IN THE MATTER OF THE INFECTED BLOOD INQUIRY

BEFORE SIR BRIAN LANGSTAFF

CLOSING SUBMISSIONS ON BEHALF OF THE DEPARTMENT OF HEALTH AND SOCIAL CARE, AND ASSOCIATED BODIES from THE DHSC LEGAL TEAM

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NOTE REGARDING REFERENCES

Without discourtesy to the witnesses, and to aid understanding, when referring to historical events witnesses are generally given the titles held at the relevant time. When referring to evidence given to this Inquiry the titles they currently hold are used.

References to the transcript of oral hearings are given in the format: **132:22-134:6.**

Section 1: Introduction and preliminary points

1.1. The Inquiry's review of over 50 years of the National Health Service's history of treating those who suffer from illness or injury requiring treatment with blood products, or who have received blood transfusions leading to infection, has been important and salutary. In its work, the Inquiry has given a powerful voice to the patients who were harmed by these treatments, and to their families and loved ones. Submissions filed on behalf of the Department of Health and Social Care cannot do justice to the powerful accounts that the Inquiry has heard, over the four years and more in which it has gathered evidence. They include harrowing accounts of the physical suffering and psychological injuries suffered by those harmed by infected blood or blood products. The infected and their families and carers have spoken of the challenges in securing necessary treatment, and counselling or other forms of support. Witnesses have spoken of the damage and sense of betrayal caused by the loss of trust in clinicians, the medical system and the NHS, and the wider Government system that directs and shapes the NHS. Many have told the Inquiry of severe financial hardship, and the loss of dignity and self-respect involved in making applications for support payments, especially those which were means tested. Campaigners have told the Inquiry of the long and – until 2017 – fruitless campaign for a UK-wide public inquiry, and their frustration and distress when lengthy and detailed arguments were felt to be 'brushed off' by standard responses that repeated inaccuracies or did not answer the questions raised.

1.2. These submissions are not the place to try to repeat the evidence that the Infected and the Affected (the IAA) have given to the Inquiry – any reflection of that will be done, much more eloquently and appropriately, by those of the IAA who are Core Participants themselves, or those who represent them. However, the Department of Health and Social Care does wish to begin its written closing submissions by acknowledging that evidence, and by stating clearly to those who gave it that they have been listened to and heard. The Government commissioned Sir Robert Francis to examine a possible

Compensation Framework, and the Chair's interim recommendation that interim payments of £100,000 should be made to those registered with the existing financial support schemes, was promptly accepted.[1] The Department of Health and Social Care will continue to listen, both to the submissions of other Core Participants and to the Inquiry itself, when it reports.

On whose behalf these submissions are made

1.3. These written closing submissions are made on behalf of the Department of Health and Social Care ("DHSC"), its predecessor bodies and relevant organisations or bodies which the department was responsible for over the years being considered by the Inquiry, including the Medicines and Healthcare Products Regulatory Agency ("MHRA"), the National Institute for Biological Standards and Control ("NIBSC"), Public Health England ("PHE") and the Blood Products Laboratory ("BPL") (for the period that it was state owned).

1.4. References to the Department in these submissions are to whichever iteration of DHSC which existed at the relevant time.

1.5. The legal team representing the clients identified above is referred to as the DHSC legal team by way of shorthand hereafter.

The purpose of these submissions

1.6. In the opening oral submissions made on 26 September 2018, our clients' commitment to cooperating with the Inquiry and assisting the Inquiry to fulfil its terms of reference in all their breadth was set out.[2] Since then and in furtherance of meeting this commitment, the DHSC legal team and its clients

[1] Compensation and redress for the victims of infected blood: recommendations for a framework - GOV.UK (www.gov.uk)
[2] Day 3 of the preliminary hearings (26 September 2018), 15:1-15:5, 16:25-17:12, 20:2-20:15, 24:12-24:17.

have worked hard to facilitate the disclosure process, including by waiving legal professional privilege in respect of material relevant to the Inquiry's Terms of Reference up to 11 July 2017 for all but two narrow categories of material;[3] to deliver the necessarily detailed and complex witness statements requested by the Inquiry pursuant to Rule 9 of the Inquiry Rules 2006; and to assist the Inquiry's legal team more generally wherever possible.

1.7. It is in the same spirit of commitment to assisting the Inquiry that these written closing submissions are drafted. Nothing in them should be taken to detract from the acceptance in opening oral submissions that "things happened that should not have happened"; "that things went wrong".[4] Or from the unreserved apology for the fact that this was so.[5] Moreover, it remains the case that the current Department does not have a 'position' or a 'case' in relation to the issues being explored by the Inquiry; nothing in these submissions should be seen as changing this. The Department has already referred to the ongoing commitment to listen to the Inquiry and its recommendations.

1.8. However, the Department does hope that it may assist the Inquiry by, in particular, summarising the perspectives of those who were involved at the time (and who acted on behalf of the Department or those executive agencies which the DHSC legal team represent); and by reflecting the reasons for their actions and commenting, where appropriate, on their impact.

[3] (a) Any legal privileged material relating to the establishment or conduct of the IBI or the DHSC's or other government department's support for or participation in the IBI; and (b) any legally privileged material relating to the conduct of any current or ongoing litigation, or proposed proceedings, against the DHSC or NHS bodies, touching upon the matters set out in the IBI's Terms of Reference. This includes any legally privileged material relating to claims that have been intimated, but in respect of which proceedings have not been issued.
[4] Day 3 of the preliminary hearings (26 September 2018), at 15:16-15:19.
[5] Day 3 of the preliminary hearings (26 September 2018), at 15:19-15:20.

1.9. Such observations are offered, first, out of fairness to those so involved. Some individuals have been asked and have been able to give witness evidence (written and/or oral), and the DHSC legal team has tried to refer to key evidence from those witnesses. However, many of those who were involved are now dead or otherwise unable to speak for themselves – the list of witnesses is limited as a result of the passage of time. Further, the Inquiry too has been necessarily limited in its ability to reach, or to call for, evidence from all those involved at the time – it has had to make choices. So, we have tried in these submissions, (in the main by reference to the documentary records) to deal with periods of time in respect of which there is no-one, or very few people, to directly speak with. We have also sought to acknowledge and reflect where practicable the assistance that has been provided by any available presentations by CTI.

1.10. Second, it is hoped that this exercise may assist the Inquiry in reaching conclusions that fairly reflect the 'state of knowledge' at the relevant time. As was highlighted in the opening oral submissions made on behalf of our clients:-

> *"One of the roles of any Core Participant, and its legal team, if it has one, is to show the Inquiry how issues were perceived by those participants at the relevant time, in the light of the information which was known at the time, and that of course includes enabling reflection on what could have been known with fuller Inquiry or what ought to have been known.*
>
> *But perspectives about what was said or done in the past, or what is submitted about it now, are likely to differ, even to collide. But the important point here today, however, is the commitment of the team which I represent, together with our clients, to ensuring that the fullest possible picture is laid before you so that you can make findings upon it."*

1.11. Insofar as these submissions aim to set out evidence relating to the perspectives of those acting at the time, they do not represent the views or the judgement of the current DHSC on past events. The exercise of making those assessments is for the Inquiry itself. DHSC Ministers and wider Government will, in due course, react to the Inquiry's findings, its report and

its recommendations. At the moment, their concern is not to pre-empt that process by offering opinions now. They have merely enabled these submissions to be made, in the hope that they assist the Inquiry.

The role of individual witnesses supported by DHSC

1.12. These submissions draw on the written and oral evidence of those witnesses whom the DHSC legal team have represented, and who have supplied R9 evidence at the request of the Inquiry. However, they have not been drawn up with the involvement of those individual witnesses. These individuals[6] do not enjoy Core Participant (CP) status, and their procedural rights, in terms of access to documents for example, have reflected that. Consistently with both that status and with the timescales for producing written submissions, these submissions have not been drawn up with their input and individual witnesses have neither had prior sight of, nor approved these submissions. They will receive them only when they are released into the public domain by the Inquiry, along with all other CP Written Submissions. For such witnesses, the R13 process, if needed, is the only means by which they would be able to respond directly to any critical perspectives put forward against them as individuals and remains an integral part of the fairness of these proceedings.

Limitations of these submissions

1.13. There are many limits on what can be covered or accomplished by these submissions. First, as indicated at paragraphs 1.1 and 1.2 above, they are not a complete reflection of the evidence heard by the Inquiry but cover the more limited ground set out at paragraph 1.8 above.

1.14. Second, they have been prepared with limited time available. From 1 September 2022 onwards, the DHSC legal team has received approximately

[6] The position of DHSC witnesses who have been asked to, and have supplied, DHSC "corporate" evidence is different insofar as they were giving evidence on behalf of the DHSC in its role as a Core Participant. These are not the witnesses referred to in this paragraph.

29 requests for R9 statements, and it has provided ongoing support for a further 25 witnesses who had already received R9 requests prior to 1 September 2022. It has also supported 11 witnesses who gave oral evidence, both in relation to past events and also with regards to possible recommendations. The DHSC legal team has prioritised these processes, given the overriding importance of enabling the provision of full and accurate evidence to the Inquiry. We have also, in common with other CPs, tried to keep abreast of new material, including the helpful presentations from Counsel to the Inquiry (CTI).[7] All these work streams have necessarily limited the time available for these submissions, and upon their contents, both in terms of topics covered and their refinement. The submissions are not exhaustive, and their focus is on the matters which DHSC and its executive agencies have been asked to address in evidence, rather than all the topics of interest to the Inquiry and its CPs.

The effect of the passage of time

1.15. Against that background, we make a few points on the nature of the task for the Inquiry, the first relating to the effect of the passage of time.

1.16. The challenges created by this are numerous. There is an extensive discussion of the process of setting, resetting and rewriting memories, and the limitations of memory from Leggatt J in *Gestmin SGPS SA v Credit Suisse* (UK) Ltd [2013] EWHC 3560 (Comm), §15 - §22. Such limitations affect the memories of all those heard in this Inquiry, whether former Ministers, officials, doctors or patients. As for the officials or former Ministers represented by the DHSC legal team, most if not all have commented that they have no, or no real memory of the events about which they are being questioned, retaining only a very general recollection of the period of time in question, or general recollections of only a few key events. Many have tried – encouraged by the nature and tenor of the R9 questions - to reconstruct

[7] It has not, however, been possible to review and incorporate the most recently published documents: for example, the CTI presentation on vCJD and the Virology Expert Report.

what is likely to have occurred based on what they think they 'would have done', based on their character or manner of working. They have tried both diligently and genuinely, the Inquiry might think, to overcome these obstacles, but they are still subject to the difficulties vividly described by Leggatt J.

1.17. In those circumstances, the documentary record is important, but it too has limitations and they are significant. First, the documentary record will always be incomplete. Not all interactions between officials, or even officials and Ministers, will have been recorded in writing. All the indications are that documents were even less likely to be generated in the early part of the Inquiry, before the widespread introduction of photocopiers and, subsequently, email. Dr Diana Walford gave evidence on how files were passed through the Department:[8] a memorandum would be given to a typist, and if no corrections were needed it could then be placed on the official file. This official file would then be delivered to the relevant person within the Department. That is not a system that would have generated either a lot of documents, or multiple copies of them, at least by the standards of today. Furthermore, documents will never record the full complexity and reality of interactions, even when they exist. See for example the oral evidence of Lord Waldegrave, who gave the apt parallel of "*it's rather like trying to understand an opera…just from the libretto.*"[9] Not only unwritten interactions, but cultural norms and structural issues within (relevantly) the Department are not likely to have been recorded at all, or will be poorly reflected in the 'blood-related' documentary material that the Inquiry has inevitably focussed upon.

1.18. In addition, not all documents have survived. The subject of the loss and destruction of relevant documents is dealt with at Section 12 in these Submissions, and is not addressed further here.

[8] Dr Walford's oral evidence on 19 July 2021 at 33:13 – 35:1
[9] Lord Waldegrave's oral evidence on 5 July 2022 at 136:23 – 136:24

1.19. The gaps in the contemporaneous records, and the challenges in reconstructing accurately what was known, thought and done at the relevant time, do heighten the real risk that any gaps are filled in by reference to what is now known, or by what later became apparent.

Fairness and guarding against hindsight

1.20. We anticipate that it would be generally accepted by both CPs and the Inquiry that decisions upon the steps taken, or not taken, to manage the infection risks posed by blood and blood products should be assessed, in the first instance, by what was known or ought reasonably to have been known at the time (as the DHSC said in its brief opening submissions, knowledge "*of course includes enabling reflection on what could have been known with fuller inquiry or what ought to have been known*"). That includes examination of the standards and norms of behaviour or conduct at the time.

1.21. We say 'in the first instance' as the Inquiry may – and it will be a matter for it – wish to reflect, at times, upon changing norms and standards, and how decisions would be approached at the present time, as part of the process of learning lessons and making recommendations.

1.22. The initial assessment of events and fact-finding would generally involve not only an awareness of standards and norms at the time, but also wider environmental issues that may have affected decision-making. For example, Dr Walford remembered how in the early 1980s, she and her colleagues only had access to print copies of medical journals, such as the New England Journal of Medicine. These had to be loaned out on special request by the DHSS library or seen when they were circulated by the DHSS Information Division. Getting information speedily in a world before email and the

internet was much more difficult.[10] Another example of the decision-making context might be the financial situation following the events of 1976, when public expenditure was exceptionally constrained.[11] Another might be how standards and practice in relation to the provision of counselling and psychosocial support have changed over the years, within the NHS.[12] Generally, the Inquiry will be aware (from sources such as the report of the Expert Group on Public Health and Public Administration[13]) how standards have not only changed, but also been codified and made greatly more explicit, over the years it has been examining.

1.23. Even bearing the historical context in mind, there are more subtle reasons why avoiding hindsight bias in the assessment of past events is, we would suggest, exceptionally difficult. There are a number of reasons for this, and what we say below will not be comprehensive.

1.24. The first and fundamental point is that it is now potentially impossible to trace over the decisions of the past (say, in relation to the risk of AIDS in the 1980s) without being influenced by the awareness of 'what came next'. Rather like trying to retrace one's way to the centre of a maze which has been successfully negotiated, the route on the second journey into the maze will be influenced, consciously or unconsciously, by the previous successful trip or route map. Less weight or attention is given to the blind alleys or false starts that seemed appropriate routes, even promising ones, at the time, but later were shown to be mistaken.[14] Time spent exploring them is more likely

[10] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §72.3
[11] Briefly referenced in the Inquiry's Expert Report in Public Health and Public Administration: see page 23 paragraph 4 Expert Report to the Infected Blood Inquiry: Public Health and Administration (EXPG0000047)
[12] It is interesting to see, for example, that there was no claim for counselling or psychological support made in A v National Blood Authority [2001] WL 239806 (Burton J, 26 March 2001).
[13] Expert Report to the Infected Blood Inquiry: Public Health and Administration (EXPG0000047)
[14] To take one potential example, Dr Pickles responded to questions about the pilot studies of the second generation of HCV screening tests by pointing out that it might be easy to discount the necessity of the pilot studies now when it is known that they were successful, however, these results could not have been anticipated at the outset. It is reasonable to infer that the consequences of discovering the tests were not sufficiently accurate would have been serious. See the oral evidence of Dr Pickles on 12 May 2022 at 178:21 – 181:24

to be discounted. Equally, it may be harder to give credence or weight to the intentions and plans of those involved at the time, when later shown to be flawed.[15]

1.25. Questioning of witnesses along the lines of 'why didn't you do X' or 'shouldn't you have done X' are examples of questions which are almost inevitably influenced by knowledge of 'what happened next', however necessary and proper, it is for those questions to be asked. In turn, witnesses too will have found it impossible to recreate, exactly, what they thought at the time or reasons for their actions. That is not only because of the issues of memory that we have discussed above, but also because of the influences of hindsight and of suggestion that are inherent in the Inquiry process (seen again, the observations of Leggatt J).

1.26. This inequality of knowledge points to a second form of hindsight, arising from the Inquiry's necessary focus on the issues encompassed by its Terms of Reference. The priority attached by the Inquiry and CPs to these issues may be at odds with how they were seen at the time, and it may be exceptionally difficult now to assess those perspectives fairly.

1.27. So for example, when Ministers made judgements on the financial support to be given to those infected, they did so against a background of the plethora of competing and deserving demands (many of them potentially life-saving or life changing) on finite Department of Health resources[16], but also without the knowledge of this Inquiry that the underlying judgement, that the Department had done what it reasonably could to avoid AIDS infections,

[15] So, for example, Mr Fenwick KC told Ministers in October 2000 that it was the view of those involved at the time of the HIV Litigation Settlement that seeking to settle at a figure put forward by the plaintiffs' Counsel would mean that the settlement was accepted to be a fair one; see the observations of Mr Fenwick KC when discussing the potential vCJD Trust in 11 October 2000 at DHSC0006245_007. Evaluation of that evidence should not be affected by knowledge of what happened later, and the lack of any long-term consensus that the financial support for haemophiliacs infected with HIV was fair or adequate.
[16] See, for example the oral evidence of Alan Milburn on 14 July 2022, at 138:22.

would continue to be contested for years and would ultimately have to be re-examined by this Public Inquiry. The evidence given by the sequence of Health Ministers from 1987 onwards on the reasons why greater financial support was not given to those infected with HIV should, it is suggested, be assessed without that background knowledge – however difficult that task is. Or, to take another example, when the same issue of whether there should be a public inquiry, and the associated 'lines to take', received limited attention in the early - mid 2000s, it did so against the background of not only work to establish the Skipton Fund (from June 2003 onwards), but also pressing work on CJD/vCJD. The Inquiry has heard evidence that the Blood Team was small and under resourced, often seeking to focus upon important delivery projects such as the roll-out of recombinants and securing sufficient supplies of non-UK plasma to counter the risk of vCJD; but overall issues of the prioritisation of resources are hard to assess, within the context of a study of this area of policy alone.

1.28. It is respectfully suggested that the Inquiry will need to take into account that many judgements, on issues such as priorities and resources, were made within a political and democratic process that supported them at the time – even if subsequent decisions, have shown how those judgements may change. This is only a brief treatment of the issue of hindsight, and we have avoided giving exhaustive examples.

1.29. With those introductory comments, we turn to the factual evidence that the Inquiry has heard.

Section 2: Self-sufficiency

Introduction

2.1. The DHSC legal team has been much helped by the detailed written chronological presentation on domestic production and self-sufficiency in England and Wales produced by Counsel to the Inquiry and members of the Inquiry Legal Team.[17] These submissions do not seek to address every development in the twenty-year period covered by that presentation. They address the key aspects of the Department's pursuit of self-sufficiency on which the Chair is likely to need to make findings of fact.

Definitions of self-sufficiency

2.2. The Chair may consider that the starting point for considering at what stage/s, if any, the UK was self-sufficient in blood products, and if not, why not, is establishing a definition or definitions for self-sufficiency. This point was made in the evidence of both Dr James Smith[18] and Dr Terry Snape.[19]

2.3. In May 1975, the World Health Organisation ("WHO") had urged Member States "*...to promote the development of national blood services based on voluntary nonremunerated donation of blood...*" having noted that:

> "*...the increasing use of blood and blood products...the extensive and increasing activities of private firms in trying to establish commercial blood collection and plasmapheresis projects in developing countries...serious concern that such activities may interfere with efforts to establish national blood transfusion services based on voluntary nonremunerated donations...the higher risk of transmitting diseases*

[17] CTI and Inquiry Legal Team Presentation on *"Domestic Production and Self-Sufficiency, Chronological Presentation: England and Wales"* (INQY0000333); referred to in this Section as "the presentation on domestic production and self-sufficiency".
[18] The Inquiry gave a presentation of the evidence of Dr James Smith on 17 and 18 March 2022 and INQ0000329 based upon Dr Smith's witness statement [WITN3433001] and documents referenced within it, including previous evidence given by him to the Lindsay Tribunal and Penrose Inquiry. Dr Smith died on 14 April 2022.
[19] Dr Snape's oral evidence on 29 and 30 March 2022, and Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §67 and §234.

> *when blood products have been obtained from paid rather than voluntary donors…*".[20]

2.4. However, Dr Smith's evidence indicated that notwithstanding the Council of Europe adopting the WHO position on 30 April 1980,[21] there were concerns in England (as opposed to Scotland which approached self-sufficiency more "*…fervent[ly]…*") "*…at some decision-making levels…*" about "*illegal government assistance*" and "*restraint of trade*", and, at a clinical level, some haemophilia directors saw the approach as limiting the clinician's choice of the best product available to his patient.[22]

2.5. This evidence about clinical perspectives was consistent with Dr Snape's evidence, that England defined self-sufficiency as providing sufficient supply so that the prescribing choices of clinicians were not restricted.[23] Similar evidence was given by Mr Wormald, who has said:

> *"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."*[24]

2.6. He took a pragmatic approach to the issue of definitions but stressed the need for adequate forecasts:

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[20] PRSE0003476.
[21] PRSE0002575.
[22] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §164; CTI written presentation on the Evidence of Dr Smith, March 2022 (INQY0000329), at §49. For Dr James Smith's perspective of how, at the Oxford regional level, there had been success in achieving plasma supply and the virtuous triangle between the Oxford RTC, PFL and Oxford HC which might have been applied nationally, see the same statement at §165 and INQ0000329 (CTI presentation) at §50.
[23] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §67.
[24] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §4.1.

> *"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."*[25]

2.7. In Scotland, by contrast, self-sufficiency was understood "*...without qualification as the quantity of factor VIIII to meet clinical need without importation of product*" (with the exception of rare products, which would inevitably have to be commercially sourced).[26]

2.8. In 1990, UK Government policy recognised the narrower definition explicitly:

> *"The principle of self-sufficiency therefore means that the supplies of domestically sourced blood products should be sufficient, both in range and quantity, to meet the needs of all patients whose clinicians prefer these to other available products."*[27]

2.9. However, given the approach attested to by both Dr Snape and Mr 24/24, the Inquiry may consider that this was not a change of policy in 1990, but rather a formal recognition of an existing, albeit not explicitly defined, approach.[28]

2.10. Dr Smith's evidence was that England could make a *"...heavily-nuanced claim..."* to self-sufficiency in terms of being able to meet demand for product in 1985 only because so many clinicians were choosing to buy imported product.[29] His evidence was that "*The BPL claim...became progressively*

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[25] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §4.1.
[26] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §234; PRSE0006025 at p.57; Confirmed by Dr Perry in his oral evidence on 31 March 2022, at 97:4–97:20.
[27] PRSE0001083_0016.
[28] The UK view that "compulsion of self-sufficiency [should not] interfere with the principle of clinical freedom" was later expressed in the memorandum at DHSC0002522_023, which is undated but must date from late 1994 / early 1995 (before 22 February 1995, see page 2 of the memo).
[29] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §166.

more realistic after 1987, due to a better balance between the RTCs' and BPL's efforts, and BPL's development of more "attractive" F.VIII products…" (i.e. heat treated products).[30] Dr Snape's evidence was that self-sufficiency was achieved in England and Wales at the end of the 1980s (according to its definition of the same).[31]

2.11. There was sometimes a divergence between the formal definition of self-sufficiency and the expectations of a number of individuals. The target for Factor VIII self-sufficiency was based on the amount required to treat a haemophiliac bleed when it occurred. By contrast, some members of the public (and even some clinicians) believed self-sufficiency meant the amount of plasma required to enable patients to live a close-to normal life.[32] Dr Lane described this difference of perspective as the "*…underlying problem…*".[33]

2.12. Having regard to the issue raised by Mr Wormald, i.e., the need for reliable forecasts, it might be referred to as one of the underlying problems. The issue of forecasting demand is discussed further below.

Background to the commitment given by Lord Owen

2.13. Dr Owen's ministerial commitment to the goal of self-sufficiency was given after the issue had been discussed amongst transfusion directors, haemophilia clinicians and fractionators in the early 1970s. Dr Lane spoke of self-sufficiency being a *"…desirable objective from about the early 1970s…"*[34] it was regarded as *"…desirable but not immediately essential"*.[35] This view was presumably based on the perception at this early stage that

[30] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §166.
[31] Dr Snape's oral evidence on 29 March 2022, at 129:23.
[32] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §231, paraphrasing Dr Lane.
[33]CTI oral presentation about the work and evidence of Dr James Smith and the work and evidence of Dr Richard Lane given on 18 March 2022, at 139:22-140:8.
[34] CTI oral presentation about the work and evidence of Dr James Smith and the work and evidence of Dr Richard Lane given on 18 March 2022, at 135:12.
[35] CTI oral presentation about the work and evidence of Dr James Smith and the work and evidence of Dr Richard Lane given on 18 March 2022, at 136:12-136:14.

foreign imports were not regarded as inherently unsafe: see for example paragraph 43 of CTI's "*Presentation on Domestic production and Self-Sufficiency: England and Wales*" and the perceived lack of relative risk from blood concentrates.

2.14. The Inquiry has in its possession extensive evidence from many sources about the limitations of the planning process that took place. These include the Report of Lord Penrose, Final Report, Chapter 19, paragraph 19.12 onwards, as well as the witness and documentary evidence it has received more directly. Without seeking to repeat the contents of CTI's presentation on self-sufficiency, important milestones prior to Lord Owen's policy commitment included:-

(1) The first grants of commercial licences in March and February 1973;

(2) Commissioning estimates of probable demand from 1973, with the formation of the Expert Group on the Treatment of Haemophilia and its advice in March 1973.

2.15. As at April 1971, *"...it was recognised that the total ideal requirement of material for treating patients with coagulation defects was not known"*.[36] It was suggested that records of annual treatment use *"...will give an estimate which would level off to the ideal requirements."*[37]

2.16. As Lord Penrose noted,

> *"These changes in perception of the likely levels of demand were taking place as construction of production facilities was at an advanced stage of planning or had already begun in England and Scotland."*[38]

2.17. In particular, the extension work at Elstree had begun in November 1969 and was expected to be completed in September 1971. However, in 1973, the

[36] Penrose Inquiry Final Report at §19.12.
[37] Penrose Inquiry Final Report at §19.13.
[38] Penrose Inquiry Final Report at §19.19.

output of BPL was *"...roughly equivalent to 2million iu [sic] per year of Factor VIII concentrate, reflecting its essential origins as a Laboratory and not a manufacturing facility."*[39]

2.18. Against that background, the first commercial licences for Factor VIII were granted, for Hemofil on 19 February 1973[40] and for Kryobulin on 22 March 1973.[41] The CMO's letter to Senior Administrative Medical Officers of 6 March 1973 recognised that "...*the production of the human concentrate in the UK is at present insufficient to meet the stated needs of clinicians .... The indications are that considerably more of this preparation would be used if it were available.*"[42] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team also recognises the impact of the availability of these commercial preparations on clinicians' choices: it was no longer regarded as ethical or necessary to 'undertreat' patients.[43] The impact of the commercial products' availability had consequences, however, both for the use of cryoprecipitate (not the treatment of choice when alternatives were available) and finance, given the costs of the commercial imports.

2.19. The DHSS reacted to this landscape by seeking expert advice on the basis on which future planning should take place. In particular, the *"Expert Group on the Treatment of Haemophilia"* was formed.[44]

2.20. The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team also suggests that the CMO's Circular of 6 March 1973

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[39] Data from Dr Lane's Fifth Draft Proof of Evidence dated 10 December 1990, CBLA0000005_002, at §77.
[40] DHSC0003741_104.
[41] MHRA0033322_061.
[42] DHSC0100005_033.
[43] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333), at §§78-70.
[44] See the CMO's letter at DHSC0100005_033; there is further extensive documentation about the formation of this expert group in the presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §§14-22.

"… is further evidence that the UK's self-sufficiency policy emerged in response to the introduction onto the UK market of expensive commercial products. No reference was made in the circular to other factors, such as the safety of the products or the defence of the principle of altruistic donation." [45] As to this:

(1) The evidence of Mr Peter Wormald is that there was awareness on the part of Sir William Maycock of the risk of hepatitis infection from transfusions rather than blood products during the 1960s and that Sir William also showed a commitment to the voluntary donor principle.[46]

(2) Whilst the topic of perceived hepatitis risks, in relation to both domestic and imported products, is addressed at Section 3 of these submissions, as of March 1973 the prevailing view was that there was limited risk arising from the use of concentrates, and that imports were not distinguished from the UK product in this regard. We have referred already to the contents of the Agenda for the Meeting of the Haemophilia Directors on 5 April 1971.[47] Minutes from the First Meeting of the Expert Group on the Treatment of Haemophilia held on 20 March 1973 further recorded that, *"In practice, studies in several centres have shown that the incidence of hepatitis among severely affected patients who have been treated with the freeze-dried preparation is not very much higher than at the centres not using freeze-dried concentrate… It was agreed that the theoretically increased risk of acquiring hepatitis (which does not seem to be borne out in practice) should not be a deterrent to using the freeze-dried preparation…"* [48]

(3) That said, Dr Lane spoke of self-sufficiency as giving rise to (among other things) *"…security of supply and the ability to control the*

[45] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §22.
[46] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §3.2.
[47] PRSE0002413.
[48] PRSE0004706_0003. See also the presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §§32 -33, §43.

standard of the product".[49] This is a wider set of concerns than cost alone; quality and access to the product are also referenced.

(4) Leaving aside the reasons that led Dr Owen himself to argue for self-sufficiency, it may be thought that the question of protecting the voluntary donor principle came more sharply in focus for DHSS officials when the question of whether to allow US firms to process plasma in the UK, or commercial firms be allowed to fractionate UK supplies arose,[50] as this constituted a direct risk to the UK voluntary donor panels. Any risk posed by commercial concentrates purchased from abroad was indirect only.

2.21. Overall, it is suggested that the Inquiry may consider that to the extent that there was, in the early part of the 1970s, a limited direct emphasis on issues of product safety in blood concentrates, documents such as those cited above demonstrate a clinical perception that the risk of Hepatitis B had been largely addressed by screening of blood donations, and that the issue of NANB Hepatitis had not come to the fore.[51] However, the issue of safety was not wholly absent: there was greater control over the standard of the UK product.

2.22. Returning to the issue of planning targets, the work of the Expert Group is discussed in the presentation on domestic production and self-sufficiency.[52] The presentation cites the evidence presented by Dr Biggs of demand based on the data from 1969 – 1971 which suggested that total demand amounted to some 400,000 – 750,000 donor units per annum. The Group recommended that the UK should aim to be self-sufficient. It advocated close co-operation on a UK wide basis.

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[49] Dr Lane's Fifth Draft Proof of Evidence dated 10 December 1990 (CBLA0000005_002), §72.
[50] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §82, noting the introduction of this suggestion in July 1974.
[51] As discussed in more detail in Section 3 of these submissions on "Knowledge of and Responses to risk of Hepatitis Infection".
[52] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §§23-46.

2.23. There was further advice in January 1974, which is also discussed in the presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team.[53] Working as part of the MRC's Blood Transfusion Working Party, in a revised report Dr Biggs presented data indicating the total demand required was between 547,540 and 750,000 donations per annum to be fractioned to produce freeze-dried Factor VIII. The paper concluded that commercial concentrates should be purchased, as an interim measure, to avoid under-treatment, but that NHS concentrate should be substantially increased in amount.

2.24. The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team sets how Dr Maycock then expressed confidence in the ability of Elstree and Liberton to meet the demands of production implied by acceptance of the Expert Group's recommendations. The presentation notes, however, that there was a shortfall in the prospective combined capacities of the 2 sites (1,145 litres/week, as opposed to 1,425 litres) and reservations about the estimates from Mr Watt's predictions for Liberton.[54] However, it appears from the efforts that followed that the assurances given led to the emphasis being firmly placed upon the need to increase supply, rather than consideration of production capacity.

Parameters – known and unknown – for self-sufficiency calculations

2.25. Whilst the history of the increasing targets that later followed efforts to increase plasma supply will be well known to the Inquiry, the Inquiry has also heard that estimating demand was inherently difficult. Dr Lane's fifth draft proof of evidence dated 10 December 1990 at paragraphs 81 – 84 set out a series of difficulties:[55]

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[53] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §§64-68.
[54] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333) at §§51–53.
[55] CBLA0000005_002.

(1) There was uncertainty as to what was actually being produced as a result of the nature of the material and the processes used ("*Plasma is variable in quality and resultant predictions of Factor VIII yield were unreliable*");

(2) Predicting demand for Factor VIII based on the previous/current use of cryoprecipitate was difficult and uncertain;[56]

(3) Predictions involved making assumptions about yield vs purity[57] (Lane paragraph 84, see further the discussion below);

(4) There were varying approaches to the definition of targets, attitudes to which might depend on whether there was a focus on what was considered to be "*needed*" for treatment, or what might be "*wanted*"[58] (Lane paragraph 84); or more broadly, on the developments in home treatment and prophylactic treatment, and issues such as the extent to which haemophiliacs should be supported to participate in activities, such as sports and games, that had not previously been possible to access. The proper or accepted approach to <u>treatment</u>, therefore, was shifting and in a state of flux.

2.26. To elaborate further: one of the difficulties in the quest for self-sufficiency was the shifting parameters that needed to be known for accurate calculations of demand and thus projections of UK need. There was an "*upward trajectory of demand*" from the 1970s which was "*...accelerated at times by new concepts such as prophylaxis and home therapy...*"[59] Dr James Smith's evidence recognised that the Department could not spend large sums on *"speculations*".[60] The Inquiry has received evidence of the wider

[56] CBLA0000005_002, §82.
[57] CBLA0000005_002, §84.
[58] CBLA0000005_002, §84.
[59] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §168; See also CTI's written presentation on Dr James Smith dated March 2022 at INQY0000329, §52.
[60] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §168.

financial position from 1976 as it affected health spending (see further paragraph 2.70 below).[61]

2.27. Calculating yield was necessarily difficult given the complex biological process used to produce Factor VIII. Although calculations anticipated a 30 – 40% yield, BPL/ PFL often achieved a yield closer to 25 – 30%.[62] Projections were distorted by the estimates provided by Dr John Watt, Director of PFC, which proved to be unrealistic; an achieved yield of 30 – 35% and an expected yield of 70%.[63]

2.28. Dr Snape's evidence summarising the parameters needing to be known for self-sufficiency calculations was as follows:

> *"To be trustworthy, self-sufficiency calculations would have required two parameters to be known with a reasonable degree of accuracy:*
> *1) The amount of factor VIII required for treatment, as determined by:*
> *a. The number of haemophiliac patients to be treated and the severity of their factor VIII deficiency.*
> *b. The treatment regimen to be followed:*
> *i. Treatment in response to bleeding.*
> *ii. Home therapy (as it developed over time).*
> *iii. Treatment by prophylaxis (as it developed over time) to normalise life as far as possible.*
> *iv. Enhanced treatment in support of major surgery.*
>
> *2) The amount of factor VIII available for treatment, as determined by*
> *a. The quantity and type of plasma available for factor VIII production.*
> *b. The capacity/capability of the NBTS in E & W to meet those demands.*
> *c. The capacity/capability of the (then) unlicensed facility at BPL, Elstree to meet those demands (even with attention to its GMP limitations, PFL in Oxford could only ever operate as a development and GMP pilot scale facility).*
> *d. The yield achievable with the manufacturing process, including any confounding effects such as:*
> *i. Patient/physician demands for desirable product characteristics (presentation, storage requirements, solubility, specific activity, convenience in use).*

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[61] Expert Report to the Infected Blood Inquiry: Public Health and Administration (EXPG0000047) see page 23 §4: "*However, the IMF crisis in 1976 saw funding for the NHS frozen - much needed capital to rebuild community and primary care services, hospitals, and laboratories was halted – while revenue was under extraordinary pressure*".
[62] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §31, quoting Dr Lane.
[63] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §232.

> *ii. The impact of any process modification(s) required to take into account newly emerging risks, in particular blood-borne infectious agents like hepatitis viruses and HIV".*[64]

2.29. As Dr Snape observed, these were the complications and variables that were involved in the 1970s and 1980s in estimating demand, without factoring in the HIV crisis which was subsequently to emerge.[65]

2.30. Dr Foster's evidence was that during the 1970s he expected that demand would plateau, whereas in reality it increased every year.[66]

2.31. In addition, the HCDO only released the figures for how much product was being used 18 months – 2 years after collecting them.[67] This meant decision makers had to rely on outdated information, akin to "*…trying to hit a moving target in the dark".*[68] In turn, planning for self-sufficiency became more difficult.[69]

2.32. These difficulties had an impact on the ground. In relation to the PFC, Dr Foster described freeze-dryer capacity as "the principal bottleneck" for plasma processing at PFC. However, to order the correct number of freeze dryers (which were bespoke and made on request) one needed to be able to anticipate demand 18 months – 2 years in advance (i.e. potentially 4 years before the HCDO figures had been released).[70] The result was that production targets were insufficient – laughably so, as Professor Cash found

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[64] Appendix to Dr Snape's witness statement dated 8 February 2022 (WITN3431001), page 112.
[65] Dr Snape's oral evidence on 30 March 2022, at 131:18–131:24.
[66] Dr Foster's oral evidence on 24 March 2022, at 102:14–19.
[67] Dr Foster's oral evidence on 24 March 2022, at 95:2–96:5.
[68] Dr Foster's oral evidence on 24 March 2022, at 96:2–96:3.
[69] See for example CTI's presentation about the work and evidence of Dr James Smith and the work of evidence of Dr Richard Lane on 18 March 2022, at 138:19–139:3, which notes observations made by Dr Lane on the difficulties of forecasting for self- sufficiency.
[70] Dr Foster's oral evidence on 24 March 2022, at 83:6–83:19.

them. Professor Cash was then instrumental in changing this and instituting realistic production targets.[71]

2.33. In their presentation on domestic production and self-sufficiency, CTI and the Inquiry's legal team have traced the estimates of production needed to meet domestic demands by the clinical groups which advised the DHSS.[72] This information is not repeated. But the difficulties inherent in the exercise as well as the shifting targets that resulted, are matters which the Inquiry is invited to consider.

Dr Owen's 1975 commitment to Parliament and why self-sufficiency was not achieved within the timeframe envisaged

2.34. The answers given by Dr Owen to a number of relevant Parliamentary Questions in January and February 1975 are set out at paragraphs 103 to 105 of the written presentation on domestic production and self-sufficiency. In summary, the combined information provided to Parliament was that: i) Dr Owen had allocated special finance amounting to £500,000 to increase domestic production of Factor VIII materials; ii) this was done with the objective of making the NHS self-sufficient "*over the next few years*"; and iii) it would "*take two or three years before we are at full production*". It was Dr Owen's evidence to the Inquiry that in April 1976 he envisaged that self-sufficiency would be achieved by the middle of 1977.[73] Dr Owen's evidence to the Inquiry was further that on leaving office in September 1976 he thought that self-sufficiency was "*within sight*".[74]

[71] Dr Foster's oral evidence on 24 March 2022, at 96:6-97:2.
[72] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333).
[73] Lord Owen's oral evidence on 22 September 2020, at 105:21-105:23.
[74] Lord Owen's oral evidence on 22 September 2020, at 104:9-105:23; see too LDOW0000045 and LDOW0000044, referred to at §§117-118 of the written presentation on domestic production and self-sufficiency.

2.35. Self-sufficiency was not achieved in line with Dr Owen's expectations. There is no evidence of which the DHSC legal team is aware that this arose because there was a decision, whether by ministers or officials, to abandon the pursuit of self-sufficiency. As is addressed further below, there is evidence that self-sufficiency was actively being pursued after Dr Owen left the Department. However, despite the plasma production targets set under Lord Owen for mid-1977 being met,[75] "*...the increased production of Factor VIII as a result of DHSS investment was insufficient to keep up with demand, equating to less than half of total requirements*".[76]

2.36. We note that CTI's Presentation on Domestic Self-Sufficiency (England and Wales)[77] has traced the use of the £500,000 allocated by Lord Owen and has demonstrated that it, together with an additional £433,000 in the financial year 1975/1976, was spent on the purposes to which it was allocated. The funding was, however, used to support RTCs rather than BPL, which received no substantial investment at this stage.[78]

Work done in pursuit of self-sufficiency and key developments from May 1976 to mid-1977

2.37. In May 1976, four months before Dr Owen left office, the Expert Group on the Treatment of Haemophilia and Allied Conditions advised that the original production target that Dr Owen's commitment to self-sufficiency was based upon was "*now quite irrelevant to the widely recognised treatment needs of haemophiliacs"; "it had been rendered out of date largely by advances of*

[75] See the answer given to the first of a number of Parliamentary Questions answered by Roland Moyle, the Minister of State for Health and Social Security on 26 June 1978, at DHSC0000291; see too the statement of Dr Walford dated 5 July 2021, (WITN4461001), §12.3.
[76] §39 of appendix 1 to the written presentation on domestic production and self-sufficiency; see too §§111 and 119 of the main presentation and §28 of appendix 2.
[77] See §108.
[78] Dr Smith's evidence was that very little of the £0.5m 1975 funding reached BPL and "it did not stimulate even ground studies for a building commensurate with the task" – See his witness statement dated 27 July 2020 (WITN3433001), at §170, See also CTI written presentation on the Evidence of Dr James Smith on March 2022 (INQY0000329), at §52.

home therapy".[79] Dr Owen was informed by Mr Dutton of the views of the Expert Group, and in particular their view that *"our present NHS Factor VIII production programme may provide no more than about 1/3 of the likely requirements for Factor VIII a few years from now"*, on 18 June 1976.[80] Dr Owen's response was set out in a minute from G E Grimstone to Mr Dutton dated 21 June 1976:

> *"Dr Owen has seen your minute of 18 June about the likely requirements for Factor VIII a few years from now and has commented:-*
>
> *"This was inevitable and comes as no surprise at all. This only demonstrates once again why we must reform the Blood Transfusion Service.""* [81]

2.38. Following a meeting of the Central Committee of the Blood Transfusion Service on 22 June 1976, at which the Expert Group's advice was considered,[82] a detailed note was prepared by Mr Dutton and Dr Waiter, departmental officials and the joint secretaries to the Central Committee for the National Blood Transfusion Service on the requirement for blood products and their availability. It was dated September 1976 and provided to Central Committee members under cover of a minute in October 1976.[83] The following prescient observation was made about the pursuit of self-sufficiency:

> *"In view of Ministers' concern that the NHS should attain self-sufficiency in blood products the Department should consider carefully what is involved. So far, self-sufficiency has been thought of almost entirely in terms of Factor VIII requirement but there are other blood components available to the NHS from commercial sources.* ***Self-sufficiency in blood products is clearly not a static situation which once achieved will require only infrequent modification.*** *In the fullest sense it would mean attempting to keep up with developments in the world industry in blood products which shows few signs of reducing its activities despite WHO resolutions about the undesirability of relying on paid donors."* [84] (Emphasis added)

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[79] The minutes of the meeting of the Expert Group on the Treatment of Haemophilia and Allied Conditions on 4 May 1976 at CBLA0007964, page 3.
[80] DHSC0100006_143 and DHSC0100006_144.
[81] DHSC0100006_145.
[82] See §7 of the minutes at DHSC0103254.
[83] The covering minute and the note are at DHSC0002181_045.
[84] DHSC0002181_045, §10.

2.39. The covering minute informed Central Committee members that representatives of the health departments had met on 20 October 1976 to consider how to form the best available view on the likely future trends in the demand for blood and blood products. They had decided to set up a small expert group to examine the literature on the subject and consult as widely as necessary to consider likely trends.[85] This led to the establishment of the Working Group on Trends in Demand for Blood Products in January 1977 and the production of its report in December 1977.[86] The advice of this Working Group and the Department's response to that advice is addressed further below, in the context of departmental decisions relating to the redevelopment of the BPL site at Elstree.

2.40. The documents summarised above suggest that:

(1) It was clear by May 1976 that self-sufficiency was not going to be achieved by mid-1977, something that Dr Owen was briefed on by officials.

(2) This was not because targets for the levels of plasma provided to BPL by the Regional Transfusion Centres had not been met (it was reported to the Central Committee at its 22 June 1976 meeting that plasma was being sent to the Blood Products Laboratories *"at a rate which is well up to the expected amount"*). It was because there had been a significant increase in demand for Factor VIII concentrates, said by the Expert Group on the Treatment of Haemophilia and Allied Conditions advising the Department to be attributable to increased use of home treatment.[87]

(3) Work was done by departmental officials to analyse the difficulties that existed in increasing domestic production of blood products and the health departments took the active step of establishing the

[85] DHSC0002181_045, §10.
[86] DHSC0001318.
[87] In addition to the minutes of the Expert Group meeting (CBLA0007964) at page 3, see §§142-143 of the written presentation on domestic production and self-sufficiency.

Working Group on Trends in Demand for Blood Products in response to the new expert advice.

Information provided to Parliament about the pursuit of self-sufficiency

2.41. It is apparent from the documentary record that Parliament was updated periodically about progress on self-sufficiency. To assist the Chair, some illustrative examples of the information provided to Parliament about the pursuit of self-sufficiency from the middle of 1977 onwards are set out below. For ease of reference, we have considered the subject as a whole, up to the 1990s, before returning to events in late 1970s.

2.42. In an answer given to a Parliamentary Question by Mr Roland Moyle (then the Minister of State) on 26 June 1978, he explained as follows:

> *"The production target of Factor VIII set for June 1977 was attained; however, new opportunities in the treatment of haemophilia and associated disabilities have been developed which have made further clinical demands for Factor VIII."* [88]

2.43. The events that led to ministers deciding to build a new laboratory on the Elstree site on a scale capable of meeting estimated future demand are set out below. When consideration was being given to involving private industry in the redevelopment of the BPL at Elstree, Parliament was told by way of a written answer to a Parliamentary Question given by Dr Gerard Vaughan, the then Minister of State.[89]

2.44. Once a decision was made to build a new laboratory at Elstree without industry involvement in November 1980, Parliament was informed by way of a written answer to a Parliamentary Question from Dr Vaughan:

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[88] DHSC0002187_049_001.
[89] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §20.10.

> *"The Blood Products Laboratory at Elstree is the main centre for developing blood products in England and Wales. The laboratory was built in the 1960s and requires modernisation and expansion. The first stage of modernisation is now under way. This will increase the capacity of the laboratory considerably, but not sufficiently to meet all the needs of the NHS in the future. We have been considering how best to develop the laboratory still further. Among a number of possibilities we have considered bringing in commercial management.*
>
> *However the blood donor service in this country is a voluntary service and we are proud of it. After exploratory discussions we have concluded that there is no place for a commercial company in the management of a service which depends on volunteer donors. There is therefore no question of commercial management of the Blood Products Laboratory".*[90]

2.45. There was an Adjournment Debate on 15 December 1980 concerning the Blood Transfusion Service and BPL in which more details about the redevelopment of the Elstree site and the events leading to it were provided to Parliament by Sir George Young, the then Under Secretary of State for Health and Social Security.[91]

2.46. A number of answers were given to Parliamentary Questions about self-sufficiency whilst BPL was being re-developed during 1983 and 1984 including, for example, the written answers given by Mr Kenneth Clarke when he was Minister of State for Health on 5 July 1983, 11 July 1983 and 28 November 1984.[92] Mr Norman Fowler also answered a Parliamentary Question relating to progress on self-sufficiency in November 1984.[93]

2.47. When it was apparent that there were implications for self-sufficiency caused by the impact of heat-treatment on product yield, this was explained to Parliament by way of a written answer given by Mr Clarke on 5 February 1985:

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[90] PRSE0000063.
[91] WITN4461044.
[92] See WITN0758002, DHSC0006401_005 and DHSC0002251_014.
[93] See DHSC0002251_012.

> *"At present the blood products laboratory, Elstree manufactures almost half of the National Health Service consumption of Factor VIII. BPL has started to heat treat its factor VIII, and limited amounts will be distributed to the National Health Service for clinical trials within the next two weeks. Heat treatment capacity is being increased, and it is hoped that, by April this year, all BPL factor VIII will be heat-treated.*
>
> *The major redevelopment of BPL is on schedule to open in January 1986. This is intended to provide the capacity to meet the forecast demand on the National Health Service in England and Wales for factor VIII. The heat-treatment process however reduces product yield and the consequences of this for the timetable for achieving self-sufficiency in factor VIII is being examined."* [94]

2.48. Further information about progress on the new BPL and self-sufficiency was provided to Parliament in 1985, including by way of answers to Parliamentary Questions given by Mr Clarke on 5 February 1985 and 19 February 1985[95], Baroness Trumpington on 24 July 1985[96] and Mr Barney Hayhoe, Mr Clarke's successor as Minister of State for Health, on 12 November 1985.[97]

2.49. An explanation for the delays in the construction of the new BPL was given in the House of Lords by Lord Hesketh on 31 March 1987, shortly before the new BPL was officially opened on 29 April 1987, in response from a Parliamentary Question from Baroness Masham of Ilton:

> *"My Lords, in 1981 approval in principle was given for the construction of a new blood products laboratory at Elstree. Construction began in May 1983.*
>
> *To enable the building to be completed earlier than traditional methods would allow, a "fast track" design system and build contract was adopted. When an innovative unit like the laboratory is built under this method, it is extremely difficult to forecast the completion date accurately at the outset. At that time our working assumption was that the new BPL would be completed at the end of 1985 or early 1986. There is no single identifiable reason for the building taking longer than expected other than the complexity of the design being greater than anticipated. The building will still have been completed two or three years earlier than traditional contracting methods would have allowed.*

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[94] CBLA0002020.
[95] See MACK0000067_007 and DHSC0002261_043.
[96] PRSE0000894.
[97] WITN0771054.

> *However, I am now pleased to say that the building will be officially opened at the end of April. After commissioning, limited production will begin later this year. Self-sufficiency will follow."* [98]

2.50. On 12 November 1987, Mr Newton gave a revised estimate of when self-sufficiency was expected to Parliament:

> "Scotland and Northern Ireland are self-sufficient in all blood products. England and Wales are already self-sufficient in many. To ensure complete self-sufficiency a new blood products laboratory has been built at Elstree at a cost of £60 million. The new factory was officially opened on 29 April 1987. Production is expected within the next few months leading to very substantial output in 1988 and self-sufficiency *in 1989."*[99]

2.51. An explanation of the government's position on self-sufficiency by the early 1990s was given to Parliament by way of a written answer to a Parliamentary Question given by Mr Stephen Dorrell, the Minister of State for Health, on 29 January 1992:

> *"To ask the Secretary of State for Health (1) what assessment his Department has made of the implications of the single European market on progress towards national self-sufficiency in blood and plasma products; and if he will make a statement; (2) by what date he envisages that the United Kingdom and Europe will have self-sufficiency in blood and plasma products.*
>
> *The EC directive which harmonises the licensing requirements for blood products promotes a policy of Community self-sufficiency in such products derived from the donations of voluntary and unpaid donors but does not forbid importation. This is consistent with our own long-standing policy of seeking self-sufficiency in blood products sourced from our own volunteer donors. Nevertheless, while promoting self-sufficiency we also recognise the clinical freedom of doctors to choose the product most suitable for an individual patient. Imported products are being prescribed in this country as the result of the preference of individual clinicians. The Bio-Products Laboratory is meeting in full the current demand for its blood products and continues to make efforts to increase its share of the blood products market but the choice of product remains with the clinician. No target date has yet been set for*

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[98] Hansard: https://hansard.parliament.uk/Lords/1987-03-31/debates/f3262c8d-c8ab-4eac-bb19-54357a14f07b/BloodProductsLaboratory

[99] Hansard: https://hansard.parliament.uk/Commons/1987-11-12/debates/710898e1-cdbb-4914-8c0e-ec62a93a1abb/BloodProducts?highlight=self-sufficiency#contribution-9c13d1ca-c8ee-46e1-a8a5-d44f98f07b28

the achievement of self-sufficiency in blood products throughout the EC." [100]

Knowledge that fractionating capacity would need to be increased significantly to achieve self-sufficiency and the timing of the decision to build a new laboratory on the Elstree site

2.52. One of the issues identified in the Inquiry's List of Issues (as amended in September 2021) is whether decisions relating to the redevelopment of BPL should have been taken earlier.[101] To assist the Chair in relation to this issue, a summary of the evidence about i) when it became known to the Department that fractionating capacity would need to be increased in order to achieve self-sufficiency; and ii) the timing of the decision to build a new laboratory on the Elstree site is set out below.

2.53. When the requirements for self-sufficiency were first being considered by the Department in the spring of 1973, the escalation in demand for factor concentrates that was to come and the implications for the capacity of UK fractionation plants to fractionate enough plasma to meet that demand were not yet forecast. As is highlighted in the written presentation on domestic production and self-sufficiency,[102] it was the view of Dr Maycock, the Director of the Blood Products Laboratory and Consultant Advisor to the Department on Blood Transfusion Policy, expressed at a departmental meeting on 14 May 1973 that the laboratories at Elstree and Liberton, once the latter was operational (expected to be by the end of 1974), would have the capacity to increase production of AHG concentrate to meet UK demand, albeit that some additional staff and equipment would be required at both

[100] Hansard: https://hansard.parliament.uk/Commons/1992-01-29/debates/f9c79e2e-3942-4843-a170-5999cc05d18b/BloodAndPlasma?highlight=self-sufficiency#contribution-a3f7594c-f26c-46dc-88be-b6ad85899fdb; see too the answer given by Mr Sackville on 21 October 1994: https://hansard.parliament.uk/Commons/1994-10-21/debates/06727b35-3de4-4d4d-a506-ef5d456683ca/Blood?highlight=self-sufficiency#contribution-714fbcea-2cd7-473b-b21e-23b82dd691e3
[101] Issue 61.
[102] At §§51-52.

laboratories.[103] When a reconsideration of future demand took place in January 1974,[104] the view being expressed at a joint meeting of the directors of Haemophilia Centres and the Blood Transfusion Centres on 31 January 1974, attended by most of the leading figures in the field as well as Dr Maycock and Dr Waiter from the Department, remained that ...*"once the new fractionation laboratories in Edinburgh and at the Lister Institute were in full production they should be able to meet the needs of the country provided sufficient plasma was available"*, albeit that additional staff, equipment and facilities would be needed to allow them to process more plasma.[105]

2.54. At the time that a decision was made by Dr Owen in December 1974 to allocate special finance amounting to £500,000,[106] the overriding concern was to increase the plasma supply to Elstree. The failure to achieve such an increase was behind the *"limited progress"*[107] made in increasing domestic supply since the first meeting of Expert Group on the Treatment of Haemophilia meeting in March 1973. Whilst a small proportion of the £500,000 provided from central resources went to the BPL at Elstree for the purchase of additional equipment that would be made necessary by an increase in plasma supply to the laboratory,[108] the vast majority was provided to regional health authorities ("RHAs") to increase plasma supplies

[103] The note of the meeting of 14 May 1973 at DHSC0100005_022; see too the view of Dr Maycock expressed at a special meeting of the Regional Transfusion Directors held on 20 July 1973 (attended by a number of Department representatives, including Dr Waiter) that meeting the total amount of plasma required for the preparation of AHG concentrate would require a large proportion of plasma used for cryoprecipitate to be sent to Elstree for the preparation of concentrate, for which the necessary fractionation capacity would be available at BPL (page 2 of the minutes at CBLA0000153, §4).
[104] As discussed at §§64-72 of the written presentation on domestic production and self-sufficiency.
[105] Minutes of the 31 January 1974 meeting at CBLA0000187, page 7.
[106] Dr Owen's decision on this was communicated to officials on 11 December 1974 (DHSC0100005_191) and announced in Parliament in early 1975 (answers to Parliamentary Questions given on 22 January 1975 (DHSC0000274), 25 February 1975 (HSOC0015202) and 26 February 1975 (DHSC0000276)); these documents and relevant correspondence from officials are summarised at §§99-105 of the written presentation on domestic production and self-sufficiency.
[107] The Department does not disagree with the characterisation of the situation suggested at §88 of the written presentation on domestic production and self-sufficiency.
[108] Appendix 3 to the written presentation on domestic production and self-sufficiency draws support from the draft proof of evidence of Dr Lane dated 10 December 1990 to give an estimated figure of £58,000 for this expenditure.

for fractionation.[109] This *"'pump priming' operation"*[110] addressed only one of the three elements that determined the UK's capacity to produce domestic factor concentrates.[111] This appears from the contemporaneous documents to have been because it was not yet appreciated that Elstree would need wholesale re-development on any scale, let alone on the scale that was ultimately proceeded with.

2.55. It appears from the documents that the first time an expert group advised the Department that the blood product laboratories in the UK did not have the capacity to produce the level of factor concentrates likely to be required to meet domestic demand was when the Working Group on Trends in the Demand for Blood Products ("the Trends Working Group") set up by the health departments in January 1977 produced its report of December 1977.[112]

2.56. The Trends Working Group had been tasked with considering the likely trends in blood products (not just factor concentrates) over the next 10 to 15 years. It is clear from the December 1977 report that the Health Department's aim was still to achieve self-sufficiency in therapeutic blood products.[113] The Trends Working Group estimated that the amount of albumin that would be required in the next 5 to 10 years was 200gm per 1000 population. Members believed that if sufficient blood were to be collected to provide 200 grams per 1000 population in albumin, approximately 1300 international units of Factor VIII would be available per 1000 population (an amount exceeding the Trends Working Group's

[109] A detailed analysis of allocation of funds between individual RHAs is helpfully set out at Appendix 3 of the written presentation on domestic production and self-sufficiency; an explanation of the programme was provided to regional health administrators in a letter from B.O.B Gidden dated 24 December 1974 at CBLA0000239.
[110] As it was described by Mr Dutton from the Department in a letter to the North West Thames RHA dated 21 June 1976 (DHSC0103283_102), cited at §96 of the written presentation on domestic production and self-sufficiency.
[111] The Department agrees with the description of the three elements at §6 of the written presentation on domestic production and self-sufficiency.
[112] DHSC0001318.
[113] See page 2 of the report DHSC0001318.

estimate of what would be needed to meet the needs of haemophiliacs in the foreseeable future of 1000 international units per 1000 population).[114]

2.57. To meet the target for albumin, the Trends Working Group suggested increasing blood collection from 50 donations per 1000 population to 60 donations per 1000 population in the next 10 years and substantially increasing clinical use of red blood cell concentrates. In terms of the investment that would be required to enable production of blood products at the level of estimated requirement, the Trends Working Group said this:

> *"Considerable further investment in collecting, testing, processing and premises will be required to meet these targets. It will be a major undertaking for most Regional Transfusion Centres to increase further both blood collection and output of red cell concentrates. It is not expected that, given adequate publicity, difficulty will be encountered in recruiting the additional donors needed to provide 200 grams albumin per 1000 population per annum but increased blood-collecting resources, accommodation and equipment will be needed in the Regional Centres.*
>
> *Additional fractionation capacity is also needed, even allowing for some possible expansion of the Liberton plant's output. The present UK capability is less than half that we regard as essential. Additional major investment is, therefore, also needed for this."* [115]

2.58. Focussing on the production capacity of the BPL at Elstree, it was apparent even before the Trends Working Group's report was produced, by the autumn of 1977, that BPL's *"stretched"* capacity would very shortly be reached[116]. The Department's acceptance by October 1977 that there was a need to expand blood products production and that a phased redevelopment solution for Elstree, such as that being put forward by Dr Lane, should be explored, is apparent from the note of a meeting held on 25 October 1977 and attended by BPL representatives (including Dr Maycock and Dr Lane)

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[114] As noted at §45 of Appendix 1 to the written presentation on domestic production and self-sufficiency, this equated to an estimated level of need of approximately 50 million international units for Factor VIII, with approximately 74 million international units provided for by the albumin programme.
[115] DHSC0001318 at page 4-5, §8.
[116] Dr Maycock's observation in a September 1977 report produced for the Advisory Sub-Committee on Blood Products and Blood Group Reference Laboratories (CBLA0000664 at page 1); the 25 October 1977 meeting between representatives of BPL and the DHSS (CBLA0000682, Dr Lane's comments summarised at §3(a).

and representatives of the Department (including Mr Parrott, Mr Dutton and Dr Waiter):

> *"The need to expand blood products production, provided this was done on the basis of low-cost, selective development, was now being accepted by the Department, and the importance of maintaining a separate production unit for England and Wales and of not being totally reliant on the Scottish PFC at Liberton had recently been affirmed. The Department would therefore welcome further development of these ideas by BPL leading to the preparation of realistic development plans, based on agreed production targets."*[117]

2.59. Also evident from the note of the meeting are the limitations for development that existed because of the size of the area that was, at that time, leased by BPL:

> *"7.3 The present area leased by BPL (about 1/8 of the whole Lister Institute 36 acre site) was too congested to allow further building there. Any new construction at the BPL would therefore involve the leasing of more land from the Institute, and informal soundings with the Governing Body by BPL would precede any formal approach."*[118]

2.60. As is recognised at paragraph 190 of the written presentation on domestic production and self-sufficiency,[119] it was not until the land surrounding the existing laboratory was purchased that *"...a more complete redevelopment..."* of the site at Elstree was possible. Following the announcement on 17 April 1978 that the Lister Institute would no longer be running BPL, early consideration was given to whether part or the whole of the Elstree estate should be purchased by the Department from the Lister Institute.[120] The decision had been taken for the Department to purchase the whole of the Elstree estate and negotiations were well underway by August 1978.[121] Although a provisional figure for the purchase of the Elstree

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[117] CBLA0000682, §4.
[118] CBLA0000682, §7.3.
[119] And apparent from Dr Lane's May 1979 paper to the Department and the Joint Management Committee for the Central Blood Laboratories (BPLL0001508, §1 of the summary and p. 18 of the report).
[120] The Lister Institute had raised the sale of the land in a letter dated 26 May 1978 and officials from the Department met with Dr Maycock and Dr Lane to discuss the options on 7 June 1978 (DHSC0002325_024).
[121] See Dr Maycock's letter to Mr Dutton dated 31 August 1978 at DHSC0020820_058; see too the witness statement of Peter Wormald dated 4 November 2022 (WITN6934001), §3.5.

site had been negotiated by December 1978, issues identified as a result of surveys done on the land meant that the sale was not completed until the following financial year, shortly before the 12 September 1979 meeting of the Joint Committee for the Central Blood Laboratories.[122]

2.61. Once a firm decision had been taken for the Department to purchase the Elstree estate, developing a new laboratory on the Elstree site with the fractionation capacity to meet the future level of demand for blood products estimated by the Trends Working Group became a possibility for the first time. Dr Lane revised his proposals for a phased development of the laboratory at Elstree[123] and his May 1979 paper for the Department and the Joint Management Committee for the Central Blood Laboratories advanced the case for "*...a new laboratory with a capacity scaled up to five times the present level*".[124]

2.62. Consideration of Dr Lane's paper at the 7 June 1979 meeting of the Joint Management Committee's Scientific and Technical Committee was overshadowed by a report on the provisional findings of the Medicines Inspectorate.[125] The report of the Medicines Inspectorate was not provided until 10 September 1979.[126] By way of a minute dated October 1979 from the Chairman of the Scientific and Technical Committee, the Committee provided its view on the implications of the findings of the Medicines Inspectorate.[127] Remedial action was needed: there was a need for

[122] See the minutes of the 13 December 1978 meeting of the Joint Management Committee for the Central Blood Laboratories at CBLA0000889 and the minutes of the 12 September 1979 meeting of the Joint Committee for the Central Blood Laboratories at DHSC0002195_028.
[123] Although it is right to note here that in his 1986 paper, Dr Lane had referred to the need for "... a new production building with relocation of production and alternative use of existing BPL buildings" being put forward by him earlier in December 1978. (CBLA0002298), page 2.
[124] Dr Lane's May 1979 paper to the Department and the Joint Management Committee for the Central Blood Laboratories at BPLL0001508, page 21. This was said to equate to 120M iu of Factor VIII per annum and the albumin and other products pro rata or according to need (page 20). See pages. 18-23 of the report for the detail of the proposal.
[125] As is noted at §195 of the written presentation on domestic production and self-sufficiency.
[126] The covering letter is at CBLA0000988 and the report is at DHSC0001812.
[127] DHSC0002195_069.

immediate upgrading but also a new plant.[128] Officials then worked up a submission to go to ministers on the *"present and future operation"* of the BPL at Elstree, the final version of which was sent on 21 December 1979.[129] One of the proposals in that submission was, as is addressed below, that ministers agree to the principle of re-building the laboratory at Elstree.

2.63. The Chair is invited to consider the chronology of events set out above when making his determinations about why it was not until December 1979 that a submission proposing the building of a new laboratory on the Elstree site was put up to ministers and whether it would have been possible for this point to have been reached sooner.[130]

1980 – 1988: Obstacles to the implementation of "stop-gap" proposals and the re-development of BPL

2.64. There is evidence before the Inquiry to suggest that there were delays in the implementation of stop-gap proposals and in the re-development of BPL. The Chair is invited, when considering this issue, to take the following points of context into account.

2.65. First, as is set out at paragraphs 187 to 189 of the written presentation on domestic production and self-sufficiency, the original stop-gap proposals presented to the Department by BPL on 20 December 1977 were impacted upon by the announcement in April 1978 that the Lister Institute was to cease running the BPL at Elstree. The revised proposals in Dr Lane's May 1979 report were then impacted upon by Medicines Inspectorate Report.

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[128] Dr Walford's witness stated dated 5 July 2021 (WITN4461001), §15.31.
[129] DHSC0002307_048 and DHSC0002307_050.
[130] See too Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §§15.1-15.3 in relation to the timeframe for officials working up the submission to ministers put up in December 1979.

2.66. Second, whilst the Minister of State for Health at the time, Dr Vaughan, declined to commit to a decision in principle to re-build BPL in January 1980, despite officials proposing such a commitment in the submission of 21 December 1979, he did agree that *"...planning should go ahead for the redevelopment of BPL"*[131]; and options for re-building should be explored. A plan was put in place by officials accordingly,[132] including consultation with industry on building and running a plant to process raw materials provided by the NHS to be completed within 6 months and work on the requirements for the new BPL if built with public money, plus costings for these requirements.[133] Work was done on both options – industry involvement and the plant being built with public money. It is also clear that by March 1980 the Minister of State had accepted that the BPL would be re-built, despite the fact that the "how" (and in particular whether industry would be involved) was still to be determined.[134] It is also right to note that even some officials were in two minds when the submission to ministers of 21 December 1979 was being drafted whether to suggest taking a decision to commit to re-building BPL at that stage, in light of all the outstanding unknowns.[135]

2.67. Third, whilst the decision was ultimately made in November 1980 not to involve private industry in the future management of BPL,[136] there were good reasons for exploring this possibility (including the fact that a private sector arrangement might include industry putting up capital to provide a new facility or facilities, and thus enable them to be brought on stream more quickly)[137]. It is the evidence of Mr Wormald, who was a departmental official advising ministers at the time, that it was not only *"...officials' duty to explore such possibilities for blood products..."*, given government policy at the time, but that this policy reflected the need to explore whether such

[131] Dr Walford's witness stated dated 5 July 2021 (WITN4461001), §17.10; DHSC0000862.
[132] See Dr Walford's summary of actions arising from ministers' decision, set out in WITN4461029.
[133] Points 1, 5 and 6 in the minute at WITN4461029.
[134] See note of discussions held during Dr Vaughan's visit to BPL on 21 March 1980 at DHSC0002307_041; and Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §18.1.
[135] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §14.18 and §§20.3-20.4.
[136] Announced on 26 November 1980: HCDO0000003_042; SCGV0000127_025; and DHSC0002307_069
[137] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §12.1.

investment or expertise might aid BPL development.[138] That this view not only held but publicly stated at ministerial level is evident from Sir George Young's speech to Parliament during the adjournment debate on 15 December 1980:

> *"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."* [139]

2.68. Fourth, there was a reluctance to commit to high levels of spending on stop-gap measures if a new laboratory was to be built in the near future. Ministers were anxious that the Public Accounts Committee should be satisfied that the cost of the short-term improvements at BPL were justified in view of the fact that the laboratory was to be rebuilt.[140] The extent of the works that ministers were willing to commit to was directly impacted on by how quickly a new BPL could be built, something which was dependant on a number of factors including whether a commercial firm would be used to plan, design, supervise construction and commission the new BPL, which could not be decided without reference to the wider decision on who would be running BPL in the future.[141]

2.69. Fifth, notwithstanding this, work on certain items did progress whilst the various options for expenditure on stop-gap measures were being explored with ministers. For example, a decision was made in December 1979 to proceed at once with a list of interim works required at BPL, on the understanding these could be met within the existing allocation for stop-

[138] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §12.1.
[139] NHBT0006435_007.
[140] See the minutes of the meeting of the Scientific and Technical Committee of the Joint Committee of the Central Laboratories on 23 April 1980 at CBLA0001093 at page 3.
[141] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §20.3; Dr Walford's minute dated 12 June 1980 at DHSC0002307_008; Mr Harris' minute of 27 June 1980 at DHSC0002307_014.

gap;[142] and authorisation was given by Dr Vaughan for up to £90,000 for the installation of 5000 cubic feet of modular cold storage at the existing laboratory in June 1980.[143]

2.70. Sixth, decisions about the future of the BPL at Elstree were being made at a time when the Department was facing notable financial pressures. The Public Health and Administration Group's Expert Report has noted how *"...the IMF crisis in 1976 saw funding for the NHS frozen – much needed capital to rebuild community and primary care services hospitals and laboratories was halted- while revenue was under extraordinary pressure".*[144] Government policy at the time was to keep public expenditure under strict control.[145] As Dr Walford explained in her written statement to the Inquiry:

> *"Funding at the time was exceptionally constrained... According to the Nuffield Trust, the Government spent approximately 4.52% of Gross Domestic Product (GDP) on the NHS in 195/76. This fell to 3.96% of GDP by 1979/80 and was then followed by a deep recession in 1980. As should be apparent from the events described below, 'the elephant in the room' for all discussions, including the redevelopment of BPL and the production of additional plasma for national self-sufficiency, was that funding from the Department's budget for centrally-funded services, such as BPL, was inadequate and capital funding was especially hard to obtain."* [146]

2.71. Seventh, despite the significant financial pressures that existed at the time, more ambitious short-term improvements allowing for an increase in

[142] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §15.40; Mr Dutton's minutes dated 5 December 1979 at WITN4461027.
[143] See the minutes of the meeting of the Scientific and Technical Committee on 18 June 1980 at CBLA0001119, Mr Wormald's minute of 24 June 1980 at DHSC0002307_010 and Mr Harley's minute of 25 June 1980 at DHSC0002197_125.
[144] Expert Report to the Infected Blood Inquiry: Public Health and Administration, August 2022, at **EXPG0000048** page 2.
[145] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §13.5.
[146] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §D5; see too Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §14.11 on the impact of spending on BPL on services elsewhere.

production and the additional sum requested to finance this were recommended and approved in July 1980.[147]

2.72. Eighth, the debate about whether the new BPL could be developed in collaboration with industry was complex and until this was resolved any real planning for the re-build (and any kind of realistic estimate of scale of the project, cost and timeframe) was not possible. This is relevant to the question of whether, even if an official commitment to the re-build had been given earlier, a plan could have been put in motion much sooner.[148]

2.73. Ninth, within a month of the public announcement on 26 November 1980 that there was no role for private industry in the redevelopment of BPL, ministers had instructed officials that planning and design should begin on the redevelopment scheme at the Blood Products Laboratory.[149] Ministers agreed to proceed with this immediately rather than waiting for estimated costs to be provided.

2.74. Tenth, whilst it was nearly five years from the start of construction on the new BPL in May 1983 until it officially opened in April 1987, some 21 months after the original completion date expected in November 1982,[150] the following features of the re-development project should be borne in mind:

(1) It was agreed that there should be a "design and build" approach to construction, whereby the design and construction of the building would take place simultaneously.[151] This was so that the project could be fast-tracked and could remain flexible enough to respond to

[147] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§20.6-20.7. Options involving lesser expenditure were rejected. of approval of capital expenditure totalling £1.3 million over the next 2 years, plus increased revenue of £0.1 million per year from 1981/2.
[148] It is the evidence of Peter Wormald that "a start could not have been made until 1981 at the earliest", allowing for planning, design and tendering: Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §14.10. §14.19.
[149] See the minute from J E Knight to Mr Harley dated 8 January 1981 at WITN4461046, confirming the outcome of a meeting between Dr Vaughan, Mr Young (PS(H)) and officials on 17 December 1980.
[150] See DHSC0002303_018.
[151] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §4.30.

changes in technology, equipment, and processes.[152] This selection also carried considerable risk, however, as it was difficult at such an early stage to properly estimate construction length and cost.[153]

(2) The Inquiry has heard evidence that it was not unusual in the 1980s, or today, for there to be unforeseen costs and delays in projects such as the re-development of BPL.[154]

(3) Ultimately, despite the delays, the "design and build" approach served its function. The view of departmental officials in 1986 was that even with the delayed completion date, the project would still be completed two to three years quicker than conventional models of construction would have allowed.[155]

(4) Throughout the redevelopment of the BPL, the Department was under immense pressure to cut spending. Lord Fowler explained:

> *"...shortly after becoming Secretary of State when the Cabinet got down to reviewing public spending following the 1981 reshuffle. Every piece of spending was reviewed at that time and would have included the £17 million planned for the redevelopment of BPL. In this spending review, there was fierce pressure for cuts in health spending..."* [156]

In oral evidence, he elaborated that in 1981/82, the Department was under even more pressure to cut spending than normal.[157] Each increase for the BPL came from the Department's budget, not the Treasury Reserve.[158] As such, a decision to spend more on the BPL came at a cost to other health care priorities. Nonetheless, ministers continued to approve the additional funding that the project required. Lord Fowler's evidence to the Inquiry on this was as follows:

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[152] Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §4.22.
[153] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §85.7.
[154] Transcript of Lord Clarke's oral evidence on 28 July 2021, at 120:18-121:15. See also Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §4.8.
[155] Lord Fowler witness statement dated 17 July 2021 (WITN0771001), §4.59; and the submission from Mr Harris at WITN0771066.
[156] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §4.67.
[157] Transcript of Lord Fowler's oral evidence on 21 September 2021, at 80:6-80:8.
[158] Lord Clarke's first witness statement dated 1 July 2021, §4.31.

> *"..... at every point, we put the goal of achieving self-sufficiency ahead of financial concerns (despite all the Treasury pressures). In short, we continually found the extra funding to keep the redevelopment project live. The £60 million to which the cost limit was amended in 1987 equates to about £180 million in today's money. I would wish to emphasise the very considerable level of investment that this represents, particularly given the financial pressures on health spending."* [159]

The difference that self-sufficiency would or might have made

2.75. One of the issues for the Inquiry's determination is what difference self-sufficiency would or might have made to the risk of infection and to the number ultimately infected.[160] This issue is not straightforward and the answer may depend in large part on the point in time by which it is assumed self-sufficiency could have been achieved. The answer may also be different for HIV and Hepatitis C.

2.76. The Inquiry has, in September 2022, received evidence from its Expert Group on Statistics of the numbers of those infected with HIV through blood products in the UK, from 1970 – 1991[161] and the numbers of those infected with Hepatitis C, during the same period.[162] In relation to HIV, there is data relating to the first date of a HIV diagnosis, showing the first recorded diagnosis to date from 1979, but the data relates to date of diagnosis rather than when the infection was contracted [163] [164]. There is further data for the first recorded positive antibody test, but again the report notes that the year of diagnosis "*...does not necessarily represent the year of infection due to delays in diagnosis, missing positive tests, and, for those infected abroad, confirmatory HIV diagnosis in the UK*".[165] There is no information available about the dates at which HCV may have been contracted.

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[159] Lord Fowler's witness statement dated 17 July 2021, §4.81.
[160] Issue 66 in the Inquiry's List of Issues (as amended in September 2021).
[161] EXPG0000049, page 1 and pages 8-18.
[162] EXPG0000049, page 2 and pages 19-32.
[163] EXPG0000049, page 14.
[164] Not all the individuals will have been infected in the UK; see EXPG0000049, page14 and page 16 for issues relating to the limitations on information relating to the country of infection.
[165] EXPG0000049, page 17.

Levels of domestic HCV infection

2.77. There is evidence before the Inquiry that prior to the introduction of heat-treated products, almost all of those treated with Factor VIII concentrates, whether from the US or from the UK were infected with HCV, at least after the introduction of large-pool concentrates.

2.78. There is further evidence that the high "attack rate" from the UK product was not appreciated until the late 1970s/early 1980s and 1983 in particular. Until then, the belief had been that UK products carried a lower risk of infection.

2.79. As to the first proposition, the matter was summarised by Lord Penrose, describing the paper co-authored by Dr Lee with TT Yee and others entitled *"The natural history of HCV in a cohort of haemophilic patients infected between 1961 and 1985",* published in 2000.[166] The paper reported on a study of the clinical and treatment records of 310 haemophilia patients registered at the Royal Free Hospital Haemophilia Centre. Lord Penrose wrote:

> *"The study provided concrete evidence for the generally held view that almost all haemophilia patients treated with Factor VIII concentrates prior to 1985 (when virucidal treatment of concentrates was introduced) were infected with HCV, at least after the introduction of large-pool clotting factors."* [167]

2.80. The Inquiry will be familiar with the academic or research literature on this issue, which includes, in addition to the 2000 paper from Professor Lee referred to above:

(1) The paper by Professor Kernoff received by British Journal of Haematology on 20 June 1984, accepted for publication on 22

[166] The paper is at PRSE0002936.
[167] Lord Penrose Final Report at §13.120; large pool clotting factor IX and VIII concentrates said to have been introduced in 1961 for Factor IX and 1976 for Factor VIII, see footnote 196 in Chapter 13 of Lord Penrose Final Report.

October 1984 and published in 1985, entitled "High risk of non-A, non-B hepatitis after first exposure".[168]

(2) The paper authored by Dr Fletcher with Dr Craske and other colleagues and published in the British Medical Journal on 10 December 1983.[169] The paper was based on a study of haemophilia patients at the Oxford Haemophilia Centre over a period of at least a year and the findings were that there appeared to be a 100% attack rate for first time treated patients who received NHS Factor VIII concentrate.[170]

2.81. The research was discussed in evidence to the Inquiry by Dr Colvin,[171] Professor Thomas[172] and Professor Lee[173]. Professor Lee's evidence in her written statement to the Inquiry about the Kernoff paper was as follows:

> *"The significance of the paper was that 100 per cent of people who received a large pool plasma derived clotting factor concentrate whether the plasma came from British donors (the NHS) or whether it came from commercial donors which at that time were mostly American would get NANB hepatitis albeit the disease was self-clearing in a minority of cases. This came as a surprise."* [174]

2.82. As to the developing knowledge of clinicians about the extent of the risk of NANB in domestic products at the time, this is charted by the progression from the paper from 1979, to those published in 1983 – 1985, and was further discussed in the hearings referred to above.

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[168] P.B.A Kernoff, C.A Lee, P Karayiannis and H.C Thomas 'High risk of non-A non-B hepatitis after a first exposure to volunteer or commercial clotting factor concentrates: effects of prophylactic immune serum globulin,' British Journal of Haematology, 1986, vol 60, p. 469-479 at WITN0644041.
[169] M.L Fletcher, J.M Trowell, J. Craske, K Pavier, C. R Rizza, 'Non-A non-B hepatitis after transfusion of factor VIII in infrequently treated patients.' British Medical Journal, 10 December 1983, vol.287 p.1754, at PRSE0002154.
[170] These findings were reported to the Haemophilia Reference Centre Directors by Dr Craske at a meeting on 6 September 1982 (see the minutes at HCDO0000410) and were referred to in a paper from Dr Craske proposing an extension of the study to other Haemophilia Centres dated 23 September 1982 (HCDO0000135_015).
[171] Dr Colvin's oral evidence on 6 October 2020, at 74:7-74:10.
[172] Professor Thomas' oral evidence on 24 March 2021, at 137:9-147:20.
[173] Professor Lee's oral evidence on 20 October 2020, at 16; Professor Lee's oral evidence on 20 October 2020, at 75 and 131-149.
[174] Professor Lee's witness statement dated 24 September 2020 (WITN0644058), in response to question 30, at page 25; see too Professor Lee's oral evidence on 21 October 2020, at 145-149.

Pool sizes and their relevance to HCV risks

2.83. Dr Snape addressed the developing knowledge of the risk of HCV infection from domestically produced products in his written statement to the Inquiry:

> *"Even with these measures in place* [the requirement to limit donation to volunteer, unpaid, donors and the implementation of donor testing for hepatitis B from 1972 onwards]*, it became clear from the mid-late 1970s that treatment with coagulation factor concentrates was associated with a significant risk of infection with non A non B hepatitis (NANBH), and a small residual risk of transmitting hepatitis B (HBV). We would later understand (see ¶133) that the incidence of NANBH infection post-treatment was high because the background incidence of the infective agent in the donor population was sufficient to guarantee that, even with the relatively small pools used in the UK in the 1970s, most pools would include one or more NANBH infected donations."*[175]

2.84. Prior to the advent of effective virus inactivation methods, there was therefore a significant risk of infectivity from all coagulation factor concentrates made from pooled plasma (including those products made by BPL). Dr Snape explained that pool sizes had to be over 1000 donations in order to achieve the range of antibodies required for some immunoglobulin preparations and to ensure cost-effectiveness.[176]

2.85. The Chair may recall Dr Snape's metaphor of fractionation being like a milking stool with three "streams", namely clotting factors, albumin and immunoglobulin.[177] Efficient extraction was needed to achieve maximum benefits for patients.

2.86. Increased pool sizes also had practical benefits. They improved economies of scale, reduced losses (e.g. for testing), provided more consistent quality (especially given the variations in plasma supplied by RTCs) and led to

[175] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §136.
[176] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §§160-161.
[177] Dr Snape's oral evidence on 29 March 2022, at 31:18–31:21.

greater production.[178] In the circumstances, therefore, larger pool sizes were a realistic and sensible option to increase production. Fractionators in Scotland took a similar view; Dr Foster described it as the *"only way"* to increase output in oral evidence. [179]

2.87. Dr Perry agreed, stating that a smaller pool size would have meant completely reconfiguring PFC to create a process which would be *"highly expensive"* and *"highly inefficient"*. Smaller pool sizes would also have led to *"very substantial losses in output"* due to 'line loss' (i.e. material lost between staged due to residues in tanks, QC sampling etc.). In smaller sizes 20% of the batch could be lost from QC sampling, which required a fixed number of samples.[180]

2.88. Reducing pool sizes was considered at the time but thought not to be viable.[181] A letter from Dr Cash to Dr Perry dated 7 December 1984 described any move to restrict pool size as having "*colossal cost and operational implications*".[182] Dr Lane described that option as "*quite disproportionate to the amount of product such methods could produce*".[183]

2.89. It is correct that larger pool sizes posed an increased risk. However, as is noted in the written presentation on pool sizes,[184] it was Dr Lane's view in September 1980 that, in connection with the risk of hepatitis, once the 100-200kg pool-size was exceeded,[185] any possibility of small-pool protection

[178] Dr Snape's oral evidence on 30 March 2022, at 134:24–135:7; CBLA0000005_002, page 219, §512.
[179] Dr Foster's oral evidence on 25 March 2022, at 145:2–145:8.
[180] Dr Perry's oral evidence on 31 March 2022, at 119:6–120:20.
[181] Dr Perry's oral evidence on 31 March 2022, at 121: 24–122:4.
[182] PRSE0003102 at §2.
[183] Dr Lane's Fifth Draft Proof of Evidence dated 10 December 1990 at CBLA0000005_002, page 219, §512.
[184] CTI presentation on *"Self Sufficiency: Pool sizes at the Blood Products Laboratory"*, March 2022 at INQY0000345, at §72. The presentation is hereafter referred to as *"the written presentation on pool sizes"*.
[185] CTI's written presentation on pool sizes at INQY0000345, at footnote 31.

had also been exceeded.[186] Dr Lane addressed this minute and the reasoning behind the conclusion reached in it in his 5th Draft Proof of Evidence, prepared for the HIV litigation.[187] Dr Lane's view was based on the belief that the Non-A Non-B virus carrier rate in donors approximated to 1%, and that 100kg of plasma would comprise inputs from a minimum of 200 donors.[188]

2.90. Whilst Dr Snape did not feel able to make a judgment on what "the tipping point was, so to speak"[189] between a pool size that would provide some measure of protection against non-A, non-B hepatitis and the pool size that would not provide a measure of protection against non-A, non-B hepatitis when he gave oral evidence to the Inquiry on 30 March 2022, he did provide this evidence:

> *"For donor plasma of the same quality, ie for a properly qualified donor, the pool size as a risk increases as -- risk increases as pool size increases. There comes a point when the -- if, for example, we are talking about one in 100 donors being infective for non-A, non-B hepatitis or, for that matter, hepatitis B, then once you exceed the 1 in 100, certainly once you exceed the 500 that we initially specified at PFL, the thousand donors that we moved on to after that, then there is a diminishing return in terms of the risk of infection."*[190]

2.91. Moreover, after 10,000 litres, however, increasing the pool size was unlikely to have any material effect on risk.[191]

2.92. For patients who were on lifelong therapy, small pool sizes would have made no difference because individuals' batches would not have lasted so long, meaning the exposure would be the same.[192]

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[186] Set out in a minute to Dr J K Smith of the PFL on 29 September 1980 (CBLA0001173). Dr Lane noted that he had *"discussed this with John Craske and he agrees exactly on this point"*.
[187] Dr Lane's Fifth Draft Proof of Evidence dated 10 December 1990 at CBLA0000005_002, §§511-512; also §433.
[188] Dr Lane's Fifth Draft Proof of Evidence dated 10 December 1990 at CBLA0000005_002, §511.
[189] Dr Snape's oral evidence on 30 March 2022, at 148:25-149:12.
[190] Dr Snape's oral evidence on 30 March 2022 at 11:10-11:20.
[191] Dr Snape's oral evidence on 30 March 2022 at 20:12-20:14.

2.93. Dr Smith[193] provided an illustration of the risks of HCV infection from concentrates made from a pool of even 500 donations for a severe haemophiliac in his written statement to the Inquiry:

> *"Using a NANBH incidence of 1:1000 in blood donors, a 100 L pool of 500 donations will have a 0.5 chance of producing an infective batch of product. A grown man with severe haemophilia may use all or part of about perhaps ten such batches in a year and is plainly going to be challenged by NANBH within a year. Small pools offer him little protection."*[194]

2.94. BPL was not alone in choosing to increase pool sizes. Scotland also did so as part of its attempt to achieve self-sufficiency.[195]

Pool sizes at BPL

2.95. CTI and the Inquiry legal Team have provided a detailed analysis of the evidence relating to the pool sizes used in the production of factor concentrates (Factor VIII and Factor IX) in England and Wales in both a detailed written presentation (which focusses on BPL)[196] and an oral presentation on 23 March 2022. However, Dr Foster's evidence was that the pool size figures provided by the Inquiry team[197] were, unfortunately, inaccurate.[198] It is further respectfully suggested that the methodology used for converting litre and kgs into the number of donations should receive further review, and that first-hand evidence or the contemporaneous sources should be used as much as possible. We have included an Appendix to Section 2 (from paragraph 2A1 onwards) on the issue of pool sizes that summarises some of the key evidence, but also highlights some of the

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[192] Dr Perry's oral evidence on 31 March 2022, at 118:9 – 118:25; Dr Lane expressed similar views in his 5th Draft Proof of Evidence prepared for the HIV litigation dated 10 December 1990 CBLA0000005_002 page 219, §512.
[193] Responsible for product development at the PFL in Oxford (1975 to 1992) and BPL at Elstree (1979 to 1982.
[194] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §116.
[195] See Dr Foster's oral evidence on 25 March 2022, at 83:10-83:25.
[196] CTI's written presentation on pool sizes at INQY0000345.
[197] CTI Presentation on the size of pools of plasma used in domestic production of blood products in Scotland, INQY0000346 at page 9.
[198] Dr Foster's oral evidence on 25 March 2022, at 81:24 – 82:14.

complexities of language used, in particular the distinction between "fractionation pool size", "donation pool size" and "donor pool size".

2.96. During the oral presentation on 23 March 2022, reference was made to an article authored by Dr Biggs published in the British Journal of Haematology in 1974.[199] This contained a table setting out the mean pool size (number of donations) for the Factor VIII concentrates used to treat haemophilic patients in Oxford from 1969 to 1971. For 1969, the mean pool size was 160 donations. For 1970 and 1971, it was 192 donations. The article also contained a table setting out the mean pool size for Factor IX concentrates used to treat haemophilic patients in Oxford from 1969 to 1971. For 1969, the mean pool size was 439. For 1970, it was 384. For 1971, it was 300.

2.97. Whilst 1975 is the earliest year for which Dr Snape provided an estimate of the pool sizes actually used at BPL in the manufacture of Factor VIII when he responded to Dr Lane's request for data in the course of the HIV litigation, the estimate given in his written statement to the Inquiry is that between 1967 and 1975, the plasma pool size for BPL and PFL factor VIII batches ranged from 50 to 100 litres (250 to 500 donations).[200] The estimate he provided to Dr Lane for 1975 was 750 donations,[201] although it was Dr Snape's evidence in his written statement to the Inquiry that by 1975 the plasma pool size for factor VIII manufacture at BPL had increased to 160 litres (~800 donations).[202] This would appear to be broadly consistent with the pool size said by Dr Maycock, the Director of BPL at the time, to be applicable by the end of 1975: 830 donations.[203] Dr Snape's estimates put the pool sizes being used by BPL in the production of Factor VIII at 2,250

[199] The oral presentation on pool sizes on 23 March 2022, at 120:4-121:10; article itself at HCDO0000581.
[200] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §214.
[201] BPLL0009120; table 3 at §28 of the written presentation on pool sizes. Although see Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §215, where it is suggested that by 1975 the pool size for factor VIII manufacture at BPL had increased to 160 litres (-800 donations).
[202] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §215.
[203] See Dr Maycock's memorandum dated 8 December 1975 at BPLL0003721; table 5 at §43 of the written presentation on pool sizes.

donations by September 1977. This is the number of donations identified in BPL's Factor VIII "batch history" for the years 1978 to 1979, as well as the start of 1980.[204] The "batch history" figure for 1978 is broadly similar to the average of the four figures for 1978 set out in table 5 of the written presentation on pool sizes, drawn from the contemporaneous documents, although the "batch history" figure for 1979 is lower than the figure given for November 1979 in table 5 (3,330 donations). It would appear from all the evidence presented in the written presentation on pool sizes, as well as the written and oral evidence given by Dr Snape to the Inquiry, that at least by the beginning of 1978 the pool size being used for the production of Factor VIII at BPL was in excess of 2,000 donations.[205]

2.98. In relation to Factor IX, although CTI made clear during the oral presentation on 23 March 2022 that the data relating to pool sizes used in the production of Factor IX was *"less satisfactory"* than the data available for Factor VIII,[206] the contemporaneous reports available do give an indication of Factor IX pool sizes from the start of 1978.[207] The reports indicate that at least by this stage pool sizes for Factor IX were in excess of 2,000 donations.[208]

The potential impact of earlier self-sufficiency on HCV infections

2.99. Taking into account (i) the chronology of events in relation to pool sizes; (ii) the reasons why higher pool sizes were adopted by fractionators; (iii) the evidence and publications in relation to the relative risk of HCV infection from commercial and NHS factor concentrates summarised above (at paragraphs 2.52 to 2.63); and (iv) the evidence of HCV infection rates in Scotland, there is a real question as to whether the earlier achievement of self-sufficiency

[204] CBLA001447; table 4 at §31 of the written presentation on pool sizes.
[205] See further the appendix to this section.
[206] Transcript of the oral presentation on pool sizes on 23 March 2022, at 118:10-118:13. For instance, the BPL Factor IX "batch history" goes back only as far as 1983 – see 119:2-5.
[207] There is some indication that pool sizes for Factor IX were already in excess of 500 donations by the start of 1975 in a minute from Dr Bidwell to Dr Maycock dated 22 January 1975 (CBLA0000253), but a lack of further documents relating to the comments made by Dr Bidwell led CTI and the Inquiry team to exclude this from table 7 of the written presentation on pool sizes, which sets out the data available from contemporaneous reports.
[208] Table 7 at §57 of the written presentation on pool sizes.

would have made a difference to the risk of HCV infection and the numbers of patients infected with HCV through blood products, during the period before the introduction of heat-treatment, from c1985.

2.100. The Chair is invited to consider in determining this question, the evidence relating to pool sizes, summarised above. This suggests that at least by 1978, the pool sizes being used in domestic production of factor VIII and IX concentrates were almost double the upper end of the pool size given by Dr Lane of 100-200kg, after which he considered there was no longer *"any possibility of small-pool protection"*.[209]

2.101. Evidence relating to the reasons why larger pool sizes were adopted has also been summarised.

2.102. As to the relative risk of the UK product rather than imported ones, Dr Smith's evidence was that substitution of UK products for imported ones would have made little or no difference to NANBH transmission to severely affected patients and even to infrequent users unless a small-pool strategy had been adopted for them. It transpired only slowly that 8Y did not transmit NANBH and it would have protected infrequent users from April 1985.[210]

2.103. Dr Smith's evidence was that a 5-year programme of rebuilding BPL would have had to have started in about 1978, not in 1982 as actually happened, in order to have had an impact on HIV and HCV infection rates because virus safe products would have been needed before 1983.[211] However, crucially,

[209] See above at §§ 2.95 to 2.98 and the appendix to this section.
[210] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §172; CTI written presentation on the Evidence of Dr James Smith, March 2022 (INQY0000329) §55.
[211] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §170; CTI written presentation on the Evidence of Dr James Smith, March 2022 (INQY0000329), at §54.

this was predicated on heat treatment being *"more than a gleam in the eye in 1982"*.[212]

2.104. There was initial consideration of the possibility of building a small pools facility into the new BPL, but this was not taken forward. It was not a practical proposition, for all the reasons relating to production necessities, as outlined by Dr Snape.[213]

2.105. Of further relevance to the issue of HCV infection and self-sufficiency is with respect to Hepatitis C infections in Scotland, which was largely self-sufficient in its supplies of Factor products. These Submissions have not attempted to summarise that evidence. But it was, for example, the evidence of Professor Ludlam that: "*Prior to 1980, there had been a policy in Edinburgh to prefer the use of NHS produced products. This was primarily related to the perceived potential infective risks chiefly related to source plasma. SNBTS products were sourced from donors within Scotland*". [214]

2.106. Thus, the Chair is invited to consider whether the key issue with respect to protection against HCV lies more in the date at which effective heat-treated products were developed and made available (the issue of research into these products is considered further at section 5 of these submissions).

2.107. The effect of such a focus by the Inquiry may, of course, lead to further scrutiny of the period from April 1985 onwards, when heat-treated 8Y was available from BPL but its production capacity was limited, as the building of the new facilities had not been completed and commissioned. During that period, heat-treated commercial products were both available to clinicians and used to fill shortfalls.

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[212] Dr Smith's witness statement dated 27 July 2020 (WITN3433001), §170.
[213] Dr Snape's oral evidence on 30 March 2022, at 38:8-39:10.
[214] Professor Ludlam's witness statement dated 25 September 2020 (WITN3428001), §163(a).

2.108. Knowledge of the extent to which these commercial products (as well as the BPL product) were effective against NANB emerged slowly, not least as the existence of the first screening test for Hepatitis C was not publicised until April 1989. The Inquiry has received evidence that some of these commercial products proved not to be "Hepatitis-safe" and that infections were transmitted by this route.

2.109. The number of infections introduced by that route would depend on factors such as whether the commercial products were being given to those who had previously received infected products, whether domestic or commercial, or whether they were being treated with blood products for the first time (for example, children).

2.110. The chronology of the withdrawal of Armour's heat treated Factorate is addressed in CTI's note on that topic.[215]

The potential impact of earlier self-sufficiency on HIV infections

2.111. There are uncertainties upon the dates at which those in receipt of blood products in England and Wales were first exposed to products infected with HIV and became infected with it, and the Inquiry's Expert Group gave, necessarily, only limited information on this issue (see paragraph 2.76, above). However, in contrast to the situation with HCV, the Inquiry may consider that it is reasonably well-established that the relative risk of the US-imported product was higher than the BPL product, particularly in the early stages of the AIDS pandemic before the disease had become established in the UK and was more widely prevalent in the US. The issue of increased protection against HIV infection is thus directly linked to the question of whether domestic self-sufficiency could or should reasonably have been achieved earlier, and (in particular) before 1985 when heat-treated products

[215] INQY0000386, 4 November 2022.

that were protective against AIDS, both commercial and domestic, became available in England and Wales.

2.112. Thus in relation to HIV, Dr Smith's evidence was that 8CRV/HL subjected to 60°C or 70°C heating was available from August 1983 and would have forestalled HIV transmission by imported concentrates until the latter began to be dry-heated. By January 1985, when BPL's heated product was unequivocally available, all imported concentrates still on the market were probably as safe from HIV as BPL's. "*8Y simply guaranteed overkill*".[216]

2.113. Dr Snape concurred that England and Wales would have needed to have been self-sufficient by 1978-80 (i.e. in advance of the Council of Europe's endorsement of the WHOs position). He said:

> *"We -- BPL, or England and Wales, couldn't have laid claim to that statement of self-sufficiency being the quantity of Factor VIII to meet clinical need without importation of product simply because product was already being imported, and in order for that to have been avoided, we would have -- BPL/PFL would have had to be producing the quantities of product that the country that clinicians in the country needed, not by 1987 or whenever, but we would have needed to be supplying that quantity of Factor VIII by 1978/1979. In other words, hard on the heels of a decision to build a factory, or at least do something on the Elstree side to produce the larger quantities of Factor VIII immediately after Lord Owen's 1975 intervention, because it would have taken that long to have the quantity of product that was appropriate by, say, 1980. But because we didn't, physicians in England and Wales had started to import commercial Factor VIII, and the rabbit was out of the hat, and we missed our chance"*[217]

2.114. Taking into account the chronology of events in relation to DHSS knowledge that significantly increased fractionating capacity would be needed to achieve self-sufficiency and the timing of the decision to build a new laboratory on the Elstree site set out above (at paragraphs 2.52 to 2.63) and ii) the evidence and publications in relation to the relative risk of HCV

[216] WITN3433001 at §173; CTI written presentation on the Evidence of Dr James Smith, March 2022 (INQY0000329) at §56.
[217] Dr Snape's oral evidence on 29 March 2022, at 127:20 – 128:14.

infection from commercial and NHS factor concentrates summarised above (at paragraphs 2.83 to 2.94, and appendix to this section), there is a significant question to be addressed as to whether it would have been reasonably practicable to achieve self-sufficiency in time to make a difference to the risk of HIV infection and if so, how much difference the earliest practicable achievement of self-sufficiency would have made to the numbers of those actually infected.

2.115. In considering this issue, the Chair is invited to take the following matters into account:

(1) Timing of estimates that further capacity was needed. As noted at paragraph 2.58 above, it was not until 1977 that advice was given that significant new capacity was needed at BPL; a request was made to BPL for development plans. The history of the earlier planning assumptions and the limitations which they reflected has been set out above.

(2) Acquisition of the Lister site. Developing a new laboratory on the Elstree site with the fractionation capacity to meet the future level of demand for blood products estimated by the Trends Working Group was only made possible by the acquisition by the Department of the land surrounding the existing laboratory in 1979.[218]

(3) The time needed to build new facilities. The time that elapsed between the start of planning (December 1980[219]) to the opening of the new laboratory at Elstree (April 1987[220]) was six years and four months. The Inquiry has received evidence that it would have taken at least four to five years to plan, build and commission a new laboratory, even assuming everything ran to plan.[221] Even assuming

[218] See above at §§2.59 to 2.60.
[219] Planning started after the instruction from Ministers to officials in December 1980: see the minute from J E Knight to Mr Harley dated 8 January 1981 at WITN4461046, confirming the outcome of a meeting between Dr Vaughan, Mr Young (PS(H)) and officials on 17 December 1980.
[220] The presentation on domestic production and self-sufficiency by CTI and the Inquiry's legal team (INQY0000333), at §211.
[221] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §31.7.

a decision had been made to build a new laboratory on the Elstree site with public funds in January 1980, following the submission to Ministers in December 1979, a four to five year timescale for the project from start to finish would have resulted in the laboratory being fully commissioned between early 1984 and early 1985. Self-sufficiency would not have followed immediately. When the new laboratory was officially opened in April 1987, it was estimated that self-sufficiency would be achieved in 1989.[222] As such, even assuming there were no problems arising relating to plasma supply, the window for the achievement of self-sufficiency would have been early 1986 to early 1987.

(4) Capacity Assumptions. Pushing back the date of a Ministerial decision to press ahead with planning for a new BPL to an earlier date, to (say) 1978/1979, obviously results in earlier theoretical commissioning dates. By 1979, the acquisition of the Lister site could have been factored in. But examining what the causative effect of an earlier decision may have been also means, it is suggested, taking into account that planning at such earlies stages would have been based on assumptions about capacity that proved to be too small and had to be revised later, with consequential knock-on problems for the design, etc.

Plasma supply issues - 1988 to 1990

2.116. A question which arises for the Inquiry is whether these plasma supply issues are material given the date by which England and Wales would have needed to be self-sufficient in order to make a difference to those infected with HCV and/or HIV.

[222] DHSC0101068.

The potential contribution of the Protein Fractionation Centre

2.117. A question which arises for the Inquiry, is whether Scottish Protein Fractionation Centre (PFC) at Liberton, Edinburgh could have been used to increase the supplies of "domestic" fractions in England and Wales, notably Factor VIII.

Relationships

2.118. Before making further observations on this topic, we invite the Inquiry to note the evidence that there were strong and beneficial relationships between PFC and BPL.

2.119. Many witnesses have noted that there was a productive relationship between staff at BPL/ PFL and SNBTS/ PFC.

(1) See, first, Dr Snape at paragraphs 60 – 61 of his Witness Statement.[223]

(2) Dr Foster's evidence was that:

(a) There was no room for improvement in terms of the working arrangements between BPL/PFL and PFC. On the contrary, the organisations *"got on extremely well [...] staff knew their counterparts and could phone you at any time [...] We saw them as being part of the same organisation".*

(b) The relationship between the organisations was such that they discussed technological developments such as CSvM *"in some detail"*.[224] A delegation of BPL staff visited to view the system.[225] There were a number of meetings to discuss BPL adopting the technology, but ultimately it chose to adopt an alternative approach.[226]

[223] Dr Snape's witness statement dated 8 February 2022 (WITN3431001).
[224] Dr Foster's oral evidence on 24 March 2022, at 49:10.
[225] Dr Foster's oral evidence on 24 March 2022, at 49:10.
[226] Dr Foster's oral evidence on 24 March 2022, at 49:18.

(c) On another occasion, BPL shared its vials with PFC when asked, enabling the latter to get through a *"difficult period"*.[227]

(3) Dr Perry's evidence was that:

(a) The informal collaboration between PFC and BPL/ PFL was "*highly productive*".[228]

(b) Dr Perry also described his delight that BPL were prepared to share their supply of 8Y so readily.[229]

2.120. Further, it was helpful to have a degree of separation between BPL and PFC because the organisations could adopt different methods and learn from one another. Dr Foster considered that if BPL and PFC had been aligned even more closely then it would have hindered the development of heat-treated product.[230] Dr Perry agreed that more formal structure might well have hindered the development of heat treatment.[231] He suggested that a formal agreement between the organisations might have led to both pursuing pasteurisation (as opposed to heat treatment) because "*there was quite a strong consensus […] that that was the preferred technology*".[232]

The consideration of a PFC Contribution

2.121. In making observations on this topic, we acknowledge the contribution of CTI's presentation on this issue,[233] and will try to avoid repeating material summarised in this. Instead, references are made to its contents.

2.122. CTI's Presentation describes the planning of the facility at Liberton in the late 1960s/early 1970s. Although it is acknowledged that the scale of the project

[227] Dr Foster's oral evidence on 24 March 2022, at 83:18.
[228] Dr Perry's oral evidence on 31 March 2022, at 58:6.
[229] Dr Perry's oral evidence on 01 April 2022, at 120:8.
[230] Dr Foster's oral evidence on 25 March 2022, at 106:7.
[231] Dr Perry's oral evidence on 31 March 2022, at 59:8.
[232] Dr Perry's oral evidence on 31 March 2022, at 58:24.
[233] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (INQY0000343).

was carefully scrutinised,[234] still it is notable that Treasury approval was given for what was described as a "*novel, one-off project*" despite uncertainties about its benefits.[235] The result was that, unlike in England, Scottish production took place at a new facility that had been purpose-built in the 1970s, in contrast to the situation at Elstree. It was said to have the potential capacity to process 60 million units of factor VIII per year dependent upon £25,000 of further capital equipment and money for extra running costs to including to effect a 24 hour shift operation.[236]

2.123. By the time the commissioning[237] process at PFC began in early January 1975,[238] a contribution of £400,000 to the capital costs of the build had been made by the DHSS, it appears on the basis that a contribution to "English" needs was envisaged; this was based on the proposition that plasma would be delivered to PFC from four northern regions in England.

2.124. As the Inquiry will be aware, the early period of efforts to raise production at BPL, and to attain self-sufficiency, focussed primarily on attempts to increase the supply of plasma to BPL. It was not considered that there was a capacity issue at BPL; rather there was a supply issue. An extension had been built at BPL, during (approximately) the period in which PFC had been planned and then built.[239] Thus, when Mr Giddens wrote to Regional Administrators on 24 December 1974,[240] he noted that BPL's capacity was limited by the amount of plasma supplied by RTCs.

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[234] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (March 2022), §18.
[235] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (March 2022), §19.
[236] Minutes of Haemophilia Centre Directors 13 January1977, PRSE0002268
[237] The term is explained in the witness statement of Dr Snape dated 8 February 2022 (WITN3431001), §248.
[238] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (March 2022), §24 (following a build process that began in 1971).
[239] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (March 2022), especially §§16-17.
[240] CBLA0000239.

2.125. This approach was consistent with the fact that initially the PFC facility was equipped for Scottish needs only.[241]

2.126. Despite these practical realities, there was still a willingness and intent to consider planning on a UK-wide basis, whether at the level of the Joint Steering Committee on Blood Products Production that first met on 20 June 1973[242] or at ministerial level (see the comments of Lord Owen quoted at paragraph 28 by CTI).[243]

2.127. The earliest discussion of a future lack of capacity at BPL noted by CTI's Presentation is from the meeting of the Haemophilia Centre Directors on 13 January 1977. The issue of when capacity constraints came to the fore has been considered above at 2.58.

2.128. In 1977 too, discussions of use of PFC facilities took place between DHSS and SSHD officials, with Dr Foster[244] noting two meetings, held on 11 March 1977 and 11 August 1977 ("Mutual Problems"), with discussion of the current Incomes Policy and the need to raise the shift issue with the Whitley Council at the first meeting. At the second, Dr Lane set out his views, focussing on BPL production. *"It would be wrong, in his view, to send plasma from Regional Transfusion Centres in England to the PFC, if this had the effect of leaving spare capacity at Elstree and meant that service charges had to be paid. In his view that would have the effect of duplicating costs…"*[245]

2.129. Dr Foster's view (see paragraph 66.3 of his statement) was that the PFC difficulties related to Incomes Policy and the approach of the employer's side

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[241] CBLA0000239, §25.
[242] CBLA0000239, §22.
[243] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (March 2022), §28 citing the minutes of a meeting held at DHSS on 11th March 1976, CBLA0000343.
[244] Dr Foster's witness statement dated 7 March 2022 (WITN6914001), §66.2 (vi) and (vii).
[245] Dr Foster's witness statement dated 7 March 2022 (WITN6914001), §66.2(vii) and CTI presentation §34.

on the Whitley Council (rather than Union stances – they would be receptive if the agreement was properly negotiated). However, there were documented concerns on the part of DHSS officials that it remained highly doubtful whether a shift-working agreement could be negotiated with staff at PFC without serious repercussions on pay of other groups in the NHS and the Industrial Civil Service.[246]

2.130. The minutes of the August meeting record, it would seem, a *"failure to reach agreement on the introduction if shift working through the Whitley Council"* and that a case had been developed to be "*accepted as a pharmaceutical factory type development out with the Whitley arrangements.*" It is not clear, from either the CTI presentation, or the statement of Dr Foster, what happened to that case – whether it was submitted or its outcome. What does seem to be the case, is that by 1981 this issue had not been resolved.

2.131. CTI's Presentation notes that Dr MacDonald (Royal Infirmary, Glasgow) stated that Liberton had the capacity to make 60 i.u million/annum but would require £25,000 for additional equipment (i.e. £25,000 by way of capital[247]), plus the funding for additional running costs, including the costs of funding a 24-hour shift system. The CTI Presentation notes that Dr Lane later suggested that this figure was "*nonsense*", although it was not challenged at the meeting. The Inquiry is invited to consider whether Dr Lane's response, while forcefully expressed, may have had underlying objective justification; that is, the later and fuller analysis of capital costs were very substantially in excess of this figure (see the letter from Mr Macpherson to Mr Harley (DH) dated 11 January 1982 discussed below). The additional running costs were not costed at all.

2.132. CTI notes (paragraphs 30 – 31) that a limited stock of plasma was sent to Scotland in 1977, but it is apparent that the need to establish "yield and

[246] See the minute at WITN6914044, page 3 §11.
[247] This is evident from the notes of the meeting at PRSE0002268.

costs" – in particular, of a move to extended shift work, were key. At this time, BPL was still able to process the plasma stocks available for its use.[248]

2.133. CTI has noted that there was an apparent shift in focus from about 1977, towards the development of BPL instead; and that this was reinforced by the replacement of Sir William Maycock by Dr Lane, as the Director of BPL. The issues that arose, in Dr Lane's view, related both to the quality of the Scottish product, and the merits of further development in Liberton, as opposed to in BPL.[249]

2.134. Despite this shift, or advocacy from BPL senior staff (which is discussed further below), it is apparent that the 'PFC option' continued to receive serious consideration from DHSS staff, working in conjunction with SHHD officials. See the witness statement of Peter Wormald and the witness statement of Dr Diana Walford.[250] In summary, there were ongoing discussions regarding PFC increasing capacity to assist with UK-wide production levels. However, there were considerable obstacles to this, including difficulties with the introduction of shift working at Liberton and the expenditure required in order to upgrade ancillary facilities at Liberton in order for it to process English plasma.[251]

2.135. There is evidence, in other words, that the merits of using potential PFC capacity continued to be scrutinised, and that the options was not neglected; rather, it was explored, despite the focus (at BPL) on the development of that site.

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[248] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §55.4.
[249] Draft witness statement of Richard Spencer Lane dated 10 December 1990 [CBLA0000005_002], see in particular §388 regarding the quality of the Scottish product.
[250] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §55.6 - §55.12 and Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§30.2-30.14.
[251] On the latter, see Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §43.4 - §43.5 [DHSC0003715_171]

2.136. As for the views of Dr Lane and the related issue of the merits of the various possible ways forward, the IBI may see Dr Lane's views as reflecting the desire of Dr Lane to put forward the case for the development of "his own" institution. Certainly, there is evidence that he was a visionary and powerful figure (see the oral evidence of Dr Snape, Transcript of 29 March 2022, pages 83 – 85, including on the contrast with Sir William Maycock who Dr Snape regarded as a more "traditional" leader). However, there were also evidence of proper reasons for the opposition to a policy based on the development of PFC, including:

(1) The stance of Dr Lane, as recorded in August 1977, reflected the concern that the effect of sending plasma to PFC would be to leave spare capacity at BPL. The issue of using PFC was intimately tied to the question of whether plasma supplies could be driven upwards and if so, how quickly;

(2) Dr Lane also had concerns about the quality of the Scottish product, or, at least, the differences between it and the BPL product (see above). We note that, for example, unlike PFC, BPL had a policy of quarantining all donations for six months before they were used;[252]

(3) The discussions in 1977 came at much the same time as Dr Lane was invited to present proposals, not only for short term measures but for the longer-term redevelopment of BPL;[253]

(4) There was no consensus about the accuracy of the PFC claims for its manufacturing capacity. Dr Snape's assessment[254] was that Dr Watt (Director, PFC) *"… could be relied upon to make ambitious (some would say overstated) claims for current and forecast yields for factor VIII …"* (see also paragraph 232, which records Dr Snape's reaction to the claims made by Mr Watt about PFC yields).

(5) The Medicines Division's unfavourable inspection report of BPL (September 1979) was followed by critical inspection of PFC in

[252] Dr Snape's oral evidence on 31 March 2022, at 147:14.
[253] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001), §4.3.
[254] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §66.

October 1981 (see the witness statement of Dr Foster, page 28[255]). Both institutions faced challenges;

(6) Dr Snape made it plain that the "*most RTDs formed up squarely behind Dr Richard Lane, behind his designs for BPL … Dr Lane was very clear on what he expected from the new BPL and on what was needed from NBTS in terms of amount, quality and presentation of plasma...*" – and these requests/stipulations were supported.[256]

2.137. Further, the costs and other difficulties of increasing capacity at PFC were real PFC did not, at any time, offer an "oven-ready" solution to any lack of BPL capacity, or (more broadly) as a straightforward means of assisting the processing of increased supplies of plasma from England and Wales. Rather, substantial development and investment would have been needed to enable this.

2.138. The best account of the issues raised by the need to make 24 hour shift-working comes from the assessment that followed the shift-working experiment that was ultimately carried out in 1981. See the letter from Mr Macpherson (SHHD) to Mr Harley (DH) dated 11 January 1982,[257] which stated that expansion would require further ancillary facilities, and more land for buildings. The capital costs were put at £6 – 7 million.[258] Additional revenue needs were not costed. Building would take approximately 2½ years, and agreement through Whitley Council mechanisms would be needed to secure agreement from staff to work in 24 hour shifts.

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[255] Dr Foster's witness statement dated 7 March 2022 (WITN6914001).
[256] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §65.
[257] CTI Presentation *"Self-Sufficiency and Domestic Production of Blood Products in Scotland and for Northern Ireland"* (March 2022), §42; SCGV0000002_032.
[258] Although it was later clarified that about half of that sum was said to be required in any event, to bring PFC up to standard following its inspection by the Medicines Division: CTI Presentation §57.

2.139. The Inquiry has received a statement from Dr Foster[259] who was critical of the cost comparisons being made at the time, and who has suggested that the comparative speed at which PFC could have been redeveloped was not given proper consideration, in the decisions made in 1982. He acknowledged that in January 1984 PFC did not have the facilities required to deal with surplus supply[260] [261] and his assessments were based on his view of potential capacity.[262]

2.140. In this regard, the Inquiry is invited to consider the evidence of Dr Lane, who (had he been available to give evidence) would likely have offered his perspective. Thus:

(1) The letter from Mr MacPherson, and the costs, were commented upon by Dr Lane in his draft proof of evidence.[263] He made the point that the costs set out were highly uncertain; "*This estimate itself could scarcely be relied upon, since… the author of the letter, made it clear that it was not possible to give any detailed break-down of this 'estimate'.*"

(2) Dr Lane made the same point about the time estimate: *"again the general air of uncertainty which pervades the letter, gives the impression that this too could not necessarily be relied upon;"*

(3) He stressed that: "*particularly significant, however, is a statement in the letter that the revenue implications of fractionating plasma at Liberton to produce, inter alia, Factor VIII had not been costed. In short, no clear idea of the cost of using PFC Liberton could be given.*" It was a *"cost that no one could predict."*

2.141. The Inquiry may think that (i) these observations are reasonable ones; and that (ii) in any event, they are indicative of the objections that would probably

[259] Dr Foster's witness statement dated 7 March 2022 (WITN6914001), pages 156-157.
[260] Dr Foster's oral evidence on 24 March 2022, at 144:12.
[261] DHSC0001671, page 2 [5].
[262] Dr Foster's oral evidence on 25 March 2022, at 143:1
[263] CBLA0000005_002 at §339, page 143.

have been raised by officials at BPL, and represent the difficulties in achieving an agreed way forward.

2.142. In addition:

(1) The comments upon both the eventual costs of the final rebuilt BPL, and how long it took to build, are (inevitably) made with the benefit of hindsight. If the estimated costs of "full" BPL redevelopment at the time of decision-making (some £21.03 million)[264] are to be compared with the final figure that eventually had to be spent, it should also be recognised that the costs of building both a smaller BPL and of redeveloping PFC to process "English" plasma are also likely to have escalated.

(2) Equally, although it is acknowledged that extending operations at PFC must have been less complicated than rebuilding BPL, still the suggested timescales were not guaranteed (see Dr Lane's comments). PFC too was grappling with the implications of the Medicines Division's inspection (with the required work taking place over a period and necessitating a three month shutdown). While there were thought to be some advantages to that shutdown, PFC too would have been required to plan for a second set of challenges.

(3) Although the view of the SHHD was that a shift-working agreement could be negotiated for PFC ("*though not without difficulty*"[265]), it is apparent that there were also concerns about the knock-on effects on the pay of other groups of NHS staff and the Industrial Civil Service[266] - in effect, a further unknown and perhaps unquantifiable cost for the NHS/DHSS as a whole, at a time of economic constraint and concern about labour relations, and that is likely to have raised concerns.

(4) There is evidence that the decision was independently considered and endorsed within the SHHD / Scotland Office: see the submission

[264] CTI Presentation, §55.
[265] CTI Presentation, §57.
[266] CTI Presentation, §§56 and 60.

of Mr Walker to the Scottish Health Minister dated 15 October 1982. This was not a unilateral conclusion; nor (presumably) was it a foregone one, given that Scotland might have an interest in securing further DHSS contribution to PFC development.

2.143. In general, whilst the difference between a figure of £21 million for BPL alone, and £18 million, plus £6-7 million[267] for the 2 options together may now be regarded as small, the overall context for the public finances was a very difficult one (it was a time of recession). The Inquiry will have noted the careful scrutiny of BPL redevelopment costs (whether of stop-gap or full redevelopment). Whilst the option of redeveloping both BPL and PFC was never put to ministers, it might be thought that the additional costs would have been regarded as an obstacle.

2.144. Overall, the Inquiry is invited to consider evidence that, first, the issue of the use of PFC did receive serious consideration and was not overlooked. However, as the Chair has previously noted, the BPL leadership were not in favour at this stage of regional English money being spent to collect plasma to send to Scotland to produce product for England. [268] It might be thought that their focus was on the redevelopment of BPL and whose plans were supported by RTDs. Further, PFC did not offer an immediate and certain solution. To have used it for plasma from the northern regions would have required substantial planning and negotiations (to introduce 24-hour shift-working) as well as significant capital development costs. Ultimately, it might be thought that the time that would have been taken to push through these obstacles is difficult to assess, with a reasonable degree of certainty.

[267] Or a reduced sum, given the costs of upgrading to meet the requirements of the Medicines Inspection in any event.
[268] Chair's Question to the Expert Group on Public Health and Administration on 4 October 2022 at 55:4-14.

APPENDIX TO SECTION 2: NOTE ON POOL SIZES

Introduction

2A1. This Appendix note addresses the issue of pool sizes for the manufacture of blood products, from the perspective of the Blood Products Laboratory ("BPL") and, in particular, Dr Terry Snape. It might be thought that in practice, Dr Snape was treated by the Inquiry as a mixed factual and expert witness when he gave evidence.

Terminology

2A2. There are factors that potentially confuse the donor pool size discussion.

2A3. The first and arguably most significant is the distinction between "fractionation pool size", "donation pool size" and "donor pool size" (the data tables referred to by the Inquiry [269] include inconsistencies arising from failures to allow for these distinctions).

(1) The fractionation pool size, normally recorded in kg plasma, is typically determined by process equipment and overall process considerations:

(a) plasma pack opening arrangements and, possibly, the need to interrupt the process for microbiological control procedures (at BPL the "tear down" machine was sanitised every two hours)

(b) "tankage" – tank volume pooling constraints

(c) centrifuge type and throughput

(d) working day and, perhaps, shift patterns

(e) process yield considerations

[269] INQ0000345. Dr Snape has commented that without access to the original BPL source material, which may be either batch documentation, BPL reports or CBLA reports, it is difficult to comment on the accuracy of interpretation in the retrospective review of documentation as undertaken in presentation INQY0000345 on *"Self Sufficiency: Pools Sizes at BPL"*. The Inquiry has only permitted Dr Snape to review selected documents it has provided to him, and those which the Government Legal Department has specifically requested that he see.

(f) downstream process considerations – plasma pooling for factor VIII manufacture is almost always the first of four or five process stages, with the subsequent process stages each on a separate day

(g) manufacturers (including BPL, on some occasions) have sometimes failed to make a clear distinction between the three possible expressions of pool size – if the measure of donor pool size (or donation pool size) has been recorded in kg, that's a pretty good indication that the manufacturer is actually referring to fractionation pool size, not the number of donors or donations contributing to the pool.

(2) The term "donation pool size" would be accessible to the fractionator if individual donations were recorded (automatically or manually) when the identity of each donation was determined by "wanding" the donation bar code before pack stripping and pooling. In this situation, donations previously flagged by the plasma supplier as "at risk" would be removed and secured, either for testing or, more likely, for return to the supplier for reconciliation and retesting. It is highly unlikely that the manufacturer would be able to link a plasma donation to an individual donor, without further interaction with the plasma supplier.

(3) The term "donor pool size" only makes sense when it is used to describe the number of individual donors contributing plasma donations to a fractionated plasma pool. In practice, the fractionator will hardly ever be aware of this at the time the pool is assembled for processing – depending on donation frequency (determined nationally) and batch periodicity, there will often be more than one donation from a given donor in any one plasma pool. Depending on donation size and donation frequency, the fractionation pool size might significantly overestimate the true donor pool size.

2A4. The second factor, which requires historical context, is the plasma donation type. Recovered plasma donations, i.e. plasma recovered by centrifugation

from anticoagulated whole blood donations, were typically 180-200ml (or g) in size, compared with plasma donations obtained by apheresis, which could range in size from 600ml to 800ml, according to local practice. Before 1980, whole blood donation frequency was limited to approximately two (possibly three) donations. Plasmapheresis donors in the US could present as often as their circulating protein levels continued to be acceptable (there was probably a defined limit, but only a specialist could comment on this).

2A5. A third factor, also requiring historical context, was the form in which (UK) plasma donations were presented to the fractionator. Between 1968 and 1975, plasma donations supplied to PFL (Oxford), from the Oxford Blood Transfusion Centre, were supplied as 23-25 recovered plasma donations in a 5 litre "Vallet pack" – colloquially referred to as a "pillow-case". Almost without exception, factor VIII batches manufactured at PFL between 1968 and 1975 were prepared from frozen recovered plasma in 13 Vallet packs – so fractionation pool size was 65 litres (or kg, since the plasma was frozen). During the same period (1970 – 1975), BPL (Elstree) processed somewhat larger batches (probably 100 up to ~160 litres) from plasma supplied by other Transfusion Centres in E&W, also in 5 litre Vallet packs.

2A6. BPL (Elstree) also received and processed so called "Time-Expired Plasma (TEP), pooled and frozen in 5 litre packs, for the manufacture of albumin and immunoglobulin products – TEP was unsuitable for manufacture of coagulation factors but was a valuable source of albumin and immunoglobulin products.

Witness statement of Dr Terry Snape

2A7. Dr Snape's comments were as follows:

> *"212. Between 1970 and 1985, there was considerable focus on "donor pool size" – sometimes expressed as plasma pool size in litres or kg of plasma, but more usefully expressed as the number of individual donations included in the plasma starting pool. This focus on*

batch size (more importantly, on the number of individual plasma donations contributing to the start pool) was not unreasonable at a time when virus inactivation techniques were not applied (they were not available), and when the inclusion of a single infected donation in a pool meant potential product infectivity for coagulation factor batches produced from the pool.

213. On average, UK plasma donations contained ~200ml, compared with an average size for commercial (mainly US) plasma donations of ~680ml [PRSE0003071].

214 Between 1967 and 1975, the plasma pool size for BPL and PFL factor VIII batches ranged from 50 to 100 litres (250 to 500 donations).

215. By 1975 the plasma pool size for factor VIII manufacture at BPL had increased to 160 litres (~800 donations), which was still small by commercial standards, where pools of 1,000 to 10,000 litres would have been the norm, even at that time. The batch size (number of vials of concentrate per batch) was correspondingly small and, because of the unavoidable requirement to take significant numbers of vials from each batch for quality control (QC) testing, yield was lower than if larger batches had been processed. For the small batches typically manufactured at BPL/PFL (100-500 vials) an irreducible minimum of 15 vials would have been required for QC testing in compliance with Ph. Eur. 1980; for batches of greater than 500 vials, the maximum number of QC samples required amounted to a fixed number of 25 vials. The maximum defined pool size was set at 2,500 donations (although to my knowledge, this limit was never approached at this time).

216 By October 1980 however, increased demand for factor VIII made it necessary to increase the donation number limit for BPL and PFL plasma pools from 2,500 to 5,000 donations, to increase factor VIII output (and reduce the QC sampling overhead costs). This, and other relevant dates, are accessible at, "Chronology relevant to "self-sufficiency", hepatitis C transmission and the establishment of terminal dry heat-treatment for UK coagulation factor concentrates" [PRSE0003122].

217. In January 1982, the donation number limit for BPL and PFL pools was further increased to 7500 donations, to increase factor VIII output through improved process efficiency at the larger scale.

218. Donor pool size would have been smaller, except that most plasma fractionated by BPL continued to be recovered plasma (recovered plasma donations were smaller than donations obtained by plasmapheresis in the UK, ~200ml[270] compared with ~500ml, and blood donors are asked to give blood less frequently – twice p.a. at that time –

[270] Dr Snape's estimate of 200ml per donation in WITN3431001 was based on memory at the time of drafting; over time Harold Gunson's 180ml should be considered authoritative for recovered plasma. Increased volume for SAG-M derived plasma. Substantially increased volume for FFP by apheresis.

so that most fractionation pools would only ever have contained one donation from a given donor).

219. Whilst this donation number limit applied to PFL batches as well as BPL batches, the much reduced batch size operated at PFL meant that, in this case, the donation number limit was never challenged.

220. Later, and certainly after the establishment of terminal heat treatment for factor VIII and factor IX concentrates in 1985, the maximum donation number limit was increased to 10,000 donations. To the best of my knowledge, regulatory approval was always sought when there were logistical reasons to increase pool size, and the pool size limits referred to in ¶212-220 were never exceeded.

221. In the 1990s, when the effectiveness of in process virus inactivation had been demonstrated, pool sizes used by main-stream fractionators increased, almost without limit. The implications of donor pool size for product safety were considered under the heading "Virus Safety considerations in the manufacture of Fractionated Plasma Products" (¶151-162).

222. The changes in maximum donation number limit are illustrated in Exhibit [WITN3431020], which includes labels for Factor VIII type HL (unheated, c.1980), Prothrombin Complex type 9D (unheated, c.1982) and Prothrombin Complex type 9A (HT3 heated, c.1987)."[271]

2A8. In summary, Dr Snape's written evidence to the Inquiry suggests that in the early 1980s increased demand for factor VIII made it necessary to increase the donation number limit in order to increase output and to reduce QC sampling overhead costs. Once heat treatment was established, the donation limit was increased again and once the effectiveness of virus inactivation by heat treatment was well and truly established, pool sizes could be increased "almost without limit" as there was no potential impact on safety.

[271] Dr Snape's observations in these paragraphs were almost entirely based on personal memory, with no access to hard documentation. They lack the granularity that Dr James Smith was able to provide in his witness statement because Jim was "man-in-plant" between 1976 and 1992, and functioned as the key link between BPL and the other significant parties involved (Angela Robinson, RTC Deputy Director at Leeds, with her considerable interest in the development of apheresis for source plasma; Haemophilia Centre Directors like Charles Rizza at Oxford, Brian Colvin at the London Hospital, and Jimmy Stewart and Sam Machin at the Middlesex Hospital). Also important, Jim Smith developed much of his thinking in preparation of his responses to the Penrose Inquiry, ten years closer to contemporaneous.

Witness statement of Dr James K Smith

2A9. The distinction that Dr Smith makes between "normal pools" and "small pools" may be key. BPL was never able to contribute to the development of "small pool" understanding – that was very much the focus at PFL. The point made by Dr Smith, that PFL "small pools" were unlikely to contain more than one donation from an individual donor is important. Many "normal pools" processed at BPL would have contained more than one donation from an individual donor.

2A10. Dr Smith dismissed as impractical, a major commitment to provision of small pool factor VIII for severely-affected haemophiliacs in England and Wales. It is hard to get beyond the reality that the establishment of HT3 heating for 8Y and 9A had made small pool processing (including what were called "Green 4" donor pools), irrelevant.

Comments on documents provided to Dr Snape by the Inquiry[272] in relation to pool sizes

Pool sizes and labelling

2A11. On 22 January 1975, Dr Bidwell sent a memo to Dr Maycock highlighting that the plan to write "*not more than 500 donations*" on the concentrate labels was no longer accurate as there were often more than that used and the exact number was often not known. Dr Bidwell asked Dr Snape to print labels "*not more than 1000 donations*" but also highlighted it may be simpler not to put anything at all.[273]

2A12. Ethel Bidwell's memo indicates that in 1975, PFL pool size for factor IX would have been between 500 and 1000 donations. Fractionators would not have known the number of donations being included in batches of plasma processed to factor VIII at Elstree up to 1975, and finished to factor IX by PFL. It might have been as high as 1000.

[272] Documents provided on 24 March 2022 shortly prior to Dr Snape's evidence.
[273] CBLA0000253.

Pool sizes in kg plasma[274]

2A13. Decisions on pool sizes probably reflected the following factors:

(1) agreed maximum pool size in donations, initially stated as a "ceiling" on the product label;

(2) guidance from HCD hepatitis WP;

(3) actual batch size in kg determined by facility and equipment at the time;

(4) information escalated to head of lab at the time, who would have notified DHSS;

(5) maximum pool size in donations became less relevant as actual pool size increased beyond the point at which it might affect onward transmission of virus, based on incidence of infection in donor population;

(6) maximum pool size escalated once virus inactivation / virus elimination established;

(7) shortly thereafter, no pool size stated on label;

(8) pool size for factor VIII batches determining factor. Downstream products might be recovered from pooled factor VIII batch supernatant.

2A14. The memo sent from Dr Lane to Dr Snape on 29 January 1990[275] attached a list of matters arising out of his reading of the litigation files and requested answers to the same. Dr Lane also attached several tables/data sheets including the number of donations in factor VIII at Elstree (1975 – 1989) and summaries of Factor VIII and IX production.

2A15. In his oral evidence, Dr Snape confirmed that the table on the right hand side showed the maximum pool size, and, on the left, the actual pool size. There

[274] BPL0009120.
[275] BPL0009120.

was headroom. The Stop Gap proposal increased processing – the increased pool size reflected that BPL was processing more plasma as a result (and increased plasma was being supplied). In his oral evidence, Dr Snape confirmed that in order to understand how much plasma was actually being processed at BPL, the plasma weight in table 1b of BPL0009120 at p3 should be used.

Pool size limit (specified in donations) B25>B27*[276]*

2A16. On 10 June 1985, Dr Snape sent a memorandum to Mr Prince (copying in Dr Smith and Dr Lane) headed 'Coagulation Factor Batch Sizes', responding to Mr Prince's memorandum of 25 April 1985[277]. Dr Snape noted his assumption that a limit of 10,000 donations maximum would not restrict operations in the present building, but that an extension of 20,000 donations would be required for the new facilities. Dr Lane approved this increase on 20 June 1986, as demonstrated by a memo from Dr Snape to Mr Prince and Dr Smith[278], asking that any manufacturing documentation was revised before the increased limit was implemented. The donation limit was stated on labels and included on licence documents. Pool size limit was explicitly stated in batch manufacturing records.

2A17. Mr Prince was the coagulation factor production manager at BPL at the time. 10,000 donations equated to ~2000kg plasma.

2A18. In his oral evidence, Dr Snape explained that this memo reflected an attempt to future proof processing: the 10,000 donations maximum that was in place was comfortably above the process that was actually being operated at the time. Product licences did not happen overnight: Dr Snape would have had to anticipate a delay, presumably of something like 6 months, or more, and so the shift to 20,000 donations made sense anticipating the sizes that were

[276] CBLA0002190 and CBLA0004791.

[277] CBLA0002190.
[278] CBLA0004791.

going to be used in the new facility. There would also have been a delay, probably of some weeks, between manufacture and release for sampling.

Communications with DH regarding increasing pool size[279]

2A19. On 20 June 1986, Dr Snape wrote to Dr Smithies (DHSS) regarding "Maximum donor pool size for coagulation factor concentrates" and to advise Dr Smithies of a proposed change to the same[280]. Dr Snape explained that it was "*proposed to increase the maximum number of donations to be pooled from 10,000 to 25,000 plasma donations*" and that *"[i]n taking this decision we were mindful of the terminal heat-treatment of coagulation factor concentrates made from such pools and the fact that any increase beyond the already large 10,000 donor limit is probably not significant.*"

2A20. There is no evidence as to whether this was copied to DHSS at the specific request of Dr Lane, or simply because it was the kind of information that it seemed appropriate to convey. There was no specific guidance on how/what information should be escalated to DHSS, or who should make such communications. It is likely that these issues arose because Dr Lane attended meetings at/with the Department (such as ACVSB) that required he communicate directly; it is likely that Dr Snape would undertake to write at his request. [281]

Product labels for Factor VIII batches and pool sizes at BPL[282]

2A21. This document sets out the three Factor VIII labels:

(1) HL5 intermediate purity (no heat treatment) — pre-June 1985 – maximum 7,500 donations

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[279] DHSC0002303_027.
[280] DHSC0002303_027.
[281] As was the case with the letter exhibited at DHSC0001049 in which Dr Snape replied to Dr Smithies at Dr Lane's specific request, on the subject of sample submission to NIBSC.
[282] BPLL0002039.

(2) 8Y1 high purity (HT3) — June 1985-February 1987 – maximum 10,000 donations

(3) FHC1 – no donation limit – 250 iu dose — February 1987 onward – no donation limit

2A22. This illustrates the transition from 7,500 (pre-June 1985), to 10,000 (June-1985 to February-1987), to no donation limit from February 1987.

Section 3: Knowledge of and response to Hepatitis infection risk

Knowledge of NANB Hepatitis between 1970 and 1991

3.1. CTI has produced a detailed chronology on the knowledge of risk of infection from blood and blood products which includes reference to extensive material relating to the knowledge of risk of NANB Hepatitis. This was supplemented by an oral presentation on 23 and 24 September 2020, during which CTI covered the developing knowledge in respect of NANB Hepatitis in the course of the 1970s, and the knowledge of the seriousness of this condition. The presentation focussed predominantly on knowledge up until 1989. These submissions focus on a similar time period and do not go beyond September 1991, when routine screening of blood donations for HCV was introduced.

3.2. This section is in two parts: the first addresses the emerging knowledge that there was another virus causing Hepatitis, apart from Hepatitis A and Hepatitis B; and the second addresses the developing knowledge around the seriousness of the disease. A detailed analysis of all of the available academic literature is not attempted, in light of the detailed chronology and oral presentation from CTI. Instead, with the aim of assisting the Chair in establishing the backdrop for relevant decision-making, the submissions which follow seek to highlight some of the uncertainties that existed in this period in relation to NANB Hepatitis and the difficulties inherent in any retrospective assessment of the collective state of knowledge of the medical and scientific community.

3.3. In relation to this area, when considering the evidence that points towards early knowledge of the severity of risk of NANB hepatitis, the Chair is also invited to take into account three general considerations:

(1) Whilst there was a significant amount of research conducted in this area, it cannot be said with precision when consensus was reached as to the aetiology and natural history of NANB Hepatitis. Studies often had conflicting results, and it would be unrealistic to expect that findings were immediately accepted, widely known or able to inform clinical practice or policy.[283]

(2) There is a risk when looking at events retrospectively of placing greater emphasis on research which is now known to be correct or a more accurate assessment of the progression of the disease, when that may not reflect what was reasonably understood about the disease at the time.

(3) An assessment of the available material suggests that, while knowledge of the infection risk and severity of NANB Hepatatis did increase over time, there was considerable uncertainty surrounding these issues. Research in this area was not straightforward; there were understandable concerns over conducting liver biopsies on haemophiliacs and much of the research was based on small numbers of patients.[284]

Recognising a NANB Hepatitis virus

3.4. During the presentation to the Inquiry on 23 September 2020, CTI described how:

> *"...from 1972 onwards we begin to see, in various medical and scientific publications, observations from clinicians that, even after the exclusion of donors who had tested positive for Hepatitis B antigen, there were still residual cases of post-transfusion Hepatitis, and so it began to dawn upon clinicians that there may be another form of Hepatitis transmitted by blood or blood products other than Hepatitis B".*[285]

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[283] This something which was recognised in the Penrose Report: Volume 2, Chapter 13 at §4.
[284] For non-exhaustive examples of the risk of liver biopsies and linked research complications, see: (i) Oral evidence of Prof. Christine Lee on 20 October 2020 at 7:1; 14:24; 119:24; (ii) Oral Evidence of Dr David Bevan on 12 January 2021 at 58:8 and 87:4; (iii) Oral Evidence of Professor Brian Colvin on 6 October 2020, at 49:13 and 77:9.
[285] The CTI's oral presentation on 23 September 2020 at 48:9-17.

CTI then referred to the important work of Prince et al in 1974, which appears to be the first reference to an unidentified 'Hepatitis C' virus.[286]

3.5. Professor Sherlock's textbook '*Diseases of the Liver and Biliary System*' provides a useful insight into the historical state of knowledge at this point in time. Described by Dr Walford as "*...the most authoritative textbook on liver disease at the time,*"[287] and by Dr Howard Thomas as being written by the "*...doyenne of liver disease*" and demonstrative of the thinking at any point in time,[288] this textbook is highly relevant to any assessment of the general medical knowledge at the relevant time. The fifth edition published in 1975 made no reference to a NANB Hepatitis virus.[289]

3.6. Throughout 1977 and 1978, there was a growing consensus that three or more viruses were responsible for Hepatitis, and a virus other than Hepatitis B was being transmitted through blood. By October 1978, research into the transmission of NANB Hepatitis was given a high priority by the Department of Health.[290] A meeting of the Medical Research Council on 12 February 1979 reflected the views of the leading professionals in this field at this time. Considerable uncertainty remained. The discussion during that meeting indicates that NANB Hepatitis, whilst concerning, was considered rare in the UK, with uncertainty around whether it was present in the British population. A discussion took place about what exactly constituted a case of non-A, non-B Hepatitis, with the conclusion that the markers were not specific enough to warrant a survey of post transfusion Hepatitis.[291] Thus whilst the risk of non-A, non-B Hepatitis was recognised, the degree of risk and what it meant for

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[286] The CTI's oral presentation on 23 September 2020, at 48:23-50:7; also see Prince M. et al, 1974, 'Long-Incubation post-transfusion hepatitis without serological evidence of exposure to hepatitis-B virus, *The Lancet,* vol 304, no. 7875, pages 241-246; PRSE0001431.
[287] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §56.4.
[288] Dr Howard Thomas' oral evidence on 24 March 2021, at 101:17-102:4. CTI described Professor Sherlock as "a leading expert on liver disease" during the oral presentation on 23 September 2020 (at 72:5-72:6).
[289] Summarised in the Penrose Inquiry Final Report at §14:69 -14.70.
[290] See letter from Professor Buller at the Department of Health & Social Security to Dr Gowans at the Medical Research Council dated 24 October 1978 at MRCO0000033_071.
[291] Minutes of meeting at PRSE0001960.

those receiving blood products in Britain was far from comprehensively understood.

Knowledge of the natural history of NANB Hepatitis

3.7. The preponderance of the evidence before the Inquiry suggests that NANB Hepatitis was initially thought by the medical and scientific community to be a benign, mild disease.

3.8. During the oral presentation on 23 September 2020, CTI in particular highlighted the conclusion reached by Prince et al in their 1974 paper, cited above:

> "*The fact that non-B Hepatitis cases are less frequently associated with serious acute illness does not imply that such cases are of lesser importance. Long-term complications of acute Hepatitis B infection, such as chronic Hepatitis, cirrhosis and hepatoma, have been reported to follow mild anicteric infections more frequently than severe icteric cases; consideration must thus also be given to the possibility that non-B Hepatitis may play a role in the aetiology of some forms of chronic liver disease.*" [292]

3.9. CTI referred to this as an "*...identification of the potential serious long-term consequences for the liver of this newly recognised third form of Hepatitis.*"[293] The hypothesis proposed by Prince et al was garnered from knowledge and experience of the natural history of Hepatitis B and put forward before it was commonly accepted that there was a third type of Hepatitis. Lord Penrose wrote in his report:

> "*...there is a serious risk, in citing the work of researchers such as Feinstone and Prince, of giving the impression that their ground-breaking research immediately entered the common currency of general medical knowledge and informed clinical practice. That would be as unfair as it would be unrealistic.*"[294]

[292] The CTI's oral presentation on 23 September 2020; also see PRSE0001431.
[293] The CTI's oral presentation on 23 September 2020 at 50:8-11; also see PRSE0001431.
[294] Penrose Inquiry Final Report at §14:68.

3.10. Dr Snape's written evidence to the Inquiry was that by the mid to late 1970's he became aware of "*...post-treatment reports of an apparently mild form of Hepatitis, with no apparent serious sequelae*[295]*, and for which Hepatitis A, Hepatitis B and obstructive jaundice had been excluded as possible causes.*"[296] He referred to Professor Howard Thomas' statement to the Penrose Inquiry which had stated that "*...in the early days the liver disease was thought to be relatively mild compared to that seen with HBV for instance. This view started to change on the basis of accumulating data from liver biopsies..*"[297] Dr Snape's oral evidence to the Inquiry was that he did not recall discussion taking place about potential long-term sequelae to NANB Hepatitis in the mid to late 1970s; he became "*...more aware of such discussions as we progressed into the early '80s – '81 through '82.*"[298]

3.11. Dr James Smith, in his Third Draft Proof of Evidence prepared for the HIV litigation dated 1 November 1990, observed that by 1982 most Haemophilia Centre Directors "*...probably*" recognised that NANB Hepatitis was a more frequent cause of hepatitis than Hepatitis B ("HBV").[299] At the same time, he observed that, *"...Most Haemophilia Centre Directors (Dr. F.E. Preston, Sheffield, a notable exception) seemed to think that hepatitis Non-A Non-B was not a very serious disease, rarely causing death, hardly ever giving clinical jaundice, and without the late sequelae of liver cancer or cirrhosis seen after hepatitis B."* Dr Smith's view was that fractionators were much more concerned about NANB Hepatitis than clinicians at this stage, a view with which Dr Snape agreed in his oral evidence to the Inquiry.[300]

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[295] That is to say no apparent serious aftereffect of the disease.
[296] Dr Terence Snape's witness statement dated 8 February 2022 (WITN3431001), at §141.
[297] Dr Terence Snape's witness statement dated 8 February 2022, §142, Professor Howard Thomas' statement to the Penrose Inquiry PRSE0004640.
[298] Dr Snape's oral evidence on 30 March 2022, at 3:11-3:17. See too, for example, the oral evidence of Dr Foster on 24 March 2022, at 149:13-150:16.
[299] Dr James Smith's Third Draft Proof of Evidence prepared for the HIV litigation dated 1 November 1990 (CBLA0000016_034), §35.
[300] Dr James Smith's Third Draft Proof of Evidence prepared for the HIV litigation dated 1 November 1990 (CBLA0000016_034), §35; Dr Snape's oral evidence on 30 March 2022, at 8:10-8:17. Dr Snape's evidence (at 7:24-8:2) was that fractionators had a different perspective to clinicians: "Our job was to try to reflect on potential risks in our products and to put in place mechanisms to limit those risks or limit those risks." He noted that Dr Smith was especially sensitive to issues of hepatitis

3.12. There were studies published in the late 1970s and early 1980s which made reference to NANB Hepatitis having potentially serious consequences. These were set out during CTI's presentation on 23 September 2020. CTI contrasted these studies and reports with a statement by Lord Cullen to the House of Lords on 24 February 1981 in which he said:

> *"There is a danger that Factor VIII which has to be injected into haemophiliacs can have in it a strain of Hepatitis and at the moment there is no way of testing for these strains. That is the one product as to whose freedom from infection we cannot be absolutely certain. However, every effort is made to see that it is not infected and although, occasionally, something may happen, it is not of a serious nature."*[301]

3.13. Unfortunately, searches of the records now available have failed to identify any briefing or other paper that might clarify the material relied upon when this statement was made to the House. In those circumstances, associated context may be provided by the medical and scientific literature as a whole and accepted textbooks in particular. The 6th edition of Professor Sherlock's textbook '*Diseases of the Liver and Biliary System*' was published in March 1981, shortly after Lord Cullen's statement. The relevant extracts were summarised in the Penrose Inquiry Final Report and replicated in Dr Walford's statement to the Inquiry:

> *"Excerpts from the book are quoted in the Preliminary Report at paragraphs 6.110-6.114. Significant points made were:*
>
> *NANB Hepatitis was largely spread by blood and accounted for about 75% of PTH and possibly 15-20% of sporadic Hepatitis; and*
>
> *Haemophilia patients receiving factor concentrates obtained from commercial sources were particularly at risk.*
>
> *The NANB Hepatitis agent had not been 'conclusively identified' and its identity remained uncertain; and*
>
> *The clinical course of the disease progressed to a 'mild, chronic Hepatitis' in about a quarter of patients but this usually improved with time although cirrhosis could develop.*

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resulting from fractionation because of the outbreak in the Edinburgh Royal Infirmary whilst he was still up there, before the building of the new PFC (at 8:17-8:22).

[301] Hansard extract at HSOC0008581, at page 981. CTI described this as being "in fairly stark contrast to the material in the medical and scientific literature that we've been looking at in the second half of the '70s." (CTI's oral presentation on 23 September 2020, at 81:16-19).

Professor Sherlock commented that:

"Non-A, non-B Hepatitis often progresses to a mild chronic Hepatitis. The prognosis of this is, at the moment, uncertain but probably benign."[302]

3.14. Lord Cullen's statement may thus be compared with the views of a leading expert on liver disease at the time, which was to the effect that the prognosis for NANB Hepatitis was "*...uncertain but probably benign*".

3.15. During the presentation on 23 September 2020, CTI referred to an internal minute between Dr Walford and Mr Harley of the Department of Health and Social Security, dated 15 September 1980.[303] The context for the minute was the potential for a takeover of BPL by a commercial company. Warning of the potential for an increase in health hazards were the company to import plasma for fractionation, Dr Walford said this:

"I must emphasise that 90 per cent of all post-transfusion and blood product infusion Hepatitis in the USA and elsewhere is caused by non-A, non-B Hepatitis viruses which, unlike Hepatitis B, cannot at present be detected by testing donor blood. This form of Hepatitis can be rapidly fatal, particularly when acquired by patients with pre-existing liver disease or can lead to progressive liver damage. It can also result in a chronic carrier state thus increasing the pool of these viruses in the community."[304]

3.16. Dr Walford has explained in her statement the review articles that she authored in 1978, which gave her significant insight into the latest research on (relevantly) NANB.[305] She noted that although NANB was a known hazard, this understanding of its potential consequences was less well

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[302] Penrose Inquiry Final Report at §15.86; Dr Walford's witness statement dated 5 July 2021, §56.4.
[303] The CTI's oral presentation on 23 September 2020 at 77:2-20; also see PRSE0001431.
[304] Dr Walford's minute at WITN0282008. See too Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§55.3-55.6 and §§55.11-55.12 and Dr Walford's oral evidence on 19 July 2021 at 95-104 in relation to Dr Walford's own knowledge in relation to NANB Hepatitis when she took up the role of Principal Medical Officer in Med SEB in September 1979.
[305] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§55.4 – 55.12 especially §55.12.

spread amongst her colleagues in the DHSS and amongst Haemophilia Centre Directors.[306]

3.17. The continued uncertainties or limits of scientific understanding about the extent of NANB Hepatitis in the UK and its severity are reflected in the 1981 report produced by the Department's Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibodies.[307] Whilst the focus of the report was on Hepatitis B, the following was said in relation to NANB Hepatitis:

> *"22. Non-A, non-B hepatitis viruses are a common cause of [post-transfusion hepatitis] in the [US] and are thought to have been responsible for cases ... in the UK. Hepatitis due to these viruses is common among haemophiliacs and follows the administration of imported, and occasionally of British Factor VIII and Factor IX. There is evidence for the occurrence of sporadic cases of non-A, non-B in the general adult population and in association with cryoprecipitate therapy in the UK.*
>
> *23. There are at the present time no screening tests for detecting non-A, non-B hepatitis viruses.*
>
> *24. We recommend that research is undertaken in the UK to determine the extent and severity of PTH due to non-A, non-B hepatitis viruses. Unless this is done we will not have the knowledge on which to base any possible future recommendations about screening blood donations for these viruses. Regional Transfusion Directors should encourage hospital haematologists to report all cases of post-transfusion jaundice and where these could be due to non-A, non-B hepatitis the facts should be reported to the appropriate Advisor in Blood Transfusion at the Department of Health and Social Security (DHSS) or Scottish Home and Health Department (SHHD)."*

3.18. Dr Walford referred in her statement to the extract from Professor Sherlock's text book addressed at paragraph 3.13 above, and recognised that:

> *"For haemophilia clinicians in the UK and for the DHSS more generally, understanding of the risks only emerged gradually, primarily through the*

[306] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §56.2, §56.3.
[307] Third Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibodies at PRSE0000862.

surveillance work done by John Craske, Chair of the UKHCDO Hepatitis Working Party". [308]

3.19. The fractionators' perspective (see further below at 3.33) can be seen in the proposal of early 1983 to develop a "*...Hepatitis safe…*" Factor VIII concentrate, which set out the problem:

> *"...The incidence of hepatitis B is diminishing …. The incidence of NANB especially on first treatment of mildly affected patients, remains very high and screening cannot yet be applied…. NANB causes increasing concern, less on account of its acute effects (although deaths have been reported) than because of its association with chronic active hepatitis in later life."*[309]

3.20. Between 1981 and 1985, research was published which continued to suggest that the risk of severe complications from NANB Hepatitis was small. For example:

(1) A study by Mannucci and others published in September 1982 concluded that "*...in haemophiliacs with nAnB chronic Hepatitis, progressive disease is not the rule.*" It noted the clinical and histological evidence of low morbidity and non-progressive disease, and describes it as "*...remarkable that only 2 of the entire series of 91 haemophiliacs since 1974 have died from cirrhosis and that both were HBsAg serum positive*."[310]

(2) In a publication entitled '*Liver Disease in Haemophiliacs: an overstated problem?*' appearing in the British Journal of Haematology on 3 June 1983, Stevens and others suggested after carrying out biopsies on 12 multi-transfused haemophiliacs with persistently abnormal liver function, that the incidence of severe histological liver damage was much lower than previously reported.[311]

(3) An article by Dr Peter Jones in the British Medical Journal dated 10 December 1983 described the high incidence of non-A, non- B

[308] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §56.5.
[309] CBLA0001781.
[310] PRSE0003351.
[311] PRSE0002564.

Hepatitis in patients who had received Factor VIII concentrate; however, it went on to state that:

> *"...despite these gloomy figures the mortality from liver disease remains low, and only two British haemophiliacs died from Hepatitis between 1974 and 1980. Thus probably most of the observed changes in liver function represent chronic persistent [thought to be non-progressive] rather than chronic active Hepatitis."*[312]

(4) The results of the largest study at the time of liver biopsies of patients with haemophilia was reported in August 1985 by Louis Aledort and colleagues.[313] This reported that the rate of cirrhosis was 15% less than previously reported, and that the incidence of the severe necro-inflammatory disease was also lower than previously indicated. The study further revealed that most haemophiliacs suffering from Hepatitis had Chronic Persistent Hepatitis, Chronic Lobular Hepatitis or mild borderline Chronic Active Hepatitis. Whilst commenting that the "*...lack of severity of the histopathological findings in the current materials may not be entirely reassuring*" in light of other research, the authors of the report also note the possibility of reversion towards normal hepatic architecture. It was further reported that there was no evidence of more severe liver disease in patients receiving large-pool concentrates over those treated with cryoprecipitate or plasma. Ultimately, the authors concluded that there was "*...no indication to alter current therapy patterns because of concern over plasma product-related liver disease*." It further suggested that the risk to haemophiliacs of liver biopsies would only be occasionally justified in light of the fact that the vast majority of biopsy specimens "*...showed histologically unimpressive lesions, and as there [was] in any case no currently effective therapy for CAH*."

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[312] HSOC0001285.
[313] Louis Aledort et al, '*A Study of Liver Biopsies and Liver Disease Among Haemophiliacs*', August 1985 available at WITN3289049.

3.21. The 7th edition of Professor Sherlock's '*Diseases of the Liver and Biliary System*' (1985) is summarised in the Penrose Inquiry Final Report as follows:

> *"Professor Sherlock noted four clinical types of NANB Hepatitis (among many). Two were enterically [314] spread and can be ignored for present purposes. The two parenterally spread types were (a) a blood transfusion related type with a relatively long incubation period, and (b) a type associated with the administration of blood products to haemophilia patients, distinguished by a short incubation period. The clinical course of infection was the same in each case. The acute attack was mild but could occasionally be fulminant (rapidly progressing). Approximately 68% of patients developed chronic Hepatitis. In 19%, this progressed slowly and almost without symptoms to cirrhosis. Fluctuating transaminases were said to be typical of the chronic state. It was commented, significantly, that a relationship to hepatocellular cancer had not been established. It was noted that there was no test for NANB Hepatitis and that there had been limited progress both in diagnosis and in assessing treatment."* [315]

3.22. The Penrose Report identifies 1985 as a turning point where information began to emerge that would lead to greater recognition of the potentially serious consequences of NANB Hepatitis.[316]

3.23. The 8th edition of the textbook '*Blood Transfusion in Clinical Medicine*' by Mollison and others published in 1987 described an "*...unsatisfactory method of diagnosis...*" of NANB Hepatitis, leading to "*...a good deal of uncertainty about the true incidence of NANB PTH.*"[317] It described the prognosis of NANB Hepatitis in the following terms:

> *"NANB PTH is usually mild and asymptomatic during the acute phase; 75% of cases are anicteric and even icteric cases tend to have mild symptoms. However, prospective studies in the USA have shown that the chronic sequelae of NANB PTH may be serious. Over 50% of patients develop chronic Hepatitis as judged by persistent or fluctuating rises in alanine amin-transferase (ALT) levels lasting for at least 1 year after the onset of the disease and in most for more than 3 years…. Although the chronic phase of NANB PTH, like the acute phase, tends*

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[314] i.e. transmitted by the faecal–oral route, either by person-to-person contact or by ingestion of contaminated food or water.
[315] Penrose Inquiry Final Report at §15.168.
[316] Penrose Inquiry Final Report at §16.70.
[317] NHBT0000033_053.

> *to be mild (Alter, 1985) some patients develop severe chronic liver disease and 10% of these patients progress to cirrhosis which is generally milder than alcoholic cirrhosis. If 7% of transfusion recipients develop NANB PTH, 50% of these develop chronic Hepatitis and 10% of these develop cirrhosis, then cirrhosis could eventually develop in 0.3%- 0.4% of recipients of blood in the USA. However, the data are based on biopsies in very small numbers of patients (Alter 1985). Moreover the figures relate to patients who have undergone cardiac surgery and do not take into consideration the numbers of transfused patients who die shortly after blood transfusion because of their underlying disease."*[318]

3.24. In the 8th edition of her textbook '*Diseases of the Liver and Biliary System,*' published in 1989, Professor Sherlock continued to suggest that NANB Hepatitis may be caused by more than one virus, and described the clinical picture of NANB Hepatitis as resembling Hepatitis B infection. The relevant section noted that:

> *"In 73% the patient is completely asymptomatic. In 25%, the picture is that of any other acute virus Hepatitis. There may be serum sickness-like prodomata. Rarely the Hepatitis is severe and even fulminant..... In 68% the disease becomes chronic and in 20% cirrhosis develops [10%].*
>
> *Hepato-Cellular carcinoma, often of clear cell type, is a rare complication. Marrow aplasia may be fatal."*[319]

3.25. Following his detailed analysis of the key research available at the time, Lord Penrose concluded in his final report that:

> *"Very little of the information relating to the natural history of HCV infection which is available now, in 2014, would or could have been known until well into the 1990s, after the patients with whom this Report is concerned were already infected by transfusion of blood, blood components or blood products. Hindsight cannot support a view of what should have been understood at earlier periods."* [320]

[318] NHBT0000033_053.
[319] BAYP0000012_011, at page 327.
[320] Penrose Inquiry Final Report at §13.149.

The perspective of fractionators

Knowledge: 1970s

3.26. For a considerable period the risk posed by hepatitis was not fully understood. By the end of 1973 the degree of risk posed by hepatitis was subject to clinical debate. However, it remained unclear whether increasing pool sizes increased the risk posed by hepatitis, or reduced it by 'diluting' any infected donation.

3.27. Dr Biggs produced a paper which was considered at the inaugural meeting of the expert group on the treatment of haemophilia on 20 March 1973. The paper concluded that around 1 in 800 donors carried the Hepatitis B antigen.[321] It recognised (as with AIDS – later), that the risk increased with the number of donors used to prepare the concentrate.

3.28. However, it went on:

> *"But there is the possibility that the development of jaundice may be dose related and that single infected bottles may be more dangerous to the individual patient than pooled material in which the virus is diluted. Despite this, the frequency of hepatitis in severely affected patients does not seem to increase significantly with increased use of freeze-dried concentrates".*[322]

3.29. Dr Biggs' report drew upon a letter written by Carol Kasper and Sally Kipnis of the University of Southern Californian to the Journal of American Medical Association.[323] Whereas Dr Biggs felt there was a possibility single doses could pose a greater danger than large pools, Kasper and Kipnis felt otherwise:

> *"...older children and adults who have had little exposure to blood products are at high risk of developing clinical hepatitis after introduction of clotting-factor concentrates. In such patients, especially those with mild haemophilia, single donor products are preferable. On*

[321] PRSE0002553 at electronic page 10.
[322] PRSE0002553 at electronic page 10.
[323] PRSE0003913.

> *the other hand, in patients with severe hemophilia who may have had many blood and plasma infusion have no increased risk of hepatitis if concentrates are introduced. Concentrates had greatly improved the effectiveness and convenience of management of severe hemophilia and should not be denied to appropriate patients."*[324]

3.30. Kasper and Kipnis' view, that the risks caused by denying patients' treatment were greater than any posed by hepatitis, resemble those later expressed in relation to AIDS (see Section 4 of these submissions, below).

3.31. Dr Snape also recalled that the view of the Oxford Haemophilia Centre during the mid-late 1970s was that NANB had no apparent serious effects.[325]

3.32. Having said that, efforts were made to monitor the effects of the disease. On the recommendation of Professor Zuckerman, a record was made of which batches led to patient sequalae. The results were, in turn, reported to Dr Craske.[326]

Knowledge: 1980s

3.33. By the early 1980s, the importance of Hepatitis B was considered to be falling. This was due to a combination of factors:

(1) Better screening;
(2) The impending introduction of a Hepatitis B vaccination;
(3) Immunity of haemophiliacs who had already been treated with infected concentrate and recovered.[327]

3.34. Dr James Smith's evidence to Lord Penrose was that most Haemophilia Centre Directors seemed to think NANB was not very serious. In their view, it rarely caused death, clinical jaundice, or liver cancer/ cirrhosis. The view

[324] PRSE0003913.
[325] Dr Snape's oral evidence on 30 March 2022, at 2:2-25.
[326] Dr Snape's oral evidence on 30 March 2022, at 2:19-2:25.
[327] Dr James Smith's draft / proof of evidence for the HIV litigation, (CBLA0000016_034), §35.

that NANBH could have serious long-term sequalae "*...was not widely held*".[328]

3.35. Fractionators (such as those at BPL), by contrast, were more concerned.[329] Dr James Smith has described BPL as being "*...very concerned...*" by 1983 about the incidence of NANBH in previously untreated patients.[330]

3.36. Here too the risk of not giving haemophiliacs the product they required was considered to be outweighed by any risk posed by hepatitis. Without treatment it was understood "*...a significant proportion of haemophiliacs would [...] die or suffer severe joint injury*".[331] Dr Snape had a similar recollection of the assessment made by physicians, including those at the Oxford Haemophilia Centre.[332]

3.37. It was also initially understood that Factor IX posed less risk than Factor VIII.[333] However, in 1978 – 79 an alarming incidence of NANB was reported in patients receiving Factor IX for the first time. This led to a reduction in the use of Factor IX product in 'virgin' (previously untreated) haemophiliacs, as the risk-benefit analysis had changed.[334]

3.38. The Hepatitis Working Party's position also changed over this period. In autumn 1981 it had concluded NHS concentrates were less likely to post a risk to 'virgin' donors. 11 to 12 months later, at the Hepatitis Working Party in 1982, the position had changed. It then concluded there was an essentially equal likelihood of transmission from NHS concentrates and commercial

[328] Dr James Smith's witness statement to the Penrose Inquiry dated 22 June 2011 (PRSE0004045), page 4.
[329] Dr James Smith's draft / proof of evidence for the HIV litigation, (CBLA0000016_034), §35; Dr Snape's oral evidence on 30 March 2022, at 2:6-25; 8:10-22.
[330] Dr James Smith's draft / proof of evidence for the HIV litigation (CBLA0000016_034), §87.
[331] Dr James Smith's draft / proof of evidence for the HIV litigation (CBLA0000016_034), §37.
[332] Dr Snape's oral evidence on 30 March 2022, at 2:6-25; 7:11-8:22.
[333] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §34.
[334] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §34.

concentrates. This was subsequently confirmed by a paper from Peter Kernoff.[335]

3.39. In addition, the transmission of hepatitis as part of a clinical trial led fractionators to conclude that only albumin was safe from hepatitis.[336] The evidence of Dr Smith was that fractionators and clinicians shared information with one another about these developments.[337]

3.40. The combination of the above developments made the decision-making with regards to treatment recommendations more difficult. Most clinicians continued to recommend / use concentrates on the basis that the benefits of doing so outweigh the risk. There were *"...lively debates in general and special conferences, as well as the medical journals..."* about the effects of NANB.[338] As Dr Smith pointed out, it was not the place of fractionators to tell clinicians how to make those choices.[339]

3.41. Dr Smith stated in his draft proof of evidence for the HIV litigation by 1982, most Haemophilia Centre Directors probably recognised that NANB hepatitis was by that time a more frequent cause of hepatitis than hepatitis B. But it was only in 1983 that it was realised that almost all first-time recipients were being infected with NANB hepatitis.[340] That change in understanding in 1983 arose after prospective ALT studies were carried out, which involved taking serum samples every 2-3 weeks and testing the level of the transaminase enzyme.[341]

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[335] Dr Snape's oral evidence on 30 March 2022, at 2:6-25, pages 4-5.
[336] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §36.
[337] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §37.
[338] The CTI's oral presentation dated 17 March 2022 at 153:14-15.
[339] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §37.
[340] Dr James Smith's draft / proof of evidence for the HIV litigation, (CBLA0000016_034), §35; (CBLA0000016_034), §35.
[341] Dr James Smith's draft / proof of evidence for the HIV litigation, (CBLA0000016_034), §35; (CBLA0000016_034), §35.

Steps taken by fractionators to reduce/eliminate the risk posed by Hepatitis

3.42. The evidence shows a number of methods were considered, at an early stage, to reduce/ eliminate the risk posed by Hepatitis B and NANB.[342]

3.43. At a meeting on 24 November 1981, Dr Smith addressed the Scientific and Technical Committee for the Central Blood Laboratories on the potential methods for inactivating Hepatitis.[343] They included:

(1) Improvements in the screening of blood donations;
(2) Limiting pool sizes for certain products;
(3) Neutralisation/ absorption of virus by hepatitis antibody;
(4) Vaccination of recipients;
(5) Selective removal of viruses during fractionation (e.g. precipitation with PFG);
(6) Inactivation of viruses (e.g. with B-propiolactone);
(7) Heating.[344]

3.44. As with AIDS, the Inquiry may wish to note the range of options considered, alongside those that were ultimately proved effective.

Quarantining / inventory hold

3.45. To reduce the incidence of Hepatitis BPL introduced a period of 'quarantine' (technically known as an 'inventory hold'). A five-week period of inventory hold was the maximum that could reasonably be achieved at the time. However, over time that was extended.[345]

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[342] Also relevant is the topic of information contained on product labels: see the written statement of Dr Terence Snape dated 8 February 2022 (WITN3431001) §202 and Dr Snape's oral evidence on 30 March 2022, at 67:7 – 66:13, as well as the written statement of Dr Duncan Thomas dated 12 May 2022 (WITN6405001) e.g. at §5.8 – 5.9.
[343] CBLA0001506.
[344] CBLA0001506.
[345] Dr Snape's oral evidence on 30 March 2022, at 116:1-117:6.

3.46. The Inquiry has heard how BPL had a policy of quarantining all donations for 6-months. It is apparent that PFC did not have a similar policy.[346]

Screening for Hepatitis B

3.47. One of the steps taken to reduce the incidence of Hepatitis B was the introduction of screening. Its effectiveness was such that the incidence of Hepatitis B was falling by February 1983.[347]

Screening for NANBH

3.48. Screening for NANBH proved much more challenging. As of February 1983, NANBH could not be screened because there was no known detectable markers of infection.[348] This also meant it was hard to establish if heat-treatment had eliminated the same, without the use of clinical studies which would take some time.[349]

Development of testing

3.49. BPL / PFL introduced RIA testing for Hepatitis B from 1976.[350] Initially both organisations relied upon a commercial test, but over time developed their own.[351] The introduction of a single-plasma pack was designed, in part, to enable more sensitive testing for the Hepatitis B antigen.

Heat treatment

3.50. The development of heat treatment to combat the risk of hepatitis infection is outlined below at Section 5.

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[346] Dr Perry's oral evidence on 31 March 2022, at 147:14.
[347] CBLA0001781, page 1.
[348] The CTI's oral presentation dated 17 March 2022 at 13:16; also see CBLA0001781, page 1.
[349] The CTI's oral presentation dated 17 March 2022 at 20:2-7.
[350] Dr Lane's draft proof of evidence for the HIV Litigation dated 10 December 1990 (CBLA0000005_002), §452.
[351] Dr Lane's draft proof of evidence for the HIV Litigation dated 10 December 1990 (CBLA0000005_002), §453.

Role of the Department of Health – Hepatitis viruses

3.51. The history of the Department of Health's actions with regards to the redevelopment of BPL has already been addressed in Section 2 of these submissions. That apart, its role with regard to Hepatitis risks was less direct than the contribution of BPL. Evidence of its further activities is to be found in a number of areas.

Encouraging or funding research

3.52. Funding for scientific research was generally the role of the Medical Research Council (MRC), which made independent decisions regarding the funding for research proposals. However, there is evidence that the DHSS sought to ensure that research into NANB should be treated as a priority.

3.53. On 24 October 1978, Mr Buller (DHSS) wrote to Dr JL Gowans of the MRC regarding research into the transmission of Non-A Non-B Hepatitis. Mr Buller stated that the subject of transmission of non-A non-B hepatitis had been given high priority by the Department of Health. Mr Buller noted that batches of Factor IX commercial product had been found to transmit non-A non-B hepatitis to chimpanzees. He highlighted the urgency of this matter and requested that the MRC assist in identifying the causal agent of the virus and studies leading to the development of a tests or markers.[352]

3.54. There was follow-up correspondence dated 1 December 1978, in which Dr Gowans wrote to Dr RM Krause (National Institute of Allergy and Infectious Diseases in the USA), regarding research on NANB viruses. He noted the "*demand*" from the UK Department of Health to look into this area, and the absence of relevant UK research at present. He asked about what research was taking place in the USA.[353]

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[352] MRCO0000033_071.
[353] MRCO0000033_062

3.55. Subsequently, the MRC formed a Blood Transfusion Research Committee's Working Party on Post-Transfusion Hepatitis, which first met on 14 February 1980 following an ad-hoc meeting convened in February 1979 at the request of DHSS.[354] The meeting of the Working Party agreed the need for research into matters including the incidence of NANB in the UK. There is an account of the work done in Dr Walford's statement, including the eventual agreement to disband the Working Party as many other groups were active, both inside and outside the MRC.[355]

3.56. Whilst the information about the research that was conducted is scattered, we also note the reference in Dr Walford's statement, to the fact that the retrospective study of hepatitis risks, headed by Dr Craske was financed by the DHSS;[356] see too her further comments about DHSS funding for the more applied end of the research work. [357]

Hepatitis advisory committees

3.57. The Department was advised upon steps to be taken by scientific Committees, namely:

(1) The Advisory Group on Testing for the Presence of Hepatitis B Antigen and its Antibody (see the statement of Dr Walford for a description of its work, in relation to Hepatitis B[358]); and

(2) The Hepatitis Advisory Group, established 27 June 1980 (Dr Walford, paras 59.16 – 29[359]), which pulled together all aspects of matters related to hepatitis viruses, including matters relating to the development of a hepatitis B vaccine.

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[354] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §59.10, §59.11.
[355] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §59.10-§59.15.
[356] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §56.7.
[357] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §58.4.
[358] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§59.2-59.9.
[359] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§59.16-29.

3.58. The content of the discussions of those Groups is not repeated.

Licensing decisions

3.59. The statement of Dr Walford notes the role of the NIBSC and the Licensing Authority, together with the Committee on Safety of Medicines and how it had (for example) taken action to restrict clinical trials of prothrombin-concentrate for indications other than haemophilia B.[360] This is simply an example of the wider role of the Licensing Authority. The topic is addressed in greater detail with respect to the emerging risk of AIDS, to which we now turn.

[360] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §56.2 and 58.3.

Section 4: Knowledge of and the response to AIDS

Knowledge of AIDS

4.1. The chronology of the emerging knowledge of AIDS and, in particular, the emerging understanding of its impact on haemophilia and other patients, is relevant for the assessment of the official response to the AIDS epidemic as it affected those who received blood products and transfusions of blood and blood components. Core participants have been provided with a detailed chronology on the knowledge of risk of infection from blood and blood products, produced by CTI, which was supplemented by an oral presentation from CTI delivered on 23 and 24 September 2020. In light of this, these submissions do not seek to provide a detailed narrative of events relating to the emerging knowledge of AIDS in the first half of the 1980s. Instead, what follows comprises:

(1) A broad overview in table form of the key published reports of cases of the condition that became known as AIDS in the United States ("US") and beyond and the scientific research findings relating to the agent of transmission in AIDS, from the first report of the condition in 1981 to the publication of the preliminary details of Dr Gallo's discovery of HTLV-III in May 1984. This is included in order to provide the contextual backdrop to the response of the Department and associated bodies to AIDS.

(2) A summary of the evidence from advisors and decision-makers within the Department and associated bodies about how their own knowledge of AIDS developed in the run up to the Spring/Summer of 1983, when a number of key decisions were made about the response to the threat of AIDS.

Key published reports of AIDS cases

Date	Event	Document reference	Key facts included in the document
5 June 1981	The first publication by the Centre for Disease Control in the United States of reports of cases of the condition that was to become known as AIDS ("the condition").[361]	*"Pneumocystis Pneumonia – Los Angeles"*, The Morbidity and Mortality Weekly Report ("MMWR")[362]	Physicians in New York, Los Angeles and San Francisco had reported five previously healthy homosexual men with Pneumocystis carinii pneumonia ("PCP"), laboratory confirmed previous or current cytomegalovirus ("CMV") and candida mucosal infection. Apart from the unusual nature of their illnesses, there was no common characteristic other than homosexual activity and in that respect the patients did not have a history of association with each other.
12 December 1981	The Lancet published a report of the condition in a patient in the UK.[363]	R M Du Bois et al, *"Gay Compromise Syndrome"*, The Lancet[364]	The article published details of a 49-year-old homosexual man (a frequent visitor to Florida), who had reported to Brompton Hospital. He was diagnosed with PCP and cytomegalovirus (CMV) but had no underlying immune deficiency.
3 July 1982	An article in the British Medical Journal ("BMJ") reported that four previously healthy Danish homosexual men had developed	J Gerstoft et al, *"Severe acquired immunodeficieny in European homosexual men"*, The BMJ Vol 285,	All previously reported cases were in patients living in the USA, except one who made regular visits. The four Danish cases had *"all the characteristics of those in the USA, which indicates*

[361] CTI's oral presentation on 23 September 2020, at 81:20-82:4; described in the Penrose Inquiry Final Report at §9.18 as "*The first published recognition by a public health body of what was to become characterised in the 1980s as 'the AIDS epidemic*".
[362] CGRA0000242.
[363] CTI's oral presentation on 23 September 2020, at 84:1-84:9.
[364] PRSE0004476.

	Kaposi's sarcoma or opportunistic infections with fever of unknown origin and lymphadenopathy.	pp. 17-19[365]	*that the syndrome has spread to Europe*".
9 July 1982	The CDC published details of reports of opportunistic infections and Kaposi's sarcoma among Haitian immigrants to the US.	*"Opportunistic Infections and Kaposi's Sarcoma among Haitians in the United States"*, The MMWR[366]	Reports of opportunistic infections and Kaposi's sarcoma among Haitians residing in the US had recently been received at CDC. A total of 34 cases in 5 states had been reported to date.
16 July 1982	The first publication by the Centre for Disease Control in the US of reports of the condition in Haemophilia A patients in the US.[367]	*"Pneumocystis Carinii Pneumonia among persons with Haemophilia A"*, The MMWR[368]	The CDC had recently received reports of three cases of PCP among patients with Haemophilia A and without other underlying disease. All three were heterosexual men with no history of intravenous drug use. Two had died. One remained critically ill. Although the cause of the severe immune dysfunction was unknown, the occurrence among three haemophiliac cases suggested the possible transmission of an agent through blood products.
24 September 1982	The total number of AIDS cases reported to the CDC in the US between 1 June 1981 and 15 September 1982 was published in the MMWR.	*"Update on Acquired Immune Deficiency Syndrome (AIDS)"* – United States, The MMWR"[369]	There were 593 reported cases, of which 2 cases were in patients with Haemophilia A (the third haemophiliac with pneumocystis exceeded the 60-year limit of the AIDS case definition).

[365] PRSE0002691.
[366] PRSE0003880.
[367] CTI's oral presentation on 23 September 2020, at 86:7-87:1.
[368] PRSE0000523.
[369] OXUH0002848.

10 December 1982	The CDC published details of a possible transfusion-associated case of AIDS in a 20-month old baby in San Francisco.[370]	*"Update on Acquired Immune Deficiency Syndrome (AIDS) among Patients with Haemophilia A"*, The MMWR[371]	The baby had received multiple transfusions including a transfusion of platelets from a male donor subsequently found to have acquired AIDS. This edition of the MMWR also reported four further cases of AIDS in Haemophilia A patients and one suspect case.
28 April 1983	A report prepared by the Council of Europe dated 28 April 1983 summarised the AIDS situation in member states and other countries represented on the committee, as then reported.	Council of Europe report prepared by the Directorate of Economic and Social Affairs: *"AIDS (Information on the present situation in Council of Europe member States and in other countries represented on the committee)"*[372]	The report was discussed at the meeting of the Committee of Experts on Blood Transfusion and Immunohaematology in Lisbon held between 16 and 19 May 1983. The UK had eight possible cases, all males, the majority of whom were known to be homosexual. None of the UK cases followed the transfusion of blood or blood products. Of the 18 countries providing information for the report, 4 had no reported AIDS cases and 9 countries had fewer than 5 reported cases and the majority of the cases were in homosexuals. Belgium had 15 cases affecting heterosexual men and women from Zaire (now the Democratic Republic of Congo). West Germany was the European country with the highest number of cases,

[370] CTI's oral presentation on 23 September 2020, at 94:13–94:24.
[371] PRSE0003276.
[372] PRSE0003366.

			18, two of whom were haemophilia patients. Spain's 3 reported cases were all in haemophilia patients from the Andalusia region (two were brothers). Cases of AIDS in Canada were also included in the report. There were 31 known patients.
30 April 1983	The Lancet published a report of the three Spanish cases of AIDS in haemophiliacs.	E Lissen et al, *"AIDS in haemophilia patients in Spain"*, The Lancet[373]	The authors reported that three haemophilia patients, treated with commercial concentrates of factor VIII, with severe opportunistic infections, were the first cases of AIDS in Spain. "*Reports of AIDS in European homosexuals point to the diffusion of AIDS beyond the USA, as do our own observations. Clinicians should be aware of the possibility of this syndrome in haemophiliacs who present with prolonged fever, respiratory symptoms, and weight loss. Other signs (lymphadenopathy, thrombocytopenia) are possible.*"
30 April 1983	The Lancet's report of the San Francisco baby case.[374]	Arthur J. Ammann et al, *"Acquired Immunodeficieny in an infant: possible transmission by means of blood*	The authors noted that despite the known association of administration of blood products and transmission of infectious agents there had been no reports of AIDS in transfused patients

[373] PRSE0002321.
[374] CTI's oral presentation on 23 September 2020, at 97:6-98:3.

		products", The Lancet[375]	except for patients with Haemophilia A. The authors believed that AIDS developed in this patient as a result of an infectious agent being transmitted by blood product administration; it was possible, however, that he was born with a primary immunodeficiency disorder which did not show until 6 months of age.
The week ending 6 May 1983	The first report of AIDS in a patient with haemophilia in the UK.[376]	The Communicable Disease Report[377]	"*Acquired immune deficiency syndrome has been reported in a 20-year old man with haemophilia in Cardiff. For three months he has had oro-pharyngeal and oesophageal candida infection and has recently been treated in hospital for epididymo-orchitis. He has lymphopoenia and a low T helper/suppressor ratio. There is no known underlying cause of immunosuppression. This is the first report of AIDS in a patient with haemophilia in the United Kingdom known to CDSC.*"
20 May 1983	An article appeared in Science reporting that the team of scientists at the Institut Pasteur in Paris had isolated a retrovirus, which they named lymphadenopathy-associated virus	Barré-Sinoussi et al, *"Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS)"*, Science, 1983; 220: 868–871[378]	The abstract summarised the authors' conclusion from the studies done as being that the virus they had isolated as well as other recently discovered human T cell leukemia virsuses ("HTLV") belonged to a general family of T-lymphotropic retroviruses that are horizontally

[375] PRSE0000317.
[376] CTI's oral presentation on 23 September 2020, at 84:5-84:9.
[377] DHSC0002227_020.
[378] PRSE0004469.

	(LAV), from cultures of T-lymphocytes derived from the lymph nodes of a patient with signs and symptoms thought to precede AIDS.		transmitted in humans and may be involved in several pathological syndromes, including AIDS. They noted as follows in the concluding paragraph: "*The role of this virus in the etiology of AIDS remains to be determined*."[379]
6 August 1983	The BMJ published a report provided by the Public Health Laboratory Service Communicable Disease Surveillance Service, which provided the results of surveillance of AIDS in the UK for the period January 1982 to July 1983.	*"Surveillance of the acquired immune deficiency syndrome in the United Kingdom, January 1982-July 1983"*, The BMJ Vol 287[380]	In September 1982 a surveillance scheme to monitor Kaposi's sarcoma and opportunistic infections in Britain was set up by the Public Health Laboratory Service Communicable Disease Surveillance Centre ("CDSC") in collaboration with the Communicable Diseases (Scotland) Unit. The results from the scheme up to 31 July 1983, included retrospective data from 1 January 1982. 14 cases had been reported to the CDSC. Of the 14 patients, 12 were homosexual, one was a drug abuser and one had Haemophilia A. The haemophiliac patient was from Wales and had received Factor VIII imported from the US. Seven patients were thought to have had sexual contact with Americans. Two of the homosexual men reported had had sexual contact with each other. "*A total of 1831 cases of*

[379] The Penrose Inquiry Final Report at 29.6 described the conclusion of the authors as "*…uncommitted on the issue of whether the new virus was the aetiological agent causing AIDS*".
[380] PRSE0000653.

			acquired immune deficiency syndrome had been reported in the United States up to 11 July 1983. The American epidemic curve showed an exponential increase in 1982, but no such rise was evident in Britain up to July 1983. As seven of the 14 British patients had had sexual contact with American nationals the current picture here is mainly a reflection of the American epidemic rather than an indication of spread in this country." "*Only one patient with haemophilia has been seen in Britain out of a population of about 2167 patients receiving treatment for this condition. Although the risk from blood products imported into Britain seems at present very small, further supplies of factor VIII for this country will be manufactured only from plasma collected in accordance with the United States Food and Drugs Administration regulations designed to exclude from plasma donations donors from high risk groups.*"
12 December 1983	A draft report from a World Health Organisation ("WHO") conference held in Geneva in November 1983 provided figures for	*"Acquired Immunodeficieny Syndrome, an assessment of the present situation in the World"*, Draft report following	There were 2868 cases reported to the CDC by 5 December 1983. Of these, 71.5% of cases were in homosexual or bisexual men, 17.1% of cases were in intravenous drug users, 0.7% of cases were in

	the number of AIDS cases reported to the WHO by the US and European countries.	the WHO conference[381]	haemophiliacs with no other risk factors and 1% of cases had received a blood transfusion in the five years before diagnosis.[382] 24 AIDS cases had been reported by the UK to the European Regional Office of the WHO as of 20 October 1983.
2 December 1983	The number of cases of AIDS in the US in haemophiliacs reported to the CDC was published in the MMWR.	*"Current Trends Update: Acquired Immunodeficieny Syndrome (AIDS) Among Patients With Hemophilia - United States"*, the MMWR[383]	As of 30 November 1983, 21 cases of AIDS had been reported in haemophilia patients in the USA, 19 in patients with Haemophilia A and 2 in patients with Haemophilia B. In addition, 7 cases from outside the USA had been brought to the attention of the CDC. "*Although the etiology of AIDS remains unknown, epidemiological evidence suggests an infectious cause. The possibility of blood or blood products as vehicles for transmission of AIDS to haemophilia patients is supported by the increased risk of AIDS in intravenous drug abusers and reports of transfusion-associated AIDS cases.*"
23 April 1984	Dr Gallo and his group announced that a retrovirus belonging to the HTLV family and designated HTLV-III had been isolated	US Government press release material[384]	Intramural scientists at the National Cancer Institute had discovered that variants of a human cancer virus were the probable cause of AIDS. A new virus, HTLV-III had been isolated

[381] PRSE0004401.
[382] See the table at PRSE0004401_033, and PRSE0004401_003.
[383] PRSE0000551.
[384] DHSC0000455.

	from a total of 48 subjects, some with AIDS, some with 'pre-AIDS' and some without symptoms but in risk groups; and that HTLV-III was the probable cause of AIDS.		from blood samples of more than 50 patients with AIDS, symptoms that sometimes lead to AIDS and some healthy male homosexuals at risk of developing AIDS. About 90% of the patients tested had high levels of antibodies to the virus (an indicator of infection).
4 May 1984	Preliminary details of Dr Gallo's discovery were published in two papers in Science.	Robert C. Gallo et al, *"Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV - III) Patients with AIDS and at Risk for AIDS"*, Science, Vol 224[385] Robert C. Gallo et al, *"Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS"*, Science[386]	A retrovirus belonging to the HTLV family and designated HTLV-III had been isolated from a total of 48 subjects, some with AIDS, some with 'pre-AIDS' and some without symptoms but in risk groups. The epidemiological data suggested that HTLV-III was the primary cause of AIDS.

Evidence of fractionators about their developing knowledge of AIDS

4.2. Knowledge of AIDS in the UK was less well developed than in the US. Dr James Smith, for example, probably first heard about AIDS in 1982 after a

[385] PRSE0001131.
[386] PRSE0001785 – a Summer 1984 re-print of the original article.

colleague brought back a cutting from an American newspaper. He did not hear about it from scientific literature.[387]

4.3. Dr James Smith's evidence was that in 1982 AIDS appeared to be confined to homosexuals, Haitians and haemophiliacs. At that time, "*...it was hard for many to accept that transmission by body fluids could be a common factor*".[388] The main alternative hypothesis at the time was that "*junk protein*" was causing immunological damage.[389]

4.4. By 1983, however, "*...most blood transfusion professionals had concluded that the patterns of AIDS transmission strongly suggested involvement of a blood-borne virus.*"[390] A meeting on 23 March 1983 brought to the CBLA's attention that blood transfusion / products were being associated with AIDS.[391]

4.5. There is strong evidence that fractionators, such as those at BPL, were more attuned to the possibility of AIDS being transmitted via bodily fluids such as blood. Dr James Smith has described the opposition of clinicians to that view as "*well established.*"[392]

Evidence of advisors and decision-makers from within the Department and associated bodies about their developing knowledge of AIDS

4.6. Dr Walford was the Principal Medical Officer in the medical division of the Department with responsibility for advising on blood and blood products, the Scientific Services, Equipment and Building Division ("Med SEB") from September 1979 to December 1983. It was Dr Walford's evidence in her written statement to the Inquiry that during this period *"...the agent causing*

[387] CTI's oral presentation on 18 March 2022, at 14:3 – 14:5.
[388] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §42.
[389] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §43.
[390] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §44.
[391] CBLA0001691.
[392] CTI's oral presentation on 18 March 2022, at 13:6-13:8.

AIDS was quite unknown and even the existence of a viral agent transmissible by blood was still very much in question". [393] Dr Walford explained this comment by reference to the research discoveries relating to the agent of transmission in AIDS:

> *"70.3. Sometime around the middle of 1983, an agent called LAV (Lymphadenopathy-Associated Virus) was described by Luc Montaignier in France, but it was not identified as the cause of AIDS. It was not until April 1984 that Robert Gallo, in the USA, described a virus that he called HTLV-III (Human T-cell Lymphotrophic Virus). After a period of controversy, LAV/HTLV-III were recognised to be virtually the same entity and also the agent responsible for causing AIDS."*

4.7. Notwithstanding this, it was Dr Walford's feeling by early 1983 that it was likely that AIDS was transmissible through blood and blood products.[394] It was Dr Walford's written and oral evidence to the Inquiry that from January 1983 onwards, the Department's awareness of the potential for transmission of AIDS through blood and blood products grew incrementally.[395] Dr Walford explained in her oral evidence that this developing awareness followed the San Francisco baby case (referenced in the table above at paragraph 4.1):

> "*Of course you could not actually conclude from the one case -- for which other explanations were being given, I may say, rather than that it was a transmission of AIDS. That was still controversial, even amongst those who knew about that case, in the medical press. But I think that gradually the feeling in the wider department, if you like, was that: actually, this is looking more and more likely that blood and blood products are certainly capable of transmitting this agent. Not necessarily we conclude that they have but they are capable of doing it.*" [396]

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[393] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §70.2. See too Dr Walford's oral evidence on 20 July 2021, at 240:12-242:14. Dr Walford's evidence was consistent with the evidence of Sir Joseph Smith: Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.2 & §3.4. He spoke of the importance of Montagnier's work; "*it only became clear that AIDS was caused by a virus at the end of 1983"; this was "preceded by much speculation and debate*."

[394] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §71.2; Dr Walford's oral evidence on 20 July 2021, at 121:8-122:15.

[395] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §71.3; Dr Walford's oral evidence on 20 July 2021, at 122:16-123:8.

[396] Dr Walford's oral evidence on 20 July 2021, at 122:23-123:8. The evidence before the Inquiry suggests that the fractionators at the BPL at Elstree and the PCF at Oxford were also operating on the basis that it was likely that AIDS was transmissible through blood and blood products by early 1983.

4.8. It was Dr Walford's evidence that there developed a "*'mainstream acceptance*", by the Department,[397] that AIDS was most likely to be caused by an infectious agent transmissible through blood.[398] There were still competing aetiological hypotheses being put forward in the medical literature in 1983, one of which was referred to by Dr Keith Fowler, a medical assessor to the CSM, in his paper prepared for the 13 July 1983 meeting of the Biologicals Sub-Committee of the Committee on the Safety of Medicines ("CSM(B)").[399] Dr Fowler gave his view in the paper that the most convincing hypothesis so far on the aetiology of AIDS was the theory of antigenic suppression of T-cell immunity. However, notwithstanding the fact that Dr Fowler found this alternative aetiological hypothesis from the medical literature more convincing, he accepted that the precautions to be taken should be based on the single unknown virus hypothesis.[400]

4.9. It appears from the evidence before the Inquiry that the first time ministers within the Department were briefed on AIDS was on 3 May 1983, when a briefing for the Prime Minister, which had been prepared by Health Services Division 1 ("HS1")[401] following press reports about AIDS, was sent to the Private Secretary to Geoffrey Finsberg, the Parliamentary Under Secretary of State for Health and the Minister with responsibility for blood and blood products.[402] It was copied to the Private Offices of other DHSS ministers in the Commons but not to PS(L).[403]

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[397] Dr Walford's oral evidence on 20 July 2021, at 123:14 – 123:25 was that there was *"reticence amongst UK Haemophilia Centre Directors that this was potentially transmissible"*.
[398] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §71.4.
[399] DHSC0002229_059.
[400] Dr Fowler's paper at DHSC0002229_059; Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §71.4; Dr Walford's oral evidence on 20 July 2021, at 124:1-124:11 ("*...although he was not sure whether a transmissible agent was actually the main cause, if you like, of AIDS, he was -- nevertheless thought that we should treat it as if it was*").
[401] It was Dr Walford's oral evidence to the Inquiry that whilst the briefing came from HS1, it would have been "*...on the advice of*" the lead medical division within the Department for transfusion-transmitted infections, Med IMCD (International Health, Microbiology of Food and the Environment and Communicable Disease): Dr Walford's witness statement dated 5 July 2021(WITN4461001), §86.4; Dr Walford's oral evidence on 20 July 2021, at 151:12 – 152:10. Dr Walford's division, Med SEB, was responsible for advice on blood and blood products.
[402] Dr Walford's witness statement dated 5 July 2021(WITN4461001), §73.12 and §86.2; minute from Mr Parker to Mrs Walden dated 3 May 1983 and line to take at DHSC0001651; Q&A briefing at WITN4461123. It was Dr Walford's evidence to the Inquiry that whilst the briefing came from HS1, it

4.10. The briefing consisted of a 'line to take' and a question and answer ("Q&A") background note, the latter of which contained the following two questions and answers:

> *"IS IT CAUSED BY A VIRUS?*
>
> *The cause of AIDS is unknown. Although medical opinion is tending to favour a virus as the agent responsible, there is no proof that this is the cause. There is no means of testing for the presence of AIDS in patients or in blood or blood products such as FVIII.*
>
> *[…..]*
>
> *IS IT TRANSMITTED IN BLOOD OR BLOOD PRODUCTS?*
>
> *As yet there is no conclusive proof that AIDS is transmitted by blood as well as by homosexual contact, but the evidence is suggestive that this is likely to be the case. The evidence relates to some 11 haemophiliacs in the USA and three in Spain, in whom the most likely explanation for the development of AIDS was their exposure to American FVIII concentrates. There is also some evidence that AIDS has been transmitted to babies in blood transfusions."* [404]

4.11. Lord Glenarthur requested a briefing on AIDS shortly after he became Parliamentary Under Secretary of State for Health in the House of Lords after the General Election, on 14 June 1983.[405] A paper written by Dr Walford was duly provided on 22 June 1983 under cover of a minute from Dr Oliver to Lord Glenarthur's Private Secretary.[406] This paper was also provided to John Patten, Mr Finsberg's successor as Parliamentary Under Secretary, on 28 June 1983.[407]

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would have been "*on the advice of*" the lead medical division within the Department for transfusion-transmitted infections, Med IMCD (International Health, Microbiology of Food and the Environment and Communicable Disease): Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.4; Dr Walford's oral evidence on 20 July 2021, at 151:12- 152:10.

[403] Lord Trefgarne was Parliamentary Under Secretary of State in the Lords at this time; his recollection was that Mr Finsberg had blood and blood products within his portfolio of responsibilities. Lord Trefgarne's witness statement dated 7 December 2022 (WITN7478001), §§2.1. – 2.2.

[404] WITN4461123_0002- WITN4461123_0003.

[405] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282021), §§12.2-12.3.

[406] The minute is at DHSC0002309_123, the paper is at DHSC0002309_124; Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282021), §12.3; Dr Walford's witness statement dated 5 July 2021 (WITN4461157), §97.7.

[407] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.2.

4.12. Among other matters, the paper dealt with the spread of AIDS and the cause of AIDS:

> *"SPREAD OF THE DISEASE*
>
> *The pattern which emerges, is of a disease which appears to be transmitted predominantly by male homosexual activity but also by heterosexual means. As a secondary method of spread, contaminated needles used by drug addicts and the transfusion of blood and plasma taken from donors carrying the AIDS agent, account of the occurrence of AIDS in intravenous drug abusers, haemophiliacs and recipients of blood transfusion. Haemophiliacs seem at greatest risk of acquiring AIDS in this way, since the clotting factor which they need (Factor VIII) is prepared from the pooled plasma from many thousands of donations. It is interesting, however, that although the numbers of AIDS cases reported in homosexuals appears to be increasing at a rate of 4-5 new cases daily, the numbers of haemophiliacs with AIDS (10 out of an estimated 12,000 haemophiliacs requiring treatment in the USA) does not seem to have altered over the past several months.*
>
> *[....]*
>
> *CAUSE OF AIDS*
>
> *The cause of AIDS is unknown, but the evidence is suggestive that it may be a virus. It also seems likely that some additional predisposing factor – perhaps a pre-existing defect in immunity – may determine an individual's susceptibility to infection by the AIDS agent. No one virus has emerged as the 'front-runner' for AIDS, but the most promising newcomer to the scene is the human T-cell leukaemia virus (HTLV). The problem to determine whether this virus is present in AIDS sufferers because it causes the disease or because it has invaded after AIDS has destroyed the patient's immune system."* [408]

4.13. On 1 July 1983, a ministerial submission was sent by officials to Lord Glenarthur's private secretary, copied to the private secretaries to John Patten and Kenneth Clarke, seeking agreement to funding and publication of an information leaflet about AIDS for distribution by the National Blood Transfusion Service.[409] The following 'background' information was provided to ministers:

> *"There is increasing evidence that AIDS may be transmitted by the transfusion of blood which is taken from a person who is either suffering from AIDS or who is in the incubation period of the disease. Blood products, such as Factor VIII for the treatment of haemophilia, may also transmit AIDS and haemophiliacs are at particular risk of contracting the*

[408] DHSC0002309_124_0001- DHSC0002309_124_0002.
[409] The covering minute is at DHSC0002309_024; the submission is at DHSC0002309_121.

> *disease because Factor VIII concentrates are made from the pooled plasma of up to 5,000 donors. In this country there have been 12 confirmed cases of AIDS, 11 of which have occurred in homosexuals and one in a haemophiliac. It is believed that there may be under-reporting of cases.*
>
> *Although there is no conclusive evidence, it seems very likely that AIDS is caused by an as yet unidentified virus. ……. "*[410]

4.14. It was Lord Patten's evidence to the Inquiry that in terms of his own understanding of the degree of risk of transmission of AIDS by blood or blood products he would have been "*...guided by the advice of officials contained in documents such as Dr Walford's paper of 22 June 1983, and the submission of 1 July 1983*".[411] In the context of the decisions in the summer of 1983 about the proposed information leaflet on AIDS (which is addressed further below), Lord Patten's evidence was that action was being taken because "*we were acting on the assumption that AIDS could be transmitted by blood*".[412]

4.15. While the Department proceeded on this basis, the Inquiry has heard evidence that there remained in 1983 a lack of consensus about the cause of AIDS.[413] In February 1984, the question of whether AIDS could be caused by transmission of an infectious agent in blood or blood products was still being debated by the experts in relevant fields (for example, at a meeting arranged by the NIBSC to examine the infectious hazards of blood and blood products).[414] The Chair is invited to consider whether any

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[410] DHSC0002309_121_0001.
[411] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.36.
[412] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.45. See too Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §7.113.
[413] Dr Walford's oral evidence on 20 July 2021, at 132:8-132:14 and 174:21-175:9; Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.4. See too: Lord Fowler's recollection that "*...in the early 1980s there were no certainties*" about AIDS (Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.2); see also Lord Fowler's oral evidence on 21 September 2021, at 133:23-134:4; Lord Glenarthur's evidence to the Inquiry that at the time when early explanations of risk were being provided to him, the risk of transmission by blood products that might prove to contain the AIDS agent was not fully understood (Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §13.3); Lord Glenarthur's oral evidence on 22 July 2021, at 36:2-5.
[414] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.4 and Draft Minutes of Meeting on the Infectious Hazards of Blood Products NIBSC, 9 February 1984 at PRSE0003071; see too the Penrose Inquiry Final Report at §9.149: "*It remained a common view*

assessment now of the adequacy of action being taken in 1983 and early 1984 in response to AIDS[415], should reflect that decisions at that time were being made when the single transmissible agent aetiological hypothesis might turn out to be wrong.

4.16. By way of further context, until early May 1983, there were no reported cases of AIDS in haemophiliacs in the UK.[416] The CDSC was not notified of a second case until September 1983.[417] There were by July 1983 some 11 recorded cases of AIDS in haemophiliacs in the US, less than 1% of the total recorded cases, out of an estimated 12,000 haemophiliacs receiving treatment in the US.[418] The relatively low number of cases was a relevant factor for Dr Walford when she was considering what action should be taken in response to the threat of AIDS both in January and in May 1983 (see further below).[419] Lord Patten's evidence was that ministers would have "*...noted that the case numbers (at this stage[420]) were small, albeit in relation to a disease with a lengthy incubation period*".[421] The early case numbers of AIDS among haemophiliacs being "*...low in absolute terms...*" was something also noted by Lord Fowler in his evidence to the Inquiry.[422]

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among most commentators in the UK until July 1984 that the cause of AIDS was unknown and that it had not been established that it resulted from transmission of a specific agent in blood products."

[415] Before Dr Gallo's discovery in April 1984.

[416] The Communicable Disease Report for the week ending 6 May 1983 at DHSC0002227_020, referred to in the table above at paragraph 4.1.

[417] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §102.7-102.9 and case 17 in the case summary attached to Dr Sibellas' minute to Dr Field at WITN4461150. In fact, there were still only two reported cases of AIDS in haemophilia patients in the UK by the time of the 9 February 1984 meeting arranged by the NIBSC to examine the infectious hazards of blood and blood products, with particular reference to hepatitis and AIDS: Draft Minutes of Meeting on the Infectious Hazards of Blood Products NIBSC, 9 February 1984 at PRSE0003071.

[418] See Dr Fowler's papers prepared for the 13 July 1983 CSM(B) meeting at DHSC0002229_059, the paper provided for Lord Glenarthur and Mr Patten on 22 June 1983 and 28 June 1983 respectively at DHSC0002309_124 and the Q&A briefing sent to Mr Finsberg on 3 June 1983 at WITN4461123.

[419] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.32 and §86.34; Dr Walford's oral evidence on 20 July 2021, at 131:20-132:1 and 174:16-174:20.

[420] June/July 1983.

[421] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.22(3).

[422] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.2. Lord Glenarthur also noted, in his evidence to the Inquiry, that at the time when early explanations of risk were being provided to him, the risk of transmission by blood products that might prove to contain the AIDS agent was not fully understood: Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §13.3.

4.17. More broadly, at this stage and for some time to come the disease was considered to be very largely a US problem.[423] The AIDS epidemic that later followed in the UK was not, at this stage, anticipated.

Response to AIDS

4.18. The documentary record and witness evidence before the Inquiry show that a number of steps had been taken in response to AIDS by the Department and associated bodies in the UK by the middle of July 1983. These can be summarised as follows:

(1) AIDS surveillance by the CDSC was conducted from September 1982.[424] The surveillance scheme was extended in March 1983 by inviting doctors working in all branches of medicine to report the syndrome to the CDSC, with appeals being made in the British Medical Journal and the Lancet.[425] Haemophilia Centre Directors, in particular, had been asked to report cases to the CDSC.[426] In addition, the Haemophilia Centre Directors had instituted a survey to receive early information on possible AIDS cases and all UK cases were also being reported to the CDC in Atlanta.[427]

(2) On 28 March 1983, Dr Joseph Smith, then the Director of the NIBSC wrote to Dr Keith Fowler of Medicines Division, DHSS, advising that the issue of "*...the problem of AIDS in relation to licensed blood products...*" should be considered at a meeting of the CSM(B), with

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[423] The Penrose Inquiry Final Report at §9.149; see, for example, the report provided by the Public Health Laboratory Service Communicable Disease Surveillance Service, published in the BMJ on 6 August 1983, which provided the results of surveillance of AIDS in the UK for the period January 1982 to July 1983: "*As seven of the 14 British patients had had sexual contact with American nationals the current picture here is mainly a reflection of the American epidemic rather than an indication of spread in this country.*"

[424] "*Surveillance of the acquired immune deficiency syndrome in the United Kingdom, January 1982-July 1983*", the BMJ Vol 287 at PRSE0000653, PRSE0000653_0001.

[425] "*Surveillance of the acquired immune deficiency syndrome in the United Kingdom, January 1982-July 1983*", the BMJ Vol 287 at PRSE0000653, PRSE0000653_0002.

[426] See the minute from Dr Sibellas to Dr Field dated 5 May 1983 at DHSC0003824_181; and the minutes of the HRCD meeting of 13 May 1983 at **HCDO0000003_008**.

[427] The briefing provided for Lord Glenarthur and Mr Patten on 22 June 1983 and 28 June 1983 respectively at DHSC0002309_124_0002.

special invitations to appropriate experts to be issued.[428] This was the genesis of the meeting of 13 July 1983 referred to further below.

(3) As is addressed further below at paragraph 4.58, in April 1983, senior management at the BPL and the CBLA considered whether the BPL could manufacture small pool freeze-dried cryoprecipitate in significant amounts, as an alternative to large pool intermediate factor concentrate. The consensus view of fractionators was that it could not.

(4) By early May 1983, the lead medical division within the Department for transfusion-transmitted infections, Med IMCD (International Health, Microbiology of Food and the Environment and Communicable Disease), had met with Dr Gunson, Consultant Advisor to the Department in Blood Transfusion, who was in touch with Regional Transfusion Directors; alternative supplies of Factor VIII were being actively considered.[429] Possible sources were then actively explored. For example, in May 1983 Dr Gunson discussed with the Director of the Swiss Red Cross whether Switzerland could supply any plasma to the UK.[430]

(5) A meeting took place at DHSS on 3 June 1983, attended by officials (both medical and administrative) from a number of Divisions – Health Services, Supply, Medicines, CHD, OCS, Med SEB, Med IMCD, as well as by the Director and another member of NIBSC, to conduct a comprehensive review of the steps being taken in relation to AIDS and examine possible further courses of action.[431]

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[428] Dr Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.18, referring to the letter to Dr Fowler, at WITN5281021.
[429] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.15; Minute from Dr Sibellas to Dr Gunson dated 6 May 1983 at DHSC0002227_021. Officials continued to explore whether alternative supplies were possible – see, for example, Dr Walford's query whether Immuno or other European manufacturers might be about to produce sufficient material derived from European plasma to supply up to 30 million i.u. of Factor VIII concentrate in her minute of 20 May 1983 (DHSC0002227_060); and Dr Fowler's (Medicines Division) reply dated 23 May 1983 at DHSC0002229_006.
[430] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.16; the minute from Dr Gunson of 16 May 1983 at WITN4461126.
[431] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §96.1; papers circulated ahead of this meeting at WITN5281023; minutes of the meeting at WITN5281022.

(6) Actions arising from and completed following that meeting included officials:

(i) exploring with the Chairman of the Regional Transfusion Directors ("RTDs") whether RTDs would reconsider their decision not to question donors about symptoms such as night sweats and unexpected weight loss;[432]

(ii) enquiring of the CBLA whether there were any plans to develop small-pool Factor VIII products or heat-treated concentrates;[433] and

(iii) ascertaining, from the statistics held by the Oxford Haemophilia Centre, the latest figures for usage of each manufacturer's Factor VIII and including these statistics in a report for the CBLA.[434]

(7) On 9 June 1983, the CMO was advised by Dr Gunson that because approximately one-half of the Factor VIII concentrate used in England and Wales was derived from US plasma, there was "*...no alternative...*" to the continuation of this policy in the short term.[435]

(8) By the end of June 1983, the Supply Division within the Department had put detailed questions to the manufacturers of imported blood products about the provenance of the plasma used to prepare their concentrates and the precautions taken by plasma collection centres in respect of AIDS, including, in the case of products manufactured in the USA, whether the concentrates were prepared from plasma collected after the 23 March 1983 FDA Regulations and whether any

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[432] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §96.17; the minute of 6 June 1983 at DHSC0002231_051; Dr Walford's discussion of the RTDs' position in her update on AID for Departmental colleagues on 20 May 1983 (minute at DHSC0002227_060). See too the briefing provided for Lord Glenarthur and Mr Patten on 22 June 1983 and 28 June 1983 respectively at DHSC0002309_124_0003.
[433] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §96.22; the paper prepared for the CBLA by Dr Walford at DHSC0002231_051.
[434] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §96.17 and §96.21; Dr Walford's paper for the CBLA at DHSC00022231_051.
[435] CTI's oral presentation on 12 November 2021, at 23:3-23:9, referencing CTI's Presentation to the Inquiry on the Blood Transfusion Service – Dr Harold Gunson (INQY0000309), at §223 (ii).

special precautions were instituted by the company before the FDA Regulations came into force.[436]

(9) On 21 June 1983,[437] the newly formed Central Blood Authority's Central Committee for Research and Development in Blood Transfusion decided to set up an ad hoc group / Working Party to consider research needs in relation to AIDS and the Blood Transfusion Service.[438]

(10) Following an early meeting between Dr Gunson and Dr Walford on 18 May 1983, initial drafting by the RTDs, and a submission dated 1 July 1983, ministers decided in the first two weeks of July 1983, to publish an information leaflet on AIDS to discourage individuals at high risk of AIDS from giving blood (addressed further at paragraph 4.88, below).[439]

(11) On 13 July 1983, the CSM(B) met to consider possible regulatory steps that might be taken in relation to AIDS in respect of licensed products, a meeting at which the subcommittee was assisted by a range of senior doctors with relevant expertise.[440]

4.19. There was a discussion on AIDS at the Haemophilia Reference Centre Directors meeting of 13 May 1983 and the letter of 24 June 1983[441] from UKHCDO's Professor Bloom which followed, advising Directors as to the steps to be taken with regard to the treatment of patients, to minimise risks. The advice was considered by Dr Walford in her oral evidence to the Inquiry, when she expressed the concern that the recommendations were "*...weak...*" because they were advisory rather than mandatory. She felt that "*...a great deal of account...*" would have been taken of them by

[436] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §97.1-97.4.
[437] PRSE0000838.
[438] The briefing provided for Lord Glenarthur and Mr Patten on 22 June 1983 and 28 June 1983 respectively at DHSC0002309_124 at page 3.
[439] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.14; Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §16.2; Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §§7.6 and 7.9.
[440] This meeting is addressed further below.
[441] BART0000844.

Haemophilia Centres and she "*...would have been surprised...*" if the advice was not followed. But her personal view was that the "*...most problematic...*" issue was the position of those patients who were at times treated outside of haemophilia centres.[442] It was this policy that was discussed at the CSM(B) meeting of 13 July 1983.[443]

4.20. We understand that a presentation is being prepared by CTI on the international position. We have not reviewed the international response for the purpose of these submissions, but would anticipate that it, for context and perspective, it would draw attention to the assessments made by similar clinical organisations at the time, such as that of the US National Haemophilia Foundation, which issued advice to groups including treating physicians and plasma fractionators in January 1983.

4.21. What follows below sets out the enquiries made and decisions and action taken by the Department and associated bodies in the following key areas identified in the Inquiry's List of Issues:

(1) Licensing decisions taken in Spring/Summer 1983 in relation to the emerging threat of AIDS;

(2) Information about AIDS provided to Parliament, clinicians and the public, including

a) statements made by ministers in Parliament, in correspondence and publicly about the transmissibility of AIDS through blood and blood products;

b) the AIDS information leaflet aimed at discouraging individuals at high risk from AIDS from giving blood;

c) the role of the Department in the provision of guidance to clinicians, and;

[442] Dr Walford's oral evidence on 21 July 2021, at 94:12-95:1.
[443] The Minutes state that the Sub Committee was informed "*...that the UKHCDs have adopted a policy for use of Factor VIII in order to minimise risks as far as possible.*" WITN5281027 at §5.4.

d) the 'Don't Die of Ignorance' AIDS public health campaign;

(3) The steps taken to facilitate heat-treated factor concentrates being made available to haemophiliacs in the UK; and

(4) The introduction of routine screening of blood donations for HTLV-III.

(1) Licensing decisions taken in Spring/Summer 1983 in relation to the emerging threat of AIDS

The Licensing Regime in the 1980s

4.22. During an oral presentation on 23 September 2021, CTI provided a helpful overview of the licensing regime in the UK in the 1980s. This built upon the summary of the licensing regime contained within Lord Fowler's witness statement at paragraph 3.6 which had been taken from the BSE Report, Volume 7, Chapter 2. The regime described therein was the regime in place in 1988 to 1989 but Lord Fowler suggested that this was an accurate summary of the position earlier in the 1980s as well, a suggestion that was accepted by CTI.[444] The key aspects of the regime which are apparent from Lord Fowler's evidence, the evidence of other relevant witnesses (including Sir Michael Rawlins[445]) and CTI's oral presentation are set out below, for ease of reference.

4.23. The licensing regime at the time had been established by the Medicines Act 1968 ("the 1968 Act"). Save for in limited circumstances, a medicinal product could not be sold unless it had been granted a product licence by the Licensing Authority. The Licensing Authority was the relevant minister, notably the Secretary of State for Health although it could include other ministers. The functions of the Licensing Authority were in practice delegated to officials working within the Medicines Division of the DHSS. This meant that licensing decisions were effectively made by officials, albeit

[444] Lord Fowler's witness statement dated 17 July 2021(WITN0771001), §3.6; see also CTI's oral presentation on 23 September 2022, at 2:2-2:10.
[445] Sir Michael Rawlins' witness statement dated 24 March 2022 (WITN6406001), at Section 4.

the relevant minister remained accountable for such decisions. Lord Fowler's evidence to the Inquiry was that in practice it was unlikely that individual issues on licensing decisions would come to ministers and he does not recall any decisions on licensing coming to him.[446]

4.24. The Medicines Division consisted of medical staff, pharmaceutical staff and administrative staff. When making licensing decisions, the Medicines Division received advice from a number of expert committees set up under section 4 of the Medicines Act; the committees advised on questions of safety, quality and efficacy of various medicines. The key committees insofar as the issues relevant to the Inquiry are concerned were the Committee on the Safety of Medicines ("CSM") and its Biologicals Subcommittee ("CSM(B)").

4.25. There were two further relevant bodies involved in the licensing of medicines:

(1) The National Institute for Biological Standards Control ("NIBSC") which was established under the Biological Standards Act 1975 to secure high standards of quality, safety and efficacy and consistency of biological substances used in medicines. In this role, it devised standards for and tested batches of biological products, carried out research and advised a number of bodies including the Medicines Division of DHSS and its Section 4 Committees.[447] NIBSC staff were members of the CSM and CSM(B).

(2) The Medicines Commission, which provided advice on setting up the Section 4 Committees and what they should be doing. This body acted as an appeals body if the CSM or CSM(B)'s advice was to reject a licensing application. The Medicines Commission could not

[446] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §3.7.
[447] For a more detailed explanation of the role of NIBSC and in particular its role in testing batches of biological products such as blood products, see Sir Joseph Smith's witness statement dated 11 December 2021(WITN5281001), §§2.7-2.20.

make binding decisions following an appeal. It would advise the Licensing Authority as to whether a licence should be granted but ultimately the decision was made by the Licensing Authority.

4.26. In deciding whether to grant a product licence, the Licensing Authority was to consider the safety, efficacy and quality of the medicine (s.19 of the 1968 Act), and these were the areas upon which the section 4 committees could advise (s.4(3)(a)). The Licensing Authority could make the licence provisional on undertakings being given from a manufacturer (s.19(3)). Licences would last for 5 years, at which time the licence holder could apply for a renewal (s.24). There were also powers to suspend, vary or revoke a licence (ss.28-30).

4.27. The Licensing Authority (in practice the Medicines Division) was required to seek advice from the relevant section 4 committee where it was minded to refuse an application for a licence or suspend, vary or revoke a licence. Otherwise, officials had discretion as to whether to seek advice from the relevant committee (s.20(3)).[448]

4.28. As was noted in the CTI presentation with reference to the evidence of Sir Joseph Smith, in practice the CSM would regularly consider applications for product licences and clinical trial certificates referred to it by the Medicines Division.[449] Sir Joseph's evidence was that in the first instance applications would be considered by the Secretariat before being presented to the appropriate subcommittee. There was a main subcommittee which dealt with most pharmaceutical products and a second sub-committee dealing with biological products, namely the CSM(B).[450] The CSM(B) was made up of senior members with expertise appropriate to assessing the safety of

[448] CTI's oral presentation on 23 September 2022, at 13:8-13:13.
[449] CTI's oral presentation on 23 September 2022 at 35:7-35:16, Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §2.21.
[450] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §2.21.

biological medicines.[451] These committees were also assisted by the Medical and Scientific staff of the DHSS as well as the NIBSC. The conclusions and recommendations of the CSM(B) would then be considered by the CSM, alongside the application papers.[452]

4.29. There were certain exemptions to the licensing regime, which were discussed in the CTI presentation.[453] These exemptions were products obtained on a named patient basis and products used for clinical trials. The presentation highlighted how the regulation of the supply of medicines on a named patient basis was strengthened from June 1984; whereas previously notice had to be given to the Licensing Authority within 21 days of the receipt of a product, doctors were now required to give prior notice before the supply of any product on a named patient basis. The Licensing Authority then had 28 days to effectively stop the use of the product. There were also limits on the amount of product which could be imported on a named patient basis.

4.30. The licensing regime operated in this way up until 1989, when the functions of the Medicines Division were then undertaken by the Medicines Control Agency, which was a self-financing agency within the Department of Health. The Medicines Control Agency subsequently merged with the Medical Devices Agency in 2003 to become the Medicines and Healthcare products Regulatory Agency ("MHRA"). The MHRA was subsequently merged with NIBSC in 2013.

Dr Galbraith's proposal of a temporary withdrawal of US blood products from the UK market in May 1983

4.31. On 9 May 1983, several days after the first case of AIDS in a UK haemophiliac was reported in the CDSC's Communicable Disease Report

[451] See Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §2.22 for more detail on the specialist knowledge of the members of the CSM(B).
[452] CTI's oral presentation on 23 September 2022, at 36:1-36:25; See also Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §§2.21-2.26.
[453] CTI's oral presentation on 23 September 2022, at 16:16-29:16.

("CDR"), Dr Spence Galbraith, Director of the CDSC, wrote to Dr Field, the Senior Principal Medical Officer of Med IMCD, to express his view that all blood products made from donated blood in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission had been clarified.[454]

4.32. One of the issues for the Chair to determine is the level of consideration the Government gave to the views and advice from Dr Galbraith in May 1983.[455] The fact that advice had already been received from Dr Joseph Smith of NIBSC to set up a meeting of the CSM(B) to consider this issue, has been noted above.[456] Against that background, and given that Dr Galbraith referred to the need for the issue to be considered by a group of experts, it appears that the views of Dr Galbraith were regarded as one that would be considered by the CSM(B).

4.33. In relation to the further consideration that *was* given to the view expressed by Dr Galbraith in his letter of 9 May 1983, by the Department and other relevant advisors and decision-makers:

(1) It appears from a letter dated 10 May 1983 from Dr Craske, a Consultant Virologist with the Public Health Laboratory Service ("PHLS"), to Dr Whitehead of the PHLS that Dr Craske had discussed "the problem of Factor VIII" with Dr Galbraith the previous day on the telephone.[457] They had agreed that Dr Galbraith should write to the Department on the question of whether American commercial Factor VIII should be withdrawn from clinical use in the UK. It would seem that this conversation precipitated Dr Galbraith's letter to Dr Field of 9 May 1983. Dr Craske provided his own view on this question in his letter to Dr Whitehead:

> *"I am not sure myself that we are at the stage where there is enough evidence to justify this step, but I think both the*

[454] PRSE0003286.
[455] List of Issues (as amended on 27 September 2021), at §29.
[456] See Dr Smith's letter of 28 March 1983, paragraph 4.18(2) above
[457] See WITN4461127.

Department of Health and the Haemophilia Centre Directors will have to face this problem in the near future, and the earlier it is seriously considered the easier it will be to make a rational decision."

(2) A special meeting of the Haemophilia Reference Centre Directors ("HRCDs") was convened on 13 May 1983 to discuss the issue of AIDS in haemophiliacs. Dr Craske attended this meeting, as did Dr Walford (as an observer). The issue of imported concentrates was discussed with the following conclusion recorded in the minutes:

"With regard to the general policy to be followed in the use of factor VIII concentrates, it was noted that many directors have up until now reserved a supply of National Health Service concentrates for children and mildly affected haemophiliacs and it was considered that it would be circumspect to continue with that policy. It was also agreed that there was, as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy." [458]

(3) Dr Walford was shown a copy of Dr Galbraith's letter of 9 May 1983.[459] Having considered this, as well as the views expressed at the HRCD meeting of 13 May 1983, Dr Walford provided her opinion on Dr Galbraith's proposal in a minute to Dr Field, dated 13 May 1983:

"In my view this suggestion is premature in relation to the evidence and unbalanced in that it does not take into account the risks to haemophiliacs of withdrawing a major source of their-FVIII supplies.

Perhaps the situation is best put in perspective by a statement which was drafted to appear in the minutes of the meeting of the Directors of Haemophilia Reference Centres which I attended today:

"Many Directors have until now restricted their use of FVIII in young children (under the age of 4 years) and in mild haemophiliacs to NHS materials and we consider that it would be circumspect to continue with that policy.

There is not sufficient evidence to restrict the use of imported FVIII concentrates in other patients in view of the benefits of the treatment but the situation will be kept continuously under review by means of a surveillance system which has been

[458] The minutes of the UKHRCD meeting of 13 May 1983 at HCDO0000003_008
[459] See Dr Walford's minute to Dr Field of 13 May 1983 at DHSC0002227_047

> *instituted and by means of regular meetings of the Reference Centre Directors.*
>
> *The Directors welcome the fact that the Regional Transfusion Directors would be meeting to consider steps which could be taken to avoid bleeding donors who might be in a category thought capable of transmitting AIDS."*
>
> *(NB: this statement is not for publication until the minutes have been formally circulated; the wording may not be precisely that of the final form.)"* [460]

4.34. Dr Walford's explanation for her view given in her minute of 13 May 1983 was set out in her written statement to the Inquiry:

> *"86.32. Whilst Dr Galbraith had set out a strong case for an epidemiological association between American Factor VIII concentrate and the development of AIDS, the cause of AIDS and the role of blood products was still heavily contested both in the UK and USA. Furthermore, the potential risks to haemophiliacs in the UK, based on the observed numbers of cases of AIDS per 1000 haemophiliacs in the USA, appeared low. This had to be compared with the known severe and potentially life-threatening risks to haemophiliacs of inadequate treatment, arising from the withdrawal of US Factor VIII concentrates, which included strokes from haemorrhage into the brain and bleeding into organs and joints. In terms of those risks, Dr Galbraith's recommendation appeared premature.*
>
> *86.33.This was also the view reached by Dr Craske (see his letter) and the UK Haemophilia Centre Directors.*
>
> *86.34. I have reflected again on this correspondence and on Dr Galbraith's observations that, in effect, the long incubation period between infection and the development of AIDS might mean that more cases would be seen than could be inferred from the low numbers of cases seen to date. Whilst this was an important observation, there were other factors which needed to be considered. For example, how many of those exposed to the infective agent would actually become infected and of those who became infected, how many would go on to develop AIDS. There was simply inadequate information on which to evaluate these possibilities. That lack of information needed to be set against the very well-known and severe harms that would be caused to haemophiliacs if American Factor VIII concentrates were withdrawn or curtailed without any realistic replacements."* [461]

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[460] Dr Walford's minute to Dr Field of 13 May 1983 at DHSC0002227_047
[461] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§86.32 – 86.34.

4.35. Dr Walford expanded upon this explanation in her oral evidence to the Inquiry given on 20 July 2021:

> *"We really had insufficient -- really had insufficient evidence that what was being suggested here was the right course of action at this time and, of course, against the fact that, actually, you were going to cause real damage potentially to patients with haemophilia who couldn't get -- who wouldn't be able to get their Factor VIII. The Factor VIII would be cut by about a half, in effect, and so there would be massive rationing because the implication -- he was actually saying withdraw now on a temporary basis. But, on a temporary basis, you would have 50 per cent less Factor VIII in the country to treat haemophiliacs. So it was a very, very draconian proposal on the basis of one case, and I totally accept that the case in Cardiff was a case, and CDSC had defined it as a case, but we had one case in this country and about 10 or 11 cases in the United States."* [462]

4.38. It was further Dr Walford's evidence that a temporary withdrawal of US concentrates would have meant removing US concentrates for a period of perhaps 2 years.[463]

4.39. In relation to Dr Galbraith's "*views and advice*" *after* May 1983, the Chair will be aware that Dr Galbraith was invited to attend and did attend the CSM(B) meeting of 13 July 1983 as one of a range of experts advising the subcommittee. Express consideration was given at that meeting to the possibility of withdrawing US factor concentrates from the UK. The Chairman of the CSM(B) was the Director of the NIBSC, Dr Joseph Smith. The expertise of members of the CSM(B) included clinical infectious diseases, clinical and experimental virology and bacteriology, haematology,

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[462] Dr Walford's oral evidence on 20 July 2021, at 174:3-174:20. See too Dr Walford's oral evidence on 20 July 2021 at 133:15-133:19, 136:1-136:3, 176:22-179:14 and 189:20-192:20; and on 21 July 2021, at 24:21-27:5. In relation to the proportion of Factor VIII used in the UK that was imported at the time and the proportion of these imports that came from the US see Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §96.9; Dr Walford's minute to Mr Cummings dated 13 June 1983 at DHSC0001659; and Dr Gunson's letter to the CMO dated 9 June 1983 at **NHBT0001067**. See too the article in the New Scientist at New Scientist article at PR5E0000726, which suggested that 50% of the Factor VIII used in the UK was imported from the US. In relation to the reliance at the time on numbers of cases, in the context of "*a total vacuum of information*" see Dr Walford's oral evidence on 21 July 2021, at 88:10-88:16, 88:24-88:25 and 89:1-89:3.

[463] Dr Walford's oral evidence on 21 July 2021, at 24:16-24:20.

endocrinology, epidemiology and the production of biological medicines.[464] In relation to the last of these areas, Dr Lane sat on the CSM(B) and had knowledge of clotting factor concentrates.[465] Two of the members in attendance, Professor Harold Lambert and Dr David Tyrell would also have had knowledge of haemophilia.[466] In addition to Dr Galbraith, the subcommittee was helped by the participation of the following invited senior doctors with relevant expertise: Professor Bloom (Professor of Haematology, an expert in haemophilia and its clinical care), Dr Craske, Dr Mortimer (also a Consultant Virologist with the PHLS) and Dr Gunson (Director of the Regional Blood Transfusion Centre, Manchester and the Department's Consultant Adviser on Blood Transfusion).[467] The meeting was attended by Dr Walford, Dr Sibellas and Dr Fowler, other representatives from the Department and a number of representatives from the NIBSC.[468] The minutes of this meeting summarise the conclusion reached at the meeting in relation to withdrawal of US factor concentrates in the following way:

> *"The possibility was considered of withdrawing US preparations from the UK. It was concluded that this is not at present feasible on grounds of supply. Moreover, the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign suppliers of clotting factor concentrates. This should reduce markedly, although not eliminate, the risks to recipients of these products, and the Sub-committee strongly supports this aim. The Sub-committee was also informed that the UK Haemophilia Centre Directors have adopted a policy for use of US Factor VIII in order to minimise risks as far as possible."* [469]

4.40. There was discussion, with Dr Walford, about the accuracy of this characterisation of the UKHCDO policy.[470] The Inquiry may consider that considerable caution has to be used in seeking to 'extrapolate' or recreate the exact discussion that took place, based on the exact wording of Minutes

[464] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.28.
[465] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.28.
[466] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.28.
[467] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.30.
[468] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.30; the minutes of the meeting at WITN5281027; Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §99.1 (Dr Walford attended only for the morning session).
[469] The minutes of the meeting at WITN5281027 at §5.4.
[470] Dr Walford's oral evidence on 21 July 2021, at 97 and 98:1-982.

that are - inevitably – short summaries of a discussion, and that there is a dearth of evidence upon which to draw conclusions. What might also be considered is that there is no evidence to suggest that the CSM(B) regarded itself as a forum in which to discuss the adequacy of the clinical response or extent of the protection that might be conferred by the UKHCDO's approach.[471]

4.41. In his written statement to the Inquiry, Sir Joseph Smith explained that "*...the Sub-Committee tried carefully to estimate the risk benefit balance of continuing the use of imported US Factor VIII in the treatment of the 2,500 (approximately) haemophilia patients in Britain, at a time when home-produced Factor VIII could provide rather less than 50% of the number of doses required*".[472] The Chair's attention is drawn to paragraph 3.45 of Sir Joseph's statement[473] in relation to the particular aspects of the problem which he considers are "*...likely to have been included...*" in the CSM(B)'s discussions, which include: the limited and uncertain understanding of the possible causes of AIDS and its transmissibility at the time; the understanding at the time that the risk to patients given imported clotting factor concentrates was small, especially in comparison with the risks from not using Factor VIII; debate at the time about whether the lower dose of Factor VIII used in the UK compared to other developed countries might mean that the risk was lower; the limited evidence on the incubation period then available; and the frequency with which AIDS would develop in an infected individual being then unknown. In all the circumstances, the subcommittee considered "*...that the evidence then available about the level of risk to recipients of clotting factor concentrates did not justify taking a step that would directly result in a drastic reduction of supply of concentrates, when no alternative product was available in sufficient quantities to make up*

[471] Relevant to this is not only the status of the CSM(B) as a Committee offering advice on licensing, but the evidence regarding the clinical freedom of HCDs in treatment of haemophiliacs and deference to knowledge of HCDO and the fact that the Department would not intervene with advice to clinicians on clinical matters (see, for example, Dr Walford's oral evidence on 21 July 2021, at 64:16-64:25).
[472] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.44.
[473] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.45.

the shortfall; a step that the subcommittee agreed would have serious consequences for patients, including fatalities".[474]

4.42. Sir Joseph Smith did say in his witness statement that he "*...gained a clear impression that UK self-sufficiency was expected soon."*[475] It is not clear why or from whom he gained such an impression, not least given the presence of experts such as Dr Lane at the meeting. Dr Walford (who was present at the meeting as an observer) noted this evidence with great surprise.[476] The minutes refer to "*...efforts being made to secure UK independence...should markedly reduce, although not eliminate, risks to recipients..."* but did not give a timescale; nor did the CSM(B) suggest that the issue should be reconsidered within a fixed timescale, i.e., suggest that reconsideration should take place when the factual matrix had altered.

4.43. Sir Joseph Smith's evidence in his written statement to the Inquiry was that whilst he had not seen Dr Galbraith's letter of 9 May 1983 at the time of the 13 July 1983 meeting, when he saw it for the first time in 2007 he saw that Dr Galbraith concerns were "*very similar*" to his own in 1983.[477] He noted that Dr Galbraith *"...participated in the Sub-Committee's 13 July 1983 discussion and would have had an opportunity to raise any views he wished at that meeting but I do not recall him being an outlier in the discussion at all".*[478] As to whether Dr Galbraith agreed with the conclusion of the CSM(B) on the question of whether or not US blood products should be withdrawn, Sir Joseph said this:

> *"As I explained in my oral evidence to the Archer Inquiry [ARCH0000009, p. 124], as far as I remember, Dr Galbraith agreed with the conclusions of the CSM(B) in this respect, in circumstances where about 50% of the material used in the UK was imported so this option could not be advised."* [479]

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[474] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.45(h).
[475] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.49.
[476] Dr Walford's oral evidence on 21 July 2021, at 93:2–93:10.
[477] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.51(b).
[478] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.51(b).
[479] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.51(c).

4.44. Whilst there has been consideration (e.g., by the Expert Group on Public Health and Administration, or in the oral questions to Professor Sir Jonathan Van-Tam in his oral evidence[480]) of the question as to how "minority" opinions should be recorded and/or reported to ministers, there is no evidence to suggest that Dr Galbraith or others disagreed with the conclusions reached or that there was a minority view that should have been recorded in the Minutes.

4.45. The CSM considered the CSM(B)'s recommendation on withdrawal of US blood products, alongside its recommendations on the other issues considered by the subcommittee (as to which see further below), at its meeting held from 21 to 22 July 1983.[481] A paper entitled "*Summary of Main Points from a Consideration of AIDS and Licensed Blood Products*" was considered by members of the CSM.[482] The CSM endorsed the conclusions and recommendations of the CSM(B).[483] In his written statement to the Inquiry, Sir Michael Rawlins referred to the fact that at the time of this meeting their understanding of AIDS was much less developed than it is now. He thought that concern about the impact on haemophiliacs of withdrawing products without there being suitable replacements would have been balanced by the CSM against the risk from AIDS as it was understood at the time.[484]

4.46. The Chair is invited to consider the above when assessing the adequacy of the consideration given to Dr Galbraith's May 1983 views and advice, and

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[480] See the oral evidence of the Public Health & Administration Expert Group on 3 October 2022, at 170:20-174:13, on 4 October 2022, at 172:7-174:15 and of Professor Sir Jonathan Van-Tam's oral evidence of 18 November 2022, at 34:19-35:11.
[481] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.52; the minutes of the meeting at WITN5281030.
[482] Sir Michael Rawlins' witness statement dated 24 March 2022 (WITN6406001), §16.15; the paper at DHSC0006259_007.
[483] Sir Michael Rawlins' witness statement dated 24 March 2022 (WITN6406001), §16.18; the minutes of the meeting at WITN5281030 at §5.2.
[484] Sir Michael Rawlins' witness statement dated 24 March 2022 (WITN6406001), §16.16.

the broader question of withdrawal of US factor concentrates from the UK market.

4.47. A further issue identified by the Inquiry in the List of Issues is whether Dr Galbraith's letter of 9 May 1983 and its accompanying report should have been disseminated more widely, and why it was not.[485]

4.48. As noted above, whilst Dr Galbraith's letter of 9 May 1983 was not before the CSM(B), Dr Galbraith was present at the meeting as one of a range of senior doctors asked to provide their expertise to the subcommittee. The Inquiry does not have the benefit of evidence from Dr Galbraith. The Chair is invited to consider Sir Joseph Smith's evidence, summarised above, that: i) the concerns raised in Dr Galbraith's letter were "*similar*" to his own in 1983; and ii) Dr Galbraith being present at and participating in the meeting of 13 July 1983. This may be thought to be relevant to the question of whether Dr Galbraith's letter not being before the CSM(B) was material.

4.49. It was canvassed with Dr Walford during her oral evidence on 20 July 2021 whether it had occurred to her to share Dr Galbraith's letter with the HRCDs.[486] It will be a matter for the Chair to decide whether Dr Galbraith's letter and accompanying report might have changed the HRCD conclusion at the special meeting of 13 May 1983 that there was "*...as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients [patients other than children and mildly affected haemophiliacs*]"[487]. Professor Bloom was present at the CSM(B) meeting with Dr Galbraith, as was Dr Craske, who had discussed the question of whether US commercial Factor VIII should be withdrawn from clinical use in the UK with Dr Galbraith on the same day that Dr Galbraith wrote to Dr Field. Dr Craske was the Chairman of the Haemophilia Centre Directors Hepatitis Working Party,

[485] List of Issues (as amended on 27 September 2021), at §29.
[486] Dr Walford's oral evidence on 20 July 2021, at 171:3-171:19.
[487] The minutes of the UKHRCD meeting of 13 May 1983 at **HCDO0000003_008**

which was considering the question of AIDS at the time and he attended the HCDO meetings. The Chair may also consider it relevant that well into 1984 Professor Bloom's view remained that the role of US concentrates in the causation of AIDS in European haemophiliacs "*...must be...*" regarded as unproven and that the "*...hypothetical dangers...*" of US concentrates had to be balanced against "*...the immense benefits that haemophiliacs have derived from*" these products.[488]

4.50. As to whether Dr Galbraith's views and advice as set out in his letter of 9 May 1983 should have been drawn to the attention of ministers, there is evidence that:

(1) The initiative to convene a special meeting of the CSM(B) pre-dated the receipt of Dr Galbraith's letter, as explained by Sir Joseph Smith and also Dr Walford (see paragraph 4.184.18(2) above).

(2) The letter must have been received by Dr Field in the DH during the course of the General Election campaign that was called on 9 May 1983[489]. With most ministers campaigning, Lord Trefgarne took over temporary leadership of the Department and has stressed that only urgent decisions would have been referred to him.[490]

(3) Whilst that detail might form a part of the story, it is unclear why the letter was not more widely circulated after the Government was returned to office on 9 June 1983, or was not referred to in documents such as the briefing on AIDS that Lord Glenarthur asked for and received shortly afterwards.

(4) Former Health Ministers have reacted to the letter, when seen in the course of this Inquiry for the first time, by saying that they would have

[488] A. L. Bloom, 'Acquired Immunodeficiency Syndrome and other possible immunological disorders in European Haemophiliacs', The Lancet, 30 June 1984 at PRSE0003037.
[489] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §§6.18-6.19.
[490] Lord Trefgarne's witness statement dated 7 December 2022 (WITN7478001), §§2.5-2.6: "*...the Permanent Secretary, Sir Kenneth Stowe, made it very clear to me that I would not and should not make any substantive new policy decisions, although I would not have been restricted from taking decisions that had to be taken urgently on safety grounds. If that had happened, then I would have been very careful to confirm any such decisions with Sir Kenneth Stowe".*

liked to have seen it. Lord Clarke's observation was that *"I mean, you can't read it without being rather startled by it"*.[491] Lord Glenarthur said that whilst he understood Dr Walford's views on the practical options available, he found it "*...quite odd, looking back, that I wasn't given the stark detail that appears in Dr Galbraith's letter*".[492] Lord Patten said that he felt "*unequivocally*" that he should have seen it and he "*...probably would have pressed the panic button*".[493] Lord Fowler stated that he felt that the Galbraith letter should have gone to the CMO and that he thought it had done, but also agreed with CTI that there was a strong case for passing it to ministers.[494]

(5) Norman Fowler, the Secretary of State, stressed the collective decision-making by experts that had followed the letter. He noted that there was no need for a meeting of experts to be called, as Dr Galbraith had asked for, as that had already been put in hand.[495] He noted that "*Well it was one man Galbraith distinguished but only one man making this fairly radical, very radical proposal and I think what happened what should have happened was exactly what did happen.*"[496] Dr Galbraith although distinguished was one person, and the experts (e.g. CSM(B)) took a collective look and came to the same conclusion as Dr Walford that a ban was premature and there was no alternative to the continuation of the importation of blood products.[497]

(6) Dr Walford's view was that to have sent the letter to ministers would have meant accompanying it with some forward advice; referral should have followed the decisions and advice of the CSM(B), in other words. Consideration of what difference an early submission to

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[491] Lord Clarke's oral evidence on 27 July 2021, at 152:1-152:2 and 152:19-152:21.
[492] Lord Glenarthur's oral evidence on 22 July 2021, at 170:3-170:6.
[493] Lord Patten's oral evidence on 20 May 2022, at 89:19-89:25; 158:20-158:25).
[494] Lord Fowler's oral evidence on 21 September 2021, at 158:7.
[495] Lord Fowler's oral evidence on 21 September 2021, at 159:10-159:15: "Well, I think probably not, on the basis of what had happened to this point. I mean, if the subcommittee of the Committee on the Safety of Medicines had decided one thing, I'm not quite sure what the argument would be in July 1983 in going to have another collective meeting."
[496] Lord Fowler's oral evidence on 21 September 2021, at 156:7-10.
[497] Lord Fowler's oral evidence on 21 September 2021, at 156:7-156:10; 157:3-157:4; see further 157:4-157:10, and his evidence on the difficulties of an expert committee taking decisions on the proposals of one person at 161:3-161:6).

ministers on Dr Galbraith's letter would have made inevitably involves a degree of speculation. The Inquiry is invited to consider whether any early submission may have been accompanied by reference to the forthcoming meeting of CSM(B) with advice to await the outcome.

4.51. On one view, therefore, the issue of earlier notice to ministers of Dr Galbraith's view may form a part of the issue of why ministers were not briefed about the CSM(B)/CSM decisions of July 1983, whether they should have been, and what difference it might have made, had they been so.

4.52. As to this, we note first that there is a gap in the evidence as to whether or not the CMO may have been briefed about the outcome of the meeting. There is no documentary evidence on the point.

4.53. As to ministers within the Department, it is not clear why they were not briefed on the fact or outcome of the CSM(B)/CSM deliberations, perhaps by Medicines Division which would have been the lead department. Lord Fowler explained the decision-making structure, and that licensing decisions rarely came to minsters (see paragraph 4.22 above). Lord Glenarthur, although he held the blood portfolio from early June 1983, did not oversee the work of Medicines Division or the licensing of pharmaceutical and biological products.[498] Lord Clarke was also not familiar with the work of the CSM or CSM(B) (at least by the time he was asked to give evidence to the Inquiry), but regarded it as the sort of expert committee which would report, in the first place, up the medical hierarchy to the CMO.[499] Whether at least a partial explanation stems from an assumption that the reporting up the medical hierarchy was the appropriate way forward is a matter that the Inquiry may wish to consider.

[498] Lord Glenarthur's oral evidence on 22 July 2021, at 18:23-18:25 and 19:1-19:3.
[499] Lord Clarke's oral evidence on 27 July 2021, at 162:11-162:22 and 164:16-164:24.

4.54. There was, however, general agreement amongst the ministerial witnesses to the Inquiry that they should have, or would have wished to, receive information about the CSM/CSM(B) decision-making.[500]

4.55. The further question that has then been asked, is what the impact of a ministerial briefing would have been. This raises one of the wider issues that the Inquiry has been considering, that of reliance on committees of scientific advisers, and of the difficulties experienced by ministers in questioning such groups, or satisfying themselves that the advice they receive is well-founded.

4.56. Ultimately, it was the evidence of the former Health Ministers in post at the time that they would have relied on the advice of the CSM/CSM(B) or clinical evidence. As Lord Glenarthur stated, he did not disagree with the decision of these committees, even if "*...at least ministers ought to be aware of the competing elements and the real concerns that are being raised*". Lord Clarke stated that "*I mean the people it [the Galbraith letter] did go to, with all these other expert advisers, assembled for the purpose, you know, were in a better position to appraise this advice.*" [501] A general point made by Lord Clarke in his first witness statement was the centrality of expert and clinical evidence in this area of policy-making.[502] Finally, Lord Fowler's written evidence was that the matter had been properly considered by the relevant expert body and he did not resile from that in his oral evidence (see the evidence referred to at 4.50(5), above).

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[500] See Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.53 and Lord Patten's oral evidence on 20 May 2002 at 93:21; Lord Glenarthur's oral evidence on 22 July 2021, at 173:17-173:22; Lord Clarke's oral evidence on 27 July 2021 at 165:15-165:21 (stating that he was "*a little surprised*" that "*...certainly Simon, as the minister responsible for blood products...*" did not receive this information). See also Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.19.

[501] Lord Clarke's oral evidence on 27 July 2021, at 165:15-165:21 and 166:14-166:18. Although Lord Clarke was plainly startled and struck by the Galbraith letter when he viewed it in the oral hearing, he acknowledged not only that he was commenting in the Inquiry hearing with the benefit of hindsight (153:3-153:5), but also the centrality of clinical decision making on this issue and the risks to be balanced (154:4-154:10).

[502] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §§2.23-2.24.

4.57. The Inquiry may wish to consider whether ministers disagreeing with or significantly challenging the advice of the CSM/CSM(B) would also have been affected by the advice given to the CMO by Dr Gunson, on 9 June 1983. He said that because approximately one-half of the Factor VIII concentrate used in England and Wales was derived from US plasma there was "*...no alternative to the continuation of this policy in the short term...*" (see paragraph 4.184.18(7), above. The Inquiry will wish to consider whether in any submission to ministers, all these strands would have been drawn together, reflecting the consensus in expert decision-making that appears to have been reached by the end of July 1983.

Cryoprecipitate as an alternative to large-pool factor concentrates

4.58. The Chair has heard from a number of witnesses that a central concern of advisors in relation to licensing action to withdraw US concentrates from the UK market was that suitable replacement products were not available to make up the significant shortfall that would result from such action. A broader question considered by the CSM(B) and by others in May/June 1983 was whether large-pool factor concentrates could be withdrawn from the market and replaced by cryoprecipitate.

4.59. It appears from the documentary record that this question had in fact already been considered by the BPL in April 1983. A CBLA meeting took place on 27 April 1983, attended by the Deputy Chief Medical Officer ("DCMO"), two Departmental officials, Dr Lane, Dr Gunson and Professor Bloom.[503] A paper from Dr Lane was discussed at that meeting, which referred to a discussion amongst the senior management of BPL about AIDS held on 18 April 1983.[504] In that paper, Dr Lane described the inability of BPL to "*...manufacture small pool freeze-dried cryoprecipitate in significant amounts, as an alternative to large pool intermediate factor VIII*

[503] See the minutes of that meeting at BPLL0003987_002
[504] CBLA0001697.

concentrate".[505] As to the views of Dr James Smith and Dr Snape on the viability of a switch to cryoprecipitate, see paragraph 4.66, below.

4.60. The issue was also raised with Dr Walford by Dr Gunson following a meeting of the Council of Europe from 16 to 19 May 1983. At the meeting possible recommendations in relation to AIDS were discussed, including a recommendation that recipients of blood products should be exposed to the minimum number of donations. Dr Gunson's report of this meeting concluded that the Council of Europe was *"…leading to…. the greater use of cryoprecipitate…"* the standard product in many European countries; and recorded that he (like Dr Walford) did not "*…think that BPL could change to freeze-dried cryop[recipitat]e rapidly and the logistic[al] problems would be considerable*".[506]

4.61. Dr Walford provided comments on the Council of Europe's draft recommendations in June 1983, by way of a minute to Mr Cumming of the International Relations Branch of the Department dated 13 June 1983. Her view expressed in that minute was that however desirable it might be to avoid the use of large-pool products, given that 80% of the total usage of Factor VIII was with large-pool products (commercial and NHS), the practical reality was "*…there is no option but to treat the majority of our haemophiliacs with large-pool products*".[507]

4.62. Dr Walford set out some of the significant implications of any significant increase in cryoprecipitate production in her Paper VI prepared for the Departmental meeting of 3 June 1983:

> *"If there were to be a significantly increased demand for cryoprecipitate, this would pose major operational and financial problems for RTCs and*

[505] CBLA0001697.
[506] DHSC0000716. See too Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.37.
[507] Dr Walford's minute at DHSC0001659. Dr Walford's evidence in her written statement was that this was consistent with Dr Gunson's views: Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.41.

> *would reduce significantly – or even totally – the amount of plasma sent to BPL. The alternative to single donor cryoprecipitate produced in RTCs would be for BPL to change to small-pool freeze-dried cryoprecipitate production. The operational problems posed by such a switch in technology would be immense and it is doubtful whether it could be undertaken in the existing facilities. Moreover, the design brief for the redeveloped BPL would have to be totally re-worked to plan for the changed requirements."*[508]

4.63. In relation to the CSM(B)'s consideration of the issue on 13 July 1983, the CSM(B)'s conclusion was recording in the minutes as follows:

> *"5.3 The possibility was considered of withdrawing clotting factor concentrates from the market and replacing them with cryoprecipitate. It was concluded that this is not feasible in the UK on grounds of supply."*[509]

4.64. Sir Joseph Smith's evidence in his written statement to the Inquiry about this conclusion was as follows:

> *"As is apparent from the minutes of the meeting and as I explained in my written evidence to the Archer Inquiry [ARCH0000442_005] at paragraph 11, we considered the possibility of withdrawing clotting factor concentrates from the market and replacing them with cryo-precipitate (from frozen plasma) which was prepared from small donor pools or single donors and might therefore pose a lower risk than Factor VIII concentrate. However, it was made clear, I think by those with particular knowledge of haemophilia, that it would not have been possible to supply and administer sufficient quantities of cryo-precipitate to treat more than a small proportion of patients."* [510]

4.65. Dr Walford's evidence in her written statement to the Inquiry was that the CSM(B)'s conclusions were consistent with Dr Lane's report for the CBLA meeting of 27 April 1983 (see above at paragraph 4.59); and that she was not surprised that the CSM(B) formed the view it did in relation to the scope

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[508] WITN4461130.
[509] WITN5281027.
[510] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.45(g). See too Dr Smith's observations in his annotated agenda circulated ahead of the 13 July 1983 CSM(B) meeting on the possibility of withdrawing all factor concentrates and using only cryoprecipitate: "Conclusion? This step cannot at present be recommended: (a) it is probably impossible to satisfy UK needs in this way; (b) even if needs could be satisfied it would involve a major rethink of UK policy for preparing blood products; (c) the perceived level of risk at present does not justify serious consideration of this solution." (DHSC0001209).

for use of cryoprecipitate since they would "*...presumably have known that imported Factor VIII concentrate constituted about 50% of the total usage of Factor VIII";* and in light of attendance at the subcommittee of experts such as Dr Lane and Dr Gunson.[511]

4.66. Dr Snape and Dr James Smith gave detailed evidence to the Inquiry in relation to the possibility of a switch to cryoprecipitate in response to the threat of AIDS. Dr Snape noted that "*...practically, BPL would have found it very difficult to assist the transfusion service in creating a supply of freeze-dried cryoprecipitate for treatment as an alternative to freeze-dried concentrates."* Further, "*... it became quite clear as time passed, that the virus had become part of our donor population..."* so the suggestion of returning to cryoprecipitate would, in his view, not reduce exposure to a potential virus unless it was single donor.[512] He stated that "*...it could not be done at BPL in Building 25, but in April 1983 Building 25 was all we had."* A decision to revert to cryoprecipitate would have to be made by Regional Transfusion Centres.[513] The Inquiry asked Dr James Smith if *"...a return to the use of cryoprecipitate rather than blood products [was] a practical possibility in the period c.1982 to 1985 given the infrastructure, equipment and personnel available at BPL/PFL*". His answer was, "*No. Provision of cryo was always considered to be a responsibility of the RTC, at the request of haemophilia clinicians in its Region. The process follows fairly naturally from the routine operations for separating plasma from the cellular elements of blood*." Asked by the Inquiry, *"Was this approach considered in the UK? If so, why was it rejected or not implemented more widely?*", Dr James Smith's answer included,

> "*Considered by whom? Not by fractionators, for the reasons already stated. Not by RTCs, who did not relish the scale of expansion predicated. Not the staff of HCs, for whom the dissolution and pooling of frozen gobbets of cryo was a fiddly job requiring air-filtration facilities and training in aseptic technique. Only a new "factory" ... probably*

[511] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §99.3(i).
[512] Oral evidence of Dr Snape on 30 March 2022, at 76:4-76:8, 76:18-76:20.
[513] Oral evidence of Dr Snape on 30 March 2022, at 94:18–95:10.

producing freeze-dried cryo, would have had the capacity to replace all large-pool concentrates."

He went on to emphasise certain limitations and risks of cryoprecipitate treatment.[514]

4.67. The evidence set out above suggests that it was not only at the CSM(B) meeting on 13 July 1983 that consideration was given to the possibility of switching from large-pool concentrates to cryoprecipitate; wider consideration was given to this question in a number of quarters. But the evidence suggests that the consistent view of the experts who considered this was that this was not a realistic option, not least as it would have reduced supplies of domestic Factor VIII.

The action taken in relation to US products manufactured pre-the March 1983 FDA Regulations

4.68. The availability of supplies was investigated, but the need to maintain UK stocks of Factor VIII was regarded as paramount, and was consistent with the advice of the CSM(B). See in this regard the evidence of Dr Walford.[515]

Alternative approaches to treatment

4.69. During the oral questions addressed to Dr Walford, CTI asked whether there could have been a period of working up to the production of increasing the production of cryoprecipitate: a conservative approach of cancelling elective surgery and home treatment and prophylaxis, batch dedication etc.[516]

4.70. Dr Walford fairly agreed that no-one in the Department applied their minds to a more 'nuanced' programme of risk mitigation than had been suggested by Dr Galbraith, such as restricting home treatment, limiting surgery and

[514] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §146 and §148 and his answers to Q39 more widely.
[515] Dr Walford's witness statement, dated 5 July 2021 (WITN4461001), §85.1-85.6 and Dr Walford's oral evidence of 20 July 2021, at §§185:5-185:25 and §§186:1-14.
[516] Dr Walford's oral evidence on 20 July 2021, at 180:12-180:21.

keeping available NHS product for life-threatening surgery.[517] The Inquiry will wish to place that evidence in the context of the evidence of deference to specialist clinical decision-making[518], coupled with the fact that the ability to initiate such steps rested with clinicians and also RTCs, which were responsible for the production of cryoprecipitate. Evidence about the logistical difficulties that would have been faced by BPL, had it been asked to increase the supply of cryoprecipitate, has already been set out above, as has the dilemma in relation to increasing RTC supplies of cryoprecipitate: it would have reduced plasma supplies to BPL. The Inquiry may wish to consider that one of the factors giving context to the DH's response to the threat of AIDS at the time was the absence of calls for such action to be taken, in particular through such routes as the UKHCDO or the Department's Advisor on Blood Transfusion.

(2) Information about AIDS provided to Parliament, clinicians and the public

4.71. The question of the developing knowledge of AIDS of advisors and decision-makers from within the Department and associated bodies is addressed in broad terms above at paragraphs 4.6 - 4.17. One of the issues for the Chair's consideration is whether any steps were taken to communicate this knowledge to others; and if information and knowledge were not shared with others, why not.

Statements made by ministers in Parliament, in correspondence and publicly about the transmissibility of AIDS through blood and blood products

4.72. A question which has been explored extensively with relevant witnesses is whether statements made by ministers in Parliament, in correspondence and

[517] Dr Walford's oral evidence on 20 July 2021, at 186:15-187:4.
[518] See for example Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §2.2 *"Perhaps it is obvious, but it is worth noting that the DHSS was not responsible for treatment decisions relating to individual patients. These lay in the hands of the treating doctors, whose clinical freedom to make such decisions was carefully guarded*". See further §4.149ff, below.

publicly about the transmissibility of AIDS through blood and blood products in 1983 to early 1984 reflected a lack of openness about the risk as it was understood by the Department.

4.73. It was Dr Walford's evidence to the Inquiry that to the best of her knowledge the first time that the wording *"no conclusive proof"* was used within the Department was in the briefing prepared for the Prime Minister following reports in the press on 1 May 1983 about AIDS.[519] One of these reports was the Mail on Sunday article entitled "*Hospitals using killer blood*".[520] There were also two articles in the Observer entitled "*Killer disease alert over gay blood donors*" and "*The epidemic spreads*".[521]

4.74. The 'line to take' set out in the briefing prepared for Number 10 read as follows:

> *"I was very concerned to read this weekend's Press Reports and can well understand the anxiety which some sensational reports may have caused. It is important to put this in perspective: there is as yet no conclusive proof that AIDS has been transmitted from American blood products. The risk that these products may transmit the disease must be balanced against the obvious risks to haemophiliacs of withdrawing a major source of supplies. Already, in this country, there is a special surveillance system, established by the Communicable Disease Surveillance Centre, to monitor the occurrence of AIDS, in collaboration with the Centres for Disease Control in the USA. Every opportunity is being taken for this country to learn from the experience of this disease in the USA."* [522]

4.75. The relevant paragraphs of the Q&A background note are set out above at paragraph 4.10 above. These paragraphs contained more detail than the 'line to take' and the answer to the question "*IS [AIDS] TRANSMITTED IN BLOOD OR BLOOD PRODUCTS?*" qualified the *"no conclusive proof"*

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[519] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.9.
[520] DHSC0001649 and DHSC0001650.
[521] MDIA0000016 and MDIA0000015. The article entitled "*The epidemic spreads*" at MDIA0000015 contained a quotation from a Food and Drug Administration spokesperson in the United States as follows: "*There is no clear-cut evidence to show that AIDS can be transmitted through blood transfusion.*"
[522] WITN4461123.

wording acknowledging that the evidence was "*...suggestive that this is likely to be the case*".[523]

4.76. It is unclear from the documents available who drafted the briefing that went to Number 10 (Dr Walford had no recollection of being so involved[524]). It was, however, circulated within the Department by Mr Parker from HS1 on 3 May 1983 and appears to have formed the basis for similar wording to the *"no conclusive proof"* line in future lines to take which were used by ministers in answers to Parliamentary Questions, in correspondence and in public statements for the remainder of 1983 into early 1984.[525] By way of example:

(1) As part of a number of answers to questions about AIDS put during Parliamentary Questions in the Lords on 14 July 1983, Lord Glenarthur said:

> *"Although there is no conclusive evidence that AIDS is transmitted by blood or blood products, the department is considering the publication of a leaflet indicating the circumstances in which blood donations should be avoided."*[526]

(2) In a letter from Lord Glenarthur to Clive Jenkins of the Association of Scientific Technical and Managerial Staffs ("ASTMS") dated 26 August 1983, Lord Glenarthur stated that:

> *"...there is no conclusive evidence that AIDS is transmitted through blood products. Nevertheless, we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products."* [527]

(3) In a letter from Lord Glenarthur to Baroness Masham dated 30 August 1983, Lord Glenarthur stated as follows:

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[523] WITN4461123.
[524] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.4.
[525] See Mr Parker's minute of 3 May 1983 at DHSC0001651 and Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.9. The line was not in fact used by the Prime Minister during Prime Minister's Questions: WITN4461122.
[526] DHSC0002229_085. In his answers, Lord Glenarthur also set out the detail of the steps being taken and highlighted that there was no cure, as noted by Lord Glenarthur in his witness statement dated 8 July 2021 (WITN5282001), §25.10(i).
[527] DHSC0002231_036. The letter went on to set out the detail of the steps taken and being taken in the US and in the UK in relation to AIDS. See further Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §25.10(ii).

"There is, in fact, no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or Factor VIII concentrates." [528]

(4) In a Departmental press release dated 1 September 1983 announcing the publication of the first AIDS donor leaflet (addressed further below) Kenneth Clarke was quoted as follows:

"It has been suggested that AIDS may be transmitted in blood or blood products. There is no conclusive proof that this is so. Nevertheless I can well appreciate the concern that this suggestion may cause. We must continue to minimise any possible risk of transmission of the disease by blood donation but it is not possible to test a person's blood for the presence of AIDS. The best measure which can be taken at the present time is to ask people who think they may have AIDS or be at risk from it, to refrain from giving blood. This is what this leaflet sets out to do." [529]

(5) On 14 November 1983, Kenneth Clarke gave a written answer to a Parliamentary question from Edwina Currie about advice to hospitals on the use of imported Factor VIII *"in light of recent concern about its possible contamination with the causative agent of acquired immune deficiency syndrome"*. He said:

"There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products. The use of factor VIII concentrates is confined almost exclusively to designated haemophilia centres whose directors and staff are expert in this field. Professional advice has been made available to all such centres in relation to the possible risks of AIDS from this material." [530]

(6) On 16 December 1983 in a letter from Lord Glenarthur to John Maples, Lord Glenarthur wrote:

"I can well appreciate the anxiety, particularly among haemophiliacs and their families which recent press reports on

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[528] DHSC0002231_037. This phrase was used in the context of the letter addressing "t*he possibility of transmission through blood products, particularly those imported from America…*", which went on to address steps taken and being taken in the US and in the UK in relation to AIDS and referred to the need to balance possible risks of infection from AIDS against the obvious risk of not having enough Factor VIII. See further Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §25.10(iii).

[529] DHSC0006401_006. Further notes on the position of Factor VIII products were included in the press release, including upon US imports and the special requirements introduced by US Food and Drug Administration to exclude high risk groups from plasma donation and the Council of Europe recommendation that all member states should make information on AIDS available to blood donors was also referenced: Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.25.

[530] PRSE0000886.

> *AIDS may have caused and would first of all like to put matters into perspective: the cause of AIDS is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products. Nevertheless, I would like to assure your constituent…"* [531]

(7) In a letter from Lord Glenarthur to Clive Jenkins of the ASTMS dated 5 January 1984, Lord Glenarthur responded to points made by Mr Jenkins in a letter dated 27 October 1983. Lord Glenarthur wrote:

> *"It remains the case that there is no conclusive evidence of the transmission of AIDS through blood products, although the circumstantial evidence is strong. These two statements in no way contradict each other as you will readily appreciate from an analysis of a similar argument which you use in paragraph 7. Whilst there is strong evidence to suppose that the hepatitis vaccine will not transmit AIDS, the evidence is not conclusive and cannot be so until a means of testing for AIDS has been devised. In both cases, the conclusive evidence awaits the development of a test which can identify the AIDS agent (or agents)."* (Original emphasis)[532]

4.77. Whilst the "*standard line*"[533] as used in 1983 to early 1984 was generally qualified by a recognition of the existence of a risk and an account of the steps taken to address it,[534] it did not, at least in 1983,[535] refer to the evidence suggesting that it was likely that AIDS could be transmitted by blood.

4.78. Relevant Departmental witnesses have addressed in their evidence the difference between the wording used in ministerial statements such as those

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[531] ARCH0000679. The letter went on to set out the steps taken in the US and the UK in relation to AIDS and made reference to action to "*minimise the possible risk of the transmission of AIDS by blood donation in this country*". See further Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §25.10(v). As noted by Lord Patten in his witness statement dated 5 April 2022 (WITN5297001), §3.37, a copy of the AIDS information leaflet for blood donors, published in September 1983 and referred to further below, was attached to Lord Glenarthur's letter.
[532] PRSE0001727. See further Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §27.4.
[533] So described by, e.g., Dr Walford in her witness statement dated 5 July 2021 (WITN4461001), §86.9 and Lord Glenarthur in his witness statement dated 8 July 2021 (WITN5282001), §25.7.
[534] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§86.9 and 86.11; Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §25.10; Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.13(iii); Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.111.
[535] The letter of 5 January 1984 did make reference to strong circumstantial evidence.

set out above and the wording contained in the AIDS information leaflet aimed at discouraging individuals at high risk from AIDS from giving blood, first published in September 1983, which included the following:

> *"Since AIDS may be transmitted by transfusion of blood and blood products, the National Blood Transfusion Service wants blood donors to have the facts about the disease."*

And

> *"Can AIDS be transmitted by transfusion of blood and blood products?*
>
> *Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital. However, in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma, obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease."* [536]

4.79. That there was a degree of tension between the wording used in statements by ministers (and in particular Kenneth Clarke's statement in the press release of 1 September 1983) and the wording used in the AIDS information leaflet for blood donors was accepted by a number of Departmental witnesses, including Kenneth Clarke and John Patten.[537] Dr Walford's evidence was that *"the leaflet for blood donors had to serve a different purpose from statements intended for more general use"*; a leaflet which was not sufficiently clear and unambiguous about the potential for a donor's blood to cause a patient to develop AIDS would provide less incentive for the donor to self-exclude or risk the embarrassment of a donor being declined at the donor centre.[538] Some insight into the intention behind the wording of the ministerial statement contained within the Departmental press release of 1 September 1983 is provided by the 'Arguments for a statement' sent under cover of a minute from Mr Parker to Dr Walford on 2 August 1983, which

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[536] BPLL0007247.
[537] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.111; Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.37. See too Lord Fowler's oral evidence on 21 September 2021, at 151:11-151:19.
[538] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.63. See too Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.111.

described the proposed draft statement as "*…low-key…*", putting the "*…problem of AIDS into perspective…"* and justifying the leaflet initiative.[539]

4.80. More broadly, there is evidence before the Inquiry that:

(1) The Department, at a time when the picture relating to AIDS was uncertain, wanted to avoid creating panic or alarm.[540] In particular:

(a) There were concerns that panic might result in losing blood donors, with consequences for the national blood supply.[541]

(b) There was a concern that alarming recipients / prospective recipients of blood products and blood transfusions might lead to patients refusing treatment, with the risks inherent in that.[542]

(2) Against that background, at a time when the risk from AIDS was considered to be small, there was a perceived need within the Department to provide a measure of reassurance to the haemophiliac community.[543]

4.81. Dr Walford's contribution to the draft wording for Lord Glenarthur's letter to Baroness Masham following her question in the Lords on 14 July 1983 *did* include some qualification of the *"no conclusive proof"* wording: "*There is no conclusive proof that AIDS can be transmitted by blood, cryoprecipitate or FVIII concentrates but the assumption is that such transmission may be*

[539] DHSC0002321_031. See too Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §7.111.
[540] Lord Clarke's oral evidence on 27 July 2021, at 80:19, 82:11-82:12 and 92:6. See too Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.13(ii); and his oral evidence on 22 September 2021, at 14:21-15:13, during which he advocated for open Government.
[541] Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §§7.20 and 7.77; Lord Clarke's oral evidence on 27 July 2021, at 80:20, 81:3-81:7 and 92:7-92:13.
[542] Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §29.2; Lord Glenarthur's oral evidence on 23 July 2021, at 50:20-51:6; Lord Clarke's oral evidence on 27 July 2021, at 80:21-80:24, 81:10-81:13, 82:19-82:20. Concerns about haemophilia patients refusing treatment were shared by the Haemophilia Society: see, in particular, the Haemophilia Society Factsheet on AIDS to members of September 1983 at WITN4461153 – whilst apparently proceeding on the assumption that blood was "a transmission agent" for AIDS, the risk of AIDS was said to be outweighed by the risk of untreated bleeding episodes.
[543] Lord Glenarthur's oral evidence on 23 July 2021, at 49:15-50:3.

possible."[544] This wording was not included in the draft wording sent to Lord Glenarthur's private office by HS1.[545] It was Dr Walford's oral evidence to the Inquiry that the line should always have been appropriately qualified and without this qualification the line might sound too definite.[546]

4.82. The perspectives of the ministers within the Department at the relevant time were explored in questioning by CTI during the oral hearings. Those perspectives given to the Inquiry included:

(1) The view that, taking the ordinary meaning of "*no conclusive proof*" and putting the phrase in the context of the situation overall and the full wording of the press release of 1 September 1983, the Department was saying that there was a strong possibility at least that blood products could transmit AIDS,[547] but "*at the moment, no conclusive proof*".[548]

(2) The view that, looking at matters now, the standard line used may have been incomplete and had the potential to mislead.[549]

(3) The view that, looking at matters now, the wording of the line should have struck a better balance and should have been amended sooner than it was.[550]

(4) The view that, looking at it now, whilst the line implicitly recognised the risk, it was "*certainly incomplete*"; there was a need more precisely to reflect the balance of the background note, which should have been spotted by the Department - it would have been better to have included a reference to the fact that the evidence suggested that

[544] DHSC0002491_013.
[545] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §99.32; Mr Parker's minute to Lord Glenarthur's private office dated 26 July 1983, plus enclosures, at DHSC0002309_032.
[546] Dr Walford's oral evidence on 21 July 2021, at 159:9-159:22.
[547] Lord Clarke's oral evidence on 27 July 2021, at 30:1-33:1, 44:6-44:13, 44:6-45:14.
[548] Lord Clarke's oral evidence on 28 July 2021, at 32:6-7
[549] Lord Glenarthur's oral evidence on 23 July 2021, at 56:17-57:3.
[550] Lord Patten's oral evidence on 20 May 2022, at 85:10-86:24.

it was likely that AIDS could be transmitted by blood; and the line should in any event have been changed by November 1983.[551]

(5) As to subjective intention,

(a) Lord Glenarthur was "*absolutely certain*" when giving his oral evidence on 23 July 2021 that "*officials in the Department, let alone Ministers, would not wish to have misled in any way*".[552]

(b) Dr Walford was asked by CTI on 21 July 2021 whether it might be said that the line was formulated as it was because it "*...excused a failure on the part of the Department to take more radical action*".[553] Her evidence was that she had never heard matters expressed in this way and had no reason to believe this was the case.[554]

There are no documents of which that the DHSC legal team is aware that contradicted this, or the evidence of those involved at the time as to the intention behind relevant ministerial statements.

4.83. DHSC invites the Inquiry to take the above perspectives into account as part of its overall assessment of both the objective effect of the statements made, and the subjective intention of those involved.

The AIDS information leaflet aimed at discouraging individuals at high risk from AIDS from giving blood

4.84. One of the issues identified in the Inquiry's List of Issues is whether the steps taken by the Government to deter donors in high-risk groups from

[551] Lord Fowler's oral evidence on 21 September 2021, at 148:7-150:1; and Lord Fowler's oral evidence on 22 September 2021, at 39:4-39:18.
[552] Lord Glenarthur's oral evidence on 23 July 2021, at 56:4-56:6.
[553] As was raised in questioning of Dr Walford by CTI during her oral evidence on 21 July 2021, at 164:2-164:8.
[554] Dr Walford's oral evidence on 21 July 2021, at 164:10-164:13. See too a report compiled by Dr Smithies and Dr Moore following a review of the files from 1982 to 1984 in 1987, which concluded that "in view of the very small number of UK cases" the standard line being used in 1983 was "intended to reduce public anxiety": DHSC0001160, page 17; and the oral evidence of Dr Moore on 18 January 2022, at 60:10-60:24.

donating blood were adequate.[555] Further issues are whether there were delays in the production of leaflets for donors about the risks of AIDS, and if so, why.[556]

4.85. Whilst it remained important to deter high risk donors from giving blood after the introduction of routine screening of blood donations for HTLV-III in October 1985,[557] given the particular importance of this in the absence of screening, the focus of this section is upon the first AIDS leaflet for blood donors published in September 1983 and the revised leaflet that followed, publication of which was announced on 1 February 1985.

The first AIDS leaflet

4.86. To assist the Chair in his consideration of the first AIDS leaflet that was published in September 1983, a brief chronology of the events leading to its production is set out below, followed by submissions addressing the following topics:

(1) The time it took to publish the first leaflet;

(2) The contents of the leaflet; and

(3) The arrangements for the distribution of the leaflet.

4.87. The knowledge of AIDS in 1983 is useful context, as set out at paragraph 4.9 above, the first time ministers were briefed on AIDS was 3 May 1983. There had only very recently been a report of AIDS in a patient with haemophilia in the UK (see the table at paragraph 4.1 above). And as is further addressed at paragraph 4.15 above, there was still no consensus about the cause of AIDS and whether this it could be transmitted through blood was still being debated in February 1984. Whilst it was Lord Patten's evidence that "...*we*

[555] Issues 28(g) and 36.
[556] Issues 28(h) and 81(c).
[557] As was explained in a circular from the Department to RHAs/SHAs dated 24 September 1985, which notified recipients of a new revised leaflet containing important new information for blood donors, being printed at that time: WITN0771214.

were acting on the assumption that AIDS could be transmitted by blood,"[558] as alluded to by Lord Patten in his oral evidence, officials and ministers also needed to consider the possibility that they might be wrong about the risk of AIDS being transmitted through blood products and that the action being taken may not have been justified at all.[559] This uncertainty and lack of consensus as to the aetiology of AIDS is one feature of the context for the contemporaneous decisions that were being taken, which the Inquiry is invited to consider.

Chronology

4.88. It appears that an information leaflet was first discussed by Dr Walford and Dr Gunson at a meeting with the RTDs held on 18 May 1983.[560] Dr Walford's evidence was that the Directors were reluctant to proceed with the leaflet due to concerns surrounding deterring donors from donating blood and possibly causing offence to the homosexual community, however, they ultimately agreed that one should be prepared.[561] The draft leaflet was subsequently prepared by the RTDs, although this did not appear to Dr Gunson and Dr Walford to be expressed in clear enough terms and was thus redrafted by Dr Gunson, in conjunction with Dr Walford.[562] Dr Walford subsequently sent it to Mr Winstanley on 17 June 1983 for onward transmission to the Information Division.[563] It was around then that Dr Walford's direct involvement in the leaflet ceased.[564]

4.89. The leaflet was subsequently raised with ministers on 1 July 1983 via a submission sent from Mr Parker to Lord Glenarthur's Private Office and copied to the Private Offices of Kenneth Clarke, John Patten and Sir Kenneth Stowe.[565] It attached a short paper by Dr Walford[566] and the draft

[558] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.45.
[559] Lord Patten's oral evidence on 20 May 2022, at 52:4-52:18.
[560] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§86.47-86.55.
[561] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§86.52-86.53.
[562] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§86.54-86.55.
[563] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.58.
[564] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.56.
[565] DHSC0002309_024.

leaflet which had been prepared by the Regional Blood Transfusion Directors.[567] The submission was copied quite widely, including to the Scottish Home and Health Department ("SHHD").

4.90. The leaflet was approved by Lord Glenarthur[568] and John Patten.[569] However, there remained concerns amongst ministers both about the content of the leaflet and the way in which it should be distributed. Lord Clarke's evidence to the Inquiry was that he recalls concerns about an increase in discrimination towards the homosexual community, and concerns that inaccurate or inflammatory reporting could damage confidence in the blood service or discourage donations.[570] In his oral evidence, he explained that because of these concerns he intervened and called a meeting on 6 July 1983 in order to ensure that the matter was handled appropriately:

> "*But my recollection is that I actually chose to intervene, for the reasons I have given. I was worried about the press creating an absolute panic. I was worried about our losing blood donors. I was worried about alarming recipients, both haemophiliacs and more -- actually, blood transfusion people as well, which I thought I was also – I think I was concerned about but it doesn't appear from this. Just -- I mean, it was -- it didn't -- you know, didn't take them long to persuade me we had to put out a leaflet. It was a very important leaflet. But that's what I intervened for, because if we'd not handled it carefully, we could have created an absolute mayhem. Somewhere in the documents I -- they had had problems in New York when they did it there. They had started losing blood donors, I think*".[571]

4.91. A record of that meeting was circulated to the private offices of Norman Fowler and John Patten amongst others.[572] It is clear from that record that ministers accepted the need for the leaflet but that this needed to be accompanied by "*...a carefully drafted Press Notice and full question and answer briefing*". It further states "*...to minimise scaremongering, the PN*

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[566] DHSC0002309_121.
[567] DHSC0002309_122.
[568] DHSC0002309_122.
[569] DHSC0002309_027.
[570] See Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §7.8; see also Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.40.
[571] Lord Clarke's oral evidence on 27 July 2021, at 80:17-81:7.
[572] DHSC0001511.

should emphasise how relatively few cases of AIDS had been reported and repeat that there was no question of donors being quizzed about their sexual habits. The main objective was to minimise any damage to the transfusion service."

4.92. At this stage the UK-wide leaflet was being widely circulated amongst Regional Transfusion Directors in what was described as "*final form*" and that the leaflet was going into print.[573]

4.93. On 8 July 1983, the Department received legal advice from the Home Office (by reference to the submission of 1 July) to the effect that the terms of the proposed leaflet were not discriminatory.[574]

4.94. Subsequently, between 18 July 1983 and 25 July 1983, there were a series of exchanges about the appropriate distribution of the leaflet.[575] These addressed how the leaflets could be publicised and distributed in such a way as to ensure that they met their purpose in reducing the number of at-risk people donating blood, but without causing unnecessary alarm and panic. It is evident from the material before the Inquiry that there were differing views, both within the Department and more widely between RTDs.

4.95. Communication was also sent between the private offices of Lord Glenarthur and Kenneth Clarke in respect of including a reference to the European advice in the leaflet.[576] Then on 29 July 1983 a further submission including a revised leaflet, detailed Question and Answer brief and draft press release,

[573] NHBT0020668 and PRSE0001609.
[574] DHSC0002229_072.
[575] Minute from Mr Parker to Dr Oliver, dated 19 July 1983, referring to the earlier Ministers' meeting of 6 July 1983 at DHSC0002321_026; response from Dr Oliver dated 20 July 1983 at DHSC0002321_027; minute from Mr Bolitho (Information Division) to Dr Oliver, dated 21 July 1983 at DHSC0002321_028; minute from Dr Oliver in response to Mr Bolitho, dated 25 July 1983 at DHSC0002321_029.
[576] Minute from Lord Glenarthur's Private Office, dated 22 July 1983 at DHSC0002309_029; Response from Ken Clarke's Private Office to Lord Glenarthur, 26 July 1983 at DHSC0002309_031.

was sent from Mr Parker to Kenneth Clarke's private office.[577] It was copied to the Private Offices of Lord Glenarthur, Mr Patten and Sir Kenneth Stowe, as well as to a number of officials.

4.96. This submission further reported on a survey of RTDs which was undertaken to determine their views on distribution of the leaflet. It noted that their views were divided, and recommended a trial period of six months in which RTDs were to be given discretion to decide which method of distribution between making the leaflet available at donor sessions or sending it out with call-up cards.

4.97. On 2 August 1983, the leaflet and suggested distribution approach was approved by Kenneth Clarke.[578] The leaflet was also approved by John Patten, who urged that arrangements go ahead as soon as possible.[579] John Patten further queried whether Directors could follow both distribution methods throughout the trial period. Lord Glenarthur approved the leaflet on 3 August and stated that he favoured using both methods of distribution.[580]

4.98. Kenneth Clarke's Private Office confirmed on 5 August 1983 that it would take three weeks for the printing of the leaflets.[581] It appears that the leaflet had been printed and distributed just under four weeks later by 31 August 1983.[582]

4.99. Up until the point of publication, discussions continued about the appropriate method of distribution. On 26 August 1983, Kenneth Clark raised concerns about recent reports in the media with provocative headlines such as 'Docs

[577] DHSC0002327_016.
[578] DHSC0002327_119.
[579] DHSC0002327_118.
[580] DHSC0002327_120.
[581] DHSC0002309_033.
[582] See submission from Kenneth Clarke's private office to Lord Glenarthur's Private Office at DHSC0002309_035.

Ban Gays' Blood' and said he was concerned by a report that similar alarmist action had caused a shortage of blood in New York. He queried what options were available to insist upon a national method of distribution.[583] It further appears by a submission from Mr Clarke's private office to Lord Glenarthur's private office on 31 August 1983 that a meeting took place to discuss distribution on 30 August 1983.[584]

4.100. The following day, Mr Clarke agreed that he was content to accept the recommendation of officials and allow distribution of the leaflet to be left to the discretion of Regional Directors, subject to the views of Lord Glenarthur.[585] Lord Glenarthur indicated his agreement on 1 September 1983, but requested a shorter trial period of 3 months, with which Mr Clarke was content.[586] The leaflet was published that same day, 1 September 1983, announced by way of a press release with a statement from Mr Clarke.[587]

The time it took to publish the first leaflet

4.101. In relation to the decisions being taken at a ministerial level in respect of the publication of the first leaflet, a number of themes can be distilled from the evidence before the Inquiry:

(1) First, the evidence suggests that ministers viewed this leaflet as important; it was a "*big step*" and something that those involved were keen to get right.[588]

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[583] DHSC0002309_034
[584] DHSC0002309_035; although Lord Glenarthur does not recall this meeting and having checked his diary appears to have been in Scotland at the time. He accepts, however, that this may have been a telephone meeting (see Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §21.2 and Lord Glenarthur's oral evidence on 22 July 2021, at 99:18-100:10).
[585] DHSC0002321_034.
[586] DHSC0002309_036.
[587] DHSC0006401_006.
[588] See Lord Clarke's oral evidence on 27 July 2021, at 75:16 – 76:5; Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.20(1); Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.40. In respect of leaflets generally, Lord Glenarthur's evidence is that "[ministers] *wanted to get it absolutely right, bearing in mind the practicalities, the politics, press interest, et*

(2) Second, there were genuine concerns about the risk of creating panic, which could have affected the supply of blood products within the United Kingdom.[589] Lord Patten's evidence was that these concerns included that misinformation may lead to people being deterred from giving blood due to a misplaced fear that being a donor would place them at risk of AIDS.[590]

(3) Third, there were concerns of the potential knock-on effect this could have on patients who required blood transfusions or blood related products. Ministers were keen to avoid undermining the trust placed in the blood services as a whole.[591]

(4) Fourth, concerns were raised about the risks of fuelling homophobia, at a time where homophobia was already widespread, coupled with a desire to avoid allegations of discrimination.[592]

4.102. The Chair is invited to consider whether the length of time it took for the first leaflet to be published is, in part, attributable to the necessary discussions which were being had within the Department in respect of the above issues. In his witness statement, Lord Fowler noted that *"...it may be said, particularly with the benefit of hindsight, that the two-month period was too long. However, it seems to me that at the time, how to balance these difficult factors was being carefully considered. In that sense it is not surprising that agreement took time."* [593] Whilst Lord Patten accepted that matters could

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cetera, and maybe I was not as sensitive – if that's the right word, I don't know – to those concerns as some of my colleagues were." (Lord Glenarthur's oral evidence on 22 July 2021, at 136:19-137:3).
[589] See Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §18.3; Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.20(2); Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.40 and §8.23(1).
[590] Lord Patten's oral evidence on 20 May 2022, at 64:23-65:7.
[591] See for example Lord Clarke's oral evidence of 27 July 2021, at 76:15-77:16; 80:16-81:7; Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.40 and §8.23(1).
[592] See for example Lord Clarke's oral evidence on 27 July 2021, at 75:16-76:14; Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.40 and §8.23(1).
[593] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.40.

have been pushed through a bit quicker. His evidence was that the issues being considered were rightly being debated.[594]

4.103. In his written statement to the Inquiry, Lord Glenarthur expressed surprise at the process taking so long and concluded that "*...perhaps [he] was naïve about the sensitivities of such publications, which other Ministers had more experience of than me.*"[595] He continued in his statement to explain the length of time between the first submission on 1 July 1983 to publication on 1 September 1983 as due to the following:

> "*There were concerns about detailed drafting, costs and methods of distribution when the leaflets were distributed. The views of the RTDs were sought. The draft leaflet was resubmitted to Ministers on 29 July, approved by them by 3 August and printed within the month, by 1 September. There is a reference in the note of 5 August 1983 that printing would take 3 weeks: [DHSC0002309_033]. Whilst I would have preferred things to progress even faster, we had been able to complete the process relatively swiftly*".[596]

4.104. Lord Glenarthur accepted in oral evidence, however, that he was concerned at the time that the production of the leaflet was taking too long.[597]

4.105. Dr Walford's evidence was also that this process took "*much too long*"[598], although it is noted that Dr Walford's involvement on the whole ceased in mid-June 1983 and she was not involved in the later discussions which arguably contributed to the delay.

4.106. Other explanations which have been put forward for the delay include a potential impact on work within the Department due to the summer recess, and the time it took for the leaflets to be physically printed and distributed.

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[594] See Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.28, also discussed in his oral evidence on 20 May 2022 (see Lord Patten's oral evidence on 20 May 2022, at 78:18 – 79:10).
[595] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §23.2.
[596] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §23.3.
[597] Lord Glenarthur's oral evidence on 22 July 2021, 102:25 – 103:9.
[598] Dr Walford's oral evidence on 21 July 2021, 169:13.

4.107. As to the former, Lord Fowler's evidence in particular was that August would be a difficult time to get things done due to staff absences. He also suggested that this may not be the most effective time to put a message out to the public.[599] However, it is unclear from the evidence before the Inquiry whether the August break did in fact have a great impact on timing. As set out above, communication on the topic continued into August when the final draft leaflet was approved. Three weeks of August then appear to be taken up with printing arrangements.

4.108. In respect of printing arrangements, Lord Patten's evidence was that whilst three weeks may appear by today's standards to be quite a lengthy time, in 1983 that period was difficult to avoid.[600] The Inquiry has been referred to a newspaper advertisement which suggests urgent print orders could be achieved in a significantly shorter period of time.[601] The Chair is invited to approach this with some degree of caution. As Lord Patten observed in his evidence:

> *"But I would stress that, in considering that issue, it may well be that there was Government-wide contracts as a matter of fact between the Government and its Departments and the stationery office, or whatever, to be the body that conventionally, for security and a whole host of other reasons, would carry out leaflets. And it suggests that it may have taken three weeks and there may be people out there who could have done it quicker if they had had the capacity. I don't know. I can't answer that question. But I think it is very important for me to say, not first order importance but maybe third order importance, that ministers normally did not get involved, Sir Brian, in deciding that we use this or that company or urge this or that company to get on with it."*[602]

<u>The content of the first leaflet</u>

4.109. There were multiple early drafts of the leaflet circulated amongst officials. The latest version prepared by Dr Walford and Dr Gunson was sent to the

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[599] Lord Fowler's oral evidence on 22 September 2021, 29:11 – 32:4.
[600] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §3.28; supported also by minute of 7 June 1983, DHSC0002321_017.
[601] **JEVA0000120**
[602] Lord Patten's oral evidence on 20 May 2022, at 76:19-77:9.

Information Division on 17 June 1983.[603] It is clear from the content of the leaflet that further amendments were made prior to it being sent to ministers on 1 July 1983.

4.110. In her witness statement, Dr Walford set out in a table the key differences between the version provided to the Information Division, and the version ultimately provided to ministers:[604]

GUNSON Version [17 June 1983]		REVISED VERSION [1 July 1983]	
CAN AIDS BE TRANSMITTED BY BLOOD TRANSFUSION?	Yes, it can. The chances of this happening with the usual blood transfusion….	CAN AIDS BE TRANSMITTED BY TRANSFUSION OF BLOOD AND BLOOD PRODUCTS	Almost certainly yes, but there is only the most remote chance…
WHOSE BLOOD IS AT RISK OF TRANSMITTING AIDS?	Until more is known about the disease, people who are in any of the risk groups with a greater risk of developing AIDS should not give blood even if they are in normal health at the present time.	HOW CAN THE RISKS BE REDUCED?	At present, there is no screening test the Transfusion Service can use to detect people with AIDS. So, until there is and until more is known about this disease, donors are requested not to give blood if they think they may either have the disease or be at risk from it.

4.111. The second of the differences between the drafts in the table above was addressed by Dr Bell of the Scottish Home and Health Department ("SHHD") in a minute to the Scottish DCMO, Dr Scott, dated 6 July 1983.[605] He also

[603] WITN4461131 and WITN4461132.
[604] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.61.
[605] PRSE0000049.

explained that he had been informed that Norman Fowler's reaction to the leaflet was that *"...the terms of this leaflet are too strong, and that the DHSS may therefore be making further amendments."*[606]

4.112. Lord Fowler's evidence in respect of this comment as attributed to him is that he cannot recall whether he had a concern that the leaflet was too strong or what this referred to but *"...reflecting on it now...the language in the draft leaflet appears quite mild."*[607]

4.113. It is unclear from the evidence to the Inquiry who was responsible for the changes between the 17 June 1983 and 1 July 1983 drafts. Nonetheless, even if the comment attributed in the Scottish minute to Norman Fowler was accurate, there were only minor changes made to the draft submitted to ministers on 1 July 1983 and the final version submitted on 29 July 1983.[608] The evidence of Lord Glenarthur is that the wording of the leaflet "...*was drawn up and agreed between medical experts, the Information Division (which advised on publicity materials). Ministers would suggest amendments, perhaps even insist on them; and the draft would go back to officials for further comment*".[609] That this was the approach that was taken is supported by the documentation, with only minor amendments being made through ministerial involvement.

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[606] It is understood that these comments would have related to the 1 July 1983 version of the leaflet, as the earlier version was not circulated amongst ministers: see Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §86.62. This is also supported by the documentary evidence which indicates that the first time the draft went to ministers was with the 1 July 1983 submission at DHSC0002309_024.

[607] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.33; Lord Glenarthur was also asked in his oral evidence if he was aware of any expression of opinion by Mr Fowler. His answer was that he wasn't and "the main reaction was from Mr Clarke." See Lord Glenarthur's oral evidence on 22 July 2022, at 73:24-74:2. Thus it is unclear whether Mr Fowler had in fact made the comment attributed to him.

[608] See the revised draft of 29 July 1983 at DHSC0002327_117 and the published version at BPLL0007247. The request to donors remained unaltered. See the comparison set out by Lord Glenarthur in his witness statement dated 9 July 2021 (WITN5282001), §17.2.

[609] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §24.3.

4.114. The evidence summarised above suggests that the preparation of this leaflet required a balancing act between a number of competing interests: there was a desire to avoid panic and also an awareness of the risk of discriminating against the homosexual community, which are factors which the Chair may consider impacted on the final content of the leaflet. Lord Patten addressed this in his oral evidence. When asked whether the leaflet was expressed in terms that were too tentative, he suggested that:

> *"I think I must say, on behalf of long ago civil servants, particularly at this stage in the development of the science and the low levels of testing that there had been, that I can see and sympathise with them being tentative to a certain extent, because they didn't want ministers in particular to go around causing alarm, which might not turn out to be justified.*
>
> *So I can understand the intellectual and policy forming context that those words were used. I suspect turning the clock on, which we can't do, another six months or a year, they would not have phrased it in that way because, by that stage, there was lots more information and we were much clearer."*[610]

4.115. Another question asked by CTI in relation to the strength of the messaging, was whether more groups ought to have been excluded at this time.[611] Lord Fowler's response to this question was that at that time limiting the advice to promiscuous homosexuals was appropriate; he expressed concern that to prohibit all homosexuals from giving blood would be "*...painting everybody with the same brush.*"[612] This is perhaps suggestive of a concern that banning all homosexuals at that time would be casting the net too wide and including those who were of low risk. See in that regard Lord Fowler's reflection now in respect of the second leaflet, which he considered "*...unfair on the people who had been in loving relationships for years.*"[613]

4.116. In respect of this question, Lord Patten's evidence was that "*...with hindsight, yes. It is manifest that they should have been – more groups*

[610] Lord Patten's oral evidence on 20 May 2022, at 52:4-52:18.
[611] Lord Patten's oral evidence on 20 May 2022, at 47:7-48:6.
[612] Lord Fowler's oral evidence on 22 September 2021, at 27:22-27:23.
[613] Lord Fowler's oral evidence on 22 September 2021, at 48:10-48:12.

should have been listed."[614] However, as set out above this question should also be considered against the state of knowledge at the time and the advice which was being given was that those most at risk were promiscuous homosexuals.[615]

Distribution of the first leaflet

4.117. As set out above, the decision taken by ministers was to allow distribution of the leaflet to be left to the discretion of Regional Directors for a trial period of three months. The evidence before the Inquiry suggests that before this decision, the method of distribution was given considerable thought and provoked discussion, both at official and ministerial level.

4.118. At official level, concerns were raised by Dr Oliver on 21 July 1983 that ministers had not fully understood the pros and cons and it was, therefore:

> *"...essential that the points [he] raised in [his] minute are brought out in the submission so that Ministers can weight the possible disadvantage of letting 'risky' blood slip through the net against the advantage of minimising any adverse publicity. On purely medical grounds I am convinced that sending out the leaflet with the call-up cars is the only sensible thing to do and indeed this is the independent advice we have received from our consultant adviser whose opinion I respect."* [616]

4.119. Lord Clarke's evidence was that he could not recall ever seeing what he describes as Dr Oliver's "*more forceful views*", "*with its reference to advice from an independent consultant*".[617] Indeed there is nothing to suggest that these discussions between officials were circulated amongst or would have been seen by ministers. Ministers appear instead to have received their advice by way of the submission of 29 July 1983.[618]

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[614] Lord Patten's oral evidence on 20 May 2022, at 48:2-48:6.
[615] See for example the briefing note prepared by Dr Walford DHSC0002309_121, which notes that *"Blood Transfusion Directors are anxious that information on AIDS should be made available to blood donors and that promiscuous male homosexuals – who as a group carry the highest risk of transmitting AIDS in their blood – should be discouraged from donating."*
[616] PRSE0003725.
[617] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.17.
[618] **DHSC0002327_016**

4.120. This submission set out the considerations which had been given to the two methods of distribution and ultimately recommended that RTDs be given the discretion to decide how to distribute the leaflet for a 6 month trial period. Whilst questioning Lord Patten, CTI summarised the pros and cons within the submission and suggested that the second method was less effective, with the only advantage being that it had fewer resource and administrative problems. CTI went on to ask that "*...if you are prioritising safety over administrative and resource implications, it was pretty obvious which method was to be preferred, namely the first method.*" I.e. sending the leaflet out with call-up cards.[619] These propositions were agreed to by Lord Patten, who at the time had proposed the use of both methods of distribution.[620]

4.121. The submission of 29 July 1983 suggests, however, that there was more being considered than simply the administrative and resource implications of the method of distribution:

> *"Although it would be possible to achieve a near-uniformity of method of distribution amongst directors, it is not immediately obvious which method is to be preferred. Indeed, it was evident that Directors' opinions were influenced by what they saw as being most appropriate in their Regions, bearing in mind the differing population characteristics, including the numbers of, and attitudes to, homosexuals. As Directors are responsible under the Medicines Act, for the safety of blood which they issue, due weight must, of course be given to their clinical decision in this matter. In addition, those Regions for whom the agreed method has resource implications might look to the Department to provide the additional resources."* [621]

4.122. It was recognised that the Directors themselves had experience of the populations within their own areas and, given that they had responsibility under the Medicines Act for the safety of medicines, the suggestion was that views of the Directors ought to be given appropriate weight.

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[619] Lord Patten's oral evidence on 20 May 2022, at 66:21-66:24.
[620] See response from Lord Patten's private office dated 2 August 1983 at DHSC0002327_118.
[621] DCSC0002327_016.

4.123. That the RTDs held strong and differing views about the approach to distribution is apparent from a letter sent by Dr Wagstaff from the Regional Transfusion Centre in Sheffield to the remaining RTDs on 6 July 1983.[622] This letter circulated the current draft of the leaflet and went on to note that:

> "*The majority of RTDs still feel strongly that approach to donors should be at the lowest key possible and were correspondingly reluctant to either hand the leaflet to every donor at a session or to send it out as part of the call-up material. However, one or two regions felt that there may be some benefit in the slightly more aggressive approach and these RTDs may be asked to run a kind of trial in their regions, by either posting of handing out the leaflets.*" [623]

4.124. These feelings may have stemmed from the initial concerns raised by RTDs when the leaflet was first suggested, namely in respect of deterring donors from giving blood and possibly causing offence to the homosexual community as described above.[624]

4.125. At the time, Kenneth Clarke also preferred that the leaflets were not delivered with call-out cards.[625] Lord Clarke's oral evidence to the Inquiry was to the effect that he was similarly concerned about creating panic and potential discrimination towards the homosexual community.[626] John Patten and Lord Glenarthur expressed different views and supported the use of both methods.[627] As is evident from the minutes between Mr Naysmith and Mr Ghagan dated 31 August 1983 and 1 September 1983, Mr Clarke and Lord Glenarthur ultimately agreed to allow RTDs discretion in this area, albeit with the shorter trial period of 3 months that had been suggested by Lord Glenarthur.[628]

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[622] NHBT0020668.
[623] NHBT0020668.
[624] See for example Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §§86.52-86.53.
[625] See for example the note from Mr Bolitho to Dr Oliver dated 21 July 1983 at PRSE0000646.
[626] Lord Clarke's oral evidence on 27 July 2021, at 86:2-86:24.
[627] Suggested by Lord Patten in minute of 2 August 1983 at DHSC0002327_118 and supported by Lord Glenarthur in minute dated 3 August 1983 at DHSC0002327_120.
[628] See the minutes of 31 August 1983 and 1 September 1983 at DHSC0002309_035 and DHSC0002309_036; Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §§7.21-7.22.

4.126. When considering the issue of the distribution of the first AIDS leaflet, the Chair is invited to consider the evidence that, as with the content and creation of the leaflet, ministers were grappling with competing concerns and were keen to get it right.

Revision of the AIDS leaflet

4.127. As per the approach taken to the first AIDS leaflet above, a brief chronology of events leaving to the announcement of the publication of a second, revised AIDS leaflet on 1 February 1985 is set out below, before the following issues are addressed:

(1) The length of time it took for the second leaflet to be produced; and

(2) The content of the second leaflet.

Chronology

4.128. The need for a revised leaflet appears to have been first suggested by some RTDs following the 3 month trial period addressed above. The minutes of the RTDs meeting of 22 September 1983 suggest that when the leaflet was issued, RTDs were encouraged to use differing methods of distribution; the three methods being used by RTDs were posting of leaflets with call-up cards, handing leaflets to donors and making leaflets available at sessions for donors to pick up and the Department had requested feedback from RTDs by the end of November at the latest (the end of the three month trial period).[629] The Welsh Regional Transfusion Centre sent its feedback on 23 November 1982.[630] The responses from the remaining Regional Transfusion Centres were collated by Dr Wagstaff following a reminder regarding follow up information sent on 23 November 1982.[631] These responses were sent to the Department by Dr Wagstaff on 3 January 1984 and he raised in his

[629] CBLA0001742 at §3(a).
[630] DHSC0002237_014.
[631] NHBT0106207_001.

covering letter the possibility of revising the leaflet prior to reprinting.[632] Dr Wagstaff suggested awaiting a revised draft from Dr Brian McClelland, Director of the Transfusion Centre in Edinburgh, as he had been involved in drafting the original leaflet. Dr Wagstaff suggested that it was hoped that the draft would be available ahead of the next RTD meeting on 25 January 1984.[633] He went on to note that he was "*...sure you will pick out from the replies that physically handing the leaflet to each donor at the session was the only method of distribution which caused offence.*"[634]

4.129. Shortly thereafter, on 14 February 1984, Dr Smithies, who had by this time succeeded Dr Walford as the Principal Medical Officer of MED SEB, provided her view that a re-draft of the leaflet was necessary in a minute to officials; her concern was as follows: "*In view of the published evidence of transmissibility of AIDS by blood transfusion, our current advice to donors could seem too lax*".[635] Dr Smithies suggested that "*...it may also be necessary to take up with the Transfusion Directors the need for more positive distribution rather than the negative approach that some of the centres have used*".

4.130. Whilst the need for a revised leaflet was being discussed amongst officials in February 1984, the new draft leaflet was not sent to ministers for approval until 10 August 1984.[636]

4.131. In the months between February and August 1984, officials worked on preparing the draft to go to ministers for approval.[637] In order to prepare the

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[632] WITN5282008_002.
[633] WITN5282008_002.
[634] It is noted that even after advice was issued in relation to the distribution of leaflets in January 1985 (see DHSC0002159) not all RTCs were able to send these out with call-up cards; the evidence of Dr Napier was that Cardiff's Regional Transfusion Centre did not have the facility to send leaflets out with call-up cards due to this being a computerised system and he understood other centres to be in a similar position. (See Dr Napier's oral evidence on 1 December 2021, at 121:20-122:4). When the revised advice was issued, Cardiff instead used alternative arrangements to ensure each donor was given a copy of the leaflet (Dr Napier's oral evidence on 1 December 2021, at 44:11–45:16).
[635] DHSC0002239_015.
[636] **DHSC0002329_044**

draft, on 12 March 1984 further feedback on the earlier leaflet was sought from RTDs.[638] Between the end of March and the end of May 1984, further drafts were circulated amongst officials.[639] In early June, Dr Smithies sent the RTDs a draft of the new leaflet and asked for comments by 6 July 1984.[640] The RTDs duly gave feedback which was incorporated into a version which was cleared by various departments on 31 July 1984.[641]

4.132. The leaflet was raised with Mr Patten and Lord Glenarthur in a submission dated 17 April 1984.[642] This noted that the leaflet and method of distributing it were under review and did not require any action from ministers. Mr Patten expressed his view that any further leaflet would need to be handled sensitively and said that Kenneth Clarke should be informed.[643] Lord Glenarthur was supportive of a further leaflet and requested a fuller note on the successful NBTS leaflet trial.[644]

4.133. The revised leaflet was then sent to ministers for approval on 10 August 1984.[645] The covering submission noted that the leaflet was now out of date in certain detailed matters and there was a need to strengthen the warning to high-risk groups not to donate. It set out the results of the trial. There had been no fall in the number of donors and little adverse comment, but wide variation in the manner in which the leaflet was distributed by the Regional Transfusion Centres (RTCs). The recommendation was now that the leaflets should be sent to all donors at their next recall. Mr Parker's minute enclosing the submission explained the cost implications of the leaflet:

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[637] The DHSC legal team has previously provided a note setting out the steps taken by officials between October 1983 and August 1983: see WITN5282008 and Lord Glenarthur's witness statement dated 8 July 2021 (WITN5282001), §43.3.
[638] WITN5282008_001.
[639] See for example DHSC0002309_039; DHSC0002321_045; WITN5282008_006; DHSC0000178
[640] DHSC0002243_026, WITN5282008_008 and WITN5282008_009.
[641] DHSC0002323_005.
[642] DHSC0002321_044.
[643] DHSC0002309_040.
[644] DHSC0002309_041.
[645] See Mr Parker's minute and the enclosed submission at **DHSC0002329_044** the draft as it stood in October 1984 is at PRSE0000136.

> *".... Ministers may wish to know that we are likely to require up to 1,500,000 leaflets which can be printed at a cost of approximately £15,000. This can be met from within the Information Division's budget in the current financial year, although this is likely to lead to the postponement of more routine publicity in relation to the National Blood Transfusion Service. Officials believe, however, that it is vital that the AIDS leaflet should be reproduced and that it should be accorded this priority."* [646]

4.134. The proposed revision and re-print was approved by Lord Glenarthur on 21 August 1984,[647] and by Kenneth Clarke on 16 October 1984, with an apology for the delay.[648]

4.135. Detailed accounts of the developments that followed before the announcement of the publication of a revised leaflet on 1 February 1985[649] are set out in the witness statements of Lord Glenarthur, Lord Clarke, Lord Patten and Lord Fowler.[650] They are not replicated in these submissions. The Chair's attention is, however, drawn to the following points from the chronology:

(1) A further version of the draft revised leaflet was provided by Janet Hewlett-Davies, an official from the Information Division of the Department, under cover of a minute dated 22 November 1984 to Mr Cashman of the Health Services Division.[651] It was her view that the first draft revised leaflet approved by Lord Glenarthur and Kenneth

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[646] **DHSC0002329_044**, page 1.
[647] DHSC0002309_046.
[648] DHSC0002309_050; the version of the draft revised leaflet as it stood at that stage is at PRSE0000136.
[649] See the Department press release of 1 February 1985 at DHSC0004764_111. The revised leaflet appears to have been printed in January 1985 (NHBT0096480_022) and the circular sent to RTDs by the Department concerning distribution arrangement for the revised leaflet is dated January 1985 (PRSE0001729), although the suggestion from the draft press statement at DH5C0004764_111 and the CMO's minute of 31 January 1985 at DHSC0002311_050 is that publication of the leaflet was expected to take place on 1 February 1985.
[650] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §§46.1-46.11; Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §§7.29-7.39; Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §§4.6-4.10 and Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §§6.58-6.62.
[651] At DHSC0002323_014.

Clarke needed to be further revised and strengthened in light of "*…recent developments and ministerial statements*".[652]

(2) Officials proposed that the revised draft AIDS leaflet should be "*held up*" until it could be considered by the NBTS AIDS Working Group, which Mr Clarke confirmed he was content to do on 23 November 1984.[653]

(3) The AIDS Working Group considered the revised draft leaflet at its meeting on 27 November 1984, had only minor comments to make on the first revised draft leaflet and did not think it was necessary to adopt a stronger line relating to high risk donors, as had been suggested by the Information Division. [654]

(4) An updated version of the draft revised leaflet incorporating the Working Group's minor comments was sent to ministers on 3 December 1984.[655]

(5) Between 3 December 1984 and ministerial approval for the final draft revised leaflet being given on 15 January 1985, there were a number of revisions made to reflect comments from ministers, in particular from Kenneth Clarke. Mr Clarke considered that the Information Division draft of 22 November 1984 conveyed the message to donors more effectively and asked for revisions to reflect this[656]. Following an update to ministers from officials that informed them about a report in the Guardian of two cases where blood donation had resulted in a 78 year-old man and a mother/baby becoming seropositive[657], Kenneth Clarke queried "*…whether it was still true to say that there was only a remote chance of getting AIDS from an ordinary blood*

[652] Which the Chair may consider to have been a reference to the developments reported in the submission to Lord Fowler of 19 November 1984 (see DHSC0002309_053 and Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §4.12) and statements made by Mr Patten on 18 and 19 November 1984 (see the Department press releases of these dates at PRSE0003367 and PRSE0002251).
[653] DHSC0000435.
[654] PRSE0000898.
[655] Dr Abrams' minute is at DHSC0002309_058. The DHSC legal team has been unable to locate the draft leaflet attached to this minute.
[656] Mr Naysmith's minute of 20 December 1984 (DHSC0002309_062); see too Lord Clarke's first witness statement dated 1 July 2021 at §7.34(e).
[657] Mr Williams' minute of 20 December 1984 (DHSC0002327_127).

transfusion"[658]. He also requested removal of reference to blood screening tests and heat treatment because these issues were yet to be considered by ministers.[659]

(6) A final draft of the revised leaflet was sent to ministers on 3 January 1985[660], as was a draft circular to RHA/SHAs mandating that the revised leaflet be brought to the attention of each donor on an individual basis[661], with ministerial approval being given for both on 15 January 1985.[662]

(7) Publication of the revised leaflet was announced by way of a press release on 1 February 1985.[663]

The length of time it took for the second leaflet to be produced

4.136. It was the evidence of Lords Fowler, Clarke, Patten and Glenarthur that it took too long for the second AIDS leaflet to be published.[664] In his witness statement, Lord Glenarthur explained the delay in the following terms:

> *"I cannot recall the reason other than that the Department and Ministers were always rightly keen to ensure as much accuracy and sensitivity as possible in published leaflets. There was a strong wish to publish the up-to-date advice, but papers do not seem to indicate exactly what the hold-up was other than that a large number of people were involved in providing comment."*[665]

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[658] Ms Bateman's minute of 31 December 1984; Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.34(e).
[659] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.35, Ms Bateman's minute of 31 December 1984 at DHSC0002309_064 and Mr Williams' minute of 3 January 1985 at DHSC0002323_088, at §3.
[660] WITN0758008.
[661] DHSC0002309_065.
[662] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §§46.9-46.10; DHSC0002482_010 and DHSC0002482_011.
[663] See the Department press release of 1 February 1985 at DHSC0004764_111. The revised leaflet appears to have been printed in January 1985 (NHBT0096480_022) and the circular sent to RTDs by the Department concerning distribution arrangement for the revised leaflet is dated January 1985 (PRSE0001729), although the suggestion from the draft press statement at DH5C0004764_111 and the CMO's minute of 31 January 1985 at DHSC0002311_050 is that publication of the leaflet was expected to take place on 1 February 1985.
[664] Lord Fowler's oral evidence on 22 September 2021, at 47:3-47:17; Lord Clarke's oral evidence on 27 July 2021, at 88:23; Lord Patten's oral evidence on 20 May 2022, at 115:5-115:9 and at 120:21-121:8; Lord Glenarthur's oral evidence on 22 July 2021, at 146:24-147:16.
[665] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §46.14. The chronology leading to the publication of the AIDS leaflet in February 1985 is addressed in the Penrose Inquiry Final Report at §§28.63 to 28.65 and to an extent, Lord Penrose expressed the similar view that the delay was in part due to the sheer number of interested parties involved.

4.137. Lord Glenarthur further suggested in his oral evidence that ministers' time and attention was required for a broad range of other issues relating to multiple policy areas, which may have meant that some things were not done as soon as was hoped. As Lord Glenarthur explained in his oral evidence:

> *"There were so many other things going on across the range of activities which all of us had to deal with, and probably Mr Clarke, in particular, as Minister for Health, that not everything came to the top of the pile of matters to be signed off at the appropriate time.*[666]

4.138. The evidence shows that there were a large number of people involved in the drafting of the second leaflet at every level. There was widespread recognition of the need for a new leaflet, and again a desire that the leaflet be published quickly whilst ensuring it was as effective, accurate and up-to-date as possible.

4.139. Against the changing landscape of knowledge of AIDS throughout 1983, 1984 and 1985, this desire to ensure the leaflet was accurate may be thought to have slowed down the publishing of an updated leaflet; the chronology suggests that multiple amendments were made to the draft revised leaflet at least in part in order to 'keep up' with the science. As the Chair commented during Lord Glenarthur's oral evidence, "*...part of the problem here is, I suspect, a perennial problem in politics, which is that events have a habit of catching up before action may be taken.*"[667]

The content of the second leaflet

4.140. The material changes in the August 1984 version of the draft revised leaflet approved by Lord Glenarthur on 21 August 1984 and Kenneth Clarke on 16 October 1984 were as follows:

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[666] Lord Glenarthur's oral evidence on 22 July 2021, at 135:1-135:7.
[667] Lord Glenarthur's oral evidence on 22 July 2021, at 134:22-134:25.

(1) The at risk groups were now said to be all practising homosexual men (rather than those with multiple partners);

(2) The message to donors now read:

> *"The National Blood Transfusion Service has a very high regard for donors as extremely responsible people who give blood for the benefit of others and is confident that they would not knowingly put patients at risk from such a serious disease as AIDS. Until there is a reliable screening test the Blood Transfusion Service can use, and until more is known about the disease,* ***donors are asked not to give blood if they think they have the disease or are in one of the risk groups listed opposite****."* [668] (Original emphasis)

4.141. The final version of the revised leaflet[669] was strengthened further as compared to the August 1984 version of the draft. The at-risk groups now included: practising bisexual as well as homosexual men and the sexual contacts of those in the other high-risk groups. The leaflet was more directive in the message not to give blood, stating "*donors in the risk group must* ***not*** *give blood. Some people in these groups may unknowingly carry the AIDS virus in their bodies"* (original emphasis). The back sheet of the leaflet also included the following reminder (taken from the Information Division draft revised version of 22 November 1984 following Lord Clarke's comments):

> *"REMEMBER, AIDS IS A SERIOUS DISEASE.*
>
> *Please do* ***not*** *give blood*
>
> - *if you are a practising homosexual or bisexual man*
> - *if you are a drug abuser who injects drugs*
> - *if you are a sexual contact of any of these people"* (original emphasis)

The effectiveness of the AIDS leaflets

4.142. A joint announcement on behalf of the Health Departments in the UK in early 1986 stated that the Blood Transfusion Services of England, Wales,

[668] PRSE0000136.
[669] NHBT0096480_022.

Northern Ireland and Scotland had tested 593,393 donations for antibody to HTLV-III up to the end of December 1985; of these 13 donors were found to be HTLV-III antibody positive.[670] Dr Vanessa Martlew, who was a consultant haematologist at the Manchester Regional Transfusion Service from January 1984 to 1988, made this observation in response to a question from CTI about whether, with hindsight, handing the leaflet to someone in the public area of a blood centre may have deterred people from being open about potential concerns:

> *"It may well have done. But I think, from the number of positive donors who were detected when we started screening in October 1985, there was not an enormous number. So I think the leaflets must have been effective to some extent certainly. Normally you expect quite a -- you know, quite a reasonable number of positive cases when you introduce a new screening test for anything. We didn't have a very large number. So I think the information must have been helpful in that respect, really."*[671]

4.143. The Chair is invited to consider the number of positive cases cited above and Dr Martlew's evidence when considering the effectiveness of the AIDS leaflets in deterring high-risk donors from giving blood.

Information and guidance about AIDS provided to clinicians by the Department

4.144. The role of the Chief Medical Officer ("CMO") in relation to sharing information with the medical profession has been addressed in a note on the role of the CMO prepared by CTI dated July 2022 and during an oral presentation from CTI on 7 July 2022.[672] The key information and guidance about AIDS which was provided to clinicians by the Department in the 1980s and 1990s is referred to at paragraphs 31, 42 and 46 to 58 of the note on the role of the CMO and at paragraphs 146 to 149, 152 and 180 of the written presentation on ethical and clinical guidance for clinicians and other

[670] See PRSE0003992.
[671] Dr Martlew's oral evidence on 20 January 2022, at 26:23-27:7.
[672] The note is at INQY0000362.

healthcare practitioners produced by CTI and members of the Inquiry team dated May 2021.[673]

4.145. The following questions have been explored with Departmental witnesses through questions in Rule 9 requests and / or during oral evidence:

(1) Whether the Department should have provided general information about AIDS directly to all doctors sooner than the 15 May 1985 'Dear Doctor' letter from the CMO;[674] and

(2) Whether the Department should have issued specific clinical guidance to relevant specialists, such as haemophilia clinicians, on matters such as the AIDS risk from blood products, the kind of information to be provided to patients in relation to this and the circumstances in which patients should or should not receive treatment with blood or blood products.[675]

4.146. In relation to the question of provision of general information to the medical profession as a whole, Dr Walford accepted during her oral evidence that it would have been helpful for a 'Dear Doctor' letter to have gone out sooner than May 1985, in light of the rise in non-haemophiliac cases, which meant that the disease, a new disease, became "*...of a much broader general interest than of a select group who might be presumed to be being told about it by their clinicians*".[676] When considering why general information about AIDS was not issued earlier by the Department, the Chair is invited to consider the following:

(1) By 30 August 1983, consideration had been given by the Department to whether there was a need to issue guidance or information about AIDS to medical practitioners. A question relating to this was raised

[673] At INQY0000249.
[674] See, for example, the question asked of Dr Walford: Dr Walford's oral evidence on 21 July 2021, at 187:17-187:21.
[675] See, for example, the question put to Lord Clarke in his Rule 9 request and addressed in his witness statement (Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §§8.1-8.5.
[676] Dr Walford's oral evidence on 21 July 2021, at 188:17-188:19.

during Parliamentary Questions in the Lords on 14 July 1983 by Baroness Gardner.[677] An answer to the question was provided by Lord Glenarthur in a letter dated 30 August 1983, not to Baroness Gardner, but to Baroness Masham.[678] Lord Glenarthur wrote:

> *"We have been looking very carefully at our position on this matter and our medical advisors consider that the publications which have already appeared in the medical press provide sufficient and adequate guidance and information about this disease for practitioners, given the present state of knowledge. As I indicated on 14 July, information about the incidence, identification and methods of control of the disease is available on request from the Communicable Disease Surveillance Centre at Colindale. The Centre has published in the Communicable Disease Report (which is issued to all Medical Officers Environmental Health), and in the British Medical Journal of 29 July, further information under the title "Surveillance of Acquired Immune Deficiency Syndrome in the United Kingdom from January 1980 to July 1983"."* [679]

It would seem, therefore, that the recent publication of a detailed article about AIDS in the BMJ was a material consideration when the Department decided against providing its own guidance or information in August 1983.[680]

(2) The "*state of knowledge*" in relation to AIDS at the time also appears to have been a material consideration on the face of Lord Glenarthur's letter. The understanding of AIDS was "*far less developed in 1983 than it was by 1985*" and even then much was still not understood.[681] The CMO was reliant for advice and information on relevant

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[677] DHSC0002229_085.
[678] DHSC0002231_037.
[679] The British Medical Journal article referred to by Lord Glenarthur is likely to be the article dated 6 August 1983 which appeared in volume 287, referred to above in the table under paragraph 4.1 PRSE0000653. See too Lord Glenarthur's oral evidence on 23 July 2021, at 23:25-30:2.
[680] That this was the case is consistent with Lord Clarke's understanding that at the time the main source of information for clinicians and doctors, apart from each other and conferences would be their medical journals: Lord Clarke's oral evidence on 27 July 2021, at 27:10-27:14 and 53:18-53:21.
[681] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §8.25(5). It is of note, for example, that even in May 1985 there were no recorded cases of AIDS in a blood transfusion recipient in the UK: see the figures (to 28 February 1985) recorded in table 1 in the document entitled 'General Information for Doctors' sent under cover of the CMO's letter of 15 May 1985 (DHSC0105232).

experts.[682] Where uncertainty about AIDS persisted, even in discussions between experts in disciplines relevant to AIDS,[683] passing on clear general information about AIDS to all medical practitioners would have been more challenging.

(3) There is evidence before the Inquiry, summarised at paragraphs 30 and 35 to 37 of CTI's note on the role of the CMO,[684] that although there were occasions where the CMO (or members of his team) would write to clinicians and health bodies, to share information or announce new developments, 'Dear Doctor' letters to all doctors were used sparingly.

4.147. It is right to note that there are examples of information about AIDS being provided to clinicians along with the public at large by the CMO before May 1985. In particular:

(1) Information about AIDS was provided in the CMO's annual reports for 1982 and 1983 (published towards the end of 1983 and the end of 1984 respectively).[685]

(2) The CMO issued a statement on 20 December 1984, which was the subject of a Departmental press release of the same date, following media reports of a blood donor who went on to develop AIDS.[686] This covered the risk associated with blood transfusions, selection of blood donors, and development of a screening test and heat treatment of Factor VIII.

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[682] See Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §73.8 and Dr Pickles' oral evidence on 12 May 2022, at 52:1-52:3, for example. See too Lord Clarke's oral evidence on 28 July 2021, at 103:6-103:9.
[683] As noted above at paragraph 4.15 above, even in February 1984, the question of whether AIDS could be caused by transmission of an infectious agent in blood or blood products was still being debated by the experts in relevant fields at a meeting arranged by the NIBSC to examine the infectious hazards of blood and blood products.
[684] INQY0000362.
[685] The information which was provided on AIDS was summarised in CTI's note on the role of the CMO (INQY0000362), §§48-49; see too the oral presentation on the role of the CMO on 7 July 2022, at 27:1- 32:9 and 46:19-49:11.
[686] BART0000814.

4.148. In addition, in response to a request from the Health Departments and the Health and Safety Executive for advice on measures which should be taken to safeguard those who because of their work came into contact with patients with AIDS or specimens from them, the DHSS Advisory Committee on Dangerous Pathogens issued guidance titled 'Acquired Immune Deficiency Syndrome (AIDS) – Interim Guidelines' in December 1984.[687] The report contained a detailed background section on AIDS, which included discussion of the agent causing AIDS, the groups in which the presence of the antibody to HTLV-III had been demonstrated in the UK, the number of established AIDS cases in the UK and the likely trend in infection rates.[688] On 16 January 1985, the Department circulated the Advisory Committee's guidance to the Regional Health Authorities, District Health Authorities, Special Health Authorities for the Postgraduate Teaching Hospitals, Central Blood Laboratories Authority, Public Health Laboratory Service Board, Family Practitioner Committees, marked 'for action', as well as Community Health Councils, marked 'for information'.[689]

4.149. In relation to whether the Department should have issued specific clinical guidance to relevant specialists:

(1) A range of Departmental witnesses have given evidence about limits on the CMO's role when providing guidance to medical practitioners. Much of this evidence is referred to in CTI's note on the role of the CMO at paragraphs 30, 32 to 35 and 37.[690] Key themes from the evidence are that it was no part of the CMO's role to provide instruction or direction to clinicians outside of the Department; and that any guidance given by the CMO (and the Department more broadly) would not extend to clinical advice.[691, 692] In particular, it was

[687] CBLA0001967.
[688] CBLA0001967, §§4-10.
[689] Departmental press release at PRSE0001192.
[690] INQY0000362.
[691] In addition to the references given in CTI's note on the role of the CMO, see, for example, Dr Walford's oral evidence on 19 July 2021, at 50:16-50:19 that the CMO did not issue "*specific clinical advice*".

Lord Fowler's evidence that the type of guidance the CMO might issue to clinicians was not *"...direction to clinicians on when they should or should not prescribe certain treatments with blood or blood products or on what information should be provided to patients"*.[693] Dr Walford explained during her oral evidence that the CMO might issue advice where, for example, there was a recommendation from an advisory committee that the whole body of external doctors and the Health Service needed to know about.[694] A further example was the provision of general advice about vaccines, something which the CMO "*very often*" wrote out about.[695] But the CMO would not issue statements based on their *"...own view of clinical matters"*.[696]

(2) It was Dr Pickles' evidence to the Inquiry that when guidance on clinical practice was needed, it was more effective for this to be delivered as a consensus through professional bodies, or even greater clout of all, the medical defence bodies.[697] The clear role of organisations other than the Department in providing guidance on AIDS (and later HIV) is evident from paragraphs 144 to 181 of the written presentation on ethical and clinical guidance for clinicians and other healthcare practitioners.[698]

(3) In the specific context of guidance for haemophilia clinicians, in a written answer given to a Parliamentary Question on 14 November, Kenneth Clarke provided the following information:

> *"The use of factor VIII concentrates is confined almost exclusively to designated haemophilia centres whose directors and staff are expert in this field. Professional advice has been*

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[692] The Inquiry also heard oral evidence from Professor Sir Jonathan Van Tam on this issue (albeit relating to more recent times). Sir Jonathan Van Tam's oral evidence on 18 November 2022 at 20:18-25:22.
[693] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §8.19, see too §6.68. In relation to the CMO's role in relation to the question of what information patients were receiving from their clinicians, see too Dr Walford's oral evidence on 19 July 2021, at 51:6-51:16.
[694] Dr Walford's oral evidence on 19 July 2021, at 50:22-50:24.
[695] Dr Walford's oral evidence on 19 July 2021, at 51:15-51:19.
[696] Dr Walford's oral evidence on 19 July 2021, at 50:25-51:2.
[697] Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §11.4.
[698] At INQY0000249.

made available to all such centres in relation to the possible risks of AIDS from this material." [699]

In the absence of any explanatory note that would have accompanied a draft answer to this question, Lord Clarke was unable to say in his evidence to the Inquiry what the "*professional advice*" he referred to in this answer was.[700] The DHSC legal team understands from the Chair's comments during Lord Clarke's oral evidence that the Inquiry Legal Team, like the DHSC legal team, has been unable to locate any form of "*professional advice*" which had been issued to haemophilia clinicians by this point in time other than the 24 June 1983 letter from Professor Bloom and Dr Rizza to all Haemophilia Centre Directors summarising the discussions at the meeting of the UK Haemophilia Reference Centre Directors on 13 May 1983.[701] In any event, the Department's understanding in November 1983 that *"professional advice"* had been issued to haemophilia clinicians is evident on the face of the answer given to Parliament.

(4) In relation to whether the Department should have informed haemophilia clinicians of the Council of Europe recommendation that patients be informed *"...of the potential health hazards of haemotherapy and the possibilities of minimising these risks*", Lord Fowler's evidence was that, as a matter of general principle, the most sensible way for the Department to have communicated with clinicians about this recommendation would have been via a letter from the CMO.[702] He stressed, however, that the Department could not issue instruction to clinicians in this regard.[703] In relation to the Council of Europe recommendation, Dr Walford's evidence was that the Department could not and did not provide relevant information to clinicians about clinical matters.[704] It was further Dr Walford's evidence to the Inquiry that Dr Gunson had informed the CMO that

[699] PRSE0000886.
[700] Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §7.117; and his oral evidence on 28 July 2021, at 17:24-18:17.
[701] Lord Clarke's oral evidence on 28 July 2021, at 18:10-18:22.
[702] Lord Fowler's oral evidence on 22 September 2021, at 15:14-16:22.
[703] Lord Fowler's oral evidence on 22 September 2021, at 16:8-16:13.
[704] Dr Walford's oral evidence on 21 July 2021, at 144:6-144:9.

haemophilia patients were being informed of the potential problem, or the hazard, of AIDS in June 1983.[705]

(5) The Inquiry has also received evidence from Professor Sir Liam Donaldson as to the role of the CMO in relation to providing guidance to clinicians:

> *"40.1 Generally speaking, the CMO does not set out to provide systematic guidance for clinical practice. There are approved curricula in 65 specialties and 31 sub-specialties of medicine. There are many different diseases and clinical conditions. All these areas are covered by good practice guidance produced by professional and scientific bodies and committees both nationally and internationally.*
>
> *40.2 Since around 1999, NICE (the National Institute for Health and Care Excellence) has issued a whole range of guidance for the NHS classified in different ways. Most of it is for clinicians to follow or to assist in the design of services. Like my predecessors, I produced guidance regularly on immunisation and in emergency situations. From time to time, there was value in issuing guidance on emerging diseases or clinical situations. I also produced guidance and recommended action on important public health topics (e.g., tuberculosis or health care infection) or guidance that clinicians could use to advise their patients or that the public could use directly (e.g., on alcohol levels or physical activity)".*[706]

4.150. While acknowledging the significance of the infected and affected's evidence concerning consent to treatment, we do not seek to address in detail here that wider issue. We note CTI's presentation on the ethical guidance for clinicians and other healthcare practitioners.[707] As was evident when complaint was made about lack of consent for Hepatitis C testing in the context of the public inquiry issue, this was a matter for the GMC to regulate and investigate (see Section 7 of these submissions). That has remained

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[705] Dr Walford's oral evidence on 19 July 2021, at 52:24-53:10; Dr Walford's oral evidence on 21 July 2021, at 65:11-65:22, 133:24-134:2, 139:4-140:6. Dr Walford confirmed during her oral evidence that the document she was referring to was Dr Gunson's report for the CBLA on 13 June 1983 at CBLA0001710. See too Dr Walford's oral evidence on 21 July 2021, at 136:4-136:7, that it was "*inconceivable*" that haemophilia clinicians would not have been aware by that stage that AIDS was an issue and an issue for haemophiliacs.

[706] Sir Liam Donaldson's witness statement dated 14 December 2022 (WITN7557001), §§40.1-40.2. The Inquiry also heard oral evidence from Professor Sir Jonathan Van Tam on this issue (albeit relating to more recent times). Sir Jonathan Van Tam's oral evidence on 18 November 2022 at 20:18-25:22.

[707] INQY0000249 and oral presentation on 28 May 2021.

the position. Sir Jonathan Van Tam was asked whether CMO's guidance might cover informed consent issues and he did not think this would be the appropriate route:

> *"Q. In terms of clinical practice more generally, so not a risk of a particular disease or the risks of a particular treatment, but, say, issues that cut across all areas of clinical practice, such as the importance of informed consent, are those matters which the CMO's office, to your knowledge, ever gets involved in giving guidance to the profession as a whole?*
>
> *A. Well, the example you've given, of informed consent, is one that is, I think, so, you know, hardwired into our system, I can't really imagine a circumstance where the CMO would need to write about informed consent. It's really kind of a lived experience at every level of healthcare. So I can't see that."*[708]

(3) The introduction of routine screening of blood donations for HTLV-III

4.151. This sub-section of these submissions focus on two specific areas:

(1) The decision in principle taken in January 1985, that blood donations should be routinely screened for HTLV-III once a reliable test was available and the associated funding decisions.

(2) The approach to HTLV-III antibody screening test evaluation and trials leading to national screening being introduced on 14 October 1985.

The decision in principle taken in January 1985, that blood donations should be routinely screened for HTLV-III once a reliable test was available and the associated funding decisions

4.152. By way of context, a non-exhaustive summary of some of the key dates / submissions within the DHSS is as follows:

[708] Sir Jonathan Van Tam's oral evidence on 18 November 2022, at 23:18-24:5, see also his answer to the follow up question using the example of the Cumberlege review and looking at sodium valproate, a range of pregnancy tests, and meshes at 24:6-25:22.

(1) 6 July 1984. Dr Smithies' minute to Dr Abrams: alerting Dr Abrams to Dr Gunson/Dr Tyrrell's investigation of the introduction of a screening test for AIDS.[709]

(2) 10 July 1984. Dr Abrams' reply proposing that a strong line be taken in support of the introduction of screening, noting the possible need to go to ministers on funding and suggesting it must be given top priority.[710]

(3) 27 July 1984. Paper circulated by Dr Smithies.[711]

(4) 31 July 1984. DHSS officials' meeting on screening and minute arising from it.[712] The pilot study at the NW London RTC as due to start in October and indication that it should be drawn to the attention of ministers.

(5) 10 August 1984. Minute from Mr Parker to Lord Glenarthur's Private Office. This referred to the work on development of the test in Middlesex and the hope to start trials in October; noted that it would be some time before the significance of the results could be assessed.[713] [714]

(6) 13 August 1984. Minute from Dr Smithies to Dr Harris addressing the proposed working group of the Advisory Committee on the National Blood Transfusion Service to provide guidance about the consequence for the NBTS of the introduction of a screening test for HTLV-III.[715]

(7) 31 August 1984. Briefing note to Lord Glenarthur including explanation of the obstacles that needed to overcome before any test could be used on donations in the UK.[716] [717]

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[709] DHSC0001680.
[710] DHSC0001574.
[711] MACK0002588.
[712] DHSC0000445.
[713] DHSC0002309_044.
[714] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §49.2.
[715] PRSE0003109.
[716] DHSC0000443.
[717] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001) §49.1- 52.1; and Lord Glenarthur's Oral evidence on 23 July 2021, at 85:21– 89:18.

(8) 19 October 1984. Dr Smithies' note to PS/CMO in response to his request for information on AIDS and blood donations.[718]

(9) 26 October 1984. Minute (Mr Williams to Mr Staniforth) addressing bid for £2m funding for the introduction of a blood test for AIDS.[719]

(10) 26 October 1984. CMO's response to Dr Smithies' note of 19 October seeking further information on whether negative HTLV-III testing should become a prerequisite for donation of blood or plasma, and regarding the timetable and cost.[720]

(11) 13 November 1984. Meeting to discuss HCHS (Hospital and Community Healthcare Services) Central Reserves funding for HIV testing. AIDS test bid for funds from HCHS funds rejected.[721]

(12) 15 November 1984. Lord Glenarthur asked if the Department was now screening all blood for AIDS and if not, when it would be possible to do so and whether there were any problems associated with it and whether the technology existed.[722]

(13) 19 November 1984. Briefing note on AIDS developments from Dr Smithies to the Secretary of State's Private Office; the latest position on screening tests was one of the issues covered.[723]

(14) 23 November 1984. Minute from Dr Abrams to Dr Smithies referring to the views of Kenneth Clarke who had received a briefing ahead of an ITV interview. Mr Clarke had explained that he felt that to spend around £2 million on testing was not cost effective when there were so few AIDS cases and the money could be better spent elsewhere.[724]

(15) 26 November 1984. Minute from Mr Williams to Lord Glenarthur's private office[725] in response to his query of 15 November. This noted

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[718] DHSC0002323_009.
[719] DHSC0101679.
[720] DHSC0000569.
[721] DHSC0002309_052.
[722] DHSC0002309_116; Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §54.1.
[723] DHSC0002309_053.
[724] DHSC0000435 and Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.46.
[725] DHSC0000436.

that screening was not yet underway but referred to: the pilot study being undertaken; the fact that the cost of a test could not accurately be predicted yet; and the fact that that Kenneth Clarke as Minister of State had indicated that allocation from central reserves would be inappropriate such that funding would have to come from RHA's existing budgets.[726]

(16) 27 November 1984. First meeting of the Advisory Committee on the National Blood Transfusion's Working Group on AIDS, chaired by Dr Abrams[727].

(17) 28 November 1984. Minute from Dr Smithies to the CMO advising that no indication had been given to her by Professor Weiss / Dr Tedder that their research was being hindered by a lack of funding and that she had asked them to let her know if that were the case.[728]

(18) 30 November 1984. Minute to Lord Glenarthur reporting that three UK blood donors had been found to be HTLV-III positive, and that their donations had been used in blood donations and the production of Factor VIII concentrates. The batch of Factor VIII concentrate had been given to 38 people with haemophilia.[729] (A statement from the CMO followed on 20 December 1984[730]).

(19) 14 December 1984. Minute from Mr Arthur to Mr Harris which referenced the fact that Kenneth Clarke had refused the £2m bid for central funding.[731]

(20) 21 December 1984. Minute re revision to AIDS leaflet. Kenneth Clarke queried whether it was still true to say that there was only a remote chance of getting AIDS from an ordinary blood transfusion, and stated that he was wary of offering to promise blood screening

[726] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §§55.1-55.4 and §58.3–58.4.
[727] DHSC0002251_011.
[728] DHSC0000565.
[729] DHSC0002309_057.
[730] BART0000814.
[731] DHSC0002331_044.

tests and heat treatments and would prefer to see this section removed.[732]

(21) 31 December 1984. Draft position paper for the CMO from Dr Smithies.[733]

(22) 11 January 1985. Draft submission from Dr Smithies, which was intended to go to ministers, attached to minute to PS/CMO on the introduction of the screening test.[734] A copy of the final as-sent version of this submission (sent on 15 January 1985) does not appear to have survived.[735]

(23) 21 January 1985. Minute from Dr Smithies to R Allen. Noting that they had discussed "*...whether or not any reference should be made to tests not being accepted in the UK unless they had FDA approval and decided that such stipulation might not act in Wellcome's best interests in the short term. FDA approval was in any case [ ] one of the factors to be considered in any evaluation".*[736]

(24) 22 January 1985. Kenneth Clarke gave his approval to the introduction of screening.[737] The terms of Mr Clarke's response are addressed further below.

(25) 29 January 1995. The Expert Advisory Group on AIDS endorsed the proposal that blood donations should be screened as soon as reliable testing facilities were available.[738]

(26) 31 January 1985. The CMO replied to Kenneth Clarke.[739]

(27) 1 February 1985. The CMO confirmed to Kenneth Clarke in a further note the reasons why both HTLV-III screening and heat treatment were necessary[740].

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[732] DHSC0002309_063.
[733] DHSC0001693, CBLA0001934_001 and CBLA0001934_002.
[734] DHSC0000562.
[735] Lord Glenarthur gave evidence that he appeared to have limited involvement at around this time, caused potentially by his forthcoming visit to the Gulf: Lord Glenarthur's Oral evidence on 23 July 2021, at 96:16-96:20; and Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §60.2.
[736] DHSC0002257_038.
[737] **DHSC0002482_012**
[738] **PRSE0002734**
[739] DHSC0002311_050, DHSC0002311_051, DHSC0002311_052, DHSC0002311_053.

(28) 20 February 1985. DHSS Press release quoting Mr Clarke: the formation of the EAGA was announced. Evaluation of tests to screen for HTLV-III was the fourth action area addressed in the announcement. It was noted that the Department was co-ordinating the necessary evaluation work and that RHAs had been written to that day to ask them to set aside funds in 1985-86 for the introduction of the test.[741]

The funding issue

4.153. Viewed in isolation, it may be suggested that the decision in late 1984 not to pursue a bid for central funding for HTLV-III testing reflected a relative lack of prioritisation. In analysing this issue, the Inquiry is invited to take into consideration the following matters and perspectives of those involved at the time:

(1) Screening and testing required nationally as a safety measure would normally have fallen to be funded by Regional Health Authorities as part of their delivery of health services, rather than be centrally funded. The central health services budget was a limited central fund[742] designed for matters which were not intended for funding as part of the ordinary delivery of health care services for the regions.[743]

(2) If the question is the *reasonableness* of this funding decision, the benefit and importance of rapid HTLV-III testing can be considered against the many other demands on health service spending. As to this:

(i) Lord Clarke emphasised in his written evidence that many worthwhile projects were funded regionally rather than centrally. Central funding was limited and it was often

[740] DHSC0002327_028.
[741] DHSC0101892.
[742] Lord Clarke explained that only a small proportion of revenue and capital available for health authorities was retained centrally: Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.51.
[743] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §5.13(2) *"... a test used nationwide in each RHA would normally be part and parcel of the running costs of each health area, rather than a specialised centrally funded service"*

considered more appropriate for Regional Health Authorities to budget locally for such projects; he suggested that this was by no means a departure from the norm.[744] Lord Clarke emphasised in his oral evidence the reality of competing demands for finite resource that spans the whole day-to-day operation of health policy.[745] The Transfusion Service was organised on a regional basis and there was a whole variety of judgments, many of them very difficult that had to be taken, including on what should be funded centrally and regionally.[746]

(ii) Lord Patten observed in his written evidence to the Inquiry that,

> *"In the Department, as in all departments, there was a constant call on public finances for worthy and important projects. Looking at it now, I think I would only observe that it is the Minister's job to balance competing requests against limited resources and make decisions on how funds should be apportioned. Mr Clarke did not decide that the HIV antibody test should not be developed or introduced. Officials dealing with the screening test were keen that it should be centrally funded by the Department, seeing this as presentationally important and perhaps also that it may help with the speed of introduction. However there would have been contrary arguments … Hard decisions had to be made on what could be funded centrally."*[747]

(iii) Lord Glenarthur could not be sure whether he knew about Kenneth Clarke's decision on central funding at the time; funding was largely left to the Minister of State[748], but Lord Glenarthur thought he probably was aware. Lord Glenarthur was generally aware of the pressures on central funding and,

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[744] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.51.
[745] Lord Clarke's oral evidence on 28 July 2021, at 52:18-52:25.
[746] Lord Clarke's oral evidence on 28 July 2021, at 54:12-56:20.
[747] John Patten's witness statement dated 5 April 2022 (WITN5297001), §5.13(2).
[748] Lord Glenarthur's oral evidence on 23 July 2021, at 95:19 – 96:9.

> *"...it would have seemed reasonable to ask for regional contribution in whole or in part".*[749]

(3) While the regions had to find funding for the screening tests, the Department did contribute in 1985 to the overall implementation costs for HTLV-III screening.[750]

(4) Lord Clarke told the Inquiry that his initial views in which he had queried cost effectiveness (expressed before the ITV interview) were at a time when had been provided with very little information and the issue had not yet been canvassed in a ministerial submission. He emphasised that it was part of his job as Minister of State to challenge proposals and require explanations and that here, having done so and received a fully reasoned explanation, he then gave his approval for the in principle decision in favour of screening.[751] He noted also that his initial view was in the context of earmarking *central* funds for the purpose of introducing screening, not whether the testing should be funded at all.[752]

The terms of Mr Clarke's response of 22 January 1985

4.154. Kenneth Clarke's response of 22 January 1985[753] to the submission of 15 January was in the terms which are reproduced below for ease of reference:

> *"Thank you for your submission of 15 January. This looks inevitable, I suppose. Could I have drafts please of the proposed public announcement of both points. Could I also have a draft of a letter to go to all Chairmen of RHAs explaining our proposals.*
>
> *How did Wellcome corner this market and why did they bring CAMR in?*

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[749] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §55.4.
[750] See the Press Release of 27 June 1985 (DHSC0001184) that made clear that the Department had given £57,000 to PHLS to enable them to carry out a full evaluation of all the test kits and that a further sum of £750,000 would be provided to them to enable them to set up the laboratory facilities to carry out the confirmatory tests following a first positive test and to test blood samples given in STD clinics.
[751] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.47. In his oral evidence Lord Clarke referred to the view on the cost effectiveness as being one that with hindsight was tragically wrong, but it was when there was just a handful of AIDS cases: see Lord Clarke's oral evidence on 28 July 2021, at 59:4-59:7.
[752] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.49.
[753] DHSC0002482_012.

> *Will the cost be met from the income now going to the blood transfusion service from the charges introduced for the handling of blood to private hospitals? I never did understand what else that money was to be spent on.*
>
> *Before we all panic further; it is presumably the case that the ending of the collection of blood from homosexuals greatly reduces the risk from blood collected in this country? Also, as only haemophiliacs have died and they may have had Factor VIII from American blood, is it the case that we have not had one AIDS fatality from blood donated in this country yet?*
>
> *Do we need this and heat treatment of the blood?"* (Original emphasis)

4.155. Concern has been expressed about the terms of this response and particularly the words, *"…as only haemophiliacs have died…"*

4.156. In assessing this issue, the Inquiry is invited to consider the following:

(1) First, the Inquiry may wish to consider the context in which these words were used in the minute from Mr Clarke.

(2) Second, Lord Clarke addressed this issue in his written and oral evidence and the Inquiry may wish to consider the explanation he gave. In particular:

(i) Lord Clarke was concerned that his use of words has previously been taken out of context.[754]

(ii) He stressed that his words, were,

> *"…most emphatically not a statement disparaging haemophiliacs or devaluing the importance of haemophiliac fatalities. What I was querying was the risk of transmission of AIDS via blood donations from British donors. I was asking whether, if it was true that those who had died had received imported American Factor VIII, this imported product was the source of the infection and not blood donated in this country."*

[754] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.66. See further Lord Clarke's oral evidence on 28 July 2021, at 71:22-73:16.

He believed that this conclusion was clear from the question read as a whole[755] and indeed was interpreted that way by the CMO, having regard to the terms of the CMO's response of 31 January 1985.[756]

(iii) Lord Clarke noted that his reference to "*Before we all panic further*" was raised out of a desire not to feed public alarm. Lord Clarke said that he wanted clarification of the effectiveness of the steps that were already being taken because he understood they would greatly reduce the risk from donated blood.[757]

(iv) Lord Clarke further denied that the terms of his minute evidenced a reluctance on his part to take measures additional to heat treatment. Rather he said he was seeking to understand the impact of the different measures, how they interrelated and the case for each one.[758] In this context, Lord Clarke underlined that it was part of his role to ask questions on the case presented, to seek further information and to understand the justifications.[759]

(v) Lord Clarke clarified that the CMO's response of 1 February 1985 had not changed his opinion about the need to introduce a screening test, because he considered that he had already agreed to the principle by this response of 22 January.[760]

(vi) On 20 February 1985, by answer to a PQ and by press release, Mr Clarke set out measures being taken to control the risk of AIDS including on testing, and that the Department

[755] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.66.
[756] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.66; CMO's response at DHSC0002311 _ 051.
[757] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.66 and see further Lord Clarke's oral evidence on 28 July 2021, at 70:20-71:12.
[758] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.68.
[759] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.69; see further Lord Clarke's oral evidence on 28 July 2021, at 69:24-70.17.
[760] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §7.70. Lord Fowler noted that he did not appear to have intervened in this exchange and would not have needed to become involved unless Kenneth Clarke had not agreed with the CMO's submission: Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.87.

was coordinating the evaluation work needed to ensure that a test could be introduced routinely in the NBTS as soon as possible.[761]

(4) The approach to HTLV-III antibody screening test evaluation and trials leading to national screening being introduced on 14 October 1985

4.157. Again, by way of context, the chronology of main developments within the DHSS for ministerial approval for the introduction of screening and its timing was as follows:

(1) Kenneth Clarke answered a number of PQs in February 1985, indicating that screening tests were currently only available for research but that it was hoped that they would be released for general use later that year, and they would be thoroughly evaluated to see which would be most suitable for use in the NHS.[762]

(2) 16 April 1985. Mr Patten answered an oral PQ from Alfred Dubs MP and a supplementary question from Robert Key MP. Mr Patten stated "*Yes, we hope to have a screening test within a few weeks*"[763]. Officials drew Mr Patten's attention to the fact that it was the evaluation of the testing that was soon to begin, not its introduction and a letter of correction was prepared.[764]

(3) 31 May 1985. Minute from Dr Harris to PS/CMO reporting on his conversation with PHLS noted that he had communicated the importance which ministers attached to the urgent evaluation of the AIDS antibody test:

> *"At CMO's meeting reviewing the AIDS situation yesterday you were able to give assurances that the financial resources needed to cover the PHLS' evaluation of the commercial kits has been*

[761] DHSC0002261_043, DHSC0101892 and circulated to RHAs asking them to set aside funds, DHSC0002261_031.
[762] DHSC0002261_080, PRSE0003350, DHSC0002261_065.
[763] DHSC0002267_034.
[764] DHSC0000555.

made available. CMO was questioned later that evening by PS(H) on the overall position and it is quite clear that Ministers need to know of the timescale for the evaluation of the test and, if satisfactory, for the introduction of the test at every transfusion centre".[765]

(4) 5 June 1985. Minute from Mr Harris to Dr Smithies which attached an early draft of the ministerial submission addressing the approach to the introduction of screening.[766] Mr Harris's minute referenced a possible meeting with on Friday 7 June, and also what was described as "*the starting point which CMO/PS(H) now want ie the speedy introduction of a screening test into BTS on available data, without waiting for confirmatory tests etc.*"

(5) 5 June 1985. Minute from Mr Harris to Christopher France attaching draft ministerial submission ("AIDS and the BTS") on the introduction of the HIV screening test.[767]

(6) 7 June 1985, final submission from Mr Harris addressed first to the CMO and secondly to Mr Patten, also copied to Kenneth Clarke and Baroness Trumpington.[768] The options set out were essentially: (i) Select an available test on current knowledge as soon as possible; (ii) Select a test after evaluation of tests by the PHLS; or (iii) To select a test after evaluation by PHLS and field trials by BTS.

(7) 10 June 1985. Note from the CMO to Mr Patten, setting out the CMO's views.[769] The CMO's advice could be considered highly significant on this issue. He advised:

"There is a finely balanced decision here but I am in favour of the suggested line. I think, however, that we must do everything possible to ensure that PHLS is able to keep to its schedule.

As far as the option to introduce a partially evaluated ELISA test forthwith is concerned I think the prospect of wasting a relatively small quantity of blood from false positive tests is not the major objection. The major problem is that the scientists concerned at

[765] DHSC0001112.
[766] DHSC0002482_031 and DHSC0002311_055.
[767] DHSC0002311_018.
[768] DHSC0002311_019. Lord Patten could not recall why the submission was addressed to him rather than to the late Baroness Trumpington but set out the various possibilities as to why this may have been the case: Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §5.34.
[769] DHSC0002311_021.

> *PHLS do not yet have confidence that the suppliers could produce testing kits which are reliable on a large scale and which would continue to be reliable on the shelf. It would be worse to be in the position of having to withdraw a test once introduced than to be in our present position of carefully evaluating the tests. There could also be ethical problems in refusing to tell donors (who are volunteers in this country) the result of a test carried out on their blood if they wish to have it.*
>
> *Ministers should recognise, however, that support for a different view is likely to appear in the medical press (see Professor Bloom's letter attached[770]) and that considerable public pressure would develop if in the meantime a case of AIDS develops in a recipient of UK blood. Such a case or cases is likely to occur sooner or later due to infection one or more years ago prior to our warnings to people at risk not to donate blood."* (Original emphasis)

(8) As the Inquiry is aware, the ministerial response to Mr Harris' submission and the CMO's views (if it was conveyed in writing rather than at a meeting) does not appear to have survived. However a series of documents dated 27 June 1985 show that the ministerial decision was in agreement with Mr Harris's recommendation as also supported by the CMO[771]. The CMO, through his Private Office stressed the need for media handling to properly set out the case *"…for the scientific reasons for this policy as it will be controversial"* (original emphasis)[772]

(9) 27 June 1985. CMO's wider strategic paper on AIDS addressed to Norman Fowler copied to the other Health Ministers.[773] The points noted included under blood transfusion, "*introduce at the earliest opportunity an effective test for all donated blood simultaneously with a similar service for STD clinic. Introduce counselling and education for donors with HTLV +ve tests. Train an appropriate number of counsellors.*"

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[770] DHSC0002489_099.
[771] DHSC0003828_186, DHSC0003828_187, DHSC0003828_188, DHSC0003828_189. Dr Smithies' later minute suggested that the approach was agreed with Mr Clarke and Baroness Trumpington [DHSC0000501]. However, Lord Clarke's understanding was that Lord Patten was leading on the policy by this time: Lord Clarke's witness statement dated 1 July 2021 (WITN0758001), §§7.83-7.85.
[772] DHSC0002482_042, original emphasis.
[773] DHSC0002114.

(10) 27 June 1985. Announcement on introduction of screening by Kenneth Clarke, by way of answer to a PQ[774] and press release[775].

(11) 16 July 1985. Update from CMO to Norman Fowler updating him ahead of their discussion on AIDS issues.[776] The CMO stated that action was already in hand to ensure the introduction of testing of all blood donations as soon as a sensitive and specific test was available. He went on to say that to introduce such a programme nationally, simultaneously with a programme involving STD clinics in the district hospitals, was a major organisational problem. Careful monitoring would be required to ensure that no unnecessary slippage took place and it would be essential that the counsellors were trained and available prior to this date.

(12) 29 July 1985. A minute was sent from Mrs Fosh to Mr Clarke's Private Office, copied to Mr Patten's Private Office, stating that the results were available and that a letter and draft summary were attached.[777]

(13) 30 July 1985. Testing discussed at EAGA meeting who agreed with the October timetable.[778]

(14) 31 July 1985. Further minute to Kenneth Clarke's Private Office.[779]

(15) 1 August 1985. Press release amended and approved by Mr Clarke and issued with letters to NHS bodies.[780]

(16) 1 August 1985. Correspondence from Mr Clarke to Sir Philip de Zulueta.[781]

(17) 2 August 1985. Briefing to Mr Clarke/Baroness Trumpington detailing why the Abbott test had not fared well in the evaluation.[782]

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[774] HSOC0018679_003; see also DHSC0003828_186.
[775] DHSC0001184, also CMO's background note at DHSC0001501.
[776] DHSC0002327_032.
[777] DHSC0002273_034 and PRSE0002078.
[778] NHBT0097458 – considered at several places in the minutes -see 7.2, 7.3 and 7.4.
[779] DHSC0000825.
[780] DHSC0002311_028, DHSC0000513, BART0000778.
[781] DHSC0000220. See also earlier correspondence, 5 June 1995 (DHSC0001569); and minute of 30 May 1985 (DHSC0002311_016).

(18) 8 August 1985. Response from Mr Clarke.[783]

(19) 8 August 1985. Publication of critical article in the New Scientist suggesting that the introduction of testing had been delayed until a British Test was available.[784]

(20) 16 August 1985. Briefing to ministers on the above article.[785]

(21) 22 August 1985. Publication of letter from Dr Napier, member of RTD working party on AIDS to the New Scientist rebutting the article of 8 August 1985.[786] Forwarded to CMO and copied to Ministers on 2 September 1985 by Dr Smithies.[787]

(22) 23 August 1985. DHSS press release giving October as the start date.[788]

(23) 1 October 1985. CMO issued 'Dear Doctor' "AIDS booklet 2: Information for Doctors concerning the introduction of the HLTV III Antibody Test."[789]

(24) 14 October 1985. Screening began.

Mr Patten's answer to Robert Key MP on 16 April 1985

4.158. In his written and oral evidence, Lord Patten stated that his answer to Mr Key had been in error and that he had either made a slip, or that he had genuinely but erroneously understood his answer to the case (whether because of a briefing error or because he had formed the wrong impression of the timing from earlier materials). Lord Patten thought that his making a mistake / slip was the most likely explanation, but (particularly in the absence of a record of the briefing on supplementaries for this PQ), he was unable to go further in positively identifying the precise reason. While the as-sent

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[782] DHSC0002116.
[783] DHSC0002327_036
[784] DHSC0000509.
[785] DHSC0000501.
[786] DHSC0002277_075; PRSE0002548.
[787] DHSC0002277_075.
[788] PRSE0002603.
[789] DHSC0000177.

correction letter was not available in the disclosure materials, a draft correction letter to Mr Key had been prepared, as was conventional.[790]

The decision to select a test after evaluation by PHLS and after field trials by BTS

4.159. The Inquiry has raised the question of whether it was correct for the Department to have carried out both test evaluations by the PHLS and field trials by the BTS before any screening test was introduced. The Inquiry's assessment may include the question of whether lives might have been saved by either the introduction of available commercial tests without testing or the introduction of tests after evaluation of tests by the PHLS without field trials, or perhaps some variant such as the temporary use of available commercial tests pending PHLS evaluation and BTS field trials. At the time of the decision by DHSS Ministers in June 1985, it was reported that testing was in use nationally in Australia, the USA and the Netherlands with the France and Germany due to introduce it national later in the summer.[791]

4.160. In assessing this issue, the Inquiry is also invited to take into account the following considerations:

(1) This was recognised at the time by those involved within DHSS to be a difficult judgement call.

(2) The CMO's assessment. While the Inquiry does not have the benefit of direct evidence from the late Sir Donald, his views can be drawn from his advice to Ministers of 10 June 1985.[792] See also the emphasis Sir Donald placed on the need for the Department to convey effectively the scientific reasons underpinning the decision taken when communicating the Department's approach through the media.[793] The CMO was plainly concerned at the harm that could be

[790] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §§5.28-5.29; Lord Patten's oral evidence on 20 May 2022, at 130:10-133:7 and 183:12-187:12.
[791] DHSC0002311_019.
[792] DHSC0002311_021.
[793] DHSC0002482_042.

done by having to withdraw a test on grounds of unreliability and his professional assessment and advice was that that the PHLS evaluation with BTS field trials was the better approach. When Mr Clarke announced the approach on 27 June 1985, there was an accompanying background note from the CMO, the terms of which the Inquiry is invited to consider in full since it was likely to be designed to achieve the communication of the underpinning scientific reasons which Sir Donald had been keen to see achieved.[794] In particular Sir Donald set out in the note that,

> *"More than two million blood donations are collected each year and it is clearly essential to ensure that any tests introduced on this scale must be known to give consistent results and be specific and sensitive. Specificity in this context means that a test which does not give rise to an unacceptable number of false positives each of which would require extensive further investigation and would waste the blood donations involved. Sensitivity is also of paramount importance in order that no genuine positives should be missed.*
>
> *While the commercial products already on sale have been evaluated elsewhere on an individual basis no comparative evaluation is available. This requires that their performance should be compared against a single carefully chosen panel of sera and that the tests should be conducted under controlled conditions. The PHLS are currently conducting such an evaluation. A field trial designed to explore both the specificity of the test and the operational aspects of its routine use throughout the country is also essential. Ease of use and consistency in large scale screening are prime requirements in selecting a suitable product for use in screening blood donations. Laboratory and field evaluations, both undertaken on a large scale, will enable an informed choice to be made and will promote confidence in those kits which are subsequently chosen."*

The CMO's note also addressed head-on the alternative suggestion of immediate introduction of available tests without this level of testing and trial:

> *"It has been suggested that testing should be introduced immediately, before the reliability of the tests available has been evaluated. Early experience of other countries and the considerations outlined in this note have led Ministers to decide*

[794] DHSC0001501.

that it would be wrong to introduce a screening test until the further evaluations mentioned above have been carried out."[795]

The DCMO's (Dr Harris') reply of 8 July 1985[796] to Prof Bloom's earlier letter of 31 May[797] explained that the need for proper evaluation had been discussed at the meetings of the EAGA. It described the introduction of an unevaluated test and discarding the blood testing as positive as "*superficially attractive*" but would lead to grave difficulties because of the large numbers of false positives. It also stressed the need for nation introduction with appropriate counselling facilities, and the need for STC clinics to be able to test to prevent at-risk individuals attending donor sessions to get tested.

(3) Lord Clarke's view. Kenneth Clarke's answer to the PQ on 27 June 1985 summarised the rationale for the course being adopted:

"I understand and share the concern to get these tests in use as soon as possible. However we must have tests which are accurate and can be trusted. A number of test kits are already available and in use abroad but reports from those countries suggest that the tests are not entirely reliable. We believe that no test should be introduced in the UK until its reliability has been established. There is no point in introducing a test which often fails to detect antibodies in blood or detects antibodies where there are none. An evaluation programme is being undertaken by the Public Health Laboratory Service and National Blood Transfusion Service experts as a matter of urgency. It is essential to complete this programme if we are to have a sensible policy that really does protect the public. Contrary to reports in today's press no decisions on choice of test kits have yet been made. We hope that we will be able to introduce a test within four to five months. We are also making arrangements to offer counselling to anyone whose blood is found to be positive."

In his oral evidence, Lord Clarke said that he thought that this announcement explained "*very carefully*" why the Department did need to be sure that the test was sufficiently accurate.[798] He felt that "*The best approach is to take the best scientific and medical advice you can, challenge it, if you wish to or things occur to you, and if it seems sound on authoritative advice, to act on it. Not start*

[795] HSOC0018679_003.
[796] DHSC0001183.
[797] DHSC0002489_099
[798] Lord Clarke's oral evidence on 28 July 2021, at 92:6-92:19.

playing amateur doctors and reaching your own judgment about how to introduce it."[799]

(4) Lord Patten's view. Lord Patten noted that he would have placed very considerable reliance on the CMO's own analysis of the balance of risk. Reflecting now on the submission of 7 June 1985 and the CMO's views, Lord Patten thought that removing a test once introduced on the basis that it had proved unreliable would indeed have been very difficult. He thought that the Department would have been open to criticism for not having evaluated or chosen the test carefully enough, and no doubt it could have produced very significant problems in terms of donors and donor recipients alike[800]. Lord Patten could not recall anything more about the early indication that he and the CMO had *"... [wanted] ...the speedy introduction of a screening test into BTS on available data, without waiting for confirmatory tests etc"*[801]. Bearing in mind the need for speed and prioritisation, Lord Patten stated in his oral evidence that what was put forward in the final submission (as supported by the CMO) still seemed at the time to be the right option. But he noted that it was a very difficult balance to strike for officials.[802] Lord Patten made *"no apology"* for deferring to the CMO on scientific issue adding, "*I think one of the things that would have made me even more determined to see this particular option pursued is because of the effects of if we had gone down a faster route and something had gone wrong with the tests, the effects on the people affected by AIDS and their families and the effects on public belief in the ability of the DHSS to handle this issue could have been devastating. That was my policy sense coming through.*"[803]

(5) Lord Fowler's view. Lord Fowler explained that because of the necessary delegation of ministerial responsibilities, the screening

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[799] Lord Clarke's oral evidence on 28 July 2021, at 95:9-95:14; see further 95:15-97:3.
[800] Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §5.45(8).
[801] Lord Patten's oral evidence on 20 May 2022, at 136:9-136:11.
[802] Lord Patten's oral evidence on 20 May 2022, at 142:14-143:6.
[803] Lord Patten's oral evidence on 20 May 2022, at 147:4-147:18; see further at 148:1-151:20.

issue was principally handled by (he thought) Kenneth Clarke and later John Patten[804] and he was not copied in to many of the detailed submissions. However, Lord Fowler commented that:

> *"Although I was not involved in the detail of this, this is an area where we (in my view justifiably) relied on the expert medical advice being given on the balance to be struck between speed of implementation and reliability. Looking at it now, while it may be said that lives may have been saved by the most rapid introduction of some testing, the concern about unreliable results and engendering a false sense of security has force too, as it did at the time. Introducing a testing system involving less reliable testing, particularly if it had a tendency towards false negatives, would risk more cases slipping through the net. I do not feel that I am able to comment more meaningfully or in more detail on whether the balance was struck correctly, whether at the time or viewed with all the benefits of hindsight. What I do know is that if the tests were regarded as unreliable then this would have been justifiably criticised by experts and laymen alike. I have no reason to doubt that the judgments made at the time were made in good faith on the merits as were assessed at the time. In particular, the strategy that was adopted – approving a two-stage evaluation of rival tests – was in line with the advice given by the CMO, in what the CMO acknowledged to John Patten was a finely balanced decision"*[805]

(6) There was no "*zero timescale*" option. Rolling out commercially available test kits was itself envisaged to take in the order of two months.[806]

(7) The concerns about the reliability of the commercially available test kits were far from trivial. As Dr Smithies commented in briefing ministers on the New Scientist article, Abbott had needed to report that one hundred thousand tests were faulty[807]. The submission of 7 June 1985 advised that, "*UK experts are not satisfied with the reports of evaluations from countries who have conducted trials*".

(8) The CMO's preference for PHLS evaluation with BTS field trials was caveated with the need for DHSS to *"...do everything possible to*

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[804] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.85.
[805] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.100. See further Lord Fowler's oral evidence on 22 September 2021, at 67:10-70:10.
[806] DHSC0002311_019; Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §5.45(2).
[807] DHSC0000501 at page 1.

ensure that PHLS is able to keep to its schedule".[808] The submission of 7 June 1985 had envisaged that implementation on this basis of approach would be in 'October or November'[809]. The CMO having re-enforced its importance, the respective bodies (DHSS, PHLS, BTS) stuck to this timescale with the screening being introduced on 14 October.

(9) While the Inquiry has raised the question whether the development of a cheaper British test, particularly the Wellcome test, was a factor in the selection of the preferred tests or the timing of their introduction, the submission of 7 June 1985 does not suggest that this was the case.[810]

(10) The Inquiry has raised the question of whether the capacity for HTLV-III testing outside the Blood Transfusion Service (that is to say testing in sexual health clinics for those who were not blood donors) influenced the decision making. Mr Patten had discussed the non-BTS testing issue with the CMO at a meeting on 22 August 1985.[811] While this was an important issue (because of the risk that those who considered they might be HIV positive would otherwise offer to give blood in order to get tested), that meeting took place after the decision on the options set out in the earlier submission of 7 June 1985.[812] On the other hand, Dr Smithies' minute of 16 August 1985 referred to "*...the probability that introduction of screening attracts high risk donors and thus the need for alternative testing sites*" as being one (but only one) factor that had pointed to a need for co-ordinated

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[808] DHSC0002311_021
[809] DHSC0002311_019.
[810] See paragraph 8 of the submission of 7 June 1985 which stated, *"We should not delay implementation of screening until this [the Wellcome test] can be supplied". "Support British industry"* had been a criteria raised in the *draft* ministerial submission of 5 June 1985 but it was entirely omitted as a factor in the final ministerial submission of 7 June 1985. See Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §5.50. See also Lord Patten's oral evidence on 20 May 2022 at 155:1-157:1.
[811] Referred to in DHSC0101705.
[812] See: (i) the commentary on this issue in Lord Patten's witness statement dated 5 April 2022 (WITN5297001), §§5.54 – 5.60; (ii) There was also no mention of this factor in the CMO's minute of 10 June 1985: DHSC0002311_021. Lord Patten accepted in his oral evidence that the issue was certainly always being raised of people coming to get a test (at a blood donation centre) because they wanted to know if they were positive or not but he also noted that this at not in fact been the experience in the USA. Lord Patten's oral evidence on 20 May 2022, at 157:22-159:9.

national implementation (although she recorded that RHAs had not been *prevented* from instituting testing should they wish)[813]. The issue was also referred to in Dr Harris' reply to Prof Bloom (see above)[814]. See also the terms of the CMO's AIDS Booklet 2, referred to above[815] and the EAGA meeting of 30 July 1985.[816]

The later exchange between Norman Fowler and Nicholas Edwards

4.161. *After* the introduction of HLTV III testing on 14 October 1985, there was an exchange of correspondence between Nicholas Edwards, Secretary of State for Wales, and Norman Fowler, concerning the reliability of testing. The initial exchange of correspondence had started slightly earlier. The chronology was as follows:

(1) 25 September 1985. Mr Fowler wrote to the Prime Minister on the wider fight against AIDS including the establishment of a ministerial steering group.[817]

(2) 8 October 1985. Mr Edwards wrote to Mr Fowler noting amongst other things the importance of Welsh representation on the ministerial steering group but also mentioning the AIDS testing kits.[818]

(3) 18 October 1985 (after the testing had started). Mr Edwards wrote a further letter to Mr Fowler. Mr Edwards had now seen the results of the NBTS evaluation of the kits and raised concern about the performance of the chosen tests, Wellcome and Organon, commenting "*Be that as it may, I accept that even unreliable testing is better than no testing at all. But clearly we must take every step to ensure that we get the system as foolproof as it can be.*"[819]

(4) 31 October 1985. Mr Harris (DHSS HS1) put a submission to the CMO copied to Mr Fowler's Private Office, attaching a robust draft

[813] DHSC0000501.
[814] DHSC0001183.
[815] DHSC0000177.
[816] NHBT0097458 at §7.3.2 in particular.
[817] SCGV0000150_067.
[818] DHSC0044118.
[819] ARCH0000068.

response for Mr Fowler to send to Mr Edwards. This noted that what Mr Edwards had been shown was the draft report of the evaluation in the BTS and that,

> "*The purpose of the evaluation was to look hard for problems. As expected it found some. The report is a highly technical document needing expert interpretation. A group of experts examined the findings. The Welsh Office were represented on this group. The group were able to put the problems found in their proper context. They had no hesitation in recommending the general use of these tests. The performance of the tests since introduction has been monitored. Experience to date suggests they are satisfactory.*"[820]

(5) 15 November 1985. Mr Fowler replied to Mr Edwards in accordance with the draft prepared by Mr Harris and cleared by the CMO.[821] The letter of reply raised concern that Mr Edwards had obtained such a negative impression from his officials not least because they had fully participated in the forums that had provided the advice on screening tests. The letter referred to the "…*most worrying misconception*…" as being that "…*unreliable testing is better than no testing*…" since,

> *"…[t]his is the complete opposite of our thinking. We have based policy on the firm conviction that unreliable testing would be disastrous and would engender a false sense of security. This was the reason why we delayed the introduction of screening until we were satisfied that the tests to be used were sufficiently reliable."*

The letter pointed to the work being done to pinpoint the causes of the problems encountered but stressed that the ad hoc panel, with Welsh representation, had had no hesitation in agreeing that testing should start using the two chosen tests.

(6) 11 December 1985. Mr Edwards responded to Mr Fowler[822]. Mr Fowler described this response as "*carefully nuanced*": Mr Edwards sought to justify the concerns which the Welsh Office had raised through the earlier letters, but acknowledged that more information had become available and they were reassured about the reliability of the testing.

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[820] WITN0771090.
[821] DHSC0002482_126.
[822] DHSC0004360_061.

4.162. The chronology set out above indicates that in this correspondence, Mr Edwards was not raising the suggestion that testing kits (even if less reliable) should have been introduced sooner. Rather Mr Edwards was concerned, *after* their introduction, about what he had read about the technical assessment of the testing kit performance.[823]

(5) Stigma and the AIDS public health information campaign

Evidence of the stigma of HIV Infection from the infected and affected

4.163. Nobody reading, let alone listening to, the evidence of the infected and affected given to this Inquiry could fail to be moved by the evidence they have given concerning the stigma associated with infection. It is an understatement to suggest that it was a consistent powerful theme. Witness after witness spoke of the fear of revealing the fact of HIV infection[824] and the stigma and discrimination (and not infrequently foul and cruel behaviour) they suffered once the infection was known.

4.164. Colin Smith Snr and his wife Janet, speaking of their son Colin who was infected with HIV and died aged seven, gave a graphic shaming account of the graffiti repeatedly victimising their family; being labelled as the AIDS family; siblings bullied; forced to move home; and Colin Snr being sacked and refused further work due to stigma[825].

4.165. Margaret Madden whose son Daniel was infected with HIV and Hepatitis C was likewise forced to move home (in her case repeatedly); had paint daubed on her house and windows smashed, her car repeatedly vandalised including with discriminatory graffiti referring to AIDS; a shopkeeper tipped the change into her hand from a height so he would not have to touch her

[823] This issue was canvassed with Lord Fowler by the Chairman; Lord Fowler's oral evidence on 22 September 2021, at 76:15-80:16.
[824] Without overlooking stigma associated with HCV infection, this section of these submissions focuses on HIV infection because of the associated issue of the AIDS public health campaign.
[825] Colin and Janet Smith's oral evidence on 24 July 2019, particularly at 18:25-21:17.

and she was left picking it up off the floor; treated, she felt, as if they had leprosy[826].

4.166. It is invidious to pick out such individual examples, but the Chairman will be entirely aware of the stark, consistent and moving evidence from the infected and affected on this issue. A selection of other examples from the evidence, by no means intended to be exhaustive, is as follows:

(1) Clair Walton[827];

(2) Suresh Vaghela[828];

(3) Alison Bennett[829];

(4) Joseph Ball[830];

(5) Mark Donnelly[831];

(6) Ms GRO-B (W2607) and Ms GRO-B (W2449)[832];

(7) Ms GRO-B (W2643)[833];

(8) John Cornes[834];

(9) Jo-Anne Cohrs[835];

(10) Martin Beard[836];

(11) Mr GRO-B W1291)[837];

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[826] Margaret Madden's oral evidence on 14 June 2019, at 100:20-104:12.
[827] Clair Walton's witness statement dated 22 February 2019 (WITN1589001), §§8, 27, 28 & 34; and Clair Walton's oral evidence on 2 May 2019, at 11:23-12:12 and 38:5.
[828] Suresh Vaghela's witness statement dated 27 November 2018 (WITN1577001), §58; and Suresh Vaghela's oral evidence on 18 June 2019 at 109.
[829] Alison Bennett's witness statement dated 22 November 2018 (WITN0553001), §§5.3-5.6; and Alison Bennett's oral evidence on 2 July 2019, at 29-30.
[830] Joseph Ball's witness statement dated 22 February 2019 (WITN1625001), §§15-29.
[831] Mark Donnelly's oral evidence on 24 May 2019, at 58.
[832] Ms GRO-B (W2607)'s witness statement of 20 February 2019 (WITN2607001), and Ms GRO-B (W2449)'s witness statement of 18 February 2019 (WITN2449001).
[833] Ms GRO-B W2643)'s oral evidence on 4 June 2019, at 103:6-11; 106:11-25; 107:11-108:2; 108:11-25; 109:8-110:10; 110:22-30.
[834] John Cornes' oral evidence on 11 June 2019, at 17-22 and witness statement dated 9 November 2018 (WITN1170001), §56-77.
[835] Jo-Anne Cohrs' oral evidence on 11 June 2019, at 80-89.
[836] Martin Beard's oral evidence on 12 June 2019, at 30-35 and witness statement dated 2 May 2019 (WITN0012002), §§85-97.
[837] M GRO-B (W1291)'s oral evidence on 14 June 2019, at 34 & 51.

(12) Susan Sparkes[838];

(13) Mr GRO-B (W2422)[839];

(14) Mr GRO-B (W1275)[840];

(15) Gaynor Lewis[841];

(16) Berverly Tumelty[842];

(17) Colin and Denise Turton[843];

(18) Baroness Campbell[844];

(19) Susan Threakall[845];

(20) GRO-B [Anon] (W1003)[846];

(21) Mr GRO-B (W1006)[847];

(22) Susan and Tara Delglyn[848];

(23) Mr GRO-B (W1005)[849]; and

(24) Mr GRO-B (W0125)[850].

Perception of the AIDS Education Campaign, particularly the "*Tombstone*" advertisement

4.167. In giving their evidence on the impact of HIV infection, and particularly in regard to stigmatisation, many of the infected and affected referred to the AIDS public education campaign, particularly (though not exclusively) to the "*tombstone*" advertisement.

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838 Susan Sparkes' oral evidence on 23 July 2019, at 78 and 100.
839 Mr (W2422)'s oral evidence on 24 July 2019, at 56.
840 Mr GRO-B (W1275)'s oral evidence on 25 July 2019, at 87.
841 Gaynor Lewis' oral evidence on 26 July 2019, at 13.
842 Beverly Tumelty's oral evidence on 26 July 2019, at 48-49.
843 Colin and Denise Turton's oral evidence on 8 October 2019, at 21 and 27.
844 Baroness Campbell's oral evidence on 9 October 2019, at 163-164.
845 Susan Threakall's oral evidence on 8 October 2019, at 65.
846 GRO-B [Anon] (W1003)'s oral evidence on 10 October 2019, at 42.
847 Mr GRO-B (W1006)'s oral evidence on 10 October 2019, at 101-103.
848 Susan and Tara Delglyn's oral evidence on 11 October 2019, at 9 and 26.
849 Mr (W1005)'s oral evidence of 11 October 2019, at 188-192.
850 Mr GRO-B (W0125)'s oral evidence of 15 October 2019, at 88-90.

4.168. The evidence in relation to the public health campaign in general, and the tombstone advertisement in particular, covered a spectrum of views[851]. It is fully acknowledged that many were expressly or at least implicitly critical, seeing the campaign, and the tombstone adverts in particular, as having had two effects.

4.169. **Firstly** to have increased (some even suggested to have created) the effect of stigmatisation of those infected with HIV and those suffering from AIDS. Examples (non-exhaustive) include:

(1) Mr GRO-B (W0125), who gave oral evidence that the Government *"actively compounded our community's plight with campaigns, such as the AIDS tombstone campaign"*[852]. Mr GRO-B went on to suggest that the Government should be the principal champion of the U=U campaign in order to endeavour to *"...undo large aspects of the harm they themselves created..."*.

(2) Frances Joy, who in her evidence about her son, Ian, said that:

> *"...I think when there were all those adverts on the television, the AIDS adverts, a lot of people were very scared. That was a Government campaign, but I think people got a fright and thought they didn't want to mix with anyone or with anything like that. You see the tombstone on the television and it just leaves you feeling awful. He carried on though, he lived his life as best he could..."*[853]

(3) W5694, who gave evidence that the campaign caused *"unnecessary hysteria"*. That her child suffered the consequences of the campaign and that her view (both as a mother and a Phlebotomist) was that the campaign was *"unnecessary, inappropriate and without consideration*

[851] A minority, even if critical of the tombstone advertisement, averted to the campaign's role in raising awareness including on the risk of transmission: For example W1406, who in his witness statement dated 1 June 2020 (WITN1406001) gave evidence at §26 of disclosing his HIV status to his girlfriend: *"I told her that I was HIV positive and I think because of the adverts with the tombstones she had some knowledge about it. She said that she loved me and that she did not care."*; W1886 who in her statement dated 3 September 2020 (WITN1886001), states at §17 that other than the adverts she had seen on television, she had known nothing about HIV at that time; and W1072 who noted in his statement dated 27 March 2019 (WITN1072001), §10: *"I was never given any direct advice about the risk of transmission or how to manage my infections. It was only when I saw the tombstone advert on television which made me realise the extent of the virus."*

[852] Mr GRO-B (W0125)'s oral evidence on 15 October 2019, at 111:10-111:14.

[853] France Joy's witness statement dated 11 February 2020 (WITN3098001), §27.

for the impact that it would cause to those children or indeed persons who were infected with HIV through receipt of contaminated blood products or otherwise."[854]

(4) Adrian Goodyear[855] who spoke of great fear generated by the falling tombstones and of the mortalities of those infected being played out in State-funded commercials.

4.170. **Second**, a number of the infected and affected described how the campaign and the tombstone advertisement in particular, had a direct negative personal and family impact in that the advertisements were hard and upsetting to watch, knowing that they (or family members) were infected, when the advertisements graphically evoked the fatal impact of HIV infection. Examples (again, non-exhaustive) include:

(1) Marilyn Ball's evidence of her son Joseph (then aged 10) asking in response to the television advert, *"mummy, is that me?"*[856] (Joseph's own evidence of the impact of stigma is referenced above).

(2) The evidence of W4830 who found himself turning to drug use as a coping mechanism.[857]

(3) Mr [redacted]s evidence that *"...it* [the campaign] *just kept reminding them that they had a very short lifespan ahead. This, of course, greatly affected loved ones and carers."*[858]

(4) The evidence of W1633 who wrote of the impact of the campaign on them and on their family: *"It* [the television advert] *was really horrendous to watch. We made a pact as a family to never talk about the infections to anyone. We didn't even mention it to each other."*[859]

(5) W1449's evidence of their Father and the impact of the stigma on their family:

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[854] W5694's witness statement dated 7 May 2021 (WITN5694001), §40.
[855] Adrian Goodyear's oral evidence on 5 June 2019, at 42:13-42:17; 43-44; 93.
[856] Marilyn Ball's witness statement dated 9 April 2019 (WITN2877001), §7.
[857] W4830's witness statement dated 14 April 2019 (WITN1483001), §53.
[858] Mr [redacted] oral evidence on 9 July 2019, at 27:14-21 and 17:3-11.
[859] W1633's witness statement dated 18 July 2019 (WITN1633001), §26.

> *"...My sister and I were brought up with a clear understanding that no-one in our household aired their dirty laundry in public. I remember with clarity the tombstone advert and the associated stigma of HIV/AIDS. It was terrifying. I knew people with HIV/AIDS were treated badly so we did not talk about it. We did not discuss my father's HIV status openly and never outside the family."*[860]

4.171. The submissions which follow are not raised in any way to diminish the importance and impact of the evidence of stigma briefly summarised above. The Chairman may however wish to consider the context of the AIDS public health education campaign and the perspective of those responsible for it.

The AIDS public health education campaign

4.172. Key aspects of the campaign were highlighted and summarised in Counsel to the Inquiry's note on the Role of the Chief Medical Officer.[861]

4.173. The catalyst for the public education campaign was Sir Donald Acheson's paper addressed to Norman Fowler the then Secretary of State and other ministers, dated 27 June 1985.[862] Lord Fowler emphasised the importance of this strategic paper, combined as it was with Sir Donald's request to see the Secretary of State personally to discuss it.

4.174. In the absence of any vaccine or effective treatment, the urgent need was for public education to reduce transmission amongst risk groups.[863]

4.175. Sir Donald is widely seen as having made AIDS his top priority from around the late Spring 1985 onward, with his 15 May 1985 'Dear Doctor' letter followed by his approach to Norman Fowler. For his part, Mr Fowler was

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[860] W1449's witness statement dated 27 February 2019 (WITN1449001), §11.
[861] INQY0000362.
[862] DHSC0002114.
[863] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.149; CTI note on CMO's Role §142*ff.*

seen by the CMO as having showed "*deep concern*" when approached by him in the summer of 1985, and thereafter gave the CMO, "*unfailing encouragement and support*".[864]

4.176. CTI has pointed to the relative lack of evidence of Sir Donald's personal involvement in matters relating to AIDS between February and October 1984. When looking at matters retrospectively, it is important to bear in mind that the fact that the CMO become more far more heavily personally involved from the late Spring of 1985, does not of itself indicate that a *lower*[865] level of direct personal involvement prior to that was insufficient. In analysing this issue, it warrants consideration that the public education campaign was going to require significant cross-Government commitment that could not be achieved by DHSS Ministers with the individual responsibly for blood products and AIDS alone. In that context, it may not be surprising to see a step change in 1985 with greater direct involvement from both the CMO and the Secretary of State.

4.177. Lord Fowler's statement[866] and CTI's note on the role of the CMO together set out some of the milestones in the public education campaign including:

(1) John Patten's visit to the USA, July 1985;

(2) Norman Fowler's letter to the Prime Minister of 25 September 1985[867];

(3) Setting up the inter-department senior officials steering group and Interdepartmental Ministerial Group (November 1985 – January 1986);

(4) The DHSS-funded Health Education Leaflet which was designed to convey the information on higher risk sexual practices that would not be through suitable for public advertising[868];

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[864] CTI's note on the role of the CMO, §101, citing Sir Donald's autobiography. Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.148.
[865] It is clear that Sir Donald did have *a* level of earlier direct involvement (as set out in CTI's note) but it is right that he became far more involved from late Spring 1985.
[866] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §§6.147-6.185.
[867] SCGV0000150_067.

(5) The guidance for schools (March 1986)[869];

(6) Briefing to all MPs (March 1986)[870];

(7) Written advertising campaign 17 March and 6, 7 April 1986 also in July 1986 ('Are you at risk from AIDS)[871];

(8) Advertising stepping up towards more direct explicit language (September 1986)[872];

(9) The establishment of the Special AIDS Committee under Lord Whitelaw – a Cabinet committee group whose formation was designed (in part) to speed up approval for the campaign (first meeting 11 November 1986)[873];

(10) Trial needle exchanges, announced in December 1986[874];

(11) The letter drop whereby every household received the leaflet, "*Don't die of ignorance*"[875] and the associated television advertisements to highlight the importance of studying it carefully (January 1987).

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[868] Draft at DHSC0002363_015.
[869] WITN0771146.
[870] DHSCO105117.
[871] WITN0771147. Lord Fowler said that the difficulty and delay caused by having to get these advertisements cleared by the general Home Affairs Committee (including objections from the Prime Minister) led he, Sir Robert Armstrong and Sir Kenneth Stowe to proposed the special AIDS Committee under Lord Whitelaw (Lord Fowler's witness statement dated 17 July 2021 (WITN0771001). §§6.165-6.167).
[872] DHSC0003836_045; WITN0771153.
[873] CTI's note on the role of the CMO refers to the fact that Sir Donald Acheson expressed concern to the Permanent Secretary Sir Kenneth Stowe in October 1986 that *"From the medical point of view, the Government's response has been inadequate and is now substantially less to educate the public than some other European countries. It is increasingly difficult to defend in public…."* and that he had advised ministers that *"from the public health point of view the education campaign to reduce the spread of infection should take priority over all other calls on finance."* [HMTR0000008_045]. The timing of this note from Sir Donald is significant because it coincides with efforts made by the Permanent Secretary and Lord Fowler to avoid the delays of the Home Affairs Cabinet Committee system and establish the Special Committee for AIDS under Lord Whitelaw. It is likely that the reference to "ministers" was aimed cross-Government and that Sir Donald was advocating against those questioning the need for further spending on the public education campaign. The pressure on funding was successful in that in November 1986, the Secretary of State was able to announce a further £20 million to be spent on the public education campaign (WITN0771175); see too HMTR0005022 Secretary of State pressing the Treasury for even further resources.
[874] To Lord Fowler's regret, the planned ministerial broadcast on AIDS in relation to which the opposition had foregone a right of reply, was vetoed by the Prime Minister: Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.181.
[875] MRCO0000554_005.

(12) Extensive worldwide AIDS trips at Secretary of State level (WHO, November 1986; West Germany and the Netherlands, December 1986; USA, January 1987; West Germany, April 1987);

(13) AIDS week advertising at the end of 1986 and "*AIDS Television Week*" in February 1987; and

(14) Establishment of the National AIDS Trust.

Stigma and the public health information campaign

4.178. While in many people's memories, the tombstone advert remains prominent in recollections, part of the aim of the campaign was to dispel myths surrounding HIV and AIDS. It can be easy to overlook the fact that the campaign did repeatedly carry messages aimed to give re-assurance that AIDS could not be transmitted through everyday social contact. For example,

(1) The guidance for schools emphasised the lack of risk in transmission in the school setting, and the need for confidentiality and support to infected children and their parents;[876]

(2) The leaflet "*Are you at risk from AIDS*" emphasised that normal social contact and being at school and work with infected people carried no risk;[877]

(3) The September 1986 advertising made clear that *"no one has been infected through day to day contact*";[878]

(4) The leaflet sent to every household "*Don't die of ignorance*" explained that,

> *"The Government's clear medical advice is that you cannot get the virus from normal social contact with someone who is infected. You cannot get it from shaking hands. Nor is there any record of it anyone becoming infected through kissing. There is*

[876] WITN0771147.
[877] WITN0771147.
[878] WITN0771153.

> *no danger in sharing cups or cutlery. Nor can you catch it from public baths or toilets."*[879]

4.179. In addition to this, ministers were personally committed to trying to dispel myths and stigma. Princess Diana shaking hands with AIDS patients in April 1987 became an iconic image, seen my many as ground-breaking and as highly important in fighting the stigma surrounding AIDS. Mr Fowler (USA January 1987) and Mr Patten had earlier done the same when visiting AIDS patients.[880]

4.180. Contemporaneous research by the British Market Research Bureau[881] demonstrated the effectiveness of the campaign: see the figures cited by Lord Fowler in his written statement[882] which showed very marked increase in awareness with proven recall figures of between 78% and 87%, *"...amongst the highest figures for any social persuasion advertising campaign in Britain*." The conclusion of the report was that "...*the advertising campaign substantially achieved the objectives of educating the public and influencing the climate of opinion as a basis for behaviour modification."*

4.181. For his part, Lord Fowler told the Inquiry that he feels strongly that the public education campaign did not *create* the stigma surrounding HIV infection and AIDS. The cause of that stigma was bigotry and prejudice on the part of some sections of the public fuelled by irresponsible comments by some public figures, powerful examples of which Lord Fowler cited in his written statement. Lord Fowler wished to make clear to the Inquiry his own opposition - then and now - to such attitudes which he and other health ministers had sought to combat [883].

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[879] MRCO0000554_005.
[880] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.175; Lord Patten's oral evidence on 20 May 2022, at 45:7-45:17.
[881] WITN0771169.
[882] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.183; also Lord Fowler's oral evidence on 22 September 2021, at 91:12 – 92:10.
[883] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.175.

4.182. It may well be said that the raised awareness of AIDS resulting from the public education campaign may have stimulated an already prejudiced minority to voice and act upon their prejudice to a greater extent. The Inquiry may wish to consider with care, however, any assertion that the public education campaign actually *created* the contemporaneous stigma about HIV infection and AIDS from which so many of the infected and affected undoubtedly suffered.

Consideration given to the distress to those already infected by the public health information campaign

4.183. As summarised above, the Inquiry heard evidence of the distress caused to the infected and affected when they saw (in particular) the 'tombstone' advertisement. Lord Fowler was asked whether the Government had taken the impact on those already infected with HIV into account when the advertisements were considered. Reflecting on this issue, Lord Fowler emphasised the following aspects:

(1) Lord Fowler was directly aware of the evidence given by the infected and affected on this issue. He found it a very difficult aspect to address because he cares passionately about helping those infected by HIV and it has become a major part of his working life.[884]

(2) During the campaign, both he and the CMO, and the Cabinet Committees had rejected some advertising proposals out of concern that they went too far[885] and would be too upsetting. The impact on those infected was considered.[886]

[884] Lord Fowler's witness statement dated 17 July 2021(WITN0771001), §0.39-0.40.
[885] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.194 (early ideas of advertising agency rejected). WITN0771171 – Cabinet AIDS Committee 14 January 1987, rejection of use of images of disfigurement from AIDS symptoms despite surveys showing that people responded more vividly to them than to the risk of death. Also Lord Fowler's oral evidence on 22 September 2021, at 95:20–96:6.
[886] Lord Fowler's oral evidence on 22 September 2021, at 98:120–100:22.

(3) The Cabinet view (through the AIDS Committee) was that "*The material in the advertisements should be visually striking and hard-hitting.*"[887]

(4) The advertisements were directly approved by both him and the CMO[888]. As above, it is evident that they were also considered at Cabinet Committee level.

(5) The Government was breaking new ground. Looked at over 35 years later, it is easy to forget the unprecedented nature of the public health campaign, particularly in how it had to engage with particular sexual practices and drug taking in the teeth of opposition to such issues addressed on the basis that it condoned "*immoral behaviour*". There was no template to follow in how to strike the balance in the public messaging. Then and now, Lord Fowler described striking the right balance as "*particularly difficult*". As Lord Fowler said in the press conference ahead of the leaflet circulation in January 1987:

> *"This has been an unprecedented campaign in this country. We have, of course, tried to learn as much as we could from other countries. But in many ways, we are pioneering here. For example in the breadth of the campaign and in the way we are working with the media to get the message across.*
>
> *Because we are pioneering, we have been deliberately taking it step by step. At the same time, we have been trying to strike the right balance on four separate aspects of the campaign.*
>
> *First in getting messages across to specific groups in the community such as homosexuals and drug misusers at the same time as getting messages across to the community at large.*
>
> *Second, in getting the messages across in language that is direct and effective but is regarded by the public as necessary and acceptable.*
>
> *Third, on the moral issues concerned …*
>
> *Fourth, and most important, we have to convince people of the urgency of the situation without causing unnecessary personal alarm and panic. AIDS is still confined very largely to particular groups. But it could spread more widely into the general population – as it has already done in Africa. So in pitching the*

[887] CABO0100010.
[888] Lord Fowler's witness statement dated 17 July 2021 (WITN0771001), §6.192.

tone and content of our message on this point we have a particularly difficult but importance balance to strike."[889]

(6) Lord Fowler further observed that:

"The final advertisements were direct and effective. The public education campaign is widely regarded as having been successful in raising awareness and saving lives. The tensions or balances about which the Inquiry asks are perhaps illustrated by the fact that the 'tombstone' advert is often mentioned as being the most memorable in the campaign that was successful in saving lives; yet that same advert is the one identified in evidence to this Inquiry as having been the most difficult for the infected and their families. I am not sure whether it would have been possible to navigate a middle course that would have avoided adding to the fears of those already infected, without detracting from need to get the message across vividly so as to avoid further fatalities. Our motivation was to prevent further infections and further loss of life. As a result of the campaign there was a reduction in HIV and other sexual disease."

(7) Lord Fowler stressed that he understood the perspective of those who were critical of the tombstone advertisement in adding to their sense of fear and isolation of those infected. But he also reflected that the Government's number one priority had to be to try to prevent that same fate overtaking other people, while still trying to respect and defend those already infected.[890]

4.184. The Inquiry has (understandably) not investigated the wider issues of overall rates of HIV infection and how they were impacted by the public education campaign. The overall impact of the campaign in saving lives would clearly be a relevant consideration in any contemporaneous assessment of the strengths and weaknesses of the campaign.

4.185. As part of its consideration of the impact of the campaign on those infected through blood and blood products, the Inquiry will no doubt wish to consider the different perspectives articulated by the infected and affected and those who had the challenging task of deciding upon the course of what was – on

[889] DHSC0003836_090.
[890] Lord Fowler's oral evidence on 22 September 2021, at 101:1-103:1.

any view – an unprecedented public education campaign to tackle a national emergency. Aspects of the campaign would of course be run differently today; but the campaign of 1985-1987 and the associated decision by Government, must be judged without the significant benefits of hindsight and those decades of greater experience.

Section 5: Heat treatment

Heat treatment: Context

5.1. As was observed by the authors of the CTI and Inquiry Legal Team written presentation *"Domestic Production and Self-Sufficiency, Chronological Presentation: England and Wales"*, the origins of BPL/PFL's heat treatment programme lie in wider consideration of viral inactivation methods intended to reduce or remove NANB Hepatitis from the laboratories' factor concentrates in 1981.[891] During the CTI oral presentation given on 17 March 2022, counsel noted the importance of recognising that heat treatment was at this stage only one of several potential methods for reducing Hepatitis infectivity in blood products to which consideration was being given.[892] It was not known which of these methods would ultimately prove effective. The Chair may wish to consider the early steps taken to develop heat treatment in this context.

5.2. At a meeting of the Scientific and Technical Committee of the Central Blood Laboratories on 24 November 1981, Dr James Smith of PFL gave a short address on the inactivation of Hepatitis in BPL products. He summarised the steps it was thought might diminish the risk of blood products transmitting Hepatitis:

(1) More specific and sensitive screening of blood donations intended for fractionation;

(2) Limiting the size of plasma pools for recovery of certain products;

(3) Neutralisation or absorption of the virus with an excess of Hepatitis antibody;

(4) Vaccination of recipients;

(5) Virus removal during fractionation through precipitation with polyethylene glycol;

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[891] CTI and Inquiry Legal Team Presentation '*Domestic Production and Self-Sufficiency, Chronological Presentation: England and Wales*' (INQY0000333), at §230.
[892] CTI oral presentation on 17 March 2022, 9:8-9:15.

(6) Viral inactivation through various methods, including heat treatment.[893] [894]

5.3. A number of options designed to inactivate Hepatitis viruses were still being considered when the original BPL proposal to develop a "Hepatitis-Safe" product was made in early 1983, a proposal which ultimately led to the development of a heat-treated product.[895]

5.4. The principal reason that attempts were not made to heat-treat Factor VIII earlier was that there was a widespread understanding that Factor VIII coagulant activity was heat-labile – i.e. unstable and likely to be changed or destroyed when subjected to heat. That point is reflected in a number of sources:

(1) Dr Snape stated that this was the generally held belief and that it was "*…assumed that heat-treatment of coagulation factor concentrates would denature the active principle (factor VIII or factor IX) rendering the products ineffective – or at least so affecting yield as to make the process untenable.*"[896]

(2) Dr James Smith has explained that it was thought Factor VIII would not survive heat treatment without the addition of preservatives, which might also preserve the viruses the treatment was intended to

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[893] CBLA0001506.
[894] The question of multiple routes of protection may also be relevant to an issue canvassed in CTI's oral presentation on the work of Dr Lane on 22 March 2022. At 6 – 7, CTI referred to paragraphs 423 – 432 of the Draft Proof of Evidence, where Dr Lane concluded that Hepatitis B was *"…controlled by donor screening and patient immunisation."* The Chair observed that Dr Lane appeared to be saying that although Hepatitis B could kill *"…it didn't do often enough"* to justify research into what might eliminate it (7:25-8:4). However, the Draft Proof of evidence outlined more than one protective factor at paragraphs 423 onwards, including not only the development of vaccination from the early 1980s, but the testing of donations for Hepatitis B at both RTCs and then again at BPL (on the efficacy of screening for Hepatitis B generally, Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §32: *"Once screening tests on blood donations had largely eliminated HBV from the blood supply…"*). The efficacy of screening tests was an ongoing area of research. Dr Walford outlined a brief history of this matter in her written evidence (WITN4461001) at §59.2-59.4. The DHSS Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody reported in 1971, 1975 and then was convened again in 1979, on the latter two occasions looking to report on the improvements in testing mechanisms and techniques.
[895] CBLA0001781, page 1.
[896] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §166.

destroy.[897] Dr Smith explained in his statement that: "*The truth is that heat treatment was one of the least likely candidates, from the universal experience of all who worked with coagulation factors… If the product experienced slight over-heating… we would be left with insoluble brown toffee*".[898]

(3) Dr Foster described it as "*shocking*" when he first heard the claim that Factor VIII might be able to be heat-treated under conditions that would destroy Hepatitis viruses.[899] Heat-treating Factor VIII was *"…so inconceivable that it literally wasn't something that I would have imagined could have been possible"*.[900] Dr Foster explained this was why experiments with stabilisers were not conducted earlier.[901]

(4) Dr Perry described a concern that modifying the Factor VIII manufacturing to include steps for virus inactivation could lead to the development of inhibitors in recipient patients, with potentially *"…catastrophic consequences for the treatment of haemophilia"*; the risk was not a hypothetical one - the Dutch Red Cross had produced a heat-treated product which generated very high levels of inhibitors in a large number of patients.[902]

(5) At a meeting of medico-scientific professionals in the US in July 1982, attendees heard that Factor VIII was considered to be heat-labile.[903]

(6) The original BPL proposal to develop FVIII free from Hepatitis, referred to above, noted that: *"Factor VIII coagulant activity has always been regarded as exceptionally labile, and it is only recently*

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[897] CTI's oral presentation on the work and evidence of Dr James Smith of 18 March 2022, at 47:4-47:13.
[898] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §49. Dr Smith went on to explain that clues to potential pasteurisation and dry heating were discovered by accident. He identified in his statement to this Inquiry (§75) and in his testimony to the Penrose Inquiry [PRSE0004045] that the early experiments (in 1982) on brief heating of concentrates had nothing to do with viral inactivation and were instead concerned with getting rid of a proportion of the fibrinogen burden.
[899] Dr Peter Foster's oral evidence on 25 March 2022, at 61:4-62:17.
[900] Dr Peter Foster's oral evidence on 25 March 2022, at 95:10-95:13.
[901] Dr Peter Foster's oral evidence on 25 March 2022, at 122:7-122:20.
[902] Dr Perry's oral evidence on 1 April 2022, at 100:15-101:20.
[903] CTI written presentation 'Pharmaceutical Companies: Response to Risk' (INQY0000311), §29: *"The meeting also heard that Factor VIII was considered to be heat labile"*; Summary of the meeting of 27 July 1982 at JREE0000019, pages 280-282.

that serious attempts have been made to apply to factor VIII concentrates some physical and chemical processes designed to inactivate hepatitis viruses".[904]

5.5. There was also a concern – correct, as it emerged - that heat-treating would lead to a reduction in available product. It was noted that (in the absence of self-sufficient domestic supplies) the commercial product would, inevitably, have to fill the gap.[905]

5.6. Although commercial organisations might have made apparent advancements in heat treatment in the early 1980s, there was reason for a degree of circumspection in relation to the claims being made: Behringwerke AG, for example, made a number of claims about their heat-treated product. However, as Dr Smith pointed out in a memorandum dated 27 July 1981, there was no reputable evidence supporting their claim.[906] Dr Smith described the reports on Behringwerke's progress on pasteurising Factor VIII as "*...intermittent and often confusing.*"[907] It is also of note that the product was neither licensed nor marketed in the UK (or in the USA). The Inquiry has also heard evidence that commercial organisations were reluctant to share sensitive commercial developments with external organisations.[908]

Development of heat treatment by BPL/PFL

5.7. The evidence suggests that Dr Lane was highly motivated to develop heat treatment for patients so the risk posed by, initially, Hepatitis in blood products could be reduced and eliminated.[909] In the latter part of 1980, Dr Lane sought the advice of senior staff at BPL about the available procedures

[904] CBLA0001781, page 1.
[905] Dr Robert Perry's oral evidence on 31 March 2022, at 158:5-158:8.
[906] CTI oral presentation on 17 March 2022, 9:21-9:23; BPLL0011141.
[907] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), §76.
[908] E.g. Dr Foster's oral evidence on 25 March 22, 58:17–59:1.
[909] By early January 1983, the proposal to develop a Hepatitis Safe product included the information that AIDS was *"... not yet proven to be of viral origin, but this is strongly presumed."* (CBLA0001781).

for inactivation of NANB Hepatitis virus, notwithstanding that this carried major resource implications for research and development ("R&D"), which at the time was fully disposed to improving Factor VIII product and production yield.[910]

5.8. Dr Lane thereafter sent a memorandum to staff at BPL inviting them to propose R&D projects for DHSS funding, DHSS having stated that central funding for R&D was available.[911] This resulted in a proposal from a BPL staff member dated 27 February 1981, which proposed research into possible methods to reduce the risk of Hepatitis infection.[912] Dr Lane put the proposal forward for funding to the Scientific and Technical Committee, which on 4 March 1981 agreed that he should put full proposals forward for consideration by the DHSS.[913] Dr James Smith, in turn, gave the viral inactivation programme A1 priority, *"... i.e. most important to BPL/PFL's immediate product strategy"*.[914]

5.9. During the CTI oral presentation given on 17 March 2022, Counsel noted the reference in Dr Lane's 'Draft Proof of Evidence' to attempts throughout 1981 to obtain central funding for research projects in this area and his statement that no additional capital was forthcoming.[915] There appears to be a dearth of evidence showing how and when Dr Lane's proposals were formally sent for consideration, the response received and its impact (the issue of funding or its lack does not appear to be picked up in minutes of the STC for the remainder of the year) and it may be that the issue was subsumed in the work done on the proposals to develop a new BPL then under consideration. However, in relation to the specific issue of research into heat treatment, the timeline given by Dr Smith in his 3rd Draft Proof of Evidence for the HIV Litigation placed more emphasis on events from 1982 onwards. He wrote:

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[910] CBLA0000005_002, §501.
[911] CBLA0001277.
[912] CBLA0001291.
[913] CBLA0001299.
[914] CBLA0001718.
[915] CTI oral presentation on 17 March 2022, at §§9-10; Dr Lane's 5th Draft Proof of Evidence prepared for the HIV litigation dated 10 December 1990 (CBLA0000005_002), §529.

> *"My involvement with the idea of heat treatment of Factor VIII can be traced back to 1981 during the course of which I reviewed potential research and development work. In the documentation produced at this time, there was a passing reference to heat treatment [**check and identify document**]*[916]*. However, it was not until November/December 1982 that heat treatment began to emerge as a topic for further study."*[917]

5.10. It possible that the document with the "*passing reference*" to heat treatment mentioned in this Draft Proof of Evidence was a reference to a record from Dr Lane of the discussions that were held on 14 September 1981 with Dr Harvey and Dr Smith to set out *"...important areas of research and development with a view to establishing closer definition on protocols to form priorities and to ascertain a reasonable time scale for implementation, bearing in mind the pressure on departments due to the Interim Programme."*[918] The record minutes not only the range of options under consideration for *"reducing hepatitis antigen"*, of which *"heat inactivation"* was one, but also the need:

> *"To collect existing approaches e.g. B-propiolactone, **heat**, PEG 4000, chemical affinity, into a protocol for presentation to the office of the Chief Scientist, DHSS, for central research funding."* [Emphasis added]

5.11. The record included reference to the need to prepare submissions on a number of subjects, of which *"hepatitis transmission"* was one, in time for the STC Meeting of 6 October 1981. It seems – as a minimum – that the research proposed at this stage was into the range of proposals that appeared to be promising (see again the reference to the STC meeting of 24 November 1981)[919] but also that no proposals were submitted to the DHSS before that date (see the minutes of the meeting of 24 November 1981,

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[916] This comment in parentheses is from the source document.
[917] CBLA0000016_034, §30.
[918] CBLA00011446.
[919] Minutes at CBLA0001506. Unfortunately, without sight of the underlying paper it is difficult to be clear which these projects were, but Dr Lane agreed to pursue other sources of funding for the remaining projects.

which record that *"projects 3 and 6"* should have protocols prepared which would be endorsed for consideration by the Office of the Chief Scientist).[920]

5.12. There is further general evidence from Dr Smith as to the lack of resources available to pursue work on heat treatment (including a lack of an R&D Department; also that there was a lack of permanent technical staff; and a lack of suitable physical infrastructure)[921]. However, in relation to difficulties for the heat treatment programme posed by the normal public-service paradigm for funding (the preparation by departments of an annual budget with the understanding that funds allocated would be spent within the following year), Dr Smith said that "*On the whole, this was recognised at the Department of Health (DH) level and we were shown flexibility.*"[922] He also explained that stop-gap funding to renovate was *"relativity generous"* and that funding for the new building seemed *"adequate"*.[923] Importantly he also identified that (in essence) access to more resources would not have meant an earlier production of a heat-treated product;[924] although he noted that if the new BPL had been built sooner they might have been able to create more options for virus reduction.[925]

5.13. Dr Smith confirmed that there was no resistance to the pursuit at BPL/PFL of pursuing heat treatment of factor products, but there were genuine concerns over safety and efficacy.[926] Dr Smith responded to the suggestion that there was delay on the part of the fractionators in addressing the issue of Hepatitis transmission by describing the early obstacles faced, the principal being that that there was no practical test for NANB Hepatitis at that time in order to test the efficacy of any inactivation methods including heat treatment on the concentrate: "*Our perceived delay in responding was due to lack of*

[920] We have not found a record of an STC meeting taking place on 6 October 1981.
[921] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §§82-90.
[922] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §92.
[923] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §92.
[924] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §§101-103.
[925] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §95.
[926] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §§69-73.

capability, not to complacency".[927] Until *"at least 1982"* they had no promising lead which they thought they had the ability to follow.[928] He spoke about the "*...first encouraging leads towards "something we could do"* thereafter.[929]

5.14. During the course of 1982, Dr Smith discussed with PFC whether, and how, Factor VIII could be stabilised for heating.[930] In addition, BPL collaborated with Speywood on polyelectrolyte fractionation.[931]

5.15. However, there was little additional information around this time which was perceived, it seems, to have required consideration. This is perhaps reflected in the decision of the UKCDO Hepatitis Working Party not to meet in August 1982.[932]

5.16. By the summer of 1982, there were rumours that some commercial companies may have had success with heat treatment. However, that information was far from clear. Dr Smith has referred to *"unconfirmed abstracts"*, brief reports and rumours about the methods used in chimpanzees.[933]

5.17. Dr Walford noted that by late 1982, she was aware of manufacturers of commercial Factor VIII working on heat-treating.[934] At that point, whilst concern about the safety of US Factor VIII products had reached the DHSS in July 1982, *"... the exposition of the cause of concern was, at that time, far*

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[927] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §§47-48.
[928] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §55.
[929] Dr James Smith's witness statement, dated 27 July 2020 (WITN3433001), §76.
[930] CBLA0000016_034 at §71.
[931] CBLA0000005_002 at §867. There is a very detailed review of the work at Speywood contained in Dr Walford's witness statement dated 5 July 2021, §25.
[932] Dr Lane's 5th Draft Proof of Evidence (CBLA0000005_002), §553.
[933] CTI's oral presentation on 18 March 2022 about the work and evidence of Dr James Smith, 48:1-48:6.
[934] Dr Walford's witness statement dated 5 July 2021 (WITN4461001), §77.2.

from clear."[935] By June 1983, Dr Walford posed the question to the CBLA whether there were any plans for BPL to develop a heat-treated Factor VIII concentrate.[936]

5.18. On 25 July 1983, Dr Smith sent a memorandum to Dr Lane explaining the preliminary results from work on the PFL heated Factor VIII product, which was heated in solution, noting that one could heat the product at 60-70°C for less than 48 hours, 75°C for about 10 hours or 80°C for about 4 hours without losing more than 5% of factor activity.[937]

5.19. Following further experiments, by 7 November 1983 PFL had produced a heat-treated Factor VIII product which it believed would be effective against AIDS – 8CRV.[938] The CBLA Central Committee for Research and Development in Blood Transfusion recommended it be subjected to clinical trials,[939] but there was a lack of enthusiasm among haemophilia clinicians in relation to the new BPL product:

(1) Dr Lane's account was that;

> *"A protocol was subsequently developed for discussion and agreement with the Haemophilia Centre Directors but this took a long time and in the meantime those Haemophilia Centre Directors I had already approached showed no immediate enthusiasm to use the new BPL product on a trial basis. Our efforts in this regard culminated in our securing three patients only, on which to try out the new heat treated product. The trial in*

[935] CTI written presentation '*Pharmaceutical Companies: Response to Risk*' (INQY0000311), §24.
[936] CBLA0001719.
[937] CBLA0001728. This would appear to be the document which was referred to in the CTI and Inquiry Legal Team written presentation '*Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)*' (INQY0000333) at §243 and during the CTI oral presentation on 17 March 2022, at 18:21-19:4, although the date for the document given in the presentations was 15 July 1983. See too Dr James Smith's account of these developments at CBLA0000016_034, §59.
[938] See the minutes of the 7 November 1983 meeting of the CBLA Central Committee for Research and Development in Blood Transfusion (CBLA0001766), §11.2.3 and the CTI oral presentation on 17 March 2022, at 21:25-22:3.
[939] CBLA0001766, §11.2.3.

actual fact never got off the ground. These three patients were recipients of heated 8CRV in 1984." [940]

(2) In his 3rd Draft Proof of Evidence for the HIV litigation, Dr Smith said that he was *"almost certain"* that Dr Rizza, Professor Bloom, Dr Preston and other Reference Centre Directors were aware that dry-heated 8CRV was available on request in 1984.[941] Despite this, take up was very limited. Dr Smith's view was that by mid-1984, with convincing evidence for a viral aetiology for AIDS and its prevention in patients undergoing trials of heated commercial concentrates, without any marked incidence in inhibitor formation or other detrimental effects, the benefits of heating *"... must be outweighing speculations ..."* about inhibitors and neo-antigens.[942]

(3) That position did not change until 10 December 1984, when a meeting of Haemophilia Centre Directors concluded the harm caused by HIV/ AIDS was greater than the risk of patients developing antibodies.[943]

5.20. Experiments continued at BPL in early 1984, including work on a pasteurisation process and development of a high purity cryoprecipitate extract that was more extensively depleted of fibrinogen, fibronectin and other redundant plasma proteins, which was ultimately dry-heated at 80°C for 72 hours to produce the BPL product 8Y.[944] 8Y was issued in a stage 1 trial in February 1985 and was available on a named patient basis from 1 April

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[940] See Dr Lane's account in his 5th Draft Proof of Evidence (CBLA0000005_002), §932, cited in the CTI and Inquiry Legal Team written presentation '*Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)*' (INQY0000333) at §248.
[941] CBLA0000016_034, §63, cited during CTI's oral presentation on 18 March 2022, at 58:3-58:8.
[942] Dr James Smith's witness statement dated 27 July 2020 (WITN3433001), cited with comment during CTI's oral presentation on 18 March 2022, at 58:23-59:4.
[943] Dr James Smith's 3rd Draft Proof of Evidence (CBLA0000016_034), §63, cited during CTI's oral presentation on 18 March 2022, at 57:22-58:2. See too Dr Perry's evidence that once the BPL product 8Y was available the UKHCDO did not create a system for 'virgin' haemophiliacs to access it; Dr Perry's evidence was that it should have done so and that omission was *"...a lost opportunity"*: Dr Perry's oral evidence on 1 April 2022, at 123:10-124:3.
[944] Dr James Smith's note dated 21 October 2011 at PRSE0004112; the 3rd Draft Proof of Evidence of Dr James Smith dated 1 November 1990 (CBLA0000016_034), §42; the CTI and Inquiry Legal Team written presentation 'Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)' (INQY0000333) at §251.

1985.[945] Dr Smith's written evidence to the Inquiry was that by August/September 8Y was available to all patients whose Haemophilia Centre Director preferred it.[946] By September 1985 at the latest, 8Y was the only Factor VIII product issued by BPL.[947] As the Chair will be aware, 8Y was later shown to inactivate not only HIV but also NANB Hepatitis.[948]

5.21. As was noted in the written presentation *"Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)"* (INQY0000333) at paragraph 254, BPL and PFL continued to heat stocks of intermediate purity Factor VIII products HL and 8CRV (at 70°C for 24 hours) as an interim measure, to provide a heat-treated product before 8Y was issued; and this was agreed with clinicians following a meeting of the Haemophilia Reference Centre Directors at Elstree on 10 December 1984.[949] After 1 February 1985, BPL only issued Factor VIII which had been heat-treated.[950]

5.22. It is evident from the detailed accounts given by Dr Smith and Dr Lane, in particular, that the path to achieving an effective heat-treated Factor VIII product was one of gradual development. Experiments trialled different methods - heating in solution, pasteurisation and dry-heating – used on different products (intermediate purity and high purity), with different temperatures and periods of heating being trialled before the formula for 8Y was settled on.

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[945] CTI and Inquiry Legal Team written presentation '*Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)*' (INQY0000333), §258 and underlying documents referenced therein.
[946] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §56.
[947] Dr James Smith's witness statement, dated 27 July 2020, (WITN3433001), §56; CTI and Inquiry Legal Team written presentation '*Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)*' (INQY0000333), §259 and underlying evidence referenced therein.
[948] As was noted in the CTI and Inquiry Legal Team written presentation 'Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)' (INQY0000333), §230.
[949] The CTI and Inquiry Legal Team written presentation '*Domestic Production and Self-Sufficiency (Chronological Presentation: England and Wales)*' (INQY0000333), §254 and underlying evidence referenced therein.
[950] CBLA0000005_002 at §589 and §980.

5.23. The development of 8Y, particularly at such speed, was *"...a remarkable achievement..."* and a testament to the work undertaken by staff at BPL.[951] As Dr Smith stated in his 3rd Draft Proof of Evidence for the HIV litigation, a programme for developing a product such as 8Y would usually take three years but this was compressed into a few months.[952] In 1986, the Haemophilia Society published an article applauding the speed with which product 8Y had been produced, under the headline "*Factor VIII 8Y – from bench lab to national product in one year*".[953] The article reflected on the safe and effective nature of 8Y.

5.24. Whilst work to develop a heat-treated Factor IX product in fact began before work to develop a heat-treated Factor VIII product,[954] developing and releasing a BPL heat-treated Factor IX product took longer. As Dr Smith explained, there were complications which arose from subjecting Factor IX to heat that did not arise for Factor VIII.[955] Unlike Factor VIII, which became non-functional when over-heated, Factor IX became dangerously activated when over-heated, leading to the formation of protein-altering enzymes, which, in high concentrations, can cause thrombosis on injection. The developments leading up to the release of the BPL product 9A are set out in detail at paragraphs 70 to 86 of Dr Smith's 3rd Draft Proof of Evidence for the HIV litigation.[956] 9A was the only Factor IX product issued from BPL by October 1985.[957] On 7 October 1985, Dr Snape wrote to Regional

[951] Dr Foster's oral evidence on 25 March 2022, at page 103:10-103:12.
[952] The 3rd Draft Proof of Evidence of Dr James Smith dated 1 November 1990 (CBLA0000016_034), §53; CTI's oral presentation on 18 March 22, 54:10-54:19.
[953] PRSE0003186.
[954] See the 3rd Draft Proof of Evidence of Dr James Smith dated 1 November 1990 (CBLA0000016_034), §67.
[955] The 3rd Draft Proof of Evidence of Dr James Smith dated 1 November 1990 (CBLA0000016_034), §69.
[956] CBLA0000016_034.
[957] The date given by Dr James Smith in his 3rd Draft Proof of Evidence of Dr Smith dated 1 November 1990 (CBLA0000016_034) at §85 is 27 September 1985 but he gives the date of October 1985 in his written statement to the Inquiry dated 27 July 2020 (WITN3433001) at §56 and the date given by Dr Lane at §1084 of his 5th Draft Proof of Evidence 9CBLA0000005_002) is October 1985.

Transfusion Centres recalling unused stocks of Factor IX which had not been heat-treated, in a move to protect patients.[958]

Patient information leaflets

5.25. As Dr Perry has noted, until the link between blood products and AIDs was satisfactorily established it was not possible to introduce a warning about AIDs on patient leaflets. In 1983 / 4 there was an awareness of potential risk, but no evidence. According to Dr Perry, had organisations such as PFC tried to put a warning on the leaflets the Regulatory Authorities would not have accepted it.[959]

5.26. Dr Perry noted that the nature of patient care was different at the time. The emphasis was on a 'paternalistic' / 'doctor knows best' system.[960] Dr Perry's understanding was that the responsibility for warning patients about any potential risks was primarily a matter for doctors, rather than manufactures/ suppliers. PFC's role was to provide the best possible information to Haemophilia Directors. It considered its role as involving consultation with them – which it did.[961]

5.27. See also the evidence of Dr Terence Snape upon the process of determining the content of BPL labels,[962] their contents[963] and the intended audience.[964] Mr Richard Gutowski gave further evidence, from the perspective of his period of time working in the Department's Medicines Division,[965] on the role

[958] CBLA0002261.
[959] Dr Robert Perry's oral evidence on 1 April 2022, at 42:25.
[960] Dr Robert Perry's oral evidence on 1 April 2022, at 59.
[961] Dr Robert Perry's oral evidence on 1 April 2022, at 59.
[962] Dr Terence Snape's oral evidence on 30 March 2022 at 60:18 – 64:2.
[963] Dr Terence Snape's oral evidence on 30 March 2022 at 64:4 - 66:25, 67:14 – 68:17; see also the written statement of Dr Snape dated (WITN3431001) §202.
[964] Dr Terence Snape's oral evidence on 30 March 2022 at 62:3 – 62:16.
[965] From 1984 – 1991.

of medical advisors in determining the content of labels and leaflets, and their intended audience of clinicians.[966]

Licensing of the commercial product

5.28. After heat-treated products had been developed, they had still to be licensed and made available to patients. Lord Glenarthur gave written evidence to the Inquiry about the period during which commercial heat-treated products became available, but the BPL product was not.

5.29. The speed of delivery was, ultimately, a question of the manufacturing companies applying to the Licensing Authority so that the latter might consider applications. Lord Glenarthur has stated that he "*...was not aware of any lack of urgency, whether on the part of government or clinicians, to provide for the use of heat-treated Factor VIII...*",[967] a view echoed by Lord Clarke in both of his witness statements, and in his oral evidence.[968] Sir Michael Rawlins stated that he did not know whether licensing could have been achieved more quickly, but that it would have depended on the manufacturers' ability to make such products, make applications for licences (if they decided to do so) and then on the ability of the Medicines Division / Medicines Control Agency to evaluate the submitted data, and possibly the ability of NIBSC to check the quality of samples of material.[969]

5.30. What is known is that the Licensing Authority took proactive steps (on advice received from the CSM) to prompt "*...manufacturing companies concerned* [in the production of factor concentrates] *to make early applications for variations of product licenses to use a dry heat treat process in the*

[966] Third statement of Richard Gutowski dated 19 May 2022 (WITN5292063) §2.3, §2.20, §2.21.
[967] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001) §66.2 (i).
[968] Lord Clarke's first witness statement dated 1 July 2021 (WITN0758001), §0.4. Lord Clarke's second witness statement dated 12 July 2021 (WITN0758012), §71.6. Lord Clarke's oral evidence on 29 July 2021, at 64:22-65:1.
[969] Professor Sir Michael Rawlins' witness statement dated 24 March 2022 (WITN6406001), §17.36.

manufacture of their Factor VIII products". [970] This position is confirmed in both the evidence of Lord Glenarthur[971] and Sir Michael Rawlins[972].

5.31. Thus by the time Professor Bloom wrote to Dr Smithies in November 1984[973] noting his concern that heat-treated concentrates were not freely available in the UK and asking when the licensing of Factor VIII in the UK would be reviewed, the advice had already been given by CSM to the Licensing Authority to approach the manufacturers proactively and to invite applications for abridged product licences or variations so that the heat-treated product would be available on formal licences.[974]

International timelines

5.32. The Chair may wish to have regard to the international perspective when considering the timeline for the development and distribution of heat-treated products in the UK. By way of example only, the point at which all factor concentrates distributed in Canada were heat-treated is identified as July 1985 in the Krever Commission Report.[975] It was in December 1985 that the NHF in America advised that only heat-treated products be provided for all patients with severe haemophilia.[976]

Transmission of HIV and HCV by commercial heat-treated products

Transmission of HIV

5.33. At paragraphs 244 of the written presentation *"Pharmaceutical Companies: Response to Risk"*, CTI referred to the review article from Professor Mannucci in 1995 on 18 "*well documented*" cases of HIV transmission

[970] Sir Joseph Smith's witness statement dated 11 December 2021 (WITN5281001), §3.16(a).
[971] Lord Glenarthur's witness statement dated 9 July 2021 (WITN5282001), §66.2 (iii).
[972] Professor Sir Michael Rawlins' witness statement dated 24 March 2022 (WITN6406001), §17.6-7.
[973] DHSC0001211, discussed in Lord Glenarthur's witness statement dated July 2021 (WITN5282001), §66.2(iii).
[974] Lord Glenarthur's witness statement dated July 2021 (WITN5282001), §66.2.
[975] The Krever Commission Report (https://publications.msss.gouv.qc.ca/msss/en/document-000416/), at page. xxvi.
[976] CTI written presentation '*Pharmaceutical Companies: Response to Risk*' (INQY0000311), §228.

through concentrates that were subject to dry heat treatment at temperatures between 60°C and 68°C.[977] It is noted by CTI that many of these cases were in patients who used batches of Factorate HT (marketed by Armour) that had been subjected to heat treatment, but which contained plasma that had been obtained before the HTLV-III screening test was introduced. In an email from Dr Foster to Dr Perry dated 11 January 2000, which was referred to during CTI's oral presentation on pharmaceutical companies on 23 September 2021, Dr Foster attributed all 18 cases to the Armour Factorate HT product; Dr Foster noted in his email that reports of these transmissions were published in 1988 and 1990.[978]

5.34. When considering the advice given by the CSM and the decisions made by the Licensing Authority in relation to the Armour Factorate HT product, the Chair will be mindful of the need to do so by reference to the information which was available to the relevant decision-makers at the time the advice was given / decisions were made, not information which later came to light. During the CTI oral presentation on pharmaceutical companies on 23 September 2021, counsel addressed the fact that the Licensing Authority had refused to grant a product licence for a Factor IX product which was later considered to be Hepatitis-safe and made this observation:

> *"The further point that I make about this is that the fact that, in 2000, one can look back and say that this was a hepatitis-safe product does not mean that the Licensing Authority somehow got it wrong at the time; they were working with different data and were responding to the application that they had in front of them."*[979]

5.35. By reference to an *"Annotation"* that he wrote for the British Journal of Haematology in 1988 entitled *"Reducing the Risk of Virus Transmission by Blood Products"*, Dr Thomas (of the NIBSC) set out the state of his knowledge about heat treatment at that time in his written statement to the

[977] INQY0000311_0076; the underlying paper at DHSC0038508_045, page. 2.
[978] MACK0002301_022; and Dr Foster's oral evidence on 25 March 2022, at 120:11-120:13.
[979] The CTI oral presentation on 23 September 2021, at 148:20-149:1.

Inquiry at paragraphs 6.1 to 6.5.[980] At paragraph 6.2, he set out this extract from the piece:

> *"...there is as yet no generally agreed approach to removing or inactivating viruses in plasma pools used by manufacturers of clotting factor concentrates. Currently, a variety of techniques is being employed, including dry heating the final product; heating in solution or with steam; employing various solvents; and using partitioning during purification by immunoabsorption, as well as a combination of two of these techniques.... Certainly, there is as yet no universally agreed method for inactivating viruses in clotting factor concentrates, although a consensus is emerging that some techniques may be safer than others."*

5.36. Dr Thomas also explained in his statement that:

> *"Viral-inactivation was a developing area of knowledge. The manufacturers would describe on their product licence applications how they were heat treating the product and we at NIBSC would see that when it came to us from the CSM. We would report back to the CSM(B) and might have discussions with the manufacturers where appropriate. We were not at that stage, however, in any position to decide which processes were more effective, whether 60 degrees for 2 hours or 80 degrees for 8 hours was better for example."*[981]

5.37. The Chair is referred to paragraphs 3.75 to 3.81 of Sir Joseph Smith's written statement to the Inquiry in relation to the response of the CSM to concerns raised by Dr Peter Jones in February 1986 about reports of seroconversion in previously seronegative haemophiliacs being infused with some types of Factor VIII concentrate, including two reports relating to the Armour product.[982] The matter was the subject of a detailed report from Dr Rotblat and was considered by both the CSM and the EAGA in March 1986. Based on the information available to the CSM at the time, it was concluded that there was insufficient evidence for action to be taken on any specific product.[983] This appears to have been influenced by the view that all cases of seroconversion apart from one could be explained by late seroconversion.

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[980] Dr Duncan Thomas' witness statement dated 12 May 2022 (WITN6405001).
[981] Dr Duncan Thomas' witness statement dated 12 May 2022 (WITN6405001), §6.9.
[982] WITN5281001; Dr Jones' letter raising the concerns is at WITN5281047.
[983] See the minutes of the CSM(B) meeting on 5 March 1986 at DHSC0001801 and the CSM meeting on 26 March 1986 (endorsing the CSM(B)'S conclusion) at MHRA0036364_002.

5.38. The discussions which took place between DHSS officials and representatives of Armour following the CSM meeting of 26 March 1986 are set out in the CTI chronology relating to the Armour product Factorate HT at pages 18 to 24 and the full summary given therein is not repeated in these submissions.[984] The Chair is, however, invited to note, in particular, the following:

(1) There were further reports of seroconversions of patients who had received Armour Factorate HT between June and the end of September 1986.

(2) The report of two haemophiliac children who were patients at Birmingham Children's Hospital having seroconverted following a course of treatment with Armour Factorate HT on 29 September 1986 led the DHSS to conclude on 1 October 1986 that one of these seroconversions was probably the result of Armour Factorate HT. Combined with a case of seroconversion in Lewisham, it was the DHSS opinion that there were by this point two established seroconversions associated with the Armour product and it may need to be removed from the market.[985]

(3) DHSS officials met with Armour two days later on 3 October 1986 and indicated that if there was no voluntary withdrawal of the product DHSS would need to consider the case and the course of action to be taken further.[986]

(4) A minute informing the responsible Minister of the position was sent on the same day recording that: *"If the Company refuses to co-operate, it is proposed to issue a formal notice to the Company on 6 October under Section 28(3) of the Act, suspending their licence on grounds of safety."*[987]

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[984] The CTI chronology is at INQY0000386.
[985] See the file note at ARMO0000590.
[986] ARMO0000510.
[987] DHSC0003963_145.

(5) On 6 October 1986, it was confirmed in a meeting with DHSS officials that Armour would withdraw both its Factorate and High Purity Factorate products and would formally surrender these two product licences by letter the same day.[988]

5.39. Whilst the DHSS took the position it did in October 1986 in relation to the reports of seroconversions associated with the Armour product, other countries took a different view. By way of example, whilst the Canadian Red Cross urged that the Armour product be withdrawn, the Canadian Board of Biologicals advised the Red Cross to continue distributing Armour concentrates.[989]

HCV transmission

5.40. It is noted at paragraph 246 of the written presentation *"Pharmaceutical Companies: Response to Risk"* that first generation commercial heat-treated products did not, in general, prevent Hepatitis infections.[990]

5.41. Dr Thomas, in summarising an observation he made in the *"Annotation"* for the British Journal of Haematology in 1988, said this about the difficulties relating to heat treatment at that time:

> *"I was optimistic that 'the risk of HIV seroconversion among patients treated with heat-treated products made from screened donors is now undoubtedly very small,' but warned of ongoing problems with the more resistant hepatitis viruses and the lack of a conclusive test for non-A non-B hepatitis in blood donors."*[991]

5.42. In the absence of a test for NANB Hepatitis, there were real difficulties in assessing whether a heat-treated product effectively inactivated NANB Hepatitis. The 1991 and 1995 studies setting out known NANB Hepatitis

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[988] DHSC0003963_137.
[989] See the Krever Commission Report (https://publications.msss.gouv.qc.ca/msss/en/document-000416/), at page. xxvii of the introductory chronology of important milestones.
[990] INQY0000311.
[991] Dr Duncan Thomas' witness statement dated 12 May 2022 (WITN6405001), §6.9.

transmissions by commercial heat-treated products cited by Dr Foster in his email to Dr Perry of 11 January 2000,[992] contained information which would not have been known by the Licensing Authority, the CSM or the NIBSC at the time that applications for product licences for heat-treated products were being made.

5.43. Concerns were raised by Dr Thomas in January 1985 arising from three sets of data for heat-treated Factor VIII provided by Miles, Travenol and Immuno.[993] These concerns related to the discrepancies between the processes of different manufacturers. Dr Thomas referred to the decision of the Licensing Authority to 'deal with the matter "in house" and not refer to the CSM. It was his view expressed in his written statement to the Inquiry that the Licensing Authority should have sought advice on from the CSM(B) / CSM.[994] The Chair may wish Dr Thomas' evidence in this respect in light of his observations about the state of knowledge of decision-makers at the time in relation to the effectiveness of heat treatment in inactivating viruses, particularly NANB Hepatitis.

5.44. The fact of HCV transmissions by imported commercial heat-treated products after 1985 has been raised with a number of departmental witnesses, including Hazel Blears[995] and Alan Milburn[996], in the context of information being provided within and by the Department in 2001 and 2002. Some lines to take / briefings and external publications from the Department suggested that heat-treatment effectively protected haemophiliacs, including against HCV, from the mid-1980s. This was to focus on the BPL NHS product, without qualification or acknowledgment of the continued role of imported commercial products and the issues summarised above, or

[992] MACK0002301_022.
[993] Dr Duncan Thomas' witness statement dated 12 May 2022 (WITN6405001), §6.14 and his letter to Dr Duncan dated 8 January 1985 at MHRA0019502.
[994] Dr Duncan Thomas' witness statement dated 12 May 2022 (WITN6405001), §6.15.
[995] See Hazel Blears' oral evidence on 21 July 2022, at 155:2-158:24.
[996] Alan Milburn's oral evidence on 14 July 2022, at 41:12-43:22.

separate issues concerning the heat-treatment chronology for the PFC in Scotland.

Section 6: Reform of the Blood Services' structure

The organisation of the Blood Services

6.1. The topic of the organisation of the Blood Transfusion Service in England and Wales, together with Scotland and Northern Ireland, is dealt with thus in the Inquiry's List of Issues: "*Why was there no centralised system for meeting the UK's requirements for blood and blood products? Should there have been? What difference might this have made?*" (Inquiry's List of Issues, paragraph 27). This Section discusses some of the matters that may be considered relevant, from the perspective of the Department of Health, which historically has had responsibility for health services in England and has (in very general terms) co-ordinated its activities, over the years with the administrations or governments in Wales, Northern Ireland and Scotland.

6.2. The Inquiry's Public Health and Administration Expert Group's Report has noted (page 25) the early decision to not to include a clause in the draft NHS Act 1946 that would have given Ministers in England and Wales the power to make arrangements for securing a supply of blood and blood products and making them available for treatment in these territories. The '*scene was set*' for more localised development of the blood service and its donor panels from that date. These founding arrangements from the 1940s contrast with the more centralised management arrangements that would be necessary for the management and funding of fractionation facilities, given their size. Further, the NHS Act 1946, which established the NHS with effect from 5 July 1948, covered only England and Wales. The Scottish NHS was constituted separately via the NHS (Scotland) Act 1947, under which the NHS in Scotland was accountable to the Secretary of State for Scotland.

6.3. The Inquiry will further be aware of the history of NHS reorganisation, and in particular, the major reconfiguration that took place in 1973/1974 (following planning dating back at least to 1970). Unified NHS management was created to manage, for the first time: "... *the hospital and specialist services*

now administered by the Regional Hospital Boards, Hospital Management Committees and Boards c [sic] Governors; the family practitioner services now administered by the Executive Council [and] the personal health services now administered by the local authorities through their health committees…".[997] As part of these widespread reforms, new Regional Health Authorities were envisaged (and created in 1974[998]) to co-ordinate and direct the Area Health Authorities. They were to embody the virtues of local knowledge:

> *"32. In theory, the regional organisation necessary in England could take the form of regional offices of the central Department. In practice, they would be much less effective than separate regional authorities.*
>
> *33. To place the whole job on the central Department and its regional offices would result in over-centralisation and delay; it would draw the Department into many matters that should be resolved locally or regionally; and it would distract the Department's attention from the policy tasks which must be done centrally and which are its proper concern.*
>
> *34. There is also a positive case for separate regional authorities rather than regional offices of the central Department. Each regional authority will be a body of local people knowledgeable about their region's needs...."* [999]

6.4. The RHAs were specifically charged with running the blood transfusion service. The 1972 White Paper stated, under the heading of the "*Other Services*" to be run by RHAs: "*These will include the provision of a blood transfusion service; and the sponsorship of some research projects, including regional epidemiological studies..."*[1000] So there had been, at that point, a positive political decision to locate the management of the blood services in new organisations that were meant to avoid the vices of over-centralisation and to draw on local knowledge.

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[997] See the White Paper, "National Health Service Reorganisation: England" of August 1972 (Cmnd. 5055), Section III, para 17.
[998] Under the National Health Service Reorganisation Act of July 1973.
[999] See the White Paper, "National Health Service Reorganisation: England" of August 1972 (Cmnd. 5055), Section IV, para 32 - 34.
[1000] See the White Paper, "National Health Service Reorganisation: England" of August 1972 (Cmnd. 5055), Section VIII, para 83.

6.5. It is not apparent, at least in terms of evidence heard by this Inquiry that an acute sense of the potential tensions between the structures for the supply of blood donations and the pan-England/Wales needs of BPL, emerged until the issue of increasing the supply of plasma to BPL, became a real one, i.e. in or by 1973/74. That is, the system of regional organisation of blood supplies appears to have managed the supply of blood and the production of cryoprecipitate adequately, even though some areas would have heavier needs, and at times there were shortages in some areas that required sharing arrangements to be made and increasing debate upon these issues (see the BMJ Editorial of 1974 cited by the Expert Group).[1001] In other words, the Inquiry may consider that there was no pressing need for a more centralised system to be considered until that date and that it may not be realistic to conclude that a centralised system "*should*" have been introduced before the point at which the need to generate increased 'central' supplies became evident.

6.6. We note that the BMJ editorial, referenced above, argued that there had been a "*...steady decline in the British Blood Transfusion Service since the late 1950s...*"[1002], that there had been no national planning and that staff, accommodation and equipment were lacking in the regional centres and fractionation centres. Whilst this may be indicative of the issues faced at that point, it would be difficult, it is suggested, for the Inquiry to gain a full picture of the state of the Blood Services in the 1960s, or for it to review, now, the decision that was taken in the early 1970s, to place the Blood Services within the new regional system that was then created. It might be thought that those involved at the time reasonably thought that this would be an appropriate means of achieving any necessary increases in the capacity for

[1001] The Expert Report on Public Health and Administration references (p25) a BMJ Editorial from 1974. This is to be found at Br Med J 1974: 3:212 (27/07/1974). It discusses the debate generated by Titmuss's tract (1967) on the Gift Relationship, which it considered had consumed time and effort and generated heat, but "in the presence of so little data". The data on blood donations suggested that "In 1967-68 there was no widespread shortage but some isolated and atypical regions with specific difficulties." However: "The increasing demand for red cells and platelets over the last fie years has produced moderate difficulties in some regions, but it is now apparent that there is a serious national shortage of certain plasma fractions." It referred to the introduction of commercial products to fill the resulting gap.
[1002] BMJ Editorial, Br Med J 1974: 3:212 (27/07/1974).

co-ordinated planning, etc. Certainly, the question of NHS system reform received full attention at that time (see the history of the 1974 reorganisation referred to above).

6.7. Thus, the Inquiry's question "*should there have been [a centralised system]*"[1003] implies an issue as to whether or when should such a system should have been introduced: perhaps at a point between c.1973/74 (when the needs for increased blood donations was first scoped out by the Expert Group) and 1993/94 (when the National Blood Authority) was established (1993) and became fully operational (1994). The identification of the need for increased blood donations in the early 1970s came broadly at the same time as, or very shortly after, the major reorganisation that saw RHAs established. The issue of a centralised system then remained a matter of debate and was not resolved until 1993/94, when the NBA was established, in April 1994.

6.8. In relation to the role of the RTCs and the supply of plasma to BPL from this point in 1973/74 onwards, the challenges caused by the absence of a central planning organisation and the variations in, e.g., quality and standards that ensued have been set out in a number of sources of evidence to the Inquiry: see for example the (i) draft proof of evidence from Dr Lane, paras 74 – 76; (ii) the views of the Regional Transfusion Directors, as set out in their submission to the Royal Commission on the NHS; (iii) the views of Dr Gunson, as set out in his evidence in the case of A and Others v National Blood Authority,[1004] and supported by the evidence to the Inquiry of Professor Dame Contreras;[1005] or (iv) the witness statement of Peter Wormald, which refers to the views held at the time when he was in post.[1006] This list is not exhaustive and these submissions do not seek to rehearse or repeat that evidence.

[1003] Inquiry's List of Issues, paragraph 27.
[1004] NHBT0000026_009.
[1005] Professor Dame Contreras's witness statement dated (WITN5711001) at §222-§224 in particular.
[1006] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001) §35.4.-§35.5.

6.9. The case for change is made out in the views noted at (i) - (iii) above, for example, and these submissions will not repeat that evidence. However, as to the response of Government to this situation, a problem for each successive administration would include that the organisation was an inherited 'given'. The question was whether to seek to reform it, or to leave it alone and to work with the inherited system, perhaps coupling that with limited improvement.

6.10. In relation to the assessment of the merits of those alternatives, the Inquiry is invited to take the following into account when making its assessment:

(1) The "*prevailing wind*" during the 1970s, when the issue was first raised by reference to the issue of blood supplies and self-sufficiency, and was in favour of localism and devolution. See not only the observations on the 1973/1974 reforms above, but the report of the Royal Commission on the NHS (1979), both in relation to its broad focus on recommendations that supported devolution, and the narrower point that, despite having received a submission from the Regional Transfusion Directors setting out the case for change, it failed to make any recommendations upon the future of the National Blood Service. (This is not to say, of course, that the absence of recommendations from the Commission prevented action, but it did mean that it was not positively encouraged or highlighted as requiring action).

(2) It may be fair to say that for some, and perhaps many, local control and direction was seen as a strength (visible in, for example, the later initiative of Dr Gillon in SE Scotland, in introducing a lookback exercise in advance of the rest of his colleagues).[1007] This reflects a longstanding debate over the merits of 'central direction vs localism', or devolution of powers. For its expression in the Blood Services,

[1007] See too the comments of Sir Kenneth Calman, who commented on the issue of localism, with reference to the Lookback exercise: Written Statement of Professor Sir Kenneth Calman dated 12 October 2022 (WITN3430001), §§29.1-29.2.

please see the evidence of the time taken for reform in 1991 – 1993/94, leading up to the creation of the NBA.[1008] There were a host of issues to be addressed, but amongst them was resistance on the part of RTCs, who were suspicious of 'centralisation' or centralism, and the potential for what would be perceived as the unfair allocation of resources.[1009]

(3) Consistently with this approach, Ministers were not advised to take steps to reform the NBTS in the late 1970s/early 1980s. See the Written Statement of Mr Peter Wormald.[1010]

(4) Part of the reason for that advice was, perhaps, that change takes time and resources, in a system in which both of these are limited and choices have to be made. See the Report of the Expert Group on Public Health and Administration on the costs of frequent reorganisations to the NHS (p21).

(5) Mechanisms for the co-ordination of standards across the blood service did develop, albeit on a gradual basis, including, from 1982, the facility and quality audits of RTCs established by Dr Snape of BPL,[1011] or the 'Red Book' which set national quality standards from 1989 onwards.[1012]

(6) Incremental steps were taken, both in relation to issue of plasma supplies to BPL (where Dr Lane championed but the DHSS supported, the shift to 'pro-rata' supplies in order to incentivise supply to the fractionation facility[1013]) and at an organisational level: see the creation of the Joint Management Committee in 1978, the Central

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[1008] See the Annex to the Written Statement of Professor Sir Kenneth Calman dated 12 October 2022 (WITN3430099), §§ 28.4-28.44 for a detailed account of its introduction.
[1009] See for example the Annex to the Written Statement of Professor Sir Kenneth Calman dated 12 October 2022 (WITN3430009), §§ 28.14 as well as the Written Statement of Baroness Hooper dated 14 June 2022 (WITN7005001), §§ 31.42. Or see the letter dated 8 November 1991 at DHSC0004584_029.
[1010] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001) §54.1-§54.7.
[1011] Dr Terry Snape's written statement dated 8 February 2022 (WITN3421001) §206; also page119 at §24-§26.
[1012] Professor Dame Contreras's witness statement dated (WITN5711001) at §226(f). There was further evidence given orally by Professor Contreras on guidance published, including the 'Notes on Transfusion' that dated from 1973. See the oral evidence of 3 December 2021, 1:11-2:20.
[1013] This is not to ignore the limitations of the pro-rata system; see for example Dr Snape's witness statement dated 8 February 2022 (WITN3431001) at §28.2, page 36.

Blood Laboratories Authority in December 1982 and (more strikingly) the creation of National Directorate of the National Blood Transfusion Service in 1988.

(7) In relation to this step, the evidence of Dr Roger Moore[1014] was that this was not only a positive change that worked well, but that it laid the foundation for the more radical or complete change that eventually took effect in 1993/94 with the creation of the National Blood Authority. This took some 2 – 3 years of careful planning work; see the evidence of Professor Sir Kenneth Calman, in particular the Annex to his statement at paras 28.4-28.44.[1015]

6.11. The Inquiry may feel that some of the issues, and the potential obstacles to change, were reasonably set out in the witness statement of Mr Peter Wormald.[1016] The view of Mr Wormald was that a more centralised organisation would not necessarily have helped, and significant other obstacles would have first needed to be overcome to effect change, such as obtaining broad support across the NHS. As explained by Mr Wormald, this would require extensive consultation and a great deal of preparatory work, such as ultimately occurred in the run up to the creation of the National Blood Authority in 1993.

6.12. Further, the discussion above centres upon the question of centralising blood services in England, which is what occurred in 1993. Given the reality of a separately administered NHS in Scotland, including the existence of a separate blood service in Scotland (SNBTS), it seems improbable that any centralisation of services would ever have included Scotland. As a result, the Inquiry is invited to consider that it is unlikely reorganisation would have impacted on PFC/BPL co-ordination or joint planning, or the need for central

[1014] The Written Statement of Dr Roger Moore dated 5 December 2021 (WITN6919001), §149.2.
[1015] Annex to First Written Statement of Professor Kenneth Calman dated 12 October 2022 (WITN3430099) §28.4-28.44.
[1016] Peter Wormald's witness statement dated 4 November 2022 (WITN6934001) §56.2-56.7.

direction to have enabled the processing of any 'northern' plasma at PFC, for example.

6.13. This touches on the second part of the question in the Inquiry's List of Issues is *"would it have made a difference"*; presumably, in the period up to 1993/94, when the NBA was created, and, potentially, by the mid-1970s, i.e., by the time that commitment to rebuilding BPL (or PFC) with a much greater capacity would have been needed, if the history of achieving self-sufficiency was to have been substantially affected. The DHSC acknowledges the uncertainties in this issue, involving issues of 'what if', and the comments which follow are offered are subject to that observation on the uncertainties involved.

6.14. It is apparent that the tools of 'exhortation and persuasion' used to get RTCs to increase the flow of plasma to BPL could, with concerted efforts at reform, have been replaced by more a system involving more centralised 'command and control', and a greater ability to allocate investment resources to support increased demands on RTCs. However, the Inquiry is invited to consider how marked the difference would have been, in practice. The process of setting targets for the RTCs was one involving local knowledge and input, and the Inquiry is invited to consider the extent to which the process of input and negotiation would have been likely to have changed, in practice.[1017]

6.15. The process of exhortation, coupled with the investment of not only the £500,000 committed by Dr Owen, but also a further £433,000 in the financial year 1975/1976 (see CTI's submission on Domestic Self-Sufficiency (England and Wales regarding the use of Lord Owen's funding, at para 108), led to the initial target for increased plasma supplies being achieved in 1977. Thereafter, further plasma supply increases were achieved to enable the increased production capacity achieved by 'stop-gap' to be fully used. The

[1017] This issue engages the issue of the difficulties of securing change in a complex system such as the NHS.

Inquiry may wish to consider whether it was in reality the capacity of BPL that was the key determining factor, rather than plasma supply.[1018]

6.16. Over those years, the processes that did emerge to create a better balance between the potential demand for blood products, and incentives to supply them, were, first, the introduction of the pro-rata system (by 1 April 1981) and, second, the cross-charging system introduced in 1989.

6.17. Finally, one of the central issues relating to the development or redevelopment of BPL were the funding constraints linked to the careful scrutiny and control of development plans by the Department. Given the sums involved in the repurchase of the Lister site and (in particular) the rebuilding of BPL, a more centralised blood service would not have side-stepped those constraints. That is, Ministers, including the Treasury, would still have been required to agree the overall budget and to commit the additional sums needed to rebuild BPL, with all the time implied for that scrutiny to take place.

Centralisation and screening or testing

6.18. In relation to the introduction of screening or surrogate tests for Hepatitis C, it might be thought unlikely that a more centralised system would have influenced events. Even prior to the reforms of 1993/94, there was a strong view that a nation-wide approach needed to be taken to the timing of the introduction of tests. The decision of Dr Lloyd to start earlier in 1991 (before September and contrary to the central planning exercise) was an expression of the freedom possessed by local RTCs; whether that might have been more difficult under a reformed NBA is a matter for speculation.

[1018] Dr Snape's witness statement dated 8 February 2022 (WITN3431001), §239.

6.19. The same applies to the earlier introduction of HTLV-III tests. The Inquiry has heard (egg from Professor Tedder[1019]) cogent evidence upon the need to co-ordinate the roll-out of testing, so as to avoid higher-risk individuals donating blood in order to ascertain their status. That was an issue which was considered in relation to rolling-out testing in GUM clinics, but it also underlines the rationale of the approach to a co-ordinated roll-out of the tests within the transfusion service. See, thus, the evidence of Sir Liam Donaldson on the 'central' reaction to the early introduction of such testing, again in Newcastle, in 1985.[1020]

6.20. The Inquiry has heard that the Regional Blood Transfusion Service was in competition for scarce resources, when seeking the allocation of funds from RHAs.[1021] A centralised system would, presumably, have diminished the potential for inconsistency of approaches between Regions, but not – perhaps – the overall pressures created by the issues of finite health funding. The Inquiry has recently received evidence from Sir Liam Donaldson upon the relative priority afforded to issues regarding the safety of blood transfusion, and the importance of the personal interventions of the CMOs in championing the "Better Blood" and "Serious Hazards of Transfusion" initiatives, to raise the profile of this issue.[1022]

[1019] Oral Evidence of Professor Richard Tedder dated 14 October 2022, 52:17 – 53; written Statement of Professor Tedder dated 31 August 2022 (WITN3436003) at §271, Q46 and §277 - §278. Written statement of Professor Weiss dated 23 June 2022 (WITN686001), §5.98 – §5.99.
[1020] Written statement of Sir Liam Donaldson dated 14 December (WITN7557001), §7.7.
[1021] Written statement of Sir Liam Donaldson dated 14 December (WITN7557001), §14.3.
[1022] Written statement of Sir Liam Donaldson dated 14 December (WITN7557001) §42 - §52.3, especially §50.1 and §52.

Section 7: Hepatitis C testing

Decisions relating to the introduction of Hepatitis C testing

7.1. The Chair is tasked with considering a large number of issues which relate to screening for Hepatitis C. An exhaustive exploration of all of the decisions concerning the introduction of Hepatitis C screening is not attempted here. Instead, these submissions seek to focus on the key developments and decisions relating first to the decision not to introduce surrogate testing in the UK, and second, in relation to the timing of the introduction of routine screening for Hepatitis C.

7.2. This section focuses upon the period between 1986, when the USA announced its decision to introduce surrogate testing, and September 1991, when screening for Hepatitis C was introduced in the UK. The Chair is invited to approach these issues against the context of what was known about NANB Hepatitis at the relevant time as set out in the section of these submissions on *"Knowledge of NANB Hepatitis between 1970 and 1991"*. Further, it is observed that much of what is known about Hepatitis C was discovered after 1991 when testing was implemented.

7.3. As with the state of knowledge surrounding the natural history of the disease, the state of knowledge in respect of screening and measures which could be used to prevent NANB Hepatitis developed incrementally. Ministers and officials were reliant on the advice and expertise of their scientific advisers in order to keep abreast of the changing landscape. In early 1988, ministers were advised that there was a need set up a body to advise the health departments on the virological safety of the blood supply. The ministerial briefing referred to screening of blood to ensure its safety, and noted that historically the blood transfusion services had adopted screening procedures in an ad-hoc fashion. It was thought that an advisory group was needed, comprised of experts from multiple disciplines able to

undertake a broad assessment of clinical and scientific matters, as well as issues surrounding practicality and the cost/benefit of testing.[1023]

7.4. The Advisory Committee on the Virological Safety of Blood ("ACVSB") was therefore set up in early 1989 to "*...advise the Health Departments of the UK on measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing.*"[1024] The ACVSB became the appropriate source of advice for the Department in relation to decisions regarding screening of blood, [1025] and therefore features heavily in the following submissions on screening decisions. Before addressing the decisions on screening, this section addresses the following preliminary matters in relation to the ACVSB:

(1) The membership of the Committee;

(2) The confidentiality of ACVSB meetings; and

(3) The decision making process of the ACVSB.

The membership of the ACVSB

7.5. The idea was that this new group should consist of members from a range of disciplines, able to represent the interests of the National Institute of Biological Standards and Control, the BTS and the fractionators. The desire was for there to be sufficient expertise so that clinical and scientific issues could be considered in a practical context. Officials suggested that the advisory body should be chaired by the DCMO who would report formally to the CMO.[1026]

7.6. The membership ultimately comprised of a representative from NIBSC, BPL, PHLS and the blood transfusion service, as well as leading haematologists

[1023] See letter at PRSE0004664, together with draft submission at PRSE0003956.
[1024] ACVSB terms of reference at PRSE0001189.
[1025] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §51.3.
[1026] See draft submission at PRSE0003956.

and virologists.[1027] The Committee was initially chaired by Dr Harris, who was then succeeded as DCMO by Dr Metters, after which Dr Metters took up the role. There were observers from both the Department of Health and the other home nations. In his written evidence to the Inquiry, John Canavan described how the Committee's 'members were some of the most eminent practitioners in this field in the country.' He noted how the Committee was chaired by the DCMO and describes the significance of this:

> *"It meant that although the ACVSB was an advisory committee, it had a very senior official as its chair. Dr Harris or Dr Metters were well placed to direct that a submission on a particular issue discussed in the Committee should be put promptly to the CMO or ministers. If either of them was in any doubt about an issue, then they could have gone straight to ministers for a decision. This was not the case of a committee made up entirely of outsiders with me as the Administrative Secretary then disseminating the advice. The Committee was wired into the Department through its chair."*[1028]

7.7. Today, it would be contrary to accepted practice for an independent advisory committee to be chaired by a senior official from the Department. There is now a Code of Practice applicable to Scientific Advisory Committees ("SACs") and Councils, with the latest version stating that:

> "*Generally, government officials should not be appointed as members of SACs as it may lead to a conflict of interest and could compromise the perceived independence of the SAC. SACs may invite officials to provide expert opinion or information, to speak to inform a particular agenda item; or to join as non-participating observers.*"[1029]

7.8. Such Codes did not, however, exist at the material time. The earliest edition of the Code of Conduct dates from December 2007, and did not contain this

[1027] Membership details at PRSE0001865.
[1028] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.8.
[1029] Government Office for Science Guidance, 'Code of Practice for Scientific Advisory Committees and Councils: CoPSAC 2021, updated 14 December 2021 at 5.2. Available at https://www.gov.uk/government/publications/scientific-advisory-committees-code-of-practice/code-of-practice-for-scientific-advisory-committees-and-councils-copsac-2021#recruitment-remuneration-liability-and-indemnity-of-members.

requirement. Rather, it made a more general reference to the need for each Scientific Advisory Group to be seen as independent of government.[1030]

7.9. It appears that the decision to have the ACVSB chaired by the DCMO originates from Dr Harris' initial proposal that the group be set up as working group under the Advisory Committee on the NBTS under his Chairmanship.[1031] There appears to be no suggestion that this was challenged or considered unusual at the time, and John Canavan's evidence, outlined above, sets out his views of the advantages of the Committee being chaired by the DCMO.

7.10. Dr Rejman commented on the consequences of the Committee being chaired by the DCMO:

> *"And it was obviously Dr Metters, as chairman of that committee, it was his role to make decisions about, well, this is something we need to send to ministers. And obviously he was much higher up the hierarchy, and therefore he would be much more attuned to what would be -- what ministers would want to know and what they should know. Not only what they wanted to know but what they should know."*[1032]

7.11. In respect of Dr Metters' role as chairman of the ACVSB, Dr Pickles evidence to the Inquiry was that Dr Metters was "*...a very good chairman*":

> *"Dr Metters was really very careful and proper in making sure he got a view round the table. Not always recorded in the minutes of what every individual said but he made sure he was reflecting on the views of the Committee and that was not the secretariat; that was of the Committee."*[1033]

7.12. John Canavan described Dr Metters in the following terms, which the Inquiry may think are consistent with the observations of Dr Pickles:

[1030] Government Office for Science, 'Code of Practice for Scientific Advisory Committees', December 2007 at §84.
[1031] PRSE0002705.
[1032] Dr Rejman's oral evidence on 10 May 2022, at 35:8-35:15.
[1033] Dr Pickles' oral evidence on 12 May 2022 at 137:17-22.

> *"Dr Metters was hugely experienced, a heavyweight character and a very good chairman. There were various disciplines around the table and Dr Metters allowed them to put in their opinions and advice. He was good at drawing the threads together. He was also politically astute and alive to the possible repercussions of the Committee's advice and decisions. I have very little recollection now of Dr Harris."*[1034]

7.13. There is thus evidence to suggest that Dr Metters carried out his role as Chairman in a balanced way, ensuring that he obtained and reflected the views of all those within the Committee.

7.14. One issue which has been raised in the course of evidence, is whether the Committee had insufficient public health expertise.[1035] Dr Pickles, who herself was a public health expert,[1036] addressed this in her oral evidence to the Inquiry:

> *"I'm not sure what the contribution would have been at that time that would have been helpful to the debate. I think either here or somewhere it was being suggested that public health would have particularly been concerned about the impact on the recipients. Can I say that, looking around that table, I didn't have any doubt that everybody was concerned and very conscious of the impact on recipients of blood. That was a given, that was well understood. And indeed, one of the greatest advocates for that was -- in my memory, was Philip Mortimer, who is one of the virologists who is here being criticised.*
>
> *... [T]he Committee reported up to the Chief Medical Officer [Dr Acheson], who was a public health specialist being an experienced epidemiologist, and of course his view, when seeing comments about HCV screening in particular, was, really, what was the science? What's the prevalence? What's the predictive value? So reminding that public health people particularly like working with data and would not have appreciated the lack of data there was here."*[1037]

7.15. She continued:

[1034] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.9.
[1035] This was a view advanced by Dr Perry who was a member of ACVSB between 1991 and 2004; Dr Perry's oral evidence on 1 April 2022 at 136:22-139:3.
[1036] The full details of Dr Pickles' qualifications and career are set out in her Statement at [WITN6965001] but they include specialist accreditation in public health [§2.1] and posts as Acting Consultant in Public Health Medicine, Director of Public Health at Hillingdon HA and Hillingdon PCT and Director of Public Health Policy at PHLS.
[1037] Dr Pickles' oral evidence on 12 May 2022 at 130:19 - 131:15.

> *"The net outcome of that is I wouldn't necessarily assume that public health would have pushed for greater screening, earlier screening, than not having public health there."*[1038]

Confidentiality

7.16. Another issue which arose during the course of the Inquiry was whether the meetings of the ACVSB ought to have been treated as confidential. Again, it is recognised that the outcome of most meetings of scientific advisory committees today would be made public. However, at the time, it was common practice for meetings of scientific advisory bodies to be confidential. We have already referred to the absence of a Code on procedures for Scientific Committees, at the time. The exact chronology in change of practice regarding public access to meetings or minutes is beyond the scope of these submissions. But we note the example of meetings of the Spongiform Encephalopathy Advisory Committee ("SEAC"), which were confidential until late 1997, after which the practice of issuing a public statement or summary of discussions after meetings had been held was instituted.[1039] It appears to have represented a compromise: thus SEAC members discussed the issue of public access to meetings at its 23rd meeting on 5 January 1996, where concerns were raised about the loss of access to data and discussions being inhibited should the meetings be made public.[1040]

7.17. This issue was addressed in the BSE Inquiry Report which was published in October 2000. Lord Phillips concluded that "*...there is inevitably a tension between being open about the details of the discussions of advisory committees and maintaining a lack of inhibition on the part of those involved in those discussions.... We do not find that the BSE experience provides a clear answer to the question of where precisely freedom of information*

[1038] Dr Pickles' oral evidence on 12 May 2022, at 132:14-132:18.
[1039] We have not traced the full history, but the "first go" at such a Statement dates from 22 September 1997; see DHSC0004550_109 and DHSC0004550_110.
[1040] CABO0000577_001.

should give way to the pragmatic requirements of confidentiality""[1041] This can be contrasted with the current Code of Practice for Scientific Advisory Committees and Councils, which indicates that *"...scientific advice to Government should be made publicly available unless there are over-riding reasons, such as national security or the facilitation of a crime, for not doing so."*[1042] It appears that there has been a shift in the approach to discussions of scientific advisory groups over the period under consideration by the Inquiry.

7.18. Dr Rejman's evidence, in both his oral and written evidence to the Inquiry, may be regarded as summarising the approach that was accepted at the time. He set out three reasons as to why the discussions were confidential:

(1) To ensure full and frank discussions could be held, and that contributions were not limited due to fear about press publicity or criticism by colleagues;

(2) To allow ministers to fully engage with the recommendations of the Committee; and

(3) Due to issues surrounding commercial confidentiality.[1043]

7.19. Dr Rejman did not believe that publishing discussions but with redactions would have been practical.[1044] He resisted the suggestion that confidentiality was designed to protect the Committee and the Department from criticism, noting:

> *"I do not believe that every single thing that was said at ACVSB was confidential to the Committee. And we've got minutes from Scotland, for example, where it was quite obvious that Ruthven Mitchell had*

[1041] Report of the BSE Inquiry, Volume 11, Chapter 4 (*"The Spongiform Encephalopathy Advisory Committee (SEAC); Lessons to be learned from the use of SEAC"),* §4.771 – §4.772; Lord Phillips discussed the Office of Science and Technology's "*Guidelines 2000 on Scientific Advice and Policy Making".*
[1042] Code of Practice for Scientific Advisory Committees and Councils: CoPSAC 2021 - GOV.UK (www.gov.uk).
[1043] See Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§15.1-15.2, Dr Rejman's oral evidence on 11 May 2022 at 63:1-64:7.
[1044] Dr Rejman's oral evidence on 11 May 2022, at 64:23 – 65:6.

> *discussed things that had been discussed at the ACVSB with Professor John Cash, for example. So, therefore, confidentiality had been breached in a sense, but I think with confidentiality -- I don't think anybody in the Department, or Dr Metters for his part, would have said to people, 'No, you cannot say anything about what we've said to anybody', because after all one of the points of the Committee was to try to get as much of information as we could."*[1045]

7.20. Dr Pickles evidence to the Inquiry was that the "*...reason for confidentiality was to ensure there were no misunderstandings or mixed messages about committee decisions, most especially those which were market sensitive or risked being exploited for commercial gain.*"[1046] Similarly, when asked whether there was a disadvantage in that others couldn't question what the committee was doing, Dr Pickles noted that:

> *"[Confidentiality] also protects the Committee from ill-informed lobbying from certain interest groups. I mean, the intention was to have a balanced Committee so all these issues could be weighed against each other, and a sensible decision reached."*[1047]

Decision making process

7.21. The minutes of the meetings of the ACVSB generally set out the views and opinions expressed by particular members, before the Chair set out a summary and consensus view on how a particular topic should be approached. It also appears that where members wanted a particular view to be expressed by the minutes, they would ask for this. An example of this can be seen in the minutes of the fifth meeting on 17 January 1990, where there is a summary of the input from various members on the topic of Non-A Non-B Hepatitis Cost Benefit Analysis, before the Chairman summed up the general consensus. There was also a note that "*...Dr Tedder wanted it to be noted that he would not give an opinion before more scientific data had been generated*" suggesting that his opinion differed slightly from that of the whole committee.[1048]

[1045] Dr Rejman's oral evidence on 11 May 2022, at 65:12-65:25.
[1046] Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §18.2.
[1047] Dr Pickles' oral evidence on 12 May 2022, at 142:5-142:9.
[1048] PRSE0001477.

7.22. The evidence before the Inquiry otherwise appears to suggest that there was genuine agreement across the committee for the most part, which informed the decisions being made. Dr Rejman summarised the decision making process in his oral evidence in the following way:

> *"I cannot recall occasions when the chairman actually asked for a vote because, obviously, if you had a vote then you'd have to have all this argument about does the chairman have a-- if it's a split vote does the chairman have a vote? So don't think there was ever any suggestion of a vote in that sense…*
>
> *Well, you see, obviously this is a long time ago and I may have confused this with other committees, but my understanding -- my recollection for the best that it is, is that Dr Metters would actually go round the table, and I think he was quite keen that people said something. So, for example, if we were discussing a particular topic and if somebody had said nothing at all about that topic, he might quite easily say to somebody "Dr So-and-So, have you a view?" or "Do you agree?" or whatever. So I think when he sums up, it's the summation of the general mood of that committee meeting.*
>
> *And there hasn't been a vote because, in a sense, usually the majority of the people would agree a particular line."*[1049]

7.23. Similarly, Dr Pickles' evidence in respect of the introduction of screening tests for HCV was that:

> *"I do not recollect at any time that the judgement was even finely balanced within the Committee to go earlier.*
>
> *I think, in principle, everyone agreed, yes, this is something we're going to have to do and want to do but the time is not right because the science is not there. So that was the feeling I had."*[1050]

7.24. Lady Hooper gave evidence on the practice that she understood should be followed in a Committee, explaining that consensus views were put to ministers, but *"...a consensus view means that it has been finally agreed by the whole group, including whoever may have disagreed… Unless there is -- unless the individual concerned explicitly asks for a minority opinion to be*

[1049] Dr Rejman's oral evidence on 11 May 2022, at 71:21- 72:25.
[1050] Dr Pickles' oral evidence on 12 May 2022, at 134:23-135:4.

given. I mean, I think that's the usual way of dealing with that."[1051] Discussing the meeting of the ACVSB in January 1990, she noted that "*...the whole Commission, I imagine, would have been shown the summing up that Dr Metters made"* and there was discussion of the fact that the minutes were agreed at the following meeting, including by Dr Mortimer.[1052] Whilst there has been exploration in the Inquiry of the issue of whether *minority* opinions should, as a matter of good practice, be recorded and reported to ministers, the Chair may consider that there is little if any evidence to suggest that minority opinions were expressed but not adequately recorded. Of course, *differing* opinions are always likely to arise in collective discussions, and it may be thought there is a difference between a mere difference of opinion or difference of emphasis in collective discussion, and a minority opinion in the sense of a member disagreeing with the collective view of the Committee reached after discussion.

The decision not to introduce surrogate testing

7.25. The Inquiry's List of Issues sets out a number of issues concerning surrogate testing for NANB hepatitis, including:

(1) Should surrogate testing have been introduced across the UK, and if so, when?[1053]

(2) What difference might surrogate testing have made to the number of people infected with HCV?[1054]

(3) What consideration was given to the use of surrogate testing in other countries?[1055]

(4) What cost/benefit analysis was undertaken in relation to the possibility of introducing surrogate testing for HCV?[1056]

[1051] Baroness Hooper's oral evidence on 30 June 2022, at 85:4-85:11.
[1052] Baroness Hooper's oral evidence on 30 June 2022, at 85:15-85:17.
[1053] Issue 134 of the Inquiry's Amended List of Issues.
[1054] Issue 135 of the Inquiry's Amended List of Issues.
[1055] Issue 136 of the Inquiry's Amended List of Issues.
[1056] Issue 129 of the Inquiry's Amended List of Issues.

7.26. Between 1986 and 1991, surrogate testing was considered by scientific advisory committees who advised on policy in respect of the safety of blood and blood products within the UK. There seems, however, to be no evidence before the Inquiry to suggest that the issue of surrogate testing was put to ministers for their consideration. In Lord Clarke's written evidence to the Inquiry he stated that he was not in a position to explain what consideration was given to surrogate testing or when, and that this may be a question for medical advisors.[1057] Baroness Hooper similarly did not recall the issue being raised with her.[1058] In oral evidence, she was questioned on whether this was a matter which should have been put to Ministers. Her response was that she "*...felt that [testing] was being considered and looked at and that we would get recommendations as soon as anything viable came up.*"[1059] She went on to say that she "*...respected the individuals who were involved in looking into it, and therefore [she] would have expected that if there were anything urgent or anything that really needed to be done urgently, that it would be brought to our attention.*"[1060] After being asked again if the matter should have been brought to the attention of Ministers, Baroness Hooper then agreed with CTI: "*...Well, when you put it like that, it seems strange that it was not underlined in some way, yes.*"[1061]

7.27. This section of these submissions address the following topics:

(1) The decision not to follow the US and introduce surrogate testing in 1986/1987;

(2) How the landscape of the debate shifted after the discovery by Chiron of the virus responsible for NANB hepatitis in 1988; and

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[1057] Lord Clarke's second witness statement dated 12 July 2021 (WITN0758012), §17.2; In his oral evidence, he said that he doesn't wholly understand what a surrogate test is and he doesn't recall the issue being raised with him; see Lord Clarke's oral evidence on 29 July 2021, at 38:4-38:14.
[1058] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §30.6; see also her oral evidence on 30 June 2022 at 68:3 – 68:13.
[1059] Baroness Hooper's oral evidence on 30 June 2022, at 87:21-87:24.
[1060] Baroness Hooper's oral evidence on 30 June 2022, at 90:3-90:8.
[1061] Baroness Hooper's oral evidence on 30 June 2022, at 91:3-91:4.

(3) The difference surrogate testing might have made to the number of people infected with HCV.

Why testing was not introduced in 1986-1987

7.28. Two markers which were possibly indicative of NANB Hepatitis were identified through research in the United Stated in the early 1980s. These were raised alanine aminotransferase (ALT) levels[1062] and the presence of the antibody to Hepatitis B core antigen (anti-HBc).[1063] The benefits of these markers were, however, highly contested within the medical and scientific communities. The surrogate tests were non-specific, risking many false-positives, and also lacking in sensitivity, risking many false-negatives. Despite these issues, surrogate testing in the US was introduced between 1986 and 1987. It was, however, never introduced in the United Kingdom, save for in very limited circumstances.[1064]

7.29. In summary, the evidence before the Inquiry suggests that the rationale for not introducing surrogate testing in 1987-1988 included the following:

(1) Doubts about the value of the 'markers' that were measured, or their association with NANB.

(2) That there was insufficient data in the UK to justify the high cost of introducing surrogate testing. The financial costs included the costs of the tests, additional staffing and also the costs of follow up care and counselling for excluded donors. These costs could be incurred without necessarily reducing the transmission of NANB hepatitis.

[1062] Aach et al, 'Serum [ALT] of donors in relation to the risk of [NANB] hepatitis in recipients: the TTV study', New England Journal of Medicine, 1981; 304:889 (the TTV study) at PRSE0001650; and Alter et al, 'Donor transaminase and recipient hepatitis', Journal of the American Medical Association, 1981; 246:630 (the NIH study) at PRSE0002216.

[1063] Stevens et al (the TTV study group), 'Hepatitis B virus antibody in blood donors and the occurrence of [NANB] hepatitis in transfusion recipients', Annals of Internal Medicine, 1984; 101:733 at PRSE0004728; and Koziol et al (the NIH study group), 'Antibody to hepatitis B core antigen as a paradoxical marker for [NANB] hepatitis agents in donated blood', Annals of Internal Medicine, 1986; 104:488 at PRSE0001533.

[1064] As discussed in CTI's oral presentation on the work of Dr Harold Gunson on 12 November 2021, at 49:8-51:22.

(3) There were ethical concerns over how to manage effectively the counselling and follow-up treatment of donors who tested positive, particularly as there was a likelihood of the tests producing a high number of false-positives.

(4) There were concerns about loss of donors to the blood service which could cause a shortage of blood, and without more data this could not be properly accounted for.

(5) Consideration was given to the approaches of other countries, albeit due to wide geographical variance in HCV levels of infection and anti-HBc and ALT levels, data from countries such as the US was not necessarily thought to be helpful for those making decisions in the UK.

7.30. These concerns are borne out in the chronology set out below. The DHSC legal team has been assisted by the detailed written chronological presentation on NANBH surrogate testing prepared by the Inquiry's Counsel Team in November 2022. The submissions do not attempt to cover all that ground but highlight some key aspects.

7.31. Following the introduction of surrogate testing in the United States in 1986, the Transfusion-Associated Hepatitis Working Party was reconvened specifically to consider whether the UK should also introduce anti-HBc and ALT screening.[1065] The working party was comprised of experts from relevant fields and included Dr Alison Smithies from the Medical Division of the Department of Health.

7.32. At a meeting on 24 November 1986, the working party discussed the data available in relation to the incidence of NANB hepatitis in the UK, as well as

[1065] The issue of surrogate testing was raised at a meeting of the Scottish National Blood Transfusion Service on 9 October 1986 and it was suggested that the most appropriate body to pursue this issue was the UK Working Party on Transfusion Associated Hepatitis. Thus Dr Cash was to write to Dr Gunson to ask that this working party be reconvened (PRSE0001880). The working party was reconvened and met again on 24 November 1986 (NHBT0000023_007).

the available data on anti-HBc and elevated ALT levels in donors.[1066] There were observed differences between the UK and the US, with rates of NANB Hepatitis thought to be much higher in the US.[1067] Dr Barbara further highlighted a number of problems which had been observed following the introduction of surrogate testing in the US, leading to some concluding that surrogate testing had been introduced prematurely there. These included:

> *"a. High false-positive anti-HBc rates with ELISA tests, compared with competitive RIA. This led to frequent disagreements in results when donors were followed up by their GPs.*
>
> *b. Uncertainty about, and variation in, the ALT cut-off, often with different action being taken for different ALT levels.*
>
> *c. Inadequate facilities or instructions for donor management after 'positive' results recorded'*
>
> *d. Uncertainty about how to take account of the other 'non-specific factors that may be causing ALT elevations.*
>
> *e. Reduction in the supply of transfusable blood since anti-HBc and elevated ALT are largely independent factors."*[1068]

7.33. The Working Party concluded that the data in the UK did not itself warrant the introduction of surrogate testing at that time, and there was insufficient data to base a decision upon in terms of cost-effectiveness. It was instead suggested that further research be carried out in the UK so that an informed decision could be made in respect of surrogate testing.

7.34. Following the meeting of the reconvened working party, a detailed research proposal was prepared.[1069] It was sent by Dr Smithies to Dr Graveney on 23 February 1987. Dr Smithies stated the study to be a priority amongst the bids for research and expressed a desire that the study could go ahead "*...with all speed.*"[1070] In this correspondence Dr Smithies identified a number of reasons why the UK may not necessarily follow other countries who had introduced surrogate testing:

[1066] NHBT0000023_007.
[1067] NHBT0000023_007 at §2.
[1068] NHBT0000023_007 at §3.
[1069] NHBT0000023_012.
[1070] DHSC0002492_031.

> *"In the first place the tests are surrogate and it is known that the use of the tests will not exclude all donations which are capable of transmitting NANBH.*
>
> *Secondly, the long term effect of NANBH infection is not really known, but it may be of only minor impact.*
>
> *Thirdly, the incidence of donations with positive results to the surrogate tests among the current blood donor population is unknown. It may be that self-deferral of high risk donors in response to the AIDS publicity has already reduced this to a minimum."*[1071]

7.35. The proposal itself referred to another problem with the introduction of surrogate testing:

> *"The use of non-specific markers will inevitably lead to the identification of donors who will not be carriers of NANB hepatitis. At present, little is known about donors who are anti-HBc positive, or have raised ALT levels, and guidelines are not available for counselling them and deciding on the need for further medical care. In the only study reported to-date, 60 per cent of abnormal levels were due to identifiable causes other than NANB hepatitis, of which the commonest were obesity and excessive alcohol consumption."*[1072]

7.36. This issue of the management of donors in light of the high risk of false-positives was elaborated upon by Professor Barbara in his oral evidence to the Inquiry:

> "If we were say to have introduced combined raised ALT and anti-HBc testing and then one of the options was to consider anyone who had raised ALT and who was anti-HBc positive as a higher risk for non-A, non-B, then the donations would have been excluded and we would have then told the donor that we were excluding future donations and we would try and explain why, which would have been a bit difficult because we would have to tell them that we were trying to err on the side of safety while we regretted having to lose their current and future donations."[1073]

7.37. Thus in addition to resource implications, there were ethical concerns about how to appropriately manage excluded donors particularly as it was unclear whether or not there would be any cause for concern over their health.

[1071] DHSC0002492_031.
[1072] NHBT0000023_012 at page 3.
[1073] Professor John Barbara's oral evidence on 26 January 2022, at 65:14-65:26.

7.38. The position of the working party that further research was needed prior to any introduction of surrogate testing also received support from others working within this field:

(1) In a letter to the Lancet on 18 April 1987, Dr Anderson and others commented on research undertaken at North London Blood Transfusion Centre into elevated ALT levels and anti-HBc within their area.[1074] The authors noted the low specificity of these tests in light of factors such as obesity or drug and alcohol use which contribute to raise ALT levels. The authors further reported on a study in which donors were screened for anti-HBc which revealed very low levels of positive anti-HBc donors, which had been reduced further following self-exclusion of donors at risk of transmitting HIV.[1075] The authors commented on the financial cost of carrying out tests, as well as potential loss to the service of donors and the cost of follow up and counselling and reached the view that at present it was difficult to justify the introduction of surrogate testing. The authors intimated that a national study was required to assess the incidence of raised ALT levels and anti-HBc in donors in different parts of the country, as well as the incidence of acute post-transfusion NANB hepatitis.

(2) On 13 June 1987, doctors from the West of Scotland Blood Transfusion service reported that their findings aligned with those of Dr Anderson, namely they had found a low incidence of post-transfusion NANB hepatitis in West Scotland. [1076] The authors also suggested that it would be prudent to do a UK study to assess the real incidence of acute post-transfusion NANB hepatitis and to assess

[1074] Anderson, C.C., et al., "*Surrogate testing for non-A, non-B hepatitis*", The Lancet, Vol. 329, Issue 8538, page 912 at PRSE0002897.
[1075] The prevalence of anti-HBc amongst donors was reported to be 1.8% between 1983 and 1985 and that this had decreased to 0.6% in 1985, thought to be due to self-exclusion of donors at risk of transmitting HIV; PRSE0002897.
[1076] Dow, B.C., and Mitchell, R., "*Non A, Non B Hepatitis Surrogate Testing of Blood Donations*", The Lancet, Vol. 329, Issue 8546, page 1366 at PRSE0002104.

the proportion of those chronically affected, before considering following the American surrogate testing policy.

(3) Also in a letter to the Lancet of 13 June 1987, Dr Gillon and others were of the view that the introduction of surrogate testing could not presently be justified. [1077] The authors suggested that "*...those who support ALT testing should recognise the tendency... of ALT levels to fluctuate: the loss of donated blood would be far in excess of that suggested by published studies, and most of the excluded donors would not be NANB hepatitis carriers*." The authors intimated that any decision to introduce testing had to be weighed against its financial cost, as well as the requirements to introduce follow up assessments and counselling and the risk of causing raised anxiety to the donors. The letter commented on how there would be no large, prospective randomised trial to test benefit of surrogate testing in America following the introduction of surrogate testing there, and of four small prospective studies, three had failed to demonstrate any reduction in post-transfusion NANB hepatitis following the introduction of surrogate testing.

7.39. The latest of these letters was considered at the Thirteenth Meeting of the Advisory Committee on the National Blood Transfusion Service on 17 June 1987, which was attended by Dr Smithies, Dr Moore, Dr Skinner and Mr Arthur from the Department.[1078] Dr Smithies and Dr Moore presented a paper which set out their view that more information was needed before surrogate testing should be introduced in the UK.[1079] Dr Cash indicated on behalf of the Scottish NBTS that they were proposing to introduce the tests in light of impending product liability legislation in 1988, and also due to concerns over falling behind the private sector. However, Dr Forrester from the SHHD said no decision would be made until the research had been

[1077] Gillon, J and others, The Lancet, Vol. 329, Issue 8546, pages 1366-7 at PRSE0002104.
[1078] BPLL0007202.
[1079] CBLA0002379.

carried out. Dr Smithies suggested that there was insufficient evidence of NANB hepatitis after the HIV deferral of donors had been introduced, making surrogate testing even less cost effective. Dr Gunson thought introduction would be premature and would cause an unjustified loss to panels. It appears that all agreed testing, if introduced, should be national and that the position should continue to be monitored.

7.40. The evidence before the Inquiry could suggest that by this time, Dr Cash from the SNBTS thought that the time for a study had passed. His and Dr McClelland's letter published in the Lancet on 4 July 1987 concluded that the introduction of surrogate testing was inescapable in light of the impending introduction of European product liability legislation in the UK and the need to avoid falling behind commercial suppliers who were using testing.[1080] In a presentation on Professor John Cash on 11 November 2021, CTI noted that these were two themes which reappeared in relation to Dr Cash's views on the introduction of surrogate testing.[1081] These views, together with the lack of funding for the study by the SHHD led to Scotland withdrawing from the multi-centre study proposed by the working party.[1082] However, Dr Cash agreed that the SNBTS would not unilaterally introduce surrogate testing in Scotland and that they would await the results of the research by Dr Gunson.[1083]

7.41. The material referred to above suggests that those involved were engaged in a balancing exercise and there is evidence before the Inquiry to suggest that those who were in favour of introducing testing, understood and respected the reasons against introducing testing. For example, the oral evidence of Professor Howard Thomas was that whilst he was in favour of introducing surrogate testing, he also had "*...heard the counter argument, which we were going to get a lot of false positives – which was reasonable*" and he

[1080] McClelland, D., et al., Testing Blood Donors for Non-A, Non-B Hepatitis: The Lancet, Vol. 2, Issue 8549, pp. 36-7 at PRSE0001444.
[1081] CTI's oral presentation on the work of Professor John Cash on 11 November 2021 at 6:23 – 7:2.
[1082] See for example PRSE0000359; PRSE0004562.
[1083] PRSE0001973.

therefore thought "*...it could be reasonable to then do a trial, just to see how many units we lost and whether we did reduce the incidence of post-transfusion non-A, non-B, and then we could work on a much better basis.*"[1084]

7.42. That there were particularly difficult issues to grapple with is reflected by the varied approach taken to surrogate testing across Europe. Dr Gunson attended the 10th meeting of the Council of Europe's Committee of Experts on Blood Transfusion and Immunohematology between the 19th to the 22nd of May 1987. He presented the responses to a questionnaire which had been circulated to member states.[1085] Different approaches were being taken across Europe, however as recorded in a document prepared by the Committee's Secretariat the issue was being given "*...careful consideration by most blood transfusion services"* and "*...the general impression [was] that the incidence of NANB-Hepatitis is rather low, but varies widely between different regions.*" It was further noted that "*...the value of 'surrogate-tests' such as ALT and anti-HBc has been studied by various groups but there is doubt about their cost/effectiveness.*"[1086] Significant geographical variation in respect of the levels of NANB hepatitis, anti-HBc and ALT levels meant that it was difficult for the Committee to recommend a uniform approach to be taken across Europe. Instead, the recommendations to come out of this meeting were:

> *"(1) The use of non-specific test for the purpose of reducing the incidence of transfusion associated NANB Hepatitis and its possible value as a public health measure remain controversial issues.*
>
> *(2) If a stance is taken that blood should have maximum safety then the tests would be introduced but the benefits derived from this testing would not be uniform throughout every country. Also, there is no guarantee that, in a given country, there will be a significant reduction in the transmission of NANB hepatitis.*
>
> *(3) The introduction of non-specific tests could lead in some countries to severe depletion of blood donors which may compromise the blood supply and this is a factor which must be taken into account.*

[1084] Professor Howard Thomas' oral evidence on 24 March 2021, at 129:11-129:19.
[1085] WITN4486059.
[1086] WITN4486059.

> *(4) When non-specific testing is introduced in a country, provision must be made for the interviewing, counselling and further medical examination and treatment which may be required for donors found to have raised ALT or who are anti-HBC positive.*
>
> *(5) The committee cannot give a general recommendation on the introduction routinely of non-specific tests for evidence of NANB infectivity of blood donors. Individual countries will have to assess the situation locally and decide on the appropriate action to take."*[1087]

7.43. Whether or not surrogate testing would be beneficial was therefore thought to be highly specific to individual populations. As set out above, in the United Kingdom, the decision was taken that further research was needed before surrogate testing was introduced.

Consideration given to surrogate testing following the identification of the Hepatitis C virus in 1988

7.44. Funding for the proposed research was sought by Dr Gunson on 25 April 1987,[1088] and approved by the DHSS on 28 April 1988.[1089] The study commenced on 1 September 1988.[1090] But by this time, Chiron had identified the virus responsible for causing NANB Hepatitis.[1091] Following this, the focus of the discussion largely shifted towards the development and use of a specific test;[1092] however, surrogate testing was kept under review.

7.45. At the first meeting of the ACVSB on 4 April 1989, a short paper titled 'Overview of Problems for this Committee' identified surrogate testing as an issue of some urgency, although it was indicated that a final decision

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[1087] NHBT0000018_005.
[1088] NHBT0000014_005.
[1089] According to Dr Gunson's witness statement prepared for the hepatitis litigation dated March 2000 at NHBT0000026_009, §64.
[1090] NHBT0000187_024.
[1091] The virus was discovered by Chiron on 14 April 1988; PRSE0003126.
[1092] Dr Rejman's written evidence to the Inquiry is that "by the time [he] started working in the DH in 1989, surrogate testing was becoming less relevant. The gene for Hepatitis C was discovered in 1988 and the first test was developed in Spring 1989. Most clinicians and scientists felt this was much better, even though in the early stages, there were problems with the tests"; See Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §49.18.

"*...might have to await UK research currently in progress.*"[1093] Similarly, the Advisory Committee on Transmission Transfusion Diseases ("ACTTD") concluded at its meeting on 24 February 1989 that "*...there should be no recommendation to institute ALT testing until the current study was completed in England.*"[1094]

7.46. Surrogate testing was considered in more detail at the second meeting of the ACVSB on 22 May 1989.[1095] A paper was presented by Professor Zuckerman titled '*Unresolved issues in non-A, non-B hepatitis.*'[1096] Commenting on research on the association between NANB hepatitis and anti-HBc, Professor Zuckerman stated that:

> *"...although the studies did show a higher incidence of hepatitis in recipients of anti-HBc positive blood, subsequent reports indicated that it was not related to the presence of anti-HBc per se, but to the higher frequence of anti-HBc in commercial blood. Others, however, failed to confirm the association between anti-HBc in donor blood and the increased risk of non-A, non-B hepatitis in recipients."*[1097]

7.47. Professor Zuckerman's report further suggested that "*...the non-specific indicator which has received most attention is serum aminotransferase levels in blood donors*," which was shown to be better than screening for anti-HBc, however, due to the low sensitivity of the test "*...almost two out of three units of blood with an elevated ALT level will not transmit non-A, non-B hepatitis. ALT levels vary with age, sex, alcohol use and geographical region and would therefore not be useful as a surrogate marker of non-A, non-B hepatitis.*"[1098]

[1093] WITN7193007.
[1094] The ACTTD also noted that there was a degree of inevitability about the introduction of testing in light of regulatory requirements of other countries and that this would be discussed with BPL in the future; NHBT0000043_002.
[1095] NHBT0000041_020.
[1096] NHBT0000078_006.
[1097] NHBT0000078_006 at page 6.
[1098] NHBT0000078_006 at pages 6-7.

7.48. A paper was also presented by Dr Rejman on 'Non-A, Non-B Hepatitis'.[1099] The paper noted that it was too early to report on the study being carried out by Dr Gunson on behalf of the UKBTS and concluded that:

> "At *present there does not appear to be any urgent need to introduce routine surrogate testing for NANB hepatitis among voluntary blood donors in the UK in respect of public health. The position should be reconsidered by this Committee when the results of the UKBTS NANB study are available. This should give an indication of the effect of donor testing for surrogate markers of NANB hepatitis on donor panels, the costs involved and an indication of its value in the UK, where NANB hepatitis incidence is lower than in the US. The availability of the Chiron test will help with interpretation of the data obtained. The Chiron test may also make surrogate testing obsolete, provided that the UKBTS and other studies confirm the promising results so far reported, and assuming that the cost benefit analysis* is satisfactory.'[1100]

7.49. After considering these papers and discussing the issue, the Committee's view continued to be that surrogate testing should not be introduced until the results of Dr Gunson's study were known, however, testing was to be kept under review.[1101] The actions arising out of the meeting on 22 May 1989 included the need for anti-HBc testing to be addressed, considering a separate requirement for ALT testing and update members on the findings of the NBTS study. It was agreed to keep the subject under close review.[1102]

7.50. The Chair may consider the issue of what cost/benefit assessment was made in respect of the introduction of surrogate testing. At the meeting of the ACVSB in May 1989, a cost benefit analysis was discussed. Similarly, there were frequent references by experts throughout 1986-1988 to the cost effectiveness of surrogate testing. Further context is set out in the witness statement of John Canavan, who stated that resource implications were not a decisive factor in the recommendations made by the ACVSB.[1103] He explained that "*...the Committee's discussion often referenced cost/benefit*

[1099] WITN4486107.
[1100] WITN4486107 at page 2.
[1101] NHBT0000041_020 at §§20-21.
[1102] DHSC0002494_048.
[1103] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.28(b).

issues, but 'costs' did not necessarily mean purely financial ones. For example, the 'cost' of a new test might be a potential negative impact on donors numbers and thus the security of the blood supply, which the ACVSB Terms of Reference explicitly required them to take into account."[1104] He later explained that whilst the "*Committee would have given regard in the general sense to the cost implication for the blood transfusion service of a particular recommendation… it was not for the Committee to make recommendations on whether a particular course of action was economically viable.*"[1105]

7.51. At the 3rd Meeting of the ACVSB on 3 July 1989, Dr Gunson provided an update on the position of ALT and anti-HBc testing in Europe.[1106] He reported on the latest results of a questionnaire sent to Member States of the Council of Europe. From the ten replies received, four countries were routinely doing ALT testing, with France also doing anti-HBc tests. One country did selective ALT testing. A report of an initial study by the NBTS on these tests was also presented, which showed raised ALTs in 25% of donors sampled.[1107] Members of the committee expressed concern that the study revealed nothing about specificity. [1108]

7.52. Surrogate testing was next considered by the ACVSB at its meeting on 6 November 1989, at which time the Committee concluded that "*...there was no case for using surrogate tests*" for NANB Hepatitis.[1109] This approach was informed by a report tabled by Dr Gunson on the results of the DH funded study on ALT and anti-HBc.[1110] Dr Gunson's conclusions at this stage were:

[1104] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.28(b).
[1105] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.83.
[1106] ACVSB meeting minutes at NHBT0000072_025, report from the European Council Committee of Experts in Blood Transfusion and Immuno-Haematology which was considered at this meeting at PRSE0003137.
[1107] PRSE0000333.
[1108] NHBT0000072_025 at §11.
[1109] NHBT0005043 at §29.
[1110] NHBT0000072_051.

(1) The introduction of surrogate testing would result in a loss of almost 4% of donors. Dr Gunson elaborated on potential impact of this in his witness statement for the Hepatitis litigation dated March 2000. He stated that "*...the loss of almost 4% of donors cannot be regarded lightly…. The recruitment of an additional 4% which would have amounted to an additional 120,000 donors, would have caused serious difficulties.*"[1111]

(2) The variability of ALT testing in the three centres was considered to be "*...a disturbing finding.*"

(3) It was difficult to conclude how many of the donors with raised ALT or anti-HBc may have transmitted NANB hepatitis without a prospective study.

(4) ALT testing was non-specific, with the correlation with alcohol intake and obesity described as striking. The significance of a positive anti-HBc result was also unknown.

(5) Following the introduction of the anti-HCV test, there would only be very limited justification for the introduction of routine ALT and anti-HBc testing.

7.53. This research further informed Dr Gunson's view as expressed during the hepatitis litigation that surrogate testing should not have been introduced at any time between 1988 and 1991. [1112]

7.54. The narrative set out above suggests that even after the Hepatitis C virus was identified, considerable attention was given to whether surrogate testing should be introduced in the UK. It appears that new data was reviewed and scrutinised as and when it became available. The ACVSB was informed of what was happening across Europe and regularly considered whether surrogate testing should be introduced. However, the conclusion remained

[1111] NHBT0000026_009 at page 26.
[1112] NHBT0000026_009 at page 27.

that it was not appropriate to introduce testing within the UK. The problems concerning the specificity and sensitivity of both tests remained, as did concerns over the cost-effectiveness and potential unjustified loss of blood donations. Ultimately this issue was overtaken by the introduction of a specific test for the hepatitis C virus.

The difference surrogate testing might have made

7.55. The Chair may wish to consider what difference the introduction of surrogate testing might have made to the number of people infected with Hepatitis C. It is exceptionally difficult to predict now what difference the introduction of surrogate testing. It is, however, submitted that the evidence before the Inquiry supports the following observations:

(1) The introduction of heat-treatment in 1985 proved to be largely[1113] effective in eliminating the risk of NANB Hepatitis from blood products. There was still, however, a risk of NANB Hepatitis to patients who received blood transfusions.

(2) The risk of NANB hepatitis to recipients of blood transfusion had been significantly decreased by screening measures, including asking drug users not to donate blood as part of the response to the risk of AIDS in 1983-1984.

(3) There was conflicting research about the efficacy of surrogate testing, with some research identifying a correlation between anti-HBc or ALT levels and NANB hepatitis, and other research suggesting that there was no significant change in occurrence of post transfusion NANB hepatitis following surrogate testing.

(4) The data available from the relevant time makes it clear that the prevalence of NANB hepatitis varied geographically, making any assessment on the potential impact of surrogate testing particularly difficult.

[1113] Though, as to cases of HCV infection from 1985 onwards from inadequately heat-treated imported blood products, see Section 5 of these submissions above.

(5) There was no scientific basis for the correlation between the presence of anti-HBc in donated blood and the transmission of HCV.

(6) Scientists had difficulty explaining why there was little overlap between patients who tested positive for anti-HBc and those with raised ALT levels.

(7) ALT levels fluctuate over time, with elevation caused by obesity and excessive alcohol consumption, making it an unreliable predictor for NANB hepatitis.

(8) The poor sensitivity and specificity of the surrogate tests would have meant a large number of infected donations would not have been detected, and the majority of positive tests were likely to have been false positives.

7.56. Lord Penrose in his final report reached conclusions as to whether surrogate testing should have been introduced and what difference it might have made. Whilst the Chair will need to come to his own conclusions, it is hoped that setting out the conclusions of Lord Penrose provides a useful reference to assist in that exercise. After having set out a detailed analysis of the scientific and medical literature on surrogate testing at the relevant time, and the actions taken in respect of surrogate testing in the US, Europe, the UK and Scotland, Lord Penrose noted that:

> *"While it seems likely, on the balance of probabilities, that ALT testing would have reduced the incidence of transfusion-transmitted Hepatitis C to some extent, given all of the difficulties set out in this chapter it was not possible at the time, nor is it possible now, to say to what extent the incidence of post-transfusion Hepatitis C would have been reduced in recipients of blood and blood components by transfusion, or at what 'cost' in terms of impact on donors and impact on the blood supply.*
>
> *The Inquiry does not attribute blame for the fact that surrogate testing was not introduced, given the diversity of respected medical and scientific views over the period 1986-91. There was no consistent support for the procedure on tenable scientific or medical grounds that would have made it possible to conclude that officials should have recommended the introduction of ALT testing, or that the question was*

so narrowly balanced that it required to be referred to ministers for decision."[1114]

7.57. As the Chair is very familiar with, in A and Others v The National Blood Authority and Others [2001] 3 All ER 289, Burton J's conclusion (applying the product liability test against the pros and cons of surrogate testing)[1115] was as follows,

"[141] The pros and cons in respect of the introduction of surrogate testing must be assessed and weighed and then placed, together with the other circumstances, into Mr Underhill's art 6 basket. I have not found this an easy task and it has required very careful deliberation. After such thought, I am left in no doubt that what I have in the preceding paragraphs categorised in almost every case as a 'However' outweighs or neutralises the contrary arguments that have been set against the arguments in favour, and I am clear that the scales have come down in favour of the introduction of these surrogate tests, and indeed of both kinds of surrogate test, both ALT and anti-HBc. The United States and France, the major countries who introduced surrogate tests at that time, introduced them both, and I am clear that, notwithstanding the lesser expert support for the latter test, once ALT testing is to be introduced, the addition of anti-HBc adds little by way of extra disadvantage, cost, blood loss or inconvenience, and may be of substantial advantage. It was, in my judgment, at least very likely to decrease the number of donors who were in any event unwanted, a factor which does not seem to have been discussed at any ACVSB or ACTTD or other meetings to which my attention has been drawn. Further, if the US research was right, the two tests did not, or not materially, overlap, and in any event the combined efficacy of the two together, on the basis of the predictive studies, was clearly greater, and there may additionally have been advantages, as discussed in [133](iii) above, in relation to counselling and diagnosis. It is both difficult, and, in my judgment, unnecessary, for me to decide a particular time for such introduction. ***I am, however, satisfied that it ought to have been at some stage after the introduction of the surrogate tests in the United States and the subsequent consideration given to them in the United Kingdom, and before, or at any rate by, 1 March 1988****."* *(Emphasis added).*

[1114] Penrose Inquiry Final Report at §§27:414-27:415.
[1115] Judgment in A and Others v The National Blood Authority and Others (2001) 3 All ER 289, §§ 119–140.

The timing of the introduction of anti-HCV testing

7.58. A number of issues relating to the introduction of anti-HCV screening have been raised, including:

(1) Why, following the discovery, in 1989, of HCV and the development of a test to screen for it, was there a delay in the introduction of screening in the UK?

(2) Should the ACVSB have recommended the introduction of routine screening sooner than November 1990?

(3) Why was there a further delay after the decision in principle had been taken before screening actually started?

Why screening was not initially introduced

7.59. The evidence before the Inquiry suggests that there were a number of problems with the first generation tests produced by Chiron and concerns around its introduction were held by those advising the Department. At the second meeting of the ACVSB on 22 May 1989, it was observed that "*The Chiron test was estimated to pick up approximately 50% only and there was a need for caution.*"[1116] The concerns were further summarised in a minute from Dr Metters to Mr Graham Hart (then Director of Operations, NHS Management Board) on 9 October 1989:

> *"The main points that concerned ACVSB at their last meeting [3 July 1989] were that the Chiron test cannot be independently validated, and as a result we have no idea of the false positive or negative rate. Some recent reports suggest that patients with chronic hepatitis test negative to Chiron, despite the fact they may be transmitting the virus, and that they were previously Chiron positive. Hardly a reassuring finding if confirmed. From Dr Gunson's letter the specificity still seems to be a problem, and if so it could well deter the Committee from recommending the general introduction of Chiron.*
>
> *Another factor that will influence the Committee is that no country has as yet put it into routine use and the test does not have FDA licence, and is unlikely to get one until next Spring at the earliest.*[1117]

[1116] NHBT0000041_020.
[1117] NHBT0000188_074.

7.60. In his witness statement to the Inquiry, John Canavan referred to a hand written note added to this minute from Graham Hart to John Canavan's superior, Charles Dobson, asking that he "*...keep an eye on this and check on progress in November.*" Mr Canavan suggested that this shows the "*...seniority of the DH personnel involved in actual decisions*..." and that "*...when these issues arose and Dr Metters was concerned about it, he took it straight up the hierarchy.*"[1118]

7.61. Practical concerns were also raised in light of the fact that the length of time the test took (three and a half hours) might cause difficulty when products need to be used on the day of donation.[1119] The decision which was therefore taken was that further data should be collected and the matter kept under review. A pilot study of the Chiron test on ten thousand samples in North London was conducted following the meeting in July 1989, with the results due to be reported at the next meeting of the ACVSB. [1120]

7.62. On 3 October 1989, in a minute from Mr Canavan to Miss Wheeler, copied to Dr Rejman, it was suggested that the Ortho test had shown positive results in pilot trials, but the test had practical drawbacks and thus further field trials were needed to assess the "*...operational implications of using the test routinely.*"[1121] £25,000 was needed for this research and was made available by the fourth meeting of the ACVSB on 6 November 1989.[1122]

7.63. The main issue for the Committee at the meeting on 6 November 1989 was "*...whether the time is right to make a decision about adopting the Chiron test.*"[1123] According to Dr Rejman's written evidence to the Inquiry, prior to

[1118] John Canavan's witness statement dated 6 September 2022 (WITN7115001), at §2.42 b).
[1119] NHBT0000061_035.
[1120] NHBT0000061_035.
[1121] NHBT0000188_062.
[1122] See the minutes from the meeting at NHBT0005043 at §30.
[1123] See the chairman's brief at DHSC0003557_051, pages 2-3.

this meeting there had been "*...no detailed discussion at ACVSB meetings," of the Ortho test, which was "under very preliminary consideration.*"[1124]

7.64. At the November 1989 meeting Dr Gunson presented a report on the data presented at the first International Meeting on the Hepatitis C virus in Rome which had taken place between the 14th and 15th of September 1989.[1125] He presented a number of conclusions which can be summarised as follows:

(1) It appeared certain that the anti-HCV test detected a viral marker associated with NANB Hepatitis;

(2) A positive anti-HCV test meant that the blood of the person may be infectious for NANB Hepatitis, but not in all instances.

(3) Routine anti-HCV testing would reduce the incidence of transfusion transmitted NANB Hepatitis, although the extent of the reduction was estimated to range between 20-60%.

(4) Anti-HCV positivity in a blood donor may not necessarily mean that the donor transmitted NANB Hepatitis. An unknown proportion may be false positives.

(5) A confirmatory test was not yet available.

(6) The anti-HCV test may become negative after a period of time, although that did not necessarily correlate with loss of infectivity. There may therefore have been a number of false negatives following use of the test.

(7) Whilst there was an association between anti-HCV seropositivity and surrogate markers, the majority of anti-HCV positives did not possess non-specific markers.

7.65. A series of recommendations were also set out in Dr Gunson's paper, including that routine screening be introduced when practical. It was

[1124] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), at §54.4.
[1125] PRSE0001071.

suggested that the introduction across the UK be simultaneous at a time when a policy for counselling and management of the seropositive donors was defined and that "*...every effort must be made to ensure that a confirmatory test is available in the UK at the time routine donor screening is introduced.*" It was recommended that routine testing not be introduced prior to the FDA licensing procedure being effected. Finally, it was noted that the UK tests had to date been conducted on frozen/thawed samples, which may have affected the quality of the test. Therefore it was suggested that studies were needed in RTCs which would allow the evaluation of the test on fresh samples and also demonstrate how the test could be integrated into working practices.

7.66. After a detailed discussion of this paper and the data available, "*...the feeling of the Committee, as summed up by the Chairman, was that the test represented a major step forward, but that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test.*"[1126] It was decided that the Committee would not want to go ahead in advance of the FDA decision, but "*...it could prove difficult if the FDA do not decide in favour of the test.*" It was suggested that the pilot studies would "*...show the feasibility of adding this test to routine practice.*"

7.67. Anti-HCV screening was considered again at the next ACVSB meeting on 17 January 1990.[1127] Dr Gunson reported on the pilot study and expressed concern over the number of tests falling within a problematic "*...grey zone*", risking a high number of false negatives. Concerns were also raised about the time taken to complete the test which could risk emergency release of products. Other problems including the lack of confirmatory test and that the test had not been approved by the FDA remained. Dr Tedder is recorded as saying: "*... it was very difficult to make any recommendations based on scientific criteria at the time, as so little was known about the virus and its antibody markers."* [Original emphasis] Dr Mortimer's view was that as the

[1126] NHBT0005043.
[1127] PRSE0001477.

perceived risk was higher than HIV, there would be inconsistency if routine screening was not introduced: "*...If we began routine use of this test we should soon have a better test to move onto.*" There is a specific record of Dr Metters summing up the "*...general consensus...*" and then asking members for their opinion. "*Dr Tedder wanted it to be noted that he would not give an opinion before more scientific data had been generated.*" After "*...further discussion...*", the minutes record that it was agreed that the costs of introducing testing would be looked at "*now*" and there would be an attempt to refine the estimate of how many cases of chronic liver disease could be prevented by routine testing. There was further discussion of the practical steps needed to gather information to give advice to Ministers on the case for testing. However, at this time "*...the Committee could give no further scientific advice.*"

7.68. Baroness Hooper's oral evidence about the process of conveying the consensus view of a committee to ministers, and her understanding of a consensus view, is referred to above at paragraph 7.24, evidence given with reference to the ACVSB meeting of January 1990. The issue which it raises is the extent to which the range of views discussed in committee should be conveyed to ministers, even when – it appears from the Minutes – following discussion, a consensus decision was reached, with no dissent from Dr Mortimer recorded. The outcome of the meeting was conveyed to Baroness Hooper in a minute dated 15 February 1990, which contained a handwritten note at the top, probably from Dr Metters, recording that "*...The clear advice from ACVSB is that, as yet, there is not enough scientific data about the test marketed by Ortho for the committee to recommend that it be introduced*".[1128]

7.69. At the ACVSB meeting on 24 April 1990, the Committee considered updates from the Ortho symposium, Abbott symposium and the Houston hepatitis

[1128] NHBT0000189_055. See further Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §§30.9-30.10.

conference.[1129] Concerns were again raised about the test not being sensitive or specific enough for reliable testing, the lack of a confirmatory test and that neither test had been licensed by the FDA. By this time, France, Belgium and Luxembourg had introduced routine screening. Italy had introduced the test on a routine basis. The Chairman, Dr Metters, suggested that the science had advanced a little but there were still questions over the reliability of the test. The discussion was summed up as follows:

> *"- there was inadequate scientific data to support the introduction of the Ortho test for routine screening;*
>
> *- a confirmatory test was needed which could be used in the RTCs and not just specialised laboratories;*
>
> *- the FDA had not yet approved the test and it would be reassuring if the regulatory authority in the country of origin had done so;*
>
> *- there was a need to learn more about the donor panels and the significance of positive reaction to the hepatitis C antibody test;*
>
> *- a prospective study involving 25-50,000 donors would generate sufficient positives for confirmatory testing."*[1130]

7.70. An update on HCV screening was sent to Lady Hooper on 1 May 1990 which referred to the introduction of screening in other countries, but noted that the ACVSB had reaffirmed its view that routine screening was not yet justified.[1131] It was noted that the Committee would report again after the next meeting.

7.71. Baroness Hooper's written evidence to the Inquiry was that whilst she "*...would have considered this submission carefully…*" she also *"would have trusted the advice given by the ACVSB, which [she] understood to have consisted of some of the best medical experts in their field."*[1132] She continued:

[1129] NHBT0000072_098.
[1130] NHBT0000072_098 at §29.
[1131] NHBT0000061_130.
[1132] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §31.6.

> *"At the time, I did not think that I needed to raise questions about that advice when there appeared to be a consensus, the basis for their reasoning seemed to be reasonable and they were best placed to advise us on the best course of action for the UK to take at any given time. Furthermore, they did not appear to be "standing still" — a pilot study was proposed and was being pursued."*[1133]

7.72. Whilst this submission did not come to the Secretary of State at the time, Lord Clarke, in his oral evidence supported the position taken by Baroness Hooper. When asked by CTI if the Minister should have started asking questions, Lord Clarke's response was that "...*anybody with common sense would have noted and waited for the next stage in this extremely expert committee's advice.*"[1134]

7.73. There were a number of significant developments following the meeting on 24 April 1990 which meant that the proposed studies were no longer considered necessary. The FDA announced on 4 May 1990 that it had licensed the Ortho anti-HCV Elisa test for use in the USA.[1135] On 11 May 1990, Ortho announced the introduction of its Recombinant Immunoblot Assay ("RIBA") for Hepatitis C.[1136] On 5 June 1990, Dr Metters wrote to all ACVSB members stating that "...*some additional scientific information is now available and FDA have approved the hepatitis C antibody test*." As a result, he suggested bringing forward the next meeting to 2 July so the committee could consider whether UK blood donations should be routinely screened. Dr Metters apologised "...*for the short notice of this meeting…*" but said that "...*events are now moving fast, and strongly indicate that we should consider again at an early date our advice to Ministers on hepatitis C testing*."[1137]

7.74. At the meeting on 2 July 1990, a decision was taken to recommend to ministers that hepatitis C testing be introduced in the UK, but that a pilot

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[1133] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §31.6.
[1134] Lord Clarke's oral evidence on 29 July 2021, at 46:1-46:3.
[1135] PRSE0002165.
[1136] PRSE0003312.
[1137] DHSC0003973_104.

study using the Ortho and Abbott test was needed to decide which the better test was.[1138] Dr Zuckerman again expressed concern over counselling of positive donors because of false positives, saying that this "*...would be a very difficult public relations exercise.*"[1139] Lady Hooper was informed of this development in a minute from John Canavan to her private office on 7 August 1990. The minute noted that a full submission setting out the case for screening, the financial implications and a cost/benefit study would follow.[1140]

7.75. As to why screening was deferred until a pilot study had been carried out, it appears that the Committee thought the study was needed to determine which test was to be preferred; Dr Gunson indicated that there was little information about the two tests but "*...there appeared to be only a 60% overlap of positive results.*" [1141] This pilot study further had the benefit of giving the NBTS experience in using both tests and indicate if either had any particular advantage.[1142] The alternative would have been to introduce both tests and undertake an assessment later of which was better. John Canavan's written evidence to the Inquiry was that he did not recall any consideration being given to that option, however, "*...any such interim measure would of course have had significant operational considerations for the RTCs, in terms of staffing, equipment and donor counselling arrangements.*"[1143]

7.76. At the meeting on 2 July 1990, it was suggested that £150,000 would be needed and that the research would take approximately 4 months.[1144] The findings were reported on by Dr Gunson at the next meeting of the ACVSB on 21 November 1990; it was noted that "*...both screening tests could be*

[1138] PRSE0000976.
[1139] PRSE0000976 at §7.
[1140] NHBT0000061_169.
[1141] PRSE0000976 at §7.
[1142] As recognised in John Canavan's minute to Lady Hooper's private office in the minute of 7 August 1990: NHBT0000061_169.
[1143] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.107 (b).
[1144] PRSE0000976 at §§18-20.

deemed to be satisfactory for routine use within RTCs from an operational viewpoint and the choice would be influenced by the equipment available in the RTC."[1145] At this meeting, the Committee recommended that 'the UK should introduce hepatitis C testing as soon as practicable.'

7.77. Ministers were updated on 7 August 1990.[1146]

Should the decision to recommend routine testing having been made sooner

7.78. The reasoning behind why the ACVSB did not initially recommend routine screening as set out above inevitably feeds into the question of whether testing should have been recommended sooner. It appears that the experts on the AVCSB were engaged in weighing the benefits of screening for the presence of NANB hepatitis through blood against other factors, including:

(1) A potential risk to the blood supply due to the exclusion of a number of healthy donors due to falsely positive tests;

(2) Implications in terms of counselling of donors who tested positive, particularly as there would be a large number of false positives; it was regarded as very difficult to decide how to manage a donor who had been told that they 'may or may not' be suffering from a particular disease. There were also concerns that this might deter individuals from giving blood, which again may have caused problems for the supply of blood;

(3) Practical difficulties in introducing the test, which in particular had implications for situations in which blood was needed on the same day on which it was donated;

(4) By July 1990, the existing of competing tests, with limited overlap in test results; and

[1145] NHBT0000073_018.
[1146] NHBT000061_169.

(5) The fact that the test also produced a large number of false negatives, which made it difficult to calculate properly the benefit of introducing testing.

7.79. The narrative set out above suggests that the ACVSB kept abreast of and responded to scientific advancements. This led to the balance shifting in favour of introducing testing despite problems still remaining, with significant developments in May and June 1990 leading to the 7th meeting of the ACVSB being brought forward to 2 July 1990.[1147] It was at this meeting, that the Committee advised that routine testing should be introduced, following a study which was considered necessary to determine which of the available tests was to be preferred.

7.80. In his oral evidence to the Inquiry, Dr Rejman agreed that "*...there were three conditions or further matters that needed to take place before the ACVSB would reach a view [on recommending routine testing]: that was a confirmatory test, FDA approval and pilot studies.*"[1148] Each of these conditions is addressed in turn.

7.81. As to the first of these requirements, a confirmatory test would assist in reducing the number of falsely positive results. In his written evidence to the Inquiry, Dr Rejman explained the particular problem caused by false positives in the context of the Ortho/Chiron test:

> *"A figure of 50% false positives was suggested in the minutes of the sixth ACVSB meeting on 24 April 1990 [NHBT0000072_098]. However, a true indication of the extent of false positivity among UK donors was given with the results of the pilot study comparing the first generation Ortho and Abbott tests in the ACVSB 9/1 paper [PRSE0003048]. Only 6 of the 65 specimens found to be repeatedly reactive in one or other, or both, of the tests, were truly positive by PCR. This suggests that approximately 90% were false positives. The figure of 10% true positives is also mentioned by Professor Leikola in his article "Viral risks of blood transfusion" in Reviews in Medical Microbiology (1993)*

[1147] PRSE0000976.
[1148] Dr Rejman's oral evidence to the Inquiry on 11 May 2022, at 103:1-103:6.

> *[WITN4486064]. False positive results meant that healthy, i.e. non-infectious donors would be excluded."*[1149]

7.82. Dr Rejman further explained the problem with this, noting that counselling donors, when it was not certain whether they were truly positive "*...would have been impossible*."[1150] Further, there was a risk that the introduction of the test might detrimentally impact donors who received a positive result which transpired to be false. This in turn could have had implications for the trust placed in the blood transfusion service, and ultimately could have deterred people from giving blood.[1151] The care of donors was a relevant factor in decision making.[1152] In terms of the need to consider both that, and the need to protect recipients of blood from disease, Dr Rejman's oral evidence to the Inquiry was as follows:

> *"My understanding of the way the Department looked at this was, obviously the recipient must come number one, because the recipient is the person who is most at risk in any situation where there is a potential for transmitting infection to a patient. So he or she must be the number one priority. But, having said that, one has to look at the broader picture of all patients within the Health service. And if you have a substantial reduction in the number of donations in the Health Service, then a lot of people will be disadvantaged; you will not have sufficient to give everybody what they need."* [1153]

7.83. As regards FDA approval, the minutes of the ACVSB's meeting on 6 November 1989 suggest that the decision was not to be dependent on the FDA making a positive licensing decision.[1154] However, as Dr Zuckerman set out in the fifth meeting of the ACBSV on 17 January 1990, "*...it would be difficult to approve a test which was not approved in its country of origin."*[1155] Dr Pickles elaborated on this in her written evidence to the Inquiry: although

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[1149] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §75.3.
[1150] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §75.3.
[1151] See discussion in Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§73.2-73.4.
[1152] Dr Rejman also refers to international recommendations which note that the well-being of the donor ought to be factored into considerations on screening. See Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§50.1-50.7.
[1153] Dr Rejman's oral evidence to the Inquiry on 11 May 2022, at 153:15-153:25.
[1154] This is implicit in the comment that 'whilst the UK would not want to go on in advance of an FDA decision, it could prove difficult if the FDA do not decide in favour of the test": NHBT0005043.
[1155] PRSE0001477 at §20.

the ACVSB were not bound by the FDA, "*...had [the FDA] decided the test in question was not appropriate, it would have caused us concern, since it might mean that there were problems we had failed to appreciate.*"[1156] A similar view was expressed by Dr Cash when he gave evidence to the Penrose Inquiry. Summarising this evidence, Lord Penrose set out in his final report that "*...Professor Cash told the Inquiry in his statement that the FDA licensing was regarded as important. The scientific process of assessment of diagnostic kits by the FDA was rigorous. No kit licensing arrangements existed in the UK.*"[1157]

7.84. As to the third requirement of pilot studies, the Inquiry has the detailed record of why such studies were regarded as necessary in the Minutes of the AVCSB. Dr Pickles referred to the "*...standard expectation about getting things right first time*":

> *"Even in retrospect I do not think that the policy decision to introduce HCV screening could have been taken much earlier. This depended on the emerging science and what the trials were showing and the standard expectations about getting things right first time. There was no consensus among our experts to make a positive recommendation earlier than they did."*

Delay following the decision in principle

7.85. Routine screening in the UK was introduced on 1 September 1991, just over nine months after the decision was made by the ACVSB that in principle routine testing should be introduced.

7.86. At the eighth meeting of the ACVSB on 21 November 1990 when the decision was made to introduce routine testing, it was suggested that some RTCs had asked for a 6 month period to set up testing, which was thought to be excessive.[1158] It was agreed that Dr Gunson would consult with directors

[1156] Dr Hilary Pickles' witness statement dated 25 April 2022 (WITN6965001), at §61.6.
[1157] Penrose Inquiry Final Report at §31.210.
[1158] NHBT0000073_018 at §21.

of RTCs but would hold off until the submission had been put to ministers. Dr Metters stressed the importance of a common date of introduction throughout the UK.

7.87. Set out below is a summary of the key decisions made in the lead up to routine testing being introduced across the UK. This chronology in respect of the implementation can helpfully be divided into three time periods:

(1) The time between the decision of the ACVSB to recommend routine screening, and ministerial approval of routine screening on 16 January 1991;

(2) The decision to delay the start date for testing from 1 April 1991 to 1 July 1991; and

(3) The decision to further delay the start date to 1 September 1991.

7.88. We set out below some general observations about the level of ministerial involvement in the decision, before summarising some of the material evidence of Departmental witnesses from the time, which goes to the question of whether testing should have been introduced sooner.

Time taken for Ministerial decision

7.89. Following the meeting on 21 November 1990, there was an intense period of work at official level so that a submission could be put to ministers.[1159] The first draft was prepared by John Canavan and circulated amongst officials on 30 November 1990, nine days after the ACVSB's meeting.[1160] During the course of the following three weeks, two further drafts were prepared following input from relevant advisers within the Department,[1161] before the

[1159] As addressed in John Canavan's witness statement dated 6 September 2022 (WITN7115001), §§2.133-2.155.
[1160] WITN7115017.
[1161] DHSC0002498_075; WITN7115019.

final draft was sent to Lady Hooper's Private Office on 21 December 1990.[1162]

7.90. The final version expressed the ACVSB's recommendation in much stronger terms than previous iterations, indicating that the Committee "*...firmly recommend the introduction of screening as soon as possible*." This choice of wording appears to be due to comments made by Dr Metters on the penultimate draft in which he expressed concern that the submission did not properly reflect the view of the ACVSB and needed to more clearly convey the committee's position that testing should be introduced.[1163] It was Dr Rejman's evidence to the Inquiry that Dr Metters wanted the submission to leave "*...no doubt that this is what we must do.*"[1164]

7.91. In terms of the projected timeframe for the introduction of testing, the submission suggested that "*...in view of the operational matters that need to be discussed and finalised, it is unlikely that routine screening could be introduced before 1 April 1991.*"

7.92. The CMO endorsed the recommendation on 31 December 1990, stating "*...I agree, I consider that a difficult balance has been correctly struck in the circumstances."*[1165] Lady Hooper confirmed her agreement to introduce routine screening on 16 January 1991.[1166] She noted[1167] that the language of her approval ("*I don't believe we have any option*") is likely to have reflected the uncertainties in the submission, which stated that *"...the conclusion about benefits must be uncertain. However based on reasonable*

[1162] PRSE0004667.
[1163] NHBT0000061_201.
[1164] Dr Rejman's oral evidence to the Inquiry on 11 May 2022, at 142:14 – 142:17.
[1165] DHSC0002498_096.
[1166] NHBT0000191_013.
[1167] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §31.25.

assumptions of costs but perhaps optimistic assumptions about benefits…[the proposal is] not very good value for money."[1168]

7.93. It was suggested in questioning that it took too long for the recommendation of the ACVSB to introduce testing to be approved at ministerial level. It appears that the time between the meeting on 21 November 1990 and the submission of 21 December 1990 was used by officials to prepare the ministerial submission and ensure it accurately reflected all of the information necessary. The oral evidence of Dr Rejman was that in relation to submissions being put to ministers, this one was "...*actually put in place pretty quickly.*"[1169] Further, the work of officials had to be managed alongside other priorities within the Department. Lady Hooper's evidence was that:

> *"The reality was that officials would have had to balance work on this matter with many other competing issues. I can see that at the time, blood policy related issues included the settlement of the HIV litigation, and more generally there was a lot of work being done to implement the NHS and Community Care Act 1990, which had received Royal Assent in the summer and was due for implementation by April 1991."*[1170]

7.94. Baroness Hooper further indicated that she would have wished to have the view of the CMO before taking action.[1171] This was provided during the Christmas period, on 31 December 1990, and Baroness Hooper confirmed her agreement on 16 January 1991.

The later start date of 1 July 1991

7.95. It was recognised in a minute from Dr Pickles to John Canavan on 5 February 1991 that the initial start date of 1 April 1991 no longer appeared

[1168] PRSE0004667 at §10.
[1169] Dr Rejman's oral evidence to the Inquiry on 11 May 2022 at 142:10 – 142:13. See also John Canavan's witness statement dated 6 September 2022 (WITN7115001) at §§2.141 - 2.153 which explains the process for drafting the submission and why it took the time it did.
[1170] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §31.23.
[1171] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §31.24.

feasible. Dr Pickles referred to recent correspondence between Dr Gunson and the RTCs and stated:

> *"There are all sorts of problems still, eg. exact choice of test, supplies of this, confirmatory testing arrangements, training etc. etc. There remains real concern about how the necessary money will get into the system. The starting date [Dr Gunson] wanted to try out on me was 1 July: would this be too late?*
>
> *My initial reaction was this would be OK. Attempting to go earlier would mean some stragglers would be left behind, the slight delayed increased the chance of the finance being sorted out, and with diversion of RTC resources to Gulf-related activities a short time date might not be feasible. Even that date was dependant on blood collection having been stable for the preceding 4 weeks, which should apply provided the ground war is over by then."*[1172]

7.96. Dr Pickles had thus outlined a number of difficulties. The reference to 'Gulf-related activities' concerned the Gulf War, with the air campaign having started on 18 January 1991. On 24 January, John Cash of the SNBTS had written to Dr Gunson suggesting "*...in the strongest possible terms, that anti-HCV donation testing should not be commenced in the UK BTS until after the Gulf conflict is over or at least until such time as we are confident our blood collection and microbiology testing teams can cope with what will be quite substantial changes and increased workloads.*"[1173]

7.97. Dr Rejman's written evidence to the Inquiry in respect of this was:

> *"Dr Pickles' minute of 5 February 1991 refers to Gulf War-related activities that were having an impact on the timing of the introduction of HCV screening. The Gulf War had a major impact on many aspects of life in the UK at the time. I recall that in DH individuals were told they were "on-call" for any emergencies. I can recall being in this situation, with a list of various contact numbers, for specialised advice on what needed to be done in particular circumstances…. Introducing an additional screening test would have posed a risk to maintaining the supply of blood at this time, not only for the armed forces, but also the home civilian population."* [1174]

[1172] NHBT0000062_028.
[1173] NHBT0000073_033.
[1174] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §70.5.

7.98. As to the choice of tests, this was considered at the 9th meeting of the ACVSB on 25 February 1991. [1175] The Committee agreed that it was important for proper evaluation of the Ortho and Abbott 1&2 tests to be carried out before RTCs decide which test to use. The view was that these tests should in principle be available for 1 July. [1176]

7.99. Dr Rejman's evidence suggested that the remaining issues required action from the RTCs.[1177] Dr Gunson had consulted with the Regional Directors as to when they would be able to commence testing.[1178]

7.100. The policy of requiring that the routine screening be introduced nationally may have slowed down the introduction of testing within the areas which could have met the 1 April 1991 deadline. As to the rationale for this policy, Dr Rejman explored some of the reasoning behind this policy in his oral evidence to the Inquiry:

> *"Well, I think, throughout the period when we were considering hepatitis C screening, it was agreed that a decision about testing should be taken across all four nations. And, otherwise, there would be difficulties in explaining to patients and to doctors as to what -- why a decision had been taken, and it was -- we were, after all -- the UK, after all, was one country, in general terms. And so decisions made in one part of that -- well, I keep on getting confused between nation and country and everything, but decisions in one part of the UK might well impact on another part.*
>
> *I mean to say a classic example of that is North Wales who were supplied by blood from Liverpool, even though they were over the border. Because the transfusion centre for Wales was in South Wales, in Swansea, and that supplied southern Wales but not northern Wales because northern Wales, obviously, was much closer and more convenient transport-wise to Liverpool.*

[1175] PRSE0002280.
[1176] Dr Pickles, while not familiar with the testing detailed recalled that the call for pilot tests carried some weight, "I think I've seen in the documentation somewhere that the second generation tests didn't have an FDA licence and, therefore, we had to have a study in our domestic circumstances, in any case, to validate them. So I think that would have carried some weight. And the first generation tests, the ones we'd done the pilots with, were being withdrawn, so we essentially didn't have much of a choice". Dr Pickles Oral Evidence on 12 May 2022; at 176:6 - 176:23. See further §7.105 below.
[1177] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §70.4.
[1178] WITN4486063.

> *So what would happen if England made a decision and Wales had a different decision? You know, you'd then even be splitting Wales into two halves."*[1179]

7.101. Further difficulties were outlined by Dr Gunson following Newcastle RTC's decision to introduce routine screening using the Abbott second generation test. [1180] Dr Gunson wrote to the Director of Newcastle's RTC on 29 April 1991 raising concerns over Newcastle's decision to introduce testing ahead of the rest of the country. He explained that there were a number of matters to be resolved, including the position of confirmatory tests, the information to be given to donors prior to testing and the counselling of donors. Concerns were also raised over the risk that Newcastle's decision could jeopardise ongoing contract negotiations between the Procurement Directorate for the supply of the tests. Dr Gunson noted in a minute to John Canavan on the same date that he had already received a phone call from Ortho asking what was happening as they had understood testing to have commenced in Newcastle using Abbott tests.[1181]

7.102. Dr Pickles' view was that Newcastle's introduction of testing could have been treated as part of the pilot scheme by way of compromise there was potential for the Service to learn from data in Newcastle alongside that of the pilot sites had Newcastle taken that approach. She made clear that she would "*...back up...*" Dr Gunson and the rest of the Transfusion Directors (in terms of their response to one centre taking a unilateral approach outside of the pilot study).[1182]

<u>The start date of 1 September 1991</u>

7.103. On 3 April 1991, Dr Gunson wrote to all Regional Transfusion Directors suggesting a new date for the introduction of routine screening of 1

[1179] Dr Rejman's oral evidence to the inquiry on 11 May 2022, at 86:23 – 87:18.
[1180] NHBT0000062_054: Dr Gunson's letter at pages 3-4.
[1181] NHBT0000062_054: minute at page 2.
[1182] Dr Pickles' oral evidence on 12 May 2022, at 176:20 – 179:13

September 1991.[1183] He explained that since the completion of the three-centre trial of anti-HCV tests, Ortho and Abbott had produced second generation test kits. Evaluation of these test kits had not started, and one of the tests would not be available until late August. Dr Gunson suggested it was undoubtedly in the NBTS' interest to complete the evaluation but a revised date of 1 September 1991 was required for the routine screening.

7.104. The history leading up to this further delay is set out further in Dr Gunson's subsequent letter to the Director of Newcastle's RTC on 29 April 1991.[1184] He explained that by January/February 1991 it was known that the major companies were proposing to introduce refined tests. On 21 March 1991, the Department of Health agreed that there should be a 'second-round' evaluation of the tests kits.[1185] However, the timing for this evaluation "*...slipped...*" due to production batches of the second generation tests from Ortho not being available until the first week in April and those from Abbott not being available until later in the month.

7.105. Subsequently, it became apparent that the first generation tests were no longer available.[1186] In a minute from Dr Pickles to Dr Metters on 10 May 1991, she highlighted that "*...the second generation tests are not FDA approved, hence proper evaluation is vital.*" The start date of 1 September looked likely.[1187]

7.106. John Canavan explained in his written evidence to the Inquiry that his "*...understanding was the evaluation was deemed necessary so the RTCs knew which test to adopt. The second-generation tests had not been used by RTCs and it was necessary to know what the advantages and*

[1183] NHBT0000073_065.
[1184] NHBT0000062_054.
[1185] Letter from Procurement Directorate to Dr Gunson on 21 March 1991 at NHBT0000191_115.
[1186] NHBT0000192_033.
[1187] NHBT0000192_033.

disadvantages [were] and which should be recommended for use."[1188] Again, the evidence suggests a desire to get things right the first time. This had an impact on the timing of the introduction of routine screening. But as observed by Dr Pickles "*...in the event, we were able to have the benefit of the more reliable second-generation tests and confirmatory tests for our donors.*"[1189]

Ministerial involvement

7.107. An issue which has arisen through CTI's questioning of relevant witnesses, is whether officials appropriately involved ministers once it became apparent that there would be delays to the timetable for introducing HCV screening.[1190]

7.108. Lord Waldegrave's evidence was that this issue was not brought to his attention.[1191] However, he did not consider that unusual. In his view, Baroness Hooper did not need to involve him in the decision making as her views accorded with the advice being given and with the views of the CMO. Lord Waldegrave suggested he would only expect to become involved if there was difficulty over a particular issue such as funding which could not be resolved without his intervention.[1192]

7.109. Baroness Hooper's made clear that her independent recollection of these matters was limited and that she relied heavily on the documentary records provided to her.[1193] She noted that it was difficult to reconstruct what she knew at the time these decisions were being made.[1194] The Inquiry is referred to the detailed account in her statement, including as to the issue of ministerial notice of the Newcastle RTC's action.

[1188] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.174.
[1189] Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §74.3.
[1190] See for example Lord Waldegrave's oral evidence on 6 July 2022, at 41:9- 43:2.
[1191] Lord Waldegrave's oral evidence on 6 July 2022, at 39:8.
[1192] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §6.2.
[1193] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §0.5.
[1194] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §31.29.

7.110. In his witness statement, Lord Waldegrave expressed the view, but with significant caveats, that officials probably should have updated Lady Hooper further:

> *"However, officials also had a judgement to make on whether, and at what time, it was necessary to go back to ministers to update on progress or advise of any delays and the reasons for them (for example, in this context, that it was considered desirable for an evaluation exercise to be carried out on the second generation tests). On balance, I think that if they did not do so, officials probably should have updated Lady Hooper on this prior to 30 July 1991. But I make that observation with some diffidence since:*
>
> *(1) The documentary record may not be complete.*
>
> *(2) I do not know now whether there may have been verbal updates provided.*
>
> *(3) Additionally, it is hard now to speculate on what our ministerial reaction would have been; it is possible that we would have taken the view (for example) that the case for evaluation of second generation kits was made out and that the implementation date of 1 September 1991 was reasonable in all the circumstances."*[1195]

Whether testing should have been introduced sooner

7.111. In the hope of assisting the Chair, set out below is a summary of the relevant evidence of Departmental witnesses from the time, on the question of whether testing should have been introduced sooner.

7.112. In *A and Others v The National Blood Authority and Others* [2001] 3 All ER 289, Burton J concluded that (applying the product liability test) routine screening ought to have been introduced by 1 March 1990.

7.113. The conclusions of the Penrose Inquiry on this issue are to be found at §31.527 - §31.530 of that Inquiry's report; they are very familiar to this Inquiry. In short summary,

[1195] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §6.10.

(1) In respect of the period from the summer of 1988 until the ACVSB recommended the introduction of screening on 21 November 1990, the Penrose Inquiry concluded that:

(a) The emergence of two committees - one established by the Department and one established by the transfusion services - created a risk of confusion as to the respective remits of each and the relationship between them.

(b) A decision to recommend to ministers the introduction of routine screening of blood donations for anti-HCV could and should have been taken by the middle of May 1990. The meetings of the ACVSB on 24 April and 2 July 1990 were missed opportunities to recommend the earlier implementation of screening.

(c) It was unlikely, however, that screening in any centre could have started much before the autumn of 1990.

(2) In respect of the period from the recommendation to introduce screening, during which implementation was arranged, until screening started across the UK on 1 September 1991, the Penrose Inquiry concluded that:

(a) There was a delay of almost ten months because a policy set at the outset - that the introduction of screening across the UK should take place at the same time - was maintained despite some areas being ready to begin considerably earlier than others.

(b) Further, the period 21 November 1990 to 12 June 1991 included a number of missed opportunities for more prompt introduction of screening (at least in Scotland).

7.114. Reflecting on Burton J's findings, Lord Waldegrave's evidence to this Inquiry was that:

(1) Looking at the matters now, based on the available papers, the main reason that the roll-out was going to be in September 1991 and not

April 1991 was said be that second generation tests had become available and it was decided to carry out evaluation of those tests.

(2) He noted reference to other factors: the policy of unified start date across the whole of the UK and the impact of the Gulf War and preparations for it.

(3) He did not feel able to judge, retrospectively, the exact reasons for the time taken from the December 1990 submission to 1 September 1991 (still less the period before he was Secretary of State).

(4) Nevertheless, reviewing Burton J's decision (and with the caveat that he was not Secretary of State for the whole period, Lord Waldegrave reflected that his own view was that "*...it is clear that it would have been possible to introduce the screening sooner.*"[1196]

7.115. Baroness Hooper has also reflected on the judgment in *A and Others.* She set out that she respects the findings of Mr Justice Burton. She was aware that several other countries commenced screening earlier than the UK; however, "*...as far as [she] could see, the expert advisory committee, the ACVSB, gave careful consideration as to when it would be the right time to introduce routine screening for Hepatitis C, and to the steps needed to implement it appropriately.*" [1197]

7.116. In her statement, Dr Pickles set out her view that the policy decision could not have been taken any sooner.[1198] However, she had expected the policy decision to be implemented faster and observed that the main barriers included general funding levels affecting budgets and staffing in the RTDs, as well as the Gulf War, both of which were outside of her control. [1199] In John Canavan's view, the delay "*...came down to a series of considerations*

[1196] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §6.6.
[1197] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §32.2.
[1198] Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §74.2.
[1199] Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §74.3.

and steps that seemed quite reasonable at the time…"[1200] but otherwise it was a matter for the Inquiry to determine. [1201]

7.117. Dr Rejman's evidence was that "*…it is difficult to see how testing could have been introduced at a much earlier date, taking into account the need to maintain confidence of donors, in order to ensure an adequate supply of blood. Without this, there would be a major impact on the ability of the NHS to provide appropriate treatment for many patients.*"[1202] Dr Rejman further elaborated on some of the practical difficulties with introducing screening in his oral evidence to the Inquiry and stressed the practical issues faced by the Transfusion Service in organising implementation.[1203]

Testing for Hepatitis C without consent

7.118. One of the issues raised in this Inquiry has been whether medical practitioners tested patients without their consent to establish whether they were infected with HCV,[1204] and, if so, the role or involvement of the Department.

7.119. As referenced in addressing HIV issues at paragraph 4.150 above, obtaining patient consent was a duty of clinicians, according to the ethical guidance current at the time, regulated ultimately by the GMC.[1205]

7.120. There is brief reference to this issue being raised in a meeting of the AIDS Group of Haemophilia Centre Directors on 12 February 1990, addressed in the Third Statement of Dr Rejman.[1206] Dr Rejman noted that in the meeting, which he attended, Professor Bloom stated that "*...he didn't see why*

[1200] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.196.
[1201] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §2.200.
[1202] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §75.9.
[1203] Dr Rejman's oral evidence on 11 May 2022, at 143:5-144:10.
[1204] Issue 255 of the Inquiry's Amended List of Issues, issue 255.
[1205] INQY0000249 and oral presentation on 28 May 2021.
[1206] WITN4486040, Q26 and Q27.

permission needed to be asked for Hepatitis C tests as this was just another LFT".[1207] Dr Rejman set out that "*...people at DH*" would not have agreed with that view. He noted that, at the meeting, Dr Savidge expressed a contrary view on the need for permission ("*...he would advise caution at present*"). Dr Rejman noted that the DH was not asked for its input.

7.121. It appears that the issue of testing for HCV without consent was raised by Carol Grayson as part of her call for a public inquiry, in an email for the attention of ministers (Lord Hunt and Hazel Blears) on 19 January 2003.[1208] At this time, Lord Morris also wrote to the Secretary of State for Health, Alan Milburn, enclosing a journal article from Louella Houldcroft on this topic.[1209] Subsequently, in an internal email, the then head of the Blood Policy Team at the Department, Charles Lister, indicated that he had *"...spoken to the Haemophilia Soc who have been aware of this issue for years and have produced reports on the subject."* Mr Lister set out the 1988 GMC guidance which implied that consent should have been given. In the interim, Mr Lister suggested a "*...holding reply*" should be sent to Lord Morris.[1210]

7.122. Thereafter, Mr Lister contacted a number of haemophilia clinicians for their comments on the allegation that Haemophilia patients were tested without their knowledge or consent, and that positive results were in some cases withheld.[1211] Dr Charles Hay, a consultant Haematologist and Haemophilia Centre Director at Manchester Royal Infirmary responded to say that he was familiar with the allegations because they were being made by at least one of his patients.[1212] He described how most Haemophilia patients with liver disease had been told prior to the introduction of testing that this was attributable to hepatitis C. He said that it would have been unusual for the test not to have been discussed, although it may have been done as a

[1207] HCDO0000271_014.
[1208] DHSC0006235_014.
[1209] Letter dated 22 January 2003 at DHSC0004003_022, letter from Ms Houldcroft at DHSC0004003_023.
[1210] DHSC0004003_036.
[1211] DHSC0004294_002.
[1212] DHSC0004294_002 at page 4.

routine test to confirm the presence of Hepatitis C, which was already expected. He explained that because of this, the discussion may have been limited and may not have been documented, although in some cases the patient was written to at the same time as their GP.[1213]

7.123. In his response to Charles Lister, Dr Mark Winter, the Director of Kent Haemophilia Centre, suggested that this "*...is a complex issue but all in all [the allegations do not] have any significant foundation.*"[1214] He noted that there was no national policy to recommend that centres counsel their patients before testing, and it was likely that some did whereas others did not. However, he was not aware of any centres having a policy of withholding results, although "*...it was not always possible to understand the full implications of a positive HCV antibody result because in theory this could mean either that the patient was infected or had been infected and had subsequently cleared the virus.*" He suggested that the UK Haemophilia Centre Doctors' Organisation ("UKHCDO") would refute the allegations "*...more or less totally*". He was not aware of any results being withheld and remembered many conversations with colleagues about how difficult it was to convey the meaning of a positive HCV antibody test.

7.124. Dr Giangrande, Consultant Haematologist at Oxford University Hospital, said that stored samples had been tested "*...as much to test the test as to test the patient*" and "*...there was a time lag of 1 or 2 years in telling patients because no one was sure until then what the results meant. However, he was confident that patients would have been aware that tests for the virus were being done.*"[1215]

[1213] DHSC0004294_002 at pages 7-9.
[1214] Email at DHSC0004294_002 page 2, attached letter at DHSC0006235_008.
[1215] DHSC0004294_002.

7.125. Subsequently, the GMC confirmed that they were investigating the issue of HCV testing without consent, but that as yet no decision had been made. On 8 May 2003, the GMC made the following request of the Department:

> *"To avoid complicating matters, it would be useful if you and/or ministers would confirm you are aware we are looking into the issue, but not give out too much further information. Our investigations are at an early stage, and we do not want to run the risk of prejudicing anything."* [1216]

7.126. The material set out above appears to have formed the basis of a submission to Hazel Blears on 21 May 2003 addressing the response to Lord Morris' question.[1217] It noted that "*We understand that one reason HCV antibody tests may have been undertaking on haemophilia patients without their written consent is because it was practice at the time to get verbal consent….. The question of informed consent for any disease or testing process is treated much more seriously nowadays, but the practice at the time was quite different."* A handwritten note at the top addressed to Ms Blears noted that "*...Informed enquiries made by officials hasn't [sic] thrown up anything that we should be concerned about. We should await the GMC investigation, but keep an eye*." The advice given was that it would be inappropriate to comment on the substance of the allegation whilst the investigation is underway.

7.127. Hazel Blears responded to Lord Morris' letter of 22 January on 5 June 2003:

> "*Since we received your letter, we have given careful consideration to the allegations in The Journal, and have begun to make our own enquiries. Department of Health officials have been in touch with the General Medical Council (GMC) and clinicians. However, as you may know the GMC has also received these complaints and has announced that they are conducting their own investigation looking into the actions of doctors responsible for the treatment of blood-borne diseases. It would therefore be inappropriate for me to comment on the substance of the allegations while the GMC investigation is underway*."[1218]

[1216] DHSC5541405.
[1217] DHSC0004003_015.
[1218] DHSC0004003_013.

7.128. Details of the complaints received by the GMC which are relevant to the Inquiry's terms of reference have been provided to the Inquiry by Charles Massey on behalf of the GMC.[1219] The GMC identified 15 cases in which consent was raised as an issue, 14 of which were considered by the Case Examiners. In all of these cases there were also other allegations being made.[1220] In no cases was a finding made that a doctor's fitness to practise was impaired or was a doctor found guilty of serious professional misconduct. No action was taken on the registration of any of the doctors.[1221]

7.129. Charles Massey has exhibited the anonymised case files. A review of these files shows that almost all of the complaints relating to HCV testing without consent were not taken forward by the GMC, after review by its Case Examiners, due to contradictory evidence in the patients' medical records which suggested that the patient had been informed about both the testing and the result.[1222] The GMC further recognised that knowledge was constantly developing at the relevant time and was not critical of doctors in relation to this issue.

7.130. The general picture with regard to guidance to professionals on patient consent for treatment and other interventions is that it has been regarded as a matter for the regulators of medical and other clinical professionals, overseen by the Courts, which have also established applicable legally-binding standards. As also addressed in Section 4 of these submissions, whether the DHSC should have a role was raised briefly with Professor Sir Jonathan Van-Tam in oral evidence on 18 November 2022. His reply suggested that he doubted that the CMO would become involved in the issue of general guidance to all clinicians on an issue such as informed

[1219] Charles Massey's witness statement on behalf of the General Medical Council dated 28 June 2019 (WITN3365001); spreadsheet summarising the complaints at WITN3365009.
[1220] Charles Massey's witness statement on behalf of the General Medical Council dated 28 June 2019 (WITN3365001), § 76.
[1221] Charles Massey's witness statement on behalf of the General Medical Council dated 28 June 2019 (WITN3365001), §77.
[1222] **WITN3365012_001-WITN3365031_001**

consent, which should be "*...hardwired into our system*". He gave evidence as to the preference to first use *"...a more sane and obviously connected route within the existing … healthcare management leadership system…*" to address specific problems, by preference.[1223]

[1223] Professor Van-Tam's oral evidence on 18 November 2022, at pages 23:18–25:22.

Section 8: HIV and HCV lookback and prevalence

8.1. The DHSC legal team has been much helped by the detailed written chronological presentation on Early Lookback Investigations prepared by the Inquiry's Counsel Team in October 2021, which *"...addresses attempts to trace infected blood and blood products in the UK blood service prior to the formal HCV lookback which commenced in 1995."*[1224] These submissions do not seek to repeat this chronology or address attempts to trace blood and blood products infected with Hepatitis C virus ("HCV") prior to the introduction of routine screening of blood donations for HCV in September 1991. They address the key considerations involved in the introduction of HCV lookback exercises from this point onwards on which the Chair is likely to need to make findings of fact.

8.2. The Inquiry's Counsel Team's presentation on Early Lookback Investigations succinctly outlines the two types of lookback:

> *"The first is when a donation is tested and indicates that a donor is infected. The possible recipients of the donation are traced to see if he or she is infected. This is commonly described as a "targeted lookback". The second type of lookback is known as "reverse lookback" which is when a patient presents with signs and symptoms of an infection and an investigation is undertaken to see if that patient has ever received blood or blood products. In these circumstances the treating clinician then notifies local or national blood banks that there is likely to be an infected donor."*[1225]

8.3. It is generally "*targeted lookback*" that these submissions focus on.

HIV lookback exercise

8.4. Before the key issues relevant to HCV lookback, on which the Chair is likely to need to make findings of fact, are explored in detail and in order to assist the Chair, these submissions will first briefly address the history of efforts to trace individuals infected with HIV through blood and blood products. This

[1224] INQY0000310, §1.
[1225] INQY0000310, §2.

section is not intended to be a comprehensive summary of all aspects of the evidence relevant to the HIV lookback exercise, but rather it intends to assist the Chair by providing context to the HCV lookback efforts that followed and point to similar themes encountered in the immediately preceding HIV lookback exercise that are likely to have informed decision-making in respect of HCV.

8.5. On 11 July 1985, a "*Report from the Working Party of the Regional Transfusion Directors' Committee*" was issued detailing the process that would be followed in relation to the introduction of HTLV-III testing, which is explored in detail at paragraphs 4.151 to 4.162 of these submissions.[1226] In relation to *"Follow-up of recipients of previous donations given by donors found to be HTLV-III positive"*, the Report noted that:

> *"Efforts will be made to determine the names of any patients who received blood and components from the donations taken during the past five years and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient."*[1227]

8.6. At its meeting on 30 July 1985, the Expert Advisory Group on AIDS reviewed the Working Party's Report and agreed with its recommendation.[1228]

8.7. HTLV-III screening was introduced in October 1985.[1229] Dr Patricia Hewitt gave evidence to the Inquiry; she was a Consultant Haematologist at the North London Blood Transfusion Centre ("NLBTC") from 1984 to 1995, where Dr Hewitt managed the HIV lookback programme for NLBTC, and then subsequently Lead Consultant in Transfusion Microbiology for the London and South East Zone of the National Blood Service from 1995 to 2000, where she managed the HCV lookback programme for NLBTC and the South Thames Regional Transfusion Centre. Dr Hewitt described the

[1226] DHSC0000406.
[1227] DHSC0000406, §7.1.
[1228] PRSE0002628, §7.4.3.
[1229] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §187.

HIV lookback exercise that commenced alongside screening in October 1985 as *"...correspondingly small-scale..."* when compared to the HCV lookback exercise that followed.[1230] Dr Hewitt explained that this was because:

> *"The NBTS could only screen donations from active blood donors. Donor education and encouragement of those who recognised themselves to be at risk of HIV infection to self-exclude from blood donation had been extremely successful, so that by the time that screening of blood donations commenced in October 1985, very few HIV positive donors were detected. The HIV status of those who had self-excluded would remain unknown, unless reports were made when any such individual was found to be HIV positive outside the blood donation setting. We therefore had to rely on clinicians and/or seropositive individuals themselves to come forward and inform the blood service. Only then could lookback on such donations be possible."*[1231]

8.8. The evidence before the Inquiry has identified some of the key obstacles with the HIV lookback exercise implemented in October 1985. In 1991 Dr Busch published an article in the journal "*Transfusion*" on HCV and HIV lookback.[1232] The article considered some of the lessons of the HIV lookback exercise when HCV lookback was under consideration.[1233] Although the article largely makes reference to the USA, in respect of HIV lookback exercises in general it noted:

> *"Standard, targeted look-back was limited, ironically, by the effectiveness of early self-exclusion measures, in that almost all of those responsible for HIV infections had stopped donating before they could be identified by anti-HIV screening. Additional limits were created by the high death rate of recipients who were identified by tracing transfused components from infected donors, as well as the delay in and logistics of manual record searching and individual recipients tracing and notification through hospitals and private physicians...Thus, even in San Francisco, where look-back probably has been pursued more aggressively than anywhere else in the world, a substantial proportion of HIV-infected transfusion recipients are undoubtedly still unaware of their infection more than 6 years after screening was implemented."*[1234]

[1230] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §§295-296.
[1231] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §187.
[1232] PRSE0004329.
[1233] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §221.
[1234] PRSE0004329 page 5.

8.9. A report by Dr Hewitt from May 1993 entitled "*Investigation of Possible Transmission of HIV by Blood Transfusion*" noted that another issue encountered with HIV lookback was that *"[l]aboratory record keeping was generally deficient prior to 1985; accurate recording of transfusion details in patient medical records remains a conspicuous problem up to the date of the report."*[1235]

8.10. When comparing the HIV and HCV lookback exercises, Dr Hewitt noted another key issue with the HIV lookback exercise was that the English blood service was not organised at the time of the HIV lookback exercise. This made collecting the results of the lookback and ensuring uniformity across regions difficult.[1236]

8.11. There are obvious parallels that can be drawn between the consideration of and implementation of the HIV and HCV lookback exercises and this preliminary consideration of the introduction of HIV lookback in October 1985 is intended to underline this point at the outset of this section of the Department's submissions on lookback.

Consideration of HCV lookback alongside the introduction of routine screening of blood donations for HCV in September 1991

Discussions on HCV lookback in 1990 and 1991

8.12. One of the issues identified in the Inquiry's List of Issues (as amended in September 2021) is whether there was any delay in undertaking lookback exercises and, if so, why.[1237]

[1235] DHSC0006351_032.
[1236] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §299.
[1237] Issue 389.

8.13. In 1990 and 1991 the Department and the Scottish Home and Health Department ("SHHD") considered whether a HCV lookback element should be introduced as an accompaniment to routine screening of blood donations for HCV.[1238]

8.14. On 21 June 1990, Professor John Cash (National Medical & Scientific Director, SNBTS) invited Dr Jack Gillon (South East Scotland Transfusion Service ("SEBTS") to chair a Working Party to draft *"...operational guidelines for BTS doctors (or other doctors engaged by the BTS), in the context of counselling anti-HCV confirmed +ve donors"* [original emphasis] for consideration by SNBTS Directors.[1239] Professor Cash requested that Dr Gillon *"...keep Dr Harold Gunson in touch with your activities as we would like to see as much harmonisation north and south of the Border as possible."*

8.15. At meetings in November 1990, the SNBTS Medical & Scientific Committee and the ACVSB each considered HCV lookback in anticipation of the announcement of the introduction of routine screening of blood donations for HCV.[1240] At its meeting on 21 November 1990, the ACVSB agreed that the issue of counselling of HCV positive donors (which included the question of lookback in relation to routine HCV screening) should be referred to the UK's Advisory Committee on Transfusion Transmitted Diseases ("ACTTD").[1241]

8.16. At its meeting on 8 January 1991, the ACTTD discussed Dr Gillon's Working Party's draft paper prepared for SNBTS Directors.[1242] In relation to HCV

[1238] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§37.5-37.17.
[1239] PRSE0004689; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §37.5(6).
[1240] PRSE0000348; ARCH0003390; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§37.6-37.7.
[1241] ARCH0003390; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §37.7.
[1242] NHBT0000073_028; NHBT0000042_067; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §37.8.

lookback, the introduction in the draft paper dated 23 November 1990 noted that the Working Group had met on 3 July 1990 and concluded that:

> *"Donors may well ask about the outcome of their previous donations, and a clear policy on lookback is essential. We note the logistical difficulties, which have been taken as justification by the AABB for not recommending a lookback, but our view was that this position is untenable in view of the desirability of informing recipients so that they can protect others, and also receive treatment with Interferon if the benefits of this form of therapy are confirmed."*[1243]

8.17. The draft paper recommended lookback following the identification of HCV positive donors. The final paper for SNBTS Directors of February 1991 reiterated this recommendation.[1244]

8.18. On HCV lookback, the ACTTD agreed at its meeting on 8 January 1991 *"…that there may be an ethical obligation to inform patients who may have received transfusions in the past from anti-HCV positive donations"* but noted that *"[t]his will involve considerable additional work including testing of library samples and will have to be funded."*[1245]

8.19. At meetings in February and March 1991, the SNBTS Medical & Scientific Committee, the ACVSB and the ACTTD each agreed that no HCV lookback element would be introduced as an accompaniment to routine screening of blood donations for HCV.[1246]

Reasons for decision not to introduce HCV lookback as an accompaniment to routine screening of blood donations for HCV

8.20. The reasons for the decision not to introduce HCV lookback alongside the introduction of routine screening of blood donations for HCV in September

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[1243] PRSE0000515.
[1244] PRSE0000823.
[1245] NHBT0000073_028; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §37.8.
[1246] PRSE0003568; NHBT0000042_058; NHBT0000073_063; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§37.10-37.13.

1991 are not well documented in the contemporaneous papers. However, these reasons have been given by some retrospectively in the context of the consideration given to the formal HCV Lookback Exercise implemented in 1995 (see further below) and include:

(1) In September 1991 there was no effective treatment for HCV.[1247] This point was explained succinctly in the briefing for supplementary questions supplied to Dr Jeremy Metters ("DCMO") when he announced the national Lookback Exercise on 11 January 1995:

> *"Until recently it was considered that look back to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress without any benefit."*[1248]

The views of Dr Metters himself on this issue are set out in a letter to Dr Nicholas dated 17 March 1994 on the topic of screening for asymptomatic HCV more generally:

> *"I am reminded of one of the Wilson and Junger (sic) criteria for introducing a screening programme, that screening programmes should only be introduced if an effective treatment is available! There would be little point introducing a screening programme if there is no effective treatment."*[1249]

The Department's consideration of the Wilson and Jungner "*Principles and practice of screening for disease*" in the context of the reasons for not introducing HCV lookback alongside routine screening in September 1991 is explored in greater detail at paragraphs 8.30 to 8.32 of these submissions below.

[1247] See PRSE0001236, paper written by Professor Cash dated 10 November 1994 "Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection to the MSBT concerning the merits of adopting an HCV "look-back" policy"; PRSE0002894, evidence of Dr Young (DCMO, SHHD) to the Penrose Inquiry, §2.
[1248] NHBT0005855.
[1249] DHSC0002546_019.

(2) In contrast to HIV, secondary transmission of HCV to sexual partners and children was considered to be relatively rare.[1250]

(3) No pilot HCV lookback study had been completed by September 1991.[1251] The feasibility of a lookback exercise was therefore unknown.

(4) The scientific and medical knowledge of the long-term effects of HCV infection were still not clear.[1252] In her evidence to the Inquiry, Dr Angela Robinson (Chief Executive of Yorkshire Regional Blood Transfusion Service from 1988 to 1994 and subsequently Medical Director of the National Blood Authority from 1994 to 2005) explained that:

> *"It had been widely believed for some time that this was usually a relatively benign illness which was frequently asymptomatic. Extended follow up of patients in the TTV study had shown that some patients might develop cirrhosis (around 20% after 20 years) and a small number might die of liver failure or hepatic carcinoma, but the mortality rate in the infected appeared in fact similar to that in the controls, that is there did not appear to be an increased death rate in those infected."*[1253]

Knowledge of NANB Hepatitis infection risk is explored in section 3 of these submissions.

(5) As explained at paragraph 4.160 of these submissions, the early screening tests for HCV produced a high number of false positive results. Dr Robinson commented that *"[t]he very real problem of false positives would have made lookback from the introduction of screening problematic."*[1254]

8.21. Against that, the Inquiry has heard evidence from some working in the National Blood Service during the relevant period to the Inquiry that a HCV

[1250] See PRSE0001236.
[1251] See PRSE0002894.
[1252] See PRSE0001236; PRSE0002894; NHBT0005855.
[1253] Dr Robinson's second witness statement (WITN6926003), §289.
[1254] Dr Robinson's second witness statement (WITN6926003), §291.

lookback exercise should have been introduced alongside the implementation of routine screening of blood donations for HCV in September 1991.

8.22. Dr Hewitt disagreed with the reasons for the decision not to introduce a lookback element to the implementation of routine screening for HCV, commenting that *"[t]he stance of the Department seemed illogical to the blood services"*, *"[t]here had been general consternation within the blood service that a lookback had not been mandated by the Department"* and that, in respect of a lack of any effective treatment for HCV, the same reasoning could have been applied to HIV, for which a lookback exercise was implemented in 1985.[1255]

8.23. Dr Hewitt explained that as hospital laboratory records were generally held for a finite period of time (10-12 years), in her view the failure to implement HCV lookback alongside the introduction of routine screening in September 1991 meant that *"...the opportunity was lost to identify and trace a small number of surviving recipients transfused in the early 1980s, because the hospital laboratory records had been destroyed in the years 1991 to 1995."*[1256] Dr Hewitt commented that she was *"...disappointed and sorry that more people were not traced"* but was *"...not sure though even now what more we could have done in the circumstances."*[1257]

8.24. In relation to the reasoning that as there was no effective treatment for HCV in September 1991, there was little point tracing recipients of blood from donors found to be infected with HCV because little could be done to help those infected and it might only serve to cause them distress, Dr Hewitt *"...strongly believed that the obligation towards recipients existed separately to any consideration of potentially available treatment. HIV lookback in 1985*

[1255] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §87.
[1256] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §294.
[1257] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §383.

took place under exactly that situation, as there were no effective treatments for HIV at that time…" and she *"…never understood why the lack of available treatment for HCV could be used as an argument for not carrying out lookback, when a precedent already existed."*[1258]

8.25. Dr Hewitt's view was that despite the lack of treatment for HCV in September 1991, those infected could have benefited from being advised to limit their alcohol consumption because this could make liver disease less likely or severe in future.[1259]

8.26. Dr Robinson's view was that *"[i]n retrospect it is clear that HCV look-back could and should have been implemented at the time anti-HCV screening commenced and probably would have been if those concerned had known what is known now."*[1260] As indicated above in these submissions, Dr Robinson did concur with some of the reasons why HCV lookback was not implemented alongside screening in September 1991. In her evidence to the Inquiry, Dr Robinson commented on the realities of informing individuals that they had been infected with HCV when there were scientific unknowns about the condition and there was no effective treatment that could be offered to the patient:

> *"Before we made the decision to tell donors or recipients, we had to know what we were telling them, that it was reliable information – and who we were telling. Hepatitis C might be serious in some people, but the serious consequences might not manifest for 30 years and even when we commenced the lookback in 1995, what treatment there was available was only recently licensed and still experimental. We could put a blight on the lives of many people, without hope at that stage for an undetermined possible good for some of them. There was a belief that we ran the risk of doing quite extensive harm, for an undefined benefit to a small number of people…All that could be done until there was a treatment was to give everybody potentially devastating news with no hope and no way of telling who out of them may suffer serious*

[1258] Dr Hewitt's second witness statement dated 24 November 2021 (WITN3101009), §312.
[1259] Dr Hewitt's oral evidence on 10 December 2021, at 5:4-6:22.
[1260] Dr Robinson's second witness statement (WITN6926003), §639.

> *life-changing or life-limiting conditions, who may have no symptoms at all and who may develop illnesses after many years."*[1261]

8.27. Dr Robinson ultimately noted that the blood services had expected lookback to be introduced alongside screening, as had been the case with HIV, it *"...should have been done at the time...in spite of the obstacles and limited effectiveness..."* and that implementing lookback earlier *"...would have allowed us to identify some additional transfusion recipients who were at risk."*[1262]

8.28. It was Dr Gillon's evidence to the Inquiry that the decision not to introduce HCV lookback alongside HCV screening was in his view *"...entirely unacceptable"*[1263] and that he *"...could see absolutely no justification for it..."* at the time.[1264] Dr Gillon initiated a targeted lookback exercise carried out in Southeast Scotland from September 1991 to February 1992, subsequently labelled a *"pilot scheme"*, which is explored at paragraphs 8.39 to 8.41 of these submissions below. In relation to the argument that a lack of treatment for HCV in September 1991 would make any lookback exercise futile, it was Dr Gillon's view that if practitioners knew about a patient's condition, *"...they would be first in line for treatment"* when it became available and informing patients would allow them to take steps to prevent sexual transmission.[1265]

8.29. Professor Dame Marcela Contreras (Chief Executive and Medical Director at NLBTC between 1984 and 1995 and subsequently Executive Director of the London and South East Zone of the National Blood Service between 1995 and 1999) added that the delay between the introduction of routine screening in September 1991 and the start of the formal HCV lookback in

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[1261] Dr Robinson's second witness statement (WITN6926003), §§413-418.
[1262] Dr Robinson's second witness statement (WITN6926003), §§641-642.
[1263] Dr Gillon's witness statement dated 21 December 2021 (WITN6987001), §250.
[1264] Dr Gillon's oral evidence on 19 January 2022, at 103:11.
[1265] Dr Gillon's oral evidence on 19 January 2022, at 104:21-105:11.

1995 was *"[t]otally inappropriate"*[1266] and that the NLBTC wanted to commence HCV lookback earlier but the Department would not provide the funding.[1267]

8.30. In determining whether or not the delay of the introduction of the HCV lookback exercise between 1991 and 1995 was appropriate, the Inquiry was not, of course, able to hear from many individuals who sat on the Advisory Committees who recommended against the introduction of a lookback exercise in 1991, and Dr Metters (DCMO) in particular. Effectively in his absence, Dr Andrzej Rejman (Senior Medical Officer for Haematology in the Department from 1989 to 1997) tried to outline the possible concerns that may have been considered by the ACVSB at its ninth meeting on 25 February 1991 when the Committee agreed that no HCV lookback element would be introduced as an accompaniment to routine screening of blood donations for HCV.[1268] Dr Rejman highlighted that *"[i]nforming apparently healthy individuals that they had a potentially serious illness, which had no established treatment available, might be difficult and was contentious."*[1269] He referred to Wilson and Jungner "*Principles and practice of screening for disease*", which were well-established at the time and are still in use.[1270] Those principles include:

> *"(2) There should be an accepted treatment for patients with recognized disease.*
>
> *(3) Facilities for diagnosis and treatment should be available."*[1271]

8.31. In their 1968 paper, Wilson and Jungner expanded upon the significance of ensuring that treatment is available for the disease when considering whether to introduce a screening programme:

[1266] Professor Dame Marcela Contreras's oral evidence on 3 December 2021, at 137:8-137:14.
[1267] Professor Dame Marcela Contreras's witness statement dated 14 October 2021 (WITN5711001), §351.
[1268] PRSE0002280.
[1269] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §122.3.
[1270] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §122.3.
[1271] Wilson JMG, Jungner G. *Principles and practice of screening for disease*. Geneva: World Health Organisation, 1968 - Principles and practice of screening for disease / J. M. G. Wilson, G. Jungner (who.int), page 26.

> *"Of all the criteria that a screening test should fulfil, the ability to treat the condition adequately, when discovered, is perhaps the most important…For declared disease there is, of course, the ethical obligation to provide an accepted treatment whether or not this is of scientifically proved value; but, when new territory is being explored by the earlier detection of disease, it is clearly vital to determine by experimental surveys whether a better prognosis is given by treating the conditions found at an earlier stage than was previously the practice. Unless this is so, there can be no advantage to the patient and, in fact, alerting him or her to a condition that has not been shown to benefit by treatment at an earlier stage actual harm may be done."*[1272]

8.32. Dr Rejman's evidence was that *"[w]hilst the situation might not be exactly parallel…the principle that identification of a disease or infection was not – generally – warranted if there was no useful treatment that could be offered, would have been widespread."*[1273] As highlighted in these submissions above, this the view held by Dr Metters, raised in the context of the topic of screening for asymptomatic HCV more generally.[1274]

8.33. Dr Rejman also highlighted other issues with introducing HCV lookback at the time including a lack of confirmatory testing, the feasibility of the exercise and the relatively small risk of sexual transmission of HCV.[1275]

8.34. Dr Hilary Pickles (a Principal Medical Officer in the Department) also outlined the possible concerns of the ACVSB when it took the decision not to introduce HCV lookback alongside screening at its meeting on 25 February 1991. Dr Pickles referred to the scientific uncertainty about the condition, the feasibility of the exercise (in particular the potential issues caused by

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[1272] Wilson JMG, Jungner G. *Principles and practice of screening for disease*. Geneva: World Health Organisation, 1968 - Principles and practice of screening for disease / J. M. G. Wilson, G. Jungner (who.int), pages 27-28. See also the "Expert Report to the Infected Blood Inquiry: Public Health and Administration" of August 2022, which at page 12 discusses the Wilson and Jungner principles in the context of screening and surveillance. The importance of and weight attached to these WHO principles thus appears to be common ground.
[1273] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §122.3.
[1274] DHSC0002546_019.
[1275] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§122.3-122.4.

inadequate hospital records) and a lack of any effective treatment for HCV in September 1991.[1276]

8.35. As far as we are aware, there was no ethical advice taken in 1991 upon the merits of a lookback exercise, or (more specifically) on the relevance of an issue such as the availability of treatment, if the disease was detected. The closest parallel would appear to be with the advice sought and received in 1996, when the issue of non-notification of those at theoretical risk of vCJD in the TMER research was raised with Professor Ian Kennedy; see the section on vCJD at paragraphs 9.29 to 9.31. At that point in time, ethical approval of the proposed strategy was based on the absence of a treatment for vCJD. Whilst there are differences in the factual scenarios considered, still both this ethical advice and the Wilson & Jungner screening criteria may be considered by the Inquiry to provide some support for the ACVSB's consideration of the question of whether there was a "*better prognosis*" as a result of diagnosis; this was not, the Inquiry may consider, based on "*simple paternalism*" but on more established principles. On the other hand, it will also have regard to the evidence of (for example) Dr Hewitt (above), who emphasised that preventative "*lifestyle*" steps could still have been advised, even in the absence of treatment.

8.36. From the point of view of Department ministers, it appears that not only the ACVSB, but also the SNBTS Medical & Scientific Committee and the ACTTD made no recommendation that a HCV lookback element should be introduced as an accompaniment to routine screening of blood donations for HCV. The general role of medical scientific committees has already been discussed in relation to the role of the ACVSB and the introduction of screening, see paragraphs 7.5 to 7.24 of these submissions.

[1276] Dr Pickles's witness statement dated 25 April 2022 (WITN6965001), §82.3.

8.37. The Penrose Inquiry Final Report reached the conclusion that *"…1 September 1991 became the earliest date at which look-back could have been commenced"* but for the reasons mentioned above concluded that *"…it cannot be said that look-back should have been introduced generally in Scotland before November 1994."*[1277] The Report highlighted that HCV screening was the rate-determining step to the speed of the introduction of lookback but that there would have been initial hurdles whenever screening was introduced that would have had a knock-on effect on any lookback exercise (for example, false positive results, the development of confirmatory testing and the preoccupation with arrangements for the counselling of individuals that tested HCV positive). The Report also highlighted that these factors would not have affected the licensing process for Interferon, which only became licensed for treatment in the UK in November 1994.[1278]

8.38. Furthermore, whilst there may be arguments that the concerns summarised by Dr Robinson at paragraph 8.26 above were paternalistic, the Inquiry is invited to consider the evidence that a balancing of harms was involved in the decision not to introduce HCV lookback, and that the considerations of causing distress and fear to patients, when no active treatment could be offered, were genuine issues.

Reasons for the recommendation to introduce HCV lookback in December 1994

Consideration of HCV lookback – September 1991 onwards

8.39. The major initiative implemented between the introduction of routine screening of blood donations for HCV in September 1991 and the recommendation to ministers to introduce a HCV lookback exercise in December 1994 was a targeted lookback exercise carried out in Southeast Scotland from September 1991 to February 1992, and led by Dr Gillon of the

[1277] Penrose Inquiry Final Report at §§35.234-35.241.
[1278] Penrose Inquiry Final Report at §35.235.

SEBTS.[1279] The targeted lookback exercise in Southeast Scotland traced the recipients of blood donations where the donor had tested positive for HCV on returning to give blood after the introduction of routine screening for HCV in September 1991.[1280]

8.40. The HCV testing available gave the SEBTS a particular advantage that made the introduction of HCV lookback possible at this time. The Penrose Inquiry Final Report commented that:

> *"– All Scottish RTCs had access to second-generation ELISAs and RIBA confirmatory tests. In contrast, for up to 18 months after September 1991 some regions in England and Wales continued to be dependent on first-generation ELISAs and RIBA confirmatory tests.*
>
> *– Highly effective PCR testing was available in south east Scotland in particular from the beginning of routine donor screening in September 1991 but PCR tests of variable quality only reached the majority of those centres in England and Wales that had a particular interest in HCV infection around 1993 and 1994.*
>
> *...*
>
> *In using second-generation tests with ready availability of PCR testing, the SEBTS had exceptional technology, possibly unique in the UK, available to undertake look-back from the outset of donor testing in September 1991."*[1281]

8.41. A paper on the targeted lookback exercise in Southeast Scotland (subsequently labelled a "*pilot scheme*") published on 21 July 1994 estimated, based on this study, that around 3,000 living individuals in the UK might be infected with HCV as a result of blood transfusion.[1282] The paper concluded that:

> *"Our experience confirms that the identification of these patients is a daunting task, but the availability of potentially efficacious treatment for chronic hepatitis C in the form of α-interferon, compels us to suggest*

[1279] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §38.2.
[1280] PRSE0001046.
[1281] Penrose Inquiry Final Report at §§35.91-35.92.
[1282] PRSE0001046.

that we have a clear ethical responsibility to these patients to identify them and offer counselling, testing and, if necessary, treatment"[1283]

Recommendation to introduce HCV lookback in December 1994 and subsequent ministerial agreement

8.42. On 5 August 1994, a meeting of the Standing Advisory Committee on Transfusion-Transmitted Infection ("SACTTI") discussed the pilot scheme and referred the topic of HCV lookback to the MSBT *"...with a recommendation that such a policy is implemented."*[1284] The SACTTI's recommendation was considered by the MSBT at its meeting on 29 September 1994 and members were invited to submit comments on the recommendation to a sub-committee before the MSBT's next meeting.[1285]

8.43. At the MSBT's next meeting on 15 December 1994 it was agreed that a HCV lookback exercise should be recommended to ministers.[1286] Quickly thereafter on 22 December 1994 a submission was sent by Roger Scofield to the Parliamentary Under Secretary of State for Health, Thomas Sackville, putting the MSBT's recommendation forward to ministers.[1287] Thomas Sackville agreed to the MSBT's recommendation on 3 January 1995.[1288]

Reasons for the recommendation to introduce HCV lookback

8.44. The evidence before the Inquiry was that the key drivers for the MSBT's recommendation to introduce HCV lookback in December 1994 were:

(1) The Scottish experience, including the pilot scheme carried out by Dr Gillon's team at the SEBTS and the subsequent decision in Scotland

[1283] PRSE0001046.
[1284] NHBT0009383.
[1285] PRSE0001428.
[1286] MHRA0020247.
[1287] DHSC0032208_149 with annexes at DHSC0002501_116, DHSC0003555_228 and DHSC0032208_161.
[1288] DHSC0003555_084.

that the SNBTS should prepare for developing a HCV lookback exercise for 1995.[1289]

(2) Greater scientific information about HCV, including as to its transmissibility to sexual partners.[1290]

(3) The licensing of the drug Alpha Interferon in the UK for treatment for HCV in November 1994.[1291]

(4) Recognition that there may be a legal duty of care owed to those infected with HCV as a result of NHS blood transfusion.[1292] The submission to Thomas Sackville dated 22 December 1994 highlighted that Department lawyers and the MSBT had concluded that there may be a duty of care to *"...do whatever can reasonably be done to identify, inform, counsel and treat any who may have been infected as a result of NHS treatment. This is not entirely clear; nor is it an absolute duty but in circumstances where:*

- *SofS acknowledges a broad responsibility for public health and the care of those in need of medical treatment;*
- *and is in the habit of issuing warnings concerning action to be taken to safeguard health and of seeking to identify those who are in particular danger of suffering ill health;*
- *and if there is action that can be taken to identify and those who may be at risk;*
- *and having identified them there is action that could be taken to assist them;*

[1289] See Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §40.3; Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §127.5; Mr Sackville's witness statement dated 19 July 2022 (WITN5249001), §§4.9-4.24; Professor Keel's witness statement dated 13 July 2022 (WITN5736003), §A37; MHRA0020247, minutes of the MSBT meeting on 15 December 1994.
[1290] See Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §40.3; Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §127.5; Professor Keel's witness statement dated 13 July 2022 (WITN5736003), §A37.
[1291] See Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §40.3; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §40.12; Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§124.1-127.5; Mr Sackville's witness statement dated 19 July 2022 (WITN5249001), §4.9; Professor Keel's witness statement dated 13 July 2022 (WITN5736003), §A37; MHRA0020247.
[1292] See Mr Sackville's witness statement dated 19 July 2022 (WITN5249001), §4.9.

- *then if no such action is taken the SofS might have a case to answer."* [1293]

8.45. Witnesses were also asked whether the Panorama Programme "*Bad Blood*" that aired on 16 January 1995, drove the decision to recommend and introduce the HCV lookback exercise. This suggestion was resisted by witnesses (given the timeline of the consideration and recommendations of the expert advisory committees), although it was acknowledged that the programme did have the effect of pushing forward the public announcement of the HCV lookback exercise on 11 January 1995, when otherwise it would presumably have waited until the detailed practical arrangements of the lookback exercise had been worked out.[1294]

8.46. There is evidence before the Inquiry that the Panorama Programme generated considerable anxiety and concern amongst members of the public, with its own helpline proving difficult to get through to and closing by 19 January 1995.[1295] In addition, the helpline set up via the NBA after the announcement of the lookback exercise had received in excess of 12,000 calls by the time of the second meeting of the Lookback Working Party (see further explanation below) on 24 February 1995.[1296] It did however, presumably, drive awareness of the issue of possible infection and the records show discussion of whether GPs should refer those worried for testing, or await the formal exercise.

8.47. It was Thomas Sackville's evidence to the Inquiry that the Panorama Programme *"…formed part of the context at the time"* but did *"…not believe*

[1293] DHSC0032208_149.
[1294] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §40.10.
[1295] DHSC0041441_173; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §43.8.
[1296] WITN3430141; Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §42.5; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §43.4.

that it had any significant influence on the actual decision to proceed with a look-back exercise. Ultimately the Department was informed by expert opinion and reached a view based on that advice."[1297] Dr Rejman considered the Panorama Programme was not a catalyst for the announcement of HCV lookback, which was already under consideration by the relevant expert committees before the Department knew about it.[1298] This is a position supported by the consideration of HCV lookback by the SACTTI and MSBT much earlier in 1994, highlighted in these submissions above.

8.48. As it was, the public announcement of the formal HCV lookback exercise was made by an Inspired Parliamentary Question on 11 January 1995[1299], immediately followed by a press conference jointly chaired by Dr Metters and Dr Robinson. On the same day, a message was sent to all Directors of Public Health.[1300] The announcement noted that the planning for the process was underway. A Lookback Working Party was then set up to make the detailed practical arrangements for the HCV lookback exercise and give guidance on the process, which was prepared for the issuing of the CMO's letter on 3 April 1995.[1301] A chronology of the key steps taken by the Department between the MSBT's agreement to recommend the introduction of HCV lookback to ministers on 15 December 1994 to the announcement on 11 January 1995 is included in the Annex to Sir Kenneth Calman's witness statement.[1302]

HCV infections not identified by the lookback exercise

8.49. On 3 April 1995, a CMO's letter was issued by Kenneth Calman, which included guidance on: (a) HCV lookback procedures for RTCs; and (b)

[1297] Mr Sackville's witness statement dated 19 July 2022 (WITN5249001), §4.13.
[1298] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§127.6-127.8.
[1299] DHSC0004175_105.
[1300] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §41.11; Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §128.7; HHFT0000002_002.
[1301] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§134.1-134.4.
[1302] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§41.1-41.11.

counselling and treatment options for those identified through the lookback exercise as HCV positive.[1303] The guidance noted that the HCV lookback exercise implemented *"...relates to donors who have given blood since HCV testing was introduced in September 1991. For patients transfused prior to September 1991, it may only be possible to provide full reassurance by offering to test them for antibodies to HCV."*[1304]

8.50. One of the issues identified in the Inquiry's List of Issues (as amended in September 2021) is why (not all of) those who received a blood transfusion or blood products between 1970 and 1991 were traced and advised to seek a test through a more comprehensive lookback testing programme.[1305]

8.51. In order to assist with the Chair's consideration of this issue, these submissions will seek to draw on key evidence to the Inquiry in order to explain: (i) why recipients of blood from donors who had not returned to give blood after routine HCV testing was introduced in September 1991 were not included within the scope of the HCV lookback exercise implemented in 1995; and (ii) efforts made beyond this to trace and test this group of individuals.

Reasons why recipients of blood from donors who had not returned to give blood after September 1991 were not included within the scope of the HCV lookback exercise

8.52. The Lookback Working Party considered the issue of donors who had not returned to give blood after September 1991 repeatedly during 1995. The method discussed for tracing HCV positive donors who had not returned to give blood after September 1991 was through the testing of stored blood

[1303] NHBT0002796_002; BMAL0000022_003.
[1304] NHBT0002796_002.
[1305] Issue 389.

samples.[1306] At its meeting on 25 May 1995, the Lookback Working Party did discuss *"...whether HCV screening might be offered to anyone who has had a transfusion..."* but it was thought that this *"...could be very costly for the diagnostic services, although many of those who are concerned may already have gone to their GP and their GP may have done a test."*[1307] (This would have followed the publicity in early 1995).

8.53. On 5 February 1996, Dr Metters sent an interim report on the HCV lookback exercise to John Horam, Parliamentary Under Secretary of State for Health.[1308] In relation to testing and tracing pre-September 1991 blood donors who had not returned to give blood and the recipients of those donations, the interim report advised:

> *"The work involved in doing so would be disproportionate to the benefit. The Working Party considered the testing of serum samples stored from before September 1991 and agreed that Ministers should be advised that the testing of such samples would also be disproportionate...where an individual who had been given blood requested a test this should be made available, particularly where there had been multiple transfusions."*[1309]

8.54. In relation to the interim report to Ministers, in his evidence to the Inquiry Sir Kenneth Calman noted:

> *"It seems to me, looking at this now, that this emphasis on what was proportionate reflects the reality of resource constraints in the NHS. It is difficult, indeed not possible, to provide the ideal services that you would like to provide. Resources used for one exercise means that they are not available for another. The constraints relate not only to money, but the availability of trained staff and equipment."*[1310]

8.55. There is consensus in the evidence before the Inquiry of both those in the Department and the National Blood Service at the time that tracing and

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[1306] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §§44.5-44.8; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§44.1-44.9.
[1307] DHSC0002557_097.
[1308] DHSC0004469_013, and Annex at DHSC0003533_023.
[1309] DHSC0003533_023.
[1310] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §44.9.

testing donors who had not returned to give blood after September 1991 would have been very difficult, costly and (it was thought) ultimately disproportionate to the benefits offered. The reasons for this can be summarised as follows:

(1) The method of tracing all pre-September 1991 donors and asking to test them was not feasible due to the numbers of donations involved as well as the practical problems and sensitivities that came with the fact that the donors may no longer be alive or living at the same address.[1311]

(2) The method of testing the stored samples of pre-September 1991 donors was not feasible because most RTCs would no longer possess archive samples for donations made prior to 1991. Many RTCs would not have archive samples beyond two years.[1312]

(3) The testing of those stored samples available would be very expensive and resource intensive because, as Dr Gillon explained in a letter to Dr Rejman dated 6 April 1995, it would be impossible to separate the samples of those donors who had and had not returned to give blood after September, so all samples would have to be tested.[1313] Dr Hewitt expanded on the detail of the unfeasibility of this exercise in her oral evidence to the Inquiry:

> *"There would have to have been an exercise to identify which donors, for example, attended in 1989 and hadn't attended after 1991 – and that would actually have been an enormous exercise, because you would have – I just can't get my head around how we would have done it. To identify all the donors who had attended indeed that year, and then interrogate the records to see if they'd attended again after 1991, and then drawn up a list for each year of those donors, and then identified whether there were donations samples stored. And if there were, identify which of the many thousands of plates that samples was in, removing the plate from storage, thawing*

[1311] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§136.5-136.6.
[1312] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §136.7; Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §369; Dr Hewitt's oral evidence on 10 December 2021, at 28:1-28:4.
[1313] DHSC0002555_010, letter from Dr Gillon to Dr Rejman dated 6 April 1995; Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§139.3-139.6; Dr Gillon's witness statement dated 21 December 2021 (WITN6987001), §§272-273.

> *it, identifying which of the 96 wells on the plate belonged to that donation, taking the tiny sample of plasma out of the plate into a tube and then putting it through a HCV test. And it was an enormous exercise. It couldn't have been done within the resources that we had."* [1314]

Dr Robinson added that testing stored samples would have required an:

> *"…extraordinary amount of work…In fact very few centres other than North London (possibly) and Edinburgh stored donor sera for more than 2 years so in 1995 there would have been very few stored sera samples available to test…This exercise would not have been much better than looking for a needle in a haystack and would have been a huge distraction which could have jeopardized our ability to fulfil our duties in the supply of life-saving and life-enhancing services."*[1315]

(4) Tracing and testing the donors who had not returned to give blood after September 1991 themselves would not have identified many positive donors whose donations could be traced. Dr Hewitt commented that:

> *"…the vast majority of donors, whether active or lapsed, are unlikely to be infected with blood-borne agents. Attempts to trace donors who did not return to donate blood after the start of HCV screening of blood donations were unlikely to have identified many positive donors whose previous donations could then be followed up."*[1316]

(5) In relation to: the considerable practical issues of tracing an individual who had not returned to donate blood after September 1991 in 1995. Blood donors may have changed address and it was not an option in 1995 to contact blood donors by email or mobile phone or keep a log of contact information on a database. In addition, contacting donors who had not been contacted for some time presented difficult ethical issues because there was no way of knowing that individual's current circumstances, for example they may have died or be living with a

[1314] Dr Hewitt's oral evidence on 10 December 2021, at 26:1-27:16.
[1315] Dr Robinson's second witness statement (WITN6926003), §§655-657.
[1316] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §326.

serious illness and contacting them in respect of HCV lookback may have caused distress.[1317]

(6) The considerable cost and resources required to trace and test pre-September 1991 donors, with limited benefit.[1318] Dr Hewitt explained succinctly that in the context of the practical issues of tracing an individual who had not returned to donate blood after September 1991 in 1995 and the low likelihood of identifying an HCV positive donor that could be included in the lookback:

> *"The resources required to attempt the contact of possibly hundreds of thousands of lapsed donors, and to obtain blood samples for testing from those who responded, would have been enormous. Furthermore, approximately 50% of blood components were transfused to recipients who died of their underlying illness within one year of the transfusion, and more would die within the next few years, so the chance of finding a living recipient for any given blood component after a lapse of 4.5 years was much less than 50%.*
>
> *...*
>
> *It is likely that all these arguments were considered by the HCV Lookback Working Group and led to their conclusion that attempting to trace lapsed donors would be disproportionate."*[1319]

(7) Concerns about burdening blood donors with the guilt that they were somehow to 'blame' for transmitting HCV through their voluntary act of giving blood.[1320] As Dr Robinson explained:

> *"Donors are volunteers, so there is the question of how far it is appropriate to chase the donors, in a system where we rely entirely upon their altruistic and voluntary donation, after they are unable or have chosen to no longer donate. We would be proactively tracking them down to ask these donors to return to be tested to see if they carry any infections, which may possibly have harmed others."*[1321]

[1317] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §§327-334; Dr Robinson's second witness statement (WITN6926003), §587.
[1318] Dr Hewitt's oral evidence on 10 December 2021, at 28:5-29:10; Professor Keel's witness statement dated 13 July 2022 (WITN5736003), §A39.
[1319] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §§334-335.
[1320] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §347; Dr Robinson's second witness statement (WITN6926003), §589.
[1321] Dr Angela Robinson's first witness statement (WITN6926001), §685.

8.56. Those working in the Department and the National Blood Service have given evidence that they consider (both at the time and with hindsight) that for these reasons it was not possible to include donors who had not returned to give blood after September 1991 (and/or the recipients of their blood donations) within the scope of the HCV lookback exercise implemented in 1995. The Inquiry may consider that the evidence before it does suggest that any exercise of seeking to trace those who received a blood transfusion or blood products between 1970 and 1991, but who were not otherwise 'caught' by the methodology adopted, may not have been a straightforward or effective exercise when the HCV lookback exercise commenced in 1995. The evidence to the Inquiry shows that there were complex ethical, practical and cost-benefit issues in play when consideration was given to tracing donors who had not returned to give blood after September 1991.

Steps taken to trace donors who had not returned to give blood after September 1991

8.57. In time, steps were taken beyond the HCV lookback exercise to alert donors who had not returned to give blood after September 1991 and transfused patients of the relevant risks, by means of a general public health awareness campaign. The public awareness campaign was launched in 2004, after the publication of the CMO's Infectious Diseases Strategy (2002), and the Hepatitis C Action Plan for England (2004).[1322]

8.58. The Inquiry has not heard detailed evidence from those most closely involved in Hepatitis strategies at the Department or the NHS Management Executive during the period from the closure of the Lookback Exercise to 2002, when the CMO's Infectious Diseases Strategy was published. However, there is some evidence in the witness statement of Sir Kenneth Calman as to the issues faced with regards to the roll out of treatment for Hepatitis C. Whilst there was, in effect, a commitment to securing access to

[1322] Sir Liam Donaldson's witness statement dated 14 December 2022 (WITN7557001) §§43.2 - 43.3.

Interferon treatment as a result of the lookback exercise, there were concerns about the numbers of those infected with Hepatitis C (which, although uncertain were known to be very large) and the ability to roll out treatment for all. See in this regard the evidence of Sir Kenneth Calman.[1323] The submissions and minutes referenced there show discussions of the realities of the limited resources available to secure treatment for all affected and of the ethical issues of prioritising treatment on any grounds other than clinical need.

8.59. Against that background, during that period from the closure of the Lookback Exercise to 2002 no 'mass awareness' campaign was launched, although steps were taken to provide funding to support charities such as the British Liver Trust.[1324]

8.60. In 2002 the CMO, Sir Liam Donaldson, published a strategy entitled "*Getting ahead of the curve: a strategy for combating infectious diseases (including other aspects of health protection)*", which considered the incidence of (amongst other diseases and blood borne viruses) hepatitis B and C.[1325] It was estimated that there were 180,000 chronic carriers of hepatitis B and 250,000 chronic carriers of hepatitis C (see page 72). The CMO's strategy was followed by the publication of a "*Hepatitis C Strategy for England*" for consultation in August 2002, noting, for example, that the offer of testing should be increased in a range of clinical settings.[1326]

8.61. In 2004, this in turn led to PHLS and its successor body the Health Protection Agency to support the Department of Health to provide an externally commissioned campaign aimed at healthcare professionals and the public called 'FaCe It', which sought to raise awareness of hepatitis C

[1323] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §§61.1- 62.27.
[1324] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §64.2.
[1325] RLIT0001745.
[1326] DHSC0041221_044.

infection in support of the Government's "*Hepatitis C Strategy for England*". This included a website[1327], poster campaigns and displays as well as advertorials and commissioned pieces for print and radio targeting groups at risk of HCV infection. The FAQs page of the website advised those who had *"...received a blood transfusion before September 1991, or blood products (such as clotting factors) before 1986..."* to consider visiting their GP for a blood test. There was a press release dated 8 December 2004[1328] and an updated website[1329], which both highlighted the risk of HCV infection linked to the receipt of infected blood or blood products. The campaign ran for a number of years.

The Current Position

8.62. The NHS England HCV Elimination Programme is NHS England's current strategy that aims to eliminate HCV in advance of the goal set by the WHO to eliminate chronic Hepatitis C before 2030.[1330] Dr Mary Ramsay (Director, Public Health Programmes, UKHSA)'s evidence to the Inquiry identified two current programmes to identify those infected with HCV, including through blood and blood products, namely:

(1) A pilot programme using Patient Search Identification Software launched in August 2022, led and run by NHS England.[1331]

(2) A University of Bristol led Hepatitis C Case Finding in Primary Care Pilot-study *"...which used an electronic algorithm to flag patients with HCV risk markers in GP practices in Southwest England and invite*

[1327] www.hepc.nhs.uk,
See also https://webarchive.nationalarchives.gov.uk/ukgwa/20041108200846/http://www.hepc.nhs.uk/
[1328] See https://webarchive.nationalarchives.gov.uk/ukgwa/20041214012122/http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4097733&chk=N0hzhD
[1329] See https://webarchive.nationalarchives.gov.uk/ukgwa/20070214235146/http://www.hepc.nhs.uk/information/avoid.html, this content was archived in February 2007, highlighting that the 'FaCe It' campaign ran for some time.
[1330] See the UKHSA's "Hepatitis C in England 2022" Short Report, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057262/HCV-in-England-2022-short-report.pdf
[1331] WITN7375005; Dr Ramsay's witness statement dated 12 October 2022 (WITN7375001), §2.2. See also Professor Foster's witness statement dated 28 September 2022 (WITN3042004), §§7-14.

them for an HCV test. The algorithm included identification of patients with a history of blood transfusion or transplant."[1332]

8.63. In his evidence to the Inquiry, Professor Graham Foster (NHS England's National Clinical Lead for Hepatitis C and National Clinical Chair for NHS England's Hepatitis C Elimination Programme) identified the six measures currently being pursued by NHS England to identify those at risk of HCV infection that are yet to be identified.[1333] In addition to the programmes noted in Dr Ramsay's evidence above, Professor Foster highlighted the following current NHS England strategies:

(1) Encouraging testing in primary care, which has included writing to colleagues, holding a number of primary care advisory boards and trialling a GP champion model in London whereby individual champions aim to encourage their colleagues to engage with the HCV Elimination Programme.[1334]

(2) An online testing portal is currently being set up that will allow at risk individuals to request a HCV test to administer at home.[1335]

(3) Testing all blood tests conducted in emergency departments for viral hepatitis and HIV.[1336]

(4) A surplus blood testing proposal in Liverpool to run 17,000 blood samples tested for other clinical reasons through a HCV testing programme.[1337]

8.64. It was the evidence of Professor Foster and Professor John Dillon (Clinical Lead for HCV in NHS Tayside and Chair of the Viral Hepatitis Clinical Leads Group of the Scottish Government's blood virus and sexual health

[1332] Dr Ramsay's witness statement dated 12 October 2022 (WITN7375001), §2.3; WITN7375006; WITN7375007; WITN7375008.
[1333] Professor Foster's oral evidence on 17 November 2022, at 13:18-30:15.
[1334] Professor Foster's oral evidence on 17 November 2022, at 13:18-14:17.
[1335] Professor Foster's oral evidence on 17 November 2022, at 14:18-17:14.
[1336] Professor Foster's oral evidence on 17 November 2022, at 17:15-19:24.
[1337] Professor Foster's oral evidence on 17 November 2022, at 19:25-20:19.

framework) that there are indications that elimination strategies have been successful in identifying the vast majority of individuals infected with HCV through blood and blood products. This is because the numbers of those identified to date exceeds the current estimate of those chronically infected with HCV through blood or blood products and alive as at the end of 2019.[1338]

Publicity given to the HCV lookback exercise

8.65. Sir Kenneth Calman's evidence to the Inquiry is that *"[t]he Guidance sent out on 3 April 1995 was then deliberately sent out as CMO letter as that would mean that it was sent directly to all registered medical practitioners (about 90,000), both in private practice as well as the NHS"*.[1339] Dr Rejman added that *"...this was the only way to guarantee that every relevant medical practitioner would receive the guidance as the letter was sent direct to the doctor and not via a third party"*.[1340] It is clear that concerted efforts were made by the Department to ensure that all medical practitioners with patients that may have fallen within the scope of the HCV lookback exercise announced in January 1995 were alerted to the programme and given detailed guidance on how to proceed, including on counselling patients identified as HCV positive.

8.66. The NHS was still grappling with the numbers of individuals that would be identified through the lookback exercise as HCV positive and may need interferon treatment after the CMO's letter was issued. Estimates of between 3,000 and 40,000 HCV infections among recipients of blood transfusions were given by commentators at the time.[1341] In the context of

[1338] See "Expert Report to the Infected Blood Inquiry: Statistics", EXPG0000049, page 50; Professor Foster's oral evidence on 17 November 2022, at 30:16-34:6; Professor Dillon's oral evidence on 17 November 2022, at 48:23-49.23.
[1339] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §55.4.
[1340] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §138.2.
[1341] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§52.1-52.8.

discussion of this higher estimate, Dr Metters commented in a minute to Drs Rejman and Nicholas dated 6 November 1995 that:

> *"1. …The only conclusion I can draw is that we really can have no certainty about the number of patients with Hepatitis C as a result of transfusion or, perhaps more importantly, the total numbers in the population who are Hepatitis C positive.*
>
> *2. We could give all the data to the mathematical modellers and ask them to come up with better estimates, but given the numerous uncertainties about transmission via different groups during the last six 5-year periods, I doubt if they will be able to give us any more robust figures!*
>
> *…*
>
> *5. While we could argue endlessly over the estimates of Hepatitis C prevalence and the extent to which these were acquired by transfusion, I see little point in that. Instead I suggest HP Division and CA-OPU2 should decide what additional information on prevalence of Hep C is required for policy and/or service purposes. These requirements would then be built in to the research programme that RDD is constructing."*[1342]

8.67. Sir Kenneth Calman commented in his evidence to the Inquiry that in his view:

> *"…this is a good example of the problem of uncertainty or decision-making with limited information. It was often not possible to have all the data that would ideally be at hand to decide a policy response, and the decisions had to be made on imperfect information. If the figure had been 40,000, it plainly would have had important implications, but the LBE was based on the best estimate available."*[1343]

8.68. Given the unknown quantity of individuals infected with HCV and any publicity given to the HCV lookback exercise could not be targeted on those who had received a blood transfusion because records of blood transfusions given prior to 1991 were not complete[1344], any publicity of the lookback exercise to those infected with HCV may have only made sense as a wider Public Health awareness campaign.

[1342] DHSC0002550_137.
[1343] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §52.7.
[1344] RLIT0001917; Dr Ramsay's witness statement dated 12 October 2022 (WITN7375001), §§2.5-2.9.

8.69. One of the issues identified in the Inquiry's List of Issues (as amended in September 2021) is why no Public Health campaign was conducted to encourage individuals to seek a HCV test.[1345] As outlined at paragraphs 8.60 – 8.61 above, a Public Awareness campaign seeking to encourage individuals to come forward was run from 2004 – 2007 (approximately), involving not only the PHA but groups such as GPs / RCGPs.[1346] The scoping of a fresh media campaign was recommended in the UKHSA's "*Hepatitis C in England 2022: Working to eliminate hepatitis C as a public health problem*".[1347]

The HCV lookback exercise in practice

The provision of information to patients

8.70. In relation to the steps to be taken once an individual had been traced and tested as HCV positive as part of the lookback exercise, the guidance attached to the CMO's letter dated 3 April 1995 provided that:

> *"The presumption will be that each identified recipient would be counselled and tested. However, in exceptional situations such as severe psychiatric illness or terminal physical illness the consultant or GP may feel it inappropriate to add to the patient's distress."*[1348]

8.71. Annex B to the CMO's letter provided detailed *"Guidelines for Counselling Patients"*[1349], which included (in summary):

> *"…that patients confirmed to be anti-HCV positive should be counselled on the implications of the test result. This included the prospect of developing liver damage without symptoms, cirrhosis, hepatocellular carcinoma and the possibility of a complete recovery. Furthermore, the guidance provided an outline of counselling in relation to avoiding infecting others. This included asking HCV positive recipients whether they had ever donated blood or a tissue. Practical advice on issues*

[1345] Issue 389.
[1346] Some of the evidence on this issue has been drawn from the DH Web Archive, rather than from a witness statement of an expert involved at the time, which makes dating difficult.
[1347] WITN7375010, at page 20.
[1348] NHBT0002796_002 §3.
[1349] NHBT0002796_002; BMAL0000022_003.

> *such as not sharing toothbrushes and razors should be given by GPs. When seeking medical or dental care, patients should be advised to inform those responsible for their care of their anti-HCV status. They should also be advised to forewarn and practise safe sex with new partners. Lastly, all anti-HCV positive patients should be referred to a specialist with an interest in the condition for a further assessment. Further counselling would be given at specialist centres, where treatment options could be discussed in more detail."*[1350]

8.72. As noted in these submissions above, these guidelines were sent to all medical practitioners by virtue of the fact that they were included with the CMO letter. See further paragraph 10.91, below.

8.73. At the Lookback Working Party on 13 October 1995, Dr Robinson mentioned that the NBA had been asked to advise on whether a patient's next-of-kin should be informed of their HCV infection when it had been decided that it was inappropriate to counsel that patient. The NBA had obtained advice from their legal advisors who had directed that there *"...was no medical or legal obligation to take such action, unless a "need to know" existed."*[1351]

8.74. It was Sir Kenneth Calman's view *"...that a clinician might – depending on the circumstances – regard it as unnecessary or inappropriate to inform the patient of a potential HCV infection. It was regarded as a matter for individual clinical judgment."*[1352]

8.75. In relation to the exceptional circumstances where patients might not be tested and counselled, Dr Hewitt outlined that *"[i]n some cases, this was because of dementia, general medical condition, (terminal malignancy) or*

[1350] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §43.11.
[1351] WITN3430014, §9.2.
[1352] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §42.15.

that the patient would be emotionally unable to cope with the information."[1353]

8.76. A similar point was noted in the "*Expert Report to the Infected Blood Inquiry: Public Health and Administration*" that:

> *"There are…occasions where it may not be in the patient's best interest to know all conceivable risks, particularly if the potential adverse outcomes are both distant and uncertain. Information about risk can end up as another burden for a patient, particularly when the information cannot lead to any meaningful action or choices."*[1354]

Progress and speed of implementation of HCV lookback exercise

8.77. The HCV lookback exercise commenced in 1995 encountered a number of difficulties during the phase of its implementation, which can be summarised as follows:

(1) Inadequate hospital records made tracing individuals that fell within the scope of the HCV lookback exercise difficult.[1355]

(2) A shortage of suitably trained staff, including counsellors, to counsel and assess patients before and after testing.[1356]

(3) Wider concerns about NHS service capacity. The interim report on the HCV lookback exercise from Dr Metters to John Horam dated 5 February 1996 highlighted that even if other areas of difficulty with the exercise were overcome, *"[t]he MSBT accepted that…it was likely that the hepatology services for specialist assessment and, where*

[1353] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §88.
[1354] "Expert Report to the Infected Blood Inquiry: Public Health and Administration" of August 2022, page 45.
[1355] DHSC0020692_118, minutes of the meeting of the MSBT on 8 January 1996; NHBT0006016, minutes of the meeting of the MSBT on 25 March 1997; Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §§56.4-56.7; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §56.3(4); Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§140.1-141.5; Dr Robinson's first witness statement (WITN6926001), §§674-692.
[1356] DHSC0020692_118; Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §§56.4-56.7; Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §56.3(4); Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§140.1-141.5; Dr Robinson's second witness statement (WITN6926003), §§517-518.

appropriate, commencement of treatment would probably not be able to cope."[1357] A paper on HCV discussed at a meeting of the NHS Executive Board on 13/14 June 1996 highlighted that:

> *"**From a public health point of view,** there is an obligation to remind health professionals, and people who may have been infected, about HCV and the desirability of counselling and testing. We have so far avoided going down this route because of the resource implications for the NHS. Raising awareness poses undoubted difficulties for the NHS. **The identification of asymptomatic patients by testing, though consistent with policy on HIV, will place increasing pressure on specialist services which are already fully-stretched** (some hepatologists have told us that hepatitis C represents 2/3 of their current workload). If the prevalence of HCV is in line with current estimates there will be medical and nursing manpower demands for increasing service availability, the scale of which has yet to be assessed. However, faced with criticism over the slow progress with the "Lookback", Ministers decided not to speed up detection as the bottleneck would then transfer to hepatology clinics."*[1358] [Original emphasis]

(4) A lack of enthusiasm about participating in HCV lookback from some hospitals and individual clinicians (those working in hospitals and GPs) already operating with limited resources.[1359] Some GPs did not feel equipped to carry out counselling of HCV positive patients because they did not possess enough knowledge about the condition or the lookback process.[1360]

8.78. At its meeting on 8 January 1996, the MSBT noted that the current evidence was of a 20-30 year time frame for significant liver damage from HCV to occur, so it was not thought that the delays to the progress of the HCV lookback exercise would materially disadvantage patients.[1361]

[1357] DHSC0004469_013.
[1358] WITN3430151, §6.
[1359] Dr Hewitt's witness statement dated 25 October 2021 (WITN3101006), §§377-378.
[1360] Dr Hewitt's second witness statement dated 24 November 2021 (WITN3101009), §73; Dr Robinson's second witness statement (WITN6926003), §511.
[1361] DHSC0020692_118; Dr Robinson's first witness statement (WITN6926001), §461.

8.79. The issues with the implementation of the HCV lookback exercise reflect the realities of executing an exercise of this scale in the NHS. In his evidence to the Inquiry, Sir Kenneth Calman commented that:

> *"The issues identified represented a dilemma that was not uncommon. That is, it might be known what the ideal solution would be (i.e., faster progress), but the resources to adopt it were not there (the progress had to match the ability of the system to cope)."*[1362]

Response to the Penrose Inquiry Final Report

8.80. When The Penrose Inquiry Final Report was published in March 2015, it made one key recommendation:

> *"That the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV."*[1363]

8.81. In his oral evidence to the Inquiry, Jeremy Hunt stated that he did not know whether any work was undertaken by the Department to consider the applicability of the Penrose recommendation to England. He commented that it may have been the Department's view that HCV testing had already been implemented in England and therefore further testing was not considered necessary.[1364]

8.82. A submission to Jane Ellison (Parliamentary Under-Secretary of State for Public Health) dated 12 June 2015 advised that the Penrose recommendation should be extended to England *"...by agreeing to remind GPs of the issue of infected blood, and that they should offer HCV testing to those at risk; and possibly also introduce a small scale awareness campaign in healthcare settings."*[1365]

[1362] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §56.7.
[1363] Penrose Inquiry Final Report at §35.248.
[1364] Mr Hunt's oral evidence on 27 July 2022, at 80:18-81:5.
[1365] RLIT0001917.

8.83. It is however apparent that following Lord Penrose's recommendation, on 3 September 2015 a NHS England Regional Action Bulletin included at paragraph 6 an entry titled "*Penrose Inquiry Recommendations for Hepatitis C Testing*". The entry in the Regional Action Bulletin was marked for the attention of NHS England Directors of the Regions and NHS England Directors of Commissioning, Heads of Primary Care and Heads of Nursing and asked that all clinical staff be reminded that where a patient's clinical history indicates that they may have received a blood transfusion before 1991, they should be offered a test for HCV.[1366]

The National HCV Register

8.84. In relation to the National HCV Register, the Inquiry's List of Issues (as amended in September 2021) asks the following questions: (i) what is it; (ii) what information is contained within it; (iii) what is its purpose; and (iv) has consent been obtained from the individuals that have their data included in the Register.[1367]

8.85. These submissions will take each of these questions in turn in order to assist the Chair with the Inquiry's consideration of the Register.

What is the National HCV Register?

8.86. Following the announcement of the HCV lookback exercise, consideration was given by Clinical Directors, the MSBT and the Lookback Working Party from March 1995 onwards to the idea of a National HCV Register.[1368] The basis of these discussions was an early research proposal entitled "*National register of Transfusion Acquired HCV infection*" prepared by Dr Ramsay (then at PHLS Communicable Disease Surveillance Centre) and Dr Philip Mortimer (Central Public Health Laboratory), which on 10 March 2015 was

[1366] RLIT0001916.
[1367] Issue 393.
[1368] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§66.1-66,14.

sent from Dr Robinson to Roger Scofield for consideration by the MSBT. At its inception, the objectives of a prospective National HCV Register were described as follows:

> *"Objectives*
>
> 1. *To establish a central, national register of cases of presumed transfusion acquired HCV infections.*
> 2. *To establish a central, national archive of sera from cases of presumed transfusion acquired HCV infections.*
>
> *This will facilitate the retrieval of important clinical and laboratory data in case of medico-legal, clinical and research purposes. It will not preclude proposals to follow up and investigate this cohort from other agencies."*[1369]

8.87. The Department commissioned and confirmed funding for the National HCV Register in March 1997.[1370] The final proposal for the National HCV Register entitled "*National Registry of Transfusion Acquired Hepatitis C Infections and of other HCV Infections with a known date of acquisition*" sent by Dr Ramsay to Dr Toy (Senior Medical Officer in the Research and Development Division at the Department responsible for the funding of the Register) on 12 May 1997 summarised that *"[a] national registry of "known date" hepatitis C (HCV) infections will be established to provide a facility for future monitoring of the natural history and long term outcome of HCV infection"* and *"[i]nfections presumed to have been acquired through transfusion of blood or blood products will form the nucleus of the register. The initial objective will be to include all HCV infected individuals identified by Blood Centres as a result of the current National Blood Authority "lookback" exercise…The register will subsequently be extended to include other types of "known date" HCV infections."*[1371] The Register was to be administered jointly by the NBA and the Public Health Laboratory Service Communicable Disease Surveillance Centre (CDSC).

[1369] DHSC0006819_078.
[1370] WITN3430195; WITN3430196.
[1371] WITN3430197.

8.88. The proposal outlined that the National Blood Service was setting up a database of those identified as HCV positive in the lookback exercise. Clinicians responsible for patients that fulfilled the registry case definition identified by the National Blood Service database would be contacted and asked to register their patient with the National HCV Register by providing certain information.[1372] A proforma letter to clinicians and an information sheet for patients about the National HCV Register were prepared.[1373] The proforma letter to clinicians explained the Register in the following terms:

> *"As relatively little is known about HCV infection, transmission, or the clinical course of the resultant disease, a National Register of HCV infections with a known date of acquisition is being created. This Register has been funded by the Department of Health and will provide a facility for the future monitoring and long term assessment of HCV infection within the UK."*[1374]

8.89. A steering group was set up and the operational and ethical issues associated with the National HCV Register were considered in detail by the responsible clinicians before the Register was launched in July 1998.[1375]

What information was contained within the National HCV Register?

8.90. Appendix B to the final proposal for the National HCV Register outlined that clinicians whose patients met the criteria for inclusion on the Register would be contacted and asked *"...to provide information about the outcome of the initial assessment and the current clinical condition of the patient by completing and returning a standard report form to the national registry (Appendix B)."*[1376] Appendix B outlined the information to be sought from the clinician responsible for initial assessment in detail.

[1372] WITN3430197.
[1373] WITN3430200; WITN3430201.
[1374] WITN3430200.
[1375] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§66.17-66.26.
[1376] WITN3430197.

8.91. The proforma letter to clinicians asked *"...the clinician responsible for the care of this patient..."* to *"...formally register your patient by completing the enclosed form."*[1377] The registration form outlined the information collected in respect of individuals who were to be included on the Register.[1378]

What was the purpose of the National HCV Register?

8.92. The final proposal for the National HCV Register outlined the objectives of the Register as follows:

> *"3.1 To describe the current biochemical, histological and clinically apparent liver disturbance in cases of HCV infection. To relate current status to the interval since presumed infection and other potential prognostic factors...*
>
> *3.2 To determine the representativeness of the registered population in relation to the total population of HCV infection in the UK...*
>
> *3.3 To pilot and establish the appropriate methods for registration, follow up, and tracking of patients on the register...*
>
> *3.4 To monitor the number of known new infections...*
>
> *3.5 To provide a shared national (or international) resource for use by those designing future studies."*[1379]

Consent and the National HCV Register

8.93. In the lead up to the establishment of the National HCV Register, the issue of obtaining consent from individuals for inclusion of their data on the Register was central to the discussions of the various committees and clinicians considering the proposal.[1380]

[1377] WITN3430200.
[1378] See WITN3430206, Registration Form.
[1379] WITN3430197.
[1380] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§66.1-66,14.

8.94. The final proposal for the National HCV Register noted at Appendix B as to the information to be sought from the clinician responsible for initial assessment, *"[c]onsent of clinician to include case on the register".*[1381]

8.95. The steering group continued to discuss the issue of consent ahead of the launch of the National HCV Register. At its meeting on 5 January 1998 the steering group noted the essential importance of either gaining patient consent for inclusion of data on the Register or anonymising patients' information. It was not envisaged that consent was required for patients' anonymised information to be provided to the Register and it was the anonymity approach that was opted for.[1382] The information sheet that was sent to clinicians of every patient whose data was to be held in the Register (and could be passed onto patients) stated:

> *"The Register itself is totally anonymous as no names are recorded within it. People who are granted access to information in the Register are therefore unable to link the information to individual patients."*[1383] [Original emphasis].

8.96. A minute from Dr Nicholas to Mr Dean in HP4B (Health Promotion Division, whose remit included research ethics) dated 23 January 1998 explained the rationale around opting for the approach of anonymising patient information on the National HCV Register rather than obtaining an individual's consent:

> *"Since the registration form is quite long, obtaining full informed consent could be time consuming and this requirement might dissuade physicians from entering their patients. It was also reported that experience has shown that a significant proportion of patients have refused consent for similar data to be given to those conducting clinical trials. Because these two eventualities could lead to only a proportion of patients being included and hence to a reduction in the usefulness of the project it was decided that the information should be held anonymously by the Registry, and that thus formal consent need not be sought."*[1384]

[1381] WITN3430197.
[1382] Annex to Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430099), §§66.17-66.18.
[1383] WITN3430201.
[1384] DHSC0046979_059, §5.

8.97. The Final Report of the National HCV Register dated December 2000 noted that:

> *"No patient names are recorded within the Registry database. Data, including non-nominal identifiers, are securely stored on a password-protected computer within a secure building, and are accessible only to key individuals. Data sets passed to external researchers, whose projects are being supported by the Registry, contain no information that could lead to identification of registered patients. As the Register collates anonymised information that is collected by clinicians during routine patient care, and requires no special intervention, there is no formal requirement to gain patient consent. The PHLS and North Thames Multi-Research Ethics Committees have approved Registry protocols and Caldicott guidelines have been adhered to."*[1385]

8.98. With the advent of the Data Protection Act 1998 and the Caldicott "*Report on the Review of Patient-Identifiable Information*", the legislation and guidance on data protection and confidentiality evolved. This is reflected in the application made to the Department for the renewal of funding for the National HCV Register on 2 April 2002.[1386] The application outlined the justification of the then current approach to anonymity and the National HCV Register as follows:

> *"We feel that our decision not to seek explicit consent is valid and that the register does not breach the Data Protection Act 1998 or the spirit of Caldicott because: (i) individual patient care is not influenced in any way by the processing of registry data, (ii) patients are never contacted by anyone other than their normal professional carer, (iii) registry data that can be linked are only accessible to individuals who are either clinically trained or who are health care professionals owing an equivalent duty of confidentiality, (iv) the processing of the data is solely for medical research that is in the public interest, (v) the patients are not identified in any publications or reports, (vi) data security is of the highest standards, (vii) a Multi-Centre Research Ethics Committee has approved the research and agreed that obtaining explicit consent is not necessary, and (viii) the denominator population are largely aware in general terms that their data have been passed to the register for research purposes."*[1387]

[1385] DHSC0038673_010 page 14.
[1386] WITN3430208.
[1387] WITN3430208, §4.2.

8.99. However, the application went onto note that *"…in the current clime, all **new** cases recruited into the register should be formally consented."*[1388] [Original emphasis].

8.100. In his evidence to the Inquiry, Sir Kenneth Calman commented that *"…it is fair to say that consent was considered by different groups of those involved as the HCV Register was developed, but the expectations and standards in relation to patient consent and data retention were also developing at the time, and can be seen to have led to an amended approach."*[1389]

8.101. The National HCV Register evolved alongside changes in the legislative framework but, as patient data was anonymised on the Register at its inception, there is no evidence before the Chair that the Register was not anonymous or that it was possible to obtain an individual's details from it.

[1388] WITN3430208, §4.2.
[1389] Professor Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), §66.4.

Section 9: The emergence of and response to vCJD

Introduction

9.1. Bovine Spongiform Encephalopathy ("BSE") in cattle, the human disease Creutzfeldt-Jakob disease ("CJD") and the emergence of variant of CJD ("vCJD") in humans caused by BSE, is a wide topic. BSE and vCJD, the link between them and government's response to BSE, was analysed in depth in the BSE Inquiry chaired by Lord Phillips of Worth Matravers. In relation to the events up to 20 March 1996, the endpoint of the BSE Inquiry's Terms of Reference, a full and accurate account of the overall response to BSE is to be found in its report, as Prof Rawlins observed.[1390] In particular, Volume 8 Chapter 5 sets out the history of the emergence of a "*novel variant*" of CJD, appearing in the relatively young, by early 1996.

9.2. On these matters, this Inquiry has a narrower focus than the BSE Inquiry. With respect to vCJD specifically, the Inquiry's Terms of Reference are *"…[t]o examine whether… people may have been exposed to the risk of ...vCJD ...in consequence of the use of infected blood or infected blood products*". Against this background, the Inquiry's List of Issues, as revised in September 2021, asks whether "*…people receiving blood products or blood [have] been exposed to the risk of' vCJD*"; *"[t]o what extent can this be assessed and quantified*"; "[*w]hat steps should be taken now to address such risks"; "[w]hen and in what circumstances"* did the Government, blood services, haemophilia centres and their directors, the UKHCDO, and other NHS bodies "*…become aware of any risks of transmission of vCJD associated with the use of blood and blood products"; "[w]hat decisions were taken, by whom and why as to what information should be provided to patients about the possibility of transmission of vCJD and/or the receipt of vCJD implicated product"'; "[s]hould the patient notification exercises have been undertaken differently"*; and to what extent "*medical and dental treatment and care for other conditions was compromised or adversely affected by*" infection with, or the possibility of infection with, vCJD.

[1390] Prof Rawlins' witness statement, dated 24 March 2022 (WITN6406001), §16.44.

9.3. Much of the direct evidence from the Infected and the Affected was largely (although not exclusively) focussed on their experience of the patient notification exercises, when individuals were told whether they were 'at risk' of vCJD as a result of previous treatment with blood or blood products. These witnesses did not speak with one voice. For some, notification was fairly unremarkable in the context of their broader and traumatic experiences;[1391] for others, the fact or manner of notification (or indeed denotification,[1392] as to which see below) was inappropriate, albeit not necessarily for the same reasons;[1393] the evidence of others can be said to have reflected the overall ambivalence in itself.[1394] As the Inquiry has conducted its investigation, its questions under Rule 9 have ranged more broadly, addressing precautions taken, including changes to the supply of plasma; the supply of recombinant products; and, most recently, general infection, prevention, and control ("IPC") measures. However, there has been relatively limited exploration of these issues in oral evidence with witnesses who have spoken of the Department's response, no doubt reflecting time constraints.

9.4. In those circumstances, and in the limited time available for the preparation of these submissions, we have tried to summarise evidence on what may be issues or points of relevance, hoping that this will be of assistance. These submissions do not address every aspect of the Department's approach.[1395] We apologise if they fail to address issues of concern, but we have tried to explain above why that might be so.

[1391] For example, Mr AM's oral evidence on 15 October 2019, at 84:18-84:23.
[1392] For example, Mr Evans' oral evidence on 10 May 2019, at 42:24-44:8.
[1393] By way of examples, Mr Kirkpatrick's oral evidence on 21 May 2019, at 33:20-38:1; and Ms Ryness-Hirsch's oral evidence on 9 May 2019, at 31:7-34:25, 37:20-38:19.
[1394] By way of examples, Mr O'Driscoll's oral evidence on 30 October 2019, at 156:8-157:4; and Ms Cooper's oral evidence on 18 October 2019, at 142:9-142:21.
[1395] The evidence before the Inquiry has inevitably focussed on the Department and wider Government in the United Kingdom, but it is worth noting that there was a European dimension to the response to BSE and vCJD: see, for example, Dr Rejman's Third witness statement, dated 27 April 2022 (WITN4486040), §§ 148.26, 148.52, and 148.58.

Nature of the disease

9.5. The Inquiry has heard evidence upon the nature of the various diseases caused by abnormal prion proteins, including Iatrogenic CJD (infection spread through from someone with CJD through medical or surgical treatment). The Inquiry's Terms of Reference encompass vCJD specifically as it may be transmitted by blood. No type of CJD other than vCJD is known to have been transmitted by blood.[1396] The nature of vCJD has been further explained by Professor James Ironside in his written evidence to the Inquiry.[1397]

Prevalence and further transmission

9.6. The Statistics Expert Group recorded in its report that "*...as of October 2021, there have been 178 UK patients with definite or probable vCJD reported by the National CJD Surveillance Unit in Edinburgh*".[1398] Four of these individuals were infected via blood transfusion[1399] and a fifth was likely infected "*...through a UK plasma product*".[1400] There has never been a case in which a person has been infected via blood transfusion and has in turn infected a second person via blood transfusion.[1401] Professor Ironside states that as far as he is aware, no instances of vCJD transmission in a healthcare setting (e.g. via surgical instruments) or via endoscopes have been identified.[1402]

9.7. The Transfusion Medicine Epidemiology Review ("TMER") has established that components from 18 vCJD-infected donors were issued to 67 identified recipients; a further six components are known to have been issued, but

[1396] Dr Hewitt's oral evidence on 10 December 2021, at 82:8-82:15. See also the guidance quoted in Appendix 6(c) to Sir Robert Francis QC, *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework*.
[1397] Prof Ironside's witness statement, dated 28 April 2022 (WITN7034001), § 7-21.
[1398] Expert Report to the Infected Blood Inquiry: Statistics, § 6.2.
[1399] Expert Report to the Infected Blood Inquiry: Statistics, §§ 6.6-6.9.
[1400] Expert Report to the Infected Blood Inquiry: Statistics, § 6.10.
[1401] Dr Hewitt's witness statement, dated 4 June 2019 (WITN3101002), §14(ii).
[1402] Prof Ironside's witness statement, dated 28 April 2022 (WITN7034001), §8(a)(ix).

have not been traced.[1403] Of these 67 recipients, 14 remain alive and none of the 13 whose fate is known have been diagnosed with vCJD.[1404]

The response to vCJD – the Department's approach

9.8. The history of precautions taken in response to the risk of vCJD is set out, first, in the witness statement of Dr Rejman (Section 13),[1405] in which he recounts the steps taken to protect the blood supply prior to March 1996. The changing position in March 1996 is addressed by Dr Rejman at paragraphs 148.34 onwards, and also by section 13 of Sir Kenneth Calman's statement and the corresponding section of the Annex to that statement. There, Sir Kenneth outlined how, on 8 March 1996, the Spongiform Encephalopathy Advisory Committee ("SEAC") met and discussed findings concerning what was later to be labelled vCJD. Ministers were advised that evening. Subsequent important meetings of SEAC took place on 16, and 19 March (in fact that meeting was resumed on 20 March) followed by announcements to the House of Commons on 20 March 1996 by Mr Dorrell and Mr Hogg.[1406] Sir Kenneth identified BSE and vCJD as "*major public health challenges*".[1407] There is an account, at paragraph 148.34 of Dr Rejman's Statement, of the public announcements by Ministers and the CMO's Statement in response, as well as of the emerging evidence of the potential link to transmission by blood (rather than by the eating of beef before safety measures had been taken).[1408]

9.9. The Department (together with the Blood Services) responded to notice of these risks by instituting precautions at considerable cost and scale.[1409]

[1403] Expert Report to the Infected Blood Inquiry: Statistics, § 6.4. The most recent information (21.06.21) can be found at http://www.cjd.ed.ac.uk/projects/transfusion-medicine-epidemiology-review-tmer.
[1404] Expert Report to the Infected Blood Inquiry: Statistics, § 6.4.
[1405] Dr Rejman's Third witness statement, dated 27 April 2022 (WITN4486040), §148.7-148.33.
[1406] Sir Kenneth Calman's witness statement, dated 12 October 2022 (WITN3430001), § 73.2. The full chronology is set out in the BSE Report Chapter 6 Section 7 particularly from §§7.261-7.379.
[1407] Sir Kenneth Calman's witness statement, dated 12 October 2022 (WITN3430001), § 0.10.
[1408] Dr Rejman's Third witness statement, dated 27 April 2022 (WITN4486040) §148.34 (debate in March 1996). See also Dr Hewitt's witness statement dated 24 November 2021 { WITN3101009 }, §328.
[1409] Dr Robinson's witness statement, dated 1 December 2021 (WITN6926001), § 306.

See, in particular, the Second Statement of Charles Lister, Section 3,[1410] which gives a detailed account of the steps taken from 1998 – 2003. Even before 1996, precautions had already been instituted and continued to be developed in response to the risk of CJD, including iatrogenic CJD.[1411] The Inquiry has heard evidence upon the history of IPC measures to guard against the risk of contaminated surgical instruments, including endoscopes.[1412] That was work which pre-dated evidence of the emergence of vCJD.

9.10. In 1996, the research study, the TMER, covering both vCJD and sporadic CJD,[1413] was rapidly put in place to try to establish if there was any link between vCJD and blood transfusion.[1414]

9.11. The main steps that were taken in response to vCJD were further summarised by Professor Ironside, who has set out a chronology of the collaborative steps taken by the Department and the Blood Services, in active collaboration with the CJD Surveillance Unit ("CJDSU"), to manage the risk.[1415] They included:

- **From 1997:** Committee for Proprietary Medicinal Products recommends withdrawal of implicated batches of plasma products where a donor subsequently diagnosed with vCJD had contributed to the plasma pool.
- **1998-99:** Introduction of Universal Leucodepletion.
- **1998:** DH announcement that fractionation of UK plasma would cease, and plasma supplies would be obtained from areas with a

[1410] Mr Lister's Second witness statement, dated 19 May 2022 (WITN4505002), § 3.17-3.233.
[1411] See Mr Lister's witness statement, dated 19 May 2022 (WITN4505002), § 3.31 for a summary of precautions taken. Also, see §3.35 (WITN4505054).
[1412] There is relevant information in Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001) as well as, of course, the Report of the BSE Inquiry.
[1413] Dr Hewitt's Second Witness Statement, dated 24 November 2021 (WITN3101009), §336; Dr Hewitt's oral evidence on 10 December 2021, at 87:23. See also Dr Robinson's witness statement, dated 1 December 2021 (WITN6926001), § 711.
[1414] Dr Hewitt's Second Witness Statement, dated 24 November 2021 (WITN3101009), §335.
[1415] Prof Ironside's witness statement dated 28 April 2022 (WITN7034001), §27-28. There is also relevant information in Dr Rejman's Third witness statement dated 27 April 2022 (WITN4486040), Section 13 and Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), (Section 13 and Corresponding Annex).

low prevalence of BSE.

- **2003-2006:** Funding for treatment with recombinant factor concentrates became available for children with haemophilia. [1416]
- **2003 - 2007:** DH Health Service Circulars HSC 2002/009 "*Better Blood Transfusion - Appropriate Use of Blood*" and 2007/001 "*Better Blood Transfusion - Safe and Appropriate Use of Blood*" gave guidance to *"further improve the safety and effectiveness of transfusion"*, *"avoid the unnecessary use of blood and blood components in medical and surgical practice"* and *"avoid unnecessary blood transfusion in obstetric practice"*.
- **2003:** Imported fresh frozen plasma introduced for the treatment of children born after the adoption of food safety measures in 1996. The imported material would be subject to methylene blue treatment to reduce the risk of transmission of blood-borne viruses.
- **2003-2006:** Funding became available for recombinant factor concentrates for all adult patients with haemophilia.
- **2004.** Individuals who had received a blood transfusion since 1980 were excluded from blood transfusion.
- **2005.** Blood donors whose blood had been transfused into individuals who subsequently developed vCJD were excluded from future donation.

9.12. Leucodepletion. A significant element of the Department's approach, so far as blood and blood products were concerned, was "*…to protect the blood supply from vCJD…*" by leucodepletion.[1417] The possibility of doing so was examined from 16 April 1996.[1418] It became "*top priority*" because it "*…could be applied to all blood components…*" and "*…wouldn't lose any donors*".[1419] A feasibility report was prepared in February 1998 and it was announced

[1416] Recombinant treatment is addressed in Section 10 of these submissions.
[1417] Dr Robinson's witness statement, dated 1 December 2021 (WITN6926001), §742. See also Mr Lister's Second witness statement dated 19 May 2022 (WITN4505002), §3.7.
[1418] Dr Williamson's oral evidence on 8 December 2021, at 108:20-109:15.
[1419] Dr Williamson's oral evidence on 8 December 2021, at 116:8-10, 117:3.

that leucodepletion would go ahead in July 1998.[1420] The process was in operation by 1 November 1999.[1421] The Inquiry has heard evidence that, given the operational challenges involved, *"...achieving [this] in 15 months was as fast as could [have been] done*".[1422]

9.13. Use of non-UK Plasma. Alongside leucodepletion as a "'*top priority*' was the '*exclusion of UK plasma from*'" blood products.[1423] The starting point in this regard was the recall on 30 October 1997 by the Bio Products Laboratory ("BPL") of batches of product derived from plasma donated by three individuals who subsequently were confirmed to have died of vCJD.[1424] On 26 February 1998, the Department set out that *"... [a]lbumin for use as an excipient should not be sourced from plasma from countries where a number of vCJD cases have occurred"*.[1425] This "*...made the ultimate debarment of UK plasma practically inevitable...*" with respect to blood products,[1426] and "*...attention* [also] *turned to the possibility of importing plasma to be used as fresh frozen plasma and cryoprecipitate for patients*".[1427]

9.14. After May 1998, the BPL began importing plasma for the manufacture of blood products from the US.[1428] However, a '*crisis*' emerged in mid-2001, when it appeared that contracts with providers in the United States "*...to supply bulk plasma for fractionation...*" were to be withdrawn. The Department addressed this by purchasing a large supplier, Life Resources Incorporated, by the end of 2002 in order to secure independent long-term supply.[1429]

[1420] Dr Williamson's oral evidence on 8 December 2021, at 117:6-22.
[1421] Dr Williamson's oral evidence on 8 December 2021, at 119:10-12.
[1422] Dr Williamson's oral evidence on 8 December 2021, at 122:4-5.
[1423] Dr Williamson's oral evidence on 8 December 2021, at 117:3-5. See also Mr Lister's Second witness statement dated 19 May 2022 (WITN4505002), §3.7.
[1424] Dr Snape's witness statement, dated 8 February 2022 (WITN3431001), § 290-291.
[1425] Dr Snape's witness statement, dated 8 February 2022 (WITN3431001), § 294.
[1426] Dr Snape's witness statement, dated 8 February 2022 (WITN3431001), § 295.
[1427] Dr Williamson's oral evidence on 8 December 2021, at 123:17-19.
[1428] Mr Lister's Second witness statement, dated 19 May 2022 (WITN4505002), §3.31.
[1429] Mr Lister's oral evidence on 8 June 2022, at 99:25-102:19; Mr Lister's Second witness statement dated 19 May 2022 (WITN4505002), §3.166 and §4.78.

9.15. Use of Imported Fresh Frozen Plasma. Imported fresh frozen plasma could not be virus inactivated in the amounts required to provide the entire supply needed and was becoming more expensive; moreover, it was clear that only male donor plasma could be used due to the risk of transfusion-related acute lung injury otherwise.[1430] Due to these difficulties, it was decided was to import plasma for "*…babies and children only…*", with "*…the supply of fresh frozen plasma for adults…*" to be derived from "*UK sources*".[1431] Dr Williamson noted in her evidence that the recommendation to this effect was made on 22 October 2002, but that the Department was only in a position to announce the decision on 16 August 2003.[1432] However, on 15 August 2002, the Department had already announced the intention that FFP for new-born babies and young children born after 1 January 1996 would be obtained from the US and treated with methylene blue[1433]. As Dr Williamson explained in her second witness statement, "…[*t*]*he need to balance the various risks associated with FFP was … complicated, and this possibly may have been a factor in the time taken to implement importation.*"[1434] According to the Statement of Dr Rowena Jecock, …"*in 2004, following further advice from MSBT, virally inactivated single unit fresh frozen plasma began to be imported from countries with low BSE risk for transfusion to those born after 1 January 1996 (ie not exposed to BSE through diet). In July 2005, as an extension to these arrangements, the National Blood Service began to import fresh frozen plasma for use in children up to the age of 16, and also virally-inactivated cryoprecipitate for the same patient group.*"[1435]

[1430] Dr Williamson's oral evidence on 8 December 2021, at 124:19-125:23.
[1431] Dr Williamson's oral evidence on 8 December 2021, at 126:10-14.
[1432] Dr Williamson's oral evidence on 8 December 2021, at 127:14-21.
[1433] See the Departmental Press release quoting Hazel Blears, WITN4505178. See further Mr Lister's Second Witness statement dated 19 May 2022 (WITN4505002), §3.208. It may be that the issue was the recommendation that the source be un-transfused males, see the 'First Annual Report (2002/03)' of 'The Chief Medical Officer's National Blood Transfusion Committee' Single unit. That note the October 2022 recommendation that, "*virally inactivated, donations from non-UK, un-transfused males, should be used for most vulnerable groups (i.e. infants born after January 1996). An announcement had already been made by the Department of Health in August 2002 about the importation of FFP from the United States for single unit methylene blue-treated FFP for infants born after January 1996. The primary motivation for this initiative was to protect those individuals who had not been exposed to BSE-contaminated beef from the possible exposure to vCJD from UK blood.* (RLIT0000848).
[1434] Dr Williamson's second witness statement, dated 21 November 2021 (WITN0643010), §698.
[1435] Dr Jecock's Third witness statement, dated 27 May 2022 (WITN0823003), §79.5.

9.16. Exclusion from donation of previously transfused patients. In addition, from October 1997, exclusion of at-risk blood donors was recognised as a possible response to the emergence of vCJD.[1436] The exclusion of previously transfused donors was implemented in March 2004.[1437] By contrast to leucodepletion, responding to vCJD by excluding donors necessitated losing part of the blood supply - Dr Williamson's evidence suggests that this prospect of there being insufficient "*blood on the shelf*" may go a significant way towards explaining the relative delay in excluding donors.[1438]

9.17. Overall, the Department has taken a range of actions to mitigate the risk of transmission of vCJD and other forms of CJD since 1996. Transmission in other healthcare settings—for example, via surgical instruments—has never been identified.[1439]

9.18. These submissions do not rehearse those steps further or in more detail in this Section (although the issue of access to recombinant products is addressed in Section 10 of these submissions).

9.19. Instead, we make a number of observations on the overall approach taken to the management of the vCJD risk.

A. The scale of the challenge

9.20. Ministers have given evidence of the scale of the challenge faced by the Department in responding to CJD and BSE/vCJD, and its costs in terms of both the resources within the Blood Safety Team and financially.[1440] This is borne out by other evidence to the Inquiry; for example, Mr Lister's written evidence was that the costs of leucodepletion were £65m pa and the

[1436] Dr Williamson's oral evidence on 8 December 2021, at 112:16-114:19.
[1437] Dr Williamson's oral evidence on 8 December 2021, at 115:24-116:5.
[1438] Dr Williamson's oral evidence on 8 December 2021, at 116:13-117:2.
[1439] Prof Ironside's witness statement, dated 28 April 2022 (WITN7034001), §8(a)(ix).
[1440] For example, Mr Alan Milburn's oral evidence on 14 July 2022, at 102:12-103:17, 137:23-138:16 and his witness statement dated 27 May 2022 (WITN6942001), § 7.18, 8.1, and 22.9.

importation of Fresh Frozen Plasma at £23m pa.[1441] A submission from the CMO, Sir Liam Donaldson, to the Secretary of State dated 8 November 1999 estimated the costs of "*minimising the theoretical costs of CJD*" at the outset of Mr Milburn's period of office at £88m pa to date, but highlighted the potential additional costs of decontamination measures, which were very considerably greater.[1442] CJD issues were dealt with on an urgent basis and plainly took up a great deal of time, for Ministers, the CMO and officials. For the blood policy team, in particular, the pressure of urgent work on CJD issues was one factor in the overall pressures they were under. The high costs involved are also relevant to the issue of how long it took to make recombinant products available.[1443]

B. Risk management

9.21. Although the possibility of human-to-human blood transmission was considered from 9 April 1996,[1444] shortly after the SEAC's recommendations, this remained theoretical, at least until the announcement on 17 December 2003 of the post-mortem vCJD diagnosis of a patient who had in 1996 received blood from a donor who subsequently developed vCJD.[1445] Even then, it was regarded as possible that both the donor and the recipient had separately acquired vCJD by eating BSE-infected meat or meat products.[1446] It was not until the identification of a second case in the following year that it was decided that human-to-human transmission could no longer be described as theoretical.[1447]

9.22. The Department adopted and maintained a "*highly precautionary*" approach.[1448] The Inquiry has heard evidence on the development of the "*precautionary principle*" from its Expert Group on Public Health and

[1441] Mr Lister's Second witness statement, dated 19 May 2022 (WITN4505002), § 3.18, 3.42.
[1442] See DHSC0004747_090.
[1443] Mr Milburn's witness statement, dated 27 May 2022 (WITN6942001), §8.1.
[1444] Dr Hewitt's oral evidence on 10 December 2021, at 84:11-84:25.
[1445] Dr Hewitt's oral evidence on 10 December 2021, at 130:9-22.
[1446] Lord Reid's witness statement, dated 20 May 2022 (WITN0793001), § 24.6.
[1447] Dr Hewitt's oral evidence on 10 December 2021, at 130:9-22.
[1448] Mr Lister's Second witness statement, dated 19 May 2022 (WITN4505002), § 3.5.

Administration. The Report does not detail the chronology of its emergence within the sphere of public health generally, or blood policy generally, but it was clearly applied with regard to the emerging vCJD threat.

9.23. Having been asked to address this question, Dr Patricia Hewitt and Dr Rowena Jecock gave evidence that the risk of secondary transmission of vCJD by blood transfusion was addressed in a very timely manner by the United Kingdom Blood Services and the CJDRSU,[1449] including by the rapid establishment of the TMER. Further, the introduction of leucofiltration of blood components was also undertaken in a very short space of time.[1450]

9.24. In addition, it is apparent that the BSE/vCJD crisis led the CMO, Sir Kenneth Calman, to sponsor extensive research and guidance within the Department on the communication of risk to the public.[1451] It was also a factor instrumental in his Better Blood Transfusion initiative[1452] and in strengthening processes for seeking informed consent to blood transfusions.[1453]

9.25. Decision-making was explicitly based on risk assessments, notably assessments by Det Norske Veritas,[1454] and from the Department's own Operational Researchers,[1455] as well as on the expert advice of Advisory Committees such as SEAC and the Advisory Committee on Microbiological Safety of Blood and Tissues ("MSBT"), which advised, for example, on the issue of the safety of Fresh Frozen Plasma.[1456]

[1449] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), § 405. See also Dr Jecock's Third witness statement, dated 27 May 2022 (WITN0823003) § 81.2.
[1450] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), § 407; see also § 408 on other steps taken.
[1451] See, for example, Sir Kenneth Calman's witness statement, dated 12 October 2022 (WITN3430001), § 12.35.
[1452] See Mr Lister's Second witness statement, dated 19 May 2022 (**WITN4505002**), § 3.8.
[1453] Dr Jecock's Third witness statement, dated 27 May 2022 (WITN0823003), § 81.5.
[1454] Sir Kenneth Calman's witness statement, dated 12 October 2022 (WITN3430001), § 86.9(a).
[1455] See Mr Lister's Second witness statement, dated 19 May 2022 (**WITN4505002**), § 3.6.
[1456] See Mr Lister's Second witness statement, dated 19 May 2022 (**WITN4505002**), § 3.9.

C. Openness and the publication of information

9.26. A further aspect of the response to the BSE/vCJD crisis was the publication of a summary of SEAC discussions.[1457] Given the focus on the confidentiality of decision-making in (e.g.) the CSM or the ACVSB in earlier periods under scrutiny, this change is of note.[1458]

9.27. More broadly across Government, the BSE Inquiry's Report and its recommendations of October 2000 were instrumental in driving consideration and change to the principles on which scientific advisory committees worked. This can be seen, for example, in the Government Office for Science's Code of Practice for Scientific Advisory Committees published in December 2007, which drew extensively on the BSE Inquiry's recommendations.[1459]

9.28. Witnesses including Ministers and Sir Kenneth Calman have given evidence of how seriously they took the obligation to report risks and emerging evidence to Parliament and the public.[1460] They sought to give both prompt and accurate information. In relation to accuracy, it is apparent that the CMOs were heavily engaged in this policy area, providing leadership and numerous briefings to Ministers.

[1457] Sir Kenneth Calman's witness statement, dated 12 October 2022 (WITN3430001), § 0.10. NOTE: Sir Kenneth Calman does not give a start date for publication.
[1458] See also those of CJD incidents panel meetings held in public such as that to discuss its consultation document on 17 April 2002, DHSC0004806_016.
[1459] This is not to say that these were the first such Guidelines. The House of Commons Select Committee on Science and Technology's Fourth Report (https://publications.parliament.uk/pa/cm200001/cmselect/cmsctech/257/25704.htm, 21 March 2001) noted that in March 1997, Sir Robert May, then Chief Scientific Adviser to the Government and Head of the Office of Science and Technology (OST), published "Guidelines on The Use of Scientific Advice in Policy Making." The "May Guidelines" set out key principles for departments to apply in the use and presentation of scientific advice, including that there should be a presumption towards openness in explaining scientific advice and its interpretation.
[1460] For example, Sir Kenneth Calman's witness statement dated 12 October 2022 (WITN3430001), § 23.5; and Lord Reid's witness statement dated 20 May 2022 (WITN0793001), § 24.3.

D. Patient notification exercises

9.29. In or around 16 April 1996, it was decided "*...to do look-back on recipients of blood donations from donors who had subsequently developed CJD*".[1461] The project was also to investigate donors in circumstances where an individual with a history of blood transfusion developed vCJD,[1462] but it was not "*...to investigate links with fractionated blood products*".[1463] The study became known as the TMER. As early as 22 April 1996, the Department required that ethical and legal advice to be taken as to whether to inform the recipients of these donations.[1464]

9.30. As the Inquiry will be aware, the proposal for the TMER recommended that recipients of these donations should not be notified.[1465] The reasons given for this were the absence of tests to determine susceptibility to the development of vCJD or infection with a causative agent and the absence of interventions to offer those at risk of vCJD or who had developed symptoms of the disease; as well as the impossibility of diagnosing vCJD with certainty without examining pathology specimens post-mortem.[1466] It was also recommended that a mechanism for notification ought to be put into place in case capacity to diagnose or intervene improved.[1467]

[1461] Dr Hewitt's oral evidence on 10 December 2021, at 86:4-86:6. There is also detailed reference to the earlier history of Lookback in Dr Rejman's Third witness statement dated 27 April 2022 (WITN4486040), §148.68 onwards. § 148.72 makes specific reference to the decisions of the MSBT on 2 May 1996.
[1462] Dr Hewitt's oral evidence on 10 December 2021, at 90:9-91:12.
[1463] Dr Hewitt's oral evidence on 10 December 2021, at 88:9-93:11.
[1464] Dr Hewitt's oral evidence on 10 December 2021, at 86:10-87:17, 93:19-93:24. Dr Rejman links the issue of ethical advice to the MSBT meeting of 2 May 1996 (Dr Rejman's Third witness statement dated 27 April 2022 (WITN4486040), §148.72). Another ethical issue that arose from TMER concerned the disclosure of the personal details of individuals diagnosed with CJD in the absence of consent, as these individuals were either deceased or without capacity: Dr Hewitt's oral evidence on 10 December 2021, at 93:8-93:18.
[1465] Dr Hewitt's oral evidence on 10 December 2021, at 96:11-97:18. The proposal is at WITN4486104.
[1466] Dr Hewitt's oral evidence on 10 December 2021, at 96:11-97:18.
[1467] Dr Hewitt's oral evidence on 10 December 2021, at 97:10-97:18.

9.31. Dr Jeremy Metters was clear that ethical approval was needed, not least as this was a research study,[1468] and ethical advice was sought from Professor Ian Kennedy.[1469] He advised that it would be unethical to notify in the absence of evidence of risk.[1470] Ethical approval was thereafter sought from the Lothian Ethical Research Committee (see the proposal document[1471] which explained the reasons why notification should not take place). The Committee was familiar with CJD issues due to previous dealings with the CJD Surveillance Unit and which granted ethical approval on 6 January 1997.[1472] Funding was supplied by DH.[1473]

9.32. Over the following years, the view was taken that recipients' blood ought not to be accepted for donation while the risk of vCJD transmission through blood and blood components remained unknown.[1474] In these circumstances, it was considered that the recipients would have to be told that they could not donate blood, and why, because they could not legally or ethically be permitted to donate blood that would not be used.[1475] This factor, and the development of a potential diagnostic test, led to further ethical advice being sought by the Blood Services in 1999 from Professor Len Doyal (Professor of Medical Ethics, University of London).[1476] By letter to Dr Hewitt dated 20 December 1999, Professor Doyal advised that the relevance of the lack of effective interventions to the policy on notification ought to be discounted (people might want information about their health even the absence of effective treatment). Instead, he emphasised the

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[1468] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), § 349; Dr Rejman's Third witness statement, dated 27 April 2022 (WITN4486040), §148.72.
[1469] Dr Hewitt's oral evidence on 10 December 2021, at 94:10-94:19. Dr Rejman's Third witness statement dated 27 April 2022 (WITN4486040), §148.76; also **NHBT0017407** Sir Ian Kennedy's witness statement dated 15 February 2022 (WITN7007001) §§13-20; §§21-35, §46-§48.
[1470] Annex to Sir Kenneth Calman's witness statement, dated 12 October 2022 (WITN3430099), § 78.6. Sir Ian Kennedy's witness statement dated 15 February 2022 (WITN7007001) §§13-20; §§21-35, §46-§48.
[1471] WITN4486104.
[1472] Dr Hewitt's oral evidence on 10 December 2021, at 94:3-94:23, 99:4-99:11.
[1473] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), § 350, 355.
[1474] Dr Hewitt's oral evidence on 10 December 2021, at 99:12-100:12.
[1475] Dr Hewitt's oral evidence on 10 December 2021, at 100:12-102:1; Dr Angela Robinson's witness statement dated 1 December 2021 (WITN6926001), § 765. Mr Lister addressed the reception of the NBA's legal advice to that effect within the DH in his Second witness statement dated 19 May 2022 **WITN4505002**, § 3.55-3.58.
[1476] Dr Hewitt's oral evidence on 10 December 2021, at 99:8-11, 104:6-105:16.

importance of, first, evidence – or, at least, the appearance of evidence - of vCJD transmission by blood. This was provided by the policies of banning blood donation by those at risk of vCJD and the policy of leucodepletion. Second, he noted the potential development of a diagnostic test for vCJD, whether that developed by Professor Collinge or in the US. Both of these factors argued in favour of the notification of recipients, in an "*appropriate and skilled manner*". [1477] Dr Hewitt's second Statement (paragraph 361 - 362) outlines the competing views on this advice.

9.33. The Inquiry has heard criticism of the fact that there was no notification of patients from 1999 through 2003.[1478] Dr Hewitt has noted that the "*...position on notification changed between 1999 and 2001. Part of this change was the result of risk modelling, which resulted in blood components being judged to be a high risk for transmitting vCJD from an infected donor.*" She noted that the UK blood services had been pressing for notification in order to protect the blood supply.[1479]

9.34. The CJD Incidents Panel ("CJDIP"), set up by the Department in 2000,[1480] was requested by DH and Blood Services to provide advice on the notification of recipients of blood components donated by individuals who later developed vCJD.[1481] This Expert Group was set up to "*...provide a mechanism for the development of a consistent approach to the handling of situations where patients may have been exposed to the potential risk of secondary vCJD infection.*"[1482] Mr Lister gives an account of its work, including in respect of the issue of notification.[1483] CJDIP began a Consultation Exercise in October 2001, including consulting as to

[1477] DHSC0046909_045, discussed by Dr Hewitt in oral evidence on 10 December 2021, at 106:6-108:17.
[1478] For example, Mr Buckland's oral evidence on 6 June 2019, at 31:21-32:6.
[1479] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), § 392.
[1480] DHSC0006494_078, page 4.
[1481] DHSC0006494_078, page 4.
[1482] Mr Lister's Second witness statement, dated 19 May 2022 WITN4505002 § 3.67(4).
[1483] Mr Lister's Second witness statement, dated 19 May 2022 WITN4505002 Section 3.

transmission by blood and blood plasma and the issue of notification.[1484] By this time, CJDIP members had changed their majority view from recommending non-notification, to notification.[1485]

9.35. The completion and/or consideration of the consultation exercise by CJDIP was a protracted exercise that generated complaints about the delay in providing definitive advice on notification, the early focus of the incidents panel having been on surgical instruments.[1486] The panel's ultimate recommendation was that at-risk patients should be notified and that support mechanisms ought to be put in place[1487] in case of psychological harm.[1488] This advice was accepted in June 2003 by the Chief Medical Officers for England and the Devolved Administrations.[1489]

9.36. While the support mechanisms were being put into place, the announcement of the post-mortem vCJD diagnosis of a patient who had in 1996 received blood from a donor who subsequently developed vCJD was made.[1490] Lord Reid's written evidence explains the statement that he made to the House on 17 December 2003.[1491] In connection with this announcement, the Department ensured that 15 recipients of blood from individuals who subsequently developed vCJD were contacted through the Health Protection Agency, working with the Blood Services, and given information and

[1484] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), §330, 391; Dr Hewitt's oral evidence on 10 December 2021, at 118:16-118:25. Mr Lister's Second witness statement dated 19 May 2022 **WITN4505002**, § 3.174.
[1485] Dr Hewitt's Second witness statement, dated 24 November 2021 (WITN3101009), §393.
[1486] See Mr Lister's Second witness statement dated, 19 May 2022 **WITN4505002**, §3.101 and §3.229.
[1487] Dr Hewitt's oral evidence on 10 December 2021, at 125:7-125:14.
[1488] WITN3101002, §11 (Dr Hewitt).
[1489] Dr Hewitt's oral evidence on 10 December 2021, at 125:17-125:25.
[1490] The TMER, for the first time in Autumn 2003, demonstrated a link between a donor and recipient in the study, both of whom had developed vCJD: see DHSC0006494_078.
[1491] WITN0793001 para 24.5. See also Mr Gutowski's Second witness statement dated 11 May 2022 (WITN5292016), §3.83 onwards.

support[1492] by an "*expert counsellor.*"[1493] Recipients of components from vCJD-infected donors were notified of this by the end of December 2003.[1494]

9.37. Dr Hewitt noted in her evidence that her view was that notification should have taken place before December 2003. Although she understood that there were concerns about the mechanism of notification and the provision/ availability of support for the affected individuals, the result of the delay was that a notification procedure had to be initiated within a very short time frame, when the first case of transmission was recognised in early December 2003.[1495]

9.38. Subsequently, 5,147 people with bleeding disorders were contacted in 2004 on the basis that they were at-risk of vCJD, having received UK pooled plasma products between 1980 and 2001; of these, 785 had received an implicated batch.[1496] See further the Statement of Lord Reid, paragraphs 25.1 – 25.24.[1497] Mr Gutowski also explained how the 2004 exercise was affected by the preferred approach of the UKHCDO. CJDIP had proposed notification on the basis of individual risk assessments but UKHCDO did not favour this and preferred an "*umbrella*" approach.[1498] He set out the challenges related to the differences in approach, with PS(PH) (Melanie Johnson) accepting the "*umbrella*" approach in July 2004.[1499]

9.39. In 2005, blood donors whose blood had been transfused to recipients who subsequently developed vCJD were notified.[1500]

[1492] Dr Hewitt's oral evidence on 10 December 2021, at 126:11-127:14.
[1493] Lord Reid's witness statement dated 20 May 2022 (WITN0793001), §24.7.
[1494] Dr Hewitt's oral evidence on 10 December 2021, at 113:12-13.
[1495] Dr Hewitt's Second witness statement dated 24 November 2021 (WITN3101009), §397.
[1496] *Expert Report to the Infected Blood Inquiry: Statistics*, § 6.3.
[1497] Lord Reid's witness statement dated 20 May 2022 (WITN0793001), §25.1-25.24.
[1498] Mr Gutowski's Second witness statement dated 11 May 2022 (WITN5292016), §3.85, 3.86. The umbrella approach was summarised thus: *".. . any patient who has received UK sourced clotting factors in a defined time period would be placed in the 'at risk' group. All these haemophilia patients would be informed about this, and given the option to find out whether they had received implicated products and what their individual risk assessment was…"* DHSC0032258_062 §4.
[1499] Mr Gutowski's Second witness statement, dated 11 May 2022 (WITN5292016), §3.94.
[1500] Dr Hewitt's oral evidence on 10 December 2021, at 133:19-134:20.

9.40. A small number of highly transfused patients identified prior to surgery on high-infectivity tissues were notified of an increased risk of vCJD in 2009.[1501] However, patients below a donor exposure limit of 300 were "*de-notified*" by means of a letter to their clinicians in 2014.[1502] This followed a change in the applicable risk assessment and is an instance of reaction to the uncertainties involved in the management of vCJD risks.

9.41. Individuals who have received or are to receive a blood transfusion are informed of the risk of infection with vCJD.[1503]

9.42. The Inquiry has heard that the notification of patients caused distress, for example to the family members of those infected with vCJD by blood transfusion.[1504] The topic of support for those patients who received such distressing news is considered below.

E. Support for patients

9.43. The topic of patient support in the 2004 patient notification exercise was addressed by Professor Ironside, who explained that, at the meeting on 10 April 2003, CJDIP members offered to support notification with the provision of information to a group of individuals with a core brief capable of counselling[1505]. Additionally, there was discussion of the need for training and support for the clinicians involved as well as the suggestion that the Incidents Panel should be strengthened by someone with expertise in the consequences of providing worrying information.[1506]

[1501] See for example the details contained in NCRU0000152_060.
[1502] See for example the PHE Template letter at WITN7091009.
[1503] Dr Hewitt's oral evidence on 10 December 2021, at 57:18-59:19.
[1504] For example, Mr Buckland's oral evidence on 6 June 2019, at 8:16-10:3.
[1505] Prof Ironside's oral evidence on 17 May 2022, at 103:16-104:15. See further Mr Lister's Second witness statement, dated 19 May 2022 WITN4505002 § 3.194, regarding that meeting.
[1506] See Mr Lister's Second witness statement, dated 19 May 2022 WITN4505002, § 3.194, regarding that meeting.

9.44. However as noted above, Dr Hewitt's view was that the timing of the limited notification exercise of December 2003 was, ultimately, poor as it had to be undertaken quickly, with adverse consequences for the support in place.

9.45. Lord Reid's statement has detailed the arrangement made, through the HPA, in the 2004 exercise; it appears that the counselling exercise was focussed primarily on the information made available to the treating clinicians, the majority of those being notified being haemophilia patients.[1507]

9.46. Policy and guidance relating to the notification of patients identified as at risk through the 'highly transfused' identification exercise included information that support from patient outreach and support groups was available for patients.[1508]

9.47. The Inquiry will be aware that there is a compensation scheme for those who have contracted vCJD and indeed their families.[1509] The decision to establish this was taken in late 2000, following the BSE Inquiry Report; it was established in 2001.

9.48. As Caroline Flint explained, "[t]*he vCJD Trust was set up in February 2002 to administer the Government's compensation scheme for victims of vCJD and their families*".[1510] The Trust was set up to be independent of the Department and this independence has been respected, albeit the Trust has kept the Department informed of its work and the Department has pragmatically assisted the Trust in carrying out that work, including with

[1507] Lord Reid's witness statement, dated 20 May 2022 (WITN0793001), §25.20 – 25.23.
[1508] For example, the CJD Support Network, a UK charity. **Papers prepared by the HPA for the CJDIP** in June 2006 explained that clinical care services were made available to at risk individuals, but the patient's GP was considered to be the key point of contact for advising on the options for clinical care.
[1509] Witness statement of Sir Robert Owen (WITN6441001), 11 May 2022. Sir Robert Francis QC, *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework*, §§ 4.88, 6.17, and 8.7.
[1510] Ms Flint's witness statement, dated 7 October 2022 (WITN5427001), § 4.5(a).

respect to the efficiency of its administration.[1511] Anyone infected by vCJD, including as a consequence of transmission by blood or blood products, can look to the Trust, as can their families.[1512] This has been borne out in evidence before the Inquiry.[1513] The methodology for the calculation of payments by the Trust was set out in Appendix 6(c) to Sir Robert Francis's report.

9.49. The Inquiry has further heard concerns expressed by those at risk of vCJD that their access to healthcare treatments was adversely affected by the perception that they might be vectors of infection.

9.50. Reports to this effect were addressed in the briefing to the CMO provided by Mr Lister on 20 November 2001.[1514] The document noted that CJDIP was providing advice on this issue and was conducting a consultation exercise on a proposed framework. Any concerned doctor or dentist was urged to contact CJDIP.

9.51. Current guidance[1515] is emphatic that —in the words of Annex J, (ACDP TSE Guidance) – "*[p]rocedures should not be delayed whilst information [as to vCJD risk] is being collected, and clinicians should be careful not to prejudice overall patient care*". Unfortunately, the effective and consistent application of such guidance is not something that the Department alone can ensure. However, the overall framework of healthcare regulation in England is established to ensure, amongst other things, compliance with applicable guidance, however difficult such consistent application is. This framework includes inspections by the Care Quality Commission ("CQC"); audit and

[1511] Ms Flint's witness statement, dated 7 October 2022 (WITN5427001), §§ 4.6-4.59, Baroness Primarolo's witness statement dated, 9 June 2022 (WITN5494001), §§ 4.8-4.18.
[1512] Sir Robert Francis QC, *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework*, § 9.26.
[1513] Mr Buckland's witness statement, dated 8 January 2019 (WITN0694001), §§ 103-109.
[1514] Mr Lister's Second witness statement, dated 19 May 2022 (**WITN4505002**), §3.181.
[1515] WITN7080005 (Although the first version of the guidance was published in 2006).

review of practice by clinical practitioners and Trusts; and the contribution of patients, who can provide feedback and make complaints.

Current approaches

9.52. The Chair may wish to consider how the response to vCJD from 1996 (which the sections above do to purport to cover exhaustively) reflects the emerging primacy given to the precautionary principle; this being – on any view – a key change in emphasis that has developed over the course of time under investigation by this Inquiry.

9.53. Evidence in relation to this was brought up in the evidence of Dr Susan Hopkins, the current Chief Medical Officer for the UK Health Security Agency ("UKHSA"). [1516] With reference to the corporate UKHSA statement provided to the Inquiry by Dr Robert Kyffin[1517], she confirmed the evolution of UKHSA from its predecessor organisations, the Public Health Laboratory Service (1940 - March 2003); the Health Protection Agency ("HPA") (April 2003 – March 2013); Public Health England ("PHE") (April 2013 – September 2021); and then the UKHSA (October 2021 – present).

9.54. UKHSA is a relatively new organisation, set up post-Covid and the UK Government's expert body responsible for preventing, detecting, analysing, responding and leading on infectious diseases. Dr Hopkins gave comprehensive evidence about the surveillance systems – both human and technological – it employs to detect a range of threats; the frameworks and toolkits used to risk assess and respond to such threats; and the variety of ways in which UKHSA communicates with and disseminates up to date information to clinicians, patients/patient groups, the public and Government. The latter included reference to the way in which the Duty of Candour and the precautionary principle are embedded in UKHSA's work, and how it is a

[1516] Dr Hopkins' oral evidence on 15 November 2022.
[1517] WITN7123001.

widely-shared organisational view that 'Patient Notification Exercises' should be the 'default' in case of risks. Dr Hopkins also described how health inequalities are reviewed whenever data is analysed.

9.55. The totality of Dr Hopkins' evidence demonstrated a complete change in the landscape of the response to infectious diseases since the 1970s, 1980s and 1990s. She was explicit in her view that to the extent that a focus on infectious diseases had moved to other pressing causes of morbidity such as cardiac, lung and neurological diseases over this period, the focus on the former had re-sharpened since Covid and an uplift in funding had enabled UKHSA to increase the capability and delivery of its functions.

9.56. Dr Hopkins was clear about the ways in which UKHSA is addressing perceived weaknesses in public health – for example, by publishing information frequently and widely to establish corporate memory. She also set out the strengths of the current system as compared to the periods of time which have been the Inquiry's focus: a dedicated workforce with wide practitioner expertise; close, joint working; recognition of the importance of learning; and holding patients at the centre of public health. Close working relationships included between UKHSA and the DHSC, with Dr Hopkins speaking regularly to the CMO and UKHSA providing weekly updates to the Secretary of State.

9.57. Professor Sir Jonathan Van Tam explained his experience of the current day application of the precautionary principle:

> *"A… the precautionary principle does exist but I think every decision is considered in terms of the harms and the benefits and the -- you know, the kind of likelihoods. I think it exists but I don't think it's kind of -- I don't think it's a kind of blanket rule that, you know, if slight doubt exists, then we always, you know, take extreme measures. I think it is more carefully quantified these days on an individual situational basis.*
>
> *Q. So it would be a question of -- its relevance and its application may depend upon the extent of the uncertainty about the evidence --*

A. Yeah.

Q. -- and the seriousness of the harm?

A. It would depend upon the extent of uncertainty, the seriousness of the potential harm, or what could be done about the potential harm, and what it was important for patients and the medical profession to know.

Q. As a principle, is this principle something that is consciously articulated in public health decision making or is it again really just hardwired into the way in which public health decision-makers approach their decisions?

A. So I can't say I've ever once kind of reached in my kind of theoretical textbook in my head and say precautionary principle applies here. But I can say that I have said the consequences of this -- perhaps I'm thinking now about the, you know, the EpiPen shortage that the UK had a few years ago. The consequences of being in that situation where your EpiPens don't fire and you're in the middle of an anaphylactic reaction are pretty grim and pretty serious for that patient. Therefore, even if there is an only likely -- and I can't remember the figures, you know, one-in-ten chance that the device would fail -- that is still a one-in-ten chance. That is not something that I believe people shouldn't know about and that we shouldn't take action about"[1518]

[1518] Prof. Sir Jonathan Van Tam's oral evidence on 18 November 2022, at 30:11-31:22 also at 50:13-51:2.

Section 10: Access to treatment and support

Access to high purity products, recombinants and other treatment, care and support

Introduction

10.1. The following section of submissions covers a number of broad topics relating to access to various forms of treatments, care and support, namely Alpha Interferon and successive treatments for Hepatitis C, high purity blood products and recombinant treatment, and the provision of counselling and psychosocial support for the infected and affected. It is not intended to be an exhaustive survey of the evidence on each sub-topic.

10.2. The organisation of haemophilia centres was originally (i.e, towards the beginning of the period with which the Inquiry is concerned) set out in the Circular HC(74)4.[1519] This set out the functions of a Haemophilia Centre, the Associate Haemophilia Centres and the more specialised Reference Centres *"...to which Haemophilia Centres can took for guidance and support".* The arrangements followed *"...a review, which was carried out in consultation with the Directors of the present Haemophilia Centres".* The functions of a Haemophilia Centre included the provision of a laboratory service to assess and monitor the use of coagulants and anti-coagulants, a clinical service for the treatment of patients *"...at short notice at any time of the day or night"*, and:

> *"...an advisory service to patients (and, in the case of child patients, to their parents) on matters of concern to them such as preventative medicine and dentistry, education, employment, genetic counselling and social medicine. Advice should also be given to general practitioners about the emergency treatment of haemophiliac patients on their list and the procedure for securing these patients' admission to hospital when required...."*[1520]

[1519] CBLA0000339.
[1520] CBLA0000339.

10.3. Revised standards of provision were subsequently set out in the NHS Executive Guidance HSG(93)30 issued on 25 June 1993, which outlined the functions of Haemophilia Centres and Comprehensive Care Centres ("CCCs"). The Haemophilia Society had been asked for its input for examples of contracting models to be recommended as good practice, following the organisational changes to the NHS of April 1991.[1521] Focussing at the issues of counselling, both the Haemophilia Centres and CCCs were expected to include, as part of their services, *"...an advisory service to patients and close relatives on matters specific to haemophilia..."*, and an advisory service to GPs; also *"...counselling in privacy of patients and their relatives"*. In addition, CCCs were expected to provide *"...social care and any other counselling services..."* as well as *"...educational facilities for medical staff, nurses, MLSOs, counsellors and other personnel as required to provide optimal comprehensive care of patients."*[1522]

10.4. The Inquiry will be aware that the prescribing of treatments has always been a matter for individual clinicians. In the early years of Factor VIII products, the evidence is that individual clinicians were free to make their own choice of product and could choose between NHS and commercial products, when both were available (issues of self-sufficiency, and the availability of NHS concentrates, are addressed in Section 2 of these submissions). Local decision-making was the preferred model and this did not change with the creation of the purchase-provider split in April 1991.

10.5. The policy of the Department towards earmarking central DH resources for various forms of treatment was generally to resist such requests. For instance, until late 1992, the Department refused requests for earmarked AIDS funds to be used to cover the costs of high purity Factor VIII.[1523] Earmarking funds generally involved 'top-slicing'. In other words, the availability of central funding was achieved by reserving money otherwise

[1521] DHSC0002435_067 HSOC0013603
[1522] HCDO0000269_062.
[1523] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289035), §§6.41-6.46.

passed to the NHS budget, instead retaining it centrally and distributing it for specific projects or initiatives. However, such a central funding initiative did not increase the size of the overall healthcare budget.[1524] The Department's basis for resisting pressure to earmark funds was its view that prescribing decisions were a matter for clinicians and the regions were best placed to decide how to introduce medical advances.[1525] However, resistance to earmarking funds for treatment was not an absolute position of the Department. For example, a change of policy in relation to using earmarked funds for high purity Factor VIII products was agreed in December 1992, as the science, and the case for high purity factor VIII, developed.

10.6. In the context of local decision-making about access to treatment but demands on the Department to introduce earmarked funding or to issue guidance for local purchasers requiring the funding of new treatments, there were various means through which practice might be standardised, with or without the Department's involvement. These included:

(1) Clinical Guidelines – clinical guidelines might be issued by bodies such as UKHCDO without the input of or the approval of the Department. An example of this is in relation to recombinant Factor VIII in which the Department did not approve UKHCDO guidelines because they did not meet the criteria for guideline approval by the Department.[1526] Equally, at times steps might be taken by the Department to support the development of clinical guidelines, although the guidelines were "owned" by the professional groups concerned. An example of this is the work done to encourage clinical guidelines on the use of Interferon.

(2) Clinical Outcomes Group ("COG") – the COG was the body responsible for independently appraising clinical guidelines.[1527] There

[1524] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §44.9. Also, see Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §23.2.
[1525] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §70.40.
[1526] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §24.18.
[1527] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §62.47. See also Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §61.19.

is evidence in the Third Statement of Dr Rejman about the potential interaction between the development of UKHCDO Guidelines and DH appraisal of such documents.[1528]

(3) Health Service Guidelines – For example, on 25 June 1993, NHS Executive Guidelines were issued on "*Provision of Haemophilia Treatment and Care*" (HSG(93)30),[1529] replacing HC(76)4.

(4) Introduction of NICE – The National Institute for Clinical Excellence (NICE) was established as a special health authority by order of the Secretary of State for Health in 1999, to create consistent guidelines about the use of treatments and to end inconsistencies in their availability.[1530]

10.7. Some services were organised on a "*supra-regional*" basis in order to rationalise and centralise the use of scarce expertise and to secure greater consistency in the commissioning of highly specialised services. On 20 June 1995, Dr Pickles[1531] wrote to the Department (Dr Doyle) raising the issue of whether the drugs used to treat haemophilia ought to be dealt with on a supra-regional basis in view of their extremely high, and increasing, cost and the possibility of local variations in approach.[1532] Such an approach would have centralised spending decisions upon haemophilia treatment. Asked for comments by Dr Doyle (who noted the role of the Supra Regional Services Advisory Group and its remit, implying that haemophilia services would not meet the criteria[1533]), Dr Rejman responded to Dr Doyle in a minute dated 28 June 1995.[1534] He outlined his opposition to the idea of a supra-regional service, noting that he believed that this had been *"...considered several years ago and was turned down".* Dr Rejman commented in his written evidence that:

[1528] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§24.4 – 24.8.
[1529] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §78.11.
[1530] Alan Milburn's witness statement dated 27 May 2022 (WITN6942001), §20.10.
[1531] Dr Pickles was on secondment from the DH at the time: see Dr Pickles' witness statement dated 25 April 2022 (WITN6965001), §2.3 and §34.2.
[1532] DHSC0003986_070.
[1533] DHSC0003986_069.
[1534] DHSC0003986_068.

> *"From my minute, it appears that if haemophilia became a supra-regional service, DH would have had a bigger say in managing care of haemophilia patients. This might have involved DH in deciding what treatment products haemophilia patients would receive. It might restrict clinical freedom for the clinicians treating haemophilia patients.*
>
> *...*
>
> *My minute states that there were a number of plasma-derived and recombinant products available at the time. Clinicians preferred particular products for a number of reasons, and not just because of price. One also assumes that if DH were to opt for particular products, the commercial suppliers of those not favoured could make complaints to competition authorities, within the UK or the EU."*[1535]

10.8. The issues relating to the mechanisms for ensuring access to treatment are explored further below, by reference first to Alpha Interferon and other Hepatitis C treatments, then High Purity concentrates and Recombinant products.

Alpha Interferon

10.9. On 1 November 1994, a licence was granted for Alpha Interferon to be used in the treatment of Hepatitis C. This was the first licensed treatment for Hepatitis C.[1536]

10.10. In August 1995, the Haemophilia Society raised issues concerning access to treatment with Interferon by haemophiliacs, including those identified as a result of the lookback exercise. Details of the issue raised by the Haemophilia Society can be found in paragraphs 61.2 to 61.5 of Professor Sir Kenneth Calman's written statement. The Department responded by conducting an investigation into the matter.[1537]

10.11. In January 1996, the Department reported back to the Haemophilia Society with the results of the investigation. It had examined all reported cases of

[1535] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§29.5-29.6.
[1536] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §124.1.
[1537] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §§61.2-61.5.

problems in accessing treatment with Interferon. They related to problems in three health authorities and one children's trust (where the primary issue was one of ethical approval). In all cases agreement had been reached that funding would follow a clinical decision that treatment was needed. The response further indicated that the patients identified by the look back exercise ("LBE") were in no different a position to those represented by the Haemophilia Society. They should be counselled and referred for specialist opinion, and the treatment offered would be determined locally. This policy was based on the principle that decisions about treatment provision were best made locally.[1538] But, as noted below, there was a commitment to treat those identified by the LBE. The Department asked to be kept informed if further issues were brought to the Haemophilia Society's attention.

10.12. Further details of DH's investigation can be found in paragraphs 61.1 to 61.7 of the Annex to Professor Sir Kenneth Calman's written statement.

10.13. There were other broader issues relating to access to treatment for Hepatitis C:

(1) Funding for Alpha Interferon treatment: in 1995, there was a lack of clarity concerning who should pay for Alpha Interferon treatment identified as required as a result of the LBE.[1539] This was explained in the written statement of Professor Sir Kenneth Calman at paragraphs 61.8 - 61.13.

(2) General Financial Pressures: There was pressure on the NHS budget as a result of HCV prevalence in the population more generally and patient treatment needs.[1540]

10.14. In relation to this last issue, in January 1996 Dr Nicholas noted that the LBE had raised expectations that treatment should be offered to infected groups

[1538] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §§61.6-61.7.
[1539] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §§61.8-61.13.
[1540] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §61.14.

who acquired their infection by other routes than blood transfusion or NHS treatment.[1541] A paper submitted for a meeting of the NHS Executive on 13/14 June 1996 noted that there were two groups of patients. The first group included haemophiliacs and recipients of blood transfusions who had been infected as a result of NHS treatment (minimum of 7000 cases). The other group were current and past drug misusers who had shared equipment (estimate of 300,000 infected; the number was likely to grow, unlike the numbers in the first group).[1542] The paper noted that, in respect of the first group Ministers had given commitments to help if haemophiliacs had experienced difficulties accessing HCV treatment. Also, a ministerial assurance had been given that patients identified as a result of the LBE would be tested and, if appropriate, treated.[1543]

10.15. The real pressures arose from the second group. It was noted in the paper that *"[d]istinguishing between people infected through NHS treatment and through other routes such as drug misuse would be contentious"*. Pressure groups, such as the British Liver Trust, would *"...rapidly identify any evidence of a two-tier approach"*.[1544] Ultimately, as noted by Professor Sir Kenneth Calman in his written statement to the Inquiry *"[t]he DH's view was...that to distinguish between different groups of patients on other than clinical grounds would not be ethical*".[1545]

10.16. There were ministerial submissions in December 1996 and February 1997 which outlined the issues with a proactive health promotion campaign on HCV prevention. Ministers did not *"...want to see a separate identifiable HCV prevention campaign which would unnecessarily raise its profile and*

[1541] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §62.6.
[1542] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §62.5 (see DHSC0006348_083).
[1543] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §62.6 (see DHSC0006348_083).
[1544] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §62.19 (see DHSC0006348_083).
[1545] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §62.7.

thus public concern".[1546] Further details of this can be found in the Annex to Sir Kenneth Calman's written statement dated 12 October 2022 at paragraphs 62.31 to 62.41. [1547]

10.17. In December 1995, Sir Kenneth Calman raised questions regarding the process for introducing new drugs, in particular querying the role of central government in issuing clinical guidelines on the use of new drugs and the appropriate machinery from which guidelines were to be issued.[1548] The issues raised by Professor Sir Kenneth Calman in this regard can be found at paragraphs 61.17 to 61.18 of his written statement. He notes that they illustrated how at the time there was no established mechanism or practice where by the DH would issue guidance on the use of licensed drug, and that possibility raised a number of issues.

10.18. In the event, the DH sought to support clinicians to produce guidelines, in accordance with the general practice that DH did not issue clinical guidelines – the professions did. The involvement of the Department to the development of interferon guidelines for HCV, in light of these issues, is explained at paragraph 62.2 of Professor Sir Kenneth Calman's written statement.[1549]

10.19. The ultimate outcome or resolution of his matter lay in the establishment of the National Institute for Clinical Excellence ("NICE") in spring 1999 to create consistent guidelines about the use of treatments and to end inconsistencies in their availability. In October 2000, NICE issued Guidance on the treatment of Hepatitis C with interferon and ribavirin.[1550]

[1546] DHSC0004203_005; DHSC0004203_003.
[1547] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §§62.31- 62.41.
[1548] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §§61.17-61.18.
[1549] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §62.2.
[1550] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §61.20.

10.20. Alan Milburn refers in his written statement to the Inquiry dated 27 May 2022 of the decision to provide support to HCV sufferers through investment in services and treatment rather than financial compensation. Mr Milburn noted the decision to refer combination therapy (interferon with ribavirin) urgently to NICE in August 1999. NICE recommended in October 2000 that patients suffering from moderate or severe Hepatitis C should be given combination therapy.[1551]

10.21. Ministers later recommended that pegylated interferon treatment for Hepatitis C (which appeared to have a higher success rate than combination therapy) should be included in NICE's work programme in February 2002.[1552]

High purity products

10.22. To aid consideration of the history of use of high purity ("HP") products as treatment for HIV positive patients, an outline of the various considerations which informed the position adopted by the Department over time is provided.

10.23. The efficacy of HP products was an issue of significant debate by medical professionals and departmental officials within the Department, particularly from early 1990 to late 1992.[1553] In essence, the debate centred on whether HP products should be used instead of intermediate purity ("IP") products for HIV positive patients. In Spring 1992, the UK Regional Haemophilia Centre Directors Committee ("the Regional Directors Committee") made recommendations to the effect that HP *"...products should replace IP materials to restrict immunosuppression"*.[1554]

[1551] Alan Milburn's witness statement dated 27 May 2022 (WITN6942001), §20.10.
[1552] Alan Milburn's witness statement dated 27 May 2022 (WITN6942001), §20.10.
[1553] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.2.
[1554] BART0000877. See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §70.16. These were the "Fourth Recommendations", replacing guidance issued in 1990.

10.24. This matter came to the attention of the Secretary of State for Health, Virginia Bottomley, in October 1992, when she asked for a briefing on a critical article in "hospital doctor".[1555] A response from John Canavan, explaining the Department's position, concluded that:

> *"(a) the department is in no way advocating denial of treatment to anyone;*
>
> *(b) it is a matter for Regions to decide what services to develop and to allocate resources accordingly…"*

10.25. He stated that the mainstream NHS allocations were sufficient, with growth money to fund new treatments as and when they came on stream.[1556] Baroness Bottomley's witness statement further notes that other Departmental letters of explanation were sent at the same time, including a lengthy letter of explanation sent by her to David Watters of the Haemophilia Society, based on these official briefings.[1557] This outlined, amongst other points, why it was not considered appropriate to use funds earmarked for the development of HIV/AIDS services for the requested purpose.

10.26. On 10 November 1992, the CMO sent a letter to Dr Winyard (Director of Public Health at Wessex RHA), in response to a request for the CMO to outline the Department's policy on the use of HP products. The CMO's letter referenced an article by Dr Charles Hay, published on 27 June 1992, which concluded that there was *"…no convincing evidence"* that ion-exchange purified Factor VIII, a type of HP product, caused less immunosuppression than IP products and further clinical trials were required.[1558] The CMO further stated in this letter:

[1555] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §6.42.
[1556] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §6.43 and DHSC0002463_024.
[1557] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §6.46, letter at UHMB0000005_097.
[1558] HSOC0002607_001. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.10.

> *"I take [t]his opportunity to reinforce the Department's view that in prescribing of any expensive new drug or treatment, clinical judgement will need to be exercised within locally agreed priorities and availability of resources. Therefore, in making decisions about whether to prescribe a high purity factor VIII product clinicians will need to have regard not only to the recommendations and to general considerations of costs and benefits, but also to policies agreed by doctors and managers locally on prescribing expensive new drugs or treatments."*[1559]

10.27. In late 1992, the CMO and departmental officials received letters and papers from public health practitioners and experts concerning the topic of HP products. In particular, the CMO was sent a letter from Dr Muir Gray of the Oxford RHA[1560] enclosing a paper by Dr Jill Meara dated September 1992 which stated that the current evidence in this area did not support a shift to new products.[1561] HP products were more expensive than IP products, and there was concern amongst some clinicians about the relative advantages of HP products.[1562]

10.28. The Inquiry has heard evidence from Dr Foster that it is not as simple as *"...high purity good, anything else bad..."*[1563] An increased incidence of inhibitors was seen with some high purity products.[1564]

10.29. Thus by November 1992, the Department's position on the use of HP products remained as articulated by Professor Sir Kenneth Calman in his written statement to the Inquiry:

> *"The Department's line was that it was a matter for individual clinicians to make prescribing decisions in accordance with local agreed guidelines and that RHAs were best placed to make decisions on how*

[1559] DHSC0002463_069. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.10.
[1560] DHSC0002462_017. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.13.
[1561] DHSC0002464_102. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.13.
[1562] UHMB0000005_097. See too Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289035), §6.46.
[1563] Dr Foster's oral evidence on 25 March 2022, at 116:18-116:20.
[1564] Dr Foster's oral evidence on 25 March 2022, at 116:13-116:17.

fast any particular medical treatment, such as HP Factor VIII, should be introduced."[1565]

Further Evidence – late 1992

10.30. However, in late 1992 the Department's position changed after it considered new evidence. On 20 November 1992, Dr Christine Lee (Director of the Haemophilia Centre at the Royal Free Hospital) wrote to the CMO and referred to *"...increasing evidence"* that monoclonal HP Factor VIII delayed immunosuppression in HIV positive haemophiliac patients and that providing such treatment to HIV positive haemophiliacs was a legitimate call on AIDS monies.[1566]

10.31. On 4 December 1992, the CMO replied to Dr Lee. He stated that "*I have asked medical and other colleagues to look at the new evidence and review the relevant papers. I will discuss the matter with Secretary of State in light of this review...*"[1567]

10.32. On 4 December 1992, a ministerial submission was sent to the Secretary of State (Virginia Bottomley) and to the CMO's office. This sought the Secretary of State's agreement to change the Department's policy and to designate HP Factor VIII as a specific treatment for HIV, as well as haemophilia, thus allowing earmarked AIDS funds to be used to meet the price differential between IP and HP Factor VIII. The submission noted:

"New Developments

Data have since been accumulating which are tipping the balance of probability that the high purity product is beneficial in respect of HIV in seropositive haemophiliacs. This view was given further support when Dr Christine Lee, Director of the Haemophilia Centre at the Royal Free presented an abstract just published in the USA Scientific Journal

[1565] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.20.
[1566] DHSC0002463_018. See Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.14.
[1567] DHSC0002464_052. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.16.

> *'Blood'…which appears to lend further weight to the view that high purity Factor VIII benefits seropositive haemophiliacs by slowing down the rate of decline in CD4 count, a marker of immune suppression and disease progression. These data when added to previous information have led medical and administrative colleagues in the Department to the view that, on balance it appears more likely than previously thought that high purity Factor VIII is of benefit."*[1568]

10.33. The written evidence of Baroness Bottomley outlined the further advice received by her, from officials and from the CMO, supporting the proposed change of approach.[1569] She noted that *"… once there was former evidence that made it appear more likely than previously thought that high purity Factor VIII was of benefit to seropositive haemophiliacs, we reversed the objection to earmarked AIDS funds being used to fund the price differential".*

10.34. On 14 December 1992, the CMO wrote to clinicians concerned with the care of haemophilia and HIV patients. The CMO provided notice that, in light of accumulating data, the Department had decided to change its position on HP Factor VIII. If clinicians felt the use of HP Factor VIII would benefit HIV positive haemophiliacs in terms of HIV infection as well as haemophilia *per se*, the price differential between IP products and HP products would be an appropriate use of earmarked AIDS funds.[1570]

10.35. In early 1994, changes were made to the formula for allocation of funding to assist with funding HP Factor VIII. Furthermore, a contribution towards the excess costs of HP Factor VIII was built into the treatment and care element of the HIV budget for 1994 to 1995.[1571]

[1568] DHSC0032075_064. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.17. See also Baroness Bottomley's witness statement dated 9 June 20022 (WITN5289001), §§6.47 – 6.50.
[1569] Baroness Bottomley's witness statement dated 9 June 20022 (WITN5289001), §§6.51-6.53.
[1570] DHSC0002464_020. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.19.
[1571] DHSC0003511_027. See Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §70.54 for further details.

10.36. The history of the funding of HP products shows a number of factors at play: a concern that the case for introducing new treatments should be evidence-based, i.e., that there should be real evidence of material benefit to patients; the general policy of the Department that clinicians and funding authorities should make local decisions on appropriate prescribing choices; against that, the pressure from clinical and other groups to endorse clinical guidelines and to provide centralised or earmarked funding; and the reality of finite resources in the Department and the concern that more expensive treatments would be funded at the expense of other needs.

10.37. Further, the evidence (summarised in Professor Sir Kenneth Calman's evidence) indicates there was an initial lack of clinical consensus as to the benefits to be derived from HP products. This led to resistance to attempts to secure earmarked funding for HP products, including from ear-marked AIDS funding. However, there was a partial change of approach in December 1992 following receipt of new scientific evidence. There was then a change in the budgeting formula made, to provide support for the excess costs incurred. [1572]

The provision of recombinant products

10.38. In early 1994 the first recombinant Factor VIII ("rFVIII") received a licence in the UK. Following this, the Department's position on the use of rFVIII for haemophilia treatment was outlined in correspondence between Dr Christine Lee and Dr Jeremy Metters (Deputy Chief Medical Officer) in late 1994 to mid-1995, set out below.

10.39. On 18 November 1994, Dr Lee wrote to the CMO in relation to a request for government to put *"...money into haemophilia treatment, in order that we can afford to use recombinant products"*. Dr Lee indicated that the cost of

[1572] Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §70.54.

synthetic rFVIII was unaffordable for her hospital. Furthermore, Dr Lee outlined the following concerns:

> *"…that we continue to use blood products that are derived from plasma when there now is a licensed synthetic, non plasma-derived equivalent. We cannot in all honesty, say that the present products we are using have exposed our patients to risk but, there are reports from time to time for example, of hepatitis A transmission and more latterly, of parvovirus or B19 transmission. There therefore lurks in the minds of both the haemophilia treaters and the patients, a concern that there may be some hidden virus with which they could become infected."*[1573]

10.40. On 14 December 1994, Dr Rejman provided for the CMO a draft response to Dr Lee's letter and a briefing document. Dr Rejman explained the content of this briefing document in his written statement to the Inquiry dated 27 April 2022:

> *"The document stated that the current recombinant products contain albumin from human plasma. Manufacturers cannot therefore claim it is safer from a viral point of view than plasma derived factor VIII. Recombinant factor VIII has some side effects, with a number of patients developing inhibitors. The frequency may be the same as with plasma derived products.*
>
> *…*
>
> *I set out figures for the amount of Factor VIII used in 1993 and the number of patients with haemophilia. These were different from those given in Dr Lee's letter and the calculated extra cost was £36.6m, rather than the £15m estimated. It was noted that purchasers decide on funding and HSG(93)30 had been issued to help purchasers to decide where to place contracts. Decisions on extra costs needed to be justified on the basis of efficacy and value for money. The briefing note stated that recombinant Factor VIII was no better at treating bleeding in haemophilia patients and that Dr Colvin was due to meet with DH officials to discuss contracts and funding of haemophilia care."*[1574]

10.41. With regards to this perspective, the Inquiry's Expert Report on Fractionation has also traced the development of recombinant products in its Section 12D.[1575] It noted that 'Recombinate' was licensed for use in the

[1573] BART0000634_003. See too Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §71.8.
[1574] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§78.10-78.11.
[1575] EXPG0000044, page 92.

US in 1992 and 'Kogenate' was licensed for use in early 1993. It noted the presence of *"...some concern..."* over the fact that these products contained pasteurised human serum albumin as a stabiliser. The Report's authors further noted the results of early clinical trials on Previously Untreated Patients, showing (amongst other results) the development of inhibitors early in the treatment: *"For that reason, some clinicians became concerned that recombinant FVIII was causing a higher incidence of inhibitors"*. The studies describing this are referenced in the Report at Section 12E and were published in 1992 and 1993.[1576] The Report further details how further work has shown that, across the variations of recombinants introduced over time, *"[e]ach of these recombinant preparations have proven to be safe and effective."* It appears from this section, and its footnotes,[1577] that this was a judgment formed over a longer period of time, i.e., after the publication of the studies from 1992 and 1993.

10.42. On 15 December 1994, Dr Metters replied, on behalf of the CMO, to Dr Lee's letter of 18 November 1994. His letter stated there was no evidence that rFVIII was any safer than plasma derived Factor VIII at that time, that rFVIII contained plasma derived albumin and that recombinant products themselves were not without side effects. He outlined that the Department had issued guidance to purchasers to help them in placing contracts for the care of haemophilia patients. Ultimately, purchasers must *"...be assured that the money they spend is determined by efficacy of treatment as well as value for money. This is to ensure that the best health care is obtained for the resources available, and that demonstrable benefit must be achieved if extra costs are to be spent on one group of patients with less available for others"*.[1578]

[1576] EXPG0000044, page 93.
[1577] The Expert Report's footnotes reference Lusher, J.M. (2004) *"Is the incidence and prevalence of inhibitors greater with recombinant products? No."* *Journal of Thrombosis and Haemostatis*, 2(6), 863-865.
[1578] BART0000634_002; Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §78.12.

10.43. On 7 April 1995, Dr Lee wrote back to Dr Metters. She said that the patients most at risk from parvovirus infection were children. Dr Lee disputed Dr Metters' suggestion that there was no evidence that rFVIII was any safer than plasma derived product. Furthermore, Dr Lee contended that there were compelling reasons to treat patients who had never received plasma derived products in the past, including the majority of newly diagnosed children, with recombinant products.[1579]

10.44. Dr Metters responded in a detailed letter dated 25 May 1995:

> *"As you are aware, it is generally accepted that the treatment of patients with blood and medicinal products derived from human blood and plasma is not without risk. Safeguards have been put in place to minimise the risk of transmission of viruses. The safety of blood products depends on a number of factors, which, taken together reduce, as far as is possible, the risk of viral transmission. These include the screening of donors, the testing of donations, plasma pool testing and the ability of the manufacturing processes to remove or inactivate viruses, and viral marker tests that can be undertaken on certain finished products. They relate to the manufacture of all blood products, Factor VIII, immunoglobulins and albumin. Although steps are taken and will continue to be taken to minimise risk, these safeguards cannot guarantee, absolutely, the removal of that risk. Consequently, the treatment of patients with recombinant Factor VIII, containing human serum albumin as a stabiliser, is also not without risk."*[1580]

10.45. Dr Metters set out the view that appropriate prescribing and funding decisions could be made by individual clinicians and local purchasers:

> *"Taking into account the state-of-art regarding the manufacture and control of medicinal products derived from blood and plasma, some patients with haemophilia may benefit from treatment with recombinant Factor VIII. In your letter you refer to certain categories of patients where you think recombinant Factor VIII may be appropriate. If this is the case, then you should be able to support this position on the basis of scientific and clinical need. I think you will agree, it is preferable to consider the individual circumstances of each patient with haemophilia rather than making generalisations.*

[1579] BART0000634_001; See too Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §78.18.
[1580] BART0000633; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.18.

> *I note in particular that you had identified children under the age of 10, where I presume the significance is that these children who have not been infected with HIV and hepatitis C. Purchasers will, I am sure, seek assurance that the money they spend is determined by efficacy of treatment as well as value for money and related of course to individual patient circumstances".*[1581]

10.46. There was an account in Dr Rejman's written evidence of the interactions between the Department and the UKHCDO, in connection with the publication of UKHCDO guidelines on the use of recombinant products. The DH view was that the UKHCDO draft guidelines did not meet the standards for approval by DH, and that they would not be endorsed by its COG. The Department was concerned to ensure that the guidelines did not imply that they had been endorsed by it.[1582]

10.47. In July 1996, the Department became aware of an imminent announcement by the Secretary of State for Scotland of £1m by way of central funding for rFVIII.[1583] The submission to Ministers on this development noted:

> *"The introduction of recombinant in Scotland has been relatively slower. This is because the Scottish National Blood Service supplies plasma derived blood products (including Factor VIII) without charge. Thus the additional cost to the health board of haemophilia centres using recombinant is very much greater than in England where cross-charging means that centres are already paying for plasma-based products. Scotland have been under pressure from haemophilia centres to address this disincentive. As a result, we understand that Scottish Ministers will shortly be announcing a central injection of £1m to meet the costs of recombinant usage in haemophilia centres."*

10.48. While it was recognised that comparisons would be made with Scotland, the position did not change in England: *"Scotland have been careful to present this development as a reflection of their funding mechanism for blood products, rather than a policy priority eg based on patient safety....In fact, even with the central injection, the pro rata provision of recombinant in the*

[1581] BART0000633; See too the Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.18.
[1582] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §24.1 onwards.
[1583] SCGV0000116_153.

two countries will be very similar and it can be reasonably argued that the Scottish decision is in fact ensuring rather than threatening equal treatment." The Department's position remained that the case for recommending the general use of rFVIII had not yet been made out. There were ongoing safety considerations relating to rFVIII as it contained human serum as a stabiliser. That meant it was not entirely without risk. It was also a more expensive product and the additional cost was considered relevant.[1584]

10.49. In his written statement to the Inquiry Professor Sir Kenneth Calman explained:

> *"The two pillars of clinical effectiveness and affordability are important because resources spent in one area of the health service necessarily means less in other areas. Plasma derived products had a good safety record since 1985, on the evidence at the time were probably just as effective and were cheaper than recombinants. Because both products were of similar efficacy, it was left to health authorities to make decisions at a local level."*[1585]

10.50. This summarises the Department's position at the time: rFVIII was available in the NHS since it was granted a licence in early 1994. Decisions about its usage were to be made at a local level by clinicians and health authorities. The Department considered the case for funding for wider usage but, for the reasons set out above, concluded at this point that it had not been made out.

Emerging concerns regarding vCJD risks

10.51. The position of the Department in relation to the use of rFVIII started to shift following concerns about the risk of vCJD. On 25 November 1997, the UKHCDO issued a public statement on vCJD. The statement referred to batches of pdFVIII withdrawn in the UK by the manufacturer (BPL) because they were produced from plasma containing donations from individuals who subsequently developed vCJD. They called for urgent implementation of the

[1584] SCGV0000116_153; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.42.
[1585] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §72.1.

recommendations contained in the UKHCDO Guidelines and recommended strongly the use of rFVIII for all people with haemophilia A.[1586]

10.52. According to the Inquiry's Expert Report on Bleeding Disorders and Blood Disorders:

> *"The first UK patient to get recombinant F8 was in 1988; it was licensed in 1994. When it was licensed, one of the patients already on this product had to be switched back to plasma-derived product as the recombinant product was too expensive. UK 1997 guidelines recommended that patients should be treated with recombinant F8 as it was licensed and they should be treated with recombinant F9 when it received a licence. Children were identified as a priority (by consensus of UKHCDO - the UK Haemophilia Centre Directors' Organisation)."*[1587]

10.53. This appears to be a reference to UKHCDO guidelines or advice. The Report continues:

> *"Of the approximately 600 children with severe haemophilia A, half were treated with a recombinant product: this was related to cost issues. Costs were borne mainly by the hospital and reimbursed by health authorities. A boy admitted to a hospital might receive a recombinant product but a boy in an adjacent bed might not because the health authority buying these services from the hospital would not pay for it."*

10.54. The timescale discussed / source of this information is not wholly clear. As set out above in these Submissions, it is the case that until 1998, no central DH funding was earmarked for recombinant products and the matter was regarded as one for clinicians and local purchasers, with the potential for variation in decision-making that this implied. The Inquiry will be aware that this was before the introduction of NICE and, thus, the establishment of a central authority with the ability to publish mandatory guidelines that, when made available, were designed to end "postcode-prescribing". But in early 1998, prior to the establishment of NICE, the DH decided to provide central funding to make recombinant products available for children and previously

[1586] SBTS0003131_180; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.74.
[1587] Expert Report to the Infected Blood Inquiry: Bleeding Disorders and Blood Disorders (EXPG0000002), pages 23 – 24.

untreated patients, in response to fears about the potential risks of vCJD. This development is outlined below.

10.55. Professor Sir Kenneth Calman described in his witness statement to the Inquiry of 12 October 2022, the concern that the risk of vCJD caused amongst haemophiliacs and what this meant in relation to rFVIII:

> *"On 6 October 1997, I made a public statement regarding the unknown risk of whether vCJD could be transmitted through blood and blood products [WITN3430053]. The possibility of transmission of vCJD through blood had raised significant public concern. I deal with these issues in more detail in Section 13 on vCJD. I see from the Annex there was an interrelationship between concern about vCJD and calls for funding of recombinant products."*[1588]

10.56. On 5 February 1998, Dr Metters and Dr Winyard sent a submission to Mr Dobson (the Secretary of State for Health) and Baroness Jay. The submission proposed four options and attached a position paper detailing the four options.[1589] Option 3 involved allowing BPL to import non-UK plasma and providing limited funding of recombinant products for children and previously untreated patients. The submission described this option as *"...probably better in terms of safety, public confidence, international support, and cost"*.[1590] The submission noted such an approach risked seriously undermining established policy that decisions on priorities for use of scarce resources should be based on evidence of clinical and cost effectiveness. The government would need to stress it was acting exceptionally to meet the understandable concern of people with haemophilia and to restore public confidence.[1591]

10.57. On 26 February 1998, the Department issued a press release about the use of imported plasma and rFVIII for children under 16 and previously untreated

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[1588] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §71.19.
[1589] DHNI0000042_081; See too Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.82.
[1590] DHNI0000042_081, §30.
[1591] CABO0000014_017; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.80.

patients.[1592] The steps to import plasma, and the extension of a recall of blood products linked to vCJD cases, were explicitly linked to further precautionary advice received the same day from the CSM about the theoretical risk that vCJD could be transmitted by plasma derived products.[1593]

10.58. Professor Sir Kenneth Calman summarised the rationale for making rFVIII available to children under 16 and previously untreated patients:

> *"The decision in early 1998 to provide central funds to make recombinant products more widely available was driven not by a change in the science nor by a change in the Department's understanding of the respective merits of plasma derived and recombinant products, but because of the entirely understandable fear felt by haemophilia patients and their carers in the face of the unknown but theoretical risk of vCJD and against a background history of infection with blood borne viruses".*[1594]

10.59. Dr Rejman in his written statement to the Inquiry dated 27 April 2022 noted that the decision in respect of nvCJD was made at a time when predictions of infection with this disease, and deaths, were very much higher than ultimately proved to be the case.[1595]

Developments from 2003 onwards

10.60. The Chair is aware that in February 2003, the position of the Department shifted towards providing rFVIII for all haemophiliac patients. In his written statement to the Inquiry dated 25 May 2022, Charles Lister outlined the key considerations within the Department between 1999 and 2003 which led to this shift in the Department's position.[1596]

[1592] WITN3430278; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.87.
[1593] WITN3430279; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.87.
[1594] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §72.3.
[1595] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§79.2-79.3.
[1596] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§4.16-4.126.

10.61. To assist the Chair in considering the Department's shift in policy towards central funding for rFVIII for all haemophiliac patients, which was formally announced in February 2003, it may be helpful to scrutinise the chronology of events which led to this. Specifically, a chronology of the series of briefings and ministerial submissions which set the foundation for the Department's shift in position, is set out below.

10.62. In early 1999, the position of the Department was that the case for general use of rFVIII had still not been made out. On 4 January 1999, Dr McGovern provided Baroness Hayman with a note about haemophilia, rFVIII and hepatitis C. The note responded to the argument that rFVIII should be available for all haemophilia A patients, and addressed some of the key issues that would impact any shift in policy towards that direction:

> *"There are three issues – clinical effectiveness, availability and cost. Clinical effectiveness: quite simply, no study to date has demonstrated that recombinant factor VIII is good value and this is the Department's current position. This is likely to change when/if prices fall. Availability: the product is made by Baxter laboratories and demand currently outstrips supply. There is not enough of the currently licensed recombinant factor VIII to support treatment of those under 16 and new patients. Other second and third generation products are under development and it is likely that the companies are depending on unsatisfied demand for the Baxter product to drive sales of these ever newer and more expensive products. Cost: the likely extra cost of providing recombinant factor VIII to all people in England with haemophilia A would be in the order of £50 million pa, bringing the average total cost of treatment alone for these 2,000 patients to £77-80 million pa.*
>
> *...*
>
> *Affordability unfortunately is part of this consideration especially in areas of high cost treatments. This is the kind of area which NICE will address when this is set up later this year."*[1597] [Original emphasis]

10.63. In March 2000, Lord Hunt had directed that the Department should look to do more for people with haemophilia infected with HCV. A submission was sent to Lord Hunt which noted the difference in policy between Scotland and

[1597] DHSC0041158_182; See too Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §71.98(d).

Wales, where policy was to provide rFVIII to all patients, and policy in England where rFVIII was for new patients and those under 16. However, despite the difference in policy in Scotland and Wales, *"...availability limits provision to about the same scale as in England."*[1598] The submission noted that one option would be to request all Health Authorities to fund recombinant for all people requiring Factor 8 and Factor 9. The cost would be that of £40 million per annum, plus the loss, for BPL, of its home market for coagulation factors. The submission also noted a potential 'elephant trap': *"...there may not be sufficient quantities available and not all haemophiliacs may want recombinant products"*.[1599]

10.64. On 9 November 2000, Charles Lister provided a revised speech for the adjournment debate raised by Robert Syms MP. John Denham responded to the debate for the Government. Mr Denham stated that the Department's position remained that the clinical case for recommending the use of recombinant clotting factors had not yet been made. Furthermore, Mr Denham asserted that:

> *"In recognising that individual health authorities have taken different decisions, it is important to note the lack of evidence that there is anything to choose between recombinant and plasma-derived products in terms of safety and effectiveness."*[1600]

10.65. However, on 4 January 2001, Mr Lister sent an email to Nick Raisen (Private Secretary to Dr Pat Troop, DCMO), which included the following:

> *"...Synthetic clotting factors offer no therapeutic benefit over plasma-derived products. The issue is one of safety. Plasma derived clotting factors have had an excellent safety record since the introduction of viral inactivation in the mid 1980s, and we have taken steps to minimise the risk from vCJD. However, the Haemophilia Society and UKHCDO argue that, as long as we continue to use the plasma-derived product, haemophilia patients are at risk from new or undetected viruses and still, potentially, vCJD - and there are products available now that could*

[1598] WITN4505229 at §12 and §15.
[1599] WITN4505229; See Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.30.
[1600] WITN4505243; See Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§4.39-4.40.

> *eliminate that risk. Scotland, Wales and Northern Ireland have all moved towards universal provision of synthetic clotting factors (Scotland aims to complete the process by April 2001) which puts us under additional pressure to do likewise.*
>
> *A shift towards provision of synthetic clotting for all haemophilia patients in England would have to be phased in over a period of perhaps 2-3 years. There is still insufficient product on the market to supply the whole of the needs of the NHS immediately. There would also be substantial cost implications for the NHS which we are currently calculating (I should have figures by the middle of next week showing numbers of haemophilia patients in England currently receiving synthetic and plasma derived products)."*[1601]

10.66. On 19 January 2001, in a submission to Lord Hunt, Mr Lister recommended a phased introduction of recombinant clotting factors for adult haemophilia patients in England over 4-5 years starting in 2002-03. This would require some re-prioritisation of funding for 2002-03 and would pre-empt decisions on priorities for the rest of the phasing period. It would also require a fully costed implementation plan in consultation with expert groups.[1602]

10.67. On 31 January 2001, Charles Lister sent a draft note to Lord Hunt to send on to the Secretary of State on the issue of rFVIII.[1603] The note acknowledged the *"…extremely high cost of providing haemophilia patients with treatments free from the risk of blood borne infection"*. However, Mr Lister believed it would be *"…almost impossible…"* to defend a refusal to move in the direction of providing rFVIII for all patients.

10.68. Mr Lister noted that although synthetic clotting factors were no more efficacious than plasma derived equivalents, they were *"undoubtedly safer in that they are free from risk of blood borne infections"*.

[1601] WITN4505247; See Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.44.
[1602] WITN4505249; See Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.46.
[1603] DHSC0042461_189; See Charles Lister's Second witness statement dated 19 May 2022 (WITN4505002), §§4.51-4.52.

10.69. The note also recognised that due to the quantity of clotting agent haemophiliacs require it would be naïve to claim that the events of the early 1980s could not repeat themselves either with vCJD or with an as yet unidentified virus.

10.70. Furthermore, the note referred to the fact that Wales and Northern Ireland already provided synthetic products for all their haemophilia patients, and Scotland would have done so by March 2001. Also, the Republic of Ireland had moved exclusively to synthetics over 3 years ago. The submission proposed to phase in by age bands, as Scotland had done. This would be on the basis of the proposed five-year phasing-in-period, starting in 2002-03, which Charles Lister supported. However, Mr Lister noted that the speed of the phasing-in-period would depend on the ability of manufacturers to supply sufficient product.

10.71. On 9 February 2001, officials sent an email to the Secretary of State's Private Secretary with responses to issues raised by the Secretary of State in regard to rFVIII, including as to where the funding would come from. Mr Lister explained the content of this email in his written statement to the Inquiry dated 19 May 2002 as follows:

> *"- A commitment to fund recombinant would lead to pressure to complete phasing in a lot sooner than in 5 years.*
>
> *- Following campaigning from Haemophilia North, Newcastle Haemophilia Centre has decided to phase in recombinant products for all their patients.*
>
> *- As to whether there was any human-sources element in the products and the risk of creating pressure to move from 1st generation to 2nd generation recombinants, I explained that 1st generation recombinant used human albumin; the 2nd generation product new to the market was 'albumin light'; and the 3rd generation scheduled for 2003 was to be entirely synthetic. The 2nd generation product was not more expensive than the 1st, but the 3rd was expected to carry a price premium. The manufacturer – Baxter – suggested they could meet the demand by the end of 2003/2004. I suggested that we could no longer rely on a phased implementation ending as late as 2006/7.*

- On the read-across to the wider options for BPL, I suggested that it was inevitable that BPL would lose NHS sales and the phasing-in would allow for proceeding in a managed way. BPL's problems were acute, with or without an NHS market for plasma-derived clotting factors, and I indicated that we considered there was nothing to be gained by holding up the decision on recombinants until the future of BPL was settled. I noted that the outcome of the BPL review would be sent to Ministers later that month. We did not assess that the recombinant decision would put off potential investment partners in BPL.

- As to the source of the funding, I noted that there were no cost commitments before 2002/3 but it would be a new cost commitment for 2002/3 not taken into account in the last spending review. It could only be afforded by pre-empting growth in HA general allocations or by replacing or deferring some existing central spending priority within the indicative plans for years 2 and 3 of the SR period. Finding savings from the wider Health Services Division allocation would be difficult as the majority was allocated to implementing the NHS Plan priorities and the recombinant costs would bite into that significantly."[1604]

10.72. On 22 February 2001, Mr Lister responded to further queries raised by the Secretary of State and Lord Hunt. He observed that the risk to haemophilia patients from these products was impossible to estimate, stating that:

*"**Although the risk would probably be reduced by using recombinant alternatives, it might not be eliminated altogether.** This is because the infective agent might survive the viral inactivation process for the human albumin used to formulate recombinant clotting factors.*

purely synthetic clotting factors are still a couple of years away from marketing and are currently an unknown quantity, in terms of safety. efficacy, price and availability (bearing in mind that initially at least they will be produced by just one manufacturer)." [Original emphasis]

10.73. Officials recommended that ministers should:

*"- agree to **a lengthy phased introduction of recombinant clotting factors starting in 2002-03**, thus ensuring consistency of approach throughout the NHS and eliminating accusations of post code prescribing;*

*- make clear that this is **conditional on the introduction of England-wide or, if possible, UK-wide contracting** to keep additional costs to a minimum;*

[1604] WITN4505253; See Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.54.

> - ***instruct HAs to fund the additional costs from reprioritisation of general allocations*** *but on the understanding that long-term phasing will spread these costs over a number of years."*[1605] [Original emphasis]

10.74. The Secretary of State's response was that *"...we cannot make specific provision in HA allocations. The funding will have to be found at the centre, eg in the NBA or a similar area."* He asked for further advice.[1606] In other words, HAs could not be expected to find the monies from their general allocations. On 2 July 2001, Mr Lister noted in a submission to Yvette Cooper that the Department could not justify re-prioritising within current funding envelopes.[1607] As noted by Charles Lister in his written evidence to the Inquiry, this would indicate that it had not been possible to find the money with the existing (central) Health Services Directorate Budget.[1608] Consequently, Mr Lister was in the course of putting together a bid for new funding for the Spending Review of 2002. On 12 July 2001, Mr Lister submitted a revised bid for the Spending Review of 2002 which included the costs of a phased extension of recombinant treatment to all adult haemophiliacs.[1609] As set out in Charles Lister's statement, the results of that bid would not be known until early 2003. Mr Lister noted that he defended the bid for funding of recombinant treatment against attempts to make reductions in November 2002.[1610]

10.75. The issue of securing an adequate supply of recombinant product is linked to the issue of the UK's acquisition of Life Resources Incorporated, in order to

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[1605] WITN4505256; See Charles Lister's Second witness statement dated 19 May 2022 (WITN4505002), §§4.59 4.60.
[1606] WITN4505260; Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.64.
[1607] DHSC0041379_179; Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.69.
[1608] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.69.
[1609] DHSC0041379_179; See Charles Lister's Second witness statement dated 19 May 2022 (WITN4505002), §4.72.
[1610] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.91.

maintain an adequate supply of US plasma. Please see Section 9 of these submissions.[1611]

10.76. On 12 February 2003, a formal announcement was made that £88 million would be provided over the next 3 years to provide recombinants for haemophilia patients in England.[1612]

10.77. The need to adopt a phasing in approach to the roll out was accepted beyond the Department. Dr Winter of the Haemophilia Alliance had recognised in a letter to the CMO, dated 24 December 2002, that there had to be a phasing in period.[1613]

10.78. In relation to the above, the Chair is invited to note the following regarding the issues which impacted the decision to provide rFVIII and the timeline of the roll out and timeline to provide funding to enable rFVIII to be provided for all haemophiliac patients:

(1) Safety of rFVIII: From 1994, a key consideration from the perspective of the Department was that the early versions of rFVIII were not clearly distinguishable from plasma-derived products in terms of safety and effectiveness. This was still the Department's position in December 2000 as demonstrated by the speech given by Mr Denham, the draft of which was provided by Mr Lister. The issue of safety comprehended concerns about inhibitors, but came to focus on the fact that the early forms of rFVIII contained albumin from human plasma. 1st generation rFVIII used human albumin and the 2nd generation rFVIII, which by 2000 was new to the market, was albumin light. In essence, the rFVIII available on the market at the time contained albumin which meant there was an insufficient safety

[1611] The issues of supply and the link to this acquisition is also set out in Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§4, 4.1-4.126.
[1612] WITN4505301; See Charles Lister's second witness statement dated 19 May 2022, (WITN4505002), §4.107.
[1613] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.198.

differential between these products and plasma-derived products. 3rd generation recombinants, which were entirely synthetic (did not contain human albumin), only became available on the market in 2003. The shift to seeking to provide full access to recombinant for all came before this date. Charles Lister indicated in his oral evidence to the Inquiry on 8 June 2022 that *"...from fairly early on"* his position was that England should provide rFVIII for all adults. Mr Lister stated that he came to the view particularly after all the concerns were raised about variant CJD and the potential for new risks that had not been anticipated through human sourced plasma.[1614] As Mr Lister indicates in his written statement to the Inquiry, in January 2001 Ministers accepted the recommendation for a phased introduction of rFVIII.[1615]

(2) Funding: Charles Lister was heavily involved in addressing the cost implications of enabling the provision of rFVIII to all haemophiliac patients. Mr Lister noted that by January 2001, Ministers accepted his recommendation for a phased introduction of rFVIII. But there was a concern, not least from the Secretary of State, to ensure that sufficient resources were available to enable this development. By March 2001, Mr Lister had established that the funding to start the roll out could not realistically be "allocated" to the health authority budgets, nor was it available from central funds within the Department. Consequently, as Mr Lister indicated in his written statement of 19 May 2022, the only option was to put a bid into the next spending review round. In July 2001, Mr Lister put this bid into the spending review for 2002, and announcement of funding, on a phased basis, was made in February 2003.

(3) Supply of Product: There were concerns within the Department relating to the availability of rFVIII, which was a limited resource. It was not clear whether there would be sufficient supply to satisfy demand. Mr Lister had noted that the speed of the phasing-in-period for rFVIII would depend on the ability of manufacturers to supply the products. When the announcement of funding was made in February

[1614] Charles Lister's oral evidence on 8 June 2002, at 117:23-117:25, 118:1 and 118:3-118:19.
[1615] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §4.6.

2003, the minister stated that *"[t]his roll out will take time to achieve because of the large volume of product involved."*[1616] As noted in the chronology, Dr Winters of the Haemophilia Alliance agreed with the necessity of a phasing in period.

Counselling/psychosocial support

10.79. The issue of the availability of counselling and psychosocial support for the infected and affected has been the subject of much witness evidence throughout the Inquiry. The "*Expert Report to the Infected Blood Inquiry: Psychosocial Issues*", dated January 2020, outlines evidence drawn from individuals' witness evidence upon the provision of counselling. There are multiple accounts of counselling and psychological support being rarely offered or not offered at all; hostile communication from healthcare professionals; and a range of specific matters, including little or no support when an infected person decided not to disclose a diagnosis to family.

10.80. Against this background, we understand that the Inquiry's interest in counselling covers, first, the provision of information about testing and a diagnosis, which would provide the patient with the necessary understanding of their condition. It also covers the longer-term support which patients may require to address problems, after being told of the infection and when living with the condition. It also encompasses the support after the tragedy of childhood bereavement.

10.81. Issues relating to the provision of counselling and psychological or psychosocial support raise, as a minimum, the issues of:

(1) Types of support: There are different types of counselling and social / psychological support. The early "*Advice, Support and Counselling for the HIV Positive*" report, prepared for the Department in

[1616] WITN4505301; Charles Lister's Second witness statement dated 19 May 2022 (WITN4505002), §4.107.

September 1987, set out three types of support: the immediate pre-test period; the post-test/immediate post result period; and the continuing period of post-result adjustment; and noted that needs in these periods may vary.[1617]

(2) Appropriate Expertise: The Inquiry may consider it relevant where the most appropriate expertise was or is likely to be located. Some of the evidence heard by the Inquiry referred to the difficulties experienced by haemophiliacs when they were diagnosed with AIDS, when expertise for one condition was located in the haemophilia centres, but developing expertise with regards to AIDS might be found elsewhere. For instance, in September 1985, the Department had to decide whether patients who tested positive for AIDS should receive counselling in genito-urinary medicine (GUM) clinics, drug clinics or haemophilia centres, each of which might have expertise.[1618] A further variant of this issue was whether charities, such as the British Liver Trust or the Haemophilia Society, might be appropriate vehicles for providing specialist help and support.

(3) Specialist Services: More recently, and during the course of this Inquiry in particular, the issue of whether counselling and psychological support should be offered as a 'bespoke' specialist service for those who were infected by NHS treatment, or services be linked to the wider NHS provision of mental health support services, has come to the fore.

10.82. We note that the Inquiry's Expert Psychosocial Evidence[1619] does not purport to chronicle changing standards in matters of counselling and support, over the years considered by the Inquiry. It acknowledges that there have been changes in practice in some areas of practice (see, for example, the comment at page 12 of the Main Report: *"There have been significant*

[1617] See DHSC0006247_003.
[1618] See DHSC0002327_161.
[1619] There have been three reports from the Inquiry's Expert Group on Psychosocial Issues: a Main Report (EXPG0000003), a Supplementary Report (EXPG0000042) and a further Supplementary Report on Childhood Bereavement (EXPG0000130).

changes in best communication practice since the time that blood and blood products were known to be infected. Communication in medicine has shifted over the past three decades from a paternalistic model of 'doctor knows best' to more collaboration with shared-decision making"), but the Main Report is generally concerned to note current knowledge and best practice, and to assess how that casts light on the impact of the experiences reported by those infected, and their families. See for example the reference to 2018 Standards at page 26, or the statement at page 27 (*"The current expectation would be that all infected individuals, who had received infected blood or blood products, as well as their affected family members, would have received some form of counselling or psychological support, particularly in the context of additional diagnoses of HIV and hepatitis C infection…"*).

10.83. This comment is certainly not intended to devalue the importance of either this expert evidence, less still the traumatic experiences which it summarises and discusses. But in assessing the evidence of provision over the years, the Inquiry may also consider whether expectations about the nature and extent of psychosocial or other support to be provided over the years have changed; and whether the NHS's capacity to provide such support has evolved.

10.84. This has not been the subject of detailed evidence, as far as the Department is aware. But by way of examples of changing expectations:

(1) CTI has previously referenced, in presentations, V. Berridge's *"AIDS in the UK: the Making of Policy, 1981 – 1994"*.[1620] This speaks of the "*rise of counselling*" after HIV testing was introduced as being part of a movement in which counselling was increasingly professionalised. The influence of the training course run through St Mary's London, which was part of this shift, was fed into national policy development though the Department's Expert Advisory Group on AIDS ("EAGA"),

[1620] V. Berridge, *"AIDS in the UK: the Making of Policy, 1981 – 1994"*, OUP (1995).

which at its first meeting established a sub-group on counselling.[1621] But the early EAGA meetings also record the limited staff available to take advantage of, and roll out training. See, for example, the notes of the Sub-Group meeting of 1 March 1985, which recorded concerns about the ability to attend the training course: *"… in the West Midlands there was only one GUM clinic covering a number of health districts and there was no consultant and no clinical psychologist."*[1622] (see further paragraph 10.88 below).

(2) This may be linked to evidence of the NHS workforce. A table showing the mental health specialists employed within the NHS workforce in England and Wales would show the increase in that workforce over the years: for example, in 1970 there were (for example) 399 clinical psychologists employed in the NHS; by 1980, there were 1078; by 1990/91, there were 2200; in 2000/01, 5316; and by 2010/11, there were 8837.[1623]

(3) The changes in the specification of services, with regards to counselling or social support, which is evident from comparison of HC(76)4 with HSG(93)30 have already been set out at paragraphs 10.2 and 10.3 above.

(4) The Inquiry may further consider that there is a contrast between the care and attention given by Sir Robert Francis KC in his report on a Compensation Framework to the issue of claims for and access to counselling, and the lack of mention of such a head of claim in the assessment of damages in *A and others v National Blood Authority* [2001 WL 239806], when Burton J assessed the claims of six lead claimants who had contracted Hepatitis C from infected NHS blood transfusions. It is true that the possibility of developing a serious psychiatric disorder was one of the triggers which would have allowed a claimant to return to court for a further assessment of damages; but

[1621] For the account in Berridge, see pages 71 – 2, also page 175.
[1622] DHSC0002263_051.
[1623] Data taken from Table 2 in "*The History of Mental Health Services in Modern England: Practitioner Memories and the Direction of Future Research*" J. Turner and others, Med Hist. 2015 Oct; 59(4): 599–624. Figures for 1970 and 1980 are said to be whole time equivalents ('wtes').

in general, there was no discussion of any claims for counselling or psychosocial support, past or future.

10.85. Against that background, it is not possible to provide, in these submissions, a comprehensive account of changes in accepted or best practice or of the steps taken, whether by the Department or more local NHS services, to provide counselling or other forms of help and support. The Department was not asked to provide such evidence; further, it would not necessarily hold information upon the exact provision made by local services to meet the needs touched on above, their successes or failures. The provision made is likely to have taken different forms over time, and to have varied in different types of centres (Haemophilia Centres, Regional Transfusion Centres, CCCs, GUM clinics, or GPs' surgeries that had knowledge of local mental health services, to name but a few). We have tried, however, to draw together the evidence that has been heard by the Inquiry that touches upon DH involvement.

10.86. Over the years, the involvement of the Department has taken a number of forms. There has been central guidance relating to counselling provision when national screening programmes have been rolled out. The reliance on 'local' delivery of counselling and psychosocial support has also been coupled with more centralised efforts to increase bespoke or additional support, over the years.

10.87. Examples of the provision for counselling that was generally made when diagnostic exercises were centrally planned may been seen from the following examples.

10.88. First, the introduction of AIDS testing. From mid-October 1985, the HTLV-III antibody test was generally made available throughout the UK for AIDS testing. Alongside the introduction of the HTLV-III antibody test, the

Department decided that counselling should be available whenever sero-testing was carried out. Advice and guidance was provided by a Sub-Group on AIDS Counselling established by EAGA in January 1985. It was considered that most genito-urinary medicine clinics in London already had personnel with experience in counselling. But the view was taken that since a very high proportion of patients at Haemophilia Reference Centres would be sero-positive, it was reasonable to assume that HRC Directors would be prepared to take on responsibility for counselling this particular group.[1624] However, counselling courses at St Mary's Hospital, London, should be provided to selected health care workers. There was discussion of how both short 2-day courses and longer, more in-depth training could be offered, the latter for designated AIDs advisors.[1625] The Inquiry has heard that at Yorkshire Regional Blood transfusion Centre, for example, HIV positive donors were seen by the Associate Specialist who had had training from St Mary's.[1626]

10.89. CTI's Presentation upon Ethical and Professional Guidance for Clinicians, delivered on 28 May 2021, referred to the CMO letter of 1 October 1985:

> *"...what had precipitated it was the introduction of the test for HTLV-III antibodies for screening purposes at regional transfusion centres. If we look at the bottom of this page, we can see the Chief Medical Officer saying: "It is essential that all individuals who are found to have positive antibody tests receive counselling both in order that they may understand the meaning of results and to advise them how to avoid transmitting the infection to others." Then, top of the next page, reference to potential availability of counselling services...."*[1627]

[1624] DHSC0001959.
[1625] See DHSC0001959; DHSC0001597; DHSC0041791_073; and DHSC0002327_161
[1626] CTI Presentation on the Yorkshire Regional Blood Transfusion Centre (INQY0000326), 9 February 2022, at 49:16.
[1627] Presentation by CTI about ethical and professional guidance for clinicians, at 166:18-167:23. CTI also references European Guidelines of Jan 1986 to the effect that individuals tested *"...and found positive should be offered individual counselling and psychosocial support"* (170:14 – 171:14), as well as a RCN publication of the same year referring to the importance of counselling.

10.90. Lord Fowler was questioned by CTI upon the extent to which guidance on counselling was implemented, in practice. CTI put to him evidence of the very limited counselling that was in practice offered to many: advice limited to the significance of a test, its health implications and the precautions to be taken. Lord Fowler reiterated the importance he attached to health education, and the desire that he had had to see this issue explored by way of an early public Inquiry.[1628] CTI further referred to the 1987 Report of the Social Services Committee, "*Problems associated with AIDS*"[1629], which referred to the fact that the Department had provided *"...each of the seven Haemophilia Reference Centres in England with £40-45,000 a year for the last 2 years to cope with the extra burden of work placed on them by HIV"*. CTI asked Lord Fowler why funding had been restricted to the Reference Centres, to which he replied:

> *"...we always are going to be working in -- where funds were limited and the priorities we made were haemophilia centres. But if I had more money we could have done more things. But, I mean, frankly, these money questions, I mean, I do really think you should ask the Treasury about this. I mean, it's always the Health ministers who get blamed, but Health ministers have often been making the case for exactly the things that you're asking, but the Treasury have been saying no."*[1630]

10.91. Second, the 1995 lookback exercise (LBE). In December 1994, the Department decided to undertake the LBE, and this was publicly announced in January 1995. As outlined in Professor Sir Kenneth Calman's written statement, counselling and testing arrangements were considered in detail by the LBE Working Party and were ultimately set out in guidance contained in the CMO's "*Dear Doctor*" letter dated 3 April 1995. Annex B of that letter contained "*Guidelines for Counselling Patients*", which explained that recipients of blood or blood components from donors now known to be carriers of HCV were to be traced, with a view to providing counselling

[1628] Lord Fowler's oral evidence on 22 September 2021, at 83:10 – 84:05.
[1629] CBLA0002374.
[1630] Lord Fowler's oral evidence on 22 September 2021, at 85:13 - 86:14.

before and after testing.[1631] There is further information about the arrangements made at paragraphs 63.1 – 63.7 of Professor Sir Kenneth Calman's written statement.

10.92. Third, vCJD Notification Exercises. The Inquiry has heard that there were a series of notification exercises (and also 'denotification' ones) about the potential risk of infection with vCJD. The Department understands that the notification exercise for 'highly transfused' patients was accompanied by guidance on communication to patients for GPs, including the possibility of referring patients to the CJD Support Network. There was evidence from Dr Connor of the HPA upon the role of the 'central experts' at the Prion Unit and the Surveillance Unit, who were expected to support GPs in their discussions with their patients.[1632] In relation to the notification exercise to patients with haemophilia, counselling was to be provided through the haemophilia centres or units with knowledge of the patients: *"So I think whatever support was available would have been through the actual individual hospital haemophilia -- you know, the haematology units –…and the idea of it being through the clinician who knew the patient best would be that they would be aware if they were already having medical -- other psychological medical concerns that maybe would make this a more difficult notification than for other patients…that's why we worked so closely with the haemophilia doctors and patient organisations. They said they wanted the umbrella -- it was kind of like -- I think that's probably why the risk management was done the way it was because that's what they thought would be best for their patients."*[1633]

10.93. Professor Sir Kenneth Calman's evidence was that the Department's general view was that the provision of counselling was a matter for local services, as

[1631] NHBT0002796_002. See also Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §42.7, §60.4 and §63.1.
[1632] Dr Connor's oral evidence on 18 May 2022, at 23:24-26:4.
[1633] Dr Connor's oral evidence on 18 May 2022, at 61:21-63:18.

part of the service offered to patients diagnosed with a condition.[1634] See, above, the specifications set out in HSG(93)30 (paragraph 10.3 above). Sir Kenneth Calman's view was that long-term support for patients (following on from the provision of "clinical" information about a diagnosis) could be offered by a range of healthcare specialists – it was not necessarily the case that those providing such support should have specialist psychological training.[1635] He outlined his experience of the range of ways in which information and practical support could be provided to patients, including by patient support groups, of which he had personal, and positive, experience.[1636] He noted further that when patients were diagnosed with hepatitis C, they were to be referred to specialist centres, which were expected to have appropriate expertise in supporting patients.[1637]

10.94. Charitable organisations, such as the British Liver Trust and the Haemophilia Society, were critical of the support offered when, for example, patients were diagnosed as suffering from Hepatitis. Sir Kenneth Calman noted that the DH funded, through an s64 Grant, a study by the Haemophilia Society into members' needs in terms of counselling.[1638]

10.95. In 2000, continued criticisms of the support available led to funding to provide more 'bespoke' approaches. In his written statement to the Inquiry, Lord Hunt stated that he was *"...naturally sympathetic to the plight of haemophiliacs infected with Hepatitis C"* and he tried throughout his tenure to find ways to help those infected.[1639] In March 2000, Lord Hunt's interventions led to a decision to provide additional funding to the Haemophilia Society over three years.[1640] The Department provided Section

[1634] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §58.4.
[1635] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §59.3.
[1636] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §59.4.
[1637] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §63.3.
[1638] Professor Calman's witness statement dated 12 October 2022 (WITN3430001), §59.6. See also Annex to Professor Calman's witness statement dated 12 October 2022 (WITN3430099), §§60.3 - 60.4.
[1639] Lord Hunt's witness statement dated 25 November 2022 (WITN4680008), §2.33.
[1640] Lord Hunt's witness statement dated 25 November 2022 (WITN4680008), §2.16. See DHSC0042298_047.

64 grant funding to the Haemophilia Society to support a project to provide advice and counselling for haemophiliacs infected with Hepatitis C through blood products.[1641] There is further detail of this initiative at paragraphs 2.16 and 2.33 of Lord Hunt's written statement.

10.96. The Inquiry may be assisted by the detailed picture of the counselling services available in early 2000, contained in the submission dated 27 March 2000, sent to Lord Hunt.[1642] This submission presented information from haemophilia/hepatitis C counsellors and from the UKHCDO. It stated:

> *"**Counselling***
>
> *3. The Haemophilia Society claim that sufficient counselling is not available for haemophiliacs with hepatitis C. Counselling needs vary - supportive counselling at times of stress, working with families in crisis, genetic counselling for people intending to start families, benefits and housing advice including home adaptions to support daily living. The UKHCDO members and social workers suggest that while counselling services for people with haemophilia are under threat largely due to financial pressures on local health economies, they are in the main holding up at present. In some places the threat is because the counsellors are employed by Social Services Departments and retained by NHS Trusts on a grace and favour basis. In others where counsellors are funded from HIV funds the reducing workload is the threat.*
>
> *4. All 18 Comprehensive Care Centres (CCCs) in England offer the full range of counselling services. However Haemophilia Centres (about 80) do not always do so, nor indeed could the smaller centres be expected to provide this very specialised care."*

10.97. The submission set out a range of actions, from short – medium term. In the short term, actions included the UKHCDO asking its members to ensure that counselling services were made available to patients who attended the smaller haemophilia centres, *"…where there is more basic provision."* This was being supported by DH, including by encouraging links with *"…local Mental Healthcare Trusts, academic psychology departments, and GP*

[1641] Lord Hunt's witness statement dated 25 November 2022 (WITN4680008), §2.16. See DHSC0006168_095.
[1642] WITN4505229.

counselling facilities to maximise current provision in systems of clinical care." However, the further solution was thought to be to incorporate minimum standards in a national service specification: *"…we plan to support the consensus specification through Regional Office Commissioning later this year"*, Lord Hunt was told.[1643]

10.98. Lord Hunt's statement explains how he asked for a "package of care" to be developed. Further details of the initiatives are set out in the documents exhibited to his statement, including that *"…funding to improve counselling and treatment facilities will be included in the general allocation for health authorities from April 2001 to complement the money already in the system intended to meet the overall cost of NICE guidance."*[1644] The proposed *"…care pathway would ensure that patients infected with HCV are referred to the nearest clinician with a particular interest in the infection. Patients would have access to counselling from a health carer with knowledge and experience of HCV and, where appropriate, other relevant conditions such as haemophilia, HIV and drug misuse. All patient would have access to the appropriate diagnostic and therapeutic options available in the management of HCV infection."*[1645]

10.99. In 2001, the process of drawing up the Service Specification by the Haemophilia Alliance concluded.[1646] The Specification included standards for the provision of counselling and psychosocial support including (for example) the role of a social worker. It set out the necessary links to be made with (for example) specialised services for hepatitis, noting that patients co-infected with hepatitis *"…may have major medical and psychosocial problems, especially those co-infected with HIV."* Whilst it was not endorsed by the DH / NHSME as a mandatory England-wide

[1643] See further DHSC0004033_002, which is a briefing for a meeting between Lord Hunt and the UK Haemophilia Centre Directors dated 19 June 2000. This records that the service specification being drawn up by the Haemophilia Alliance included counselling services.
[1644] Submission dated 26 October 2000, DHSC0020784_008.
[1645] Undated submission to the Secretary of State from Lord Hunt, DHSC0004294_019. See Lord Hunt's witness statement dated 25 November 2022 (WITN4680008), §2.35.
[1646] WITN4081003.

specification, its use by commissioners to define appropriate provision was encouraged; a ministerial introduction from Mr Hutton, Minister of State for Health, was included in the document, commending the standards to NHS commissioners of haemophilia services.[1647]

10.100. In January 2011, there was a review of support available to those infected with HCV. Lord Lansley's witness statement to the Inquiry refers to the recommendation in the review to make an additional £100,000 payment per annum in England to selected national charities for three years to provide additional counselling access for individuals infected with HIV and/or HCV by NHS supplied blood transfusions or blood products.[1648] The review's report outlined that the basis for this additional funding for counselling were the complaints that individuals and families had made about receiving no counselling through the NHS.

10.101. The 2015 APPG report subsequently outlined (page 43) that the Macfarlane Trust, the Caxton Foundation and the Eileen Trust enabled primary and secondary beneficiaries to access counselling services delivered by the Hepatitis C Trust, funded by a government grant covering the years 2011/12 – 2015/16. The APPG did not make further comments about this provision.

10.102. When the Alliance House Organisations Schemes ('AHOs') were reformed and English Infected Blood Support Scheme ('EIBSS') created, the scheme that was established provided for a payment for counselling, normally of up to £300 per year (non-means tested). This was intended to help beneficiaries to address short-term mental health issues; it was expected that longer term mental health issues should be explored with local NHS professionals. Beneficiaries could select local counsellors; if there was a

[1647] HSOC0024533 HSOC0014657
[1648] Lord Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §19.8. See PRSE0004024.

requirement for further sessions after an initial amount this would be considered on a case by case basis.[1649]

The current position in England

10.103. Currently, there is psychological support for the IAA accessible via different routes. The paragraphs below provide a summary of the support available and routes through which they can be accessed. Further detail on the available support and recent issues can be found in: Claire Foreman's second witness statement,[1650] William Vineall's third witness statement,[1651] Luisa Stewart's witness statement,[1652] and Luisa Stewart's oral evidence to the Inquiry.[1653]

10.104. There are psychological services currently available for the general population, including the IAA, directly from the NHS. This includes the NHS's Improving Access to Psychological Therapies ("IAPT") which offers psychological therapy services for common mental health problems and accepts self-referral.[1654]

10.105. The universal psychological services described above which are available directly from the NHS is distinct from support for psychological services that can be accessed by beneficiaries through funding from EIBSS. NHSBSA administers EIBSS on behalf of the Department. Currently, those infected and affected can access £900 funding of independent psychological therapy (non-NHS services) through EIBSS as an alternative if: specific needs

[1649] See WITN4688039 at page 38.
[1650] Claire Foreman's second witness statement dated 18 February 2020 (WITN3953053), §§10-17.
[1651] William Vineall's third witness statement dated 23 April 2021 (WITN4688055), §§61-63.
[1652] Luisa Jewell Stewart's witness statement dated 27 October 2022 (WITN7272001), §§8-17.
[1653] Luisa Jewell Stewart's oral evidence on 11 November 2022, at 121:1; 123:2; 127:21; 134:4; and 153:19.
[1654] Luisa Jewell Stewart's witness statement dated 27 October 2022 (WITN7272001), §13.

cannot be met by IAPT, if there are any delays to access, or if an individual would prefer an independent practitioner for any other reason.[1655]

10.106. Previously, it was necessary for infected beneficiaries, bereaved spouses/partners and their families seeking funding from EIBSS to obtain a letter from their GP and be on the NHS waiting list before support via EIBSS could be accessed. In May 2020, a change of policy agreed between NHSBSA and the Department, which meant that beneficiaries could receive support without a referral or having to be on the waiting list.[1656] This had the goal of making it easier and quicker to access support, and coincided with the Covid-19 pandemic which, it was recognised, could put extra pressure on already vulnerable groups.

10.107. Previously, one of the features of the provision of psychological support through EIBSS had been limited uptake of the offered provision from the IAA. However, following these changes there has been an increase in uptake. This was explained further in paragraph 64 of William Vineall's third written statement.

10.108. Alternative models for psychological support and how this can be achieved have been considered. In February 2020, it was decided that the preferred option was to create a bespoke psychological support service for those registered with EIBSS.

10.109. The Department has recently been asked for further details of the current position regarding the provision of counselling and psychosocial support, and for information about future plans. Mr William Vineall's further witness statement to the Inquiry dated 14 December 2022 outlines the current position.

[1655] Luisa Jewell Stewart's witness statement dated 27 October 2022 (WITN7272001), §§16-17.
[1656] William Vineall's third witness statement dated 23 April 2021 (WITN4688055), §§61-63.

Section 11: The HIV Litigation

Overall perspective

11.1. The topic of the HIV Litigation (1988 – 1991) is dealt with thus in the Inquiry's List of issues: "*How did the Government respond to the HIV Litigation and was its response appropriate?*" (Paragraph 50, List of Issues).

11.2. That is a wide question. During the hearings, more specific but still very varied issues were then canvassed. Arising out of this, the submissions below seek to address the following issues:

(1) The initial approach to the litigation: defending or settling;

(2) The propriety of the steps taken to identify and disclose documents and to instruct experts;

(3) The nature of the Department's claim for public interest immunity ("PII");

(4) Approaches to settlement;

(5) The waivers or undertakings required in order to access the settlement sums;

(6) Liaison with Scotland.

11.3. The issues addressed may not be exhaustive; see 'Limitations of these Submissions' in Section 1, paragraph 1.13 above.

11.4. Further, the word "appropriate" in the List of Issues is open of a number of interpretations, depending on the context. In particular, the high-level decisions as to whether or not to defend the HIV Litigation or to seek a settlement may be regarded a political choice, as to which politicians were ultimately accountable to Parliament at the time, and upon which views might reasonably differ. On such topics, the Inquiry may consider that its consideration may be directed at the issue of whether the choices made were reasonable ones, having regard to the nature of the briefings and other information before ministers.

Conduct of HIV Litigation, to November 1990

Initial assessment of merits and decision not to pursue no-fault compensation scheme

11.5. The initial issue for the government (or, more precisely, the Central Defendants, consisting of the Department of Health, the Licensing Authority and the Committee on the Safety of Medicines[1657]) was whether or not to respond to the initial writ by seeking to defend the action, or by immediately seeking to follow the path of some sort of compromise.

11.6. Thus, on 15 June 1989, a submission was sent by Department officials to the Parliamentary Under Secretary of State Roger Freeman, aiming:

> *"i. to inform ministers of legal action being taken on behalf of a number of haemophiliacs who have been infected with the AIDS virus through blood products, and a smaller number of people infected by blood transfusion*
>
> *ii. to seek ministers' views on the case for resisting the plaintiffs' attempt to proceed by way of a group action*
>
> *iii. to seek ministers' views on other options for handling the litigation and the controversy which it is likely to engender."* [1658]

11.7. The submission also contained an initial assessment of the government's prospects of successfully defending the action:

> "*We believe that the government has a fair chance of successfully defending its role and that of the HAs [Health Authorities] in the court actions, given that at every stage it has acted as swiftly as possible to minimise the risk of infecting haemophiliacs with AIDs in the light of the best expert opinion available at the time."*

11.8. In her oral evidence to the Inquiry, Dr Hilary Pickles was asked about the last part of the passage, with CTI querying whether in order to *"...put forward that positive narrative, there would need to have been some form of assessment, investigation, inquiry, into what it was the Department had*

[1657] This section of these submissions will refer to the Department as shorthand for the three Central Defendants save where otherwise specified. This reflects the fact that the central governmental decisions in the HIV Litigation were predominantly made at the Departmental level.
[1658] DHSC0004776_039.

done, what evidence and advice had been available to it." In her response, Dr Pickles pointed out that among the recipients of the submission were *"...several of the people who may have been involved at the time"*. This included Dr Harris who, according to Dr Pickles, *"...would have been the lead person, I think. So if he felt that wasn't right, he would have said so."*[1659] Reference might also be made to the views of the CMO on the issue of negligence (paragraph 11.58 below). Further, in-depth investigations and enquiries would inevitably follow, through the medium of preparation of the material needed to pursue and defend the litigation.

11.9. On the initial 'positive' advice of officials as presented in this 15 June 1989 ministerial submission and following through that point, the Chair is also invited to take into account that a positive view upon the prospects of success was ultimately put forward by counsel for the Central Defendants when they came to advise their clients upon the HIV Litigation (see below at paragraph 11.65). See too, the attitude of the Haemophilia Society, which had received legal advice that the negligence action would not be likely to be successful[1660], and pressed for additional ex-gratia recompense or support.[1661] The Inquiry may consider that, overall, the Central Defendants' defence of the litigation took place against these contemporaneous views that the central charges of negligence and breach of statutory duty were, indeed, properly defensible.[1662]

11.10. On 26 June 1989, a further updated submission was sent by officials to the office of the Minister of State for Health, David Mellor.[1663] This submission included an indication from counsel that:

[1659] Dr Pickles oral evidence on 12 May 2022, at 104:18-107:6.
[1660] Mr Watters's oral evidence on 11 February 2021, at 75:25-80:7: the Society *"...has been advised that claims for compensation as such are most unlikely to succeed because of the difficulty of proving negligence."* The point being made does not relate to what government knew of those views, but the nature of the contemporaneous assessments, even outside government.
[1661] See WITN0758026 and DHSC0004415_155.
[1662] There were separate issues raised by some of the medical negligence claims, but the Inquiry will be aware that these were ultimately addressed separately in the Settlement Agreement.
[1663] MHRA0017681.

> *"[Counsel] will wish to establish that, in respect of choice of patient treatment, the 'duty of care' lay with the HAs and not with the Department… he regards it as necessary to establish this principle both as a precedent for future litigation, and for tactical reasons so that he can argue that proceedings against the Department should be withdrawn."*

11.11. The discussion of the 'duty of care' point is illustrative of the frequent fact that government decisions on defending / settling litigation must necessarily have regard to the wider consequences or precedent values of the stance taken. The possibility of the government pursuing a no-fault compensation scheme as was pursued in West Germany was also discussed in the submission of 26 June 1989; however, it was not proposed to examine this further because *"…allowing no-fault compensation in this case would create a precedent which would un-doubtedly be exploited by other groups of patients…"* and *"Treasury permission even for a limited scheme could not be taken for granted."* David Mellor agreed with this position, as recorded in a reply sent by him dated 24 July 1989.[1664] When asked the reason for this position by CTI during his oral evidence, David Mellor responded:

> *"…if you are going to offer people compensation it should be proper compensation. And no – we've never adopted no-fault liability because no-fault liability in a way is the easy way out for those who should have to judge themselves as to what they did. Because no-liability means you get money but they never then go on to ask… You don't end up with enough for the people who really ought to get more."*[1665]

11.12. The topic of 'no-fault' compensation arises in other contexts in particular in sections 13 and 14 of these submissions. The Chair is invited to consider however, that Mr Mellor's response illustrates the wide range of views upon the potential implications of settling the litigation, both as to his position that it could mean that 'hard questions' about fault would not be explored, and also as to the potential for a no-fault compensation scheme resulting in reduced payments and unfairness. The Chair will be familiar with the range of no-fault schemes operated internationally, which, whilst ensuring that

[1664] DHSC0003989_071.
[1665] Mr Mellor's oral evidence on 19 May 2022, at 84:18-85:5.

negligence no longer has to be proved, sometimes offer reduced payments to balance wider access against affordability (see for example the New Zealand scheme[1666]). The submission also contains an early reference to the Treasury interest in such policy issues.

11.13. The Inquiry is also invited to assess the decision to defend the litigation against the backdrop of the Macfarlane Trust, which had only recently been established. An initial £10m was made available in March 1988 to provide assistance, albeit on a needs-based discretionary basis. It is apparent that the defence of the HIV Litigation ran in parallel with not only genuine sympathy for the plight of haemophiliacs infected with HIV[1667], but also a continued interest in making further support available. Thus in late 1989, the support available was bolstered by a further £19m of funding (later increased to £24m), making lump-sum payments of £20,000 per person available. There was no attempt made to link these payments to a settlement of the litigation. In other words, the evidence shows that although the claim seeking to establish legal liability on the part of the government was resisted, the topic of ex-gratia support continued to receive attention.

11.14. The Inquiry will be aware that the implications of litigation against government departments will always be carefully scrutinised for indications of possible precedent or other unintended, wider effects. This can be seen in the HIV Litigation, with the early reference to issues about the scope of duties of care in the submission to David Mellor of 26 June 1989 (paragraph 11.10, above), and its continuation in the later detailed consideration of

[1666] This aims to provide "real" but not "full" compensation: see "Redress Schemes for Personal Injuries", S. Macleod, C. Hodges, Hart Publishing (2017) at Part 2, Section E (New Zealand, Compensation).

[1667] This was a common thread in the evidence of all ministers who gave evidence: see: Lord Clarke's second witness statement dated 12 July 2021 (WITN0758012), §32.2; Mr Mellor's witness statement dated 25 April 2022 (WITN7068001), §0.3; Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §0.3; Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §4.128. In addition, it was the evidence of Lord Clarke that the sympathy was shared by Mrs Thatcher: see Lord Clarke's oral evidence, 28 July 2021, at 146:7-147:5.

these issues in relation to the position of the Licensing Authorities and litigation raising the same issues (the 'Opren' litigation).

11.15. Given all these factors, the Chair may consider that the initial decision of the Central Defendants to defend the litigation was not altogether surprising, and that there were well-considered reasons to support it given how the balance of considerations was perceived at that time.

The decision to pursue the duty of care argument

11.16. On 17 October 1989, a submission was sent by officials to the Minister of State for Health David Mellor regarding whether the Department should raise arguments that it owed no duty of care to individual patients.[1668]

11.17. Ministers adopted differing positions on this matter, with MS(H) David Mellor considering that the point should not be pursued and Kenneth Clarke considering that it should be.[1669] When canvassed by Kenneth Clarke in November 1989, the Attorney General (Sir Patrick Mayhew MP as he then was) expressed his opinion that the Court would be likely to rule that the NHS did not owe a duty of care to individual patients in respect of the matters raised by the HIV Litigation.[1670]

11.18. In a note dated 23 November 1989 the view of the Department's counsel was recorded as being that the duty of care point should be pursued.[1671]

[1668] **DHSC0041034_021**
[1669] See **DHSC0041034_009** for David Mellor's view and WITN0758069 for Kenneth Clarke's view.
[1670] HMTR0000001_012.
[1671] WITN0758068. The note states: "*Counsel has argued that in the HIV litigation… he should raise as a preliminary issue the question of duty of care. The argument would be that as a matter of law neither the Licensing Authority nor the Committee on Safety of Medicines (CSM) owe a duty of care and hence had no case to answer…Counsel has also proposed that the no duty of care argument should be made in respect of the Secretary of State's responsibilities under NHS legislation.*" [Original emphasis].

11.19. Kenneth Clarke's view was set out in a minute dated 1 December 1989:

> *"[The Secretary of State's] view is that Counsel should argue… the duty of care argument in respect of S of S's responsibilities and NHS legislation. S of S has commented that it would have wide implications for Government if the Government itself, as well as the Health Authority, is found to owe a duty of care to an individual patient."*[1672]

11.20. When asked about his view in his oral evidence, Lord Clarke remarked as follows:

> "*Any reasonable argument that counsel thinks is arguable and is not wasting the court's time and has a chance of success should be argued. Otherwise the Government is going to be in frightful trouble in lots of other litigation that comes along from time to time. The Government is always involved in litigation.*"[1673]

11.21. In light of the above, if considering the government's decision to pursue the duty of care point, the Chair is invited to have regard to the following matters:

(1) This was an area in which there were legitimate differences of opinion as to the course which government ought to pursue.

(2) In deciding to pursue the duty of care point the government was acting in accordance with the views of both the Attorney General and counsel. It was the Secretary of State's position that if a decision was taken to litigate then the government ought to pursue the reasonable points which were arguable, based on legal advice it had received.

(3) In determining whether to pursue the duty of care point the government had wider considerations in mind concerning the setting of a precedent that a duty of care was owed by government to individual patients. This encompassed a concern that bodies with no involvement with the day-to-day treatment of patients, such as the Licensing Authority and the Committee on Safety of Medicines, could

[1672] WITN0758069.
[1673] Lord Clarke's oral evidence on 28 July 2021, at 200:16-200:22.

come to be seen as owing a duty of care to individual patients if the point was not pursued.[1674]

(4) At the same time as it was determining to contest the HIV Litigation, including the duty of care point, ministers were working to increase the level of support available through the Macfarlane Trust.

11.22. Given all these factors, the Chair may consider that the decision not to concede the duty of care issue was a reasonable one in the circumstances, founded in particular on the Department's position that it should pursue arguments which were properly legally open to it.

Limitation

11.23. On 30 May 1990 a ministerial submission was sent seeking views on whether the Department should plead the defence that the HIV Litigation had been brought out of time.[1675] As recorded in the submission, it was the recommendation of counsel that the Department should reserve its position on limitation.

11.24. As with the duty of care issue, the views of ministers differed.[1676] The view taken by Kenneth Clarke was that the Department should not abandon the limitation point.[1677]

11.25. In his second written statement, Lord Clarke explained this view as follows:

> "*To me it seemed a sensible approach; if litigation is to be fought, arguable points should generally not be abandoned. The Court would*

[1674] See DHSC0007045_006, in which counsel display a particular concern that the duty of care point should not be conceded in respect of the Committee on Safety of Medicines and the Licensing Authority.
[1675] DHSC0038699_023.
[1676] See DHSC0046957_044 and DHSC0046957_043 for Baroness Hooper and Virginia Bottomley's views.
[1677] DHSC0046957_026.

> *make a judgment on whether the limitation period should be waived."*[1678]

11.26. In light of the above, if addressing the Department's approach to the limitation point the Chair is again invited to consider:

(1) This was an area where there were legitimate differences of opinion as to which course the government should pursue.

(2) In deciding to reserve its position in relation to the limitation point the Department was following the advice of counsel.

(3) The Department acted on the basis that government should pursue the legitimate legal points which were open to it, it being for the courts to ultimately determine issues such as whether the limitation period should be extended.

Experts and expert reports

11.27. This section addresses the process of identifying expert witnesses and oversight of draft expert witness reports.

11.28. The Department observes as a preliminary point that the identification of suitable witnesses was overseen by both departmental solicitors and counsel, who were required to consider the list of experts drawn up and be content that they could give an independent medical view.[1679] Within the Department itself, the process of identifying the Department's expert witnesses for the HIV Litigation and providing comment on draft expert reports was led by Dr Rejman, as an official with the requisite technical knowledge.

[1678] Lord Clarke's second witness statement dated 12 July 2021 (WITN0758012), §47.5. See also Lord Clarke's oral evidence on 28 July 2021, at page 203:7-204:3.
[1679] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §4.93.

11.29. On 15 August 1989, a note from John Canavan to Dr Rejman contained the following passage:

> *"In a discussion Mr Arthur had with Mr Powell before his annual leave, SOL C3 asked again for names of expert witnesses for the defendants. We advised the difficult, if not impossible task of finding a Haemophilia Centre Director untouched by the litigation, and who could give independent testimony supportive of the Department's case."*[1680]

11.30. In his written evidence, John Canavan explained his view that what was meant by the minute was that:

> *"…it might be difficult to find experts who were both willing and able to offer independent testimony in the HIV litigation. Haemophilia Centre Directors (who had the necessary expertise) might be defendants in individual cases brought by those infected, and even if they were not involved in treating patients who had been infected and so could be reluctant to risk compromising their relationships with them."*[1681]

11.31. As was explained by Dr Rejman in his oral evidence to the Inquiry, a particular challenge for the Department in identifying expert witnesses was that *"…all of the expert witnesses in the UK would have been doctors who would have been part of the infection problem, and so trying to get a completely independent expert witness report from one of those would have been, well, impossible, really, to be honest."*[1682]

11.32. Despite these challenges, Dr Rejman was clear in his oral evidence that the Department sought people who they felt could give a *"balanced view"*.[1683] This was supported by John Canavan's observation in his written evidence that, although he was not personally involved in the search for expert witnesses, to the best of his knowledge no one was excluded from the search on the basis that they were unsupportive of the Department's

[1680] DHSC0040903_018.
[1681] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001) §4.89.
[1682] Dr Rejman's oral evidence on10 May 2022, at 131:18-131:24.
[1683] Dr Rejman's oral evidence on 10 May 2022, at 131:25-133:10.

case.[1684] Indeed, as far as the DHSC is aware, such a case has not been highlighted by scrutiny of the documentary record.

11.33. On being asked by CTI during his oral evidence to the Inquiry about the phrase *"supportive of the Department's case"* within his note of 15 August 1989, John Canavan commented that:

> *"I think we were expecting that some of the experts would have critical comments to make. I think that [i.e. the note of 15 August 1989] could be read more that obviously if somebody had been publicly critical of the Department's case, that might not be the best person to ask."*[1685]

11.34. On 27 April 1990, Dr Rejman circulated a minute enclosing a preliminary report prepared by expert witness Dr Williams. In this minute Dr Rejman commented that *"[t]his report, if anything, errs on the side of being too supportive of the Central Defendants"* (original emphasis) and suggested a number of points which may need factual amendment.[1686]

11.35. An example of the Department's difficulty in identifying expert witnesses who had not been involved in the issues raised by the HIV Litigation was discussed by Dr Rejman in his oral evidence to the Inquiry in relation to Professor Bloom, whose involvement in events will be well known to the Inquiry.[1687] On 27 July 1990, Dr Rejman sent a minute to a departmental solicitor Ronald Powell in respect of an expert report prepared by Professor Bloom, which included the following observation:

> *"In general, the report is interesting to read and contains some important information. However, in certain parts it reads like a Defence of the actions of the Haemophilia Centre Directors and Professor Bloom*

[1684] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §§4.93-4.94. See also Dr Rejman's oral evidence on 10 May 2022, at 134:15-137:15.
[1685] Mr Canavan's oral evidence on 22 September 2022, at 106:13-107:17. See also Dr Rejman's oral evidence on 10 May 2022, at 134:15-137:15: *"I think what [Mr] Canavan is saying there is not so much supportive of the Department's case, but if we know a particular expert is publicly known to be critical of what the Department is doing or has done, then perhaps we should seek another witness".*
[1686] DHSC0046942_017.
[1687] See Dr Rejman's oral evidence on 10 May 2022, at 137:16-145:13.

> *in particular, rather than a dispassionate view of an independent expert witness."*[1688]

11.36. There are various instances in the documentary record where Dr Rejman commented on draft expert reports and identified passages which were not advantageous to the Department.[1689] There is no indication in the documentation that these comments ever resulted in an expert witness being asked to alter the contents of their report to be more favourable towards the Department.[1690] In his oral evidence to the Inquiry Dr Rejman explained the purpose behind his comments as follows:

> *"Well, in essence it was so that colleagues were aware – because, you see, I think you have to remember that not everybody is going to spend that amount of time reading these expert witnesses. And some of them were very long, a lot of them were detailed, a lot of them you needed a bit more medical knowledge to be able to understand exactly what was being said. And so my task was to look at the expert witness report and say: this is useful, this is less useful, here he's criticising the Department."*[1691]

11.37. Dr Rejman did discuss in his oral evidence to the Inquiry instances in which he would discuss the contents of an expert's draft report with them.[1692] It is observed, however, that Dr Rejman stated that his comments were limited to: (a) factual inaccuracies; (b) pointing out where experts had provided evidence beyond their expertise or gone off on tangents[1693]; and (c) omissions. He did not suggest that he ever indicated to witnesses that they

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[1688] DHSC0004360_114. It should be noted that Dr Rejman's reference in his oral evidence to suggesting to expert witnesses that they 'tone down' parts of their reports was made in the context of considering that Professor Bloom had been too personally exculpatory in his expert report: see Dr Rejman's oral evidence on 10 May 2022, at pages 144:6-145:13.
[1689] See, for example, MHRA0019894, DHSC0038699_004 and DHSC0046942_017.
[1690] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §4.94: *"The various minutes from Dr Rejman which dealt with the preliminary reports of various experts pointed out areas in which the expert was critical of the Department, but to the best of my knowledge those experts were not discounted on the basis of those criticisms…Experienced counsel were advising on the Department's case in the HIV litigation and, from the documents I have seen and to the best of my knowledge, experts were not excluded from the search on the basis that it was known or thought that they might not be supportive of the Department's case."*
[1691] Dr Rejman's oral evidence on 10 May 2022, at 146:3-146:23.
[1692] Dr Rejman's oral evidence on 10 May 2022, at pages 135:6-137:15.
[1693] For the point regarding tangents, see Dr Rejman's oral evidence on 10 May 2022, at page 145:3-145:13.

should alter opinions expressed in draft reports to be more favourable to the Department.

11.38. In light of the above, when considering the Department's approach to expert evidence in the HIV Litigation, the Chair is invited to consider:

(1) The process of identifying witnesses was overseen by departmental solicitors and counsel. Litigation is generally a team effort, and there was a system which oversaw the involvement or contribution of individuals.

(2) Although the Department had no desire to seek out expert witnesses who had already been publicly critical of the Department, potential expert witnesses were not excluded from consideration on the basis of an expectation that they would not be supportive of the Department.[1694]

(3) Although there were difficulties in identifying expert witnesses without personal connection to or involvement in the matters in issue in the litigation, the Department sought balanced views from the experts it instructed.

(4) Although the involvement of some of the Department's staff has been subject to intense scrutiny, there is no evidence to support any suggestion that experts were (or might have been) subject to any pressure to alter their views. Reports were analysed in order to understand their implications and brief colleagues (especially those without medical or technical scientific knowledge) and not for improper purposes.

[1694] It may be noted that the current approaches to experts in litigation, in which, for example, there is discouragement of changes of expert or 'expert shopping' (as well as greater clarity on the expert's duties to the Court), have developed since the 1990s. Contrast the High Court of *Kenning v Eve Construction Ltd* [1987] 1 WLR 1189 in which Michael Wright QC sitting as a Deputy High Court Judge noted: "*The reality is, of course, that if an expert witness is approached by a solicitor on behalf of his client and overall the expert's view is unfavourable to the merits of the case that he is having to consider, the solicitor has a choice. He can either call him (in which case, as it seems to me, he ought to be prepared to disclose his evidence with both the favourable and unfavourable parts contained) or he does not call him and he goes and seeks another expert's opinion which may be more favourable*".

Disclosure of documents for the HIV Litigation

11.39. The process of document discovery for the HIV Litigation in the Department is dealt with in detail by John Canavan in his witness statement dated 6 September 2022.[1695] What follows below is intended to address certain issues raised in questions by CTI during oral questioning.

11.40. The Department began to address the issue of disclosure soon after the first submission was received from the plaintiffs. On 14 July 1989, for example, a minute was sent by Charles Dobson to Alan Barton of the AIDS Unit which advised:

> *"Precedent suggests that we should not volunteer disclosure but wait until a court order is made; however SOLC3 advise that we should already be getting ready for this by identifying and listing all the documents likely to be relevant to the litigation."*[1696]

11.41. On 21 July 1989, in a minute sent from Ronald Powell to John Canavan copied to Dr Rejman, the principles applicable to the disclosure process and public interest immunity (see below) were set out.[1697] In relation to the discovery exercise the note emphasised that:

> *"Whenever discovery takes place, the parties concerned must first of all list all documents they have. You must disclose every document you have in your possession, whether you are bound subsequently to produce it or not."* [Original emphasis]

11.42. In the months that followed Department officials worked to identify relevant documents for the HIV Litigation. This process was led by David Burrage and supported by Dr Rejman and John Canavan, who prepared lists of documents in their possession for review by departmental lawyers.[1698]

[1695] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §§4.346-4.471.
[1696] DHSC0006401_087.
[1697] DHSC0040692.
[1698] See, for example, a note from Dr Rejman at DHSC0006481_020 and disclosure lists sent by John Canavan to departmental solicitors on 31 January 1990 at DHSCO043400.

11.43. The process of document discovery was overseen by departmental solicitors. As explained by John Canavan in his witness statement:

> *"David Burrage did most of the work in reviewing the documents for the disclosure process. He would have taken advice on particular documents from departmental solicitors, and I would have provided input in respect of policy papers*
>
> *...*
>
> *The concepts of withholding documents from disclosure in the HIV litigation on the basis of either relevance, legal professional privilege or PII were legal concepts and I was reliant on guidance from legal colleagues in respect of decisions on the same when working with David Burrage on the discovery process."*[1699]

11.44. Regarding the thoroughness and impartiality of the discovery exercise, the Chair is invited to consider:

(1) As discussed above the disclosure exercise was overseen by a team of lawyers and the departmental officials (primarily, John Canavan, David Burrage and Dr Rejman) were not acting without supervision.

(2) Dr Rejman's evidence was to the effect that he and his colleagues had "*go[ne] through all the papers that we had*" including officials' own filing cabinets, the official files as well as asking bodies such as the AIDS Unit for papers held by them.[1700]

(3) In determining what was relevant, Dr Rejman's evidence was that he and David Burrage had *"tried to err on the side of over-including than under-including"*.[1701]

(4) Although those carrying out the exercise did not receive specific guidance regarding the identification of relevant documents, John Canavan's oral evidence was that "*most of it would have been self-evident if they were relevant to the issues."* He also stated that *"if David Burrage had any concerns about whether it was relevant... he*

[1699] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §§4.368-4.370.
[1700] Dr Rejman's oral evidence on 10 May 2022, at 152:19-156:2.
[1701] Dr Rejman's oral evidence on 10 May 2022, at 154:7-154:13.

would come and ask for my advice and, at that point, I would have read the document."[1702]

(5) There is nothing to suggest that Dr Rejman or any other Department official did not disclose any documentation on the basis of partiality.

(6) Even when erroneous opinions were expressed, they were rightly corrected by supervising lawyers or other team members. Thus, whilst some attention has been given to a letter from Mr Hugh Rossi dated 4 May 1984 to a constituent[1703] (which has been suggested shows that ministers knew that the 'no conclusive proof' was inaccurate), see the second statement of Lord Clarke that Mr Rossi was not the responsible minister at the time, but merely responding to and quoting from a newspaper article.[1704] Furthermore, whilst there was a suggestion that the letter might not need to be disclosed on the (wholly erroneous) basis that it was subject to legal professional privilege, that was as a result of the reaction to it by a junior official conducting the discovery 'trawl' in 1990.[1705] Examination of the List of Documents of the Central Defendants shows that the letter from Mr Rossi MP was, quite properly, listed for disclosure. See the General List (as at 7 June 1990), and DOC 2547 (page 72) of that list.[1706]

11.45. In light of the above, the Chair is invited to consider that the Departmental officials, administrative and legal, charged with carrying out the disclosure exercise for the HIV Litigation acted reasonably and appropriately in seeking to identify relevant documentation held by the Department. The Chair may wish to consider that there was no intention to avoid disclosure of documentation, whether generally or in relation to material perceived to be damaging to the Department's case in the HIV Litigation.

[1702] Mr Canavan's oral evidence on 22 September 2022, at 94:9-98:3.
[1703] DHSC0003824_178.
[1704] Lord Clarke's second witness statement dated 12 July 2021 (WITN0758012), §§69.4-69.5.
[1705] DHSC0046942_084.
[1706] Contained within DHSC0013051.

11.46. This is not to say that the exercise was perfect. The Inquiry may wish to note that whilst there is evidence that the disclosure of documents was carefully considered by Department officials at the time, the system depended on the 'manual' identification of relevant files. The extensive searches of records which took place in 2006 – 2008 appears to have resulted in the identification of a small number of documents from Lord Owen which were not listed in the PII list: see the statement of William Vineall and Lorraine Jackson for a summary.[1707] Generally, it is apparent that records from the 1970s appear to be limited, including the records of ministerial involvement. Dr Rejman gave evidence that he thought that limited records relating to hepatitis might remain, as it had not been seen as a controversial subject.[1708]

Public interest immunity

11.47. A related issue concerns the government's decision to claim public interest immunity ("PII") over certain documents as part of the disclosure exercise for the HIV Litigation. Greater detail than would be appropriate to include in these submissions can be located in the witness statement of John Canavan.[1709]

11.48. In a minute dated 13 September 1989, John Canavan and Dr Rejman were advised by a departmental solicitor as to the principles applicable to PII.[1710]

11.49. A note of a conference held with counsel on 18 May 1990 records advice given to Department officials as to the scope of PII.[1711] This was followed by

[1707] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §§1.11-1.14.
[1708] Dr Rejman's oral evidence on 10 May 2022, at 170:14-171:21.
[1709] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §§4.346-4.468.
[1710] DHSC0040692.
[1711] DHSC0043223.

a written opinion on PII produced by Justin Fenwick dated 4 July 1990.[1712] This advice considered six different types of document and whether a claim for PII could be made in respect of them.[1713] In this advice:

(1) A distinction was drawn between: (a) *"…operational matters"* such as the implementation of policy which would not likely attract PII and (b) *"…the type of major policy-making which the court has in the past protected by public interest immunity"*.

(2) Mr Fenwick recorded that *"[i]t is clear from the authorities that where documents are protected by public interest immunity, the department or person concerned has no discretion but is under a duty to claim the privilege. It is then a matter for the court to decide whether the balance of the competing public interests lies in favour of or against disclosure."*

(3) Mr Fenwick stated his opinion that *"[t]here is nothing in the documents that I have seen which I would expect to have any significant adverse effects on the case to be put forward on behalf of the Central Defendants in this litigation. Indeed, many of them may be helpful in explaining the careful consideration which was given to various matters at the time."*

(4) Mr Fenwick stated that *"…it now seems beyond doubt that documents relating to the formulation of policy will attract such privilege. However, such protection does not extend to briefings and exchanges relating to policies already in existence."*

(5) Mr Fenwick provided a detailed analysis for each of the different types of document as to whether PII could be claimed.

[1712] DHSC0004360_072.
[1713] In his oral evidence Justin Fenwick KC confirmed that he had looked at all 600 documents for which PII had been originally claimed – see Mr Fenwick KC's oral evidence on 9 June 2022, at 72:7-72:11.

11.50. John Laws, then the Senior Counsel to the Crown (Common Law), was subsequently consulted and gave his approval to the approach suggested by Mr Fenwick in his advice.[1714]

11.51. In relation to the Department being under a duty to claim PII, in giving judgment for the plaintiffs on 20 September 1990 the Court of Appeal recognised the obligation. Gibson LJ stated that: "*The Department does not [raise the matter of public interest immunity] in order to put difficulty in the way of plaintiffs, or to withhold from the court documents which might help the plaintiffs… The Department raises the matter because it is the duty of the Department in law to do so in support of the public interest in the proper functioning of the public service.*"[1715]

11.52. This point was made further by Kenneth Clarke in a written answer to a Parliamentary Question dated 15 October 1990.[1716]

11.53. In relation to Mr Fenwick's view that the documents for which PII was being claimed would have little impact on the Department's prospects of success, the Department's counsel team provided advice in October 1990 which concluded that the Department was likely to successfully defend the HIV Litigation.[1717] This advice was written after the documents for which PII had been claimed had been examined by the counsel team.

11.54. This accords with the written evidence of Justin Fenwick KC to the Inquiry, in which he stated that: *"In view of the contents of the PII documents, rather than their status as attracting the privilege, the order for wider disclosure did not affect our view of the likely outcome. Overall, I do not recall [the Court of*

[1714] Mr Fenwick KC's witness statement dated 25 May 2022 (WITN7067001), §18.2.
[1715] DHSC0003620_039 at page 13.
[1716] HSOC0001459.
[1717] DHSC0007039_001.

Appeal's] judgment having a significant impact, other than bringing it closer in focus to ministers and parliament."[1718]

11.55. It can now be seen that the views of the Department's counsel team also accorded with those of the plaintiffs' counsel team in their advice dated 12 December 1990.[1719] This advice, also written after the documents for which PII had been disclosed (and must therefore be assumed to have taken them into account), quantified the plaintiffs' prospects of success at about twenty per cent. (It was not, of course, available to the defendants at the time but was put into the public domain c2010).

11.56. In light of the above, when addressing the issue of the Department's conduct in relation to PII in the HIV Litigation, the Chair is invited to consider:

(1) The Department did not seek to use PII as a mechanism through which to avoid disclosing potentially damaging documents. Rather, the Department was under a legal duty to claim PII where it thought appropriate.

(2) The Department followed detailed and careful advice provided by both junior and very senior counsel as to which classes of documents it should claim PII over and those which it should not.

(3) The documents which were disclosed as a result of the Court of Appeal's judgment had no bearing on both sides' counsels' assessment of the legal merits of the HIV Litigation.

Intervention of Ognall J and the exchange between the Chief Medical Officer and ministers

11.57. In a letter written following an interlocutory hearing on 26 June 1990, Mr Justice Ognall made observations to encourage settlement, giving some

[1718] Mr Fenwick KC's witness statement dated 25 May 2022 (WITN7067001), §31.1.
[1719] WITN4486030.

views on the legal and wider issues involved.[1720] He recognised the *"legal difficulties"* for the plaintiffs, while describing the proceedings as *"unique in their surrounding circumstances"* and urged the parties to *"give anxious consideration to the prospects of any compromise of these proceedings."*

11.58. In light of Ognall J's comments, on 20 July 1990 the Chief Medical Officer Sir Donald Acheson wrote to Kenneth Clarke and Virginia Bottomley to express his hope that the Secretary of State would *"take account of my view that the problem of HIV infection in haemophiliacs can in fact be regarded as a unique catastrophe."*[1721] He hoped that *"for humanitarian reasons the Government will find some way to make an ex gratia settlement to the infected haemophiliacs in relation to this unique tragedy."*

11.59. One suggestion that was aired during the course of the Inquiry was that the CMO had advised Kenneth Clark to reach a settlement with the plaintiffs in order to avoid the government being required to hand over sensitive documents.[1722] The Chair is invited to consider the minute of 20 July 1990 as evidence that the CMO's interest in reaching a settlement was motivated by a genuine and humanitarian concern for the infected and affected rather than a desire to avoid disclosure of documents. There was a further expression of the CMO's views in December 1990. A departmental minute dated 7 December 1990 stated:

> *"CMO has now put on record his view, with which we all agree, that there has been no negligence by the central defendants and those advising them."*[1723]

11.60. This further demonstrates that the CMO's concern was not to avoid 'damaging' disclosure.

[1720] DHSC0046964_024.
[1721] DHSC0004708.
[1722] WITN0123001, §§179-180.
[1723] DHSC0004365_006. See further the underlying minute from Ms Jane Verity behalf on the CMO a **DHSC0046939_009**, discussed further in Section 13 (The timing of a Public Inquiry).

11.61. In a ministerial submission dated 24 July 1990, the views of the Department's leading counsel Andrew Collins QC were provided to ministers following Ognall J's intervention.[1724] Counsel's view remained that "*we have a very good chance of a successful outcome for the great majority of cases*". He added that the Department should nonetheless "*...consider seriously the judge's proposal...*" on the basis of his view that "*...government would do well to make a further 'political' gesture'...*" but made clear that the "*...final judgment is a political not a legal one.*"

11.62. On 27 July 1990 Virginia Bottomley indicated her view that "*...we should maintain our present position. Once we move towards conceding on cases like these it will have inevitable long-term implications for the Department.*"[1725]

11.63. On 31 July 1990, Kenneth Clarke provided his view "*in favour of sticking to our legal defence and continuing to fight the action.*"[1726]

11.64. On 18 October 1990, Kenneth Clarke met with the Prime Minister and the Lord Chancellor (Lord Mackay). The note of this meeting records the Prime Minister's view that:

> *"The best court was to get the fundamental legal issue on the Government's liability settled as soon as possible. She believed the courts would uphold the principle that the Government could not be considered negligent for having offered treatment which was considered safe in the light of the best scientific advice at the time even if, subsequently, such treatment was shown to have had harmful effects. She hoped, therefore, that an expedited hearing could be obtained. This would be better than settling out-of-court as this would not determine the matter should a similar incident occur in the future; nor would it prevent those who had not issued writs from pursuing their case."* [1727]

[1724] DHSC0004360_147.
[1725] DHSC0046964_008.
[1726] DHSC0046964_007.
[1727] CABO0000044_002.

11.65. As referenced above, in October 1990 the Department's team of counsel provided written advice on liability expressing their view that the Department had good prospects of success.[1728] Although the advice considered that the Central Defendants would likely succeed on the duty of care point, counsel were also clear in their view that the merits of the case were with the Central Defendants generally and did not depend on what might be considered more 'technical' legal points.[1729]

11.66. On 1 November 1990, Kenneth Clarke met with the Department's team of counsel. The note of the meeting stated as follows:

> *"The line was confirmed that there should be no offer from the Department. However, our Counsel would make known to the Plaintiffs that if they were to offer a settlement around £20 to £25 million plus costs this might be considered. Any settlement have to be acceptable to all plaintiffs and end the litigation. No money has been agreed with Treasury for an out of court settlement, and this could be difficult to obtain as the prospects for successfully defending the action are reasonable."*[1730]

11.67. Kenneth Clarke left the role of Secretary of State for Health on 2 November 1990.

Overall approach to the HIV Litigation, to 2 November 1990

11.68. When considering the overall approach taken to the HIV Litigation up to 2 November 1990, the Chair is invited to consider the following:

(1) The HIV Litigation was defended throughout this period on the basis that counsel's advice throughout was that the Department had good prospects of successfully defending the claims. The Prime Minister supported this course of action.

[1728] DHSC0007039_001.
[1729] See, for example, the discussion related to the risk of hepatitis infection and self-sufficiency at DHSC0007039_001, §§23-25.
[1730] DHSC0046962_187.

(2) This reflected the view that government should (a) generally follow the advice given by counsel and (b) pursue reasonable legal arguments that were open to it, as reflected in the positions adopted on the duty of care and limitation points.

(3) At the same time, the Department was not closed off to the potential for settlement or dogmatic about pursuing litigation at all costs, as evidenced by the note of 1 November 1990 (see paragraph 11.66 above); rather, the strategy was to see what offer might be put forward by the plaintiffs.

(4) No formal offer of settlement was received from the plaintiffs during Kenneth Clarke's tenure. Various sums were mooted at various stages, such as a suggestion of around £100,000 per family made by the Haemophilia Society in November 1989,[1731] but no formal approach was made until 9 November 1990 – in response to the strategy agreed on 1 November.

(5) Whilst the HIV Litigation was being conducted, the Department worked to agree with the Treasury lump-sum payments of £20,000 per infected were made available (payments made specifically as a response to the argument that lump-sums rather than means-assessed payments were required by the infected).[1732] The Macfarlane (Special Payments) Trust received funding of £19m (later rising to £24m) as a consequence. This reflected the Department's view, which was shared by the Prime Minister[1733] that the government should support the infected and affected financially, but not in a manner which would appear to concede a legal liability.

Events from 2 November 1990 onwards

11.69. The period from 2 November 1990 saw not only the appointment of a new Prime Minister and Secretary of State for Health, but also the first definite

[1731] DHSC0004415_155.
[1732] For detail on the Department's interactions with the Treasury on this point, see Lord Clarke's second witness statement dated 12 July 2021 (WITN0758012), §§36.1-37.7.
[1733] See HMTR0000001_012, DHSC0002536_031 and **CABO0100002_008**

offer outlining a possible settlement from the plaintiffs' side. Thus, on 9 November 1990, a note was sent to William Waldegrave's Private Office containing details of a proposed scheme of compromise put forward by the plaintiffs' counsel team. This note indicated that the total value of the settlement would likely be around £50m.[1734]

11.70. On 23 November 1990 William Waldegrave was provided by Department officials with briefing materials in advance of a planned meeting with the Chief Secretary to the Treasury to discuss the settlement proposal.[1735] The note assessed the proposed settlement favourably. Referring to this document in his written evidence to the Inquiry, Lord Waldegrave indicated that this briefing document "*would have been an expression of my own views*".[1736]

11.71. It is apparent that now, at the point at which there was a concrete proposal for settlement, William Waldegrave's view differed from that of his predecessor Kenneth Clarke. As Lord Waldegrave commented in his written evidence to the Inquiry (referring to the 23 November 1990 briefing materials):

> *"I thought it right to change the policy in order to bring an end to an extremely stressful and unpleasant process for the victims while delivering a reasonable settlement quickly. The moral case for the proposal – the sense that it was 'the right thing to do' – was not spelt out in those terms in this briefing. But it was the underlying rationale for wanting to change the policy."*[1737]

11.72. The rationale underpinning Mr Clarke's approach to the HIV Litigation has been addressed above. The Chair is invited to consider that whilst there appears to have been a difference of approach between Kenneth Clarke and William Waldegrave over what was a difficult and multi-facetted issue, not only did both Secretaries of State hold reasonable positions, but by the time

[1734] DHSC0046962_067 and DHSC0003654_117.
[1735] DHSC0003654_115.
[1736] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.31.
[1737] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.31.

when Mr Waldegrave took office, the position had shifted with the advancement of an offer from the plaintiffs. Lord Waldegrave himself noted in his written evidence that, "*the previous policy to pursue to trial the defence of the litigation had merit and strong arguments behind it*".[1738] Furthermore, the impetus to reach an agreement was also influenced by a change in Prime Minister from Mrs Thatcher to Mr Major, who on 10 December 1990 indicated his agreement to the proposed terms.[1739] By contrast, the judgment reached by Mrs Thatcher had been that the government should contest the HIV Litigation while at the same time increasing the level of ex-gratia support available.[1740] Once the funds available to the Macfarlane Trust had been increased in late 1989, Mrs Thatcher took the view that further money should be made available only once the HIV Litigation had been resolved.[1741]

Parliamentary announcement and court approval

11.73. Once the approval of the Prime Minister had been secured, Mr Waldegrave then decided that in order to avoid leaks to the press it would be advisable for the Prime Minister to announce its support for the proposed settlement the following day, shortly after the decision had been conveyed to the Plaintiff's Steering Committee.[1742]

11.74. On 11 December 1990, the Prime Minister made an announcement in Parliament that the government supported the proposed settlement although made clear that the proposals had yet to be formally approved by the individual plaintiffs.[1743] On the same day William Waldegrave provided an answer to a Written Question in Parliament in which he stated that although the government considered its legal case to be strong, it "*recognised the*

[1738] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.58.
[1739] HMTR0000002_020.
[1740] See HMTR0000001_012, DHSC0002536_031 and CABO0100002_008
[1741] CABO0000044_002.
[1742] DHSC0003383_003.
[1743] DHSC0003654_003.

very special and tragic circumstances of the haemophiliacs infected by HIV and of their families."[1744] William Waldegrave also emphasised that:

> *"Because the proposed settlement will require the formal approval of all individual plaintiffs, and in the case of minors, of the court, it would be inappropriate at this time to publish further details until all plaintiffs and the court have had an opportunity to consider the full terms of the settlement and to approve them."*

11.75. During Lord Waldegrave's oral evidence to the Inquiry, he was asked by CTI why he decided that the government's in-principle agreement to the proposals should be announced whether or not the steering committee of lawyers representing the plaintiffs had signalled its agreement to the proposals put forward by its counsel team.[1745] It was suggested to Lord Waldegrave that in doing so the government had effectively precluded the plaintiffs from seeking a higher settlement. It has also been suggested that the government's objective was to achieve the maximum public relations benefit from the eventual settlement.[1746] Lord Waldegrave gave evidence that this was not the intention behind the approach pursued and explained that he was concerned that waiting until every plaintiff had agreed before making an announcement "*...would be bound to result in a public auction*". His view was that there was a "*...real risk that the whole deal was going to come to pieces at that point*" and, as a result, it was necessary to make the announcement quickly.[1747]

11.76. The Inquiry is invited to consider that in making its announcement on 11 December 1990 the government was not seeking to put undue or unfair pressure on the plaintiffs to accept the terms of the proposed settlement. The announcement made it quite plain that any agreement had still to be approved by the individual plaintiffs and Lord Waldegrave was clear in his evidence that this was not his aim. The Chair is also invited to consider in this regard that the plaintiffs would have received advice from their own

[1744] WITN7005005.
[1745] See HMTR0000002_021.
[1746] See Mark Mildred's second witness statement dated 9 November 2022 (WITN5258003), §7.7.
[1747] Lord Waldegrave's oral evidence on 5 July 2022, at 93:8-98:1.

lawyers regarding whether to accept the settlement or not, a point made by the Steering Committee in response to the Secretary of State's announcement.[1748]

11.77. As set out above, it is now known (although it was not at the time) that the plaintiffs' counsel team provided advice on 12 December 1990 which put the plaintiffs' prospects of success at about twenty per cent.[1749] The advice addressed the settlement proposals as follows:

> *"Compared with the chances of success in the litigation, this offer is a very good one, and we have no hesitation in recommending that the plaintiffs accept it."*

11.78. Following negotiation between government lawyers and the plaintiffs' lawyers, on 3 May 1991 William Waldegrave announced in Parliament that a formal offer conveying the detailed terms of settlement had been made to the plaintiffs' representatives.[1750] He stated that payments could begin being made as soon as acceptances had been received from individual plaintiffs and the settlement had been approved by Ognall J.[1751]

11.79. Hearings took place on 9 May and 10 June 1991 before Ognall J at which he approved the settlement figures.[1752]

The features of the settlement

11.80. The settlement figure has been criticised for being too low, and failing to reflect the real losses of those haemophiliacs and their dependants. Consistently with a negotiated settlement, the full potential value of the claims was being discounted against the prospects of losing the litigation. Further, it seems probable that the sums considered by all lawyers

[1748] DHSC0003654_029.
[1749] WITN4486030.
[1750] See HSOC0023174 for the full terms of settlement.
[1751] DHSC0032157_112.
[1752] See WITN4486026; WITN4486027 (hearing of 9 May 1991) and BNOR0000357; WITN4486028 (hearing of 10 June 1991).

concerned reflected the sums awarded by way of personal injury damages at the time; awards have increased over the years. However, it would be fair to highlight particular features of the settlement agreement:

(1) The payments made under to the settlement agreement/by the new Macfarlane Trust which administered those payments were disregarded for the purposes of social security benefits. This was in contrast to the recoupment scheme in operation at the time for damages by way of negligence.

(2) The payments were made available to both those who had been part of the HIV Litigation and those who had not been, avoiding a potential inequality.

(3) The figures for settlement were initially proposed by the plaintiffs' counsel team; and it was thought at the time that this would be a guarantee of perceived fairness (see the observations of Justin Fenwick QC when discussing a potential vCJD Trust in 11 October 2000: *"With haemophiliacs infected with HIV the approach had been to invite them to name a sensible figure, so that there was no criticism that the Government were being mean."*[1753])

(4) The settlement figure was in addition to £34m in ex-gratia payments already provided through the Macfarlane Trusts. As was noted by Department officials at the time, the combined total of the settlement figures added to the money made available through the Macfarlane Trust (c. £76m) amounted to the full value of the claims.[1754] This is a view which is endorsed by Mark Mildred, a solicitor for the plaintiffs in the HIV Litigation.[1755]

(5) At the time, the figures for settlement compared favourably with schemes abroad, with the Macfarlane Trust sums factored in. Although by modern standards the figures appear comparatively modest, as acknowledged by a solicitor for the plaintiffs, Mark Mildred,

[1753] DHSC0006245_007.
[1754] DHSC0046962_067
[1755] See Mark Mildred's second witness statement dated 9 November 2022 (WITN5258003), §12.1.

the figures were provided by experts in personal injury claims and were presumably in accordance with contemporary practice.[1756]

11.81. The Department also continued to provide support through the first Macfarlane Trust scheme, which provided support on the basis of financial need.[1757]

The waiver / undertaking in respect of Hepatitis viruses

11.82. CTI raised with a number of witnesses:

(1) The condition of settlement whereby those to whom payments were to be made (unless they had outstanding clinical negligence claims) had to undertake not to bring fresh proceedings against the defendants or any other government department in respect of HIV or viral Hepatitis infection arising from the use of blood products or cryoprecipitate administered before 13 December 1990[1758];

(2) The fact that those accessing funds from the Macfarlane (Special Payments) (No.2) Trust were required to sign a waiver to similar effect.[1759] This would relate to non-litigants in the HIV Litigation seeking to obtain sums to which they were entitled under the settlement agreement.

11.83. Detail about the exchanges which resulted in the waiver can be located in the written statement of John Canavan[1760] and the written statement of

[1756] See Mark Mildred's second witness statement dated 9 November 2022 (WITN5258003), §7.3. The Chair will be very aware of the growth in award figures since the HIV Litigation. Particularly important in this regard are: (a) 10% uplifts applied to general damages as a result of both *Heil v Rankin* [2001] Q.B. 272 and *Simmons v Castle* [2013] 1 All ER 334; and (b) inflation. By way of example of the latter, on the Retail Prices Index measure of inflation a sum of £42m in June 1991 would have a relative value of £106.49m in "today's money" (as of June 2022 - see page 217 of the most recent edition of *Facts and Figures 2022/23: Tables for the Calculation of Damages* for a table of the relevant Retail Prices Index figures).
[1757] The fund was provided with a further £5 million in funding on 16 March 1993. See MACF0000072_046.
[1758] HSOC0023174.
[1759] MACF0000086_225.
[1760] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §§4.306-4.325.

Justin Fenwick KC.[1761] The observations below address what the Department perceives to be the central issues. It should be noted that the Department refers in these submissions only to the draft terms and amendments made in respect of litigants in the HIV Litigation. This is on the basis that materially the same amendments were made in respect of non-litigants accessing funds through the Macfarlane Trust under the terms of the settlement agreement and therefore to include both would produce unnecessary repetition.

11.84. A draft of the Terms of Agreement attached to a minute dated 11 December 1990 contained clauses requiring the plaintiffs to undertake not to bring fresh proceedings.[1762] The wording used was very general.

11.85. Various drafts of the terms of settlement produced between 11 December 1990 and 26 April 1991 were referenced in John Canavan's written statement.[1763] The changes between different iterations were gone through in detail during Justin Fenwick KC's oral evidence.[1764] By the time of a draft dated 22 March 1991 the general reference to not bringing fresh proceedings had been revised to:

> *"The Plaintiffs will discontinue their actions against all Defendants and will undertake not to bring fresh proceedings against any Defendant or against any other Government Department, Health Authority or treating doctor in respect of the administering of cryoprecipitate, Factor VIII or Factor IX…"*[1765]

11.86. On 16 April 1991, Mark Mildred of Pannone Napier (part of the steering group of the plaintiffs' solicitors) sent an amended draft of the Terms of Settlement to departmental solicitors which under the heading *"Plaintiffs' suggested amendments by riders"* included a new proviso to the waiver which stated:

[1761] Mr Fenwick KC's witness statement dated 25 May 2022 (WITN7067001), §§45.1-51.2.
[1762] DHSC0003654_032.
[1763] Mr Canavan's witness statement dated 6 September 2022 (WITN7115001), §§4.306-4.325.
[1764] Mr Fenwick KC's oral evidence on 9 June 2022, at 146:17-178:4 and 193:9-205:8.
[1765] DHSC0003660_019.

> *"(2) Nothing herein shall prevent a Plaintiff from bringing proceedings in respect of the administering prior to 13th December 1990 of Cryoprecipitate, Factor VIII or Factor IX where:*
>
> *...*
>
> *(ii) the damage alleged does not include infection of the risk of infection by HIV and/or the hepatitis viruses."*[1766]

11.87. This wording was retained in materially the same manner in subsequent drafts and then in the final settlement terms sent to the plaintiffs on 26 April 1991 which included:

> *"5. The Plaintiffs will discontinue their actions against all Defendants and will undertake not to bring fresh proceedings against any Defendant or against any other Government Department, Health Authority or treating doctor in respect of the administering prior to 13th December 1990 of cryoprecipitate, Factor VIII or Factor IX, save that:-*
>
> *...*
>
> *(2) nothing herein shall prevent a Plaintiff from bringing proceedings in respect of the administering prior to 13th December 1990 of cryoprecipitate, Factor VIII or Factor IX where the damage alleged does not include infection or the risk of infection by HIV and/or the hepatitis viruses."*[1767]

11.88. The terms of the settlement in respect of non-litigants entitled to payments under the new Macfarlane Trust were couched in materially the same way. This is reflected in the wording of the undertaking to be given by individuals under the deed of the Macfarlane (Special Payments) (No.2) Trust set up to make these payments, which precluded claims *"involving any allegations concerning the spread of the human immune-deficiency virus or hepatitis viruses through Factor VIII or Factor IX whether cryoprecipitate or concentrate) administered before 13th December 1990."*[1768]

11.89. The various iterations set out above indicate that some form of waiver was included in the initial versions of the terms of settlement; however the specific reference to Hepatitis was suggested later on by the plaintiffs'

[1766] DHSC0003661_022.
[1767] See SCGV0000233_040_0015, SCGV0000233_038_0017 and DHSC0045721_004_0014.
[1768] MACF0000086_225.

solicitors firm leading the negotiations. This accords with the oral evidence of Justin Fenwick KC.[1769]

11.90. By the time that the terms of settlement were drawn up (i) it was well-established that the majority of haemophiliacs treated with Factor VIII concentrate were likely to be infected with non-A, non-B Hepatitis; and (ii) awareness of the seriousness of HCV infection was more extensive than it had been at the time of the earlier events and decision making which were the subject of the litigation.

11.91. The plaintiffs' lawyers were apparently aware of both this high level of risk of infection and of its potential consequences, stating in their amended Main Statement of Claim that:

> *"At all material times, haemophiliacs were at great and particular risk of infection with hepatitis B and/or NANB viruses and/or other viral infections from blood products used by them, which, in the case of Hepatitis B and/or NANB could cause the serious illness of jaundice, liver disease, and could sometimes lead to death, and in the case viral infections could cause serious illness and could lead to death. Haemophiliacs are at particular risk because of their exposure to blood products."* [1770]

11.92. Similarly, in the advice from the plaintiffs' counsel on the settlement of the HIV Litigation dated 12 December 1990 there were multiple references to Hepatitis including that statement *"...in relation to the case on self sufficiency, we allege that the Department negligently exposed to the Plaintiffs to an increased risk of infection with hepatitis viruses in the 1970's and early 1980's."*[1771] Furthermore, in summing up the plaintiffs' case before Ognall J on 10 June 1991, counsel for the plaintiffs stated that *"...our case*

[1769] Mr Fenwick KC's oral evidence on 9 June 2022, at 165:9-169:23.
[1770] ARMO0000716.
[1771] WITN4486030. See also the section entitled "Conclusion on Liability and Quantum", where counsel for the plaintiffs referred to the negligent infection of a haemophiliac with hepatitis as *"our principal case"*.

focussed heavily on the hepatitis risk, because many of the Plaintiffs were infected with HIV before the AIDS risk was reasonably foreseeable."[1772]

11.93. In light of the above, when addressing the issue of the waiver and undertaking in the Chair is invited to consider the following:

(1) The draft terms of settlement were negotiated and agreed by teams of lawyers on both sides. There is no evidence of which the DHSC legal team is aware that the plaintiffs' lawyers took issue at the time with the inclusion of the waiver / undertaking. [1773]

(2) The plaintiffs' legal team were aware, as was common knowledge by that point in time, of the likelihood that haemophiliacs treated with blood products such as Factor VIII would be infected with non-A, non-B Hepatitis.

(3) The risk of infection with Hepatitis had formed part of the plaintiffs' claim.

(4) The provision of the terms of settlement which specifically referenced Hepatitis was contained in a draft originally circulated by one of the plaintiffs' solicitors; the evidence suggests that it was regarded as uncontroversial or unremarkable at the time.

(5) The attitude towards this issue was influenced by the understanding, at the time, that an infection with the HIV virus would lead to death within a short space of time. However difficult and sensitive this issue is, given the developments in treatments and thus life expectancy for those suffering with HIV, it seems that at the time, it was not considered that Hepatitis would lead to further or independent suffering.[1774] As stated by Justin Fenwick KC in his written statement, *"...as then perceived, injury by hepatitis did not have any of the characteristics of*

[1772] NHBT0091946.
[1773] Consider also the view of Mark Mildred, a solicitor for the plaintiffs, who stated "*I do not recall there being much controversy over the waiver*". See Mark Mildred's second witness statement dated 9 November 2022 (WITN5258003), §8.4-8.5.
[1774] See for example Mark Mildred's second witness statement dated 9 November 2022 (WITN5258003), §9.2.

exceptional and appalling suffering as justified the special treatment for infection by HIV and the development of Aids".[1775] The waivers were never, of course, addressed to those who had been infected with Hepatitis viruses but not HIV.[1776]

11.94. It would reasonably be expected by the Central Defendants that the terms of the settlement would be explained by the plaintiffs' lawyers to their own clients. It would not have been appropriate (even if possible) for the Central Defendants to communicate directly with the individual plaintiffs, who were legally represented.

Liaison with Scotland

11.95. A further issue raised with Lord Waldegrave by CTI concerned the extent of liaison with the Minister of State for Scotland and Northern Ireland and lawyers for plaintiffs based in those parts of the UK. In his written evidence to the Inquiry, Lord Waldegrave commented that:

> *"While I do not recall this issue having prominence, I expect that we could have handled this better, and I include myself in that. Certainly, from the records to which the Inquiry has directed my attention, there would appear to have been little formal involvement of the Scottish and Northern Ireland Offices early in the process. I can only assume that this arose because the English cases were more advanced, and perhaps because of the fast-moving nature of the liaison between the Department, the Treasury and No 10 to secure the settlement. I cannot imagine that any conscious decision would have been taken not to involve the Scottish and Northern Ireland Offices. But from the records I have been shown, perhaps we should have involved them earlier, having regard to their own litigation and the plaintiffs involved there; but I think it very likely there were informal discussions between Secretaries of State."*[1777]

11.96. Whilst this is evidence from Lord Waldegrave that involvement should perhaps have been earlier, the Chair may wish to consider whether this had

[1775] Mr Fenwick KC's witness statement dated 25 May 2022 (WITN7067001), §50.1. See also Mr Fenwick KC's oral evidence on 9 June 2022, at 165:9-171:18.
[1776] When this issue arose in relation to the Skipton Fund in 2003, a decision was taken not to require undertakings.
[1777] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.101.

any significant ramifications. As recorded in a letter from Mr Waldegrave to the Secretary of State for Scotland dated 30 January 1991, the Department note that it was willing to permit Scottish litigants additional time in which to be advised by their lawyers on a response to the offer. It was emphasised that there were important reasons why the settlement arrangements should be the same throughout the United Kingdom.[1778]

[1778] DHSC0003660_010.

Section 12: Retention of records and destruction of Department of Health documents

12.1. According to section 3 of the Public Records Act 1958 ("PRA 1958"), "*...every person responsible for public records...*" i.e. civil servants, have a duty to preserve public records for their safekeeping,[1779] and, where records are not required for permanent preservation, to follow arrangements for their destruction.[1780] During the relevant period, public bodies were obliged to consider records for permanent preservation before the records reach 30 years of age.[1781] This period was reduced to 20 years following the enactment of the Constitutional Reform and Governance Act 2010.[1782] Records that are selected for permanent preservation should be deposited at a "*...place of deposit...*"[1783] The National Archives appoint "*Places of Deposit*" and maintains a list of those places.[1784] Public records which are rejected for permanent preservation were required to be destroyed.[1785]

12.2. Throughout the period under investigation, there was guidance in place for records management at the Department of Health to ensure that these statutory duties were met. By 1994, the key guidance in the Department of Health was provided in the publication "*[F]or the record [-] A guide for Records Managers and Reviewing Officers*" ("For the Record").[1786] This document set out the responsibilities and procedures for both file offices (alternatively named "*registry*") (where records were kept which are actively being used[1787]) and the Department Records Office (which provided storage

[1779] Public Records Act 1958, s. 3(1).
[1780] PRA 1958, s. 3(4).
[1781] PRA 1958, s. 3(4).
[1782] Available at https://www.legislation.gov.uk/ukpga/2010/25/contents. The Act specified that records should be transferred at 50 years, but this was reduced to 30 years by the Public Records Act 1967 (which is available at https://www.legislation.gov.uk/ukpga/1967/44/contents).
[1783] PRA 1958, s. 4(1).
[1784] https://www.nationalarchives.gov.uk/archives-sector/legislation/approved-places-of-deposit/
[1785] PRA 1958, s. 3(6).
[1786] For the Record (WITN0001002).
[1787] Mr Sheehy's witness statement dated 10 October 2018 (WITN0001001), §6.

facilities for records that were no longer actively needed by the business units for the remainder of their lifecycle).[1788]

12.3. Section 10 of For the Record contained instructions for reviewing files, including guidance for a Branch Reviewing Officer ("BRO") who had to be of grade Executive Officer or above.[1789] The BRO was required to have a thorough knowledge of the administrative needs of the branch.[1790] A BRO decided whether the file should be destroyed at the first review by the DRO. This decision could only be made where the file had no further administrative value at all or only a short to medium term continuing administrative need.[1791] If the file had *no* further administrative value then it may have been destroyed two years from the date of the last document, but if it had *limited* administrative value it may have only been spared destruction until any date between 2-15 years from the date of the last document.[1792] Retaining a file for a Second Review meant that it would be kept until the first paper was 25 years old.[1793] These files were likely to be needed for long term administrative reasons or have potential historical or research value. If the latter, this was because the files held details of

> " ...
>
> a. *the DH's history, its organisation and procedures;*
> b. *the formulation of policy and legislation or, more selectively, its implementation and interpretation;*
> c. *notable events or persons not available elsewhere;*
> d. *major events, developments or trends in political, social, or economic history;*
> e. *scientific, technological and medical developments;*
> f. *regional or local conditions where information is either not available locally, or it is convenient to hold it centrally; or*

[1788] Brendan Sheehy's witness statement dated 10 October 2018 (WITN0001001), §5.
[1789] For the Record (WITN0001002_0033).
[1790] For the Record (WITN0001002_0033).
[1791] For the Record (WITN0001002_0033-0034).
[1792] For the Record (WITN0001002_0034).
[1793] For the Record (WITN0001002_0034).

g. statistical or qualitative research useful for demographic, medical, social or economic history …".[1794]

12.4. While the Inquiry has focussed on the For the Record document, earlier guidance had also been in place. "*GUIDANCE FOR FILE SECTIONS*" was the preceding guidance, having been issued in 1989.[1795] The 1989 guidance itself provides some insight into the yet earlier system that was in place, stating, "*Prior to 1979 DHSS [the Department for Health and Social Security] had only one registry, serving all Central Office and HQ Branches. Following a decision to "de-centralize", individual branch registries were created...*"[1796]

12.5. The Inquiry has seen various reminders and updates on record keeping that were issued by the Department. These included:

(1) A document entitled "*MANAGING REGISTERED FILES*"[1797] from 1990 which was a comprehensive account of how to close files; the review procedure; post-review procedure and action at the DRO.

(2) A minute from the Permanent Secretary to *"All DH Staff"* regarding the "*DEPARTMENTAL DOCUMENT MANAGEMENT INITIATIVE*" dated, 16 May 1994, noted that, "*…considerable changes in Departmental organisation and staffing over the past few years which have led to weaknesses in Departmental record keeping*". [1798] Staff were reminded of the reasons why traceable records were needed. The minute noted that an initiative had been approved and would be rolled out to improve record keeping, ensure electronic media was integrated with paper records and to provide training to staff organising registered files as part of their day-to-day work. This minute was noting weaknesses in record keeping at that time as well as setting out the corrective measures being taken. In the context of the destruction of records relating to the ACVSB (see further below) the Inquiry may wish

[1794] For the Record (WITN0001002) pages 34-35.
[1795] WITN0001003.
[1796] WITN0001003_003.
[1797] WITN0001004.
[1798] WITN6955036.

to consider that it was at this stage, the mid 1990s, that these weakness were being identified.

(3) A Health Service Circular HSC 1999/053 (Managing records in NHS and Health Authorities) dated 19 March 1999.[1799] This was directed at improving the management of NHS records in Health Authorities and NHS Trusts.[1800]

(4) A leaflet on "*Record Keeping in the Department of Health*" dated November 1998.[1801] This was a two page 'animated' document which provided advice on finding a file; types of registered files; opening a new file; what should be filed; why records should be kept; who is responsible for filing; and using electronic systems.

(5) A paper entitled the "*Management of Electronic Documents Strategy: Information Management Standards*" ("MEDS") dated August 1999.[1802]. This was a "*noticeboard*" paper concerning the MEDS which was said to be a *"…project [which] builds on the awareness and good practice established in the For the Record initiative in 1994/5 and places existing procedures in an electronic environment*".[1803]

(6) A MEDS dated February 2000[1804] which contained more information regarding the MEDS.

12.6. Civil servants working at the Department who were asked about document management practice in their evidence were generally well familiar with the underlying principles detailed within such guidance,[1805] even if, due to the passing of several decades, they could not recall the individual guidance documents themselves.[1806]

[1799] WITN6955045.
[1800] WITN6955045, page 3.
[1801] WITN6955037.
[1802] WITN6955042.
[1803] WITN6955042, page 1.
[1804] WITN6955041.
[1805] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389_0036), §36.
[1806] E.g. see Mr Rutherford's witness statement dated 6 September 2022 (WITN7224001), §3.9 (Mr Rutherford was the Secretariat of the ACVSB from January 1991 – 1993) Mr Burrage's witness statement, dated 1 September 2022, (WITN7149001), §§6.1-7.2 (Mr Burrage took over from Mr

12.7. In terms of Private Office files, where significant papers were sent to ministers, each Private Office would keep a working folder on the issue for reference.[1807] In addition, the originating Branch would keep a copy of the document and then put it on the registered file with the returned minute from the Private Office recording the ministerial reaction.[1808] This practice, which was supported by and consistent with the Department's guidance, was further explained by Sir Christopher France and Sir Graham Hart[1809] in their witness statement to the BSE Inquiry:

> "*As stated in Liaison Unit's memorandum (DH01, tab 17), the practice in the Department of Health was for the Minister's private secretary to consider any annotations made by the Minister and to send a minute to the originating branch summarising the Minister's decision and/or comments. The private secretary would record in a minute any decision or any comments of substance made by the Minister on his or her papers. The private secretary's minute would thereafter have been placed on registered files and formed part of the public record".*[1810]

12.8. Essentially, any annotated Ministerial papers "*of substance*" were recorded in the private secretary's minute and recorded on registered files.[1811] If a minister's annotations on a document were not captured in a minute sent out by the minister's Private Office, they would not have been preserved for public record under the Departmental guidance. Since Ministers' annotations of substance would have been converted by a private secretary's minute, it was considered not necessary to retain the ministers'

Rutherford in September 1993); Ms de Sampayo's witness statement dated 5 September 2022 (WITN7914001), §§11-12 (Ms de Sampayo was Dr Metters' Senior Personal Secretary).
[1807] Witness statement of Sir Christopher France and Sir Graham Hart dated 11 October 1999 (for the BSE Inquiry) [WITN7112004], §5.
[1808] Witness statement of Sir Christopher France and Sir Graham Hart dated 11 October 1999 (for the BSE Inquiry) [WITN7112004], §5.
[1809] Both, of course, former Permanent Secretaries.
[1810] Witness statement of Sir Christopher France and Sir Graham Hart dated 11 October 1999 (for the BSE Inquiry) [WITN7112004], §9.
[1811] Witness statement of Sir Christopher France and Sir Graham Hart dated 11 October 1999 (for the BSE Inquiry) [WITN7112004], §10.

annotated copy for the long-term record, since they would have constituted duplicate documents.[1812]

12.9. This system (with its emphasis on retaining minister's views and decisions by reference to the minutes returned by their Private Office) explains contemporaneous references to the fact that papers kept by the Private Office were never kept after a change of government and were either shredded or handed back to the relevant policy section.[1813] Temporary files held in Department of Health Private Office would have been kept for short term administrative convenience to find back papers etc.; they were not the registered formal files. If not earlier, such files would have been destroyed or returned to policy branches on a change of administration because of the convention that new ministers should not be able to access the advice given to or responses of the previous administration.

12.10. Decisions upon destruction or retention of the registered files should have been taken at a First Review stage after 5 years.[1814] Mr Sheehy explained in his witness statement that at this stage, further decisions on retention would have been taken, including marking files as suitable for a Second Review, approximately 25 years after their creation, at which point transfer to the National Archives would be considered. He went on to say, *"...given the intervention of the HIV litigation in (I understand) 1988 — 1991 or thereabouts, it seems likely that this process would have been interrupted by any recall of files that took place as part of that process*".[1815]

12.11. If followed correctly, the DH process for retention of the private secretaries' minutes conveying ministerial comments of substance and decisions, met the requirements of the PRA 1958. However, it did mean that in subsequent

[1812] Witness statement of Sir Christopher France and Sir Graham Hart dated 11 October 1999 (for the BSE Inquiry) [WITN7112004], §9.
[1813]See for example the email dated 10 June 2003 from Charles Lister (WITN5426331).
[1814] Guide for Departmental Records Officers, 1971 (WITN0001013_0006, §12(2).
[1815] Brendan Sheehy's second witness statement dated 2 February 2022 (WITN0001015), §§44d.

inquiries, the minister's own copy with handwritten annotations, underlining etc. may not have been preserved because what will often have been preserved was only the private secretary's minute back to the policy branch rather than the minister's annotated version. This was apparent from the BSE Inquiry where some ministers commented on their inability to see versions of submission as they had annotated them.

12.12. Former health ministers giving evidence to this Inquiry made the same point about the relative lack of access to their own annotated versions of papers once held in their Private Office. *This is an illustration of the difficulties of the passage of time, as addressed in the introduction section of these submissions.* Lord Clarke[1816] stated that some papers that he had underlined which were held in the Private Office had not been retained in the archives, and without them, the only way of spotting which papers he had been personally been shown was to identify occasion when comments of decisions were sent out of this Private Office recording his reaction or where there is a meeting minute.[1817] Similarly, Lord Waldegrave, Mr Clarke's successor,[1818] caveated his evidence to the Inquiry by stating that in most cases, the versions of the submissions annotated to him with his contemporaneous views did not seem to be the ones routinely filed for retention (although on some submissions he could see his endorsed comments of decisions).[1819]

12.13. The Department's approach was and remained one that was permitted under the guidance. Mr Sheehy explained that guidance around records management in ministerial Private Offices developed substantially in the late 1990s/early 2000s.[1820] He referred to the "*Guidance on the Management of*

[1816] Minister of State for Health between 5 March 1982 and 2 September 1985, subsequently Secretary of State for Health.
[1817] Lord Clarke's first witness statement dated 12 July 2021(WITN0758012), §3.3.
[1818] Secretary of State for Health 2 November 1990 – 9 April 1992 (WITN5288001).
[1819] Lord Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §0.6.
[1820] Brendan Sheehy's second witness statement dated 2 February 2022 (WITN0001015), §41.

Private Office Papers" published in 2001[1821] which recommended the adoption of one of two models of records management:

> "*a. Model 1 - Reliance on policy areas to retain full and accurate records. All original papers and other action papers, as annotated by the Minister (or a Private Secretary Note) were to be sent back to the policy area to be placed on the appropriate registered file. Copies might be kept by the Private Office for ease of reference, but as they were copies they would not be kept indefinitely and might be destroyed, at the latest, upon a change of Administration or as otherwise agreed with the DRO. Only if subjects were dealt with solely by a Minister would it be necessary for a Private Office to keep their own registered subject files.*
>
> *b. Model 2 - This involved Private Office records keeping papers to support Ministers, and policy areas also being required to retain records. Private Office would keep the top copies of papers and file them in their own series of registered subject files. A copy of the annotated submission or the Private Secretary note should be sent to the policy desk, recording the response to the submission. The registered files from the Private Office were to be passed to the keeping of the DRO at an agreed point, at the latest at a change of Administration".*[1822]

12.14. The Department of Health had adopted "*Model 1*" in the terms set out above, as Mr Sheehy confirmed (see below). In terms of ministers' differing experiences over the years, the Inquiry may think it relevant that ministers who served in different departments and who had cause to review their own past papers from another Department, may have had experience of "*Model 2*", which would have maximised the number of 'minister's own copies' of submissions retained for the public record and available for review if they asked to see their own previous papers.

12.15. Updates to the guidance in 2004 and 2009 (the current guidance) kept to these two models. Mr Sheehy stated that his understanding was that the Department's existing established practices during the time of concern to this Inquiry (i.e., when Lord Owen was in office, and also in the period 1987-1988) reflected Model 1, although Private Offices could retain files for

[1821] WITN0001016.
[1822] Mr Sheehy's second witness statement dated 2 February 2022 (WITN0001015), §41.

administrative convenience, either as registered files or alternatively as loose folders.[1823] As seen from the above, these would not have been subject to formal retention or destruction policies and were periodically "*weeded*".[1824]

12.16. The Department's internal audit review[1825], conducted in April 2000, into the destruction of documents relating to the Advisory Committee on the Virological Safety of Blood between July 1994 and March 1998 is discussed further below.[1826] In terms of practice and guidance, this report made various recommendations for staff dealing in record keeping. These included:

(1) **Training** - The DRO supplements current training for new staff on the importance of record-keeping including the review process; the DRO and Staff Development Unit incorporate effective messages in proper record keeping into the induction programme; and that a case study is developed for induction and ongoing training.[1827]

(2) **File retention periods** – the DRO updates "*For the Record*" to include indicative timescales for certain types of file records.[1828]

(3) **Authorisation** – "*For the Record*" is updated so that branch reviews are conducted at IP3 standard level or above.[1829]

(4) **Staff competencies** – the DRO initiates the process to raise the profile of the record keeping competence (which is currently seen as a competence mainly relevant to lower grades of staff) with the Department's Competency Framework.[1830]

(5) **Management of Electronic Documents Strategy (MEDS)** - the MEDS team incorporates improvements they identify as a result of this investigation into the MEDS rollout programme.

[1823] Mr Sheehy's second witness statement dated 2 February 2022 (WITN0001015), §43.
[1824] Mr Sheehy's second witness statement dated 2 February 2022 (WITN0001015), §43.
[1825] Internal audit review, Hepatitis C Litigation, Final report dated 1 April 2000 (WITN3996018).
[1826] At §12.2 above.
[1827] WITN3996018, §§5.1-5.6.
[1828] WITN3996018, §§5.7-5.8.
[1829] WITN3996018, §§5.9-5.10 – this would have meant reviews being conducted at SEO rather than EO level as had been the practice.
[1830] WITN3996018, §5.11.

12.17. The recommendations appear to have been accepted apart from the recommendation to change the grade of staff member who was permitted to make retention decisions.[1831] It was instead envisaged that staff at IP3s (and above) would be reminded of the delegated responsibility to satisfy themselves that the systems were adequate and were properly implemented, in others those managing IP2/EO level staff were to ensure that such staff were competent to undertake the retention decisions and managers were responsible for ensuring that the system was working adequately.[1832] At present, the Department has applied a moratorium on routine destruction of registered paper records, given the existence of various Inquiries. The Departmental Records Officer will endorse destruction decisions only where material has no relevance to ongoing Inquiries.

The destruction of documents

12.18. Against the background of the principles and practice of how Department documents should have been retained, the Department recognises that incidents of inappropriate destruction of some documents, and failure to retain others have caused genuine and justified concern. In the context of the issues under examination by this Inquiry, this has exacerbated distrust of the Department and itself become the basis for allegations of wrongdoing.

12.19. The submissions below address the main episodes concerning the retention and destruction of records raised by the Inquiry, in broadly chronological order.

Lord Owen's papers

12.20. We note for the record that Lord Owen was not a witness who was represented by the DHSC legal team, although he was offered and received

[1831] Mr George's witness statement dated 24 August 2022 (WITN6963001), §§3.94-3.98 and §3.53.
[1832] See Email chain re: destruction of DOH files dated 7 April 2000 (WITN6963006) and Minute from Alice Perkins to Helen Causeley dated 11 May 2000 (WITN6955008).

assistance in the further provision of access to materials by the Department and the DHSC legal team ahead of his own evidence to the Inquiry.

12.21. The Department has apologised to Lord Owen for the lack of assistance and support given to him by the Department when he first sought access to his papers concerning the Department's original commitment to self-sufficiency. Maria Caulfield MP, Parliamentary Under Secretary of State for Primary Care and Patient Safety wrote:

> *"I wish to apologise that the Department did not offer more help and support when you requested your papers in 1987/1988 as this issue should have been discovered and resolved at that stage. I understand that those papers that have been found and are available, have already been provided to you in September 2020. I apologise if you feel your position was compromised by the lack of supporting information when you gave evidence, or indeed at any other time."*[1833]

12.22. Lord Owen, as Parliamentary Under-Secretary for Health and then Minister of State for Health from 1974 – 1976, at a time when self-sufficiency was being considered, was (and still remains) a significant figure involved in issues regarding infected blood. Like any minister, he was entitled to access to the material papers from his time in office including the documents relevant to policy development.[1834] Such material papers ought to have been retained. There were several overlapping difficulties, and in some cases, it is accepted, shortcomings on behalf of the Department, which in combination meant that Lord Owen was not provided with sufficient access to his records from his time.

12.23. Lord Owen first started to make requests for his ministerial papers between late 1987 and 1989.[1835] At the time of these requests, it seemed that Lord Owen's office was told by an unknown official that his papers had been

[1833] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.39. Apology made on 27 April 2022.
[1834] See above at §§10.7-10.17 re policy.
[1835] Lord Owen's witness statement dated 5 February 2020 (WITN0663001), §58.

destroyed under a "*10 year rule*".[1836] In fact, there was no such rule for routine destruction of files after ten years.[1837] A possible explanation for this mis-characterisation is that the official had in mind the periodic review points at which papers might be assessed for retention or destruction. Zubeda Seedat (who obviously was not the official in question) recalled that there may have been a "*ten year*" option available for selection when choosing when a file should next be reviewed.[1838]

12.24. Ministerial papers chosen for retention from Lord Owen's time should have been available at this time (and the surviving documents were later provided to Lord Owen). But they should have been provided at this much earlier stage, as acknowledged in the apology offered to Lord Owen. However, due to the Department's preference for the system where policy teams filed the ministerial submissions and responses (as explained above) there would not have been a designated Private Office file containing ministerial submissions put to Lord Owen and his responses. Rather, the records would have been on the various relevant registered files on the relevant policy topics.[1839] Private Office papers were not routinely retained; registered files were expected to hold copies of ministerial submissions and any response from the minister's Private Office. There was no repository of "*Ministerial papers*".[1840]

12.25. In around 1990, official papers were searched for the purpose of disclosure in the HIV litigation.[1841] At this stage, the retained, identified documents for which Public Interest Immunity ("PII") was claimed were produced, following

[1836] LDOW0000318 – A handwritten note from one of Lord Owen's secretaries at the time (probably written in January 1988; see Lord Owen's witness statement WITN0663001, §58).
[1837] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.40(b); Mr Sheehy's second witness statement dated 2 February 2022 (WITN0001015), §§60-66); Lord Crisp's witness statement dated 3 September 2020 (WITN3996001), §29; Ms Seedat's first witness statement dated 23 August 2022 (WITN4912001), §§181-183; Mr Gutowski's first witness statement dated 10 May 2022 (WITN5292001), §§79-81.
[1838] Ms Seedat's first witness statement dated 23 August 2022 (WITN4912001), §183.
[1839] As explained about at §12.7.
[1840] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.40(a).
[1841] Details on material not retained will be addressed in later sections of this topic.

the Court of Appeal hearing upon the PII claim in September 1990.[1842] There is no suggestion that any of the documents listed on the PII Lists had been lost at this stage or that disclosure of the documents listed was not made, as required, in the course of the litigation prior to its settlement.[1843] It is recognised that, where relevant to Lord Owen's time in Office, such documents could therefore have been made available to Lord Owen at that stage.

12.26. It was later discovered in 1996 that some of the HIV litigation files, which were likely to hold some of Lord Owen's Ministerial papers, could not be located.[1844]

12.27. Considerably later, on 7 October 2003, Lord Owen wrote to the-then Secretary of State for Health, John Reid, to ask that he be told of the outcome of the Departmental study of its records on this topic (that is, the study that became the Self-Sufficiency Report). Lord Owen stated that he was encouraged by the Department's review of its papers on self-sufficiency, and he expressed his surprise that he had been told that "*...the papers had been pulped without reference to [him]!*"[1845]

12.28. An internal departmental minute dated 15 December 2003[1846] stated as follows:

> *"Unfortunately, none of the key submissions to Ministers about self sufficiency from the 70s/early 80s appear to have survived. A search of relevant surviving files from the time failed to find any. One explanation for this is that papers marked for public interest immunity during the*

[1842] WITN4486030 at §5c.
[1843] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052, §1.40(d).
[1844] See WITN5426083 minute to Dr Rejman and Mr Pudlo from Ms McEwen dated 2 May 1996, as referred to in Ms James' witness statement dated 18 May 2022 (WITN5426001), §§ 2.86 & 5.16.
[1845] LDOW0000142.
[1846] DHSC0003606_077 which Lord Owen saw due it being mistakenly attached to a letter sent by Ms Johnson, Parliamentary Under Secretary of State, on 17 March 2004 in reply to his letter to John Reid. This understanding as to what had happened drew from the earlier email dated 10 June 2003 from Mr Lister (WITN5426331) and Mr Lister had gained this understanding from Mrs James.

> *discovery process on the HIV litigation have since been destroyed in a clear out by SOL. This would have happened at some time in the mid 90s."*

12.29. When a more comprehensive search was carried out in 2006 – 2008, a number of documents on the HIV Litigation PII lists were confirmed to be missing and have never been found.[1847] However, some of the documents relating to Lord Owen were amongst the catalogued documents.[1848]

12.30. The Inquiry has asked witnesses who were involved later in the blood policy teams whether, when further documents were found (for example, the return of papers from plaintiffs' firms and the finding of HIV litigation papers at Wellington House), the Department contacted Lord Owen to indicate that more documents had been found and to research within them for documents relevant to Lord Owen that he might wish to inspect relevant to his requests from some years earlier.

12.31. Lord Owen was contacted. Ten documents were provided to Lord Owen by letter dated 8 October 2008.[1849] Lord Archer was also contacted[1850] and the documents were to be added to those being made available to the public on the Department's website as part of the wider release of self-sufficiency related documents. The letter to Lord Owen stated:

> *"You are aware that the Department has previously been unable to locate many of your papers on this subject during your period in office as Minister of State. I am therefore pleased to be able to tell you that we have located a small number of documents dating from 1974-75 that appear to have been sent by your Private Office to the policy division. These include in some cases your personal comments on this initiative*

[1847] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.40(e).
[1848] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.40(f).
[1849] See DHSC6694278 letter from William Connon, DOH to Hugh Taylor, re: Self-sufficiency in blood products 1970-85 which attached letters sent to Lord Owen and Lord Archer enclosing documents found at Wellington House, dated 2 October 2008; and Letter from Liz Woodeson to Lord Owen dated 8 October, LDOW0000226.
[1850] DHSC6700949; Letter from William Connon (Head of Blood Policy), Department of Health, to Lord Archer dated 8 October 2008.

> *and I am enclosing copies of these documents for your information. I can only apologise, on behalf of the Department, that these documents have not been located previously."*[1851]

The Department (through the DHSC legal team), along with the Inquiry, provided Lord Owen with all of the documents that could be found based on e-searches ahead of his appearance before this Inquiry.

12.32. Lord Owen has told the Inquiry that no explanation has been given to him as to why the ministerial papers from his Private Office were destroyed without any reference to him, or why he was not asked if he wanted to keep the papers for his own records before they were destroyed, as happened when he was Foreign Secretary.[1852]

12.33. Considering Lord Owen's account of his request for documents, it is accepted that he was not given the assistance that he should have been entitled to expect, as a former Minister, to trace relevant Ministerial papers held on the registered files.[1853] Further, it has been accepted by Mr Vineall and Ms Jackson that: "*As far as we are aware, there has never been a satisfactory explanation for why some of the HIV Disclosure files were permanently lost after the litigation ended*".[1854] Against this background, it is entirely understandable that Lord Owen felt let down by the failure to retain his records and give him access to them. The Department has apologised.

12.34. The Department is not aware of any evidence that has yet emerged that would suggest that Lord Owen's records were destroyed or withheld from him deliberately or with malign intent.

[1851] LDOW0000226.
[1852] Lord Owen's witness statement dated 5 February 2020 (WITN0663001), §58.
[1853] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.40(b).
[1854] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.40(g).

12.35. The Department recognises that the poor handling of Lord Owen's access to records has exacerbated concerns and suspicions, including his own, of deliberate and malign destruction of documents.

Lord Jenkin's papers

12.36. The late Lord Jenkin, former Secretary of State for Health (1979-1981) gave evidence to the Archer Inquiry that Sir Nigel Crisp (now Lord Crisp) had told him on 13 April 2005 that papers relating to infected blood and blood products had been intentionally destroyed.[1855]

12.37. Lord Jenkin initially contacted the Department, via Lord Warner (the Minister in the Lords), on 14 December 2004.[1856] Having been contacted by a member of the public (known to the Inquiry and Core Participants but name redacted), Lord Jenkin stated that he had no recollection of what the correspondent had referred to as a "*secret Westminster-funded report*". Lord Jenkin stated, "*...it may be that the files could disclose something along those lines",* and Lord Jenkin made clear that he was happy to attend a meeting if that would assist. Lord Warner replied on 27 January 2005.[1857]

12.38. The provision by Lord Warner of a report of the Haemophilia Centre Directors' Hepatitis Working Party for 1980/81 in his reply of 27 January 2005 appears to have satisfied the immediate request for the specific document, as there was no further mention of the "*secret report*" to which Lord Jenkin had referred.[1858] However the reply of 27 January 2005[1859] had also included the comment that, "*As you rightly say, however, it is very difficult to go back some 25 years to recollect details, especially as many of the people involved are, sadly, no longer with us*" and that officials could find "*...no trace of information relating to the 'secret Westminster-funded*

[1855] ARCH0002968.
[1856] Letter from Lord Jenkin to Lord Warner dated 30 December 2004 (WITN3996004).
[1857] WITN3996005.
[1858] Lord Crisp's first witness statement dated 3 September 2020 (WITN3996001), §41.
[1859] WITN3996005.

report…" (albeit that the report attached was believed to be what the correspondent was referring to). Lord Jenkin contacted the Private Office of Sir Nigel Crisp, the Permanent Secretary, and in the course of that call expressed concern about the Department's filing and record management systems. As a result, Zubeda Seedat was requested to prepare a further response to Lord Warner. When that letter was sent on 10 March 2005,[1860] it inadvertently included the accompanying note which had been prepared to explain the background to Ministers authorising the further reply. That note included the comment that the original reply to Lord Jenkin of 27 January was *"…drafted by the correspondence unit using a number of standard lines… It also left Lord Jenkins [sic] with the impression that we had inadequate file records*".[1861]

12.39. From this combination of events, Lord Jenkin believed that he was being denied access to his Ministerial papers to which he had a right of access under the Ministerial code and he requested a meeting with Sir Nigel.[1862]

12.40. In the conventional way, on 11 April 2005 Sir Nigel was sent a briefing for his meeting for Lord Jenkin, to take place on 13 April:

"LINE TO TAKE

- *Many key papers from the 1970s and 1980s have been destroyed. During the HIV litigation in 1990 many papers from that period were recalled. We understand that papers were not adequately archived and were unfortunately destroyed in the early 1990s.*
- *We have been in touch with Departmental Records Office to check which files related to the treatment of haemophilia patients and blood safety are still in existence from the period between 1979-1981. We have obtained a list of some files from this period. However, at first glance it is not clear about the extent to which these files will hold papers that Lord Jenkin will have*

[1860] WITN3996008.
[1861] WITN3996007.
[1862] Email chain between William Connon, Shaun Gallagher and Zubeda Seedat dated 16 March 2005 (WITN3996009).

> *handled. It would require significant staffing resource to go through these files to identify official papers that Lord Jenkin handled at the time."*[1863]

12.41. The meeting took place on 13 April 2005 attended by Sir Nigel, Lord Jenkin, Shaun Gallagher (Sir Nigel's Private Secretary) and Zubeda Seedat. The outcomes of the meeting of 13 April 2005 were recorded in an email from Shaun Gallagher to Zubeda Seedat that same day, although - because the email focussed on the actions to be taken - it did not record what was said in relation to the destruction of documents.[1864] Mr Gallagher also wrote to Lord Jenkin updating him on the work done to retrieve his Ministerial papers and explaining that he would soon be invited to come to the Department to view them.

12.42. Lord Jenkin was then given access to the retrieved papers from his time in office and copies were provided once the documents were redacted, see letters of 6 and 19 October 2006.[1865] In the second letter sent to Lord Jenkin on 19 October 2005 disclosing some of his papers, William Connon explained:

> *"I understand that you have concerns about the fact that there were limited files available to you. As you know we requested all files relating to your period in office, dealing with haemophilia patients who were infected with contaminated blood products. A number of files from the 1970's and*

[1863] Briefing note for Sir Nigel Crisp from William Connon dated 11 April 2005 (WITN3996010) and Letter from William Connon to Lord Jenkin dated 19 October 2005 (WITN3996014).
[1864] WITN3996011.
[1865] Cover letter from Zubeda Seedat to Lord Jenkin dated 6 October 2006 (DHSC0046961_016); Letter from William Connon to Lord Jenkin dated 19 October 2005 (WITN3996014). From the latter letter it is apparent that William Connon met Lord Jenkin on one of his visits to the Department to view his papers. Lord Jenkin's statement to Lord Archer's inquiry on 20 April 2007 (ARCH0002968) included Lord Jenkin's opinion that there was something in William Connon's manner when speaking to him about his search of files that led Lord Jenkin to suspect he may have known more about the files than he was prepared to disclose. William Connon was not able to give evidence to the Inquiry to respond to that suggestion and Lord Jenkin died in 2016 so no further evidence or testing of it was available from him before this Inquiry. However Zubeda Seedat made clear that the destruction of papers had occurred before she and William Connon were involved; that they had gained their understanding of the circumstances from William Connon's predecessor Mr Lister, and that "I have no knowledge of any reason why William would not have disclosed what we were informed about on this subject." (WITN4912090) §34.2.

> *1980's have in fact been destroyed but we have made available to you all those which are currently held".*[1866]

12.43. While expressing gratitude for the work of Ms Seedat in arranging access to the many files that did survive, Lord Jenkin continued to express his concerns about the fact that limited files had been retained and papers from the litigation had been destroyed: see Lord Jenkin's reply of 25 October 2005.[1867] At this stage, Lord Jenkin expressed himself in terms that Sir Nigel had,

> *"...warned me when I saw him earlier in the year that a number of files dealing with contaminated blood had been destroyed after the settlement of all the HIV claims. While this may in fact represent what happened, I find it difficult to believe that this was an appropriate cull. I intend to make a further appointment to see Sir Nigel with a view to seeking an explanation of why this happened. The Department must have known that there were many more outstanding cases of people who claimed to have been infected by contaminated blood, and indeed, many of the present generation of haemophiliacs fall into this category. However, that is not a matter for you and I will pursue it with Sir Nigel."*

12.44. Lord Jenkin duly wrote to Sir Nigel on the same day, 25 October 2005, raising further concern about the destruction of files.[1868]

12.45. In terms of the content of correspondence sent to Lord Jenkin, it was only at this stage (and in preparing to draft a report to Lord Jenkin's letter of 25 October 2005) that Zubeda Seedat picked up on an earlier reference to the internal audit report and asked for and obtained a copy in relation to it.[1869]

12.46. Ms Seedat provided a submission to Sir Nigel on 29 November 2005 and a draft reply to Lord Jenkin.[1870] As a result of Ms Seedat now being aware of the internal audit report from 2000, her draft letter included reference to the

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[1866] Letter from William Connon to Lord Jenkin dated 19 October 2005 (WITN3996014).
[1867] WITN3996015.
[1868] WITN3996016.
[1869] WITN3996017 and Zubeda Seedat's second witness statement dated 23 August 2002 (WITN4912090), §§30.2 – 30.4.
[1870] DHSC0046961_009.

destruction of documents that was the subject of that review. Accordingly, when Sir Nigel replied to Lord Jenkin on 1 December 2005 adopting the draft letter that had been prepared, the explanation of document destruction actually referred to two separate episodes of document destruction:[1871]

(1) Reference was made to the destruction of papers from the 1970s and 1980 that had been discussed at the 13 April meeting: "*As previously mentioned, it is our understanding that during the HIV litigation in the 1990's many papers from that period were recalled for the purpose of the litigation. We understand that papers were not adequately archived and were subsequently destroyed in error in the early 1990's.*"[1872]

(2) Reference was then made to what officials had "*...also established...*" namely that, "*...a number of files were marked for destruction in the 1990's. Clearly, this should not have happened. When the discovery was made that files had been destroyed, an internal review was undertaken by officials... The decision to mark the files for destruction was not a deliberate attempt to destroy documentation*".[1873]

12.47. In response to a request for evidence from the current Department on this and related issues, Mr Vineall and Ms Jackson commented on the letter of 1 December 2005 as follows:

> *"Looking at that answer now, it seems to us that the distinction between these two groups of files / losses was not clearly identified. As the ACVSB was set up in 1989, its files had never been part of the disclosure exercise for the HIV litigation. Whilst of course it was right to detail the full extent of the known losses to Lord Jenkin, it might have been useful to have been clearer about the nature of the two sets of files being discussed."*[1874]

12.48. Against this background, Lord Jenkin wrote further to Sir Nigel on 14 December 2005, including the statement that,

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[1871] Note from Zubeda Seedat to Sir Nigel Crisp dated 1 December 2005 (WITN3996019).
[1872] WITN3996019, page 3.
[1873] WITN3996019, page 3.
[1874] Mr Vineall and Ms Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.41(e).

> *"The immediate point that occurs to me is that your fourth paragraph entirely contradicts the explanation you gave me to me [sic] orally when we met in your office on Wednesday, 13th April. You then gave me to understand that the destruction of the contaminated blood files was the result "of a decision" to dispose of them as, following the settlement of the HIV cases, there seemed to be no useful purpose in retaining them in the PRO. I am quite certain that I did not misunderstand you; there was no suggestion whatever in what you said that the destruction of the files was the result of an administrative cock-up! Despite what you say that this did not represent "a deliberate attempt to destroy documentation", I am sure that you will recognise that this latest explanation will do nothing to dispel the widely held view among haemophiliacs and others that this was in fact the true explanation."*[1875]

The "*fourth paragraph*" being referred to was in fact the part of Sir Nigel's letter of 1 December 2005 where he had been referring to the different episode of destruction of documents, namely that covered by the internal audit. This does not alter the fact that Lord Jenkin had clearly taken away from the meeting of 13 April 2005 an understanding that document destruction had been a deliberate decision. Nevertheless, the Inquiry may wish to consider whether a degree of confusion may have arisen in this correspondence, derived from the fact that a second episode of document destruction was introduced into the correspondence by the Department.

12.49. On 6 February 2006, Zubeda Seedat[1876] provided further briefing / advice to Sir Nigel with a suggested reply to the letter of 14 December 2005.[1877] Sir Nigel sent the further response in the terms that had been drafted.[1878]

12.50. The Inquiry will no doubt wish to consider in full the account of Lord Jenkin to Lord Archer's Inquiry and that which is apparent from the 2005-2006 correspondence, including that (on any view), Lord Jenkin was quite contemporaneously expressing the view that he understood from the meeting of 13 April 2005 that the destruction had been a deliberate decision.

[1875] WITN3996020.
[1876] Although the briefing / advice was from Zubeda Seedat, it would have been cleared by / discussed with William Connon (Zubeda Seedat's first witness statement dated 23 August 2022 (WITN4912001), §97.
[1877] WITN3996022.
[1878] WITN3996022.

12.51. For his part, Sir Nigel explained in his evidence that he had no independent recollection of the meeting. In his written evidence, Sir Nigel made clear that he did not know why Lord Jenkin believed, as the latter said in his letter of 14 December 2005, that Sir Nigel had said that the destruction was "*...the result "of a decision" to dispose of them...*".[1879] Sir Nigel noted that there were no records to indicate that the destruction was the result of a deliberate decision in the sense of anyone knowingly acting outside Departmental policy.[1880] Sir Nigel considered that he would have followed the "*lines to take*" in the briefing, which was his usual practice, especially as he did not have any personal knowledge of this issue beyond the briefing he had received. He noted also the lack of any internal minutes to suggest that he had not followed the 'lines' during the meeting.[1881] He would have expected Shaun Gallagher or Zubeda Seedat to have alerted the relevant civil servants so that this was taken into account in future correspondence, had he not followed the "*lines to take*" document, but there was no subsequent evidence of that.[1882] In his oral evidence[1883], Sir Nigel expanded on these themes. He thought that the final letter of 6 February 2006 had not responded on the substance of Lord Jenkin's point about the discrepancy because it was trying to close down the correspondence on the issue and he could see reasons not to go back to Lord Jenkin disagreeing and continuing the correspondence. He added,

> "*The way I see it is that, obviously, he heard something from me that he interpreted in a certain way and, as I said, if you look at his evidence to Lord Archer's Inquiry, you will see that he doesn't quite say it as strongly as he does within this, and he talks about surmising what was meant by something. So I think, while it is puzzling, there is clearly some discrepancy in all of this, and some misunderstanding. But, as I say, I can see absolutely no reason why I could or would have said that,*

[1879] Lord Crisp's first witness statement dated 3 September 2020 (WITN3996001), §69(3).
[1880] Lord Crisp's first witness statement dated 3 September 2020 (WITN3996001), §69(4) – he added that at least some of the destruction appeared to have been deliberate in the sense of being the result of poor and unjustified decisions and/or bad archiving practice.
[1881] Lord Crisp's first witness statement dated 3 September 2020 (WITN3996001), §55.
[1882] Lord Crisp's first witness statement dated 3 September 2020 (WITN3996001), §55.
[1883] See in particular, Sir Nigel's oral evidence on 12 September 2022 at pages 89-113 including the passages directly quoted; and further at pages 124-127.

> *and it would have been out of character for me not to have followed the line to take, particularly in an area where I didn't know the subject area.*"

And later,

> *"But, as I say, there's a very simple point here on one level, which is that, if I had said something like that, it would have been straightforwardly wrong. I didn't have any other information from any other source. This was not a topic I knew anything about and, as it turned out, the files that we described as having been destroyed weren't destroyed. So I agree it's puzzling"*

12.52. Sir Nigel was very sorry that his meeting with Lord Jenkin in April 2005 had confused matters, when he had in fact sought to clarify matters. He also reflected that he was now very sorry that he had not met Lord Jenkin for a second time to sort the matter out at the time.[1884]

12.53. Zubeda Seedat remembered the meeting of 13 April 2005 but principally because it was the first time that she had been the sole policy team representative at a meeting with people as senior as the Permanent Secretary and a former Secretary of State.[1885] Her oral evidence was that if Sir Nigel had said something wrong or that went against the line, both she and Shaun Gallagher would have said something to Sir Nigel after the meeting.[1886]

12.54. On 16 February 2007, Lord Hunt offered Lord Jenkin the opportunity to attend the Department to review the further documents which had been returned by Solicitors and were being considered in the Department's further report, and the alternative option of attending when the report was completed. Lord Jenkin indicated that he would await the completion of the report.[1887]

[1884] Lord Crisp's first witness statement dated 3 September 2020 (WITN3996001), §73 and oral evidence on 12 September 2022.
[1885] Zubeda Seedat's first witness statement dated 23 August 2022 (WITN4912001), §65.
[1886] Zubeda Seedat's oral evidence on 14 September 2022, at 105:12.
[1887] Collection of documents regarding correspondence with Lord Jenkin, letter of 16 February 2007 (WITN7420004).

HIV litigation documents

12.55. As regards the HIV litigation documents, the retention of records issues principally concern:

(1) the initial loss of litigation files from the HIV haemophilia litigation;

(2) documents located at Wellington House (102 registered files);

(3) the return of papers from the plaintiff's solicitors; and

(4) the later discovery of litigation papers in unregistered files.

12.56. In addition, the issue of the retention of copies of the undertakings given in respect of future litigation, in the context of access to payments from the Macfarlane Trust, has also been raised and is addressed below.

(1) The loss of litigation files from the HIV haemophilia litigation

12.57. In 1995/1996, documents from the HIV litigation, including the documents over which the Department had claimed PII over, were sought as a part of the response to claims / potential claims in respect of Hepatitis C.[1888] In the initial stages, in 1995, the documents were being sought because Ministers wanted advice on the Department's vulnerability to claims relating to HCV infection, despite the fact that the Department had not at that stage been made a party to such litigation (some writs had been issued, but not yet against the Department).

12.58. However, a minute from Ms McEwen (who was taking over the area from Ms James) of 2 May 1996, shows that officials had discovered that some documents were missing.[1889] Ms McEwen stated that some of the documents were being held by the Department's solicitors in filing cabinets in the basement of their offices at New Court, but they were copy files and so

[1888] Witness statement of Anita James's witness statement dated 18 May 2022 (WITN5426001), §§2.1-2.84.
[1889] Email from Ruth McEwen to Dr Rejman dated 2 May 1996 (WITN5426083).

she asked administrators for the originals. However, there were documents missing: "*...we have only been able to find half of the HIV discovery [disclosure] documents. We have files 21-43 and 45 onwards.*"[1890]

12.59. Dr Rejman[1891] replied the following day stating that he thought the remainder were likely to be in a locked cabinet close by and that they were trying to find the keys or would break into it.[1892]

12.60. It is unclear from the evidence if the locked cabinet did contain further documentation. It is acknowledged that there is no evidence that, at this point, anyone had comprehensively studied which documents were missing and which had been retrieved.[1893] Nor is it apparent whether an inventory was made to ascertain how many of the HIV discovery files were retrieved; what they contained and how they were then stored. However, Mr Vineall and Ms Jackson have observed, it may be that the losses were comparatively small since Dr Rejman had located files 1-30 and the Department's Solicitors held 21-43 and 45 onwards and therefore the apparent gap was file 44 from storage (although it is unknown what file 44 contained).[1894]

(2) Documents located at Wellington House (102 registered files)

12.61. To the best of the understanding of DHSC, the materials located at Wellington House were transferred to registered file series HIM 22/1 and were files containing a collection of documents which were initially removed

[1890] Email from Ruth McEwen to Dr Rejman dated 2 May 1996 (WITN5426083).
[1891] The Department's senior medical officer who undertook, for example, medical verification of claimants under the Government's payment scheme for patients infected with HIV through blood transfusion.
[1892] Email from Dr Rejman to Ruth McEwen dated 3 May 1996 (WITN5426084).
[1893] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.21.
[1894] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.21.

from the registered files for the purpose of discovery in the HIV litigation, some of which were later thought to be missing.[1895]

12.62. These documents were mainly released into the public domain via the Department's website between June and October 2007 (Files 1 – 101 out of 102 in all). The release was in line with FOIA.

12.63. The 102nd file contained 35 documents which were, at the time, withheld in line with FOIA exemptions, the breakdown being set out in the statement of Mr Vineall and Ms Jackson.[1896]

12.64. With the encouragement of Baroness Primarolo, the Minister of State for Public Health, DH officials further reviewed the use of FOIA exemptions in relation to these 35 documents. All but eight of the documents (that is to say 27 of the remaining 35) were cleared for release and made public by 20 April 2009.[1897] The reasons for the eight documents still being withheld were that they contained personal information or legal information.[1898] However, these eight documents are in the disclosure to this Inquiry and have been identified and disclosed (in some cases with redactions decided upon by this Inquiry).[1899]

[1895] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.22- §1.32.
[1896] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §§1.28 – 1.29.
[1897] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022, (WITN7193052), §1.30.
[1898] Addendum to written statement of Ms Vineall and Ms Jackson dated 26 October 2022 (WITN7193070); Baroness Primarolo's written statement dated 9 June 2022 (WITN5494001), §3.14.
[1899] Addendum to written statement of Ms Vineall and Ms Jackson dated 26 October 2022 (WITN7193070); Baroness Primarolo's written statement dated 9 June 2022 (WITN5494001), §3.114. The 8 documents are: WITN5494038; WITN5494039; WITN5494040; WITN5494042; WITN5494044; WITN5494046; WITN5494048; WITN5494050.

(3) The return of papers from plaintiffs' solicitors

12.65. Documents disclosed by the Department in the HIV litigation and the Hepatitis C litigation were retained by several firms of solicitors and some were returned to the Department in 2006.[1900]

12.66. On 7 February 2006, The Treasury Solicitor was contacted by Blackett Hart and Pratt Solicitors ("BHP"), who had acted as co-ordinating Solicitors for the claimants in the *A & Others v National Blood Authority* litigation.[1901] The solicitors enclosed a copy of an order dated 11 December 1991 made by Mr Justice Ognall in the HIV Haemophiliac litigation, enabling documents disclosed in the HIV litigation to be used by claimants' lawyers in the Hepatitis litigation, subject to an undertaking that the documents or information gained from them would not be used for any purpose other than establishing liability in the litigation. BHP stated that they took the view that it was now time to return these documents to the Department. They noted that they had been in correspondence with Mrs Carol Grayson, who had noted that the Department had stated that all relevant documents and information had been put into the public domain, save where documents had been mistakenly destroyed.[1902]

12.67. The Department replied to ask that the papers be returned as suggested.[1903] The files consisted of seven lever arch files from J Keith Park and Co and Ross and Co Solicitors, and five lever arch files from BHP, which amounted to 623 documents in total. These were returned in May 2006.

12.68. Upon instructions from the Department, independent counsel conducted a review of the material and produced an 84-page report dated 26 June 2006

[1900] Parliamentary Question dated 24 May 2005 (DHSC0041304_052); Appendix B to the submission to Caroline Flint of 7 July 2006 re: early documents missing from DH archives or known to have been destroyed (DHSC0041159_226 (submission) (DHSC0041159_228) Appendix B); email chain between Zubeda Seedat and others dated 19 May 2006 (DHSC0015834).
[1901] Letter from Paul Saxton to The Treasury Solicitors dated 7 February 2006 (DHSC0015865).
[1902] Letter from Paul Saxton to The Treasury Solicitor dated 7 February 2006 (DHSC0015865).
[1903] DHSC0015857.

which contained an inventory of the documents examined and notes concerning these documents.[1904] While an FOI request for these documents may have exceeded the resource limit, the Department nevertheless proceeded to release them. By November 2006, the Department had released 604 of the 623 documents into the public domain via its website,[1905] and the inventory was placed in the Commons Library (the 20 volumes of "*HIM 22/2 series*").[1906]

12.69. The remaining 19 documents were initially withheld under FOIA.[1907] Following an internal review by the Department's FOIA Unit, a further nine documents were released,[1908] and following a further review an additional nine documents were released.[1909] The only the remaining document was a personal CV.[1910] The documents released by the Department at this time corresponded with the "*MACK*" files held by the Inquiry.[1911]

12.70. The Inquiry asked the Department to specify which of the returned documents were those for which the Department claimed PII in the HIV Litigation; and to specify which of the returned documents were previously thought to have been destroyed.[1912] A full inventory of the documents returned by the plaintiffs' solicitors (the "*Mulcahy Inventory*") has been provided to the Inquiry and is exhibited to the witness statement of William

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[1904] DHSC5428781.
[1905] https://webarchive.nationalarchives.gov.uk/ukgwa/20080103120000/http://www.dh.gov.uk/en/Publicationsandstatistics/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_076693.html
[1906] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.50; see inventory at Annex B to Vineall and Jackson's witness statement; WITN7193059; and Progress Report of 3 January 2007: DHSC0004232_037.
[1907] Due to commercial confidentiality (s11, FOIA); personal data (s40); frank and open discussion to develop policy documents (s35) and s34 (Parliamentary Privilege); see Review of Documentation Related to the Safety of Blood Products dated 3 January 2007 (DHSC0004232_037).
[1908] Email from Linda Page to Z. Seedat dated 6 February 2007, DHSC0103399_065.
[1909] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.50.
[1910] DHSC5528801.
[1911] Listed at §§1.54-1.55 of the Witness statement of William Vineall and Lorraine Jackson dated 20 September 2022, (WITN7193052, page 24-25).
[1912] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.56.

Vineall and Lorraine Jackson,[1913] as has a spreadsheet which lists the documents for which the Department claimed PII in the HIV litigation, and identifies what is now available for scrutiny.[1914] As explained by Mr Vineall and Ms Jackson, whilst it is possible to identify the PII documents now available, it is not possible to say "*…which of the documents… were thought to have been destroyed…*"[1915] since the extent of the missing files were not identified in 1996 when it was discovered that some of the files could not be located.[1916] The focus of the 2006 - 2008 disclosure exercise seems have been on ensuring that key blood-related documents were made available to Lord Archer and were placed in the public domain.[1917] It was not focussed on investigating whether material that had been available in the late 1980s/1990 was now missing, or on reconciling what was now available with the document lists from the HIV Litigation, or upon scrutiny of the Department's conduct of that litigation more generally.[1918]

(4) The finding of HIV litigation papers in unregistered files

12.71. 47 lever arch files containing unregistered files were discovered in July 2006.[1919] These were in fact the same files that were reorganised into the 102 volumes of the HIM 22/1 series outlined in sub-section (2) above.

12.72. A further 41 folders of unregistered files were discovered in Wellington House in July 2008.[1920] A full inventory has been provided to the Inquiry.[1921] The files were discovered whilst Patrick Hennessy and Laura Kennedy (who

[1913] DHSC0015729.
[1914] WITN7193054.
[1915] Witness statement of William Vineall and Lorraine Jackson dated 20 September 2022, (WITN7193052), §1.17.
[1916] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.58.
[1917] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.59.
[1918] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.59.
[1919] See "Progress report, Review of Documentation Related to the Safety of Blood Products: 1970 – 1985" dated 14 July 2006" (DHSC0004232_066).
[1920] See email exchange between William Connon and Patrick Hennessey dated 18 July 2022 (DHSC5533007) and Email exchange between Linda Page and William Connon on 29 September 2006 (DHSC5435079).
[1921] WITN7193056.

later provided an inventory) were reorganising the filing cabinets in room 517 of Wellington House.[1922] Five documents relating to Lord Owen, some of which paraphrased Lord Owen's views or had his notes on them, were regarded as significant and had not previously been published.[1923] As discussed above, in October 2008 they were released to Lord Owen and Lord Archer. On 20 May 2009, 468 documents from these files were released on the Department's website.[1924] An explanation of what these documents were and why they had not been previously identified was summarised in a note placed on the DH Website:

> *"Many of the documents from the relevant period were found to be copies of those already released. 469 previously unreleased documents were identified, none of which was judged to add materially to the knowledge of events in the years before 1985. One document from this batch was withheld as it contained personal information about a patient. The remaining 468 were released as soon as practicable … The documents in question were found in around 40 folders apparently compiled in the late 1980s and 1990, with papers from those years. In total there were around 2000 documents in these folders, of which around 1000 were from 1970-85. We released 468 of these documents, as the remainder of the approximately1000 [sic] from 1970-85 were either copies of papers that had already been released, or were not relevant to the issue of safety of NHS blood supplies and blood products. One document was withheld under an exemption in FOI as it contains personal information about a patient."*[1925]

12.73. Since these further files were found, despite the belief that they were the last of such papers held by the Department, it was agreed to conduct a Division wide search of all cabinets.[1926]

12.74. PII was claimed over seven of these documents in the HIV Litigation.[1927] This included meeting notes and internal minutes from 1980 and 1985

[1922] Email chain between Laura Kennedy and Elizabeth Woodeson on 16 July 2008 (DHSC5532594_001).
[1923] DHSC5061894_002.
[1924] Suggested Reply and Background note for a Parliamentary Question for answer on 13 July 2009 (DHSC5260906).
[1925] DHSC5260906.
[1926] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.66(7) and DHSC5114710.

concerning for example, the evaluation of AIDS screening tests and AIDS and the treatment of haemophiliacs.[1928] As set out above, it was not clear whether these are documents which were previously thought to have been destroyed because the missing documents in the 1990s were not itemised.[1929]

12.75. Exhibited to the statement of William Vineall and Lorraine Jackson is a spreadsheet dated 24 September 2008 recording the analysis of retained files carried out across 2006 – 2008, and summarising the information put into the public domain.[1930] As set out above, the focus of the 2006-2008 disclosure exercise seems have been on ensuring that key blood-related documents were made available to Lord Archer and were placed in the public domain.[1931] It was not focussed on investigating whether material that had been available in the late 1980s/1990 was now missing, or on reconciling what was now available with the lists from the HIV Litigation, or upon scrutiny of the Department's conduct of that litigation more generally. The Inquiry may wish to take into account, however, the nature of the efforts that were made by the Department across this period to place material in the public domain.

(5) Macfarlane Trust Waivers

12.76. Linked to the HIV litigation, the Inquiry has raised the issue of "*the Macfarlane Trust Waivers*" that have been lost or destroyed. The Department understands that the waivers referred to were the undertakings required of individuals as a condition of receipt of payments made under the

[1927] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §§1.69-1.70.
[1928] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §170.
[1929] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.71.
[1930] WITN7193060.
[1931] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.59.

Macfarlane (Special Payments) (No. 2) Trust Deed dated 3 May 1991, (i.e. under the terms of the settlement of the HIV litigation).[1932]

12.77. There were differences in the way in which payments were made depending on whether the person receiving the payment was a litigant or non-litigant.[1933] It seems that records of undertakings given by litigants is contingent on the process adopted by the plaintiffs and the Department's Solicitors at the time, an explicit account of which has not been traced. Whilst for non-litigants in England and Wales who received payments from the Trust, the Department should have received the original undertakings,[1934] the process followed by litigants is not now so clear. Scrutiny of the Court Orders and Notices of Discontinuance filed in the HIV Litigation instead raises the possibility that the terms on which the actions were discontinued stood in lieu of any signed undertaking from an individual plaintiff, and constituted the plaintiff's acceptance of the terms of the Main Settlement Agreement. The Main Settlement Agreement, in turn, contained the terms of the undertaking or waiver.

12.78. The Department currently holds a small number of files containing a small number of undertakings.[1935] The files were marked "*Restricted-Medical*" and they contain paperwork related to claims for the lump sum payments administered under the Macfarlane (Special Payments) (No. 2) Trust Deed, signed approval forms from the Macfarlane Trust (certifying that the claimant was eligible for the payment requested) and copies of the signed undertakings.[1936] Both substantially post-date the main efforts to meet these

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[1932] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.75.
[1933] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.76.
[1934] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.77.
[1935] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.79.
[1936] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.80.

claims in 1991-1992.[1937] Other files found included four legal files of letters from solicitors acting for the Plaintiffs in the HIV Litigation in mid-1991 sending in acceptances of the terms of settlement in the "*non-negligence* cases" (i.e. those who were not continuing claims against Health Authorities).[1938] There is no reference to waivers/undertakings and they are not contained within these files.[1939] Another file that was found was one entitled "*Haemophiliacs with HIV – Legal*" Vol 1 (HWK 1/2, Vol 1, 19/09/91 – 22/04/92) which held various papers including confirming the fact that by 4 October 1991 the Trust had made 1,366 payments with 63 outstanding.[1940] Again, there is no reference to waivers and the bulk of file deals with legal costs.[1941]

12.79. In relation to waivers, what has not been found to date is either:

(1) Definitive repositories of further files, perhaps "*Restricted – Medical*" files relating to litigants' claims in 1991-1992, in particular, and containing signed undertakings; or

(2) The undertakings that were sent to the Department by the Trust over the same period, when it accepted claims from non-litigants.[1942]

Therefore, it appears that this material has been lost or destroyed. Mr Vineall and Ms Jackson conclude that "*However, without a better sense of how such files might have been stored, it is not possible to make any further comment on what led to this occurring*".[1943]

[1937] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.80.
[1938] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.81(1).
[1939] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.81(1).
[1940] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.81(2).
[1941] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.81(2).
[1942] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.83.
[1943] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.84.

12.80. It seems likely from analysing Parliamentary Questions and their answers from April 2006-July 2009[1944] concerning those waivers, that searches were undertaken for the files containing waivers or undertakings during that period but that only limited documents were found,[1945] and that some had been inadvertently destroyed with the files which they were held in.[1946] Mr Vineall and Ms Jackson conclude that "*No formal investigation into the reason for the destruction or loss of the documents was undertaken at the time, and it is difficult to comment further now*".[1947]

Destruction of registered files containing materials relevant to the ACVSB

Dockets and related information

12.81. As detailed below, it first became clear in June 1995 that a registered file containing relevant documents to the Advisory Committee on the Virological Safety of Blood ("ACVSB") had been destroyed.

12.82. Attached to the front of each file or contained within each volume were "*dockets*" which were created by the policy team with responsibility for the file. This was a proforma grid which was filled in by hand. The first docket contained information such as the file name; the timeframe covered; the subject of the docket; the date when the docket was closed and sent to the DRO repository; and the date for branch review decision, together with the initials of the person making that decision. The second was stamped with "*DESTROYED*" with a date and sometimes, handwritten initials of a person next to the date.

[1944] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052)), §1.86-1.100.
[1945] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.101.
[1946] Caroline Flint's response to a PQ on 14 May 2007 (WITN7193065).
[1947] William Vineall and Lorraine Jackson's witness statement dated 20 September 2022 (WITN7193052), §1.101.

12.83. Ms Jackson in her first witness statement set out a table,[1948] reproduced below, which shows what the dockets contained including the file name; timeframe; date of closure; date of final review and date of destruction.[1949]

File name	Timeframe	Date of Closure	Date of final review	Date of destruction
GEB1/4	16.05.1989 - 19.07.1990	09.02.1993	19.07.1995	29.09.1994
GEB1/5	14.08.1989 - 19.12.1989	09.02.1993	XX.08.1995	15.10.1997
GEB1/6	10.01.1990 - 31.12.1989	09.02.1993	31.12.1994	14.10.1997
GEB1/7	01.01.1990 - 24.04.1990	09.02.1993	24.04.1995	15.10.1997
GEB1/8	24.04.1990 - 26.07.1990	09.02.1993	26.07.1995	15.10.1997
GEB1/9	27.07.1990 - 21.11.1990	09.02.1993	21.11.1995	17.03.1998
GEB1/10	26.11.1990 - 07.01.1991	09.02.1993	07.01.1996	17.03.1998
GEB1/11	08.01.1991 - 21.02.1991	09.02.1993	21.02.1996	15.10.1997
GEB1/12	28.02.1991 - 21.05.1991	09.02.1993	21.05.1996	15.10.1997
GEB1/13	22.05.1991 - 21.06.1991	09.02.1993	21.06.1996	17.03.1998
GEB1/14	21.06.1991 - 18.10.1991	09.02.1993	18.10.1996	15.10.1997
GEB1/15	23.10.1991 - 01.11.1991	09.02.1993	01.11.1996	illegible
GEB1/16	06.11.1991 - 05.02.1992	17.03.1996	05.02.1997	01.02.1997
GEB1/17	13.02.1992 - 06.04.1992	17.03.1993	06.04.1997	01.04.1997

Events in 1995

12.84. ACVSB papers were searched for in 1995 when the Department was considering its potential vulnerability to claims from those infected with HCV in the context of Ministerial consideration of whether there was justification for a payments scheme for those so infected. This was also being done in the knowledge that some writs had been issued, albeit not yet against the Department. The distinction is significant in that the decision, in the summer of 1995, to concentrate the collection of documents on key materials was to facilitate the advice to Ministers. Focussing the search in this way was not a breach of disclosure obligations, such obligations having not yet arisen. The primary focus at this time appears to have been the provision of advice to

[1948] Lorraine Jackson's first witness statement dated 1 September 2022 (WITN7193001), §4.5.
[1949] The first set of dockets can be found at WITN6955039 (Cover pages for the ACVSB files 16.05.1989 – 06.04.1992, volumes 4-17). This shows the closed file and branch review dates and signature. The second set of dockets can be found at WITN6963004 (List of documents and dockets of destroyed files with reference numbers GEB/1) and they show the date of destruction (occasionally with a signature of a person's initials). These were created at the point at which the file was sent to the DRO, and held there.

Ministers on vulnerability to claims to inform the policy decision on whether to have a payments scheme. It first became clear that one volume had been destroyed shortly before 7 June 1995. Dr Rejman (a Senior Medical Officer) had been asked to collate documents to assess the Department's potential liability to negligence claims. Dr Rejman sent a minute to Anita James enclosing a list of documents from 1989-1991 stating as follows:

> *"I have gone through all my files, and have gone through the files made available to me by Mr Burrage, GEB vols 1-14. Unfortunately vol 4 for part of 1989 has apparently been destroyed. Mr Burrage has asked for the individuals responsible to write to him formally confirming this".* [1950]

12.85. The docket records that volume 4 had been destroyed on 29 September 1994.[1951] The docket shows that the status of volume 4 was due to be reviewed on 19 July 1995 and ought to have been retained until review then.[1952]

12.86. In 2000, some five years later, in the context of the A & others v NBA litigation in which the Department had agreed to give third party disclosure, it was then discovered that further volumes in the GEB 1 series had been destroyed. Between 1996 and 1998, a further 12 volumes of the GEB 1 series were destroyed (the details of which are discussed further below).[1953]

12.87. Anita James accepted that in 1995 when GEB 1/4 had been found to have been destroyed, between the teams involved (policy, medical and legal) a clear message ought to have been delivered that such files should obviously be retained or marked for lengthier retention to ensure no more files of that nature were destroyed.[1954] Ms James could not be sure if a written or oral

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[1950] Minute from Dr Rejman to A James dated 7 June 1995 (DHSC0200022_002). See further the First witness statement of Dr Rejman dated 17 April 2021 (WITN4486001) which records his discovery of the missing file and that he alerted Ms James and Mr Burrage of that fact.
[1951] List of deleted documents and dockets of destroyed files dated 17 March 1998 (WITN6963004_0004).
[1952] Cover pages for the ACVSB files vol 4-17 (WITN6955039), page 1.
[1953] Email chain between Charles Lister, Laurence George and others dated 24 February 2000 (WITN6955040).
[1954] Anita James' witness statement dated 18 May 2022 (WITN5426001), §6.14(2) & (4).

message was delivered since there is no written record of one having been made, nor could she recall whether one had been made or not.[1955] However she was clear that what should have been done was to ensure that anyone involved in the management of the files understood their importance.[1956] Ms James accepted in oral evidence that it was down to a senior figure, such as herself as a senior lawyer or Dr Rejman, as a doctor (as opposed to Mr Burrage who was a higher executive officer) to deliver this message.[1957] Mrs James' evidence included a contextual explanation of the working pressures of this time.[1958]

12.88. Dr Rejman agreed that someone ought to have sent a clear message to prevent further destruction of files, and suggested that David Burrage may have done so when he was told to write to the individuals responsible.[1959]

12.89. Mr Burrage could not now recall writing letters to individuals he believed responsible for the destruction of volume 4, or whether replies were received.[1960]

12.90. Since the destruction of GEB 1 Volume 4 was known about in June 1995 (and should not have occurred), as witnesses have accepted, the subsequent destruction of further files was avoidable and should not have happened.

2000 stage – audit

12.91. Anita James[1961] and Charles Lister[1962] (Head of Bloody Policy at the Department at the time) gave evidence of their extensive efforts to find the

[1955] Anita James' witness statement dated 18 May 2022 (WITN5426001) §6.14(3).
[1956] Anita James' oral evidence on 13 September 2022, at 44:8-13.
[1957] Anita James' oral evidence on 13 September 2022, at 44:20-25 and 45:6.
[1958] Anita James' witness statement dated 18 May 2022 (WITN5426001), §6.39-§6.44.
[1959] Dr Rejman's oral evidence on 12 May 2022, at 210:8 – 203:18.
[1960] David Burrage's witness statement dated 1 September 2022 (WITN7149001), §95.
[1961] Anita James' witness statement dated 18 May 2022 (WITN5426001).
[1962] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §§2.3-2.42.

ACVSB documents as part of the third-party disclosure exercise in the HCV litigation in 1999-2000. Once the gaps were identified, significant inquiries were made to try to obtain copies of the missing documents. Mr Lister contacted former ACVSB members to see if they still held copies of documents.[1963] Dr Metters (the retired DCMO who had chaired the ACVSB) was contacted but his personal papers had been passed on to Dr Pat Troop (his successor as DCMO),[1964] which, later, it was revealed, had then been shredded.[1965] Mr Lister went to Professor Zuckerman's office at the Royal Free hospital to search through his old papers.[1966] Some (around two thirds) of the missing documents were found.[1967] Sarah Falconer was also contacted and was able to provide copies of some missing ACVSB meetings.[1968] Mr Lister was also in correspondence with Brenda Pheely of the Scottish National Blood Transfusion Service, who was able to locate missing minutes for a particular meeting.[1969]

12.92. Once it was apparent that the registered files (the GEB series) had been destroyed, the approach taken by the Department was that the destruction of these documents would need to be disclosed in the litigation.[1970] The Department's instructed counsel, Justin Fenwick QC's advice was that a low key internal investigation should be undertaken in order to try and establish why the files were destroyed.[1971] The Permanent Secretary, Sir Chris Kelly, agreed to this approach and an internal audit was commissioned by William

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[1963] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §2.18.
[1964] Email from Jeremy Metters to S. Edwards, re: Hepatitis C litigation dated 25 November 1999 (MHRA0024553).
[1965] Minute from A. James to Charles Listed dated 29 November 1999 (WITN5426139). On the propriety of such a course of action, which did not concern registered files, please see the oral evidence of Dr Pickles in the hearing of 12 May 2022, 194:20 – 196:1.
[1966] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §2.19.
[1967] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §2.19 and Email chain between Charles Lister and Anita James dated 28 February 2000 (DHSC0046972_133).
[1968] Email chain between Charles Lister, Sandra Falconer and Anita James dated 2 March 2000 (DHSC0046972_130).
[1969] Email from Charles Listed to Brenda Pheely dated 2 March 2000 (DHSC0046972_128)
and Email correspondence between Brenda Pheely, Charles Lister dated 6 March 2000 (DHSC0046972_117).
[1970] Instructions to counsel to advise re Hepatitis C Litigation dated Match 2000 (DHSC0046972_131; §7).
[1971] Minute from Charles Lister to Dr Troop dated 3 March 2000 (DHSC0046972_126_0001) and Minute to the Permanent Secretary dated 3 March 2000 (DHSC0046972_125_0003); Justin Fenwick QC's witness statement dated 25 May 2022 (WITN7067001).

Burleigh (Head of the Internal Audit Branch at the Department) assigning Laurence George (an experienced auditor) to conduct the review.[1972]

12.93. Questioning during this Inquiry has critically explored the fact that the internal audit did not identify the person, or persons, who had marked the papers for destruction. And it remains the case that the person, or persons, who authorised the documents' destruction has, or have, not been identified:

(1) The "*destruction dockets*" have an indecipherable signature in the "*Branch review decision*" box for all but one docket.[1973]

(2) The destruction docket for GEB 1 Volume 4 (the first of the GEB 1 volumes to have been destroyed) shows handwritten initials of "*LB*" under the date that the file was destroyed on.[1974]

(3) Unfortunately, none of the witnesses were able to identify the signature, nor did they know who the initials belonged to.[1975]

(4) "*JR*" appears on another set of dockets for the same files as the person who authorised the "*Branch review decision*", but notably, this is not a reference to the person authorising destruction.[1976] John Rutherford gave evidence that he could not recall sending or authorising another person on his behalf to send these documents for destruction.[1977] He stated that "*JR*" was not his handwriting and a full signature would have been required before the DRO would accept a file for review or destruction.[1978] He had been asked by Mr Lister at the time of the audit report about the dockets and he indicated that he had no direct recollection and the dockets did not suggest that he was the person who had marked the files for destruction.[1979]

[1972] Email from Bill Burleigh to Sammy Foster dated 13 March 2000 (WITN4505394).
[1973] DHSC0014975_033.
[1974] DHSC0014975_033.
[1975] David Burrage's witness statement dated 1 September 2022 (WITN7149001), §11.2.
[1976] DHSC0014975_033, pages 11-14.
[1977] Witness statement of John Rutherford dated 6 September 2022 (WITN7224001), §§3.19 and 3.23.
[1978] Witness statement of John Rutherford dated 6 September 2022 (WITN7224001), §§3.19-3.23.
[1979] Laurence George's witness statement dated 24 August 2022 (WITN6963001), §3.53.

(5) It appears that the initials of the person on the destruction dockets was likely to be the person who simply carried out the destruction at the DRO, rather than the person who authorised the destruction.

(6) When dealing with a FOIA request in 2005, Anita James identified David Burrage as the person responsible for the document destruction.[1980] However she has realised since that she was mistaken. She has explained this mistaken belief in her witness statement. She stated that she had previously identified Mr Burrage as the last person to leave his section on voluntary early retirement and as such, she believed that he would have been the person setting the destruction date on the documents before he left. However, she was clear in her evidence that she was mistaken, in particular, having seen that Dr Rejman had recorded in the 7 June 1995 minute that Mr Burrage had asked for the individuals responsible to write to him.[1981]

12.94. For the purposes of this full statutory public inquiry, no-one could doubt the desirability of that person or persons having being identified so as to have the greatest level of confidence in understanding the circumstances in which the GEB 1 volumes were wrong marked for destruction.

12.95. In considering the reasonableness or otherwise of the level of investigation that was carried out in 2000, the Inquiry is invited to include in its consideration the following matters:

(1) The terms of reference included that the Internal Audit team should:

"…

- *establish what happened;*
- *identify the extent to which procedures have not been followed; and,*

[1980] See Email chain between Anita James and Zubeda Seedat dated 22 February 2005 (WITN5426332).
[1981] Anita James' witness statement dated 18 May 2022 (WITN5426001), §§5.10-5.11 and Minute from Dr Rejman to A James dated 7 June 1995 (DHSC0200022_002).

- *make recommendations to prevent such incidents occurring again*".[1982]

(2) At the outset, as the internal audit was being set up, William Burleigh noted that the "*...review needs to be handled sensitively and with a focus on lessons for the future.*"[1983] The scope of the audit review was explicit that it would "*...not apportion any blame in this case. The purpose of the review is [clearly] to identify any weaknesses in control and to recommend how they can be correct. [Clearly the purpose of the review is to prevent such things from happening again.]*"[1984] Dr Pat Troop sought assistance from her colleagues, Dr Mike McGovern, Dr Jeremy Metters, Yvonne de Sampayo and Charles Lister, asking them to make time to speak with Mr George, and reiterating the point about not wishing to apportion blame.[1985] She also said that the review was aiming to be completed by the end of April and the results would be reported to her in May.[1986]

(3) From the viewpoint of those conducting the audit, the identification of the person(s) who had marked the materials for destruction had less significance than it perhaps does now to this Inquiry. As Mr George remarked in his witness statement: "*The fact of the destruction was clear from the dockets, and in the absence of any evidence pointing to who had asked for the documents to be destroyed, we became more interested in the systemic weaknesses and management's desire to learn any lessons for future.*"[1987]

(4) William Burleigh reiterated the forward-looking nature of the audit review in his witness statement. He described the review as:

> *"...by no means an investigation in a disciplinary sense, nor a forensic investigation focusing on the culpability or lack of it of individuals. Our central role as auditors was to identify any*

[1982] Internal audit review, Hepatitis C Litigation, Final report dated 1 April 2000 (WITN3996018), page 4.
[1983] Email from Bill Burleigh to Sammy Foster dated 13 March 2000 (WITN4505394).
[1984] Terms of Reference (WITN6955028) §2.2.
[1985] Letter from Dr Troop to Mr Burleigh dated 22 March 2000 (WITN5426240).
[1986] Terms of Reference (WITN6955028 §4).
[1987] Laurence George's first witness statement dated 24 August 2022 (WITN6963001), §3.72; see also WITN6963001_0038; §3.80 and WITN6963001_0046, §5.2.

weaknesses in controls and to recommend how they could be corrected"[1988].

(5) Mr Burleigh suggested additional factors at play which may explain why the person who authorised the destruction was not identified or interviewed. These factors were listed as: the fact that the information on the records did not indicate who had authorised the destruction; the current policy team had already spoken to Mr Rutherford (whose initials were on some of the dockets) who did not remember; and the short timescales to which the auditors were working.[1989]

(6) The restrictive nature of the timescales and the terms of reference were highlighted by both Mr Burleigh and Mr George. Reflecting on the process, they have told the Inquiry that perhaps more time could have been given for the audit to take place and that it should have gone further. Laurence George highlighted the "*...extremely short time frame in which the Report was delivered to the Permanent Secretary; the terms of reference were first drafted on 20 March 2000 and finalised on 24 March 2000, and the Permanent Secretary received the Report on 4 April 2000."*[1990] As Mr George has pointed out, the Report was delivered in ten working days and ordinarily he would take 15-40 days to complete an audit.[1991] Mr George further reflected on the purpose and conduct of the Report:

> "*I would stand by these recommendations today in the sense that I think they were a sensible attempt to address the weakness in the system. I think this also reflects that our focus in the audit was not on blame and individuals but on the system. We had to do what was proportionate in the time available, and clearly the kind of quick internal audit which I was undertaking was massively different to the level of investigation by this Inquiry*".[1992]

(7) Mr George accepted that in retrospect they ought to have interviewed Dr Metters (they had not done so because they had mistakenly believed that he had left the Department).[1993] Mr Burleigh echoed this,

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[1988] William Burleigh's witness statement dated 7 October 2022 (WITN7305001), §2.5.
[1989] William Burleigh's witness statement dated 7 October 2022 (WITN7305001), §3.11.
[1990] Laurence George's witness statement dated 24 August 2022 (WITN6963001), §3.53.
[1991] Laurence George's witness statement dated 24 August 2022 (WITN6963001), §3.83.
[1992] Laurence George's witness statement dated 24 August 2022 (WITN6963001), §3.82.
[1993] Laurence George's witness statement dated 24 August 2022 (WITN6963001), §5.7.

stating that with hindsight, it might have been better to seek more time and interview more members of staff (such as Dr Rejman, who had not been interviewed as he had retired).[1994]

(8) Reflecting on matters in his conclusion. Mr George has expressed the view that:

> *"Having completed the interviews and document review, I believe it was reasonable to draw the conclusions we did, and whilst providing a likely explanation was not wholly satisfactory, it enabled us to develop a set of sensible recommendations to ensure the measures in place to ensure the proper retention of important files were strengthened in the long run".*[1995]

12.96. The Inquiry may wish to subject the destruction of the GEB1 volumes to critical analysis and judge the above insights from those involved at the time against the concerns that have been expressed about judgements being made without the destructor of the documents having been identified. Another relevant factor may be how likely it would be that an official or officials would have destroyed the papers with malign intent given that the minutes of, and papers for, the ACVSB were circulated to a significant number outside the Department. That permitted a certain degree of reconstitution of the files for disclosure by the Department in the HCV litigation and the papers have been further reconstituted as part of the process of this Inquiry (see further below). Witnesses have accepted that the destruction of volumes of GEB1 was clearly wrong and should not have occurred, especially given that the fact that the destruction of one volume had been noticed in June 1995, before others went on to be destroyed.

[1994] William Burleigh's witness statement dated 7 October 2022 (WITN7305001), §3.14. Dr Rejman's First witness statement dated 17 April 2021 (WITN4486001) explains at §4, §20 that by 2000, he had left the Department of Health, but that the Audit's reference to him leaving as early as 1994 was erroneous.
[1995] Laurence George's witness statement dated 24 August 2022 (WITN6963001), §5.7.

The position reached now regarding the ACVSB records

12.97. The current position is that all of the minutes and (with very limited and minor exceptions[1996]) the papers before all the fifteen ACVSB meetings (held between 4 April 1989 to 9 February 1993) have been re-constituted.[1997] Most of the Chairman's briefings have also been recovered, except for five (those for the eighth to the twelfth meetings).[1998]

12.98. Ms Jackson explained in her witness statement that she has sought to explore any reason why the Chairman's briefs for meetings 2-7 (22 May 1989 - 2 July 1990) have been found while those for meetings 8-12 (21 November 1990 - 21 February 1992) have not.[1999] She accepted that the destruction of GEB 1, volumes 4-17 cannot be the entire explanation for why these briefs are missing since GEB1 volume 4 spanned records from 16 May 1989 to 6 April 1992, and meetings 2-12 were held within that destruction period.[2000] Ms Jackson has drawn from a minute dated 20 January 2000 from Anita James to Deas Mallen Souter (representatives for the claimants in the Hepatitis C litigation), that minutes (and perhaps other documents, such as the Chairman's briefs) were split in to two separate "*Parts*" (or files/boxes) according to the split of meetings 1-7 and 8-15.[2001] The missing briefs were for "*Part II*" meetings. Ms Jackson has therefore observed that a possible explanation could be that Part II (held in a different place to a "*GEB*" file or copies held elsewhere) was lost/destroyed, but not Part I.[2002]

[1996] The following remain missing: work plan annexed to the first ACVSB meeting; a proposed EU Directive amendment annexed for the 2nd meeting; the deadline for implementation and proposals to take the Directive forwards ought to have been annexed for the 3rd meeting; a paper "*Re-instatement of donors found to be reactive in previously used HIV screening tests*" by Professor Tedder for the 8th meeting; and appendix VI of HTLV1 Testing of Blood Donations is a paper on Human Immunodeficiency virus antibodies in Sera of Australian Blood Donors, 1985-90 — The Medical Journal of Australia 2 September 1991 of the 12th meeting. Lorraine Jackson's first witness statement dated 1 September 2022 (WITN7193001) §5.2.
[1997] Lorraine Jackson's first witness statement dated 1 September 2022 (WITN7193001) §§5.1-5.3.
[1998] Lorraine Jackson's second witness statement dated 24 October 2022 (WITN7193071), §§5.1-5.6.
[1999] Lorraine Jackson's second witness statement dated 24 October 2022 (WITN7193071), §§5.10-5.13.
[2000] Lorraine Jackson's second witness statement dated 24 October 2022 (WITN7193071), §5.11.
[2001] WITN5426162; and Anita James' witness statement dated 18 May 2022 (WITN5426001), §4.53.
[2002] Lorraine Jackson's second witness statement dated 24 October 2022 (WITN7193071), §5.12.

12.99. Ms Jackson also commented that the Chairman's briefs would have been circulated on a far more limited distribution than the minutes because they were created by the Secretariat for the Chairman in advance of the meeting and would not (as the Department understands it) have been circulated to the Committee as a whole[2003]. Therefore, she suggested, that it is perhaps explicable that the briefs have been more difficult to locate when the relevant registered file in the GEB1 series was destroyed.

12.100. For the avoidance of doubt, however, it is no part of these submissions to suggest that the fact that the ACVSB minutes, papers and Chairman's briefs have very nearly been reconstituted should lessen the need for the Inquiry to consider the earlier destruction of volumes of the GEB/1 series.

[2003] Lorraine Jackson's second witness statement dated 24 October 2022 (WITN7193071), §5.13; see also John Canavan's oral evidence on 22 September 2022 (INQY1000244), at 30:3-15.

Section 13: The timing of a Public Inquiry

13.1. It is apparent that, if a Public Inquiry is warranted by circumstances, then normally it would be desirable for it to take place reasonably promptly after the events in question. In this case, that would have been more satisfactory for the Infected and Affected, for reasons that need no detailed exploration. Depending on precisely when an inquiry was held, it may have avoided some of the forensic difficulties experienced in this Inquiry: that is, the difficulties of exploring events that took place up to 50 or so years ago. Whether this has led to greater difficulties in retrieving paperwork, or in filling the gaps left by the written record, the impact of delay on the Inquiry's task is undesirable.

13.2. The evidence presented in this section indicates that an inquiry should have been held more promptly. That does not, of itself, make past judgements on this issue ones that were unreasonable at the time when they were made. At all times, decision-makers considering this issue were making a judgement. These submissions seek to explore some of the factors that bore on these judgements at the time, even though very many of those involved – viewing matters retrospectively – have readily accepted that an earlier statutory inquiry would have been desirable.

Historical context

13.3. The Inquiry will be aware of the legislative context. Prior to the passage of the Inquiries Act 2005 (and its commencement in June 2005), there was no adequate framework governing public inquiries. In force was the Tribunals of Inquiry (Evidence) Act 1921, but this was cumbersome, requiring for example an affirmative resolution of both Houses to establish an Inquiry.[2004] It was supplemented by 'subject-specific' legislation, which had limitations when issues covered more than one policy area. There was no scope for

[2004] See https://www.justice.gov.uk/downloads/publications/moj/2010/Post-Legislative-Assessment-Inquiries-Act.pdf

procedural rules under either framework. The Inquiries Act 2005 was intended to remedy these deficiencies. The test for whether or not an inquiry should be established was one for a Secretary of State, who would look to see if there were *"...events which have caused or have potential to cause public concern, or where there is public concern that particular events may have occurred."* That test is notably 'low'. Many issues are the cause of public concern. Very many are the source of considerable public concern. Consequently, there was (and remains) a very significant element of judgement and discretion to be exercised as to when a statutory inquiry is appropriate. Ministers were answerable to Parliament for the exercise of that discretion.

13.4. In looking more broadly at the historical context, the first issue that the Inquiry is invited to consider is the historical growth in Public Inquiries, which has made them an increasingly common feature of the political landscape. During the 1980s and early 1990s, public inquiries under the 1921 Act remained relatively rare events. Since then, they have increased greatly in number and have largely come to replace Royal Commissions of Enquiry (including Commissions such as the Royal Commission into the NHS which reported in June 1979 and would have been in the memory of politicians in the 1980s).

13.5. There is a useful table showing the numbers of concurrent Public Inquiries produced by the Institute of Government (see https://www.institute forgovernment.org.uk/explainers/public-inquiries). This gives a chart of Public Inquiries within the UK, including Scotland and Northern Ireland. Numbers were limited to a maximum of 3 concurrent Public Inquiries until 1997, when they began to grow sharply in number (with many commissioned by the new Labour administration). By 1998 there were 9; the numbers dropped down to about 5 by 2005 (which saw the passing of the Inquiries Act 2005) and then began to rise again, peaking at 16 in 2011.

13.6. The Inquiry has also received evidence from its Expert Group on Public Health and Administration about the growth of reflective practice. The earliest reference to the concept that government departments should be "learning organisations" was dated back to a Cabinet Office paper from 1999 (see p56 of the Expert Group's report). Both the relative rarity of public inquiries until c1998, and the concurrent absence of 'reflective practice' as an organisational norm within government until the end of the 1990s, are matters to be considered when the Inquiry considers the absence of a formal review of 'lessons learnt' from the AIDS pandemic and/or its specific impact upon those in receipt of blood or blood products, in the period from the mid-1980s – end 1990s.

A Public Inquiry – 1980s and Early 1990s (Thatcher and early Major administrations)

13.7. Consistently with this background, there was an absence of calls for an Inquiry into infected blood during the period from c1985 to the mid-late 1990s. Lord Fowler observed that no consideration was given to a public Inquiry during his time in Office and that, to his knowledge, the matter was not raised until 1991, when he advocated an inquiry into the handling of AIDS pandemic as a whole, including the area of health education.[2005] Baroness Bottomley noted that calls were not a significant feature of her tenure at the Department for Health (including her period as Minister of State).[2006] However, Baroness Hooper recalled being copied into a submission on 26 October 1989 which set out various proposals on the approach to be taken on the HIV litigation; one suggestion (which was said to have been made by an NHS Haemophilia Centre Director attached to the Haemophilia Society) was to establish a Commission of Enquiry. Baroness Hooper was not able to provide any insight into why the submission was not taken forward[2007] and David Mellor (to whom the submission was principally

[2005] Lord Fowler's oral evidence on 22 September 2021, at 83:10-84:5, 129:5-25, 133:1-13.
[2006] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.10.
[2007] Baroness Hooper's witness statement dated 14 June 2022 (WITN7005001), §36.1.

addressed) did not think that he had seen it before he moved on to the Home Office.[2008]

13.8. This option appears to have remained as one possible option in officials' thinking concerning alternative approaches in the context of handling the HIV litigation: the Inquiry has seen the reference in the submission from Charles Dobson dated 24 July 1990[2009] to the potential options available in the earlier stages of HIV Litigation, following the intervention by Mr Justice Ognall. This submission proposed several options, including a 'commission of enquiry' where a commissioner would be tasked with considering whether haemophiliacs constituted a sufficiently special case to justify an ex-gratia award and, if so, on what basis. However, the submission highlighted that there was no guarantee that such a commission would be quicker than permitting the litigation to run its course. Baroness Bottomley could not provide detailed information on why the submission was not actioned but observed that it was likely that the prospect of an inquiry was unattractive based on the reservations in the submission, coupled with Kenneth Clarke's decision, as Secretary of State, to defend the HIV litigation.[2010] As matters stood in 1990, an inquiry was considered an unattractive option because (i) it was unlikely to report quickly enough to deal with the immediate calls for financial help, and (ii) there were concerns that an inquiry would stray outside of payments for those infected and into wider issues of compensation.

13.9. Whilst options for settling the litigation were explored, there is no record of this attracting support from Ministers at the time – but there is, equally, no suggestion that a public inquiry was an option being strongly advocated by the litigants or their legal representatives as an alternative way forward.

[2008] David Mellor's witness statement dated 25 April 2022 (WITN7068001), §4.46d.
[2009] DHSC0004360_147.
[2010] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.10.

13.10. Following the settlement of the HIV litigation, there were no concerted calls for a public inquiry. Baroness Bottomley observed that, "*Once the litigation had been settled, my sense is that the settlement deal was seen as having been the mutually-agreed compromise of the issues that had been raised.*"[2011] Thus, the focus was on providing financial support to those infected and consideration as to whether such support should be extended to blood transfusion patients and, subsequently, those infected with HCV.[2012] The civil service 'commission of enquiry' option in July 1990 therefore seems to have been a 'one-off' and, given the historical context set out above, may explain the lack of traction it gained with Ministers at the time. The view advanced by Government and subsequent Governments, was that the payment made to the HIV sufferers was in light of their very special circumstances (including, the great reduction in life expectancy and the significant social problems they faced).

13.11. The Inquiry heard evidence from Lord Fowler on this issue.[2013] In addition to his clearly and strongly articulated current view that this Inquiry should have been held much sooner, he had considered at an early stage that an inquiry should look at the handling of the AIDS pandemic as a whole, and specifically that there should be a searching inquiry into the whole area of health education which could have considered "*the effectiveness of our current approaches…*".[2014] It is likely that any such inquiry would have considered the matter of infected blood in the round. When Lord Fowler left office in 1987, he stated that no consideration had been given to the holding of a public inquiry. His views featured in his 1991 autobiography (Ministers Decide: A Memoir of the Thatcher Years, 1991). But it is apparent that this was not pursued as an option within government. It is clear his immediate reflections were informed by the desire to have a 'lessons learnt' approach to prevent any future health scandal.

[2011] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.10.
[2012] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.14.
[2013] Lord Fowler's oral evidence on 22 September 2021, at 129:5-135:24.
[2014] Lord Fowler's oral evidence on 22 September 2021, at 83:19-84:5.

13.12. During Lord Fowler's tenure as Health Secretary, there was a feeling within Government that the main issues had been largely eradicated and there was nothing that the Department could do to influence the outcome. In his evidence, Lord Fowler emphasised that decisions were being made "*...against challenging uncertainty...*"[2015] where there were rival theories about what had caused AIDS. He noted that a PMQs background brief from May 1983 still posed the question as to whether AIDS was a virus.[2016] The uncertainty surrounding the understanding of AIDS during the early 1980s resulted in circumstances whereby the Government was trying to battle against a poorly understood virus where the obvious solution (stopping imports from outside of the UK) posed the dangerous situation whereby sufferers would be at risk of bleeding.

13.13. It is also worth noting that Lord Fowler said in his autobiography, referring to the 1980s and health spending in particular, that health provides "*...just about the bloodiest battleground in British politics...*"[2017] and that it is easy to underestimate the "*...intense financial pressures of the time*".[2018]

13.14. Lord Fowler was clear in his reflections that a broader inquiry would have benefitted the government's understanding of what had occurred. He referred to the delay as the "*...worst of every conceivable world*".[2019] When his views were put to other witnesses, it was widely accepted that having an inquiry sooner rather than later would have been more appropriate. To take just two examples:

(1) Baroness Bottomley reflected now that the commissioning of an inquiry at the time of the HIV litigation would have avoided some of the practical difficulties of having an inquiry such a long time after the

[2015] Lord Fowler's first witness statement dated 17 July 2021 (WITN0771001), §0.12.
[2016] Lord Fowler's first witness statement dated 17 July 2021 (WITN0771001), §§6.5-6.7.
[2017] Ministers Decide: A Memoir of the Thatcher Years, 1991, page 166.
[2018] Lord Fowler's first witness statement dated 17 July 2021 (WITN0771001), §7.36 and see also §4.67.
[2019] Lord Fowler's oral evidence on 22 September 2021, at 131:17-131:19.

events being studied. She accepted that it would have been better for the inquiry to have taken place sooner.[2020]

(2) Lord Horam accepted that the quality of evidence before an inquiry will be better in circumstances where an inquiry is held as soon as reasonably practicable.[2021]

13.15. 'Fear of the results' was not, however, identified by officials or Ministers of officials from this time[2022] as a reason for not holding a statutory inquiry. Rather, at this time:

(1) The HIV Litigation had been settled without findings of fault on the part of the Central Defendants;

(2) The legal advice received as the litigation was considered had been broadly favourable; that advice was based on a wide review of papers and draft expert reports and supported by Ognall J's indication of the various hurdles which the plaintiffs would have to overcome;[2023]

(3) The plaintiffs' Counsel, at the infant settlement hearing in May 1991,[2024] had expressed pessimistic views about the chances of success, had the litigation continued (see section 11 of these submissions on the HIV litigation);

(4) The CMO, Sir Donald Acheson, had made it plain that he did not consider that there had been negligence in the handling of the response to AIDS. In his minute to Kenneth Clarke of submission of 20 July 1990,[2025] Sir Donald made the case for settlement not because of perceived breach of duty or wrongdoing but on purely humanitarian grounds:

> *"I hope therefore, that for humanitarian reasons the Government will find some way to make an ex gratia settlement to the infected haemophiliacs in relation to this unique tragedy. I cannot*

[2020] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.13.
[2021] Lord Horam's written statement dated 13 May 2022 (WITN5294001), §4.8.
[2022] The evidence of Andy Burnham and Jeremey Hunt is addressed later in this section.
[2023] DHSC0046964_024.
[2024] Referred to in WITN7068009.
[2025] HSOC0017025_004.

> *personally see how this could be regarded as implying any responsibility for other accidents…".*[2026]

(5) This was followed, on 7 December 1990, by further advice from the CMO to the effect that the Department's scientific advisors at the relevant time had not, in his view, been negligent:

> *"[CMO] has stated that he is satisfied that since the emergence of this problem in 1983 the advice given by medical and scientific staff of the Department of Health to Ministers has been both correct and timely bearing in mind the state of knowledge at the time and that there has been no negligence in relation to this advice."*[2027]

13.16. It might now seem regrettable that steps were not taken in the late 1980s/early 1990s, to conduct a review of the response to the pandemic and/or to the specific issues raised by infected blood. It may well be that, had there been something approaching an 'official record of events' available in later years, some of the choices faced by civil servants and/or Ministers, in developing accurate 'lines to take' could have been avoided or at least reduced. But, as noted above, none of the DHSS witnesses from this time evidenced that this was due to any 'fear of what might be found'.

The Major Administration (cntd.)

13.17. Between 1992 and 1997, following the settlement of the HIV Litigation, there were limited calls for a public inquiry. Under this period under the premiership of John Major, the Department focussed more on responding to calls for the establishing of improved treatment for those infected and obtaining improved medical understanding, management and treatment of their conditions. With discussion also focusing on the 1995 Look-Back exercise and whether the HIV payment scheme should be extended to those who had been infected with HCV, little consideration was given to whether an inquiry should be established but nor did the calls for an inquiry attain the level reached in later years. As noted above, Baroness Bottomley

[2026] See too Lord Clarke's Oral Evidence on 29 July 2021, at 33:18-33:19.
[2027] DHSC0046939_009, minute dated 7 December 1990.

(Secretary of State from April 1992 – July 1995) explained that calls were not a significant feature of her tenure at the Department for Health.[2028] An example of the limited profile of the public inquiry issue in Stephen Dorrell's period as Secretary of State (July 1995 – May 1997) is his meeting with John Marshall MP on 24 April 1996. At that meeting, in the context of the calls for an HCV ex gratia scheme, Mr Marshall raised the suggestion of an inquiry but within the same meeting indicated that he had decided not to pursue it.[2029] At this stage, therefore, there is some evidence that the calls for an inquiry were secondary to the increasingly high profile case being made for an HCV payment scheme.

13.18. John Horam (Parliamentary Under Secretary of State under Stephen Dorrell in this period) reflected in relation to the public inquiry issue that:

> *"There may have been limited calls for a public inquiry at the time and some other references to it in correspondence. However, my impression was that the overwhelming majority of communications from fellow MPs and the public, as well as the Haemophilia Society was to establish robust treatment for those infected and of course, for the Government to look at a payment scheme.*
>
> *… my focus was on immediate policy areas. I do not recall and could not comment more widely on why the Government did not establish a public inquiry during my time in office. My understanding is that pressure from the public as well as politically became increasingly persuasive in subsequent years."*[2030]

The Blair Administration

Before the self-sufficiency review was commissioned (1997-2002)

13.19. May 1997 saw the election of a Labour administration and shortly thereafter, commitments to several public inquiries including:

(1) The BSE Inquiry: established in December 1997 and reporting in October 2000.

[2028] Baroness Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.10.
[2029] DHSC0042289_144.
[2030] Lord Horam's witness statement dated 13 May 2022 (WITN5294001), §§4.3-4.4.

(2) The Bristol Royal Infirmary Public Inquiry: established in June 1998 and reporting in July 2001.

(3) The Bloody Sunday Inquiry: established in 1998 and reporting on 15 June 2010.

(4) The Shipman Inquiry: announced on 1 February 2000 with the fifth and final report published on 27 January 2005.

(5) The Climbié Inquiry: established in April 2001 and reporting in January 2003.

13.20. Under the Secretary of State for Health, the late Frank Dobson (May 1997 – October 1999), the main focus remained on whether the payment scheme should be extended to those infected with HCV. In relation to a public inquiry into infected blood, the Labour Government maintained the view of the previous Government. In the Lords on 24 May 1999, for example, Baroness Hayman indicated in answer to Lord Morris that, "*The campaign that the Haemophilia Society waged was moving and forceful. However, we concluded that a public inquiry was not the way forward and would not help prevention of future transmission.*"[2031]

13.21. This was not merely a Departmental position, but one shared by the Prime Minister. On 11 May 1999, Lord Morris wrote to the Prime Minister seeking a meeting to discuss the case for a public inquiry.[2032] Tony Blair responded on 23 June 1999, stating:

> *"As you know, we have given a great deal of careful thought to a range of issues associated with haemophilia. I have to say, however, that I do not think a public inquiry would be justified.*
>
> *Infections with HIV and hepatitis C occurred, as you know, before advances in technology allowed blood products to be virally inactivated. These viral inactivation processes were introduced in 1985, as soon as it was possible to do so, and since then blood products have been treated effectively to destroy HIV and hepatitis C. Though I recognise that people with haemophilia and their families feel a sense of injustice,*

[2031] Baroness Hayman's witness statement dated 12 September 2022 (WITN5523001), §6.2(16).
[2032] HSOC0014459.

> *I am not convinced that a public inquiry would provide greater insight into the problem or pave the way for any further improvements in the safety controls which are now in place."* [2033]

Such responses from No.10 were, of course, written following liaison with the Department and reflected the Department lines that had been developed.

13.22. The use in 1999 of the line about the introduction of heat treatment of blood products in 1985 is of note in part because of how this was later to be expanded to cover the introduction of HCV screening. It is also noteworthy because, as the Inquiry has remarked, it failed to take account of the evidence that there continued to be some transmission of both HIV/AIDS and Hepatitis C by commercial blood products, in particular, after 1985. The evidence in relation to this issue has been touched upon in Section 5, paras 5.33 – 5.44, yet the Department's 'line' focussed, it would seem, on the provision of the NHS product and did not recognise or acknowledge this further issue.[2034]

13.23. Despite these express rejections of a public inquiry by Government, calls for a public inquiry continued through the early years of the Blair administration.

13.24. Charles Lister[2035] explained in his written evidence the broad underlying rationale against a public inquiry that was the policy position adopted during his time in the blood policy team:

> *"• There was no evidence of wrongdoing by the Government or the NHS*
> *...*
> *• There was nothing of fundamental significance that was not already*

[2033] HSOC0002041.
[2034] Reference was made, in Section 5, to the Inquiry's questions on this issue: see Hazel Blears' oral evidence on 21 July 2022, at 155:2-158:24 and Alan Milburn's oral evidence on 14 July 2022, at 41:12-43:22, reflecting on (for example) a letter signed by his as Minister of State in 1997 as well as the Department's consultation document on a Hepatitis C strategy (2002) [WITN6942004]. Mr Milburn noted that he would not have been aware of this at the time and reflected on the issues of how the past could be effectively interrogated, when ministers were *"...inevitably focused on the mandate that they have received and the agenda that they have created, which is inevitably about the present and the future"* (oral evidence of 13 July 2022, at 43:3 – 44:25).
[2035] Mr Lister's evidence is used here as a vehicle to draw the lines used together. But they are not peculiar to Mr Lister; rather they reflected the Department's position at this time.

known, and the relevant facts were all in the public domain. …

- *There was no evidence Parliament had been misled. …*
- *This was a problem linked to the state of science and technology at the time, rather than an isolated UK problem, and so any inquiry would be unlikely to provide the infected and affected with a satisfactory answer. …*
- *The focus was instead on looking forward and on how to assist the infected and affected with improving their health and wellbeing. An inquiry would not help prevent future transmission. …*
- *There was concern that a public inquiry would raise the profile of potential no fault compensation at a time when litigation in the NHS was an increasing problem. …*
- *The time that a public inquiry would take to complete. …*
- *The initial trawl of documents had concluded that the reason self-sufficiency had not been achieved was due to increased demand for clotting factors, not a failure to implement Ministerial initiatives. On the contrary, there was evidence significant efforts had been made to achieve self-sufficiency. …*
- *Self-sufficiency in blood products would not have prevented haemophiliacs from being infected with hepatitis C. …"* [2036] [2037]

13.25. Viewed critically now, with all the detailed understanding that the Inquiry has gained from its investigation, the conclusion may be that some of the justifications were wrong (whether in whole or in part) or at least did not carry the weight which they were given at the time. That is a different question, however, from the further questions of:

(1) whether these arguments were unreasonable at the time with the understanding officials and ministers of the Department had at the time;

(2) whether the arguments were deployed by anyone knowing them to be wrong.

[2036] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §4.60.

[2037] Mr Lister was asked about some of these lines to take in his oral evidence, given on 8 June 2022. For example in relation to the line to take that the facts were in the public domain, he accepted that clearly not every fact was in the public domain. He also accepted that there may have been prejudgment in relation to what further information may have come from outside the Department. His experience was that if there was a change in circumstance or new evidence then the policy should be reconsidered and that it was always open to new ministers to change a policy if they considered that it was not correct (evidence of 8 June 2022, 27:3-28:1; 31:4-33:6).

13.26. As in other areas, in considering below the justifications given for not holding an inquiry sooner, these submissions seek only to refer to the evidence of views and considerations that were current at the time, to which the Inquiry is invited to give consideration. These examples are not exhaustive, but are intended to illustrate the range of views expressed by those involved in the Department at the time.

13.27. There is evidence that, in this period, more formal consideration was actively given to the question of whether an inquiry should be held. A prominent example of that was the submissions to Yvette Cooper of 2 July 2001 which set out the different options for action following the *A and others v NBA* litigation.[2038] The options set out were:[2039]

(1) Do nothing;

(2) Public inquiry, lump sum, and hardship fund for all haemophiliacs infected with Hepatitis C by blood;

(3) Lump sum and hardship fund for all haemophiliacs infected with Hepatitis C by blood, and low-key inquiry;

(4) Lump sum and hardship fund for all or some haemophiliacs infected with Hepatitis C by blood;

(5) Hardship fund for haemophiliacs infected with Hepatitis C by blood and who have severe liver disease.

13.28. The options involving an inquiry were not favoured in the submission: the recommendation was that if Ministers were in favour of a payments scheme for HCV, then option (5) was the most appropriate course.[2040]

13.29. In the attached option paper, the reasons against option (2) included:

(1) Relevant facts largely established; information in the public domain;

[2038] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §2.23.
[2039] SCGV0000243_051.
[2040] SCGV0000243_051.

(2) Lengthy time period for Inquiry to report;

(3) Public inquiry would raise the profile of potential no fault compensation at a time when litigation in the NHS is an increasing problem.[2041]

13.30. Yvette Cooper stated that, at the time, her focus was on compensation for those affected as opposed to the "*...merits of a public inquiry...*" as *"...that was the immediate issue raised by the High Court judgment, and I was advised it was the issue of most concern to the affected families and campaigners.*"[2042] She also commissioned a review of the facts relating to the attainment of self-sufficiency; see further below. Reflecting on matters now in her statement to the Inquiry, however, Yvette Cooper recognised the weakness in the assertions made that the facts were known. She said:

> *"In the case of infected blood, it had become the established Departmental view, repeated often in advice to Ministers that all the facts were known, established and well-rehearsed. However, that was simply not the case. Neither Ministers nor officials had the full facts about what happened in the 1970s and 1980s, and in key areas internal departmental judgments had been made about what was reasonable or an appropriate balance of risk at the time that had not been independently reviewed or tested even though immense suffering had been caused for those who were affected. As a result, the Government failed to provide either truth or justice for those families who were affected."*[2043]

13.31. The Secretary of State for this period was Alan Milburn. In his written statement, Mr Milburn's observations about his likely approach at the time included the following:[2044]

(1) The question of a public inquiry was not raised to him in formal submission for decision; however

(2) Had he been asked at the time, he would probably not have agreed to an inquiry since:

[2041] SCGV0000243_051.
[2042] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §2.24.
[2043] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §4.30.
[2044] Alan Milburn's witness statement dated 27 May 2022 (WITN6942001), §§21.3-22.10.

(1) There was no evidence that he was aware of suggesting wrongful action or serious fault on the part of the NHS;

(2) While he recognised it was a controversial matter, at the time Ministers were being briefed that the facts were largely established;

(3) Later, an internal review had been commissioned (the Self-Sufficiency Report, considered further below);

(4) The main focus of debate was on securing financial support;

(5) His view would have been that inquiries were most helpful where there was substantial doubt about events that had happened, where it appeared there had been systemic negligence or serious fault on the part of the care system and where lessons had arguably not been learned (while there had not been a 'lessons learnt' exercise regarding infected blood, there had been very substantial change in practice);

(6) The costs of an inquiry would have to have been weighed against the benefits. Mr Milburn noted the costs of some including the Bloody Sunday Inquiry (£191m), the Shipman Inquiry (£21m), and BSE Inquiry (£26m); these headline cost figures were underestimates as they typically related to the costs of the Inquiry itself and publicly funded participants, not the costs incurred by government departments or other public authorities. Mr Milburn would have had to weigh the point that the money spent on any inquiry could have been spent instead on direct patient care. He would also have had to consider the resource costs in the sense of the ministerial and civil service time, when there was already a huge policy and delivery agenda in play.

13.32. In his oral evidence, Mr Milburn was asked further questions about these considerations[2045] and added the following about considerations that would have informed any decision-making at the time:

(1) Had he felt that there was a situation where there was substantial doubt, that issues had not been aired in the public domain, that there was evidence of systematic negligence and critically, that there had not been some evidence of lessons being learned, then he might have concluded that a public inquiry was necessary. However, there was a very well-established view in the Department that transcended successive governments and ministers that 'the facts were established'. He recognised that this engaged issues around 'lines to take' and 'groupthink' addressed earlier in his evidence.

(2) He felt that with the amount of debate that the subject had received, it was not a case where there was something which had somehow not been uncovered.

(3) He felt that infected blood did not have the same level of uncertainty as other issues (for example how Dr Shipman had been able to operate unchecked and undetected).

(4) He would certainly have wanted to wait and see what the internal investigation (i.e. the Self-Sufficiency Report) found (although at the time he did not think he was aware of it having been commissioned). The fact (had he known it) that Scotland had also been investigating aspects of heat treatment would also have militated against an inquiry.

(5) The lessons learned point was very important. While criticisms were being levelled at the Department and aired, it was clear to him that lessons had been learnt; he saw that in how vCJD risks were addressed and the primacy of the precautionary principle.

[2045] Alan Milburn's oral evidence on 14 July 2022, at 173:12-190:9.

13.33. Mr Milburn raised an issue that the Inquiry may consider significant (a missing piece in the jigsaw); namely, how capable Ministers are of assessing contested accounts of events in the past, given that there was (and is) no mechanism that exists to do so in these kinds of difficult situations. He said this:

> *"Public inquiries, my point is, are pretty rare events. And so we don't have a systematic way, currently, of being able to interrogate the past to ensure that the story that is being told is a wholly accurate one. Now, the problem with the truth is that there are always different versions of it. That's what happens. There is one truth and then there is another truth. And if you are in a decision-making position you are having to arbitrate between them. That's where you sit. I do think that these questions about how you do interrogate the past, they sort of need better mechanisms, other than the blunt instrument and sometimes the happenstance of a public inquiry being established, on the one side, or reliance upon the system to do its own interrogation. That's why I have been thinking about this a lot. This is why I think we need something different as a vehicle to enable us to do that. Not for everything, because of course you can't keep going over everything, because if you keep doing that you can never make progress, clearly, but where there are issues like this, you know, which are substantive issues because of the harm that was inflicted, and where there is a contest about what the truth is, it would be good to think that we can come up with something that could do that job of work."*[2046]

Similar concern and thinking was expressed by Baroness Primarolo in relation to her later period as Minister of State for Public Health; see paragraph 13.62 below. These may be matters for the Chairman to consider in the context of recommendations.

Self-sufficiency review underway but delayed completion (2002-2006)

13.34. As was touched on in Mr Milburn's evidence, part of the factual context in which the Public Inquiry issue was being considered was what became the Department's Self-Sufficiency Report, commissioned in 2002 but not published until 2006. Allegations were made by the Haemophilia Action UK Group and others that the money allocated by Lord Owen to achieve self-sufficiency had not been spent appropriately. When a letter from Carol Grayson was sent to Yvette Cooper, raising a number of serious delays to

[2046] Alan Milburn's oral evidence on 14 July 2022, at 185:5-186:5.

achieving self-sufficiency, lack of advice to patients on risks and judgements on the relative risks of different treatments (as well as concerns that Lord Owen's files had been 'pulped'), officials confirmed that they were looking at files from the 1970s and 1980s to look into these matters. [2047]

13.35. Without here recounting in the detail of the chronology of the Self-Sufficiency Report (with which the Inquiry is well familiar), it is sufficient to note here that:

(1) Officials' *initial* trawl of documents suggested that the funding provided by Lord Owen' to achieve self-sufficiency had been properly invested but that demand had increased rapidly above predictions, such that self-sufficiency had not been achieved.[2048]

(2) There was advice from Janet Walden in the Departmental team dealing with inquiries that officials should locate whatever papers were in existence and that they should ask someone fairly senior and experienced to put together a chronology of events and key background papers.[2049]

(3) In their advice, officials accepted (and Yvette Cooper strongly emphasised) that it was not sustainable to leave matters at the initial trawl of documents.[2050]

(4) Accordingly at a meeting on 9 May 2002, it was agreed by Yvette Cooper that officials should undertake a more detailed internal review. This was initially undertaken by Peter Burgin, an official in the Department.[2051]

13.36. Yvette Cooper explained her reasoning in her written statement, including that,

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[2047] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §2.45.
[2048] See for example DHSC0020742_093 and Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §4.80.
[2049] DHSC0041379_023.
[2050] DHSC0042461_064.
[2051] The meeting outcome is referred to at DHSC0041305_030.

> *"I believe I was becoming increasingly concerned that, despite receiving previous advice that "relevant facts [are] largely established; information in the public domain,". The reality was that we did not have a clear account of decisions that had been taken in the 1970s and 1980s, and therefore I could not be confident in the advice I was being given to answer campaigners' serious questions, nor could I be confident that previous official advice or subsequent Ministerial decisions on this issue were right as a result. In the case of CJD and vaccines where I had similarly become aware that the Department did not have important answers and that previous advice to Ministers was not reliable, the urgent reviews I had commissioned had been taken extremely seriously by the Department and had reported very quickly with important new information which allowed Ministers to take informed decisions about what the next steps should be. Based on my experience handling CJD and vaccines, I would therefore have been looking for a thorough review that uncovered new questions, that investigated the campaigners concerns and exposed any further problems so that we could then consider what the next appropriate steps might be."*[2052]

She considered that the review would be the first step in a decision-making process which would then be able to consider whether some form of independent inquiry or review might be appropriate.[2053]

13.37. Lord (Philip) Hunt noted in his written evidence that there was a general consensus throughout government to resist calls for public inquiries unless there were compelling reasons for one to be held. Lord Hunt also stressed the significance of the early findings of the initial trawl of documents. He noted that it was a key plank of the calls for a public inquiry that there had been a breach of Lord Owen's commitment to self-sufficiency and:

> *"In that regard, the information and advice we had received was that the funds allocated had been appropriately invested but that massive growth in demand had meant that self-sufficiency had still not been achieved, even though the production target had been met."*

Like Yvette Cooper, however, Lord Hunt was another who saw matters differently with the benefit of hindsight, continuing in his statement:

> *"Now, with the benefit of hindsight and more fulsome information and knowing something of the many strands being investigated by the*

[2052] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §3.22.
[2053] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §3.27.

> *current Inquiry, I do believe the calls for a public inquiry were justified."*[2054]

13.38. Hazel Blears took over from Yvette Cooper as the Parliamentary Under Secretary of State for Public Health on 28 May 2002 very shortly after the internal review had been commissioned. Like Lord Hunt, in her early involvement, her approach to the calls for a public inquiry were shaped by advice that the initial trawl of documents had suggested that the funds allocated for self-sufficiency with respect to blood products were spent and appropriately and production increased. Moreover, that issue was now being considered in the more detailed internal review, the results of which would be shared.[2055] The issue of testing without consent was later raised, but (albeit in part after Ms Blears had moved Departments) the information obtained was that the GMC had confirmed they were to examine such allegations.[2056] Shortly before she moved to the Home Office in June 2003, Ms Blears queried progress on the internal review in considering the draft response to correspondence raising the issue of a public inquiry.[2057] Ms Blears considered that the fundamental and more pressing issue was whether there should be a financial assistance scheme for those with Hepatitis C.[2058] In her oral evidence, Ms Blears noted that holding a public inquiry clearly was a significant step and was conscious of the long time they took to come to a conclusion. She took into account the extent of debate there had been in Parliament, and she was conscious that a public inquiry would again extend the period of time it was taking to deal with these issues. She did not have previous experience of establishing an inquiry and was not aware of the legal threshold to be applied in establishing one. She saw force in Mr Milburn's evidence that there was a need for a mechanism to enable the circumstances surrounding contested events to be assessed, in order to inform the decision about whether to have an inquiry. On reflection she

[2054] Lord Philip Hunt's second witness statement dated 25 November 2022 (WITN4680008), §5.13.
[2055] Hazel Blears witness statement dated 9 June 2022 (WITN6658001), §§3.8-3.14.
[2056] Hazel Blears witness statement dated 9 June 2022 (WITN6658001), §§3.15-3.20.
[2057] Hazel Blears witness statement dated 9 June 2022 (WITN6658001), §§3.21-3.22.
[2058] Hazel Blears witness statement dated 9 June 2022 (WITN6658001), §§3.25.

thought that the line taken at the time was wrong (though that was not a conclusion reached based just on the numbers of those affected).[2059]

13.39. At paragraph 13.24 above, these submissions have quoted Charles Lister's summary of the contemporaneous reasons for declining to establish a public inquiry. Mr Lister was a witness who explained to the Inquiry in some detail his reflections from his time in blood policy. He stressed how seriously he took the principles of the Civil Service Code and noted his own experience that Ministers were always prepared to challenge the advice they were given and had ample opportunity to do that. On the question of compensation for those infected with Hepatitis C, Mr Lister had asked himself the question whether he and others may have been affected by a collective mind set or 'Group think' when addressing this issue. He said that this issue of a collective mind set (rather than civil service 'resistance' as described by Mr Burnham) was what he had cause to ponder. But he felt it was impossible to say how much this impacted on the Department's actual decision making. Mr Lister made these observations in his written statement in the context of the issue of a payment scheme for HCV but in oral evidence included the public inquiry issue in the same bracket.[2060] Specifically in relation to the public inquiry Mr Lister, with his own emphasis that this was with hindsight, offered the following view:

> *"(a) The measures that were taken (including DH's internal review and the subsequent report in 2007) and the litigation that was concluded did not dissipate public concern; and*
>
> *(b) an earlier UK-wide inquiry would have*
>
> - *have answered campaigners' questions about what happened sooner, and perhaps achieved much-needed closure*
> - *reduced the stress on campaigners who had to fight for an Inquiry for longer;*
> - *ensured that more campaigners would have lived to see the outcome*

[2059] Hazel Blears' oral evidence on 21 July 2022, at 192:20-198:8.
[2060] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§2.96-2.98; Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §4.93. Further discussed in his oral evidence on 8 June 2022, at 78:4-87:23.

> • *had the opportunity to call on witnesses now too ill or deceased and would have benefited from clearer memories.*
>
> *(c) While blood policy and safety had already moved on considerably, the lessons derived from a full inquiry could have been acted upon sooner.*
>
> *As so often, these issues are much clearer and easier to identify with hindsight but I certainly accept that the balance would have been better struck in favour of an earlier inquiry."*[2061]

13.40. The Inquiry has noted the development of a 'line to take' concerning the timing of the introduction of HCV screening, which Departmental witnesses have now accepted was plainly wrong. The essence of the line to take concerning the introduction of heat treatment for blood products in 1985 (see paragraph 13.21 above) was adapted for use in relation to the introduction of HCV screening of whole blood in 1991. Thus, for example, in January 2004, briefing for an oral PQ for a supplementary question included the line:

> *"A number of Pressure Groups have raised the question of a public inquiry into the infected blood issue. However, the Government does not accept that any wrongful practices were employed and does not consider that a public inquiry is justified. Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time."*[2062]

13.41. Richard Gutowski (who took over from Charles Lister in the summer of 2003) accepted that this and similar statements could have better reflected the findings of the Court in the HCV litigation in *A & others v NBA,* which had found that consumers were entitled to have expected that routine HCV screening to have been introduced from 1 March 1990, and surrogate testing before that.[2063] He thought, however that he would have been drawing on

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[2061] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §§4.95-4.96. Further discussed in his oral evidence on 8 June 2022, at 23:19-33:6.
[2062] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), at §4.6; WITN5292050.
[2063] See the judgment in *A and Others v National Blood Authority* at §8; further, surrogate testing should have been put in place by March 1988, Burton J concluded.

established 'lines to take' and the advice of others in the Department, in putting forward this proposed answer.

13.42. However, and by whoever, this particular line to take was first introduced, it was (as witnesses have accepted) clearly wrong, yet was maintained for many years. Witnesses accepted that it evidenced poor corporate memory in that the findings of the Court from only a few years ago should clearly have been properly analysed and reflected in the wording of this line to take.

13.43. John Reid, Mr Milburn's successor as Secretary of State (June 2003 – May 2005) referred to this issue in his oral evidence. He was taken to a letter signed by him on 4 April 2005[2064] which had contained the line that, *"Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time.*" Counsel to the Inquiry put that '*...it may be said what's recorded in this letter is simply inaccurate.*" Lord Reid accepted that it could be positively said that the line was inaccurate. For the reasons he explained, he would not have queried this line at the time, but clearly accepted that with the knowledge he now had, the line used was inaccurate.[2065]

13.44. More widely, Lord Reid noted that his own views in relation to a public inquiry were based on (i) not having been provided with information or evidence that suggested, as a minimum, a prima facie case that there had been a history of fault or culpability – whether consisting of fraud, negligence, cover-up or similar; and (ii) in the absence of such a case, his focus was on providing practical help (what became the Skipton fund) and help that could be put into place relatively quickly.[2066] He had not identified any submission where the question of holding an inquiry came to him for

[2064] DHSC6264733.
[2065] Lord Reid's oral evidence on 21 July 2022, at 88:13-90:14.
[2066] Lord Reid's witness statement dated 20 May 2022 (WITN0793001), §17.2.

decision, although it was referred to amongst other issues in briefings. While he had not seen any briefings which were suggestive of fault or culpability, Lord Reid thought it "*...a very fair question...*", viewed now, that Departmental officials might not be the best placed to provide evidence on whether or not there had been such culpability. During his period in office, Lord Reid considered that there were no major demands for a public inquiry, and none which he had identified which had come to him directly.[2067]

13.45. The recent statement of Melanie Johnson, Parliamentary Under-Secretary for Public Health at the time, has noted that:

> *"...whilst I was PS(PH) there was a significant amount of work which the Department was undertaking in this policy area particularly regarding the establishment of the Skipton Fund, and the response to the vCJD issue. At the time, I considered that focusing on providing practical support for those people infected was a more fundamental and pressing issue that could be practically addressed. Given the amount of work involved in establishing the Skipton Fund, along with my other Ministerial responsibilities, although I had great sympathy for the people infected and affected, I accepted the view that the issue of contaminated blood was a historical issue which had already been considered by previous governments of both parties. The issues relating to contaminated blood had been debated and considered by both Houses on many occasions and the fundamental issue which we needed to address was delivering financial support for those people infected, to the best of our ability, as well as working on the Hepatitis C strategy to pick up any further infections and deliver treatments to those with infections."*[2068]

13.46. While work on the Self-Sufficiency Report was underway there is evidence that the fact that the internal review, together with its emerging conclusions,[2069] was being undertaken, became a further reason not to hold a statutory inquiry.[2070] Officials were also aware that the Scottish Executive

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[2067] Lord Reid's oral evidence on 21 July 2022, at 92:1-93:1.
[2068] Written statement of Melanie Johnson dated 15 December 2022 (WITN7496001), §12.8.
[2069] See the Health Protection Divisional Update dated 15 September 2004 (DHSC5042710).
[2070] See for example Hazel Blears' oral evidence on 21 July 2022, at 201:17-201:23; Charles Lister's Third witness statement dated 19 May 2022 (WITN4505389), §4.86. Per contra, see the written statement of Mr Peter Burgin dated 15 December 2022 (WITN7485001), §6.2: "*I was not aware of any suggestion at the time about not having a public inquiry because I was doing my review*".

were facing similar pressures for a public inquiry, but were resisting it for similar reasons to those being adopted in England.[2071]

13.47. In the event, the Self Sufficiency Report was not published until February 2006. None of the Departmental witnesses involved sought to justify the time that was taken. Yvette Cooper, who (as above) had commissioned the internal review in early 2002, considered the delay 'extremely troubling' and could see no justification for it.[2072] Mr Burgin himself had completed his work on the internal review – in the form of a full first draft – by the Christmas of 2002.[2073] Neither Charles Lister nor Richard Gutowski sought to justify the time that was taken. They did provide context which the Inquiry is invited to consider: the further work that was done on the report, the very significant resource and other pressures on their team, with competing priorities including: the roll-out of recombinant products, the important work in sourcing a sufficient supply of non-UK plasma in the light of the vCJD risks, and the creation of the Skipton Fund.[2074]

13.48. These submissions do not seek to address the Self-Sufficiency Report itself which will be for the Inquiry to review and consider. It is plain, however, that while the Report did not identify fault on the part of the Department, it did nothing to satisfy the infected and affected or campaigners, who both disagreed with its findings and questioned how the report could reach the conclusions it did when documents were missing and or had been destroyed.

13.49. Reflecting on matters now:

[2071] DHSC5325865. Richard Gutowski's Second witness statement dated 11 May 2022 (WITN5292016) §4.20, §4.21.
[2072] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §3.26.
[2073] See DHSC6700702; DHSC0020720_082, WITN4505402; and Mr Peter Burgin's witness statement dated 15 December 2022 (WITN7485001), §3.6, §3.9.
[2074] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §4.85; Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §§4.44-4.45 and §4.56; William Connon was not able to give evidence but a chronology was supplied addressing his period of involvement (WITN6887001).

(1) Charles Lister's view was that with hindsight, while the assessment of the reasons against a public inquiry was, he believed, genuinely made at the time, with hindsight he could see that the internal review did not dissipate public concern and an earlier UK-wider inquiry would have had significant benefits, see paragraph 13.39 above;[2075]

(2) Yvette Cooper's view was that the report did not fulfil the aims she had identified when commissioning it:

> *"In the event, however, it is also clear that the Review did not play that role — partly because of the long delays in concluding it and partly because of the approach taken. Instead of being a swift, initial stage in a process to identify where problems, gaps or further questions might lie, it lists what are presented as Government conclusions on what happened, including, effectively making judgements about what action was reasonable and about what the balance of risk was at the time and without also providing transparency, independent oversight or published evidence for those judgements and conclusions. Those judgements are of course heavily contested and for families who had suffered so much as a result of what happened, it would of course not be credible for those judgements to be effectively made in an internal process within the Department that was historically responsible for many of the decisions about what happened."*[2076]

Between the publication of the Self-Sufficiency Report and the publication of Lord Archer's report (2006 – 2009)

13.50. Following the publication of the Self Sufficiency report, calls for a public inquiry increased. Such calls cited disagreement with the conclusion of the report itself, but also the fact that papers believed to be missing / destroyed from the HIV litigation were returned, followed by the discovery of further papers at the Department's Wellington House (see Section 12 of these submissions).

[2075] Charles Lister's third witness statement dated 19 May 2022 (WITN4505389), §4.95.
[2076] Yvette Cooper's witness statement dated 19 August 2022 (WITN7187001), §3.28.

13.51. As a result, the period 2006-2007 saw further direct consideration being given at Ministerial level to whether or not to hold an inquiry, and if so, what form it should take.

13.52. One response to the return of papers was the further *internal* assessment those papers commissioned in June 2006 and conducted by Linda Page leading to the Department's further report, published in May 2007, '*Review of Documentation Relating to the Safety of Blood Products 1970 – 1985 (Non A Non B Hepatitis).*'[2077]

13.53. Beyond this, however, active consideration was given to whether a further form of inquiry should be initiated. In particular:

(1) At a meeting attended by Ministers Caroline Flint and Lord Warner on 24 May 2006, the inquiry issue was raised, albeit that the main focus was on dealing with document issues.[2078] One of the resulting actions was for officials to draft a paper that they could send to the Secretary of State (by now Patricia Hewitt, Secretary of State from May 2005 – June 2007) to discuss the possibility of "*…conducting a Public enquiry (sic)*".[2079] Caroline Flint did not think that they were considering establishing a statutory inquiry at this stage, but the problems with the documents needed to be addressed and were contributing to calls for an inquiry. They wanted to set out the options for the Secretary of State.[2080]

(2) On 26 June 2006 a revised submission was put to Caroline Flint and Lord Warner, including the pros and cons (as they were assessed to be) of holding an Inquiry. The advice of officials was against the holding of an inquiry:

[2077] PRSE0000642.
[2078] DHSC0015812 and Caroline Flint's written statement dated 7 October 2022 (WITN5427001), §3.111 and §3.118.
[2079] DHSC5286062.
[2080] Caroline Flint's written statement dated 7 October 2022 (WITN5427001), §3.120.

> *"On balance therefore, we consider an inquiry to be disproportionate and not justified in the circumstances. This is in line with the views of the Scottish Minister, and we will continue to keep in close touch with officials in the Devolved Administrations, including Scotland."*[2081]

(3) In response to this, Lord Warner (c 5 July 2006) indicated that while not in favour of a full statutory Inquiry, he was in favour of using powers under the NHS Act 1977 to commission a review of all the documents with a view to producing an independent legal / judicial commentary on them and putting them into the public arena. He had in mind a retired Judge or QC conducting the exercise.[2082] Caroline Flint endorsed in hand that this was "not a bad idea".[2083]

(4) On 24 July 2006, Caroline Flint and Lord Warner put their paper to the Secretary of State, Patricia Hewitt. This referenced the existing internal review being undertaken, which was expected to take six months, and the importance of that being undertaken to establish the facts and the Department's position in relation to an Inquiry. They noted officials' advice that a (full statutory) Inquiry would be disproportionate and not justified. They then set out the alternative:

> *"As an alternative we have explored the possibility of commissioning an independent review and commentary on all the papers. With regard to the relevant statutory powers, this could be done under the NHS Act 1977, as something incidental to your duty as SoS to continue to promote a comprehensive health service designed to secure improvement in treatment of illness, and to provide services required for treatment, as it would amongst other things be a way of passing information to the public about these issues. It would provide additional reassurance and information to the public, and would build on the steps officials are already taking to review all the existing papers. It would however not provide powers to compel witnesses to give evidence or produce documents, and we would need to draw the terms of reference accordingly."* [2084]

[2081] DHSC0041159_204.
[2082] DHSC0041159_251. For detailed comments from Lord Warner on why he saw an external review under the 1977 Act as a good idea, but not a full statutory inquiry, see Lord Warner's Witness statement dated 22 November 2022 (WITN7501001), §5.37.
[2083] DHSC0041159_204; Caroline Flint's written statement dated 7 October 2022 (WITN5427001), at §3.131.
[2084] DHSC0103399_003.

They invited the Secretary of State to note the line they proposed to take against the need for an inquiry and further to consider the option of producing an independent commentary on the papers under the 1977 Act.

(5) On 4 August 2006, Patricia Hewitt's response and the further input of Lord Warner were provided as follows:

> *"SofS has seen your/Lord Warner's note and commented that if you really believe an independent commentary is worth it and affordable, then she is content. However, she feels that it will fuel rather than deflect calls for a public enquiry (sic) - which we are absolutely right not to do.*
>
> *Lord Warner's view is that this is really your call as it is your policy area. He does not think the calls for a public inquiry will go away whatever we do but thinks an independent commentary on all the papers available will help to resist a public inquiry – he still thinks the commentary is worth doing if the money is available."*[2085]

(6) The option of an independent review under the 1977 Act was not dropped at this stage, nor was a full Statutory Inquiry removed from the options to be considered:

(1) In late August 2006, Caroline Flint sought and received advice on how much it would cost and how long it would take and intended to speak further with Lord Warner on the issue.[2086]

(2) In undated draft submissions that appear to have been drafted in January - February 2007, Linda Page was preparing to put the options to Ministers afresh with the completion of her report.[2087] One of the undated draft submissions[2088] suggested that that CMO had looked at the *"Review of Documentation Relating to the Safety of Blood Products 1970 – 1985 (Non A Non B Hepatitis)"* and stated that he agreed with its "rigorous analysis" and that the conclusions seemed sound.

[2085] DHSC0041159_139.
[2086] WITN5427031.
[2087] DHSC5162643; DHSC5459681; DHSC0015740_001.
[2088] DHSC5459681.

13.54. It was at this stage in the Department's own deliberations upon the approach to be taken, that Lord Archer's independent, but non-government commissioned Inquiry was announced (19 February 2007).

13.55. The Inquiry may wish to include in its consideration how this impacted on the internal Departmental thinking. On 24 April 2007, Elizabeth Woodeson put the final submission to Caroline Flint on Linda Page's work on the '*Review of Documentation Relating to the Safety of Blood Products 1970 – 1985 (Non A Non B Hepatitis)*'. Following the establishment of Lord Archer's Inquiry, and in contrast to the draft submissions from January / February, that submission now stated:

> *"'Given that this inquiry [Lord Archer's] is going ahead, we assume that you will not want to pursue the option of commissioning an independent review by a QC for the time being. (We did not recommend this in our earlier submissions because we estimate that such a review would cost in the region of £200,000. We do not have funds available for this. And we doubt that it would satisfy external parties anyway as an independent review by a QC would not be able to compel witnesses to give evidence.)"*[2089]

13.56. The relevant Ministers' reflections on these events include the following:

(1) Caroline Flint observed that the idea of an independent commentary by a retired lawyer had probably now been overtaken by Lord Archer's inquiry, though she did not think it had been permanently ruled out as a future option.[2090] In her oral evidence she noted, however, that the view that there had not being wrongdoing had a negative effect in that it tended also to shut down opportunities to discuss other ways to deal with the many serious issues that individuals and families were facing.[2091]

(2) Patricia Hewitt has explained her own experience as a campaigner and her grounds for doubting whether the 'half-way house' of an

[2089] DHSC0041193_026.
[2090] Caroline Flint's witness statement dated 7 October 2022 (WITN5427001), §3.181.
[2091] Caroline Flint's oral evidence on 16 September 2022, at 120:3-121:5.

independent review of the documents would be effective in achieving any resolution of the issues.[2092]

(3) Lord Warner felt on reflection that:

> *"…the Department got itself into a bad position because of the way documents were lost or destroyed. It landed itself in a position where it looked as though there was a cover-up. That is why I thought we needed an independent review to try and establish what happened and possibly see if the policy position was well-founded. I still think this would have been a sensible way forward in 2006. Because a convincing public position could not be established on what happened, a public inquiry became almost inevitable".*[2093]

13.57. This section of these submissions does not seek to cover in detail the question of the Department's engagement with the Archer Inquiry. The Inquiry has received substantial evidence on that issue. The Department's overall approach was settled in February – April 2007 (although it was accepted by witnesses that it would have been open to later Ministers to change the approach had they felt it appropriate). In that period February 2007 – April 2007, there were essentially three stages in the approach under consideration:

(1) Initially officials' advice was not to become involved in the Inquiry at all;

(2) Subsequently, following a meeting involving Patricia Hewitt, Caroline Flint, Lord Hunt and Lord Warner (13 March 2007) and a further meeting between Patricia Hewitt and Permanent Secretary Sir Hugh Taylor (20 March 2007), there was agreement that the Department should adopt a more co-operative approach including providing documents to Lord Archer's Inquiry, and it was also envisaged that Department officials would give evidence, but only after they had completed and compiled the report being prepared by Linda Page.

(3) Thereafter, when officials raised concerns about the implications of giving evidence to Lord Archer's inquiry (including legal advice

[2092] Patricia Hewitt's witness statement dated 28 November 2022 (WITN7420001), §3.36.
[2093] Lord Warner's witness statement dated 22 November 2022 (WITN7501001) §5.60.

received), the position reached was a middle course: documents would be provided, and officials would meet with, but not give evidence to, Lord Archer's Inquiry team. The first such meeting then took place on 25 April 2007.

13.58. The perspectives of those involved in the advice and decisions on this issue are set out in their statements and evidence and are not repeated here.[2094] At the invitation of the Inquiry these witnesses have given their views on the statement in the Lord Archer report that:

> *"The Department of Health maintained its view that the Inquiry was unnecessary, and declined to provide witnesses to give evidence in public, but supplied documents which we requested, and responded to questions from us and sent representatives to three private, informal and unminuted meetings."*[2095]

The Brown Administration

Between the publication of the Self-Sufficiency Report and the publication of Lord Archer's report (2006 – 2009) (Cntd)

13.59. After this initial period where the Department's approach to Lord Archer's inquiry was settled, there was a further change of Health Ministers at the start of Gordon Brown's Premiership, with Alan Johnson becoming Secretary of State for Health and Dawn Primarolo taking over from Caroline Flint as Minister of State for Public Health.

[2094] Caroline Flint's first witness statement dated 7 October 2022 (WITN5427001), §§3.120, 3.127, 3.149, 3.267, 3.268, 3.276, 3.271, 3.273-4; Patricia Hewitt's first witness statement dated 28 November 2022 (WITN7420001), §§4.11, 4.20, 4.23, 4.25, 4.40-4.42, 4.46; Lord Warner's first witness statement dated 22 November 2022 (WITN7501001), §5.60; Alan Johnson's first witness statement dated 27 August 2022 (WITN7197001), §§1.12, 2.10; Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §16.2; Baroness Primarolo's witness statement dated 9 June 2022 (WITN5494001), §§3.6-3.7, 3.12, 3.22, 3.23, 3.24, 3.32, 3.35, 3.39-3.40, 3.42, 3.53, 3.84; William Connon's chronology of documents dated 31 August 2022 (WITN6887001), §§3.9-3.11, 3.13, 3.15-3.16, 3.19, 3.23, 3.26, 3.32, 3.34-3.35, 3.42, 3.45, 3.47, 3.54, 3.58, 3.64, 3.74, 3.80, 3.105; and Lord Hunt's witness statement dated 25 November 2022 (WITN4680008), §5.4.
[2095] ARCH0000001.

13.60. Alan Johnson[2096] noted that in early weeks as Secretary of State he received briefing ahead of his appearance before the Health Select Committee on 25 July 2007, receiving advice that was unchanged from that settled under his predecessors and setting out the reasons why successive Secretaries of State had resisted calls for a statutory Inquiry. He accepted that the line (repeated again) that, "*Donor screening for hepatitis C was introduced in the UK in 1991 and the development of this test marked a major advance in microbiological technology, which could not have been implemented before this time*" should not have been so phrased but should have reflected the decision of the High Court in 2001. In overview, he observed:

> *"...on balance I considered that DH's approach to this area was appropriate. I did not feel it was right to rescind previous Governments' decisions not to hold a public inquiry. ... I was aware that Dawn Primarolo was heavily involved in the detail of these issues with officials. I do not recall, and nor do the documents suggest, that DH officials concluded there was a good case to hold a public inquiry and, therefore, such a submission did not reach me. I was also conscious that the matter was being investigated by Lord Archer. On that basis, I did not feel it was appropriate to alter the approach set by my predecessor".*[2097]

13.61. Much of Baroness Primarolo's evidence concerned the question of the response to Lord Archer's recommendations particularly in relation to level of ex-gratia payments under the Macfarlane, Eileen and Skipton Funds and the efforts she made to seek to provide a more positive response to Lord Archer's recommendations. Baroness Primarolo's written statement also summarised for the Inquiry the various strands of argument that were apparent, from her time, for the view against holding a Statutory Inquiry. She noted:

> *"(1) As with other policy issues, on the question of whether to hold an Inquiry, I was provided with information and advice from the Department of Health Officials and legal advisers. The consistent advice was that no new information justifying an Inquiry had become available and that a range of factors militated against holding a statutory public inquiry.*

[2096] Alan Johnson's witness statement dated 30 August 2022 (WITN7197001), §§4.6-4.12.
[2097] Alan Johnson's witness statement dated 30 August 2022 (WITN7197001), §4.18.

(2) The reasons underlying that advice were expressed slightly differently at different times but were principally these:

(i) The Department had carried out internal reports into the events the conclusions of which were not supportive of the need for an Inquiry and were not suggestive of wrongdoing.

(ii) The documents from those reports had been made public.

(iii) There had already been litigation and settlements.

(iv) There were ex gratia payments schemes in place.

(v) The events were historic and there had been significant improvements in blood safety as a result of the lessons learned.

(vi) The costs of an inquiry would be very high (though this was not a factor which particularly persuaded me).

(vii) The legal grounds necessitating an Inquiry in Scotland did not apply to England.

(3) At the time, based on the advice I received, I concluded that the previous decision not to hold a public inquiry should not be rescinded. Had I the slightest inclination that there had been a cover-up, I would not have hesitated to recommend that the previous decisions about a public inquiry be overturned."[2098]

13.62. Baroness Primarolo cited the example of a conversation with an official who appeared to suggest in conversation that the Trusts had been set up because it was very difficult to justify that the Government did not know what was going on and that the Government could have done more to ensure self-sufficiency. She called for an explanation for this because it was contrary to what she had previously been told. She received the response from Liz Woodeson that:

" 3… all the department's paperwork has been trawled through very thoroughly. I have employed staff specifically over the past two years to read every single piece of paper from the relevant files, to catalogue them and to publish them on the DH website. I have recently put up a submission attaching copies of the only papers that we wish to continue to hold back (submission dated 19 March 2009). I don't know if MS (PH) has had time to look at them yet but she will immediately see that they contain nothing of significance.

4. Lord Archer and the patient groups have of course had access to all these papers and we have read them too. None of them have been able

[2098] Baroness Primarolo's witness statement dated 9 June 2022 (WITN5494001), §3.53.

> *to find anything in them which suggests that the Government at the time knew "what was going on" as [the official concerned] puts it, which I take to imply that the Government was hiding something and was negligent in some way. Lord Archer himself, in urging the Government to increase the payments to those affected, specifically states in his report: "We do not recommend that such payments should be construed as an admission of guilt by the Government that previous Governments, or the BTS, were at fault".*[2099]

13.63. Beyond this explanation of the contemporaneous thinking, Baroness Primarolo indicated in her written statement that the holding of this Inquiry had caused her to reflect carefully on the fact that Ministers in her time did not agree to calls for such an Inquiry and she set our her thinking extensively on this.[2100] Counsel to the Inquiry and the Chairman explored these extensively in her oral evidence.[2101] Her reflections included that both the holding of the Archer Inquiry, and the establishment in Scotland of the Penrose Inquiry, to some extent militated against the holding of a UK-wide Statutory Inquiry. In the case of Lord Archer's Inquiry, its conclusion that a full Public Inquiry should have been held much earlier to address the concerns of the haemophilia community fed into the advice that the events were historic, limiting what would be gained by further Inquiry. In the case of the establishment of the Penrose Inquiry in Scotland, Baroness Primarolo noted that the establishment of a Scottish Inquiry added to the political and policy reasons against having an Inquiry that was UK-wide. There was considerable concern (she shared) that a precedent would be set either for a Scottish Inquiry being a backdoor to examining events in England or that, once announced, a Scottish Inquiry would in practice become a UK-wide Statutory Inquiry.

13.64. In a number of aspects Baroness Primarolo's evidence mirrored (though was independent of) the observations made by Mr Milburn concerning the need for a further mechanism for scrutiny (she raised "...*whether the whole model*

[2099] DHSC0041157_011; Baroness Primarolo's witness statement dated 9 June 2022 (WITN5494001), §3.128.
[2100] Baroness Primarolo's witness statement dated 9 June 2022 (WITN5494001), §§5.12-5.24.
[2101] Baroness Primarolo's oral evidence on 23 September 2022, at 109:10-116:11 and 126:20-133:11.

needs to be reviewed"). As with Mr Milburn's evidence, the DHSC understands that this is a matter which the Inquiry may wish to consider further, when looking at recommendations.

Following Lord Archer's report (2009 – 2010)

13.65. In the months following the publication of Lord Archer's report, the Inquiry may consider that the main focus returned to the issue of the level of support provided to the infected and their families.

13.66. In terms of the Public Inquiry issue, while finding that a full public inquiry should have been held earlier, Lord Archer had not recommended that a further, statutory UK-wide Inquiry should be held. In parallel, in furtherance of its engagement with Lord Archer's Inquiry, the Department released into the public domain all bar a very small number of the documents underlying its own reports, and those found in the return and recovery of documents (as set out in Section 12 of these submissions). While many of these were made public in line with FOIA during Lord Archer's inquiry, the release of some came afterwards.

13.67. There was, in particular, a focus on that part of the Government's response to Lord Archer which had rejected any immediate increase in the levels of payment under the Skipton Fund, with the intention that HCV payments should be reviewed in 2014. Thereafter on 6 April 2010, Ms Gillian Merron announced an early review of the Skipton Fund.

13.68. Andy Burnham succeeded Alan Johnson as Secretary of State in June 2009. He reflected on the fact that immediately prior to taking up post as Health Secretary, he had attended the 20th anniversary of the Hillsborough Disaster and, in April 2009, had put forward to the Cabinet (as Culture Secretary) proposals for an independent panel to review that disaster. Shocked at the disclosures made in his meeting with Paul Goggins, Brian Iddon and their

constituents in January 2010, Mr Burnham explained that he asked officials to consider "*...establishing an independent disclosure process of contaminated documents held at the hospital level, and every level above, so that families could at least have answers on some of those troubling questions about the handling of medical records.*"[2102] Mr Burnham explained that the advice he received was that all significant documents were already in the public domain and the disclosure process would not achieve much. He said that at the time he accepted what he was told on this. With the approach of the dissolution of Parliament in 2010, Mr Burnham decided that bringing forward the view of the Skipton Fund "*...was more achievable and would also send a clear sign to the next Parliament that issues related to contaminated blood were not resolved and would need to be looked into further.*"[2103]

13.69. Mr Burnham explained in his written statement his contributions to the House of Commons Debate on 15 January 2015 and what had led him to those views. In a passage since raised with many other witnesses, Mr Burnham said:

> *"I want to bring a new perspective to this debate–that of a former Minister who tried to do something; indeed, a former Secretary of State, because that is what I was at the time. I do not say this to blame any individual in the Department of Health, but more in terms of speaking as I found as I tried to lift the shutters that had been pulled down on an issue that the Department wanted to go away.*
>
> *[...]*
>
> *I do not detect the failure being caused by Members of Parliament or, indeed, Ministers; I have met many who want to resolve this in the right way. I have to say that in my experience the resistance is found in the civil service within Government. That is often the case in examples such as this; I found the same with Hillsborough too. It is very hard to move that machine to face up to historical injustice."*[2104]

[2102] Andy Burnham's witness statement dated 24 June 2009 (WITN7060001), §18.5.
[2103] Andy Burnham's witness statement dated 24 June 2009 (WITN7060001), §18.5; see further his contribution to the debate on 26 March 2015 [RLIT0001575] addressed in his statement at §§20.1-20.8.
[2104] Andy Burnham's witness statement dated 24 June 2009 (WITN7060001) §12.1.

13.70. Mr Burnham's account in his witness statement of the resistance he encountered was in these terms:

> *"During all of my time as Secretary of State, I got the strong impression that the Department did not want the position agreed by my predecessor to be in any way revisited. This much is evident in the advice not to meet protestors and the preparation of "strong defensive lines" for meeting with MPs, but it was also clear in my interactions with civil servants."*[2105]

Drawing on all his wider experience, he also stated that:

> *"From all of the work I had done on justice campaigns, from Bloody Sunday, Hillsborough to contaminated blood, I was clear that the same pattern of events keeps repeating. A major disaster or act of harm happened. The State would form a narrative to protect itself reputationally or financially. It would have access to all the levers of power to entrench that narrative at inquiries or inquests. And then families would be left fighting for years in the wilderness to try and unpick that narrative and get some form of redress. While we could individually help the Hillsborough families or those infected with blood, what was needed was a complete rebalancing of the system to prevent this pattern repeating and recurring long injustices that have scarred this country."*[2106]

And, later:

> *"This brings me back to the view that I had formed in early 2010, without all the evidence at the time, that the official line that the Department of Health had pursued through the 1970s, 1980s and into the Government in which I served, was unsustainable. Looking back, I am concerned that the letter I signed and sent to David Tonkin, prepared by the Department and repeating the official line, was not accurate. I believe there is in fact evidence that it was known that individuals were likely to be infected, with contaminated blood products being given to them. More than that, I believe there is plentiful evidence that, once those infections had occurred, the patients involved were not informed of them. I cannot see how that is anything other than gross and wilful negligence."*[2107]

13.71. Mr Burnham's oral evidence emphasised, amongst other things, his very deep level of concern about inaccurate and misleading government lines that were adhered to rigidly. He regretted not pushing harder at the time for the same sort of independent panel as he achieved in the Hillsborough Independent Panel. He described the active support he felt had from Gillian

[2105] Andy Burnham's witness statement dated 24 June 2009 (WITN7060001) §12.4.
[2106] Andy Burnham's witness statement dated 24 June 2009 (WITN7060001) §21.14.
[2107] Andy Burnham's witness statement dated 24 June 2009 (WITN7060001), §23.12.

Merron and pressing for a commitment to the earlier review of the Skipton Fund where he felt that the approach of officials was totally wrong. Mr Burnham queried whether an independent body could consider whether there was a case for a public inquiry, noting the failure of the parliamentary process currently to achieve this. He felt that this Inquiry was getting to the heart of something wrong with the British establishment – the established structures have too much control and act to maintain the status quo.[2108] He considered the role that could be played by the introduction of a statutory duty of candour as a mechanism for redress.[2109] As with Mr Milburn, Baroness Primarolo and other witnesses who have reflected on the need for change to the process of how decisions are made about the holding of an inquiry, the Department understands that the Inquiry will wish to consider this evidence when looking at recommendations as well as in its wider assessment of the events.

The March Judicial Review

13.72. Immediately prior to the change of government in 2010, on 16 April 2010, judgment was delivered in the High Court in the case of *R(March) v Secretary of State for Health*.[2110] Whilst not directly bearing on the issue of a Public Inquiry, the Department notes that it is linked to the issue of Departmental 'lines' and the accuracy of public statements made, in Parliament and elsewhere, upon the reasons why a compensation scheme for those infected with both HIV and Hepatitis was established in Ireland. Former Ministers have given evidence to the Inquiry that statements made by them reflected advice or briefings given to them by civil servants.[2111] In turn, there is evidence regarding the nature and extent of the steps taken by officials to check the underlying facts, and statements made, with their counterparts in the Irish Department of Health, whether in the context of that

[2108] Andy Burnham's oral evidence on 15 July 2022, at 120:15-123:8.
[2109] Andy Burnham's oral evidence on 15 July 2022, at 123:8-126:24.
[2110] [2010] EWHC 765 (Admin).
[2111] See for example (the list is not complete) Baroness Merron's witness statement dated 29 June 2022 (WITN6603001), §13; Lord Warner's witness statement dated 22 November 2022 (WITN7501001), §5.17-5.32; Anne Milton's second witness statement dated 28 November 2022 (WITN6437002), §§4.6-4.17 regarding the response to the March judgment.

legal challenge or more generally.[2112] The Inquiry is referred to this material, which is not summarised here.

2010 – 2017

13.73. In the coalition Government, Andrew Lansley was Secretary of State for Health between May 2010 and September 2012. Lord Lansley received a briefing on commencement of taking office. In his evidence he stated he did not recall the issue of a public inquiry being raised with him at the time.[2113] Part of his evidence concerned the commitment and intention to bring forward the Review of the Skipton Fund.[2114] His view was that:

> *"During my time in office, we set out substantially to improve the level of payments made to alleviate hardship. Practically speaking, given the limits on governmental (sic) (including civil service capacity), a public inquiry would have resulted in cost and delay to that process, both of which would have been detrimental to the interests of those affected".*[2115]

13.74. Lord Lansley further noted:

> *"… when I was Shadow SoS, this issue was raised at least once with me [details of particular correspondence were then set out]… I responded to her by expressing the Conservative Party's belief that there should have been full engagement with the Archer Inquiry, that we welcomed the Archer Report and that the Government's choice to review financial support in 2014 was arbitrary and essentially unacceptable. However, I do not remember that a policy on whether a full public inquiry was necessary was formulated".*[2116]

13.75. Lord Lansley could not recall giving specific consideration to requests for a public inquiry though he did not seek to suggest he was unaware of such

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[2112] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §4.24 (discussion of the reasons for distinguishing the Skipton Fund from the Irish scheme); Deborah Webb's witness statement dated 2 November 2022 (WITN7409001), §§4.15-4.16; §§4.19-4.21, §§4.25-4.26 and the statement generally. There is also material in Lord Warner's witness statement dated 22 November 2022 (WITN7501001), §§5.15-5.26.
[2113] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §27.2.
[2114] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §§15.4-15.7.
[2115] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §33.2.
[2116] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §26.2.

calls being made. He suggested that the issue had not been put to him for consideration by officials or raised by other Ministers.[2117] In his view:

(1) *"…there was no substantial political drive or debate for such an inquiry"*;[2118]

(2) *"It would be very unusual for a Minister to seek colleagues and the PM's agreements for a Public Inquiry, where other Ministers did not think there was an issue to be examined. I do not remember there being a demand, let alone political consensus, amongst Coalition Ministers that this step was needed".*[2119]

13.76. Lord Lansley noted that he had established the Mid-Staffordshire Public Inquiry under Robert Francis QC (as he then was), in July 2010. Lord Lansley could not recall having received comparable and pressing calls for a public inquiry into the Infected Blood issue.[2120]

13.77. Anne Milton, Parliamentary Under-Secretary for Public Health, has stated:

> *"I knew that a public inquiry might reveal more about what happened at the time but only after several years of investigation and still no additional money would have been allocated to those infected and affected by contaminated blood. My concern with public inquiries was, and still is, that the costs are significant and they take a great deal of time to conduct. I would have liked to have met the families of those infected and affected without a public inquiry so saving not only precious time but also directing the money to where I felt it should go i.e., to those infected and affected."*[2121]

September 2012 to May 2017

13.78. During this period, Jeremy Hunt was the Secretary of State for Health. For the reasons explained in his statement (his direct contact with his constituent, the late Mike Dorricott) Mr Hunt said that he was acutely conscious from the outset of a historic injustice in the contaminated blood

[2117] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §28.3.
[2118] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §29.2; see also the number of inquiries under way at this time – Institute of Government table §13.5 above.
[2119] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §29.3.
[2120] Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §29.2.
[2121] Anne Milton's second witness statement dated 28 November 2022 (WITN6437002), §5.8; see also §5.9.

scandal.[2122] But in his opening comments in his written evidence, Mr Hunt stated that when he became Health Secretary:

> *"… it was made clear to me that the Treasury[2123] would not support an inquiry because of the potential cost to the taxpayer which (taking into account any decisions on financial support which might follow, such as a recommendation for a compensation scheme similar to that in place in Ireland) could amount to billions of pounds. I did not therefore pursue the issue and followed the official government 'line' in correspondence with all campaigners".*[2124]

13.79. In his oral evidence, Mr Hunt accepted that it was ultimately his position that an inquiry should have been established decades earlier; the question was how it could have been "…*established by the establishment*…" that nothing wrong was done and that line was then "… *religiously stuck to by government after government*".[2125] He further stated that lines used in correspondence during his time to justify not having an inquiry were wrong. He considered they reflected the kind of "groupthink" that was in the Government that said, "…*this scandal happened because, you know, good people were trying to do their best, something terrible happened, it wasn't anyone's individual fault, and -- … therefore when it comes to compensation the matter is closed.*"[2126]

13.80. Whilst in his letter to the Prime Minister dated 30 June 2015, Mr Hunt wrote:

> *"Should there be calls for a further inquiry in England, I recommend that they be rejected, as all our documentary evidence will be in the public domain very shortly, and further inquiries would hinder scheme reform".*[2127]

Mr Hunt's explanation for this was that pragmatically, it would be unlikely that major reform to the payment schemes would have been attempted alongside a public inquiry. Since Mr Hunt did not believe that the government position

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[2122] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §0.3.
[2123] See further Jeremy Hunt's oral evidence on 27 July 2022, at 116:8-117:21 as to how this had been made clear to him.
[2124] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §0.4.
[2125] Jeremy Hunt's oral evidence of 27 July 2017, at 135:17-136:17.
[2126] Jeremy Hunt's oral evidence of 27 July 2017, at 119:11-119:18.
[2127] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §43.1; CABO0000163_003.

on an inquiry would change, he stated that he was "*...keen to focus energy on improving the schemes*". Mr Hunt gave evidence, however, that this note to the Prime Minister was not a full reflection of his position (because he was personally in favour of an inquiry).[2128]

13.81. Mr Hunt indicated that essentially the same rationale lay behind his November 2016 letter to Diana Johnson in which he had said that he did not support the establishment of an independent panel or public inquiry as it would *"...detract from the work we are doing to support sufferers and their families."*[2129] In 2016, Mr Hunt said the Treasury were firmly against a public inquiry, and he felt constrained by collective responsibility to defend the public 'line' even though this did not reflect his personal views.[2130]

13.82. In his oral evidence, Mr Hunt further indicated that he thought that 'the machine' was very uncomfortable with the fact that he set up so many independent inquiries but he became aware that he "*...couldn't ask the Department to do these inquiries because that would be like asking them to mark their own homework. So you had to ask someone trusted from outside to look into the issue*." [2131]

13.83. Mr Hunt explained what had led to the change whereby he felt able to seek agreement to the establishment of the Inquiry. Following the 2017 election, the Prime Minister (Theresa May) was due to respond to a debate.[2132] Mr Hunt stated that:

> *"I sensed an opportunity to change the government position. I have no doubt that it was because of the impression made on me by Mike Dorricott over many years. I had felt unhappy about the government position throughout my time in office and thought this could be the moment, with the government distracted and weakened by the election*

[2128] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §43.2b.
[2129] HSOC0029781.
[2130] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §43.4.
[2131] Jeremy Hunt's oral evidence on 27 July 2022, at 138:14-140:2.
[2132] There was initial reference to a PQ but Mr Hunt later clarified that this was in fact a debate not a PQ; it was the debate secured by Diana Johnson MP on infected blood issues.

> *result, to secure justice. I knew that from her response to the Hillsborough families as Home Secretary Theresa May had a strong sense of duty to those whose voices were shut out by the system, but do not know if she consulted the Treasury before making her decision to hold a public inquiry, which to her great credit she did."*[2133]

Mr Hunt confirmed in his oral evidence that, in his view,

> *"The real reason why the Department of Health's position was against a public inquiry was because they thought that the costs of any compensation that was decided by a public inquiry would have to be met from the NHS's budget and that was the heart of it."*[2134]

Asked about the contribution of adverse media, the prospect of matters being raised with the police and fresh legal claims, Mr Hunt maintained that the real thing that caused the "goal to be open" to holding an inquiry was that a debate was going to be held, and that allowed him to approach the Prime Minister with the case that an inquiry was the right thing to do.[2135]

13.84. On 11 July 2017, the Prime Minister announced that a public inquiry would be established to examine the circumstances that led to individuals being given contaminated blood and blood products in the UK.

[2133] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §0.6; see also §42.4; CGRA0001119; and see Further Jeremy Hunt's oral evidence on 27 July 2022, at 123:7-138:8.
[2134] Jeremy Hunt's oral evidence on 27 July 2022, at 127:13-127:18.
[2135] Jeremy Hunt's oral evidence on 27 July 2022, at 131:18-131:24.

Section 14: Financial support and Alliance House Organisations

14.1. The evidence on the financial support schemes has spanned 1987 to the present day and touches on a large number of issues in the Inquiry's list of issues. The Department's submissions address only a portion of this evidence and a sub-set of these issues, and focus on the financial support schemes as they were before reforms in 2017. The Chair is obviously aware that the government responded to his interim recommendations by announcing interim payments of £100,000 for infected beneficiaries and bereaved partner beneficiaries currently registered with the existing schemes, with these payments being made in October 2022.

Purpose/philosophy underpinning financial assistance schemes

14.2. The Inquiry's list of issues asks what the purpose of setting up schemes to provide financial assistance was; what principles or philosophy underpinned their introduction; and, if infections were considered not to have been caused by fault, on what basis it was decided that financial payments should be made. The Inquiry also asks what principles should have been adopted, given the philosophy or purpose underpinning the financial assistance schemes.[2136] These submissions do not address that normative issue. However, the Inquiry may wish to consider practical issues, such as finite funding and financial pressures, when evaluating the purpose, principles or philosophy underpinning the introduction of schemes.

14.3. This section of submissions focuses on the establishment of the Macfarlane Trust and the Macfarlane (Special Payments) Trust ('MSPT'). Brief observations are made about later reforms to the financial payment schemes. The establishment of the Eileen Trust, Skipton Fund and Caxton Foundation are addressed separately.

[2136] Issues 448 – 450 (summarised).

Initial decision to provide financial support

14.4. Each of the Alliance House Organisations[2137] ('AHOs') and the MSPT was established as an ex-gratia scheme. The position is more complicated in relation to the Macfarlane (Special Payments) No. 2 Trust ('MSPT2').[2138] Put in simple terms, this reflected the government's position that infection of those eligible for the schemes did not result from fault on the part of the Department (or those it was responsible for). This section of submissions does not address the correctness or otherwise of that position, and nothing below should be read as doing that.

14.5. Yet payments were made. The evidence suggests the initial decision to provide financial assistance was motivated by the suffering of infected haemophiliacs and family members, by sympathy for their position, and by recognition of the strength of the Haemophilia Society's case for financial support. By late 1987 these factors outweighed the countervailing reasons against providing ex-gratia support.

14.6. A minute from John Moore, Secretary of State for Social Security, to the Prime Minister, dated 24 September 1987, set out reasons against providing *"compensation"* to haemophiliacs infected with HIV from blood products.[2139] He considered it was logically difficult to distinguish these claims from the claims of others damaged in the course of medical treatment; that compensating haemophiliacs would lead to pressure from other groups; and

[2137] Meaning the Macfarlane Trust, Eileen Trust, Skipton Fund, Macfarlane and Eileen Trust Limited, and Caxton Foundation.
[2138] The position is more complicated in relation to MPST2 insofar as the main bulk of payments were made to honour the terms of the HIV litigation settlement, however the settlement was made without an admission of liability. Payments made to non-litigants were ex-gratia.
[2139] Edwina Currie Jones' witness statement dated 9 August 2022 (WITN5287001), §§6.2 – 6.14, set out discussions in the Department in the months before 24 September 1987, including a submission from Tony Newton (Minister of State for Health) dated 26 August 1987 which recommended providing financial support for haemophiliacs infected with HIV (DHSC0004541_079). Her statement also explained that she disagreed with the Department's policy at this time of not providing financial support to this group.

referred to competing demands on limited funding. At this point he had reached the judgment that although:

> *"... all of us must have every sympathy with haemophiliacs who have been infected with the HIV virus, I do not feel it would be wise to set a general precedent by accepting that the Government should provide a special compensation scheme."*[2140]

14.7. In the following weeks there was movement from this position from the Secretary of State. By the end of October 1987 John Moore and Tony Newton (Minister of State for Health) had concluded that *"... the line we have been taking is unlikely to prove politically sustainable"* and that, at the upcoming meeting with the Haemophilia Society, ministers should respond more positively and consider how best to respond.[2141]

14.8. On 3 November 1987 the Secretary of State met with the Haemophilia Society and three young men who were infected with HIV. Dr Roger Moore's oral evidence to the Inquiry was that the accounts given by the three young men were *"... extraordinarily moving"*. The Inquiry has not heard evidence from John Moore (deceased), but Dr Moore explained in oral evidence:

> *"And we listened and we were really moved. I mean, I don't think I've ever seen a minister weep before but John Moore – and we were totally, totally dumbfounded, really. And, anyway, the Haemophilia Society delegation left, and we sat round and it wasn't a question of whether we do anything, it was, you know, what can we do? What actually can we do? And I've never really seen any meeting that's kind of changed direction so quickly or to such great effect as that.*
>
> *And so we – I mean, John Moore was adamant that we had to do something, and we were – had to work out quite what we could do, and that's when – I mean, it took off – it took off then. We were – we couldn't – even then, we couldn't involve the Department in the sort of 'no fault' compensation scheme. We had to say if we are going to compensate this group, or give this group money, then how do we ring-fence it?"*[2142]

[2140] SCGV0000007_050.
[2141] WITN0771209.
[2142] Dr Roger Moore's oral evidence on 18 January 2022, at 95:6-96:21.

14.9. The Chair may consider that the evidence may suggest that, while factors such as the Haemophilia Society's campaign influenced the change in policy, human and sympathetic instincts tipped the balance in favour of providing financial support, in the absence of fault being accepted.

14.10. Having determined that the Department must *"... do something ..."* ministers needed to rationalise this. There was a need to explain, including to the Cabinet and Treasury, why this group of people should be treated differently from others who had suffered injury resulting from NHS treatment.[2143] That entailed 'ring-fencing' this group of people. The Chair is referred to the Secretary of State's paper for the Cabinet Home and Social Affairs Committee's sub-committee on AIDS, in which he wrote *"I believe that we must accept that haemophiliacs face a unique set of problems."* He then identified these. *"The affected haemophiliacs form a distinct, identifiable and finite group, which makes it feasible to devise a one-off solution, which could be defended as a 'special case'".*[2144]

14.11. The evidence indicates that the Department did not view the decision to provide financial support as compensation in response to a legal wrong.[2145] At the Cabinet Home and Social Affairs Committee's sub-committee on AIDS meeting on 10 November 1987 the Secretary of State proposed that up to £10 million should be made available to the Haemophilia Society for distribution in *"...cases of need..."* and relied on the Society's prior experience of dealing with *"...hardship cases ..."*.[2146] A briefing for ministers dated 13 November 1987 referred to *"...the special and urgent needs of this small group of people."*[2147] The Department did not seek to define or assess

[2143] Dr Roger Moore's oral evidence on 18 January 2022, at 96:16-98:6. See also DHSC0014947_034.
[2144] Secretary of State's paper for the sub-committee at JEVA0000021.
[2145] '[I]n response to a legal wrong' is intentionally included here, acknowledging Sir Robert Francis QC's 'Infected Blood Compensation Study' at §2.1.
[2146] CABO0100016_011.
[2147] DHSC0002375_052.

need – when the Macfarlane Trust was established, this was for the trustees.[2148]

14.12. While there has been considerable criticism of using a 'needs-based' approach, and of the means-tested applications process that was associated with it, the Chair may wish to assess the approach in the context of:

(1) The comparison made in the documents that financial assistance for haemophiliacs could be provided in a way similar to the Family Fund, which itself was administered by a charity, the Rowntree Trust (see below at paragraph 14.27, below).[2149]

(2) Wider norms in relation to social security in the late 1980's, following a review of social security support initiated by Norman Fowler (White Paper published in December 1985). So, in 1987 – 1988 a 'Social Fund' was introduced with the intention of providing assistance to individuals on the basis of specific needs or in emergency situations, with the scheme being administered at a local level and decisions on eligibility geared to local conditions.

(3) There was a link between a needs-based approach and the charitable purposes of the Macfarlane Trust (and later, the Eileen Trust and Caxton Foundation). The policy decision that payments would not represent compensation for losses suffered, but instead were to mitigate hardship, implied a needs-based approach. That said, over time this approach shifted towards greater use of lump sum payments and, more recently, to recurrent annual payments.

14.13. In late 1989 the available financial support was added to by a further £19 million (later becoming £24 million). The Chair has heard evidence that the Department planned to make lump-sum payments of £10,000, with the balance being used to enable the Macfarlane Trust *"...thereafter to give more*

[2148] Dr Roger Moore's oral evidence on 18 January 2022, at 102:22-103:5.
[2149] E.g. DHSC0004541_079 and JEVA0000021.

generous help than at present to families in particular need."[2150] However, the lump-sum amount was doubled to £20,000 after the Prime Minister and Virginia Bottomley met Robert Key MP (and Vice-Chair of the Haemophilia Society) and other MPs. They urged a departure from the 'needs-led' approach of the Macfarlane Trust and the payment of substantial lump-sums.[2151] Lord Kenneth Clarke's evidence was that the increase from £10,000 to £20,000 was *"...clearly as a result of the discussion with the PM on 23 November [1989] and in response to the points made by campaigners who saw her and Mrs Bottomley, about the preferences of families."*[2152] These lump-sums were viewed by the Department as part of a package aimed at mitigating suffering and hardship, alongside the Macfarlane Trust's ability to make payments based on need, and social security assistance.[2153]

14.14. The Chair has received evidence about policy and financial considerations that influenced the financial assistance provided to haemophiliacs infected with HIV (and which continued to influence the financial support provided after the Macfarlane Trust was established). It is for the Chair to assess their impact when he examines the principles or philosophy underpinning the schemes. Examples of evidence that the Inquiry may wish to consider:

(1) Lord Norman Fowler's witness statement explained that, while there was sympathy for those infected, when compensation issues were raised, there was a concern about setting a precedent for no-fault compensation and that:

> *"[i]t is very easy to underestimate – or indeed overlook – the intense financial pressures of the time. There was a very significant Treasury-driven concern that establishing a (what would have then been fairly novel) scheme of financial support for a group of patients affected by a medical accident in the absence of negligence could have a floodgates effect.*

[2150] HMTR0000001_012.
[2151] Lord Kenneth Clarke's second witness statement dated 12 July 2021 (WITN0758012), §§34.1 - 34.3, 35 and 36.2.
[2152] Lord Kenneth Clarke's second witness statement dated 12 July 2021 (WITN0758012), §36.2.
[2153] Lord Kenneth Clarke's second witness statement dated 12 July 2021 (WITN0758012), §43.2; and Lord Kenneth Clarke's oral evidence on 28 July 2021, at 183:13 – 183:14.

The move taken later that year towards making a special case for infected haemophiliacs and providing a form of financial support was the right thing to do. The award of 'full compensation' is a very much wider question and certainly would not have been countenanced at that time."[2154]

(2) Lord Kenneth Clarke's evidence that:

"As for the question why a compensation scheme was not set up, we took the view that the Department could not reasonably provide general compensation schemes for all groups of individuals who had suffered from harm as a result of treatment, without proof of negligence. [The statement refers to HSOC0001459]. *But we still tried to make exceptional payments, on a reasonable basis, to provide financial assistance for haemophiliacs who we recognised had suffered and continued to do so. There was a balancing exercise, and we did our best to balance the compassion we all felt with realism both about overall public finances and the demands on those resources from other groups suffering from health-related needs."*[2155]

and

"But we wanted to help, but we had to be cautious."[2156]

(3) Baroness Virginia Bottomley's oral evidence to the Inquiry (in relation to funding for what became the Macfarlane (Special Payments) Trust ('MSPT'):

"…but I was very worried about the precedent. I really did understand this problem that the NHS is trying to do something unique, we're trying to give everybody everything forever for free. No other country in the world does that. We were terribly worried about the litigation taking place in the US and that the whole of the budget could be taken up with litigation, and the hole that defensive medicine – maybe I'm skipping ahead a bit, but this was in my mind, even then, that really was a difficult area….And for a limited amount of resource you want to give the maximum out into improving patient care. And no-fault compensation which it would have led to, inevitably leads to a diversion of a limited budget away from direct patient care."[2157]

(4) Baroness Virginia Bottomley's further evidence:

[2154] Lord Norman Fowler's witness statement dated 17 July 2021 (WITN0771001), §§7.36-7.37. See also the chronology at §§7.1-7.30 which outlines discussions at the time about risks of extending "compensation" outside of negligence-based fault.
[2155] Lord Kenneth Clarke's second witness statement dated 12 July 2021 (WITN0758012), §62.5 and §32.3.
[2156] Lord Kenneth Clarke's oral evidence on 28 July 202, at 140:9-140:11.
[2157] Baroness Virginia Bottomley's oral evidence on 28 June 2022 at 70:24-72:2.

> *"Q: Mr Justice Ognall during his intervention in June 1990, recovered to a moral duty on the state as opposed to legal?* [sic]*...Did you think, and do you think, that there was a moral obligation on the state to do something to provide financial support for people with haemophilia who had been infected?*
>
> *A: I thought I had an even greater moral duty to ensure the resources available for health were used to the best possible effect, and hugely sympathetic, as I was to all those involved and did appreciate the suffering involved, I didn't think that that overrode a wider view that we could not embark on no-fault compensation and the resources needed to be used for the Health Service as a whole.*
>
> *So I am never sure whether the word "a moral responsibility", how helpful it is, because I felt I was trying to behave in as moral a way as I possibly could, every day in office, with all of the conflicting priorities….*
>
> *But, remember, I was talking to different patient groups who had no compensation, no ex gratia payment."*[2158]

(5) David Mellor's recognition (in the context of the HIV litigation) of the *"...awfulness of HIV"*[2159] and his acceptance when giving oral evidence that there was a *"...broad political or moral responsibility that rested..."* [2160] with the Department; but there were also concerns about opening the door to no-fault liability across the NHS.[2161]

(6) Lord William Waldegrave's evidence:

> *"The early concern that providing payments to the blood transfusion patients would be moving closer to no-fault compensation was heightened by the Parliamentary Bill, originally introduced by Harriet Harman and then taken up by Rosie Barnes, for the award of compensation for mishaps during NHS treatment without having to prove negligence."*[2162]

and

> *"Viewed in hindsight, it may be easy to say that the similarities between the haemophiliacs infected with HIV and those infected through blood transfusions were so great that they deserved parity of treatment and that the unsustainability of this distinction should have been recognised and acted upon sooner. However,*

[2158] Baroness Virginia Bottomley's oral evidence on 28 June 2022, at 185:5-185:25 and 187:11-187:13.
[2159] David Mellor's oral evidence on 19 May 2022, at 85:23.
[2160] David Mellor's oral evidence on 19 May 2022, at 80:20-80:24.
[2161] David Mellor's oral evidence on 19 May 2022, at 81:2-85:25.
[2162] Lord William Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.110.

> *that is to overlook the considerable force of the contemporaneous pressure that widening the policy would be an unacceptable step towards no-fault compensation, the Parliamentary majority being against such compensation. It was far from straightforward to achieve the further change in policy at the end of 1991 / early 1992…even when the campaign had increased the pressure considerably."*[2163]

Subsequent developments to financial support schemes

14.15. This section of submissions aims, in a limited way, to assist the Chair in relation to subsequent developments, reviews and reforms of the financial support schemes.

14.16. The Chair is aware that the "*Scheme of Payments for those Infected with HIV through Blood or Tissue Transfer*" was announced in February 1992 and the Eileen Trust was set up in March 1993. Submissions on how that came about, any why, are at paragraph 14.42 below.

14.17. Similarly, from paragraph 14.60 below, factors relevant to the Skipton Fund being established are identified, including the Secretary of State for Health's announcement that the scheme was being introduced on *"…compassionate grounds…".*[2164]

14.18. In late 2010 the Department announced and undertook a *"Review of the Support Available to Individuals Infected with Hepatitis C and/or HIV by NHS-Supplied Blood Transfusions or Blood Products and their Dependents".*[2165] The Review's key aims were to enhance the payment arrangements for those with HCV and work towards greater parity in HCV and HIV arrangements, thus reducing anomalies in payments.[2166] Through the AHOs (including the new Caxton Foundation) the Department sought to

[2163] Lord William Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.116.
[2164] NHBT0015207_002.
[2165] Written ministerial statement at DHSC5222778 and the Review at WITN4509006.
[2166] As per Dr Ailsa Wight's first witness statement dated 20 June 2022 (WITN4509001), at §63.

have a mix of lump sum and flat rate payments; along with additional discretionary payments for those in greatest need; and an extension of HCV-related payments in respect of those who had died before 29 August 2003. The Department's view was that this could provide some of the financial certainty that campaigners had asked for (although not the large financial settlement that many would have liked).[2167] Again, decisions were made in a climate of funding pressures.

14.19. This review led to an oral statement by Andrew Lansley (Secretary of State for Health) on 10 January 2011, in which he announced changes to the schemes for financial support and also expressed *"...deep regret for the pain and misery that many [had] suffered..."*.[2168] The Chair is aware that the Caxton Foundation was subsequently established. As explained below from paragraph 14.88, a key aim of the Caxton Foundation was to try to create parity, fairness and transparency across the HIV and HCV AHOs.

14.20. The Chair is aware that further reforms to financial support were examined in 2015 – 2017, leading to the establishment of the English Infected Blood Support Scheme ('EIBSS') and the other devolved administration support schemes. While these reforms did not re-design the schemes entirely, a fundamental principle underpinning decision-making was that existing AHO beneficiaries *"...should not be financially worse off under the reformed support scheme"*.[2169] Other principles behind these reforms and shaping the policy, are set out in the witness statement of Donna McInnes,[2170] and in the Department's 2016 and 2017 consultation documents.[2171]

[2167] Ministerial submission dated 7 December 2010 (DHSC0003814_090).
[2168] ARCH0001478.
[2169] William Vineall's second witness statement dated 29 April 2021 (WITN4688003), at §99. See statement from Nicola Blackwood, Parliamentary Under Secretary for Health, in a House of Commons debate on 24 November 2016 (WITN4688036 at page 23).
[2170] Donna McInnes' witness statement dated 22 December 2021 (WITN5737001).
[2171] "*Infected blood: reform of financial and other support*", published in January 2016 (CVHB0000041); "*Infected blood: government response to consultation on reform of financial and other support*", published in July 2016 (WITN3953052); "*Infected blood: consultation on Special Category Mechanism and financial and other support in England*", published in March 2017

Support for haemophiliacs infected with HIV

14.21. Financial support for haemophiliacs infected with HIV from blood products was provided through the Macfarlane Trust, a charity; through the MSPT, a discretionary trust established to make lump sum payments of £20,000; and through the Macfarlane (Special Payments) Trust No. 2 ('MSPT2'), which delivered the lump sum payments agreed under the HIV litigation settlement. This section of submissions seeks to assist the Chair with three issues relating to the provision of this financial support, namely:

(1) The bodies used to make payments;

(2) Eligibility for payments; and

(3) The transfer of the Macfarlane Trust's assets to the Terrence Higgins Trust ('THT').

Funding is addressed separately from paragraph 14.94 below.

The bodies used to make payments

14.22. The Inquiry's list of issues asks why payments were made by *"... (allegedly) arms-length bodies rather than directly by the Government..."* and *"...why some payments were made via a charitable trust..."*[2172] This section of submissions seeks to assist the Chair with addressing these questions in respect of the Macfarlane Trust and MSPT. For clarity, none of the AHOs was a 'Next Steps Agency' (now an Executive - Non Departmental Public Body), which was a specific category of central government public body.

14.23. The Macfarlane Trust: On 15 July 1987 Tony Newton and Edwina Currie agreed that a minute would be sent to the Secretary of State seeking approval for officials to carry out further investigations on possible options for compensation (in the sense of financial support) for haemophiliacs infected

(WITN4688037); and "*Government response to consultation on Special Category Mechanism and other support in England*", published in October 2017 (WITN4688038).
[2172] Issue 457.

with HIV through blood products. Both ministers favoured the idea of giving the Haemophilia Society a sum of money to distribute as it thought best.[2173] Tony Newton then minuted the Secretary of State on 26 August 1987 setting out two options for providing financial assistance: (1) giving a lump sum payment to all those infected, with total expenditure of £10 million; or

> *"[2] to give a lump sum, perhaps £3 million to the Haemophilia Society to administer and distribute to cases of need on the lines of the Family Fund. This individual amount would depend on the level of need, and how many such people were identified. This Fund, which was introduced in Keith Joseph's time, is administered for use by the Rowntree Trust and makes one-off grants to families with disabled children, eg for washing machines."*[2174]

14.24. For reasons explained below, Tony Newton preferred the second option (ultimately £10 million was provided, not £3 million).

14.25. These options were repeated in a memorandum, dated 4 November 1987, from the Secretary of State to the Cabinet Home and Social Affairs Committee's sub-committee on AIDS, albeit that option (1) stated that a once and for all lump sum would be given directly by government; and option (2) proposed giving £10 million to the Haemophilia Society. The Secretary of State explained that:

> *"The second option is particularly attractive as it minimises Government intervention; and it would be consistent with the policy of not accepting any direct responsibility for damage caused in this way. The Haemophilia Society already administers a small hardship fund (financed by voluntary donations etc) and currently spending at a rate of £3,000 per month, mainly on those suffering from AIDS. They thus have experience in targeting relief to haemophiliacs and their families."*[2175]

The Secretary of State sought agreement from this sub-committee to do further work on exploring option (2). The sub-committee's discussions recorded *"... [i]t was probably right for the proposed scheme to be administered by the Haemophilia Society..."* and noted it had

[2173] Minute of meeting at DHSC0004541_183 and witness statement of Edwina Currie dated 9 August 2022 (WITN5287001), §6.2
[2174] DHSC0004541_079.
[2175] JEVA0000021. See also David Watters' witness statement dated 18 January 2021 (WITN3429001), §§156-157, in relation to the hardship fund.

"...substantial experience in dealing with hardship cases..." (while also recording that the Secretary of State should satisfy himself so far as possible that the Society would be capable of taking on this task and ready to take the hard decisions necessary to ensure that financial help was focussed on those with the most pressing needs).[2176]

14.26. Shortly afterwards it was agreed at meetings with the Haemophilia Society that a special fund of £10 million would be established and the Society would be involved in the administration of this fund.[2177] On 16 November 1987 Tony Newton announced in the House of Commons that an ex-gratia grant of £10 million would be made to the Haemophilia Society, *"...to enable it to establish a special trust fund. It will be able to make payments to the affected individuals and families throughout the United Kingdom, and to do so with greater flexibility than could readily be achieved in any other way."*[2178]

14.27. The Chair may consider that the evidence suggests:

(1) Amongst its options the Department did consider providing equal lump sum payments that would be given directly by government.

(2) However, the preference was for a fund distributed on the basis of need. The Family Fund was seen as a precedent for this. It had been established in 1973 by the then-Secretary of State for Health and Social Services against a backdrop of public campaigning on behalf of families affected by the thalidomide drug, and provided money to help families caring for a disabled child. The Family Fund operated as part of a charity, the Joseph Rowntree Foundation.

(3) An advantage was perceived in the Haemophilia Society being involved in administering the fund, given its experience of targeting relief to haemophiliacs and their families. The initial £10 million was first paid to

[2176] Minutes of the sub-committee on AIDS of the Cabinet Home and Social Affairs Committee, on 10 November 1987 (CABO0100016_011).
[2177] DHSC0002375_007 and DHSC0002375_008. See also Edwina Currie's witness statement dated 9 August 2022 (WITN5287001), §6.36.
[2178] LDOW0000241.

the Haemophilia Society because the Macfarlane Trust did not yet exist (and it made payments for a short period). The Haemophilia Society was involved in setting up the Macfarlane Trust and then appointed the majority of its trustees. Reverend Alan Tanner, who was Chair of the Haemophilia Society, became Chair of the Macfarlane Trust

(4) The Haemophilia Society was willing to work with the Department to set up this special needs trust.

(5) The funds being administered by a body outside of government was viewed as consistent with the government's position that it was not directly responsible for haemophiliacs becoming infected. The Chair is aware of the concern, at this time around the possible introduction of no-fault liability.

14.28. When considering the decision to establish a charity to make payments, the Chair may also wish to consider:

(1) Edwina Currie's evidence:

"If applicants were to be paid according to their financial needs, then that would require means-testing, would be slow and bureaucratic and expensive to administer…. If instead the scheme gave everyone a lump sum, that could be done quickly, but then inequity was inevitable: some would need it more, others less so. The same issues plagued the Chancellor during the recent COVID pandemic. In 1987 however we had little experience of administering such a scheme, there were no computers, and it seemed best to entrust the Haemophilia Society, who were likely to be most sympathetic, with the administration of the scheme with the funds being provided by us".[2179]

(2) Dr Rowena Jecock's evidence:

"Despite these tensions, I nevertheless understood why DH chose to use "arms-length" vehicles to provide support for people whose health had been seriously harmed; other examples include the Thalidomide Trust and the vCJD Trust. I felt that when I was working at DH that the Department had neither the skills nor the resources to deliver services directly itself. Furthermore, the great benefit of a charitable vehicle was that available funding could be prioritised for those whose need was

[2179] Edwina Currie's witness statement dated 9 August 2022 (WITN5287001), §6.53.

> *greatest — although I accept that this process of determining relative needs was unpopular."*[2180]

14.29. MSPT: On 29 November 1989 officials informed Virginia Bottomley (then Minister of State for Health) about Charity Commission advice that the Macfarlane Trust could not distribute the lump sum payments of £20,000 that were intended by the Department, because its trust deed required trustees to take account of need. Two options were considered. The first option was for the Department to set up a new trust. That would be legally separate from the Macfarlane Trust but would have clear associations with it, and could have trustees in common. The submission stated that:

> *"Ministers may regard this as presentationally desirable. Having the same administrators could also help speed up the payments and would avoid duplication of effort, e.g. in validating claims by the new trust."*[2181]

14.30. The second option was for the government to make the payments directly. The submission explained this could theoretically provide more effective control but the actual control would depend on how claims or applications were validated. It pointed out that undertaking this *"...validation..."* would entail much more work and would delay payments.[2182]

14.31. Lord Kenneth Clarke's written evidence explained that the points in favour of creating a new trust were taken as considerable and the Department would not have been able to use the Macfarlane Trust's existing records on the grounds of confidentiality: "...[i]*t was for that reason that the creation of a new trust was preferred to direct departmental control of payments.*"[2183] The Macfarlane Trust's annual report for year end 31 March 1990 recorded that the trustees were willing to take on the extra work of the MSPT for the benefit of the registrants and *"...thus to preserve the confidentiality of Trust*

[2180] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), at §13.8.
[2181] DHSC0003849_065. See also Baroness Virginia Bottomley's witness statement dated 9 June 2022 (WITN5289001), §4.32.
[2182] DHSC0003849_065 at §5.
[2183] Lord Kenneth Clarke's second statement dated 12 July 2021 (WITN0758012), §38.5.

records".[2184] The Chair will be aware of the importance of confidentiality of personal information at this time.

Eligibility for payments

14.32. The Chair has heard evidence about eligibility for financial support for haemophiliacs infected with HIV and affected family members. The Department seeks to assist with a small number of issues arising from this evidence.

14.33. The Chair is familiar with the 'objects' clause of the Macfarlane Trust deed (clause 4), which effectively set out the eligibility criteria for support from the Trust.[2185] It was for the Macfarlane Trust trustees to determine whether an applicant was eligible for payment(s), although clearly the level of funding provided by the Department influenced the payments actually made. The evidence suggests that the Department did not issue guidance on the meaning of 'need' or how that should be interpreted. In his oral evidence Dr Roger Moore said:

> *"I think it [the fund] was intended to be "welfare" so therefore it was to be distributed in accordance with a level of need, rather than to be distributed per capita to everybody. But I don't think the Secretary of State specified what, or defined "need" particularly. It was the Macfarlane Trust that I think interpreted it quite rigorously, but I think they had the capacity to have made a higher threshold, if you like."*[2186]

14.34. The Department wanted the Macfarlane Trust to make progress with distributing payments to infected haemophiliacs and their families. Media reports in October 1988 that the Trust had only paid out £132,000 drew the

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[2184] MACF0000045_029.
[2185] MACF0000003_064.
[2186] Dr Roger Moore's oral evidence on 18 January 2022, at 102:23 – 103:5. A minute from an official to the Secretary of State, dated 17 November 1988, also said that trustees were "*...concentrating on meeting financial need which they are interpreting as alleviating poverty*" (DHSC0020286). There is evidence that the Macfarlane Trust trustees in later years received legal guidance on the meaning of need: see the "Trustee Information" pack prepared by Berwin Leighton Paisner in 2008 which advised that need *"...refers to financial need. Financial need is not an absolute term and the Trustees have a discretion as to how to assess whether a person is in need. However there must be some form of objective assessment"* (MACF0000018_024).

attention of the Minister of State who expressed the *"...personal view...that the Trust is being over-cautious in its approach"* (emphasis in original).[2187] However, ministers did not intervene, recognising that the Trust was an independent charity. The Minister of State did ask for 2 monthly updating reports, aiming to assure himself that the *"...work of the Trust was proceeding expeditiously"*.[2188]

14.35. The MSPT was established on 29 January 1990.[2189] The Trust deed stated it was for the primary benefit of those persons suffering from haemophilia who, as a result of receiving infected blood products in the UK, had been infected with HIV (the "*Primary Class*"). The categories of possible beneficiaries (the "*Available Beneficiaries*") was wider, including the Primary Class, any dependent of the Primary Class or any person entitled under the will or intestacy of a deceased member of the Primary Class. (Peter Stevens' evidence that the MSPT payment was only available to infected individuals is mistaken.[2190])

14.36. Again, eligibility was set out in the Trust deed. The MSPT report and accounts for the period ending 30 September 1991 explained that:[2191]

(1) From the time of their nomination on 29 November 1989 the trustees had played an active part in drafting the MSPT deed and in developing administrative procedures.[2192] Other documents suggest that the Macfarlane Trust solicitors drafted at least some of the Trust deed.[2193]

(2) Trustees' discretion did not apply to the amount of any payment.

[2187] WITN0758023. See also Lord Kenneth Clarke's second witness statement dated 12 July 2021 (WITN0758012), §28.10.
[2188] David Mellor's witness statement dated 25 April 2022 (WITN7068001), §3.19(b).
[2189] Trust deed at MACF0000003_058.
[2190] Peter Stevens' witness statement dated 29 April 2019 [(WITN3070001), §23.
[2191] HSOC0013352.
[2192] See also WITN0758050.
[2193] Letter from John Canavan at the Department to John Williams, administrator at the Macfarlane Trust, dated 19 January 1990 at MACF0000003_047.

(3) However, trustees did make decisions about whether or not a payment should be made (i.e. whether an applicant was eligible), and to whom a payment should be made. They could decide whether a lump sum payment should be split between two or more beneficiaries.

(4) Decisions about whether a person was eligible were *"...largely straightforward..."* as the same verification process was used as for the Macfarlane Trust and the trustees had access to those records.

(5) 93% of all payments had been made by the end of March 1990.

(6) The trustees considered that the work of the MSPT was complete as far as possible at the time. The Trust would therefore sit dormant but would not be wound up to take account of the possibility of future applications.

Transfer of assets and liabilities to the Terrence Higgins Trust

14.37. The Chair may be considering the appropriateness of the Macfarlane Trust's decision in late 2018 to transfer its assets and liabilities to the THT.[2194] In December 2018 Alasdair Murray, interim CEO of the Macfarlane Trust, wrote to Jackie Doyle-Price (Parliamentary Under Secretary for Public Health) notifying her this step had been taken. It was the Department's understanding that, under the Macfarlane Trust's deed, this decision did not require its input.[2195] Jackie Doyle-Price's evidence was that she had no control over this decision.[2196]

14.38. Clause 14.2 of the consolidated Macfarlane Trust deed, dated 30 April 2012, provided:

> *"In the event of dissolution, any part of the Trust Fund remaining after the satisfaction of the Charity's debts and liabilities shall not be paid or distributed among the Trustees but shall be applied in one of the following ways with the consent of the Founder:*

[2194] Issue 492 on the Inquiry's list of issues.
[2195] DHSC0050006.
[2196] Jackie Doyle-Price's witness statement dated 8 March 2022 (WITN6650001), §16.

14.2.1 to one or more bodies established for Charitable Purposes within, the same as or similar to the Objects

14.2.2 directly in furtherance of the Objects."[2197]

14.39. Prior to this making the transfer to the THT, the Macfarlane Trust had taken legal advice about disposal of residual funds. This was summarised in a report to the Macfarlane Trust board for a meeting on 1 November 2018.[2198] It appears the advice was that the Secretary of State's consent to transfer funds (i.e. an application of clause 14.2) was only required following a formal decision by trustees to wind up the charity, whereas a transfer of funds to another organisation prior to the charity closing could be decided on by trustees alone, subject to *"...being in line with the objects in the Trust's Deed..."*.

14.40. The Macfarlane Trust's assets were transferred to the THT by a deed of gift on 11 December 2018, i.e. before the Macfarlane Trust was wound up.[2199] The Terrence Higgins' annual report 2019 reported that the funds received from the Macfarlane Trust were treated as restricted funds, to be used to support beneficiaries that the Macfarlane Trust was set up to work with.[2200]

14.41. In light of this, the Chair is invited to consider whether the appropriateness or otherwise of the transfer of assets and liabilities is an issue for the Macfarlane Trust.

Support for non-haemophiliacs infected with HIV

14.42. This section of submissions addresses the timing of the introduction of financial support for non-haemophiliacs infected with HIV, the application of

[2197] WITN3078002.
[2198] MACF0000028_045.
[2199] Ian Green's (Chief Executive of THT) witness statement dated 24 April 2019 (WITN3075001), §7.
[2200] RLIT0000493, at pages 35 and 74.

the undertaking to this financial support, and eligibility for the "*Scheme of Payments for those Infected with HIV through Blood or Tissue Transfer*".

Timing of introduction of financial support

14.43. The Inquiry's list of issues asks whether a scheme for financial assistance should have been established earlier than it was.[2201] The following submissions seek to assist the Chair with identifying the reasons behind the timing of the introduction of financial support for those infected with HIV via blood or tissues, or non-haemophiliacs infected via blood products.[2202] For simplicity, in this section this is referred to as infection of non-haemophiliacs with HIV.[2203]

14.44. It is suggested that the key departmental evidence on this issue comes from William Waldegrave, Secretary of State for Health from November 1990 to April 1992. The extension of financial support was announced on 17 February 1992. The "*Scheme of Payments for those Infected with HIV through Blood or Tissue Transfer*" (the 'Scheme of Payments'), which applied to those who had received treatment in England, Wales and Scotland, was set up to:

> *"...extend the payments already provided for HIV infected haemophiliacs to non-haemophiliacs who acquired HIV in the course of receiving treatment by blood or tissue transfer or blood products."*[2204]

A similar scheme was set up in Scotland.

14.45. The declaration of trust for the Eileen Trust was then made on 29 March 1993.[2205] This was intended to replicate the 'needs-based' payments made by the Macfarlane Trust.[2206]

[2201] Issue 451.
[2202] See §1.1 of the "*Scheme of Payments for those Infected with HIV through Blood or Tissue Transfer*" at EILN0000016_001.
[2203] No disrespect is intended by this abbreviation.
[2204] EILN0000016_001 at page 4.
[2205] Declaration of trust at EILN0000016_017.
[2206] EILN0000016_001: the Scheme of Payments refers to this as a "*special needs fund*" at §4.1.

14.46. The conduct and settlement of the 'HIV litigation' is addressed elsewhere in these submissions. However, the timing and challenges of settling that litigation (including the challenge of securing funding for the settlement) provide context for the timing of the introduction of Scheme of Payments. The Chair may consider that the following factors are relevant:

(1) Non-haemophiliacs infected with HIV did not immediately receive the same financial support because the lump sum payments made to haemophiliacs arose out of the HIV litigation.[2207]

(2) Lord Waldegrave's written evidence described the considerable force of contemporaneous pressure that widening the policy would be an unacceptable step towards no-fault compensation and that the Parliamentary majority was against such compensation. His evidence was that this concern was heightened by the Parliamentary Bill directed at compensating for injuries arising from NHS treatment without proving negligence (originally introduced by Harriet Harman and taken up by Rosie Barnes).[2208]

(3) Having reached a decision that the HIV litigation should be settled, and having gained permission from the Treasury in the face of considerable concern about setting a precedent for no-fault compensation, it was Lord Waldegrave's evidence that *"...there was little real alternative in practice other than, initially, trying to hold the line"*. However, this was being kept under review.[2209] On the same date as the Secretary of State agreed to the sending of the government's final offer in the HIV litigation, he asked for a detailed note on the position of non-haemophiliacs infected with HIV. That submission (dated 23 April 1991) stated that the Treasury would strongly resist extending financial support and that the real difficulty

[2207] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001), §4.109.
[2208] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001), §§4.109-4.110. In addition, a briefing to William Waldegrave, dated 29 January 1991, stated at §4 that "[a]*ny extension beyond haemophiliacs would make it harder to resist general "no fault" compensation for medical accidents and would undermine the Government's stance on the Rosie Barnes bill"* (DHSC0041437_018).
[2209] William Waldegrave's statement dated 28 April 2022 (WITN5288001), §4.115.

would be re-establishing a credible ring fence if the scheme was extended.[2210]

(4) Lord Waldegrave had *"…significant doubts…"* about whether attempts to change policy would have been successful if made considerably earlier and, *"…still less if this had been attempted in parallel with the settlement of the haemophiliac HIV litigation"*.[2211] He has reflected that trying to extend the payment scheme from the outset *"…may have risked losing the argument for haemophiliacs"*.[2212] His evidence was that the timing of bringing arguments about extending financial support to the Treasury needed to be carefully considered.[2213] An earlier minute, dated 21 July 1988, from Dr Moore to Tony Newton's private secretary and others observed that there was no existing provision in that year for any level of funding for financial support for non-haemophiliacs infected with HIV and that *"[t]he assurances given to HM Treasury about the haemophiliacs' unique treatment make their response to a request for additional funding predictable."*[2214]

(5) By the end of November 1991 the Secretary of State concluded it was the right time to approach the Treasury with the case for changing policy and extending financial support, and had an informal conversation with David Mellor, Chief Secretary in the Treasury. By letter dated 2 December 1991, the Secretary of State wrote to David Mellor, setting out his view that the needs of non-haemophiliacs infected with HIV, and the needs of their families, should be

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[2210] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001), §4.115; and DHSC0003662_080 and DHSC0003560_051.
[2211] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001), §4.116.
[2212] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001), §8.6. See also Lord William Waldegrave's oral evidence on 5 July 2022, at 146:20 – 147:16, when he said the chances of getting agreement to settling the HIV litigation would have been zero if he had sought to widen the *"…perimeter…"*.
[2213] Lord William Waldegrave's oral evidence on 5 July 2022, at 167:10 – 167:15. See also Dr Roger Moore's oral evidence on 18 January 2022, at 109:8 – 109:16, when he said he did not think the Department could have gone back to the Treasury in 1988 seeking further funds for non-haemophiliacs infected with HIV when the Treasury had just provided £10 million.
[2214] DHSC0003960_006 at §10.

recognised in the same way as haemophiliacs. He proposed a way of funding this, with some recourse to the Treasury's Reserve.[2215]

(6) David Mellor's reply expressed reservations about this policy change, referring to the difficulty of ring-fencing such payments and suggesting this would be a "*...long stride towards no-fault compensation in general.*"[2216] In the end, the Treasury withdrew its objection to the extension but did not contribute to funding the policy change. However, approval for the spending was still needed from the Treasury.[2217] The Prime Minister also provided support for a change in policy.[2218]

(7) Lord Waldegrave's reflective evidence is that the Department responded efficiently to his wish to change policy, while "*quite properly*" warning of the risks of doing so.

14.47. The Chair may also wish to consider the wider context described by Lord Waldegrave in his written evidence, that:

> *"It is hard now to describe fully the enormous pressures on the Department at the time with the fundamental reforms of the structure of the NHS, the Health of the Nation public health campaign, issues around pay for doctors, nurses and dentists and many other matters, including preparation for what were expected to be heavy casualties in the war which was known to be coming in the Gulf."*[2219]

14.48. The Inquiry has considered the length of time taken to establish the Eileen Trust. There is limited evidence about events between February 1992 and March 1993. Baroness Bottomley's evidence was that there are "*...a lot of difficulties setting up trusts...*" (giving the example of the MSPT) and it appeared there was a lot of work to do to establish the Eileen Trust. However, she also reflected that this seems to have taken longer than it

[2215] DHSC0002921_009.
[2216] HMTR0000003_051.
[2217] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001), §§4.134 and 4.146. See also David Mellor's oral evidence on 19 May 2022 at 182:14-183:1.
[2218] Lord William Waldegrave's oral evidence on 6 July 2022 at 34:11-34:16.
[2219] Lord William Waldegrave's statement dated 28 April 2022 (WITN5288001) at §8.7.

should have. Her evidence was that she was not receiving feedback or complaints about from Parliamentarians about this passage of time.[2220]

The undertaking

14.49. The Inquiry's list of issues asks why ex-gratia payments for HIV infection were made conditional on waiving rights to bring further proceedings in respect of infection with HIV or HCV and whether that was appropriate.[2221] The HIV litigation and the terms of the undertaking are addressed at section 11 of these submissions. This short section of submissions is intended to assist the Chair with the application of the undertaking to non-haemophiliacs infected with HIV.[2222]

14.50. As set out above, the purpose of the Scheme of Payments was to extend the payments already provided to haemophiliacs to non-haemophiliacs infected with HIV. Dr Rejman, who was involved in designing the procedure for applications to the Scheme of Payment, has explained that:

> *"The undertaking was included to mirror the undertaking in the settlement of the HIV litigation… My understanding is that the two schemes were to be as similar as possible."*[2223]

14.51. A Ministerial submission, dated 20 February 1992, sent to William Waldegrave gave an outline of the Scheme of Payments (and also recommended having a 'needs-based' fund).[2224] The submission's annex referred to the fact those receiving payments under the Scheme of Payments would be required to enter into an undertaking not to take legal action in certain circumstances. Lord Waldegrave could not recall if he considered this in detail at the time but said that, if he had, he thought he would have understood that this Scheme was to be a parallel to the financial

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[2220] Baroness Virginia Bottomley's oral evidence on 28 June 2022, at 138:1-139:12.
[2221] Issue 488.
[2222] The terms of the undertaking are at §9 and Annex C of the Scheme of Payments (EILN0000016_001).
[2223] Dr Andrzej Rejman's third witness statement dated 27 April 2022 (WITN4486040), §103.1
[2224] Submission at NHBT0015117_001 and annex to submission at DHSC0002642_004.

support for haemophiliacs.[2225] A submission dated 13 April 1992 to the private office of the new Secretary of State, Virginia Bottomley, explained that this financial support scheme was based on the litigation settlement for haemophiliacs and the same provisions had been made, where appropriate; and that comments from various individuals and bodies had been taken into account, including the two lead firms of solicitors acting for blood transfusion recipients.[2226]

Eligibility for the Scheme of Payments

14.52. Eligibility for payments was to be determined in line with the criteria and procedure in the Scheme of Payments (which was, in effect, the 'gateway' to payments from the Eileen Trust).[2227] When the Scheme of Payments was being drafted, it was recognised that establishing eligibility in some cases was likely to be more difficult than in cases involving haemophiliacs. It was decided that the balance of probabilities should be when applied when considering the source of infection. The Department put in place a system whereby a Panel would consider difficult cases (on causation or the category into which a person fell) or cases where the applicant was unhappy with his/her application being rejected.[2228]

14.53. At least in the earlier years of the Scheme of Payments, where necessary, departmental officials undertook investigations aimed at gathering more information about a person's application. For example, Dr Rejman recalls travelling to hospitals to look at an applicant's medical records.[2229] Bearing in mind the small numbers of applications being made, this could be done by an official, if needed.

[2225] Lord William Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §4.153. He also said he would not have seen a provision about the cessation of future legal action (save in cases of individual negligence) as being unusual, and referred to the reasons given in relation to the HIV litigation (at §§4.94 – 4.96 of his statement).
[2226] SCGV0000238_025 and annex at NHBT0015113_001. See also Baroness Virginia Bottomley's witness statement dated 9 June 2022 (WITN5289001), §6.37.
[2227] EILN0000016_001.
[2228] EILN0000016_001, at §8.
[2229] Dr Rejman's oral evidence on 11 May 2022, at 49:5 – 50:17.

14.54. The Chair has received evidence that there was no specific 'cut-off' date before which HIV infection had to have occurred in order to be eligible. A ministerial submission for William Waldegrave, dated 20 February 1992, stated that, while most HIV infections would have occurred between 1979 and October 1985 when testing was introduced, "*...it would be difficult to apply a cut-off date...*" and "*...we think it would be better to leave the scheme open rather than fix a closing date which might result in hard cases. However, claims of infection from blood or tissue after 1985 would have to be examined particularly closely in view of the safeguards then in place.*"[2230]

14.55. As stated, a Panel was set up. This had a legal chair (a Silk) and two medical assessors.[2231] The Panel rules provided for an oral hearing, with an entitlement to legal representation[2232] (although it is not clear how often this occurred). By 2009, Dr Rowena Jecock did not recall this Panel operating and recalled only a very small number of new applications were being made. At that time it was proposed that the Blood Service should become involved in determining new applications. Later in 2015, it appears the Department sought the help of a clinician to assist with assessing the cause of HIV infection.[2233]

14.56. As the Chair is aware any new applications are now decided by EIBSS.

Support for those infected with HCV (via the Skipton Fund)

Timing of introduction of financial support

14.57. The Chair has received evidence about pressure to provide compensation or financial support to those infected with HCV via blood products, transfusions, or tissue/ organ transplants. For many years the Department's policy

[2230] NHBT0015117_001.
[2231] EILN0000016_001 at annex B, §1.
[2232] EILN0000016_001 at annex B, §§6-7.
[2233] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §§14.15-14.22.

position was against this. A number of departmental witnesses have addressed the underlying factors involved, among them Baroness Jay, Dr Graham Winyard and Mr Alan Milburn (Secretary of State for Health from October 1999 to June 2003). Mr Milburn explained:[2234]

(1) The general principle that compensation for injury sustained through NHS treatment was usually only provided where there was fault.[2235] The Chair has received extensive evidence on the significance attached to this principle over the years.[2236] Alan Milburn's evidence was that he had asked the CMO to consider these issues as part of his review of the clinical negligence system. The CMO rejected a 'no-fault' approach in a June 2003 report, which set out proposals for a scheme of redress in the NHS. The Chair may wish to refer to Alan Milburn's oral evidence on how concerns about the introduction of no-fault compensation related to legal advice about the vulnerabilities of the National Blood Authority's defence in *A v NBA*.[2237]

(2) The risk that providing financial support for HCV sufferers would lead to similar claims for other groups.[2238]

(3) While governments occasionally make ex-gratia payments to patients, this is done in exceptional circumstances. (Although the Inquiry has heard evidence that, within the Department, it was recognised by some that the rationale for treating those with HCV differently from

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[2234] Alan Milburn's written statement dated 27 May 2022 (WITN6942001), §§20.5-20.10 and his oral evidence on 14 July 2022, e.g. 81:2-83:3.
[2235] The Chair will be aware this is put in different ways in different evidence and documents, and this wording is simply an attempted summary.
[2236] For example: (a) the Scottish Health and Community Care committee's October 2001 report, while identifying a "*...moral case...*" for providing financial assistance for those infected with HCV, agreed with the Scottish Minister's concerns about establishing any principle of compensation for harm caused by NHS treatment, without fault (MACK0001929_001 at §§90 – 91); (b) Thomas Sackville's witness statement dated 19 July 2022 (WITN5249001), §§8.34, 8.43 - 8.48; (c) Hazel Blears' oral evidence on 21 July 2022, at 182:1 – 183:15; (d) Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §2.
[2237] Alan Milburn's oral evidence on 14 July 2022, at 67:17-86:16.
[2238] This factor was raised as a concern in a submission, dated 19 July 2001, to Yvette Cooper, Parliamentary Under Secretary for Public Health (DHSC0042461_182).

those HIV (and vCJD) involved fine lines that were difficult to draw).[2239]

(4) The financial costs associated with establishing a HCV scheme and the political reality that each decision-maker has to make difficult decisions about prioritising finite resources.[2240] The Chair may recall Lord John Horam was asked what role compassion or a moral case played in the Department's thinking about a HCV scheme. His oral evidence was that:

> *"…however you describe it, whether it's an ex gratia payment or compensation, it's money spent. How is this money best spent; on treatment and patient care or on compensation? I would say that's the moral element in the Government's position…Same thing* [for compassion]."[2241]

(5) In addition, the Chair has heard evidence about the realities of the Department trying to identify and obtain funding for a HCV financial support scheme.[2242]

(6) When Alan Millburn was in office, the Department chose to invest in services and treatment for all those with HCV.

14.58. The case for providing financial or other support was examined seriously in the Department over the years before 2003.[2243] In reaching these conclusions, Mr Milburn echoed the conclusions that had earlier been reached by Mr Frank Dobson, the former Secretary of State for Health, when the issue of introducing payments for haemophiliacs infected with HCV was

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[2239] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §2.18. See also Alan Milburn's witness statement dated 27 May 2022 (WITN6942001), §20.7: "*I am, of course, aware that the distinctions* [between HIV and vCJD on one hand and HCV on the other] *were fine ones and that these lines were difficult to draw.*" By contrast, see Thomas Sackville's witness statement dated 19 July 2022 (WITN5249001), §§8.74-8.77, which set out reasons for the distinction between HIV and HCV that were drawn in 1995.

[2240] See also: (a) Lord John Reid's oral evidence on 21 July 2022, at 81:18-82:15; (2) Alan Milburn's written statement dated 27 May 2022 (WITN6942001), §§3.5 and 7.2; and (c) Hazel Blears' oral evidence on 21 July 2022, at 181:2-181:16.

[2241] Lord John Horam's oral evidence on 29 June 2022, at 122:2-122:13.

[2242] See Lord John Reid's oral evidence on 21 July 2022, at 17:17-17:22, in relation to 1997 – 2000.

[2243] See Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §2 for a chronology in relation to the period 1998 – 2003. Other examples are: (a) Lord John Horam's witness statement dated 13 May 2022 (WITN5294001), §§2.78 – 2.103; and (b) Hazel Blears' oral evidence on 21 January 2022, at 152:2-152:8 and 189:21-189:25, explaining that she viewed the report by the Haemophilia Society as a "…*serious piece of work*…" and considered it in detail.

considered by his administration in 1997 – 1998. Evidence relating to the matters then considered is contained in the witness statement of Baroness Jay.[2244]

14.59. In the course of the Inquiry, scepticism has been expressed towards the concern that establishing wider systems of ex-gratia payment risked undermining resistance to 'no-fault compensation' in the NHS. If examining this issue, the Inquiry may wish to take into account:

(1) The fact that the issue of 'no-fault' NHS compensation was considered, and decisions taken, at a senior ministerial level, and were subject to the scrutiny of Parliament; so too were the issues of widening access to the financial support schemes that existed;[2245]

(2) That judgments on the potential impact of a change were necessarily taken prospectively, without (inevitably) the means of predicting the outcome exactly; and

(3) It might be thought that concerns about the difficulty of 'ring fencing' the ex-gratia payments were made under successive governments were ultimately not without justification. Each successive scheme attracted criticism, and pressure for further change, as each was (in essence) found wanting when measured against a standard of full compensation.

[2244] Baroness Margaret Jay's witness statement dated 1 November 2022 (WITN7410001), §§11.1–11.22.

[2245] The Inquiry will be aware of the long history of Parliamentary scrutiny and debate relating to the issue of support for those infected with NHS-provided blood or blood products. On the specific subject of Parliamentary scrutiny of the principle of no-fault compensation within the NHS, see for example: (i) the NHS (Compensation) Bill, a Private Member's Bill introduced by Mrs Rosie Barnes MP in February 1991, which was debated but did not receive a second reading (see the summary contained in (WITN5249024), as well as the written statement of Thomas Sackville dated 14 July 2022 (WINT5249001), §§8.59 - 8.72, discussing the House of Commons debate of 11 July 1995: see further RLIT0000887); and (ii) the written statement of Lord Andrew Lansley dated 12 October 2022 (WITN6884001), §§3.4, discussing the NHS Redress Act 2006. On the subject of Parliamentary debate of the issue of compensation for the infected and affected, see (in particular) the Parliamentary debate on the topic of parity with Ireland held on 14 October 2010; a House of Lords motion that would have committed the government to parity with Ireland was defeated by 285 votes to 44 (see the written statement of Dr Jecock dated 27 May 2022 (WITN0823003), §§64.1 - 64.8.

14.60. However, there is evidence that, from the turn of the century, a series of other factors gradually took effect: (1) the High Court judgment in the HCV group litigation; (2) campaigning efforts; and (3) the Scottish Executive moving towards a payment scheme which gave impetus to a change in policy in 2003.[2246] The Chair may note that before this, the Scottish Executive and the Department held the same policy position and there had been close liaison between ministers and officials on the question of financial support for those infected with HCV.[2247]

14.61. Against this background, John Reid, who became Secretary of State for Health in June 2003, reached a different political judgement from his predecessors.[2248] When announcing that a new financial support scheme would be set up, he said this was being done "*...on compassionate grounds that this is the right thing to do in this situation.*"[2249] His written evidence to the Inquiry was that, while the "*Scottish initiative did have an impact on the timetabling of the English decision*...[and] *may also have added leverage to my own case for change...the decision to introduce an English scheme was a positive one, taken primarily because I considered that it was the appropriate thing to do. I would not have pursued it simply to achieve unity of policy with Scotland.*"[2250]

14.62. In his oral evidence Lord Reid identified three principles influencing his decision:[2251]

[2246] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §2.8. See Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §§8.10 and 8.42. §8.42 provides an assessment of the impact of Scotland's initiative.
[2247] See e.g. letter from Susan Deacon, Minister for Health and Community Care in the Scottish Executive, to Yvette Cooper, Parliamentary Under Secretary for Public Health, dated 6 July 2001 (DHSC0038520_109).
[2248] See: (a) Lord John Reid's oral evidence on 21 July 2022, at 97:16 – 97:18: *"...And a political judgment – because, you know, all politicians are human beings, a political judgment can differ".* See also Alan Milburn's witness statement dated 27 May 2022 (WITN6942001), §7.2: *"Of course, Ministers were free to change that policy, as my successor John Reid MP chose to do when he became Secretary of State. Inevitably these are matters, not of science, but of political judgment."*
[2249] NHBT0015207_002.
[2250] Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §8.42. This was expanded on in his oral evidence on 21 July 2022, at 58:18-62:2.
[2251] Lord John Reid's oral evidence on 21 July 2022, at 25:4-26:7.

(1) He felt *"…HIV sufferers had obviously gone through terrible traumas, pain, anxiety, and so on. But so had sufferers from hepatitis C."*

(2) *"…the cause of that suffering, for both of those groups of people, was the same route. It was infection through blood products or blood transfusions supplied by the state."*

(3) *"I didn't believe there was a legal liability but that, in my view, shouldn't – the obligations of the state go beyond legal liability. There is a moral compulsion on the state to protect its people….and when an agency of the state, which is the National Health Service, by its conduct, whether culpable or otherwise, results in the suffering of a lot of people, I thought that they should be treated in a manner that was just."*

14.63. The Chair has received evidence that the decision to establish a payment scheme was taken in the face of significant financial pressures. The Treasury's position was that there would be no additional funding for a HCV scheme and any such funding would need to come from the Department's existing budget.[2252] On 27 August 2003 Paul Boateng, Chief Secretary to the Treasury, wrote to John Reid expressing in robust terms his *"…real reservations…"* about a HCV scheme, saying *"… [t]he risks…are real and the precedent for other cases where there is no formal liability profoundly unhelpful..."*[2253] He was "*…reluctantly prepared to agree to* [John Reid] *making an announcement…*" about the scheme, but only subject to a series of conditions about funding, including that:

(1) The Department agreed to meet the full costs of the scheme from its current settlement;

(2) The Department agreed not to make a claim on the reserve to meet these costs or seek additional funding to cover them in the forthcoming spending review;

[2252] WITN5292023A, at §23.
[2253] DHSC0014997_116.

(3) The Department agreed, and secured similar agreement with the devolved administrations ('DAs'), that they would meet future costs arising from any *"…compensation awarded as a direct result of the precedent set by the establishment of this scheme."*[2254]

14.64. The Chair is invited to consider this, both in relation to the decision to establish the Skipton Fund and decisions about its parameters, which were influenced by the limits of funding available. Lord John Reid's evidence was that he knew *"…whatever could be done would have to be affordable..."*[2255] His evidence is that there were general constraints on government and departmental spending – there was (and is) a "*finite*" health budget and "*…funding one initiative means not funding another*". No funding for a HCV scheme had been provided for in previous settlements and so had to be found from the Department's existing settlement.[2256] The Chair is referred to section 11 of Lord John Reid's witness statement for further detail on funding pressures.[2257]

14.65. The evidence suggests the funding position had a number of consequences:

(1) The scheme proposed in the 'Report of the Expert Group on Financial and Other Support' commissioned by the Scottish Executive (the 'Ross Report') was not considered affordable – that was assessed as costing up to £600m.[2258]

(2) Funding the estimated costs of the Scottish Executive's proposals (staged payments of £20,000 and then £25,000) was noted to require

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[2254] DHSC0014997_116.
[2255] Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §8.6.
[2256] Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §8.6.
[2257] Lord John Reid's witness statement dated 20 May 2022 (WITN0793001).
[2258] DHSC5094083: submission dated 1 July 2003 from Richard Gutowski to the private secretaries of John Reid, Alistair Darling (Secretary of State for Scotland), Andrew Smith (Secretary of State for DWP), and Paul Boateng. Malcolm Chisholm's oral evidence on 28 July 2022, at 65:23 – 66:4 was: *"…the one problem, the only problem I would say, with expert groups [here the Ross report] is when it comes to financial recommendations, because clearly the expert group is not able to take into account the other funding pressures and priorities of the particular departmental budget. So that is one problem that does arise from expert groups".*

"...*some tough decisions and leave* [the Department] *very vulnerable for the rest of the year.*"[2259]

(3) The cost of extending the scheme to dependents was, at that time, assessed to remain "...*unaffordable within the existing budgets of all the four Health Departments*".[2260] The Treasury position was that the Department had to operate within its existing budget and could not bid for additional funding in the upcoming expenditure rounds. The evidence is that choices therefore had to be made on affordability grounds and support was focussed on those who were living with HCV.[2261]

14.66. When considering criticisms of the scope of the Skipton Fund and level of payments made, the Chair may wish to consider these factors as well as Lord John Reid's reflection that:

> *"...Even looking back, the scheme that was set up seems to me to have represented the best that could actually have been achieved, at the time. It may not have been ideal, or perfect, and I understand that further support has been agreed over the years. But it did make a substantial start to addressing the plight of those infected with Hepatitis C."*[2262]

Selected issues relating to the Skipton Fund

14.67. Counsel to the Inquiry gave a presentation on the Skipton Fund. Because of that, the following section focuses only on a relatively small number of issues relating to its establishment and operation, all of which have been explored in the evidence.

14.68. First, the starting point for designing the HCV scheme was "...*the scheme which the Scottish Executive had already been working on and intended to*

[2259] DHSC0042275_010.
[2260] DHSC5328495. See also Richard Gutowski's oral evidence on 10 June 2022, at 48:24-49:7 and Richard Gutowski's witness statement dated 11 May 2022 (WITN5292016), §2.136.
[2261] See Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.136 and Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §11.6.
[2262] Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §12.8.

implement".[2263] The Inquiry has heard evidence that the scheme initially planned by the Scottish Executive was heavily influenced by affordability in Scotland.[2264] There was also a view in Scotland that lump sums were more likely to be *"...health payments..."* and so fall within devolved powers (at a time when neither the Scottish Executive nor the Westminster government was clear about this).[2265] While these factors were specific to Scotland, and the devolution issue fell away when a U.K. wide scheme was planned, they may assist with the context in which the Skipton Fund was designed. In addition, there is evidence that lump sum payments were seen as following the pattern of the Ross Report recommendations.[2266]

14.69. The Inquiry has received evidence that there were practical reasons for the Department to favour the approach that Scotland had been developing. Initial work on the outline of a scheme had already been done by Scotland. There was limited time in which to set up a scheme and the lump sum payments proposed by Scotland could be met within the Department's budget (although there were concerns about finding these proposed sums).[2267] The DAs agreed that the new scheme should follow the proposed outline Scottish scheme.[2268]

14.70. However, the evidence indicates this was only the starting point. Changes were made based on feedback from interested parties, e.g. making stage 1

[2263] See Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §§2.91; 2.96.
[2264] Malcolm Chisholm's oral evidence on 28 July 2022, e.g. at 63, 85-87, 93-94, 102.
[2265] Malcolm Chisholm's oral evidence on 28 July 2022, e.g. at 76-77.
[2266] Malcolm Chisholm's oral evidence on 28 July 2022, at 109:9-109:20.
[2267] Lord John Reid's witness statement dated 20 May 2022 (WITN0793001), §10.2. See also:
(a) John Reid's oral evidence on 21 July 2022, at 33:2 – 33:14: "*...we had a very cooperative discussion over the coming months...basically we accepted for reasons of speed – because it was, you know, 20 years overdue – to give financial compensation; reasons of coherence that we thought that the same system should apply to everyone in the UK; simplicity, we basically accepted the Scottish scheme...Because if we'd have brought in a scheme that was more generous than the Scots, well, we couldn't afford it anyway...*"
(b) DHSC5328495: Ministerial submission, dated 10 November 2003, on the costs of extending the HCV financial support scheme, at §12.
[2268] DHSC0016672.

payments available to the co-infected and to those who cleared HCV following successful drug therapy.[2269]

14.71. Second, after the HCV scheme was announced, designing and establishing the Skipton Fund was a "*...joint venture* [between the four DAs]. *All decisions on structure, eligibility criteria, level of payments, guidance and application forms had to be agreed by all of the four administrations and signed off by their respective Ministers.*"[2270] Methods of publicising the scheme were also agreed between all four DAs.[2271] Although the primary interface was between the Skipton Fund and the Department, the evidence indicates that the DAs took shared policy decisions.

14.72. Third, the DAs obtained the input of others when designing the scheme. Richard Gutowski's written evidence was that, "[w]*e spent a lot of time consulting with medical and patient organisations*" and "[w]*e also sought extensive input from medical experts and organisations representing patients such as the Haemophilia Society and the UKHCDO.*" The AHOs were also involved.[2272] A working group of hepatologist's and haematologists was set up to advise on criteria for the stage 2 payment.[2273] Medical expert input was obtained to assist with the question of whether 'natural clearers' should be eligible under the Skipton Fund.[2274]

[2269] DHSC5328495.
[2270] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.3 and see also §2.45. Malcolm Chisholm's witness statement dated 5 July 2022 (WITN0794001), §§43 – 45 explained that, from the end of August 2003, the four DAs had equal influence in deciding the parameters and administration of the scheme.
[2271] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.105.
[2272] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §§2.103, 2.107 and 2.165.
[2273] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.43. See also Professor Howard Thomas' oral evidence on 24 March 2021, at 24:1 – 24:5: "*You might rightly say that I and three or four other people were involved in setting up the rules, at least for stage 2, and that's the case, so we would take responsibility for those rules that were stemming from the stage 2 policy decisions...*".
[2274] See Dr Ailsa Wight's witness statement in *R Moore v (1) Skipton Fund Limited and (2) the Secretary of State for Health* (WITN4509004), §18.

14.73. Changes to the proposed scheme were made in response to feedback. For example, it had been a planned condition of the scheme that ex-gratia payments would be deducted if compensation from another source had been received. Following lobbying, this was removed.[2275]

14.74. The Chair has heard evidence about problems with the Skipton Fund application forms, in particular, potential limits on the evidence that could be presented to support an application. Richard Gutowski's evidence is that there had been consultation on the forms, *including* with the Haemophilia Society, the Hepatitis C Trust and the Manor House Group.[2276] The groups "*…actively participated in the process and* [were] *satisfied with the outcome…Clinicians were also involved in the consultation process*".[2277]

14.75. Fourth, the scheme designed and established by the DAs included a 'cut-off' date whereby, to be eligible, a person needed to be infected with HCV through treatment prior to September 1991 (or have acquired it from someone infected in that way).[2278] In his oral evidence to the Inquiry Richard Gutowski was unable to recall why the date September 1991 was included in the Skipton Fund eligibility criteria.[2279] The Chair has received evidence that NBTS introduced routine screening of all donations from September 1991 and some regional transfusion centres had already begun testing months before this.[2280]

14.76. The Ross Report considered whether a general no-fault scheme in Scotland should be recommended and concluded such a recommendation would not be made. The scheme recommended in the Ross Report was an ex-gratia

[2275] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.122 and DHSC0004425_029. Application forms were also reviewed in response to feedback from patient groups: see MACK0002371_002 at pages 4-5.
[2276] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §§2.124 – 2.125; and WITN5292026 and DHSC5982561.
[2277] WITN5292026.
[2278] SKIP0000033_066: as reflected in the Skipton Fund Agency Agreement at Schedule 2.
[2279] Richard Gutowski's oral evidence on 10 June 2022, at 81:15-81:20.
[2280] See, e.g., CTI's presentation about the work of Dr Harold Gunson on 11-12 November 2021.

scheme which relied on considerations of fairness and the State's moral obligation to justify payments. But, its recommendations would have entailed having a 'cut-off' point date, as it recommended making payments to:

> *"...people who can demonstrate, on the balance of probabilities, that they received blood, blood products or tissue from the NHS in Scotland before the dates when they were made HCV-safe and who were subsequently found to be infected with Hepatitis C virus..."*[2281] [emphasis added].

Since the Ross Report did not recommend introducing a general 'no-fault' scheme, it followed that any person who considered him/herself infected after that point would then rely on general principles of negligence, or, subject to potential issues with regard to limitation periods, by actions under the Consumer Protection Act 1987.

14.77. Fifth, people who cleared HCV after the infection was in the chronic phase (i.e. beyond 6 months) could be eligible for the Skipton Fund. Bob Stock from the Scottish Executive proposed that it *"...should be assumed that the virus has been cleared in the acute phase unless robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection..."*[2282] Questions have been asked about use of the phrase "*...unless robust medical evidence is cited.*"[2283] To place this into context and hopefully assist the Chair: first, while this refers to "*robust medical evidence*" being required, the standard or proof remained the balance of probabilities; second, the explanation for this approach was predicated on evidence that the vast majority of 'natural clearers' cleared the virus in the first six months. The understanding of those involved was that spontaneously clearing the virus in the chronic phase was the exception to this 'general rule'. A policy decision had been reached on excluding those who cleared the virus in the acute phase and the DAs collectively agreed

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[2281] HSOC0020367 at recommendation 1. See also §§3.32, 3.35 and 4.11 of the Ross Report.
[2282] DHSC0004520_057: email from Bob Stock dated 13 October 2004. See also DHSC0006798_072: memorandum from Richard Gutowski to Alison Langley, dated 19 November 2004.
[2283] Rule 9 request to Richard Gutowski and Richard Gutowski's oral evidence on 10 June 2022, at 92:13-92:20.

that an applicant was required to provide evidence to show he/she fell outside the vast majority of cases and into an exceptional case.

14.78. Sixth, the Inquiry's list of issues asks how the Skipton Fund took decisions on eligibility, including what evidence it was willing to consider.[2284] The DAs set the Skipton Fund eligibility criteria and designed the application forms (see above). It was for the Skipton Fund to decide the applications in line with those eligibility criteria.[2285]

14.79. The Chair is aware that applicants were required to provide evidence of infection with NHS blood, blood products or tissues, and the standard of proof to be applied was the balance of probabilities. The practical issue of unavailable medical records, i.e. gaps in the supporting evidence, is touched on below. However, on the principle of this burden and standard of proof, the Chair may wish to consider the following context:

(1) As referred to above, the Ross Report's recommendations included paying compensation to people who could demonstrate, on the balance of probabilities, that they were infected through NHS blood, blood products or tissue.

(2) Establishing the Skipton Fund amounted to a policy decision to set up a further ex-gratia scheme and a decision was made about the limits of this scheme which had a potentially large number of applicants and would be distributing public money. Dr Rowena Jecock, when asked about whether the Skipton Fund's application system was fair for applicants where medical records were not available, explained the need for an evidential basis for distributing public money.[2286]

(3) Mark Mildred, legally qualified Chair of the Skipton Fund Appeals' Panel ("SFAP") (and one of the lead claimant lawyers in the HIV

[2284] Issue 486.
[2285] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.76. See also Nick Fish's oral evidence on 23 March 2021, at 158:13-161:14.
[2286] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §21.11.

litigation), said that the SFAP applied the criteria laid down by the Department. In his evidence he referred to Court of Appeal authority that a civil court should not approach causation on the basis of the least unlikely explanation for an outcome.[2287]

(4) The SFAP, although not the Skipton Fund, used the principle of 'clinical plausibility'. In practical terms this could shift some of the burden of proof from the applicant.

14.80. The Chair has received evidence on applications being turned down, or appeals dismissed, because of a lack of supporting evidence that a transfusion had taken place, often because medical notes were unavailable or did not record a transfusion. The Inquiry's legal team prepared a presentation on the destruction and retention of medical records,[2288] which set out guidance/ codes on records management (initially departmental, and subsequently NHS). The expert report on Public Health and Administration also assists with this.[2289]

14.81. The possibility of gaps in the medical records resulting in difficulty proving the source of HCV infection was anticipated by Charles Lister in two ministerial submissions in 2001.[2290] At this time, no financial support scheme was planned. When the Skipton Fund was being designed, the extent to which this was considered does not appear to be well documented.

14.82. The operation of the Skipton Fund, including how applications to the Fund were decided, was examined in the hearings with Nick Fish, the Fund's administrator for many years. [2291] The Chair also received evidence from Mark Mildred. It will be for the Chair to consider this evidence and the

[2287] Mark Mildred's oral evidence on 25 March 2021, at 99:12-100:14, referring to *Nulty v Milton Keynes Borough Council* [2013] EWCA Civ 15.
[2288] INQY0000378.
[2289] EXPG0000047.
[2290] DHSC0006983_129 and DHSC0004601_021.
[2291] Nick Fish's oral evidence on 23 March 2021.

relationship between policy, which the DAs set, and operational matters, which were for the Skipton Fund and SFAP. The Chair may also wish to consider the extent to which the Department or other DAs were made aware of the operational issues encountered by the Skipton Fund in making eligibility decisions, where supporting medical records were not available or the design of the application form limited the evidence submitted.

14.83. There is evidence that in late 2010/ early 2011, when the Skipton Fund was being extended to provide payments in respect of those who died before 29 August 2003, the issue of unavailable medical records was considered:

(1) On 15 November 2010 Peter Stevens emailed a departmental official referring to an earlier discussion about the absence of medical records being a major handicap, but also saying that, if the standards of proof were relaxed then, "*…we might have quite a few of those who have already applied and been rejected who will have to be re-examined.*"[2292]

(2) The Department referred to this risk in the "*Review of the Support Available to Individuals Infected with Hepatitis C and/ or HIV by NHS-Supplied Blood Transfusions or Blood Products and their Dependents"* (published January 2011, the '2010 Review').[2293]

(3) Dr Rowena Jecock, who worked on the 2011 Skipton Fund changes, has provided evidence that she felt the Skipton Fund would do everything they could to come to a fair judgment on each case. She also relied on the expertise of the SFAP and also considered that the appointment of medical experts to the Skipton Fund (Professor Thomas in 2012 and Professor Dusheiko in 2015) was likely to assist with the assessment of applications.[2294] In addition, Nick Fish, while

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[2292] DHSC5126209.
[2293] PRSE0004024 at §5.19: "*This is an identified risk, although the aim would be to strike the right balance between meeting genuine claims and avoiding inappropriate ones.*"
[2294] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §21.11. See also §§14.8-14.10 which explained that, in June 2011, the Minister was made aware of concerns that the 'balance of probabilities' test was not being properly applied. A suggestion was made that

sharing concerns about documentary evidence of infection, expressed optimism in the Skipton Fund's decision-making processes. In an email dated 27 January 2011 and copied to Dr Rowena Jecock, he set out a combination of evidential sources the Fund could rely on and wrote that "*...most people will be able to receive a payment where it is due*". For those rejected, he placed reliance on the knowledge and experience of the SFAP.[2295]

14.84. Seventh, the Chair is aware of the changes made in 2011 to financial support for those infected with HCV. Prior to the general election in May 2010 the Conservative party had committed to a review of financial support.[2296] During the summer of 2010 Anne Milton, the Parliamentary Under Secretary, had several meetings with campaigners, haemophilia groups and representatives of the AHOs.[2297] The 2010 Review was carried out in late 2010 and aimed to enhance the payment arrangements for those infected with HCV and work towards greater parity between HCV and HIV arrangements.[2298] Changes flowing from the 2010 Review were announced by the Secretary of State, Andrew Lansley, on 10 January 2011.[2299] The changes were summarised in Lord Andrew Lansley's witness statement. The estimated cost of the package was a one-off cost of £49 – 78 million, with a recurrent cost of £12 million.[2300]

14.85. The funding of these measures had to be accounted for in the 2010/11 financial year as the additional payments were available because of in-year savings in the Department's central budgets. That was the reason for 31 March 2011 being set as the date to notify the Skipton Fund of an intention

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medical input into the initial assessment of an application and medical members were subsequently appointed.
[2295] DHNI0000314_003: emails between Professor Hay and Nick Fish dated 27 January 2011, with Dr Rowena Jecock copied into Nick Fish's email.
[2296] Lord Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §19.4.
[2297] Anne Milton's second witness statement dated 28 November 2022 (WITN6437002), §4.12.
[2298] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §63.
[2299] ARCH0001478.
[2300] Lord Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §§19.8-19.9.

to claim (it was not an application deadline). Anne Milton made a written ministerial statement on 30 March 2011 indicating that the Skipton Fund would consider registrations after 31 March 2011 on a case by case basis.[2301] The evidence suggests that this flexibility on the deadline was also communicated on the Skipton Fund's website.[2302]

Caxton Foundation

Establishment of the Caxton Foundation

14.86. The Department's 2010 Review was undertaken in the context of considering Lord Archer's inquiry report, Andrew March's judicial review, and as part of increasing awareness of tensions within the beneficiary community.[2303] It was decided that the review would proceed for England only, although contact was made with the DAs, who were to be consulted on any recommendations which touched on matters within their responsibility.[2304]

14.87. On 8 December 2010 Anne Milton met the Secretary of State and others to discuss the proposed outcome of the 2010 Review. An aim was to satisfy the majority of campaigners, while recognising that would not be possible for everyone.[2305] Anne Milton was keen to achieve the most generous financial package possible.[2306]

14.88. The Secretary of State's announcement in January 2011 included the establishment of the Caxton Foundation, a new charitable trust empowered to make payments to meet the charitable needs of those infected with HCV, who had received a payment from the Skipton Fund; and their families and

[2301] DHSC0004218_109.
[2302] RLIT0001734. See also Lord Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §21.6.
[2303] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §15(b)
[2304] Anne Milton's second witness statement dated 28 November 2022 (WITN6437002), §4.33.
[2305] Anne Milton's second witness statement dated 28 November 2022 (WITN6437002), §4.39.
[2306] Anne Milton's second witness statement dated 28 November 2022 (WITN6437002), §4.42.

dependents.[2307] A key aim of the new charity was to try to create parity, fairness and transparency across the HIV and HCV AHOs.[2308]

14.89. A charitable model was used because the Skipton Fund, being structured as a company, could not make discretionary payments. The Department wanted to create a body that could make discretionary payments in respect of HCV, in the same way that payments could be made through the Macfarlane and Eileen Trusts. It was intended that the approach should be mirrored, as far as possible, across the AHO charities.[2309] The Chair has heard evidence about the Ministerial objective of 'read across' between the three charities. This was about fairness, equity and transparency.[2310] The aim was not to dismantle existing arrangements, nor to create new anomalies, but to make them more consistent, and to complement the structure of payment already in place.[2311]

Caxton Foundation: funding

14.90. As identified elsewhere in these submissions, the financial allocation for the AHO charities was constrained by allocation pressures within the Department.

14.91. The Caxton Foundation made a business case for increased funding in 2014/15 for a regular payments scheme. The estimated cost was an additional £3.03 million in the first year and £4.805 million in subsequent years. The Department turned this down in February 2014. The context for this decision was that ministers were considering the best system of support

[2307] For the precise scope of potential beneficiaries, see the Caxton Foundation deed at CAXT0000095_006, clause 5.
[2308] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §15(b).
[2309] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §41.
[2310] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §42.
[2311] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §42 and Lord Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §24.2. See also HPCT0000210_015: minutes of a meeting between DH and the Trusts on 18 February 2011.

following the Westminster Hall debate on 29 October 2013, and there were downward pressures on government spending.[2312]

14.92. In relation to the holding of reserves at the Caxton Foundation, departmental lawyers had advised (albeit in respect of the Macfarlane Trust) that there was no strict requirement for charities to maintain a reserve, and that a charity could lawfully operate without one.[2313] As money held by the Caxton Foundation was money that was intended to be paid out to beneficiaries, the Department did not consider it necessary for the Caxton Foundation to hold a large reserve.[2314] Accordingly, funding allocations reflected that position.

14.93. The Chair has heard evidence that Caxton Foundation underspends were set against the allocation in the following financial year. Dr Rowena Jecock's understanding of the reason for this was that, if the Caxton Foundation did not spend its whole allocation in one year, then the Department regarded this as if the Foundation had not identified a need to spend all the money. Since there were other financial pressures in the Department, setting the underspend off against the following year's allocation released some of that pressure to allow other spending.[2315]

Funding and budgets

14.94. The Chair has received evidence about funding for the AHOs. This section of submissions addresses three funding-related issues; namely, the source of funding, competing demands on funding, and the security of funding and funding provided to the Macfarlane Trust.

[2312] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §44.1 and Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §22; see business case AHOH0000001
[2313] DHSC5007810. See also Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §28(a).
[2314] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §31.
[2315] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §48.

Source of funding

14.95. Funding for the AHOs came from a different 'budget stream' than NHS funding. Ultimately however, the funding came from the Department's overall budget allocation. The Chair has heard evidence from numerous witnesses that the consequence was that an increase to AHO-funding would mean a funding decrease in other areas for which the Department had responsibility.

14.96. In very limited circumstances the Department could seek and obtain additional funding from the government's contingency reserve, a fund held by the Treasury for unexpected expenses.[2316] David Mellor's evidence (as Chief Secretary to the Treasury) was that the reserve had to cover all government departments and was carefully guarded.[2317] Access was only allowed when there was no alternative.[2318] The Treasury gave access to the contingency reserve in 1991/92 for a maximum of £47 million to fund settlement of the HIV litigation and therefore, MSPT2.[2319] The Chair has also heard evidence about the need for Treasury approval for a department to spend its allocated money other than against the 'item' in the budget. Thus, in the early 1990's the Department required Treasury approval to spend money from within its own budget on the Scheme of Payments and Eileen Trust.[2320]

Competing demands on limited funding

14.97. The Chair may be considering the adequacy of financial support over the years (along with the manner in which it is provided). Various departmental witnesses have sought to explain the wider context in which decisions about funding were made, and some examples of this evidence have already been

[2316] David Mellor's oral evidence on 19 May 2022, at 129:19-130:1.
[2317] David Mellor's oral evidence on 19 May 2022, at 130:24-131:22.
[2318] David Mellor's witness statement dated 25 April 2022 (WITN7068001), §6.11.
[2319] DHSC0003100_001: letter from David Mellor to William Waldegrave dated 1 May 1991.
[2320] See the principles set out in David Mellor's oral evidence on 19 May 2022, at 128 – 133. See also the explanation given in Baroness Virginia Bottomley's witness statement dated 9 June 2022 (WITN5289001), §§6.5; 6.6.

referred to in these submissions. An example is Baroness Virginia Bottomley's evidence:

> *"I have referred a number of times to the fact that as Health Ministers it would have been inhumane not to want to go further or faster than we did, but that at the same time we had to weigh up the countervailing impacts on other health priorities in areas of severe unmet need. Any reference to such countervailing impacts (principally the immediate cost and the wider precedent) risks sounding theoretical if not uncaring, whereas for us as Ministers they were serious and compelling. They involved our ability to spend in other vital health areas. Our strategy for improving The Health Of The Nation had to address key areas of poor health outcomes most notably cancer, heart disease and stroke, mental health as well as the wider HIV and AIDS epidemic. Balancing such critical competing demands is the central conundrum and responsibility which Ministers in the large spending Departments face…"*[2321]
>
> and
>
> *"…every decision had an opportunity cost. So if we'd put more into compensation payments, then there is less for mental health, less for, you know, child – for paediatric health, less for dementia. So it's - - it's a limited pool…"*[2322]

14.98. More concrete examples of this "*conundrum*" are:

(1) The decision to increase the lump sum payments to be made under MSPT1 (from £10,000 to £20,000) required the Department to reduce its budget by £12 million in other areas. Lord Kenneth Clarke's witness statement explained that this would mean a reduction to other budgets, including the AIDS budget.[2323] He described these lump sums as a mitigation of financial hardship, not a measurement of it and said he needed to balance the requirements of other health expenditure.[2324] On the same issue, Baroness Virginia Bottomley's evidence was that:

> *"…this was the reality of the allocation of finite resources to deserving causes…What is of note here is that this was the very real impact of finding additional funds for a deserving additional area:*

[2321] Baroness Virginia Bottomley's witness statement dated 9 June 2022 (WITN5289001), §8.3.
[2322] Baroness Virginia Bottomley's oral evidence on 28 June 2022, at 164:21-164:15.
[2323] Lord Kenneth Clarke's second witness statement dated 12 July 2021 (WITN0758012), §§29-37, 43
[2324] Lord Kenneth Clarke's oral evidence on 28 July 2021, at 183:13-183:14 and 183:23-184:1.

unless the Treasury provided extra money, hard cuts/ savings had to be made elsewhere."[2325]

(2) In relation to decisions about how to make changes to financial support provided by the AHOs in 2010/11, Lord Lansley's evidence was:

> *"But what is true is that the overall financial position was dire. The DH budget increased in the years 2011–12 and 2012–13 by the least amount (in real terms) since the 1970s. Nonetheless and despite this very difficult background, as Ministers we wished to enhance the financial support available and the payments, not least to those infected with Hepatitis C. I knew that with stricter controls on spending in-year in fiscal 2010-11, I might had headroom for a number of priorities, of which this financial support would be one."*[2326]

(3) Jeremy Hunt explained the pressures on departmental budgets in 2014. He said the Treasury was clear that any extra funding would have to come from the Department's own resources and:

> *"…we had run out of money. I mean, we were in an absolutely desperate state, financially.*
>
> *We were constantly going round trying to find money that we could put into the NHS frontline. We were raiding capital budgets for the construction of new hospitals, in order to fund the cost of frontline doctors and nurses. That was my motivation for seeking the £10 billion rise in the NHS budget in 2015…and it became my motivation for seeking a £20 billion rise in the NHS budget in 2018. But I knew that to do justice to the wrong that had happened was likely to be a multi-billion-pound settlement and the national finances would not allow that and the Treasury certainly would not allow that and that's why they were saying to me. So that's - so I had a sense, I suppose, if you ask me how I felt, of great frustration that it was going to be difficult to make progress."*[2327]

14.99. In addition, Dr Rowena Jecock's evidence was that from around 2010 on, and as a consequence of the recession and spending constraints, there was

[2325] Baroness Virginia Bottomley's witness statement dated 9 June 2022 (WITN5289001), §6.19. See also §§6.13-6.20.
[2326] Lord Andrew Lansley's witness statement dated 12 October 2022 (WITN6884001), §18.5.
[2327] Jeremy Hunt's oral evidence on 27 July 2022, at 49:8-50:5.

increased financial scrutiny from the Finance Division. In the following years there was a "*...downward pressure...*" on all Departmental funding.[2328]

Security of funding and funding provided to the Macfarlane Trust

14.100. The following submissions focus on the security of funding for the Macfarlane Trust (and, to a much lesser degree, the Eileen Trust). This includes assistance on the question of how funding for the Macfarlane Trust changed over the years.[2329] A table showing the capital funding provided to these Trusts is included at the Appendix to this section (i.e. capital payments only and not s.64 funding or funding for lump sums that were administered by the Trusts on behalf of MSPT, MSPT2 or the Scheme of Payments).

14.101. There was a desire in the Department that the money initially provided to the Macfarlane Trust should be distributed quickly and efficiently to those in need.[2330] It was also understood that continuing financial support from the Department would likely be needed. At a meeting on 7 September 1989 between the Macfarlane Trust and the Department, the Department communicated that it did not want trustees to give limited assistance to beneficiaries because they were concerned about running out of money.[2331] A response to a submission dated 14 September 1989 recorded that David Mellor was "*...most sympathetic to the idea of increasing the fund in due course*".[2332] In around October 1989 an exchange of letters between officials and the Trust was proposed. This would set out the Department's understanding that trustees would not make more limited offers to help simply to conserve funds, and that the Trust should approach ministers for more funding when the funds were sufficient to meet commitments for only

[2328] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §§36.1 and 38.3-38.4.
[2329] Inquiry's list of issues at number 471.
[2330] See WITN0758025: minute from Kenneth Clarke's private office to an official, dated 9 November 1988, questioning why only £132,000 out of £10 million had been paid out. See also DHSC0003311_014: David Mellor requesting regular updates on the Macfarlane Trust starting in January 1989.
[2331] MACF0000076_026.
[2332] DHSC0003511_066.

another two to three years. Documentary evidence records that the Trust warmly welcomed these assurances.[2333] David Mellor's evidence was that that he tried to do what he could, constitutionally, to reassure the Macfarlane Trust of ongoing funding.[2334] The chronology indicates that this planned exchange of letters was overtaken by the announcement, in November 1989, that lump sum payments would be made (via MSPT).

14.102. In March 1992 Reverend Tanner, as Chair of the Macfarlane Trust, wrote to William Waldegrave asking for an indication of future funding for the Trust.[2335] William Waldegrave replied on 13 March 1992. His letter included:

> *"As you know the Government has given assurances on several occasions that it would continue to keep under review the amounts available to the Trust. I can confirm that a Conservative Government would continue its policy of support for the Trust.*
>
> *I understand that you know that the Government did not plan to provide further funding for the Trust for the financial year 1992/93, as the Trust had adequate resources to enable it to maintain spending at present levels for the coming year. However, I am able to give you the assurance that I will look again at the financial position of funding for the Trust in the autumn of 1992 for the financial year 1993/94."*[2336]

14.103. Reverend Tanner replied on 23 March 1992, saying he was comforted by this assurance which allowed trustees to continue their present allocation policy without making arbitrary cuts and, in turn, reassure beneficiaries.[2337]

14.104. The Macfarlane Trust then received 'top-up' capital funding of £5 million at the end of March 1993.[2338] On 22 February 1993 a ministerial submission was sent to Thomas Sackville (Minister for Health) informing him there was a potential underspend of £6m in the Department's Central Finance Services

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[2333] DHSC0002536_079. However, the Chair may wish to compare Peter Stevens' evidence on this issue (Peter Stevens' oral evidence on 23 February 2022, at 75:20-76:8 and 81:15-83:15).
[2334] David Mellor's oral evidence on 19 May 2021, at 67:17-68:2 and 68:8-69:2.
[2335] MACF0000076_049.
[2336] Letter at MACF0000072_052. Referred to in Lord William Waldegrave's witness statement dated 28 April 2022 (WITN5288001), §5.23.
[2337] Letter at MACF0000072_051.
[2338] MACF0000045_026.

budget for 1992/93 and seeking the minister's agreement to use that money to meet pressures for 1993/94, including for the Macfarlane Trust. It was recommended that £5 million be provided to the Trust to give it sufficient resources to meet commitments for the next 3-4 years.[2339] By letter dated 7 April 1993 Reverend Tanner observed that this funding fulfilled the assurance given by Mr Waldegrave in March 1992 and would give trustees confidence that they could continue, for the next 3-4 years, the level of support that had been given. The letter stated that the Trust may need to approach the government again in the future for further funds.[2340]

14.105. In the financial year 1995/96 John Horam (Parliamentary Under Secretary for Health) approved another £2.5 million of capital funding to the Macfarlane Trust, which came from in-year underspends in the centrally funded service programme. Lord Horam explained in his witness statement that he was not given any indication that the Macfarlane Trust considered itself underfunded or that this had been communicated to the Department. On 8 March 1996 Reverend Tanner wrote to Mr Horam to thank the Department for the funding and gave no indication that the funds were inadequate.[2341]

14.106. In the financial year 1997/98 a further £3 million of capital funding was provided to the Macfarlane Trust.[2342] Charles Lister's evidence was that the Trust would not have received capital funding in 1998/99 as in 1997/98 the Trust's balance "*...was a healthy £9.3m (rounded) at 1 April 1998*".[2343] At this time the Macfarlane Trust aimed to hold a reserve of around £4 million and would approach the Department for more funding when its balance got close to that sum.[2344]

[2339] DHSC0003124_007.
[2340] MACF0000072_045.
[2341] Lord Horam's witness statement dated 13 May 2022 (WITN5294001), §§3.12-3.13. Reverend Tanner's letter, dated 8 March 1996, is at MACF0000081_025.
[2342] MACF0000045_020: Macfarlane Trust's annual report and accounts for year end March 1998.
[2343] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.132.
[2344] Charles Lister's oral evidence on 8 June 2022, at 81:15 – 81:21.

14.107. In January 1999 the Macfarlane Trust completed its 'Strategic Review'.[2345] This indicated that continuing the current level of support to beneficiaries would cost no less than £2 million/ year over the next 5 years. Further funding would be needed if the additional needs identified in the Review were to be met. Lady Hayman met the Macfarlane Trust on 17 June 1999. After that meeting Charles Lister wrote, on 7 July 1999, that Lady Hayman had committed to provided £2 million in 2000/01 and:

> *"[t]here is an ongoing commitment on the part of the Department to give periodic top-ups to the Trust Fund. Unfortunately, we did not realise when the BPRs were being written that a further sum would be needed in 2000/2001. By the end of this financial year, the Trust Fund is expected to be down to £5m or under. At least £4m of this is kept in capital investments in order to maintain payment levels, and grants from the fund currently total around £2m pa. It is therefore clear that a top up will be needed in 2000/2001, and the £2m suggested by the Trust seems reasonable. A further sum is likely to be needed in 2002/2003."*[2346]

14.108. By letter dated 28 October 1999 Ann Hithersay wrote to Charles Lister:

> *"We pointed out at the meeting* [a meeting between the Department and the Macfarlane Trust on 12 October 1999] *that the Strategic Review had identified that in order to meet current levels of payments to those registered with the Trust, top up of £2 million would be required in 2000, and a further £3 million in 2002."*[2347]

14.109. The Department provided £2 million to the Macfarlane Trust in the financial year 1999/00. The Macfarlane Trust's annual report and accounts for year end 31 March 2000 stated that "*...in the course of the* [Strategic] *Review many registrants had expressed concern about the long-term existence of the Trust, and Lady Hayman assured the Trustees of the Government's continuing support. The Trustees are most grateful for this assurance."*[2348]

[2345] MACF0000045_019.
[2346] DHSC0006162_003, at §1.
[2347] DHSC0003209_009.
[2348] MACF0000045_017. See also Lady Hayman's letter, dated 1 July 1999, to Reverend Tanner following the meeting on 17 June 1999 at DHSC0006162_006.

14.110. By April 2000 the Macfarlane Trust communicated to the Department a different and increased request for funding. The Trust said it proposed to increase payments to beneficiaries:

> *"...from around £2m pa in 1999/2000 to £2.5m in 2000/2001 (against a planned spend in 2000/2001 of £2.3m), rising to nearly £3m in 2005/2006. This increase in payments would need to be funded by the Department."*[2349]

14.111. Charles Lister's evidence was that top-up funding had not been set aside by the Department for the Macfarlane Trust in 2001/02 as it was expected the need would arise in 2002/03, based on earlier information and requests from the Trust.[2350]

14.112. Over this period:

(1) In 2000/01 the Department provided funding of £2.5 million.[2351]

(2) In 2001/02 the Department provided funding of £2.25 million to the Macfarlane Trust.[2352] £500,000 was provided to the Eileen Trust. The Eileen Trust's annual report and accounts for year end 31 March 2002 described this as *"...tangible evidence of the long-term commitment by* [the government] *to this small but uniquely damaged group of people."*[2353]

(3) In 2002/03 no capital payment was made to the Macfarlane Trust because the payment planned for that year was brought forward to 2001/02.[2354]

14.113. Charles Lister's written evidence set out in detail the chronology and challenges of securing funding over this period.[2355] At this time the

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[2349] WITN4505341. This was also addressed in Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.149.
[2350] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.154.
[2351] MACF0000006_009.
[2352] MACF0000045_015.
[2353] WITN4505355.
[2354] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.171. See also §5.155 of that statement, in response to Peter Steven's evidence.

Macfarlane Trust's funding was not covered by the Spending Review process.[2356] It was Charles Lister's view, which was acted on, that the inherent uncertainties in the top-up process and the need for annual top-ups following the Strategic Review, meant that inclusion in the Spending Review process was a logical move for Macfarlane Trust funding.[2357]

14.114. The outcome of the 2002 Spending Review was a commitment to annual funding over the spending review period for the Macfarlane Trust of:[2358]

(1) £3 million in 2003/04 (in fact approximately £3.15m was provided[2359]);

(2) £3 million in 2004/05; and

(3) £3.05 million in 2005/06 (i.e. to the level requested by the Macfarlane Trust for 2005/06 in April 2000). The Chair has heard evidence that in fact £3 million was provided in this year.

14.115. With this funding set for 3 years, one of Charles Lister's main concerns was to stress the need for the Macfarlane Trust to manage within this budget. His evidence was that the budgets were based on the Trust's own estimates of future spending. Within that funding envelope, Mr Lister's evidence was that decisions on how to spend the allocated funds were for the trustees.[2360] The increased funding was an acknowledgement that the circumstances had changed from when the Macfarlane Trust was first established.[2361] Future requests for increased funding should then be made in a business case.[2362]

14.116. Charles Lister's oral evidence was that using the Spending Review process gave the Macfarlane Trust a good deal of clarity about ministers' ongoing

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[2355] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§5.117-5.201.
[2356] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§5.125-5.126.
[2357] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.128.
[2358] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.129.
[2359] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.171. See also MACF0000045_013 (Macfarlane Trust's annual report and accounts for year end March 2004).
[2360] Charles Lister's second witness statement dated 19 May 2002 (WITN4505002), §5.20. See also Charles Lister's oral evidence on 8 June 2022, at 84:3-84:21.
[2361] Hazel Blears' witness statement dated 9 June 2022 (WITN6658001), §2.26.
[2362] Charles Lister's second witness statement dated 19 May 2002 (WITN4505002), §5.464.

support and the certainty of that 3 years of funding. But he did not think that meant the Macfarlane Trust was, prior to this, justified in feeling uncertain about the security of funding:

> *"By "certainty", I simply meant that we'd moved away from the ad hoc style of funding we'd discussed earlier, where the Trust would come to us and say, "We need an extra 2 million next year" and we'd go away and find it. We always went away and found it, and sometimes a little more than they'd asked for. But it because done in that ad hoc, end of year underspend way that didn't feel satisfactory for me, and was one year at a time…*
>
> *…you know, I think always they had no reason to believe that if they asked for money we wouldn't find it, because we did. But what we were able to do later on was to say "Well, you know, you've not only got funding for next year but you've got funding clearly set out for the next three, that will hopefully then go on to a rolling cycle."*[2363] (sic).

14.117. After being notified of the 3 year funding agreement, Peter Stevens wrote on 27 February 2003 to Hazel Blears (Parliamentary Under Secretary for Public Health) to say "…[w]*e were greatly heartened to receive the assurance of the Government's continued commitment to the Trusts* [Macfarlane and Eileen]…" and "…[t]*he certainty of the financial commitment over the next 3 years will also enable us to plan with greater confidence the development of our support for our registrants and their families.*" Peter Stevens also wrote that the Trusts had found Charles Lister and his team "…*consistently helpful and patient*".[2364]

14.118. The Chair is aware that the Macfarlane and Eileen Trusts submitted a business case to the Department in November 2005. The chronology of the Department's response to this is set out in detail in the witness statement of Caroline Flint[2365] and the narrative chronology prepared on behalf of William Connon.[2366] In essence, the Trusts sought combined annual funding of

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[2363] Charles Lister's oral evidence on 8 June 2022, at 89:12-90:5.
[2364] DHSC0042275_042.
[2365] Caroline Flint's witness statement dated 7 October 2022 (WITN5427001), §§2.83-2.195.
[2366] Narrative chronology submitted by legal representatives for the Department in response to a rule 9. Request sent to William Connon, dated 31 August 2022 (WITN6887001), §§5.1-5.23.

£7.25 million/year from 2006/07, with £7 million of that for the Macfarlane Trust.

14.119. The documents suggest that, at least in May 2006, officials thought provisional budgets for 2006/07 might allow the Department to make a one-off payment of £9 million to the Macfarlane Trust and £1 million to the Eileen Trust, with the annual (i.e. recurrent) funding remaining static.[2367] It appears this draft submission was prepared before budgets had been allocated.[2368] However, by 8 June 2006, officials were proposing an increase in funding of £400,000. Unfortunately, the documents identified to date by the Department do not assist with decisions on budgets between mid-May and 8 June 2006. On 9 June 2006 Jonathan Stopes-Roe emailed William Connon and Dr Ailsa Wight, saying that Brian Bradley was preparing a Ministerial submission on the Trusts' bid for increased funding "*...now that central budgets are (almost!) settled.*"[2369]

14.120. A ministerial submission, dated 14 June 2006, was sent to Caroline Flint (then Minister of State for Public Health) on responding to the Trusts' requests for significantly increased funding.[2370] That stated:

> *"8. As you know, DH has faced acute pressure on NHS funds and (as a consequence) on the raft of central budgets from which MFT and ET are funded. Major ALBs* [arm's length bodies] *are being required to make challenging cuts in expenditure, to the point of 'thinking the unthinkable' about service reductions. The upshot of the prolonged review is, quite simply, that an extra £4m for MFT and £137k for the ET is not available. The most that could be found, within the budgets now available to us, might allow for growth of around 10%, or £400k across both Trusts. Officials have so far informally advised the Trust to plan on the basis of 'flat cash' funding for 2006/7."*

[2367] DHSC5011529: draft submission dated May 2006, prepared by Brian Bradley. See also DHSC5011528: email dated 17 May 2006 from Brian Bradley to Gerard Hetherington and Jonathan Stopes-Roe.
[2368] Caroline Flint's witness statement dated 7 October 2022 (WITN5427001), §2.126.
[2369] WITN6887013.
[2370] DHSC0041159_207.

14.121. The Chair is also aware that, in this submission, officials commented that blood policy colleagues did not consider any increase in overall funding was justified.

14.122. Caroline Flint wrote to the Trusts on 28 July 2006 to inform them there would be an increase in funding of £400,000. The Chair is referred to her evidence about the terms of this letter.[2371]

14.123. The Macfarlane Trust's capital funding was £3.754 million in 2006/07, 2007/08 and 2008/09.[2372] The Eileen Trust's capital funding was £177,000, £177,000 and £178,000 in those financial years.[2373] This was the first time the Eileen Trust had received regular, annual funding.

14.124. Lord Archer's report was published on 23 February 2009 and made recommendations in relation to financial support. Baroness Primarolo's witness statement explained her interest, as Minister of State for Public Health, in responding with care to Lord Archer's recommendations and efforts to explore options for changes to financial support.[2374] A Ministerial submission dated 31 March 2009 included information about the cost of possible changes to the financial support schemes and advised about the significant difficulties of finding funding:

> *"4. Finance advise that reaching agreement both within DH and with Treasury and the devolved administrations over any financial implications will be challenging. As announced at the Pre-Budget Report, Treasury will allocate £5bn in additional efficiency savings*

[2371] Caroline Flint's witness statement dated 7 October 2022 (WITN5427001), §§2.174-2.185 and Caroline Flint's oral evidence on 16 September 2022, at 33:18-34:22.
[2372] See the Macfarlane Trust's annual report and accounts for these financial years at MACF0000045_010, MACF0000045_009 and MACF0000045_008.
[2373] See Eileen Trust's annual report and accounts for these financial years at EILN0000017_007, EILN0000016_038 and EILN0000016_037. EILN0000016_038 is not entirely clear about the funding in 2007/08. It stated the Eileen Trust received £177,000 in capital funding plus separate s64 funding, but also that the Trust received £140,000 in capital funding and £38,000 in s64 funding. The Trust's annual report and accounts for 2008/09 stated that it received £177,000 in capital funding plus separate s64 funding in 2007/08.
[2374] Baroness Dawn Primarolo's witness statement dated 9 June 2022 (WITN5494001), e.g. §§3.86, 3.110 and 5.8.

> *across Departments in the Budget, in order to reduce public expenditure. They will be particularly concerned at any increase in spending in 2010/11 and beyond, both because of the wider fiscal position and because these can represent long-term commitments crossing multiple spending reviews. Both DH and the devolved administrations will face the challenge of reducing spending elsewhere to meet any additional costs as, even if they agree to these proposals, Treasury will not provide any additional funding.*"[2375]

14.125. On 23 April 2009 Dawn Primarolo put a note to Alan Johnson (Secretary of State) about responding to Lord Archer's recommendations, saying she *"...would like to respond positively as far as possible, whilst recognising that some of the recommendation are simply unaffordable, particularly at the present time."*[2376] As part of this, she recommended a change to the discretionary nature of payments under the Macfarlane and Eileen Trusts, so that all recipients would receive an annual sum; and that the current average annual amount of £6,400 should be doubled to £12,800. She explained that this would cost around £7.6 million per year, a total increase of £3.8 million. The Minister recognised that this step did not rectify the key anomalies relating to payments to those infected with hepatitis C, as this was considered unaffordable.[2377]

14.126. The MFET was subsequently established to make these non-discretionary payments, initially at a rate of £12,800/annum. As a consequence, the annual funding to the Macfarlane Trust for discretionary payments was reduced, but it was also possible for the Trust "*...to provide more effective help for widows and dependents*".[2378]

14.127. The Macfarlane Trust annual report and accounts for year end 31 March 2010 stated that Macfarlane Trust funding from 1 April 2010 (i.e. 2010/11) would be £2.301 million.[2379]

[2375] DHSC0041157_035.
[2376] WITN5494055 at page 1.
[2377] WITN5494055.
[2378] MACF0000047_017: Macfarlane Trust's annual report and accounts for year end 31 March 2011.
[2379] MACF0000047_023.

14.128. As set out above, it was Dr Rowena Jecock's evidence that financial scrutiny from the Department's finance division increased from around 2010 as a consequence of the recession and spending constraints.[2380] In 2012/13 the Macfarlane Trust's allocation was lower than in 2011/12. At the time Dr Jecock explained that there was *"...downward pressure on all DH funding..."*[2381] Finance colleagues in the Department were limiting funds for non-NHS programmes and the Blood Policy team were concerned that the Macfarlane Trust's funding could be reduced in light of the level of reserves it held (around £1 million in December 2011). In addition, the position of the Department's finance division was that the charity should hold reasonable operating balances, enabling it to cover unexpected costs, rather than holding reserves.[2382]

14.129. The funding for the Macfarlane Trust (separate from MFET) stayed broadly static over the following years. This was a significant concern for the Macfarlane Trust trustees. In 2013 the Macfarlane Trust requested an increase in its allocation from £2.2 million in 2013/14 to £3.2 million in 2014/15. The Trust described this request as *"...a major challenge, given the state of the economy and general reductions in public spending. The DH agreed a figure which is, effectively, the same as the previous year."*[2383] The Trust had decided to continue supplementing the annual allocation from the Department with its reserves but pointed out that was not sustainable, and in the future it would have to review the feasibility of its funding policies unless the annual allocation increased.[2384] Further context was given by Jane Ellison (Parliamentary Under Secretary for Public Health) in her written evidence to the Inquiry:

> *"Decisions at that time not to make significant changes to the existing financial support schemes were influenced by two overriding factors;*

[2380] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §36.1.
[2381] MACF0000025_046.
[2382] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §§39.2 and 47.2.
[2383] MACF0000026_058, at page 3.
[2384] MACF0000026_058.

> *firstly, the fact that given the feedback from the infected and affected and from their Members of Parliament, we had decided to look in detail at the options for the reform of the financial support schemes…Secondly, the pending Penrose report which loomed large over all our deliberations*."[2385]

14.130. In November 2014 the Macfarlane Trust made a further request for increased funding from 2015/16. By letter dated 11 December 2014 Dr Jecock wrote to Roger Evans to stress the pressures on the health budget, with "*…rapidly rising demand…*" and "*…significant and increasing pressure on the Department's central budgets*".[2386] Dr Jecock's oral evidence was that, at this point, the Blood Policy team was communicating that financial pressures on the system were such that the Department could not give a guarantee about the level of funding, although "[w]*e weren't anticipating any significant reduction in money…*"[2387]

14.131. These submissions have already referred to Jeremy Hunt's evidence in relation to the wider financial context in the Department at this time (see paragraph 14.98(3)).

14.132. The Chair has received evidence about the additional funding of £25 million announced by the government on 25 March 2015. This amounted to half of the contingency 'pot' held by the Department at this time, and needed Treasury approval.[2388] Jeremy Hunt's written ministerial statement acknowledged criticisms of the existing system for financial support and continued:

> *"The challenge for any future Government will be to identify the most appropriate way of targeting financial assistance, while ensuring that any system can be responsive to medical advances and is sustainable for Government in financial terms.*
>
> *... We had hoped to consult during this Parliament on reforming the ex-gratia financial assistance schemes, considering, amongst other*

[2385] Jane Ellison's second witness statement dated 5 May 2022 (WITN3904009), §32.
[2386] MACF0000061_066.
[2387] Dr Rowena Jecock's oral evidence on 13 July 2022, at 154:15-154:25.
[2388] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §33.14.

> *options, a system based on some form of individual assessment. However, I felt that it was important to consider fully Lord Penrose's report before any such consultation. Given its publication today, we clearly are not in a position to launch a consultation, on one of the last sitting days of this Parliament.*
>
> *... it will be for the next Government to consider all of Lord Penrose's findings, I would hope and fully expect proposals for improving the current complex payment system to be brought forward, with other UK health departments. ... I will be allocating up to an additional one-off £25 million from the Department of Health's 2015/16 budget allocation to support any transitional arrangements to a different payment system that might be necessary in responding fully to Lord Penrose's recommendations."*[2389]

14.133. That £25 million which was ultimately used, alongside £100 million, for the creation of the reformed scheme in England.[2390]

The independence of the charities from the Department

General principles

14.134. The Inquiry has heard much evidence, particularly in February/ March 2021 when the AHO witnesses gave evidence, going to the question of whether the AHO charities were independent or sufficiently independent from government.[2391]

14.135. In seeking to assist the Chair with the issue of what was required to be "*sufficiently independent*" the Department has identified a 2009 Charity Commission publication, "*The Independence of Charities from the State*" (review of the register report 7, 'RR7').[2392] It appears this was first published in 2001 and republished in 2009.[2393] The substance is the same and RR7 is referred to in these submissions.

[2389] MACF0000022_045.
[2390] Jeremy Hunt's witness statement dated 28 June 2022 (WITN3499001), §31.4.
[2391] See issue 463 on the Inquiry's list of issues.
[2392] Independence of charities from the state (RR7) - GOV.UK (www.gov.uk).
[2393] 2001 publication from the British Library: "*The Independence of Charities from the State*", Charity Commission, 2001.

14.136. RR7 summarised the Charity Commission's views about the extent to which charities were required by law to be independent of the state. The Chair may wish to consider the whole publication. The extracts below have been selected as they address some of the issues raised during the course of the evidence:[2394]

(1) "*Charity law is clear that governmental authorities can set up charities…What is important is that the purposes for which the new body exists should be exclusively charitable.*"[2395]

(2) For a body to be a charity, it must be independent. This means that "*…it must exist in order to carry out its charitable purposes, and not for the purpose of implementing the policies of a governmental authority, or of carrying out the directions of the governmental authority.*"[2396]

(3) Paragraph 8 set out characteristics of an independent charity, when negotiating for government funding. These characteristics were not preconditions but rather, the fewer characteristics present, the less likely that the organisation had a charitable purpose. The Chair will note that these characteristics included matters such as the charity taking its own legal and financial advice, drawing up its own policies and business plan, and not committing itself simply to giving effect to the policies or wishes of the governmental authority.

(4) Charities were required to be independent in the sense that anyone who exercised powers in relation to the governance of a charity was bound to act solely in the interests of the charity.[2397]

(5) A governmental funding body could not insist on appointing a trustee to protect its interest, as a condition of providing funding. Rather:

[2394] For example, Ann Lloyd, Chair of the Caxton Foundation from 2013 – 2015, was asked whether an arrangement whereby the Department provided all the funds for the Caxton Foundation and then held it to account on how the funds were spent, was consistent with the Caxton Foundation operating as an independent charity. Her answer was, "*No, but it was a fact of life. I did not feel beholden to the Department of Health. I just knew we had to account effectively for the use of their resources for the purposes intended*" (Ann Lloyd's oral evidence on 22 March 2021, at 152:8-152:16).
[2395] RR7 at §3.
[2396] RR7 at §5.
[2397] RR7 at §11.

> *"The legitimate concern of governmental authorities that public funds for which they are responsible should be:*
>
> *applied for the purposes for which they were given;*
>
> - *properly accounted for; and*
> - *used in such a way as to give value-for-money must therefore be met by other means, such as monitoring and liaison."*[2398]

(6) Appointment of trustees:

> *"Where a governmental authority has been given powers under a charity's governing document, it is bound to exercise those powers solely in the interests of the charity. A power to appoint trustees, for example, must be exercised so as to select the individuals best suited (in the opinion of the appointer) to act as trustees of the charity. If a governmental authority could exercise a power in the administration of a body for its own benefit, the body in question would not be a charity, since it would exist in part for the benefit of the governmental authority."*[2399]

(7) The state as a funder:

> *"It would be unrealistic to expect a charity to be given an entirely free hand given that funding authorities have a responsibility to protect the interests of taxpayers and service users. Moreover, it has to be recognised that in practice funding authorities generally enjoy a strong bargaining position. However, simply carrying out the policies, wishes or statutory duties of a governmental authority is plainly not the same as carrying out a charitable purpose."*[2400]

14.137. While much of RR7 was aimed at identifying when a charity may not in fact be a charity, its terms also suggest that:

(1) Governmental authorities could establish and fund charities;

(2) To be independent, the charity had to exist for charitable purposes and not to implement the government's policies or to carry out the directions of government. Anyone who exercised governance powers had to act solely in the interests of the charity;

(3) A governmental authority that funded a charity had a legitimate concern that public funds provided are properly applied and

[2398] RR7 at §13.
[2399] RR7 at §14.
[2400] RR7 at §21.

accounted for, and used in a way to give value for money. RR7 said it was unrealistic to expect a charity to have an entirely free hand in how it spent public funds. The governmental authority's legitimate concern could be met by, inter alia, monitoring and liaison with the charity;

(4) A governmental authority could appoint trustees to a charity. In doing so, it had to select individuals best suited (in the authority's opinion) to act as trustees.

14.138. Charles Lister's evidence on this subject included:

(1) Reference to the Charity Commission's publication, "*The Essential Trustee: what you need to know, what you need to do*" which states (in the current edition):

> *"9.2 Being accountable to people with an interest in the charity*
>
> *It's important to take account of what your members, beneficiaries, supporters and funders say. Use this information to inform decisions and improve the charity's services."*[2401]

(2) As with any charity, it was the trustees' role to ensure compliance with the governing documents (the charity's deeds), to comply with charity law, to act in the charity's best interests to manage the charity's resources responsibly, and to be accountable to those with an interest in the charity, including beneficiaries and funders.[2402]

(3) He considered it both conventional and appropriate that a charity should take account of what its funders said (in these circumstances the government was the sole funder).[2403]

(4) The principles for managing public resources in the Treasury's document "*Managing Public Money*" (May 2021) were in place during his time in the Blood Policy team.[2404]

[2401] Publication at (WITN4505320). Referred to in Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.15.
[2402] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.15.
[2403] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.16.
[2404] Publication at WITN4505321. Referred to in Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.19.

14.139. Jan Barlow was Chief Executive of the Macfarlane Trust and Caxton Foundation from 2013 – 2017. Before this she had worked in the charitable sector since 1997, including as a Chief Executive of other charities. When asked in oral evidence whether she regarded the Macfarlane Trust or Caxton Foundation as an arm of government or the Department's agent, she stated:

> *"No, I wouldn't describe it that way. Both of the charities were independent legal entities. They were independent of Government and of the Department of Health but you can't get away from the fact that the Department of Health was the sole funder for those organisations and, therefore, you know, the Department of Health could exert a certain influence by virtue of the amount of money that it allocated each year for…the purposes that it wanted to…get that money out to. But again, having said that, there's nothing unusual about funders in the charity sector…putting conditions on the way that it worked and, in my experience, the Department of Health actually didn't really put conditions, per se, on what was done, whereas…I'd worked in other charities where funders provide restricted funds, where it's -- you know, what the charity can do with that money is very, very tightly controlled."*[2405]

14.140. Charles Lister also described his experience as a trustee for other charities, informing the Inquiry that any funder – whether in the public or private sector – will expect assurances that funds are spent for the purposes intended. His evidence was that funders will often set performance or outcome targets for the charity to meet and some form of formal reporting back to the funder was inevitable. His opinion, based on his other experience, was that the Department was "…*light-touch*…" with the Macfarlane and Eileen Trusts.[2406]

The Department's influence on the charities

14.141. The three charities were established with broadly defined 'objects' clauses giving trustees a wide discretion in how they exercised their powers and therefore distributed each charity's funds.

[2405] Jan Barlow's oral evidence on 2 March 2021, at 16:23-17:17.
[2406] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.21. This statement related to his role as an official and so did not address the Caxton Foundation.

14.142. The Chair heard evidence from AHO witnesses that (albeit expressed in different ways):

(1) The Department exercised a degree of influence on the charities by virtue of it being the sole funder and therefore determining the amount of capital funding that was allocated to each charity;[2407]

(2) The Department, however, did not dictate the policies of the charities or determine how money was disbursed to beneficiaries. For example, Alasdair Murray, Macfarlane Trust trustee from 2014 and Chair from 2016 – 2019, said that the Department did not try to influence the Macfarlane Trust in how it spent its funding.[2408] Ann Lloyd's evidence was that the Department did not interfere in the Caxton Foundation determining its own vision and priorities, and she did not think it was the Department's intention to interfere with the charity seeking to work in the beneficiaries' best interests.[2409] Jan Barlow's evidence was that the Department did not have any active involvement in day to day decisions about how money was disbursed and did not have to justify its decisions to the Department.[2410]

(3) There was some degree of obligation (which changed over the years) to report back to the Department or account for the way in which public funds were spent.[2411]

14.143. Of course, the Chair will recall Roger Evans' email to the Macfarlane Trust trustees, dated 26 January 2013, which arose out of a dispute amongst the trustees about whether a draft letter should be sent to the Department objecting in strong terms to the charity's likely funding allocation.[2412] In that email Mr Evans wrote that the Department had "*...a lot...*" of influence over

[2407] Examples of this evidence are: (a) Jan Barlow's oral evidence on 2 March 2021, at 17:1 – 17:9; (b) Russell Mischon's witness statement dated 22 January 2021 (WITN4474001), §7; (c) Alasdair Murray's oral evidence on 9 March 2021 at 106:8 – 106:13; (d) Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §11.
[2408] Alasdair Murray's oral evidence on 9 March 2021, at 106:14-106:20.
[2409] Ann Lloyd's oral evidence on 22 March 2021, at 152:20-153:6.
[2410] Jan Barlow's oral evidence on 2 March 2021, at 38:24 -39:20.
[2411] For example, see Ann Lloyd's oral evidence on 22 March 2021 at 151:4-151:17.
[2412] A version of the draft letter is at WITN4474004. Roger Evans' email is at WITN1122029.

the Trust. He said the government set the Trust up, "*...could close us down at any time if they so wished...*", appointed 3 out of 9 trustees and was the sole funder. The Chair may wish to consider the context in which this correspondence was written, the extent to which the factors identified by Mr Evans affected the day to day operation of the Trust (taking into account all the evidence), whether these factors meant the Trust was not sufficiently independent from the Department, and how representative Mr Evans' opinion was.[2413]

14.144. In addition, the Chair may wish to consider whether there is any evidence that Department appointed trustees did not, in fact, act in the best interests of beneficiaries. Russell Mischon did not agree that Department appointed trustees owed loyalty to the Department (giving Elizabeth Boyd as an example).[2414]

14.145. On the question of the influence the Department had on the charities, the Chair has also received evidence from the perspective of Department witnesses. Dr Rowena Jecock's evidence may assist in summarising the key elements:

> *"I have been asked by the Inquiry whether the DH considered the AHOs to be independent of government. Those AHOs which were charities were independent of Government; their duties and the scope of their work were set by their Trusts Deeds. They were required to act in accordance with these Deeds, in the interests of their beneficiaries. Their policies and payment schemes were determined by their Trustees. But because they were established and fully-funded by DH, they also had a degree of accountability to DH, e.g. on issues that related to the Trustees' ability to manage spending within the funds that had been made available to them. I would also say that the Department had a right to understand what the AHOs were doing and wanted to*

[2413] For example, Jan Barlow said that this email did not reflect her views (Jan Barlow's oral evidence on 3 March 2021, at 11:17-12:22. Charles Lister, as an AHO witness, said that the Caxton Foundation was not in the Department's "*pocket*" and the Department did not interfere with policies or the day to day running of the organisation, but he wondered whether "*...the very fact that we were funded by the Department..., had an accountability relationship with the Department..., perhaps made us less inclined, for that reason, to challenge a decision that we were all vastly disappointed by*" (Charles Lister's oral evidence on 26 March 2021, at 104:8 – 104:20).
[2414] Russell Mishcon's oral evidence on 9 March 2021, at 36:21-37:16.

> *make sure they were doing what they were set up to do, given the Department's ongoing financial role as funder from year to year, including the pressure — speaking very generally — to increase the funding allocations. I believe that aligns with Charity Commission guidance on accountability to funders, as I understand it. There were also accounting procedures within DH (perhaps even involving the National Audit Office) which had to be taken into account: see for example [DHSC5003907], which is a record of meeting between the Blood Policy Team and DH Finance, discussing the statement of financial procedures for the Caxton Foundation on 24 November 2011.*"[2415]

14.146. The Chair may also be assisted by:

(1) John Canavan's evidence (in relation to the Macfarlane Trust) that the Department's role was to provide support to the trustees and satisfy itself that the Trust was being run properly, rather than to direct the work of the Trust.[2416] The Chair is aware that, in the early days of the Trust, it was slow in making payments leading to David Mellor, as Minister of State for Health, requesting two-monthly reports.

(2) Charles Lister said that the Department's main concern was "*...around good governance...*", wanting to establish a budget for the Macfarlane Trust to work to and operate within, with a system that allowed the Trust to put a case for increased funding based on the needs of the beneficiaries.[2417] His evidence was that the Trust occasionally asked him for an opinion on proposed new areas for spending but ultimately such decisions were for the Trust alone.[2418]

14.147. The evidence above is, naturally, only a portion of the evidence on this issue. However, the Chair may wish to consider this evidence, and the

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[2415] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §13.3. See also Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §11.
[2416] John Canavan's witness statement dated 6 September 2022 (WITN7115001), §5.6.
[2417] Charles Lister's oral evidence dated 8 June 2022, at 81:2-81:10.
[2418] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.20. In this statement and oral evidence Charles Lister was asked about specific examples of the Macfarlane Trust approaching him on matters such as the interpretation of the trust deed or eligibility for assistance (see e.g. §§5.385 – 5.397 of his second witness statement). In relation to interpreting the trust deed, Charles Lister said he did not encourage or request this, but also did not question it. He explained that final decisions on such matters were for the Trust and that trustees at times took their own legal advice.

various examples of interactions between the charities and Department that have been explored in this Inquiry, in light of the principles in RR7 (or any other relevant publication/guidance the Inquiry has identified).

Role in appointing trustees to the charities

14.148. The precise role the Department had in appointing trustees to the Macfarlane and Eileen Trusts changed over the years, along with the numbers appointed. These submissions do not seek to chart those changes.[2419] The Caxton Foundation's trust deed provided for three founding trustees. Other trustees were to be agreed by the trustees.[2420] An open competition was run for the appointment of trustees, an executive search agency was used, and advertisements were placed in the national media.[2421] The names of candidates were sent to the Secretary of State with a request for consent to the selected candidate's appointment.[2422] The Department's understanding is that there is no evidence of the Secretary of State withholding consent. More generally, the Chair may wish to examine the available evidence and reach a conclusion on how involved the Department was in identifying and/or appointing trustees.

14.149. The Chair is aware that, of the trustees appointed by the Department, some were former departmental officials.[2423] Charles Lister's evidence was that Peter Stevens and Ann Hithersay (administrator/ Chief Executive of the

[2419] The Chair may be assisted by the various trust deeds (as varied/consolidated) and the '*Appointments Protocol for the Appointment and Reappointment of Trustees to the Macfarlane Trust, Macfarlane Special Payments Trusts and Eileen Trust*" as agreed between the Department and Macfarlane and Eileen Trusts, dated March 1996: EILN0000009_099.
[2420] CAXT0000095_006: see schedule 2 of the Caxton Foundation trust deed.
[2421] Dr Ailsa Wight's witness statement dated 20 June 2022 (WITN4509001), §51(b).
[2422] CAXT0000095_006: see schedule 2 of the Caxton Foundation trust deed. Under schedule 2, §6, if the Secretary of State did not give or refuse consent within 8 weeks of the request, the trustees could, by resolution, give effect to the appointment of the candidate as trustee.
[2423] For the Macfarlane Trust, the establishing trust deed provided for 10 trustees, 6 appointed by the Haemophilia Society and 4 appointed by the Secretary of State for Social Services. Of the 4 appointed by the Secretary of State, one was to be a haemophilia reference centre director and one a haemophilia centre social worker (MACF0000003_064 at clause 10).

Macfarlane and Eileen Trusts from late 1993 – late 2003)[2424] were very keen on this. He believed that Reverend Tanner held this preference too.[2425]

14.150. Documents from the early 2000's indicate that the Macfarlane and Eileen Trust requested the appointment of former senior civil servants, as they valued the experience they could bring.[2426] Further, in 2002 Yvette Coper (Parliamentary Under Secretary) was asked to appoint trustees to the Macfarlane and Eileen Trusts. At this point, while the Secretary of State was responsible for appointing the five Eileen Trust trustees, the Trust itself nominated three of these.[2427] Yvette Cooper raised concerns about the candidates, saying it seemed a bit like an "*...old boys network...*" especially as the recommendations were all male. She wanted to know who in the Trust had stated they would like the reliance on retired civil servants to continue.[2428] The Chair is referred to Charles Lister's witness statement for the full chronology but, in essence:[2429]

(1) The minister was informed that both Peter Stevens (chair) and Ann Hithersay (chief executive) had said they were very keen to have former civil servants as they provided specific experience that complemented the backgrounds and expertise of the other trustees.[2430]

(2) The minister remained concerned and asked if the office of the Department's Permanent Secretary's was satisfied that due process had been followed.[2431] The Permanent Secretary's view was that, based on the evidence presented to him, he was content that due

[2424] Note the transcript of Ann Hithersay's oral evidence on 25 February 2021, at 1:24 – 2:1, incorrectly records that she took up these posts in 1987.
[2425] Charles Lister's oral evidence on 8 June 2022, at 90:24-91:11.
[2426] See, e.g., ministerial submission from Charles Lister to Lord Hunt, dated 27 March 2000, at DHSC0003434_004 and WITN4505324.
[2427] DHSC0002961_013 and WITN6658006. The submission explained that the trustee posts had not been advertised for reasons of proportionality but that the appointment process had been carried out alongside the criteria set down in "*DH Guidance on the Appointment of Chairs and Members of SHAs, NDPBs, and other Public Bodies*" (DHSC0002961_013).
[2428] WITN4505330.
[2429] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§5.89-5.109.
[2430] WITN4505330: email from Robert Finch, dated 21 May 2002.
[2431] WITN4505330.

process had been adhered to and there was no obstacle to appointing the two recommended candidates.[2432]

(3) Peter Stevens was also asked to explain his reasons for wanting former civil servants as trustees. He did so by email dated 25 May 2002, saying that he hoped his explanation met the minister's concerns.[2433]

(4) Further, the criteria against which candidates were interviewed and assessed included being prepared to accept the legal duties, responsibilities and liabilities of trusteeship; being committed to public service values of accountability, probity, openness and equality of opportunity; and demonstrating sound, objective and independent judgment.[2434]

14.151. The Chair may be considering whether the Department appointed trustees, in particular former civil servants, were able to and did act independently and in the interests of beneficiaries. Counsel to the Inquiry has asked questions about whether such trustees were subconsciously or unconsciously biased (this may be a different question from whether beneficiaries held concerns about this).[2435] Ann Lloyd rejected the idea that the Caxton Foundation board could not challenge the Department because some trustees had held senior roles in the Department or NHS.[2436] Peter Stevens, who was in many respects critical of the Department, gave evidence that Mr Spellman's experience at the Department would have, if anything, "*made him more aggressive*".[2437] Russell Mischon's evidence on this issue is summarised above (at paragraph 14.144), as is Roger Evans' email in January 2013. Charles Lister reflected on this issue, saying actual or an appearance of lack

[2432] Charles Lister's submission to the Permanent Secretary, dated 28 May 2002 (WITN4505332); and response, dated 5 June 2002 (WITN4505333), at page 13.
[2433] WITN4505331.
[2434] WITN6658006. See also Hazel Blears' witness statement dated 9 June 2022 (WITN6658001), §2.44.
[2435] For example, questions to Peter Stevens on 24 February 2021, at 149:8-149:13.
[2436] Ann Lloyd's oral evidence on 22 March 2021, at 134:10-134:23.
[2437] Peter Stevens' oral evidence on 24 February 2021, at 149: 8-149:17. He said the suggestion that Mr Spellman might have had a less than neutral or a subconsciously or unconsciously biased view would be a "…*highly improper statement*…" to make.

of independence did not occur to him at the time and was not raised with him as a concern. He would have been extremely concerned if there was evidence that trustees acted other than in the best interests of the charities.[2438]

14.152. The Chair may also wish to consider if there is any evidence the Department intended to influence decision-making in the charities by the appointment of trustees (who would be subject to trustee's duties). The Chair may be assisted by Dr Rejman's minute dated 21 December 1995, referring to the appointment of Dr Winter and his "*...outspoken criticism...*" of the Department, but making clear that the Department should not oppose his nomination.[2439]

Steps taken to make people aware of trusts and schemes

14.153. The Inquiry's list of issues asks if the Trusts and Schemes reached all of the individuals they should.[2440] As this issue extends over a long period of time, this section of submissions seeks to summarise the main steps taken by the Department, and focuses on the Eileen Trust, the Skipton Fund and the Caxton Foundation (because the evidence suggests identifying potential Macfarlane Trust beneficiaries was more straightforward).[2441] Brief points are made on the scheme reforms leading to EIBSS being established.

Scheme of Payments/Eileen Trust

14.154. Clause 10 of the Scheme of Payments set out the ways in which the Secretary of State would "*seek potential qualifying persons*".[2442] The

[2438] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §5.54.
[2439] See Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §116.9 and the documents referred to therein: WITN4486083, DHSC0003431_004 and DHSC0003427_005.
[2440] Issue 475.
[2441] Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), at §5.367 (note only the Macfarlane and Eileen Trusts had been established when he was in post).
[2442] EILN0000016_001. In summary, these were: (1) seeking Communicable Diseases Surveillance Centre and National Blood Transfusion Service records; (2) sending circulars to NHS consultants and GPs; (3) contacting solicitors acting in the HIV litigation; and (4) making a press release.

'Scheme of Payments' acted as a 'gateway' for Eileen Trust eligibility. Dr Rejman, a departmental official who has given evidence in relation to the early 1990's, was unable to recall specific details about publicising the Scheme of Payments or Eileen Trust but relied on documents to assist, referring to: (1) a letter from the CMO dated 30 April 1992; (2) a press release; (3) writing to all those who had received a lump sum under the Scheme of Payments to notify them about the Eileen Trust; and (4) further steps taken.[2443] The CMO letter was sent to all hospital consultants and all GPs in the NHS in England and had an extensive copy list beyond that.[2444] It expressly asked for "*...help in identifying those patients who may be entitled to payments under* [the Scheme of Payments]." It also listed further steps being taken by the Communicable Diseases Surveillance Centre and NBTS Directorate to identify those who were potentially eligible for payments. Each nation had its own "CMO letter".[2445]

14.155. After this initial publicity, further steps were taken in around 1994/95. This was done in response to concerns raised by Eileen Trust trustees about a gap between the number of people who had qualified under the Scheme of Payments and the number who had contacted the Eileen Trust. The evidence supports two steps being taken. First, it was agreed the Department would send out "*...another circulation to potential beneficiaries who had not registered with the Trust with a further invitation to do so*". Second, the Eileen Trust wrote to medical and social work staff at hospitals and to voluntary organisations connected with HIV to provide information and inviting referrals. The Eileen Trust also arranged to appear in the National Aids Manual and similar publications. It appears the steps had some, but fairly modest, success in increasing registrations with the Eileen Trust.[2446]

[2443] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§107.1-107.5.
[2444] OXUH0001251_004.
[2445] Dr Rejman's oral evidence on 11 May 2022, at 56:20-56:22.
[2446] See DHSC0002779_002: Eileen Trust annual report and accounts for year end 31 March 1995.

14.156. Evidence suggests that in the following years, the Eileen Trust concluded it had probably reached the people it was going to reach.[2447] However, the Eileen Trust's annual report for year end 31 March 1998 then reported that the Department had advised it about 5 possible new registrants.[2448]

14.157. During Charles Lister's time as Head of Blood Policy (1998 – 2003) there was ongoing consideration of publicising the financial support and identifying potential beneficiaries. In response to a request in December 2001 from Ann Hithersay to the Department, the Department agreed for information to be put into the CMO's bulletin, sent to all doctors in England.[2449] In addition, the Eileen Trust took steps to reach new beneficiaries.[2450]

14.158. The evidence indicates that, over the years, including up to 2016, there were small numbers of new Eileen Trust registrants.

14.159. Finally, the Chair has heard evidence from Peter Stevens that he believed the "*…very tight timetable and the general lack of publicity and the fact that the Eileen Trust was set out outside the period of that timetable were designed to deter estates from approaching the Eileen Trust for assistance.*"[2451] The Chair may wish to assess if there is evidence to support a 'design' to deter people from approaching the Eileen Trust, including against the evidence summarised above and clause 12 of the Scheme of Payments, which set a time limit for making applications but had an open-ended extension when an applicant could show a reasonable cause for delaying the application.

[2447] EILN0000016_058 and EILN0000016_057: Eileen Trust annual report and accounts for years end 31 March 1996 and 1997, respectively.
[2448] EILN0000016_056: Eileen Trust annual report and accounts for year end 31 March 1998. The document also stated that only 2 "*…new registrations took place, the others dying before registration was possible*."
[2449] See WITN4505379 at §12, EILN0000016_052 at page 2, DHSC0003242_008 at §2, and EILN0000016_051 at page 3. See also Charles Lister's second witness statement dated 19 May 2022 (WITN4505002), §§5.371-5.378.
[2450] EILN0000016_055. See also Charles Lister's second witness statement dated 25 May 2022 (WITN4505002), §5.382.
[2451] Peter Stevens' oral evidence on 24 February 2021, at 47:11-47:16.

Skipton Fund

14.160. As stated above (paragraph 14.71), methods of publicising the Skipton Fund were the responsibility of the four DAs.[2452] Richard Gutowski has provided evidence about steps taken. It was his evidence that the numbers of applications and registrations in the early days of the Skipton Fund suggests it was well-publicised.[2453] In addition, a submission from Richard Gutowski to Melanie Johnson (Parliamentary Under Secretary for Public Health), dated 23 June 2004, stated that a copy of the Skipton Fund application form was sent with a detailed covering letter to all 2100 registrants on the Department's confidential mailing list and would be circulated to voluntary organisations and targeted hospital centres.[2454]

14.161. There is evidence that the Department's Hepatitis C Action Plan, launched in mid-2004, may have led to Skipton Fund applications.[2455]

14.162. On 10 January 2011, Andrew Lansley, Secretary of State for Health, announced a number of changes to the system of financial support. The Department publicised the changes through a range of routes, using press notices, news items in NHS bulletins for medical and nursing professionals, the Skipton Fund itself, the Hepatitis C Trust, NHS Choices, the Department's Twitter feed and website, and local information bulletins. The Skipton Fund, with assistance from departmental officials, completed a 'ring-around' of existing stage 2 claimants who had not yet come forward. Unfortunately a significant number could not be contacted in this way because the Skipton Fund did not have up to date contact details (the nature of the previous lump sum payments meant there had been no ongoing need to maintain contact).[2456] The Department was aware that the UKHCDO was

[2452] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.105.
[2453] Richard Gutowski's second witness statement dated 11 May 2022 (WITN5292016), §2.127.
[2454] WITN5292026.
[2455] See SKIP0000030_178 and DHSC6269087 at page 23.
[2456] WITN0823007: submission dated 26 April 2011.

trying to identify individuals with bleeding disorders who had died before 29 August 2003 and may have had HCV.[2457] The Chair will find a list of communication activities undertaken at DHSC5131026 (the document is undated but appears to have been prepared in early 2011).[2458]

14.163. A submission to Anne Milton, Parliamentary Under-Secretary for Public Health, dated 26 April 2011, stated that the new measures for existing Skipton Fund had been "*...publicised as widely as practicable, without paid-for advertising or public relations...*" (as explained below, this was considered in relation to the Caxton Foundation, but appears not to have been pursued because of doubts about the ability to target the 'audience' and cost).[2459] The Chair is referred to paragraph 14.85 of these submissions which describes Anne Milton's WMS on 30 March 2011 and the Skipton Fund's website providing information that it would consider registrations made after 31 March 2011.

Caxton Foundation

14.164. The introduction of discretionary support for those with HCV and their dependents was announced in January 2011.[2460] This was publicised as part of the 2011 announcement (see above for steps taken) and potential beneficiaries were encouraged to register their interest.[2461] It appears further steps to publicise the Caxton Foundation were taken in around September 2011 (i.e. shortly after the first trustee's meeting), namely: emails to relevant professional bodies asking them to draw the Caxton Foundation to their members' attention (e.g. British Viral Hepatitis Group); asking the British Liver Trust to include information about the Caxton Foundation on its website (the same was intended for the Hepatitis C Trust); and exploring putting

[2457] DHSC5164390.
[2458] DHSC5219548: this may have been attached to an email dated 1 February 2011.
[2459] WITN0823007.
[2460] The Caxton Foundation was established on 28 March 2011 (CAXT0000095_006).
[2461] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §§14.12 and 26.1.

information on various websites and social media.[2462] The possibility of using "*...PR work to get media coverage...*" was considered but this would cost £15,000 – 25,000 and its effectiveness at targeting the relevant audience was doubted.

14.165. The Chair has heard that, in 2014, the Department asked the Skipton Foundation to update its contact details for beneficiaries and inform its beneficiaries about the Caxton Foundation. This was a significant and resource-intensive piece of work for the Skipton Fund, requiring temporary staff to be employed, and funded by the Department. Dr Rowena Jecock's evidence is that, while work had been done in the past to try to identify potential Caxton Foundation beneficiaries, by 2014 it was thought more action was needed.[2463]

Reforms/EIBSS

14.166. The Department carried out a public consultation on reforming the AHOs, making clear that the provision of financial support was to change. The Department wrote to all registrants of the AHOs to make them aware of the consultation and to MPs who had raised issues on behalf of constituents over the years prior to the consultation (and received 1557 consultation responses).[2464] The Haemophilia Society and Hepatitis C Trust were made aware that a new scheme was being established. Documents indicate that NHSBSA, the administrator for EIBSS, also worked with its communications colleagues to inform people of changes to the schemes.[2465]

[2462] DHSC5680861.
[2463] Dr Rowena Jecock's third witness statement dated 27 May 2022 (WITN0823003), §26.2; SKIP0000057_052; and Ann Lloyd's oral evidence on 22 March 2021, at 132:21-133:11.
[2464] Jane Ellison's witness statement dated 5 May 2022 (WITN3904009), §71.
[2465] William Vineall's second witness statement dated 29 April 2021 (WITN4688003), §§27-28.

14.167. The Chair has received evidence that the AHOs, as data controllers, declined to share beneficiary data with EIBSS.[2466]

Conclusion

14.168. The consultation documents that preceded EIBSS being established are referred to in paragraph 14.20 above. The reforms to the system for financial support were funded by the additional £125 million identified under Jeremy Hunt, as Secretary of State for Health, and David Cameron, as Prime Minister. Evidence on the reforms is contained in a number of witness statements, including Jackie Doyle-Price[2467] and William Vineall.[2468] William Vineall has also provided evidence on changes made in more recent years to support provided under EIBSS, including steps towards closer parity of support across the devolved administrations.[2469]

14.169. In response to the Inquiry's interim recommendation to make interim payments, £406.1 million had been paid as at the end of October 2022.

14.170. The Minister for the Cabinet Office, the Rt Hon Jeremy Quin MP, made a statement in Parliament on 15 December to update the House on Government preparations for the conclusion of the Infected Blood Inquiry. The statement advised that:

> *"In the first recommendation of his study, Sir Robert [Francis] sets out that there is in his view a moral case for compensation to be paid. This Government accepts that recommendation. There is a moral case for the payment of compensation. We made that clear in our actions with the payment of interim compensation. I now want to make it equally clear on the floor of this House. The Government recognises that the scheme utilised must be collaborative and sympathetic, and as user-friendly, supportive and as free of stress as possible, whilst being*

[2466] For more detail see William Vineall's second witness statement dated 29 April 2021 (WITN4688003), §§17-40.
[2467] Jackie Doyle-Price's witness statement dated 8 March 2022 (**WITN6650001**
[2468] William Vineall's second witness statement dated 29 April 2021 (WITN4688003).
[2469] See, for example, William Vineall's third witness statement dated 23 April 2021 (WITN4688055); William Vineall's fourth witness statement dated 15 July 2021 (WITN4688059); and William Vineall's fifth witness statement dated 6 December 2021 (WITN4688061).

consistent with Government's approach to protecting against fraud. The government will ensure those principles are adopted."[2470]

THE DHSC LEGAL TEAM

16 December 2022

[2470] https://hansard.parliament.uk/commons/2022-12-15/debates/9AC14928-1A37-4DD3-9CA6-8627C94ADD92/InfectedBloodInquiry.

Appendix to Section 14

	Macfarlane Trust ('MFT')	Eileen Trust ('ET')	Skipton Fund (sums below are payments made to beneficiaries)	Macfarlane and Eileen Trusts Ltd ('MFET')	Caxton Foundation ('CF') (sums below are only for payments to/ regarding beneficiaries)
1987/88	£10 m Transferred on 17 March 1988[2471]				
1988/89					
1989/90					
1990/91					
1991/92					
1992/93	£5 m This was paid to MFT on 30 March 1993	Declaration of Trust on 29 March 1993			
1993/94		£500,010			
1994/95					
1995/96	£2.5 m				
1996/97					
1997/98	£3 m				
1998/99					
1999/00	£2 m				
2000/01	£2.5 m				
2001/02	£2.25 m	£500,000			
2002/03					
2003/04	£3.1565 m[2472]				
2004/05	£3 m		£63.03 m		
2005/06	£3 m		£13.36 m		
2006/2007	£3.754 m **From 2006/07 onwards** figures **include** running costs as s64 funding stopped being provided separately	£177,000	£7.425 m		
2007/08	£3.754 m	£177,000[2473]	£6.605 m		

[2471] MACF0000045_033

[2472] This figure is taken from the MFT annual report for 2003/04 (MACF0000045_013). Compare Charles Lister's second witness statement dated 19 May 2002 (WITN4505002), §5.171 which stated that capital funding of approximately £3.15 m was provided in 2003/04.

[2473] Note the ET annual report for 2007/08 is not clear about the funding. It states the ET received £177,000 in capital funding plus separate s64 funding, but also states the ET received £140,000 in capital funding and £38,000 of s64 funding (EILN0000016_038). The ET's annual report for 2008/09 states that the ET received £177,000 in capital funding plus separate s64 funding in 2007/08. Hence £177,000 has been used.

	Macfarlane Trust ('MFT')	**Eileen Trust ('ET')**	**Skipton Fund (sums below are payments made to beneficiaries)**	**Macfarlane and Eileen Trusts Ltd ('MFET')**	**Caxton Foundation ('CF') (sums below are only for payments to/ regarding beneficiaries)**
2008/09	£3.754 m	£178,000 **From 2008/2009 onwards** figures **include** running costs as s64 funding no longer provided separately	£4.5 m		
2009/10	£3.754 m plus £825,418 received via MSPT2[2474]	£181,705[2475]	£5.19 m	Until MFET was incorporated, non-discretionary payments were made **via MSPT2**. Relevant MPST2 financial documents have not been located. However it appears £2,838,877 was paid to MFT beneficiaries via MSPT2 in 2009/10[2476]	
2010/11	£2,348,543 Paid to MFT via MFET	£97,725[2477] Paid to ET via MFET	£4.37 m Note that funding received was approx. £19.5 m[2478]	£7.6 m **Note:** this **includes** sums paid by MFET to the MFT and ET (as set out in this table). £5,081,580 was paid to registrants and	

[2474] MACF0000047_023.
[2475] £178,000 directly from the Department and £3705 received via MPST2 (EILN0000016_035).
[2476] See MFT annual report for 2010/11 (MACF0000047_017).
[2477] Received via MFET (EILN0000016_035).
[2478] SKIP0000057_059.

	Macfarlane Trust ('MFT')	**Eileen Trust ('ET')**	**Skipton Fund (sums below are payments made to beneficiaries)**	**Macfarlane and Eileen Trusts Ltd ('MFET')**	**Caxton Foundation ('CF') (sums below are only for payments to/ regarding beneficiaries)**
				£2,443,124 paid to the MFT and ET[2479] MFET commenced operation on 1 April 2010	
2011/12	£2,410,406 Paid to MFT via MFET	£100,293[2480] Paid via MFET	£52,307,168[2481]	£7,634,846 **Note:** this **includes** sums paid by MFET to the MFT and ET (as set out in this table). £5,083,100 was paid to registrants and £2,507,321 paid to MFT and ET[2482]	£523,858 Annual report and accounts running from 1 October 2011 – 31 March 2012
2012/13	Approx. £2 m[2483] Paid to MFT via MFET	£108,752[2484] Paid via MFET	£18,323,468	£7,341,013 **Note:** this **includes** sums paid by MFET to the MFT and ET (as set out in this table). £5,222,951 was paid to registrants and	£755,504 Overall, £2.8m was made available by the Department in this year, to include administrative costs[2486]

[2479] Under the terms of an agreement with the Secretary of State for Health, MFET was a "*…conduit…for the transfer of funds from the Department to the charities to finance their charitable disbursement and their operating expenses…*" Figures used are taken from the MFET directors' report and financial statement for 2010/11 (MFET0000004_095) but do not exactly match the figures in the relevant Macfarlane and Eileen Trust accounts.
[2480] Received via MFET (EILN0000016_034).
[2481] SKIP0000057_056. Increase in total payments resulted from the Department's announcement on 10 January 2011.
[2482] Figures used are taken from the MFET directors' report and financial statement for 2011/2012 (MFET0000004_094) and again do not exactly match the figures in the relevant Macfarlane and Eileen Trust accounts.
[2483] There are two different figures in the MFT's annual report for 2012/13, namely £1,999,870 and £2,001,373 (MACF0000045_004).
[2484] Comprising £83,328 received via MFET and £25,424 for the contribution towards service delivery costs via CF (EILN0000016_033).

	Macfarlane Trust ('MFT')	Eileen Trust ('ET')	Skipton Fund (sums below are payments made to beneficiaries)	Macfarlane and Eileen Trusts Ltd ('MFET')	Caxton Foundation ('CF') (sums below are only for payments to/ regarding beneficiaries)
				£2,081,407 paid to MFT and ET[2485]	
2013/14	Approx. £2.037 m[2487] Allocation from the Department was £2.2 m[2488]	Approx. £100,000[2489]	£24,080,235	£5,283,750[2490] MFET stopped making payments to MFT and ET	£981,291
2014/15	£2,040,635 Allocation from the Department was £2.2 m[2491]	Approx. £100,000[2492]	£16,807,139	£5,346,704	£1,646,936
2015/16	£2,010,334 Allocation from DH was £2.2m[2493]	Approx. £100,000[2494]	£18,111,421	£5,294,171	£1,860,534
2016/17	£1,986,904 Allocation from DH was £2.2m[2495]	Approx. £100,000[2496]	£41,470,189	£6,316,856	£1,293,873

[2486] EILN0000034_010.
[2485] Figures used are taken from the MFET directors' report and financial statement for 2012/13 (MFET0000004_093) and again do not exactly match the figures in the Macfarlane and Eileen Trust accounts.
[2487] There are two different figures in MFT's annual report for 2013/14, namely £2,036,408 and £2,037,542 (MACF0000026_058).
[2488] See MFT's annual report for 2013/14 (MACF0000026_058).
[2489] Comprising £75,865 received via the Department (in previous years this capital funding had been received via MFET) and £23,984 for administration costs via the CF. The ET's annual report for 2013/14 states that the ET received funding from the Department of £100,000, including the contribution via the CF towards service delivery costs (EILN0000016_032).
[2490] From 31 March 2013 MFET ceased acting as a conduit for payments to the MFT and ET (MFET0000004_088).
[2491] See MFT's annual report for 2014/15 (MACF0000045_002).
[2492] Comprising £76,055 received via the Department and £23,945 for administration costs via the CF. the ET annual report for 2014/15 states that the ET received funding from the Department of £100,000, including the contribution via the CF towards service delivery costs (EILN0000016_031).
[2493] See MFT's annual report for 2015/16 (MACF0000045_001).
[2494] Comprising £74,884 received via the Department and £24,739 for administration costs via the CF. the ET's annual report for 2015/16 states that the ET received funding from the Department of £100,000, including the contribution via the CF towards service delivery costs (EILN0000016_030).
[2495] See MFT's annual report for 2016/17 (MACF0000027_096).

	Macfarlane Trust ('MFT')	**Eileen Trust ('ET')**	**Skipton Fund (sums below are payments made to beneficiaries)**	**Macfarlane and Eileen Trusts Ltd ('MFET')**	**Caxton Foundation ('CF') (sums below are only for payments to/ regarding beneficiaries)**
2017/18	£977,087 From 1 April – 31 October 2017	£39,613[2497] From 1 April – 31 October 2017	£14,055,728 For period ended 31 January 2018	Have not located MFET directors' report and financial statement. Plan was to bring financial year end forward to 31 Jan 2018[2498]	£601,978 For period ended 31 January 2018

[2496] Comprising £71,501 received via the Department and £28,499 for administration costs via the CF. the ET's annual report for 2015/16 states that the ET received funding from the Department of £100,000, including the contribution via the CF towards service delivery costs (EILN0000016_029).
[2497] Comprising £20,643 received via the Department and £19,156 for administration costs via the CF (EILN0000016_028).
[2498] MFET0000004_108.

These changes were applied by the Infected Blood Inquiry on Monday 16th January.

CORRECTIONS REQUIRED TO CLOSING SUBS

AS AT 10 JANUARY 2023

Corrections required are shown in strikethrough and yellow highlighting

1. Paragraph 8.47 at page 339 of the closing submissions should read:

   It was Thomas Sackville's evidence to the Inquiry that the Panorama Programme *"…formed part of the context at the time"* but did *"…not believe that it had any significant influence on the actual decision to proceed with a look-back exercise. Ultimately the Department was informed by expert opinion and reached a view based on that advice."*[1] Dr Rejman considered the Panorama Programme was not ~~to be~~ a catalyst for the announcement of HCV lookback, which was already under consideration by the relevant expert committees before the Department knew about it.[2] This is a position supported by the consideration of HCV lookback by the SACTTI and MSBT much earlier in 1994, highlighted in these submissions above.

2. Footnote 1508 at page 382 of the closing submissions should read:

   For example, the CJD Support Network, a UK charity. ~~Papers considered at the CJDIP meeting of~~ Papers prepared by the HPA for the CJDIP and others in June 2006 explained that clinical care services were made available to at risk individuals, but the patient's GP was considered to be the key point of contact for advising on the options for clinical care. Morwenna Carrington's witness statement dated 20 December 2022 (WITN7590001), §6.35.

[1] Mr Sackville's witness statement dated 19 July 2022 (WITN5249001), §4.13.
[2] Dr Rejman's third witness statement dated 27 April 2022 (WITN4486040), §§127.6-127.8.

These changes were applied by the Infected Blood Inquiry on Monday 28th February.

CORRECTIONS REQUIRED TO CLOSING SUBS

AS AT 28 FEBRUARY 2023

Corrections required are shown in strikethrough and yellow highlighting

Paragraph 7.8 of DHSC's written closing submissions (pages 267-268) should read:

1. 7.8 Such Codes did not, however, exist at the material time. The earliest edition of the Code of Conduct dates from ~~December 2007~~ March 1997, and did not contain this requirement. Rather, it made a more general reference to the need for independent scientific advice ~~each Scientific Advisory Group to be seen as independent of government~~.

2. Footnote 1030 (page 268) should read:

   Office of Science and Technology, 'The Use of Scientific Advice in Policy Making: A Note by the Chief Scientific Adviser, Sir Robert May', March 1997, [ARCHIVED CONTENT] OFFICE OF SCIENCE AND TECHNOLOGY (nationalarchives.gov.uk), at §6.