mr Vaughan in a minute dated 26 September 1979 **[DHSC0002195_045]**. This subjected Mr Smart's calculations of savings to "broad brush" reductions to reflect the increased RTC and BPL costs when production was scaled up, and also suggested an alternative means of calculating costs/savings based

on a comparison with Travenol. The author noted that "*these two methods are based on very broad brush assumptions*", but "*significant error*" would be needed before "*the viability of the project would be seriously threatened*" and it was worth developing the option for rebuilding in more detail.

c) I personally had no means of evaluating Mr Smart's figures, but they seemed sufficiently plausible, and Mr Smart was of sufficient expertise and standing, to use them to support the basic point.

14.14. Paragraph 13 of the submission noted that "*A radically new method of management would be required; the hiring of commercial management might need to be considered.*" I have been asked to explain why it was felt that a major weakness in the NHS option was the lack of expertise within the Department and the NHS in the field of industrial management and manufacture. The Medicines Division report said: "*The key [BPL] personnel are scientists with research and development experience but have not had the opportunity to gain experience of modern large-scale sterile production requirements in the pharmaceutical industry."* I was later told by Mr R N Williams of Medicines Divisions that their objection to increased BPL production was based not merely on premises etc, but on lack of manufacturing expertise in the management and staff of BPL. Equally the Department did not have such experience. The submission to Ministers was saying that such experience would have to be found and that the private sector option could provide it ready made.

14.15. I have been asked to explain the rationale for the three matters that the Ministers were invited to decide, at paragraph 18 of the submission. These were:

(a) to agree that the Blood Products Laboratory should continue to function, until it can be replaced, on the basis of a short-term upgrading, accepting that this will fall short of the upgrading recommended by Medicines Division;

(b) to decide, in principle, to rebuild the BPL, but without any commitment as to the method or precise timing;

(c) to agree to further exploration of the possibilities of rebuilding either within the NHS or in collaboration with industry.

14.16. As to (a), no-one in the Department doubted that production at BPL should continue, the alternatives being still further increase in the use of more risky commercial products and/or patients being denied treatment. The proposal was a programme of short-term upgrading (parts of which had already started) which was judged sufficient to enable BPL to function at a very low risk for some years, but which fell short of the recommendations in Medicines Division's report. Short-term financial constraints dictated this, although some extra money was found in the following year (1980/81). As to (b), I would refer the Inquiry to paragraphs 14.17 and 14.20 below. As to (c), I would refer the Inquiry to Q17 above, particularly paragraph 12.1.

14.17. I have been asked to provide any further comment that I am able to provide on the difference of opinion between myself and Dr Oliver about whether to make an early decision (and then announcement) on the redevelopment of BPL (paragraphs 3 to 5 of my minute of 17 December 1979). It appears from the final Submission that Dr Oliver's view was preferred and a recommendation was put to Ministers to agree to an early decision in principle, albeit without commitment as to method and timing. Thus, paragraph 11 stated that *"Officials are unable to suggest any realistic alternative to replacing the laboratory. If a new laboratory is to be NHS-financed it should on the basis that will be planned and built when the necessary resources can be found in competition with other demands. This need carry no commitment as to timing".*

14.18. I had always thought that a redevelopment was the right course if a satisfactory and affordable means could be found. My own preference was to examine the options before taking, or at any rate announcing, a decision in principle; and then to announce the decisions about whether and how, and if possible the timing, together. To take an immediate decision in principle to rebuild, and by implication to let it be quite widely known, would be more positive and would perhaps add impetus to the study of options, but I feared it might offer a hostage to fortune if the private sector option proved unworkable and NHS money could not be found fairly quickly.

14.19. As to why a decision to recommend an early decision was taken, I have been referred to the comments of Mr Harley at paragraph 2 of his minute of 20 December 1979 **[DHSC0002307_049]**. Mr Harley sent a draft to Mr Nodder. It was said to be based on my draft of 17 December 1979. He stated that "*The principal changes are the inclusion of a brief history of the BPL, the advocation of acceptance of a short-term upgrading which falls short of the ideals of Medicines Division, and the removal of a discussion about whether a decision to rebuild the BPL at some unspecified time should be deferred. The suggestions for redrafting which you and others gave me added up quite clearly, in my mind, to the unavoidability of rebuilding sooner or later, either with NHS funds or in collaboration with industry.*"

14.20. The decision to recommend an early decision was taken at the level above me, presumably in discussions in which I do not recall taking part. I do not see this as any more than a different view on the balance of advantage. In the event, the Minister, Dr Vaughan, declined to make an immediate decision; see Q22 below. I do not know what his reasoning was.

Q20: Passage of Time to December 1979

15.1. The provisional findings of the Medicines Inspectorate had been discussed by the Scientific and Technical Committee of the National Blood Transfusion Service ("NBTS") at their second meeting on 7 June 1979 **[CBLA0000952]**. At that point, according to the Minutes, the Inspectors had not yet completed their visits to BPL. They had identified the shortcomings and were now considering how these might be remedied. It was said that it might be "some time" before their report would be available. After discussion, "*It was unanimously agreed that it would be inadvisable to approach Ministers until a complete appraisal of the possibilities open and their cost effectiveness had been prepared, which the Department undertook to do in time for consideration by the Committee in September.*"

15.2. In the event, the Inspectors' Report was sent to the Department on 10 September. The submission was sent to Ministers on 21 December, just over 3 months later. In the meantime, much work had been done in the Department

to identify an affordable programme of early action on the report, to appraise the options available for the longer term (which went some way beyond the report) and to decide what recommendations to make to Ministers. The Submission also included a memorandum by the Chairman of the STC, prepared specifically to convey to Ministers the views of the non-Departmental members of the Committee.

15.3. As a result, it seems to me that to ask why it took six months from the June meeting of the STC is inappropriate. Looking rather at the period from September 1979, it is impossible to say that this submission could not have been prepared in less than three months, but I do not believe that it could have been done much quicker without reducing its coverage or quality. It must be remembered that the officials concerned all had a wide range of responsibilities which they had to continue to discharge whilst working on blood products.

Q21: Views of the Scientific and Technical Committee

16.1. The Inquiry has noted that a paper prepared on behalf of the Scientific and Technical Committee for the Central Blood Laboratories was attached to the submission to Ministers, and to my minute of 17 December 1979 **[DHSC0002195_069]**. This recorded that the Committee had, *"been emphasising the need for new plant for some time. The Inspectors' report simply increases the urgency of this requirement."*

16.2. I have been asked whether I was aware of the Committee's views on the need for a new plant before the Medicines Inspectorate report. I have also been asked why there had been a lack of investment in BPL in the years before 1979; and who (if anyone) was responsible for that lack of investment.

16.3. As to this, what became the BPL was established as a manufacturing unit in 1952, mainly to salvage plasma from time-expired blood. A new factory became operational in 1972 with the primary purpose of producing blood fractions. It was managed by the Medical Research Council (MRC), funded by the Department, until 1976, when the Lister Institute took over. In October 1978 the management passed to the Department and the NW Thames Regional

Health Authority jointly. It was at this point that any representations about BPL's development needs would have come more directly to the Department.

16.4. Through the 1970s BPL had been faced not only with increasing demand but also with technological developments and developing criteria for medical manufacturing. I simply do not know what the views of the MRC and the Lister Institute were about the implications of these changes, or what representations, if any, they made to the Department. Nor do I know at what stage the Laboratory's growing inadequacy might have been judged sufficient to require significant investment.

16.5. I do not recall being made aware of strong views held by the STC during the time gap between my arrival on the scene in 1978 and the start of the Medicines Division's inspection in 1979. Note that the STC was a relatively new creation, having first met on 26 March 1979. Some of the views referred to may have been those of the people who became its members rather than of the STC as a body.

16.6. In this context it may be worth mentioning that on 25 October 1977, before my time in post, the Department took part in a meeting at BPL to discuss the Laboratory's immediate and long-term future **[WITN6934010]**. This agreed to further examination of a phased redevelopment programme, as proposed by the then Director of BPL (Dr Maycock), and also initiated "stop-gap", the short term development programme referred to at 9.2 above. This was designed not only to increase production but also to remedy some deficiencies in the Laboratory. This programme was later modified in the light of the Medicines Inspectors' report.

Q22: Ministerial Response

17.1. The Minister's response was given on 7 January 1980. He agreed to the recommendations that "*BPL should continue to function, until it can be replaced on the basis of short term upgrading, accepting that this would fall short of the upgrading recommended by Medicines Division.*" He also agreed to *"further exploration of the possibilities of rebuilding either within the NHS or in*

collaboration with industry." He declined to *"decide, in principle, to rebuild the BPL, but without any commitment as to the method or precise timing."*

17.2. I do not know the reason(s) why the Minister rejected the recommendation to decide, in principle, to rebuild BPL. He may have thought that a private sector solution might have been via more than one facility, provided by different agencies. But this is speculation, based on the fact that he knew that several firms had expressed interest in establishing fractionation facilities in the UK – see paragraph 12.1 above.

17.3. As to my own response to the decision, I would not have expected nor do I recall anything more than "what do we need to do next?". To the best of my recollection, I was never directly involved in advising the Minister.

Q23: Minister's request to Medicines Division to reduce the standards sought

18.1. In a memo to Mr Dutton on 11 April 1980 **[DHSC0002313_034]**, I referred to a phone call from Mr R N Williams of Medicines Division (MD) about a Minister's request direct to him to review their report with a view to reducing the standards sought at BPL. MD were reviewing the Report but did not expect to be able to modify it to any significant degree. I had told Mr Williams that we proposed to work out, with Dr Lane (Sir William Maycock's successor as Director of BPL), what we regarded as a reasonable package to improve safety to an essential minimum level, and to enable some increase in production. We would seek MD's comments before putting the proposals to Ministers. He had accepted this, though I did not record that he had offered any prospects of agreement.

18.2. I have been asked which Minister made the request. I do not know for certain, but I believe it was Dr Vaughan, who had previously expressed the wish that short term expenditure should be kept to a bare minimum and had instructed officials that the short-term proposals should be completely re-examined to this end. I do not think I can provide any further information about the circumstances in which the request was made.

18.3. I have been asked (i) why I had expressed agreement with the MD's position, namely that they applied the same standards to the public sector as to the private, and that if there were to be a decision not to enforce their findings then

that must be someone else's and not theirs; and (ii) who that "someone else" would be.

18.4. I cannot now recall Medicine Division's written remit, but it would be bound to adversely affect their credibility if they were to apply different criteria to different establishments. It could also be expected to give rise to great public criticism if they were seen to judge public sector establishments less rigorously than others. It follows that they could not take any sort of lead in deciding not to implement their recommendations, though they might acquiesce in a decision taken by someone else in authority. In the case of BPL that someone could only be a Minister, the possible political implications being too great for a decision by officials.

18.5. I am not aware of any other occasion when a Minister made such a request to Medicines Division. But as I said at 13.4 above, I have never known anything about any other Medicines Division report.

Q24/25: Departmental Meeting 29 April 1980

19.1. At a meeting held at the Department on 29 April 1980, the short-term funding of BPL was discussed with a view to further reducing costs. The Minutes record me as expressing concern about the escalating costs of upgrading, as the Minister had firmly expressed his view that very little should be spent on BPL. The background to this was a private indication from Dr Lane (I think to Dr Walford) that the costs of his proposals for short term improvement might amount to £2 million or more, which I could not see being approved.

19.2. I have been asked to give my views on why this was the Minister's position at this time, and to explain what advice he was receiving on this point at that time, and from whom.

19.3. It was Dr Vaughan's position throughout that expenditure which was for the short term only should be kept to a minimum. When he visited BPL in March 1980 he said that if BPL was to be replaced [sc. fairly soon] short term expenditure should be kept to a minimum. And when in June 1980 he agreed to additional expenditure of up to £100,000 on cold storage, he did it subject to

our being satisfied that the facility would be reusable as part of the long term development.

19.4. I am not aware of any advice which Dr Vaughan was receiving other than from officials. I have described in this statement the main advisory submissions which Ministers, including Dr Vaughan, received from HS2 and medical colleagues, and from our superiors. They also received advice from Medicines Division, and from Finance Division concerning the financial context and priorities. Like other Ministers, Dr Vaughan might also have discussed NBTS and CBL issues from time to time with officials at the most senior levels, though I would not have been privy to any such discussions.

19.5. The Minutes of the meeting on 29 April 1980 record Dr Harris, who chaired it, as saying that "it might not be possible to ensure product safety to the extent which the Director of a manufacturing laboratory would naturally wish, but the Secretary of State would carry the responsibility until the new plant came on stream". I have been asked to say what I understood Dr Harris to mean by this comment, and whether I agreed with it; and whether the tenor of the comment was explained to Ministers, and if so, what was their response.

19.6. The constitutional position is that the Secretary of State carries responsibility for what happens in his or her Department, whether or not they have specifically approved or even know about It. Internally they can hold officials to account for their actions (or inaction). It behoves officials, for Ministers' sakes and their own, to ensure that Ministers are warned about any potentially serious possibilities and asked to take decisions as appropriate. I do not see Dr Harris as saying more than that, though I might have expressed it differently. And I do not think Ministers would have needed to be told, since they would know it already.

19.7. I think it possible that Dr Harris said this for the benefit of any attendees at the meeting who might not already know it.

Q26: My minute of 28 November 1980

20.1. I have been referred to a minute which I wrote to Dr Vaughan's Private Secretary, Mr Knight, on 28 November 1980 **[DHSC0032948]** as a brief for a

forthcoming TV interview. I have been asked to explain the following points from it:

(a) Why I referred to the Minister never having made a formal commitment to the redevelopment of BPL and what were the reasons why I believe this commitment was not made at this point;

(b) what was meant by the phrase "*self-sufficiency was an aim, not a promise*";

(c) to what extent did the Government's *"general anti-centralisation policy"* at this time affect decisions regarding the management structure of BPL; and the funding of upgrades and redevelopment of BPL.

20.2. I have said in answer to Q22 that I do not know why the Minister (Dr Vaughan) would not make a decision in principle in January 1980 to rebuild BPL. I speculated that it might have been because he thought that a private sector solution might be via more than one facility, perhaps provided by different agencies.

20.3. The purpose of my minute to Mr Knight on 28 November 1980 was to brief the Minister for a forthcoming TV interview. The Ministerial decision not to involve the private sector had been announced to Parliament, two days earlier (see the Written Answer of 26.11.80 **[DHSC0000286]**). However, many questions about BPL's future remained under consideration. We needed an informed forecast of future demand for fractionation products. Could we be reasonably certain that sufficient plasma could be obtained from UK sources to meet that demand? What should be the Edinburgh (Liberton) plant's contribution? Should the new BPL consist entirely of new building and plant or could some of the existing facilities be re-used (as would have been the Minister's preference)? Was the BPL site big enough? If not, could it be expanded? What was the intended timetable (which ultimately depended on when sufficient funding could be obtained)?

20.4. To have made a public commitment at this stage to redevelop BPL would have begged all these questions. What would have been the nature of the commitment? The most the Minister could have said was that options not involving the private sector were being examined with all speed and an announcement would be made as soon as possible. In any case it would not

have been appropriate to announce a commitment in a TV interview. It would properly have been made to Parliament.

20.5. The chief reason why I regarded self-sufficiency as an aim rather than a promise was that it would require a greatly increased amount of plasma – our best guess was about 5 times the amount being fractionated at that time, and we could never be sure that such an amount would be available. There was also the possibility that demand for blood products would increase to much higher levels than the forecast on which fractionation capacity had been planned, as had happened between 1975 and 1977 – see para 3.3 above. This had to be a real possibility. It was important that we employ the best experts to produce the forecasts and to recommend what steps should be taken to secure sufficient supplies of plasma. On this please see paragraphs 35.6 to 36.2, and 42.1 to 42.2 below. There were then the possibilities of building some spare capacity into the system and/or designing the new BPL to be easily expandable if need arose. I do now know what, if anything, was done on these lines. Detailed planning of BPL redevelopment was not undertaken until after I had left for a different job.

20.6. With regard to the Government's anti-centralisation policy (see 20.1(c) above), I have the following observations.

20.7. At the time BPL was managed by a Joint Management Committee of the Department and the NW Thames RHA. This was a holding device pending decisions on longer term management arrangements. Please refer to my answer to Q41 for a more detailed explanation of the issues. In November 1980 there were too many uncertainties for a decision to be made. This, rather than "anti-centralisation policy", was what delayed matters. Ultimately a Special Health Authority was created – see Q43. It is certainly arguable with hindsight that this could have been done earlier, but it was not everyone's favoured solution, and the case had to be made.

20.8. The funding of upgrading and redevelopment of BPL was, in my view, entirely unaffected by centralisation v decentralisation arguments. Money was, in fact, centrally allocated for both once the case for it had been made, and no less quickly than Government funding systems allowed

Q27: Minute from Dr Harris dated 8 May 1980

21.1. In a minute about the minimal acceptable improvements required to keep BPL running **[DHSC0002307_042]** Dr Harris said *"If Ministers do not like the results of our reappraisal it is up to them to carry the responsibilities and the subsequent serious consequences".* I have been asked to give my understanding of why Dr Harris would have written in those terms.

21.2. I have set out the constitutional position and its corollaries at 19.6 above. In this case Dr Harris was urging Dr Walford and myself to finalise a submission to Ministers seeking agreement to the proposals as to the minimum acceptable improvements. I think his point in the quoted excerpt was that he wanted to give Ministers the earliest possible warning, as envisaged in 19.6.

Q28: Ministerial Submission, July 1980

22.1. Further work continued in 1980 on the short-term upgrade of BPL (see **[DHSC0002307_009]** and **[DHSC0002307_010]**), before a submission was made on 24 July 1980 **[SCGV0000127_046]**, recommending capital expenditure totalling £1.3m over the next 2 years, plus increased revenue of £0.1m from 1981/82. The proposals were accepted by the Minister of State in a minute dated 29 July 1980 **[DHSC0002307_023]**.

22.2. I have been asked to explain my reference in paragraph 2 of my covering minute of 24 July 1980 to the need to meet part of the 1981/1982 cost by increasing the centrally financed programme or displacing other expenditure. As to what this meant, the BPL's provisional allocation for 1981-82, determined in the 1979-80 public expenditure discussions, was not sufficient to cover the whole cost of the short term upgrading proposed, and agreed by the Minister, for that year. The extra money would be a call on the centrally financed programme. This call could be met either at the expense of something else in that programme or by increasing the size of the programme, which would mean reducing the sums provisionally allocated for other parts of the NHS.

22.3. I do not know what course was adopted. This was a matter for Finance Division.

22.4. I have been asked for any further evidence that I am able to provide on my reasons for the views that I expressed in my minute of 24 July 1980. I do not think that after this lapse of time I can provide any further evidence in support of the proposals in the submission of 24 July 1980 than is contained in the submission itself. The proposed programme would make its contribution to the improvement of BPL and its workings. It would also enable BPL to begin to increase production, with the co-incidental benefit of beginning to build up the plasma intake from Health Authorities toward the levels which a redeveloped BPL (if redevelopment were agreed) would need. The financial pay-off would be from savings on commercial purchases. There were various ways of computing the cost-benefit relationship. In my view the calculations in the submission were conservative, though still amply good enough to support the case.

Q29: Financing short-term upgrade of BPL

23.1. At Q29, the Inquiry has asked about the passage of time before this submission was sent to Ministers, in July 1980. The submission was sent some 10 months after receipt of the Medicines Inspectors' report (which was presented in September 1979, not June 1979). It was not the case that we were only then, in July, getting any approval for financing short-term upgrading. The Minister agreed in January 1980 to short term measures (in addition to what was already being done) to make BPL reasonably safe for the time being, but questioned their scale. A case had to be made, which required a good deal of work and consultations. There was no huge rush, given that no extra money would be available until 1981-82. It was better to do a thorough appraisal than a skimped one, and this was justified by the approval which was given in July.

Q30: Minute of 10 April 1981

24.1. I have next been asked by the Inquiry about a minute that I wrote on 10 April 1981. I should first note that between the matters discussed above in July 1980 and this minute, the decision had been taken and announced (on 26 November 1980) not to involve the private sector in BPL redevelopment. See 12.3 - 12.7

and 20.3 above. Also, as recorded in a minute from Mr Knight to Mr Harley dated 8 January 1981, MS(H) and PS(H) (that is Dr Vaughan and Sir George Young) had asked on 17 December 1980 that planning and design should begin on the redevelopment scheme. Mr Knight also recorded that Ministers were content to consider the estimated costs at a later stage. In a minute also on 8 January, Mr Harley added that this work should proceed as rapidly as possible **[WITN4461046 and DHSC0002315_036]**.

24.2. On 10 April 1981, I provided a minute on the BPL redevelopment to Mr Knight in the Minister of State's Private Office **[DHSC0002315_049]**. This referred to two principal reasons for "early rebuilding" of BPL, the unsatisfactory nature of the current buildings, and the *"potential benefits from replacing expensive and, in the case of Factor VIII, relatively dangerous (hepatitis) imported blood products by our own products".*

24.3. I have been asked to comment on the purpose and context of this minute. My minute of 10 April 1981 was a supplement to one from Finance Division (Mrs Banks) which I do not have available and cannot recall in detail. Mrs Banks' minute was to the head of Finance Division (Mr Hulme) and the Private Secretary to the Secretary of State (Mr Brereton). I cannot now recall the context, but I was clearly anxious that any consideration of redevelopment of BPL should be fully informed and up to date. And I wished to reassure the recipients that necessary work was in hand. I cannot now say more than that.

24.4. As to my comments about the "relatively dangerous" nature of imported blood products, it was common currency amongst my medical colleagues that imported blood products carried a much higher risk of transmitting infections, particularly hepatitis, because the (paid) donors from whose blood they were made included people who had an increased liability to carry such infections and would therefore not be regarded as suitable in the UK. This was not to say that such transmission was impossible with domestic products, but the risk was judged to be much smaller. Note that HIV had not yet been heard of.

24.5. As far as I can recall, I never saw the various risks quantified or saw any figures as to the incidence of transmitted infections in other countries.

24.6. I have been asked to comment on the relative importance of financial expense and safety in the discussions about the redevelopment of BPL in and around 1981. As to this, I do not suppose that everyone took the same view of the relative importance of finance and safety. There was probably more focus on finance because it was quantifiable and problematic, but safety was always in mind as an important factor.

Q31: Investment appraisal of BPL redevelopment

25.1. I have been referred to a draft minute from myself to Mrs Banks (Finance Division) in April 1981 **[DHSC0002207_018]** concerning a proposed investment appraisal of BPL redevelopment. I have been asked to provide what context I can to this document, including why it was drafted and what I was seeking to achieve by it.

25.2. Searches have failed to find a copy of Mrs Banks' minute. Without it I cannot answer this question properly. However, Treasury approval was required for the redevelopment, as for any capital project costing more than £4 million. My speculation is that this was the purpose for which the appraisal was required. I would have been aiming to ensure that it was comprehensive, up to date, accurate, and did full justice to the case. I would also have been seeking to anticipate possible questions.

25.3. I have also been asked to explain, so far as I can, the basis for my view that I "*would not expect significant savings to be made if we were to aim for producing say 90% of the products required*". It was not to be expected that the scale of the development would precisely reflect the planned output, and I was probably responding to or anticipating questions about possible reductions in estimated costs. To illustrate the point, if a piece of essential equipment cost £10,000, and would produce 100 units of output, it would be most unlikely to be possible to reduce the cost by reducing the planned output to 90 units. Similarly for floor space, the number of staff who would be working there and the circulation and storage space required would be the critical factors, not the precise output expected. To put the point another way, it would have been necessary to make

a really major reduction in planned capacity to effect a significant reduction in costs.

25.4. I have also been asked to provide any further comment which I consider to be relevant on this document. Without the missing minute I cannot think of any.

Q32-36: Decisions of June 1981 concerning BPL redevelopment, and subsequent events

26.1. On 18 June 1981, I recorded in a minute that the then Secretary of State had agreed that Regional Health Authority ("RHA") capital allocations could be top-sliced to pay for the redevelopment of BPL, and that this allowed for detailed planning to proceed. I attached a submission for Ministers proposing the formation of a sub-committee to handle the redevelopment **[DHSC0002309_004, DHSC0002327_009]**. The proposals were agreed by the Minister of State for Health on 1 July 1981 **[DHSC0002309_005]**.

26.2. I have been asked to explain the reference to top-slicing. This meant that the money for BPL would be provided by reducing the amount to be allocated to Regional Health Authorities for NHS capital expenditure in their regions. Individual RHAs would not be told how much they had "lost" for BPL purposes. They would simply be given smaller sums than they might otherwise have got. Spread between 14 RHAs the impact on any one RHA would not be very great, and it is impossible to say what the effect would be. Funds available to the Department would not be affected.

26.3. I have been asked to provide any further detail that I can about the Secretary of State's decision. I was not party to the Secretary of State's deliberations, nor to the briefings which he received.

26.4. The decision opened the way to detailed planning because detailed planning of major capital developments is time consuming and expensive and needs to be focussed by a clear brief to the planners about what they are to provide and the scale and timing of the finance expected to be available. Otherwise, there is a risk of much nugatory effort and expenditure. Some organisations may be prepared to take such a risk, but to do so with public money would be likely to be heavily criticised.

26.5. I have further been asked to comment on the time that had elapsed from the receipt of the Medicines Inspector's Report (September 1979, not June as suggested), the initial submission to Ministers on the future of BPL (December 1979), and these decisions. As to this, the Minister's decisions on the initial submission led to a huge programme of work and discussions to explore the possible involvement of the private sector in the manufacturing and supply of blood products and to consider and appraise the options for a purely NHS solution. Further Ministerial decisions had followed; see para 24.1 above. This work was a necessary precursor to the Ministerial decisions referred to. I really do not think that it could had been completed in a much shorter time.

26.6. I have been referred to a handwritten note dated 3 November 1981, recording that Ministers had agreed to the development of BPL at a capital cost of £17 million and that Treasury approval in principle had been obtained **[DHSC0001129]**. I was not listed among the recipients of this note, no doubt as by November 1981 I had moved to another role.

26.7. I have been asked whether I know when a final decision to fund the redevelopment of BPL was taken, and by whom; and whether there was any delay to the redevelopment in the period between the Secretary of State's decision in or around June 1981, and the date of this note, 3 November 1981.

26.8. As noted, by November 1981 I had been moved to another job, so I cannot respond to this question.

26.9. The Inquiry has referred me to documents **[DHSC0002309_017, DHSC0002309_019]** indicating that final ministerial authority was given to a detailed proposal for the redevelopment of BPL on 7 October 1982, and asked me to comment.

26.10. Because of my change of job, referred to above, I do not know why it took from June/July 1981 to September/October 1982 to progress from a decision leading to detailed planning of the redevelopment to a final decision approving the resulting plans.

26.11. I have also been asked whether, based on my wider experience, this timescale seems surprising to me, or whether it is in line with what I would expect for such a project. I do not know precisely what stage had been reached with the detailed

planning by October 1982, but assuming it was quite a late stage, I am not surprised by the timetable.

26.12. I played no part in the detailed planning of BPL's redevelopment.

26.13. I have been asked to comment on the events that led to the redevelopment of BPL. In relation to the issue of whether the redevelopment progressed as quickly and effectively as it could have been, I have already given my views on progress up to July 1981. I cannot comment beyond that.

26.14. As to whether “errors and misjudgements” were made, looking at events up to July 1981, there were quite legitimate differences of opinion at a number of points. I would not characterise any of these as "errors or misjudgements". I cannot comment on later events.

26.15. I have been asked whether I was conscious, at the time, of any difficulties with the proposed redevelopment, and the amount of time that it was taking to make progress with it, and if so, what I did.

26.16. I am not sure to what time period this question is intended to relate. During the time that I was in post there were many difficulties to be overcome. I saw my role as ensuring that any for which my command was responsible were being expeditiously and effectively tackled, which they nearly always were. In the case of other commands, I would have had a quiet word with the senior officer in charge, or asked my superior to do so.

26.17. I might add here that Mr Harley, my immediate deputy, was an officer in whom I had great confidence, which I never had occasion to think misplaced.

26.18. I have been asked if I remember concerns being raised at the time as to the length of time it was taking to progress the BPL redevelopment. The opinion of the Scientific and Technical Committee, including the Director of the BPL, was that the BPL should be redeveloped as a matter of urgency. This concern was expressed at a STC meeting in September 1979, very shortly after the Medicines Inspectors reported, and was reiterated by one of its members in a letter to Dr Vaughan in June 1980. They did not express their concern publicly, as far as I can remember, and it was explained to them why time was needed to study options and formulate proposals. The STC members continued to give their services. I do not now recall any other concerns that were being raised

about the length of time that it was taking to progress BPL redevelopment, although this is not to say that the documentary record would not show issues being raised in forums such as Parliament or the media.

Funding and Management of BPL

Q37/38: Funding Decisions

27.1. Questions 37 and 38 ask me to (i) explain the way in which Public Expenditure Survey (PES) allocations for the DHSS were decided upon in the late 1970s and the late 1980s and (ii) to explain how, and by whom, decisions were made on the level of funding to be provided to BPL (and the other Central Blood Laboratories).

27.2. These were matters within Finance Division's remit, and any account which I might give would be incomplete and potentially misleading.

Q39: Research and development on blood products

28.1. I have then been asked to say, to the best of my knowledge, how much consideration was given to funding research and development on blood products by BPL and the Central Laboratories; who was responsible for taking decisions on how research and development should be funded, what the level of funding should be, and which projects should be pursued; and what role, if any, I played in such questions.

28.2. I cannot answer this question from first-hand knowledge, and I would risk misleading the Inquiry if I were to attempt to answer it. I did not play any part in these decisions.

Q40: Management of the Central Blood Laboratories

29.1. The Inquiry has noted that in 1981 I was involved in discussions about reforming the management of the Central Blood Laboratories (BPL, the Protein Fractionation Laboratory and the Blood Group Reference Laboratory). My proposal involved replacing the existing structure – a Joint Management

Committee ("JMC") involving both the Department and the North West Thames RHA – with a new Special Health Authority, which became the Central Blood Laboratories Authority ("CBLA").

29.2. The Inquiry has referred me to a number of papers ranging in date from January 1979 to December 1982. These show that, from the beginning, a wide range of issues was under consideration concerning the organisation and management not just of the Central Laboratories but of the BTS as a whole. There were a number of background uncertainties which needed to be resolved before long term decisions could be reached, and it was not until 1981 that we were sufficiently confident to make a recommendation for a SHA, and even then on the basis that its role could be expanded if desirable. I do not think it would profit the Inquiry to concern itself with the detail except as will be set out in the following paragraphs, in which I have aimed to identify the key points.

Q41: Lifespan of the JMC

30.1. The Inquiry has suggested that from those documents, it is clear that the JMC was intended to be a temporary measure, yet it remained in place from 1978 to 1981 (and indeed to December 1982, when it was replaced by the CBLA).

30.2. I have been asked whether, when the JMC was established, there was a planned period for which it was intended to remain in existence. There was no such time. Indeed, it would have been almost impossible to decide on one except arbitrarily, not least because of the number of imponderables concerning the future organisation of the NHS. One of these was whether the recommendations of the Royal Commission on the NHS would have any implications for the organisation and management of the BTS. In the event, the Commission reported in July 1979 and there were no significant implications.

30.3. I have been asked why this "*temporary measure*" (the Inquiry's wording) remained in place for so long and whether this was linked to the exploration of commercial options (see my letter to Mr Harley on 15 September 1980 **[DHSC0002199_100]** in which I wrote *"I did not propose to take the matter further unless and until the commercial option was ruled out*"). However, the

exploration of the commercial option was only one of the factors contributing to the continuance of the JMC. The whole organisation of the BTS came into question, as did the management and interrelationships of the Central Blood Laboratories, including that in Edinburgh. The long-term management of BPL could not be decided until these questions were decided, and it would have made no sense to move from one temporary arrangement to another unless the existing one had proved hopelessly unsatisfactory, which it had not. There were certainly problems, but not such as to require emergency action.

30.4. I have been asked if the continuation of the JMC had a detrimental effect on the way in which the Central Blood Laboratories, and in particular BPL, were run. In my view, the running of the CBLs (excluding the Edinburgh plant, which was unaffected) must have been affected by the uncertainty about their future. But the continuance of the JMC was an effect of this, not the cause.

Q42: Role of the RHA

31.1. In my minute to Mr Harley on 15 September 1980 **[DHSC0002199_100]** I stated *"I am still of the view that the RHA, even with imported industrial/commercial help, is unlikely to make a satisfactory management agency*". I have been asked to elaborate on that view.

31.2. There were a host of reasons for it, including the difficulty of one RHA running a national service, and taking decisions which affected all the other RHAs, both as regards supply of plasma and as regards the allocation of the available products. This would have been a likely source of friction, requiring significant amounts of time from the RHA's top management, which they could not afford without adverse effects on their regional responsibilities. Another difficulty was that the RHA (indeed any RHA) did not have staff with experience of managing an industrial-type manufacturing unit such as BPL and the Oxford Fractionation Laboratory.

Q43: My Minute of 6 April 1981

32.1. In a minute of 6 April 1981 to Mr Nodder, my immediate superior, I set out proposals for the future management structures of the Central Blood Laboratories **[DHSC0002307_034]**.

32.2. I have been asked to comment about the circumstances in which the minute was written, its intended purpose, and my views on the proposals that it contained, including why I returned to the matter of BPL's management at that time.

32.3. Many management issues needed to be resolved once there was sufficient certainty about the future of the laboratories, BPL in particular. And there was pressure from many quarters to get them resolved. Ministerial decisions would be required. There had been a lot of work and discussion in the Department, from which a clear view had emerged as to the favoured option; and work had begun on a submission to Ministers. The time was now ripe to go forward. It would have wasted a lot of time if the submission had not found favour with more senior officials. I may have known or suspected that Mr Nodder would need some persuasion to accept our favoured option; and so it proved. When he put forward the Ministerial submission on 29 May 1981 he made it clear that he had accepted it with reluctance. My minute of 6 April had served its purpose of securing unanimity at official level. I cannot say what line the submission would have taken if there had not been such unanimity. It would probably have set out the main options and recorded that officials were not unanimous without saying what officials' individual views were. It could then have simply left it to Ministers to choose; or recommended, possibly via a covering minute, the option favoured at the most senior level.

32.4. Dr Harris and I were both of the view that there should be no consideration at that time of the proposal for an integrated, national blood transfusion service to take over from Regional Transfusion Centres (paragraph 5 of my minute).

32.5. A proposal for an integrated national blood transfusion service would have required extensive consultation and Parliamentary approval. As I recall it, we thought it might even need primary legislation, though I do not think legal advice was taken on this. Even without primary legislation this would have involved considerable delay, particularly as the proposal would have been likely to be

controversial, and the more so against the background of the thrust for decentralisation in the Report of the Royal Commission on the NHS and of Government policy generally. The proposal itself would have needed some difficult decisions, such as whether the new service would cover Scotland. All this would have meant further extending the temporary management arrangements for BPL, which would have had to see through the major development of BPL which had now been agreed. Dr Harris and I were anxious to move as quickly as possible away from the existing arrangements with their attendant difficulties as outlined in paragraph 31.2 above. We were not rejecting the idea of an integrated service permanently and on merits. The role of the Special Health Authority which we proposed could be expanded later if desired.

32.6. At paragraph 5, I wrote that I also believed that the CMO (Sir Henry Yellowlees) shared my views. I did not have any personal interaction with the Chief Medical Officer on this. But Dr Harris, as a DCMO, would regularly do so, and might also learn on the Medical network of any views which the CMO might have expressed to anyone else.

Q44: Dr Oliver's Minutes of 29 January and 6 March 1981

33.1. I have been asked to elaborate on the following (with reference to Dr Oliver's views in his minutes to me of 29 January 1981 **[DHSC0003726_076]** and 6 March 1981 **[DHSC0003726_069]**):

a) The "doctrinal reasons" why DHSS couldn't run BPL;

b) Why the Department believed central management of the NBTS would be "totally unacceptable" to Ministers;

c) Why Dr Oliver stated that setting up a Special Health Authority would be an "embarrassment"; and

d) Why Dr Oliver's suggestion of the DHSS running BPL would be viewed as "heretical".

33.2. I will first answer these questions as they apply to the Central Blood Laboratories (CBL). The general thrust of Government policy was decentralisation/delegation. It was to be expected that Ministers would need

some persuading to approve a form of central management for the CBL. Dr Oliver's minutes of 29 January and 6 March 1981 reflected that expectation. I cannot say why he chose to use particular wording. His views were not idiosyncratic, as is shown by the events recorded in my reply to Q43.

33.3. In the event it took some time to secure Ministers' agreement to establishing a Special Health Authority for the CBLs. As noted at 32.3 above, Mr Nodder put forward a submission with that recommendation on 29 May 1981. I seem to have had no further involvement in the matter after putting forward a draft submission on 27 May, but from documents which I have seen it seems that other options were seriously considered by Ministers. From Mr Harley's minute of 6 August to Mr Nodder **[WITN6934011]** it appears that Ministers wished to explore the possibility of putting the CBLs under the aegis of the Public Health Laboratory Service Board. And Lord Fowler's Statement to the Inquiry says in paragraph 4.9 that a submission was put forward on 18 February 1982 to the then Parliamentary Under Secretary, Mr Finsberg, setting out "the pros and cons of the different management structures.....with a Special Health Authority being the preferred option". His paragraph 4.11 describes events from February to the announcement on 18 May that a SHA would be set up. The CBLA was eventually established on 1 December 1982 (see SI No 1982/1515, signed by Mr Fowler on 26 October 1982).

33.4. Returning, then, to Dr Oliver's questions, there is nothing in the above to indicate that Ministers were strongly opposed in principle to centralised management of the CBLs. There remained the question of central management of the whole NBTS. This option had support within the BTS and from some RHAs. But it was contentious and raised a number of issues which could not have been resolved quickly. The submission to Ministers recommending a SHA canvassed some of these, and concluded that RTCs should remain with RHAs "for the time being". However, it advanced as a major advantage of the SHA its ability to take on board other responsibilities if necessary.

Q45: A fully integrated NBTS?

34.1. I have been asked whether, in my opinion, the lack of a fully integrated national blood transfusion service had an effect on the supply of blood and plasma for fractionation by BPL.

34.2. I never formed an opinion on this. Indeed, in my minute of 6 April 1981 to Mr Nodder I said that the balance of advantage could change over time. When I left the job in late 1981 the time was still not ripe for further consideration of the matter.

34.3. For further consideration of integrated management of the NBTS, please see my replies to Qs 67-69 below.

Plasma Supply

Q46: Supply of plasma to BPL

35.1. I have been asked to explain the role that I played in seeking to ensure that the supply of plasma to BPL increased sufficiently to allow for self-sufficiency in England and Wales to be achieved. I have been asked to address the following in particular (I quote):

a) any difficulties that I encountered in seeking to increase the supply of plasma, in particular the challenges posed by the regional nature of the Blood Services in England and Wales **[DHSC0100041_006; DHSC0002307_041]**;

b) the extent to which I and/or the DHSS could and/or did influence how Regional Health Authorities ("RHAs") and/or Regional Transfusion Centres ("RTCs") used their funding to harvest plasma;

c) the extent to which I and/or the DHSS supported the pro-rata system of plasma supply and distribution to the regions, and the considerations that informed my and the DHSS's position on this issue **[DHSC0002199_035; DHSC0001323; DHSC0002207_018]**;

35.2. The first involvement I can trace in this issue is in 1977, before I took on policy responsibilities for the BTS. I was in the Regional Division and conducted on behalf of the Health Services Division some correspondence with Regional Health Authorities, following some changes in regional boundaries, about a

proposal that within the next 2 years Regions should become self-sufficient in blood transfusion services. (See the correspondence at **[DHSC0100041_006]**, a letter to me dated 4 August 1977). This meant collecting within the Region enough blood for the region's needs and arranging its own processing, either at the Regional Transfusion Centre or via the Central Laboratories. The purpose of this approach was not primarily to increase the supply of plasma, though this would have been an incidental benefit where Regions collected more blood.

35.3. I do not think the Department was focussing on plasma supply at this time because BPL would not have been able to process much more. It was not until December 1977 that BPL, at the Department's invitation, produced its short term upgrading proposals (stop-gap), which made future plasma supply a key issue. See 35.5.

35.4. As regards 35.1(a) and (b) above, I know that the BPL Director, Dr Lane, felt that some, at least, RTDs did not regard plasma supply to BPL as a high priority, but merely sent to BPL any plasma for which they had no further use; and that this was the cause of the situation in which some RTCs were sending much more and some much less than their "fair" share. It was this which gave rise to the pro rata initiative described in the next paragraph. Certainly this situation resulted from the regional nature of the BTS. I do not know how successful the pro rata initiative was, nor any later Departmental efforts to increase supply. I therefore cannot say how great the "challenges" were, nor how successfully the Department influenced RHAs.

35.5. As noted above, plasma supply became a critical issue when Ministers approved the stop-gap programme, which was in June 1978. This programme would significantly increase processing capacity, provided that the quantity and quality of plasma available could be sufficiently increased. The Department wrote to RHAs in Sept 1980 **[DHSC0001323]** proposing that from 1 April 1981 the products supplied to each region by BPL should broadly reflect the quantity and quality of plasma supplied by that Region, which was not then the case. In the short term this policy meant increased expenditure on commercial products by the Regions which supplied less than their share of plasma. It was hoped that this would encourage them to effect plans to increase supply. This would

not only bring immediate benefits but would make a move towards the still greater plasma supply which would be needed for a redeveloped BPL. The Department (and I personally) fully supported this "pro rata" initiative.

35.6. I have been referred by the Inquiry to the June 1981 Preliminary Report of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products **[CBLA0001377]**. This report estimated that by the mid-1980s there would be a need for a major increase in plasma supplies. Among its recommendations were "*Wide consultation...to determine how and when regions could implement agreed targets for the production of fresh plasma.*" and that *"Consideration of a trial of manual plasmapheresis to obtain plasma is an urgent requirement."* I do not know what happened as a result of this report, which I assume would have been after my time.

35.7. I have been asked about the extent to which the DHSS supported plasmapheresis domestically, as a means to increase plasma supplies by RTCs to BPL/PFC. The Working Party's report contained a lengthy section on plasmapheresis, both manual and machine procedures, referring to some experience in the Yorkshire region. If anyone in the Department was familiar with the technique, and had formed a view on its possibilities, it would have been my Medical colleagues. I was not aware of it except in the most general terms, and to the best of my knowledge the Department had not yet adopted a position, supportive or otherwise.

35.8. In short, the difficulties faced in seeking to increase the supply of plasma were mainly for the future, and promised to become substantial. There was some concern about whether plasma would be readily forthcoming to take full advantage of the short term BPL improvement programme (the modified "stop-gap"), but we were optimistic that regions would be forthcoming, it being in their financial interest to do so.

Q47: Obstacles to Self-sufficiency

36.1. In my appraisal of BPL re-development **[DHSC0002207_018]**, I wrote: *"whether we achieve that"* [self-sufficiency] *"depends more on the ability of RHAs to produce the raw material, rather than of a redeveloped BPL to fractionate it."* I

have been asked whether, prior to the completion of redevelopment, which was the more significant obstacle to self-sufficiency; the supply of raw material or the capacity to fractionate those materials.

36.2. During the time when I worked in this area of policy, there was never any possibility (ruling out private sector involvement) that self-sufficiency could be achieved prior to redevelopment of BPL; the proposals for an interim increase in production fell short of meeting NHS demand. Whether it could be achieved thereafter depended on (i) whether the supply of raw materials could be sufficiently expanded and (ii) the forecasts of the demands for products on which the redevelopment was based proving to be reasonably accurate. I left the job before the outcomes were known.

Q48/49: Effects of doubts about plasma supply on decision making

37.1. The Inquiry has further asked whether concerns around the supply of raw materials from RTCs contributed to the length of time that it took to gain approval for the redevelopment of BPL, or whether (Q49) plasma supply was seen as a limiting factor in determining what BPL's fractionation capacity should be **[DHSC0002207_022; DHSC0002315_064]**.

37.2. The time between receipt of the Medicines Inspectors' Report and the submission to Ministers in June 1981, which led to the Secretary of State's decision in effect to guarantee funding for BPL redevelopment, was taken up by examination of options and how to resolve problems to which they gave rise, and of funding issues, including an investment appraisal. Work was being done on plasma supply but I cannot recall it being a delaying issue, and have not found any papers suggesting that it was. And I understand (final decisions being taken after I left) that the capacity of the redeveloped BPL was set to secure self-sufficiency. In short, the answer to both the Inquiry's questions is "no".

37.3. Please see also my reply at 40.1 below.

Q50: Plasma Targets

38.1. I have been asked how and by whom were plasma targets for each RTC set, and did this change over time. I do not recall any targets being set by or in agreement with the Department during my time. I would expect, but do not know, that planning figures were agreed between RTDs and the Director of the laboratories. RHAs might have been informed, if only for resource allocation purposes.

Q51: Plasmapheresis

39.1. I have been asked why a study on the use of plasmapheresis to increase plasma supply was not conducted before 1981 **[DHSC0000184; CBLA0001377]**. I do not know, and do not recall being involved in the consideration of this issue; I would suggest that this would have been a matter for those with technical expertise in this area.

Q52: Minute of 24 July 1980

40.1. In my minute of 24 July 1980 (paragraph 5 **[SCGV0000127_046]**), I expressed slightly cautious optimism ("*I think we can be fairly optimistic...*") that plasma supply could be increased. There were strong incentives for the NHS to increase plasma supplies, given the savings to be made on purchases of commercial products. As my minute said, some had already offered to do so. And the Department could be expected to put strong pressure on the others (see, for example, my answer at 35.5). I noted that it would "be the job of the reconstituted Co-Ordinating Committee" to tackle this. I cannot recall that anyone in the Department believed that the additional plasma would probably not be forthcoming, but I dare say opinions differed as to how hard we should have to work to secure it.

Q53: Cryoprecipitate Use

41.1. The Inquiry has noted that on 30 November 1978, Mr Dutton wrote a minute to Dr Waiter, copied to me **[DHSC0000184]**, in which he raised the possibility of phasing out cryoprecipitate. I have been asked if I had a view on whether

cryoprecipitate should be reduced or phased out, and if I know what consideration was given to this proposal in 1978 and thereafter.

41.2. I did not think it necessary for my purposes to familiarise myself with the issue in 1978, nor to keep track of progress in considering it. As far as I can see, I was not asked for any input on issues relating to this question.

Q54: Estimating Demand

42.1. I have been asked to explain what role, if any, I played in estimating, or arranging for estimates to be made about:

a) Plasma supply;

b) demand for Factor VIII; and

c) demand for other blood products.

42.2. I played no role in this. My only concern was that estimates should be prepared in good time by competent and reliable people. Thus:

a) Report in 1979: we can see, for example, that at the 175th meeting of the Regional Transfusion Directors held on 27 June 1979, it was reported that a Working Group to study the implications of the "Trends" Working Party report was being set up.

b) The process of assessing demands was resumed, when Dr Gunson chaired the Working Party referred to at 35.6 above.

Scotland, Wales and Northern Ireland

Q55 a-b: Conduct of relationships and my role

43.1. I have been asked about my view, during my time at the Department, of the relationships and levels of communication between DHSS and the Scottish Home and Health Department (SHHD), the Scottish Office, the Welsh Office, and the Northern Ireland Office on matters relating to blood and blood products. I have also been asked how the relationships were conducted.

43.2. When I joined HS2 in 1978, Wales and Northern Ireland obtained blood via their Regional Transfusion Centres (RTCs) and blood products from BPL. Scotland likewise collected blood for their own needs, and also obtained nearly all their blood products from their Protein Fractionation Centre (PFC) at Liberton, Edinburgh. I think I am right in saying that they looked to BPL for products which the PFC did not produce. Basically, these arrangements ran without the need for any formal machinery at Departmental level. Communication was ad hoc as circumstances required. This was much more frequently with SHHD because of Liberton. I do not recall the Scottish Office ever being involved. I never saw any evidence that DHSS relationships with the others were anything but cordial.

43.3. I have been asked what role, if any, I played in these relationships, and with whom in the DHSS and other Government Departments and agencies did I liaise on matters relevant to Wales, Scotland and Northern Ireland. My role in the relationships with bodies outside DHSS was small. I do not recall being involved at all with Wales and Northern Ireland. The paragraphs that follow will detail some communications between myself and Mr Angus MacPherson of SHHD. In DHSS the key players, as usual, were Messrs Harley and Dutton, and Dr Waiter followed by Dr Walford.

Q55 c: Relationships between DHSS and SHHD

43.4. In the early 1970s, the English Ministry of Health had contributed to the cost of building Liberton with a view to using its spare capacity to help the UK to achieve self-sufficiency, alongside BPL. See the note from HS2A, prepared in 1978, at **[DHSC0003715_171]** which sets out this history. This noted, in particular, that:

"To date Liberton has not fractionated any plasma for BPL. This is due to several factors, in particular:-

1. *BPL has been able to fractionate all the available plasma up to now;*
2. *there are difficulties about shift work at Liberton (although PFC is designed to operate three shifts, the unit is only working one shift a day*

because the trade unions involved will not agree to any expansion unless a suitable pay settlement is reached).”

43.5. Liberton had been designed for continuous (shift) working, which would have substantially increased its capacity, but this had never been introduced because of lack of need.

43.6. On 20 June 1979, Mr Harley and Mr Dutton visited SHHD and Liberton, meeting a number of people from both. Mr Harley reported to me that Liberton had spare capacity, and recommended that the question of England’s use of that capacity should be re-opened. He recorded that there would be difficulties and suggested how they should be tackled, beginning by asking the Scientific and Technical Committee to investigate problems relating to the quality of materials and products and to determine standards acceptable to both England and Scotland.

43.7. I replied to Mr Harley on 11 July, asking him to proceed as he suggested, subject to some qualifications. There appear to have been some follow-up discussions, but I was not copied into the papers and I do not know what action, if any, resulted. It is possible that the discussions took a back seat in September when the Medicines Inspectors’ report on BPL was presented.

43.8. However, I remained keen to get a return on our investment in Liberton. Greater point and urgency was given to consideration of this (a) by the Medicines Inspectors’ report on BPL, and because of the need to plan the long term capacity of BPL or whatever was to succeed it; and (b) because of the desirability of reducing purchases of commercial blood products.

43.9. In May 1980 I took an opportunity to discuss this and other associated matters with Mr A Macpherson of SHHD. On 2 June 1980 I wrote him a lengthy letter **[DHSC0002313_044]**. I noted that although no decision had been yet on the redevelopment of BPL, there was a need to determine its future capacity; which in turn raised the issue of what part Liberton would play in meeting capacity. I recorded the discussion with him and his assurance that he would come back to us as soon as he could.

43.10. It should be noted that Liberton was having some problems at this time, partly because they too had a Medicines Inspectors’ report to deal with (see my letter).

Introduction of shift working was also problematical because of Trade Union opposition to it unless a favourable pay deal was negotiated. And shift working would have to be planned in detail (e.g. flows and storage of raw materials and storage and distribution of finished products). I therefore accepted that we could not expect an early Liberton contribution.

43.11. There are minutes from Mr Dutton **[WITN6934012]** and Dr Walford dated 1 July 1980 which imply that a response was received from Mr Macpherson on 24 June 1980. I am told that a copy of this letter has not to date been found. The minutes referred to suggest that it must, as a minimum, have dealt with the subject of a committee to discuss technical issues.

43.12. The Liberton possibility remained open. Thus Dr Walford, in a minute dated 15 September 1980 on the subject of commercial involvement in BPL, also recorded that she had just visited PFC Liberton with colleagues from HS2. She set out her understanding from the visit that *"Liberton had a substantial capacity for expansion"* notwithstanding *"substantial"* staffing difficulties. However, the expansion proved difficult and expensive to realise –see Q59 below.

Q55 d: Role of other Government Departments in policy formation in respect of blood and blood products

43.13. I have been asked what role did the Scottish Office, the SHHD, the Welsh office and the Northern Ireland Office play in policy formulation in respect of blood and blood products. As regards the Scottish office, none that I know of, though they might have been consulted by SHHD. As for the others, the only example which I can now find is a meeting held on 1 December 1980 between DHSS (led by Mr Harley) and officials from SHHD (including the National Medical Director of the Scottish NBTS), DHSS N Ireland and the Welsh office. This followed closely on from the Ministerial decision to reject commercial involvement in the redevelopment of BPL. The meeting covered a range of issues relating to blood products: the total need for blood products in the UK and how these needs could be met, requirements of the Medicines Act, blood product specifications, funding of the laboratories and pro-rata distribution of

blood products to N Ireland. Various points of action by different participants were agreed on, and some points were noted for later consideration.

43.14. If the Inquiry wishes to see greater detail, I would refer them to the full Minutes of the meeting, at **[DHSC0000064]**.

43.15. I was copied into the Minutes of the meeting but played no other part except as recorded above in relation to SHHD.

43.16. I do not know what, if any, relevant dealings others in DHSS (e.g. Finance Division) may have had with the other Departments.

Q56: Recoupment of DHSS investment in Liberton

44.1. I have been asked what efforts were made to recoup the investment by the Department of £400,000 in the Scottish fractionation plant at Liberton; as to this, please see above (Q55).

44.2. The Inquiry itself has also referred to a minute on this topic, a note dated 22 September 1982 from Mr Godfrey of a meeting with Mr Shaw. Mr Shaw stated that the £400,000 (sent in the early 1970s) might need to be written off in a "'knock for knock' understanding", as there had been so many inter-Departmental transfers of this sort **[SCGV0000002_011]**.

44.3. The File Note referred to was written nearly a year after I left. The "knock for knock understanding", whatever it was, was clearly something within the responsibilities of Finance Division and I would, had I still been on this work, have been in no position to take a view on it. I could certainly not have argued that that the PFC money should be treated in isolation from the wider context in which Finance Division were operating.

Q57: Liberton's contribution of blood products to England and Wales in the 1970s and 1980s

45.1. I have been asked for my view on why *"Liberton failed to contribute a significant amount of blood products to England and Wales in the 1970s and 1980s".*

45.2. My understanding is that during the 1970s and the very early 1980s (up to the events dealt with in Q59) BPL could deal with all the plasma available from England and Wales. In other words, Liberton did not "fail"; it was never asked. But please note that this is what I was told by colleagues. I had no personal knowledge of the situation. I cannot say anything about what happened after my departure in late 1981.

Q58: My exchange of minutes with Mr Harley, June 1979

46.1. In his minute to me dated 25 June 1979 **[DHSC0003715_139]**, Mr Harley reported back on his visit to PFC with Mr Dutton in June 1979. Having dealt with the matters recorded in paragraph 43.6 above, he concluded:

"There will be objections from some quarters to going ahead as I propose, and personality clashes will almost certainly occur. A firm hand and some determination will be needed …"

46.2. In my response to Mr Harley **[SCGV0000001_117]**, I wrote: "*You suggest asking the Scientific and Technical Committee to review various aspects. I agree with that, and that we should neither let personality problems get in the way nor accept that BPL should have first choice of material…"* I have been asked to elaborate on this reference to personality problems. However, my reply was merely agreeing that we should not let such problems stand in our way. If I ever knew anything specific which lay behind Mr Harley's statement, I am afraid I have forgotten it. Nor can I recall any instance of personality problems, as opposed to honest differences of opinion, impeding relationships.

Q59: Mr Macpherson's letter to Mr Harley, January 1982

47.1. In a letter to Mr Harley dated 11 January 1982 **[CBLA0001532]**, Mr Angus Macpherson of SHHD wrote that it would take a total expenditure of £6-7m in order for the ancillary facilities at Liberton to be upgraded to process English plasma. I have been asked about:

a) My knowledge of how that came to be the figure;

b) My role, if any, in discussions regarding potential expenditure on Liberton at this time;

c) Whether I received a further breakdown of the estimated expenditure referenced by Mr Macpherson;

d) Whether this estimate was influential in the decision to proceed with BPL redevelopment rather than further collaboration with Scotland and the PFC.

47.2. I had moved on before Mr Macpherson's letter was written, and I am afraid I cannot assist the Inquiry with questions (a)-(d).

47.3. I have been asked what further role, if any, I played in seeking co-operation between BPL and PFC in the production of blood products for the whole of the UK. I have nothing which I can add to my reply to Q55.

Q60: Possibility of bringing Liberton and BPL under same management

48.1. On 6 April 1981, I wrote a minute to Mr Nodder on the topic of the future management of the Central Blood Laboratories (see paragraph 32.1 above). On the subject of Liberton, I wrote:

"One eventual possibility, in which I personally see considerable attraction, is to bring Liberton and BPL under the same management - particularly as we are already expecting Liberton to meet some of the needs of the rest of the UK for Factor VIII. This is not an immediate runner - the Scots are afraid that a merger would operate to Scottish disadvantage until England is more nearly self-sufficient - but our administrative colleagues in Scotland agree that it is a possibility which should be allowed for in our management arrangements."

48.2. I regarded this possibility favourably as I thought that a single management body would be able to arrange for the two laboratories' capabilities to be used to best advantage and/or more economically, to plan any beneficial rationalisation and to weigh up the advantages of different developments. For example, would greater and higher quality output be best (or more quickly) achieved by developing the ancillary facilities at Liberton and introducing shift working or by increasing the capability of BPL? Sharing of expertise might also

be easier and there could be greater opportunities for training and career development of staff.

48.3. I referred to an expectation that Liberton would *"meet some of the needs of the rest of the UK for Factor VIII"* because when Liberton was built in the 1970s DHSS contributed part of the cost in the expectation that its capacity would exceed Scotland's needs and that the excess would be used by England. This had not yet happened, but neither DHSS not SHHD had ever taken the possibility off the table. It is recorded in the minutes of the meeting of officials of the four UK Departments on 1 December 1980 to discuss UK self-sufficiency in blood and blood products that Liberton "could play a role in helping to meet total UK needs" (see paragraph 43.13 above).

48.4. I have been asked to provide any further evidence that I can on my understanding that, *"the Scots are afraid that a merger would operate to Scottish disadvantage until England is more nearly self-sufficient".* I can find no documentary evidence for this prior to my minute and have not been supplied with any. It is likely that my statement was founded on a discussion with SHHD colleagues.

48.5. I have been asked for my view on why no joint body emerged to coordinate the management of the Scottish fractionation site at Liberton and BPL, or of the supply of blood products to the whole of the UK. As to this, in 1981 I thought that there was at least a possibility that the remit of the new SHA for the English Central Laboratories would eventually be extended to include Liberton. The time frame for this would have been after I had, in the event, left HS2. I cannot answer for what did or did not happen then.

48.6. I have also been asked what effect, if any, I think that such a joint body would have had on the prospects of attaining self-sufficiency across the whole of the UK. I doubt that a joint body would *per se* have altered the prospects of attaining self-sufficiency, given the common ground recorded at 48.3 above. I thought it possible that a joint body would be able to bring self-sufficiency about more quickly and/or economically - see 48.2 above.

48.7. The assumption underlying all the above was that Liberton had the potential for further development to make a significant contribution to total UK needs.

SHHD's conclusions as reported at Q59 above put a question mark over this, and in the event, as I now understand it, BPL was redeveloped to supply all the wider needs.

Section 3: Other Risk Reduction Measures

Hepatitis B screening

Q61/62: Delayed roll out of BPL's radioimmunoassay test for Hepatitis B

49.1. The Inquiry has noted that I was copied into a memo dated 17 July 1980, which indicates that in 1980, the DHSS delayed the roll out of BPL's new radioimmunoassay test for Hepatitis B, BPL-RIA, due to concerns that BPL-RIA would present unfair competition for the British pharmaceutical industry **[DHSC0002197_141]**. Ultimately, BPL-RIA was also priced higher than the near-cost price BPL had initially proposed, for the same reason. In a minute dated 17 September 1980 **[CBLA0001167]**, it indicates that these decisions were taken "at the very highest level".

49.2. I have been asked to explain whether I was involved in any discussions surrounding these matters, as well as further questions based on any such involvement.

49.3. The memo of 17 July 1980 was from Dr Harris (DCMO) as Chairman of the Joint Management Committee for the Central Blood Laboratories to Mr (now Sir Graham) Hart of the DHSS Supply Division. I received a copy. I have no memory of subsequent events, and I cannot find that I received copies of any further papers. Nor am I familiar with any protocols which should have applied. I am therefore afraid that I cannot assist the Inquiry with these questions.

Q62/63: Other issues concerning testing for hepatitis

50.1. The Inquiry has further referred to a letter to Dr Walford from Dr Lane, in which he stated that Burroughs Wellcome visited RTCs offering free trials of their test during the period that BPL-RIA was delayed **[CBLA0007637]**. I have been asked whether, to my knowledge, the DHSS would have been aware of and/or sanctioned this behaviour on the part of Burroughs Wellcome, and if so, at what point in time.

50.2. In the minutes of the Eastern Division Consultants of Blood Services meeting **[NHBT0092845_026]**, a proposal referring to BPL handing over the manufacturing of BPL-RIA to Wellcome was discussed, despite there being a

distinct “lack of confidence” in Wellcome as a manufacturer. The Inquiry has asked whether I was involved in these discussions.

50.3. On these two further questions, I refer the Inquiry to my answer to question 61; for the reasons set out, I am afraid that I cannot assist the Inquiry with these questions.

Section 4: DHSS, Regional Health Authorities and NBTS Relationships

Q64: Relationships

51.1. I have been asked a series of questions about relationships between the DHSS, the National Blood Transfusion Service (the NBTS) and the Regional Health Authorities (the RHAs). Please note that I cannot speak for the situation in Scotland or Northern Ireland – my answers relate to England and, where indicated, Wales.

51.2. I have first been asked to describe, from my knowledge and perspective, the working relationship between the DHSS and the NBTS.

51.3. The NBTS was not a corporate entity, consisting as it did of the Regional Transfusion Centres, which were funded by and accountable to the RHAs, and the Central Blood Laboratories, which were funded by the Department and accountable to Ministers. Therefore, in relation to the following questions:

a) *The lines of communication between the DHSS and NBTS, including how information was shared between the organisations:* setting aside the role of the Advisory Committee for the NBTS (effective from December 1980 onwards and discussed at para 55 below), there were no formal lines of communication between DHSS and the NBTS as a whole, communications with RTCs being via RHAs and their officials. Regional Transfusion Directors met from time to time under the chairmanship of the Chief Medical Officer's Consultant Adviser, with, I believe, the heads of the Central Blood Laboratories in attendance. The Consultant Adviser could thus channel information and opinions in both directions, but without any executive authority or in any other way derogating from the position of RHAs.

b) *The internal structure at the DHSS for managing the relationship with the NBTS, including the role of the DHSS official(s) present at any NBTS meetings*: For the reasons explained, there was thus no standing

relationship between DHSS and the "NBTS", nor, so far as I know, did any DHSS official regularly meet with RTDs. So to speak of "managing the relationship" is a misnomer, and there was no Departmental structure for it;

c) *Any areas of overlapping responsibility between the DHSS and the NBTS, and how these were navigated*: DHSS and the various parts of the NBTS each had their own responsibilities as appropriate to their positions in the various hierarchies. If co-ordinated action was needed on any issue it would be arranged ad hoc, including RHAs in respect of matters concerning RTCs;

d) *How Ministers were kept up to date with developments in the NBTS:* Ministers were kept informed about NBTS matters by Departmental officials, as on any other issue. This would happen when officials judged that a situation or issue was such that Ministers should know of it in case problems developed with which they might have to deal, or when a Ministerial decision was required. Sometimes a Minister might take a special interest in the NBTS and ask for regular briefings. Occasionally a Minister might visit a NBTS establishment, as Dr Vaughan visited BPL. This could lead to direct communications between the Minister and people whom he had met.

Q65: Funding

52.1. I have been asked to explain how the blood services were funded during my time in the Department. I can only speak for the period 1978 to 1981, and only for England. RTCs were funded by RHAs and the Central Laboratories by the Department. Blood services were provided to patients by local Health Authorities and funded by them from their allocations from RHAs.

52.2. Further specific issues have been raised:

a) *RTC allocations*: RHAs decided allocations to RTCs, not the DHSS;

b) *RHA autonomy*: Generally RHAs had autonomy over the monies allocated to them, always subject to Ministerial/Departmental policies, guidance and exhortation. They were required to seek specific approval for major capital programmes and some individual developments. I am

pretty sure that there were none such concerning the NBTS during the time in question;

c) Except as aforesaid, and the rare occasions when an Authority was given special funding earmarked for a particular purpose, the Department did not decide how Health Authorities should spend their money. However, the Department had considerable powers of persuasion, especially where Ministerial policies were concerned.

Q66: Mechanisms for influencing decisions made by RHAs

53.1. The Inquiry has asked whether the Department had any further mechanisms (other than funding) for influencing the decisions made by RHAs. As to this, the Department had regular meetings with senior RHA officials - Regional Administrators, Medical Officers and Treasurers. These could be used to promote national policies, and sometimes to get agreement that all RHAs would behave in a particular way. Minorities might be won round with the aid of peer pressure. In addition to this, senior Departmental officials could bring pressure on individual RHAs via their senior officials. In the last resort a Minister could ask to see the RHA Chairperson.

53.2. It is possible that things happened on medical networks which I did not know about, but I do not recall any cases of the Department having to persuade RHAs to adopt policies or practices which the Department favoured in relation to blood and blood products, except where there were resource implications to which an RHA was reluctant to give priority. An example of what the Department might then do was pro rata distribution of blood products – see para 35.5.

Q67: Proposals for the Reorganisation of the NBTS

54.1. I have been asked to describe my knowledge of, and involvement in, a proposed plan for the reorganisation of the NBTS, and to say to what extent this plan was implemented. The question presumably relates to a paper with that title prepared by Dr Tovey and five BTS colleagues which Dr Tovey sent to the Department (Dr Oliver) on 28 February 1980.

54.2. The other papers referred to in the Inquiry's question were of earlier date – a minute from myself to Dr Harris dated 13 March 1979 headed "Organisation and Management of Blood Transfusion Services", and the note of a meeting chaired by Dr Harris on 27 March 1979 "To Consider the Long Term Management of the Central Blood Laboratories and the Organisation of the National Blood Transfusion Service". Dr Tovey and I were among those attending this meeting. An important point is that the two latter preceded the Report of the Royal Commission (RC) on the NHS, established in 1976, which was delivered in June 1979.

54.3. My minute, as it said, was intended as a basis for discussion. It canvassed a range of issues, some of them organisational, assuming that the RC's report would not include radical recommendations about the future of RHAs (and hence RTCs), and acknowledging that if it did the whole matter could need "fundamental reconsideration".

54.4. Dr Harris' meeting agreed that "*it was unrealistic to try to consider the management of the Central Laboratories without taking a look at the organisation of the NBTS*". It did not regard the case for a completely centralised service as having been satisfactorily made out. It thought that the advantages lay "*with a federal arrangement, possibly with improved co-ordination in order to ensure that the NBTS developed broadly on the lines of nationally agreed policies*". The note of the meeting does not say whether these conclusions were unanimous, but it does record that "*Dr Tovey thought that some form of central co-ordination, amounting possibly to direction, might be unavoidable*".

54.5. The meeting then agreed to seek Ministerial agreement to continuing, for the time being, the existing arrangements for managing the Central Laboratories, i.e. the JMC. This is what in fact happened – see Q41 above.

54.6. Dr Harris' meeting also decided to leave the Central Committee for the NBTS undisturbed, at least for the time being, but to also establish an ad hoc Committee whose function would be "*the planning and co-ordination of the activities of the Regional Centres and the Central Laboratories so as to ensure*

that the NBTS was able to meet the future requirements for blood and blood products".

54.7. The paper put forward by Dr Tovey in February 1980 was said by its authors to represent, they thought, the views of all Consultants in the NBTS. It set out some problems from which the NBTS had been suffering for some time, referring in that connection to a "Submission Prepared for Consideration by the Royal Commission on the NHS", dated May 1977. The paper then summarised the steps already taken to improve matters, but stated that "*Despite these measures it is becoming increasingly evident that....the major defects in the Service are unlikely to be overcome in the absence of an Executive Committee or Board constituted statutorily by Act of Parliament*". It recognised, however, that such a major constitutional change would take time to effect, and proposed a number of measures to be taken in the interim, and as a matter of urgency. As a platform for these it made one organisational proposal, the creation of a Central Co-ordinating Committee for the NBTS, whose task would be "*to formulate and co-ordinate national policy for the Transfusion Service and through its membership accomplish implementation of this policy at Central and Regional levels*". Although the Committee's membership would not include anyone from Scotland, it would have power to invite Scottish representation as observers.

54.8. The "Plan" thus consisted of long term aspirations, which were not expected to be implemented for some time, and short term improvements. Organisationally, the outcome was the creation of the Advisory Committee on the NBTS, which was approved by Dr Vaughan on 17 July and first met on 1 December 1980. See also Q68. I believe that some of its other recommendations were also implemented, but I do not have chapter and verse for this.

54.9. As to my personal involvement, I seem to have chaired a meeting which took place on 22 April 1980, the note of which records agreement to "*Consider the practical implications of Dr Tovey's proposed Central Co-ordinating Committee, especially how Regions could be made to feel that they were adequately represented without making the Committee unwieldy. How would SHHD and the Scottish NBTS be associated with the Committee? There was complete agreement that national co-ordination of the NBTS was essential to meet the*

plasma requirements of a developed BPL." **[WITN6934013]** I attended one of two other meetings, but I cannot remember, or find any record of, any very active involvement. The July submission to Dr Vaughan was put forward by CMO.

Q68: Advisory Committee on the NBTS (December 1980)

55.1. The Advisory Committee on the NBTS ("ACNBTS") was set up in October 1980 to replace the advisory Central Committee on the NBTS that had been set up in 1975. It was chaired by Dr E L Harris and the DHSS provided its secretariat. Its Terms of Reference were as follows:-

"To advise the Department of Health and Social Security and the Welsh Office on the coordination of the development and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales, and the English and Welsh Blood Transfusion Service with those of Scotland and Northern Ireland".

(**[CBLA0001207]**, the minutes of its first meeting on 1 December 1980).

55.2. The reason for disbanding the Central Committee and setting up a new advisory body, was that the Committee had proved unable, by the nature of its membership, to provide the necessary quality of advice; it had not met since 1978 because this. The ACNBTS was set up to replace it.

55.3. As to why the ACNBTS was set up rather than embarking on reform of the RTCs, the future management of RTCs was a substantial part of the wider question of the management of the NBTS as a whole, on which see the second part of my reply to para 33.4 above. It would not have made any sense to change the management of RTCs in advance of whatever wider changes were to be made, since it might have resulted in a second change for the RTCs within a quite short period. A new Advisory Committee, for which there was a pressing need, could be established quickly without any prejudice to the wider issue. I was in full agreement with this reasoning.

55.4. The Inquiry has asked whether I personally agreed with the reasoning behind these changes. The only point on which I had doubts was the new Committee's terms of reference – see 55.6 below.

55.5. The ACNBTS was given an advisory role, as opposed to an executive or supervisory one, because an executive role would have cut across the existing management structure, and would have been contrary to all organisational principles. The inclusion of the word "supervisory" in the terms of reference was proposed (I do not know by whom) at the first meeting of the ACNBTS "*in order to suggest an active role for the Committee in monitoring developments in the Transfusion Service, especially the progress towards self-sufficiency in the collection of blood and the manufacture of products*." The opposite view was that "Advisory" conveyed all that was necessary. No change was sought. **[DHSC0002307_009, CBLA0001207 and SCGV0000127_046]**.

55.6. I have been asked to confirm whether I was the author of the handwritten note addressed to Mr Harley, at the bottom of a copy of minutes dated 24 June 1980 **[DHSC0002307_009]**, which I was. The note argued that the terms of reference of the ACNBTS should be limited to "*matters affecting the Central Laboratories, the supply of plasma thereto and the supply of products therefrom*". I cannot now recall my full reasoning, but I think I was afraid that if the ACNBTS were given a wide remit it might suffer the same sort of problems as the Central Committee, and would not provide advice which we particularly needed on the affairs of the Central Laboratories. Looking at that now, I think I was wrong. The Committee was in fact given a wider remit.

Q69: Structure and Achieving Self-Sufficiency

56.1. I have been asked for my views on whether a more centralised organisation would have improved the prospects of the UK becoming self-sufficient in factor concentrates.

56.2. Basically, the requirements for self-sufficiency in factor concentrates were (i) accurate forecasts of need/demand; (ii) sufficient supplies of plasma of satisfactory quality; (iii) sufficient fractionation capacity, skilfully and efficiently run; and (iv) efficient distribution systems. It had to be achieved without

detriment to the supply of blood for other purposes. A "more centralised organisation" would not necessarily have helped. To have any real chance of significant improvement it would, in my view, have been necessary to go the whole way, and bring the whole NBTS under central management which would have facilitated planning, determination of priorities and co-ordination between its various parts.

56.3. Please note that I am not saying that centralisation of management would certainly have produced the hoped for improvements, only that it would have given a chance of doing so. Even then it would not necessarily have made any difference to requirement (i) above. In my view a well designed system, staffed by good people with relevant experience, and adequately funded would have had the potential to improve performance on the other three.

56.4. But a centralised organisation would not per se have produced the required results. Significant obstacles would first have needed to be overcome. Most importantly the change would have had to be supported by the rest of the NHS, otherwise there could have been friction between NBTS management and Health Authorities over any shortages, real or alleged, of blood for Health Authority purposes, and also because the new management body would still want services such as Works and Personnel, desirably from Health Authorities. Health Authority support would probably not have been easily obtained, particularly at a time when the general thrust of the Royal Commission report and of general Government policy was for decentralisation. And in the case of RHAs there would have been a perceived loss of the planning and operational advantages of their having control of RTCs.

56.5. Similarly Scottish interests might not have favoured full UK integration – see Q60. This might not have prohibited a change for the rest of the UK, but it would have lost the UK focus which is in the Inquiry's question, and which DHSS would, I am sure, have seen as desirable.

56.6. Before a change could be made, extensive consultation and a lot of preparatory work would have been required. Even if primary legislation would not have been needed (see paragraph 32.5 above) this would have taken a long time, particularly against the background set out in paragraphs 56.4 and 56.5 above.

The Inquiry may be able to get some idea of the requirements from what happened in the run up to the changes made in 1993, though I am not myself familiar with those events.

56.7. In short, the change, however desirable, was not one which could be realistically contemplated during the period when I was in the HS2 post, i.e. up to late 1981; and probably for some time after that.

Section 5: General Issues

Q70: Briefing Ministers

57.1. I have been asked to describe the role I played in deciding what information should and should not be provided to Ministers within the Department, and what criteria were applied.

57.2. All senior Civil Servants must have continuously in mind the need to keep Ministers sufficiently informed and to seek Ministerial decisions when appropriate. Examples of the questions to ask are: (i) is this a matter of main policy or principle? (ii) does it have major resource implications, and thus opportunity costs in terms of time as well as financial resources? (iii) does it impact upon or conflict with other Departmental policies or programmes? (iv) is it a matter in which a particular Minister has a close interest? (v) may the Minister wish to inform any MP because of an impact on their constituency? (vi) is there a possibility or likelihood of generating public or political interest, or perhaps controversy, to which the Minister may wish, or be obliged, to respond? and (vii) is there an actual or possible impact on the responsibilities or interests of any Government colleague(s)? Sometimes the answer is obvious, and the decision to brief will be taken by the official most competent to provide the briefing. Sometimes the Minister's Private Secretary will advise. If in doubt, an official should consult his superiors.

57.3. As will be gathered from the above, there are no set criteria. Much depends on "feel" and experience. I would make it my business to ensure that Ministers were briefed when they should be on the affairs of my command, whether by myself or by an appropriate member of the Division's staff or, on matters of high importance, by one of my superiors.

Q71: Briefing Incoming Ministers.

58.1. The Inquiry has asked what briefings new Ministers were given when taking up their positions within the Department.

58.2. Not having worked in a Minister's Private Office, I cannot reliably answer this question. I was often called upon to brief incoming Ministers on particular topics, but no more than that.

Q72: The Chief Medical Officer

59.1. I have been asked to explain my understanding of the role of the Chief Medical Officer, and in particular:

a) *My interactions with the Chief Medical Officer(s) during your work in the Department:* apart from my spell as the Permanent Secretary's Private Secretary (see 1.3a) above) I had very little to do with CMOs except for rare occasions when we were at the same meeting. I had a lot to do with other medical colleagues, up to and including the rank of DCMO.

b) *To my knowledge, the degree of involvement and interest Sir Henry Yellowlees and Sir Donald Acheson had in respect of blood and blood policy;* I have no clear picture. This question would best be put to a senior member of the Department's medical establishment.

c) *Any observations I may have on the approach that Sir Henry and Sir Donald took to their role as Chief Medical Officer*: for the reasons explained above, I have no clear picture. This question would best be put to a senior member of the Department's medical establishment.

Section 6: Other Information

60.1. I have been asked if I have any other information that may be relevant to the Infected Blood Inquiry. I have not been able to think of any.

Statement of Truth

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

Signed..... GRO-C .....

Dated..... 4 NOVEMBER 2022 .....

Appendix A: List of acronyms

ACNBTS	Advisory Committee on the National Blood Transfusion Services
BGRL	Blood Group Reference Laboratory
BPL	Blood Products Laboratory
BTS	Blood Transfusion Service(s)
CBL	Central Blood Laboratories, ie BPL, PFL and BGRL
CBLA	Central Blood Laboratories Authority
CFS	Centrally Financed Services (by DHSS)
CMO	Chief Medical Officer
DCMO	Deputy Chief Medical Officer
DHSS	Department of Health and Social Security
HBV	Hepatitis B virus
HBC	Hepatitis C virus
HIV	Human immunodeficiency virus
HS[D]	Health Services Division (of DHSS)
IBI	Infected Blood Inquiry
JMC	Joint Management Committee (of BPL by DHSS and North West Thames RHA)
MD	Medicines Division (of DHSS)
MRC	Medical Research Council
NBTS	National Blood Transfusion Service(s)
NHS	National Health Service
RC	Royal Commission (on the NHS)
RIA	Radioimmunoassay (in this context, a test for HBV)
RHA	Regional Health Authority
RTC	Regional Transfusion Centre

RTD	Regional Transfusion Director
SHA	Special Health Authority
SHHD	Scottish Home and Health Department
STC	Scientific and Technical Committee