Witness Name: Peter Burgin
Statement No.: WITN7485001
Exhibits: WITN7485002-WITN7485007
Dated: 15 December 2022

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF PETER BURGIN

Contents

I, Peter Burgin, will say as follows: -

Section 0: Preface

0.1. My address and date of birth is known to the Inquiry.

0.2. I am providing this statement in response to a Rule 9 request from the Inquiry dated 2 November 2022. The focus of the Inquiry's request is the report titled *"Self-sufficiency in Blood Products in England and Wales: A Chronology from 1973 to 1991"*, published in 2006 (hereafter referred to as the "Self-Sufficiency Report").

0.3. At the outset I wish to make clear the extent of my involvement in what came to be called the Self-Sufficiency Report. In the summer of 2002, I responded to an internal DHSC advert that sought an official *"to review documents from this period [1971 to 1985] and to produce a chronology of events and an analysis of the key issues"* as they related to the UK's policy on self-sufficiency in blood products [**WITN7485002**]. I started work in September 2002 (having previously worked in areas unrelated to blood policy since I joined the Department in 1992). I reported to Charles Lister and on 24 December 2002, I emailed him the final draft of my report (hereafter referred to as my "2002 Document Review Report"). I then took up a different DHSC role, entirely unrelated to blood policy, on around 9 January 2003. I did not hear anything further about my review until I was contacted by Zubeda Seedat in 2005. I was not aware that the Self-Sufficiency Report had been published until someone told me about it in 2018.

Section 1: Introduction

Civil service career

1.1. I have worked for the Department of Health (DH) (as it was then called) since 1992 and for most of the period since 2009 have worked on non-statutory inquiries or investigations.

1.2. During my time at the Department, I have worked as a generalist, by which I mean that I have worked in specific areas but have no professional policy knowledge of those areas. Prior to my work in Charles Lister's team on my 2002 Document Review Report, I worked for the sponsor team for the National Institute for Clinical Excellence (NICE). When I applied for the role in Charles Lister's team, I was a Senior Executive Officer (SEO) grade civil servant. The role involved a three-month temporary promotion to Grade 7. After I completed my document review, I worked as a permanent Grade 7 in the External Gateway policy team responsible for reducing bureaucracy on the NHS.

1.3. During my DH career, I have held two other public health roles - working for the team responsible for implementing "Health of the Nation" from around 1994 to 1997 and as the Healthy Weight lead for Yorkshire and the Humber Region from about 2007 until 2009. Apart from my work on the document review, I carried out no other work in relation to blood, blood products or related matters either before or since.

1.4. I went part time in November 2019 and am now semi-retired. I am currently seconded from the DHSC to work for the Independent Inquiry into the issues raised by the David Fuller case.

1.5. I did not hold any professional qualifications relevant to my work for Charles Lister's team.

Other inquiries and investigations

1.6. I have not provided evidence to, or been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus (HIV) and/or hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infections and/or variant Creutzfeldt-Jakob disease (vCJD) in blood and/or blood products.

Section 2: Background to the Self-Sufficiency Report

2.1. The Inquiry asks me a series of questions about the *"background to the self-sufficiency report"*. I have pointed out already that there is a distinction between the Self-Sufficiency Report (published in 2006) and my 2002 Document Review Report (which I provided to Charles Lister in December 2002). I have addressed my answers, as best I can, to the background to the review of the documents that I was tasked to carry out in late 2002.

Purpose of the 2002 document review

2.2. The Inquiry refers me to a note of a meeting that took place on 15 May 2002 (so pre-dated my involvement) between the then Parliamentary Under Secretary of State for Public Health, Yvette Cooper MP, Charles Lister and others at the DH and the Manor House Group [**WITN4505032**]. The Inquiry asks (Q4(a)) why Yvette Cooper commissioned an internal review into the history of the DH's original commitment to self-sufficiency and what were its aims and objectives.

2.3. I recall that I saw the self-sufficiency review role advertised internally within the DH in the summer of 2002 (by which time I am told Hazel Blears MP had taken over as Parliamentary Under Secretary of State for Public Health). The job description is probably the best guide to what I knew then about the background to the review [**WITN7485002**]. It said,

> *"Job Purpose*
>
> *This is an excellent opportunity to look in detail at the development of an area of health policy that has had a lasting impact on the patient group affected.*
>
> *Almost all haemophilia patients treated with blood products in the 1970s and early 1980s were infected with hepatitis C, many with HIV. Lord Owen, a Health Minister in the 1970s, has suggested that this might have been avoided had the UK achieved self sufficiency in blood products, a policy he inititated (sic) in 1975.*

> *Haemophilia campaigners have raised other concerns about policy decisions taken at the time in the context of demands for compensation and a public inquiry. Ministers have asked officials to review documents from this period and to produce a chronology of events and an analysis of the key issues. The Haemophilia Treatment Review Manager will be responsible for conduting (sic) this review. The work is expected to take around 2-3 months to complete.*
>
> *Key Reponsibilities (sic)*
>
> *(i) Review documents held by the Department and other bodies for the period 1971 to 1985, identify key documents and produce a chronology of events. Interviews with officials, clinicians and others active in this area at the time may be necessary to build up a full picture.*
>
> *(ii) Produce an analysis of the key issues, including:*
>
> *- the development of policy on UK self sufficiency in blood, the factors that influenced it and the reasons why it was never achieved;*
>
> *- the ability of NHS blood products fractionators to produce the volumes of product required;*
>
> *- the evolving understanding of the viral risks associated with pooled blood products, both domestically produced and imported, and how this influenced policy;*
>
> *- the extent to which patients were informed of these risks;*
>
> *- the developing technologies to enable viral inactivation of blood products and the timing of their introduction in the UK.*
>
> *(iii) Summarise these findings in a report for Ministers."*

2.4. I am asked (Q4(b)) why I was selected. It was simply the case that I saw the advert, applied and was successful. Candidates were not required to have any experience or knowledge of blood policy issues. Indeed, in my view it was appropriate that the review was carried out by someone who had not worked previously in the blood policy teams. I was looking to move from my previous role in the NICE sponsor team and the work looked interesting and worthwhile. I applied for the role and in July or August of 2002 I was interviewed by Charles Lister, who was the Head of the Blood Policy Team.

Remit of my 2002 document review

2.5. The Inquiry refers me to Charles Lister's earlier minute to Yvette Cooper dated 8 May 2002 which referenced a meeting with Yvette Cooper on 9 May (again,

prior to my involvement) to *"discuss handling the haemophilia & hepatitis C compensation/public inquiry issue"* [**WITN5426324**]. At paragraph 6, Charles Lister stated that,

> *"We are currently seeking funds to employ an official for a short period to undertake a detailed review of the surviving papers between, roughly, 1973 and 1985 and put together a chronology of events. Without this it will be difficult to answer any detailed accusations levelled against the Department by Lord Owen and others. However, given the need to recruit someone to do this work and the huge volumes of paper to be read and analysed, a complete chronology is unlikely to be ready for at least 2-3 months."*

2.6. The Inquiry asks (Q6(a)) whether I was aware that a *"key driver"* behind the review was to address potential *"detailed allegations levelled against the Department by Lord Owen and others".* After my appointment, I met Charles Lister for an initial discussion of the task. This would have been in around September 2002. He told me that the primary reason for the review was the concern raised by Lord Owen about the failure to achieve self-sufficiency. The job description also alluded to Lord Owen's criticism that infections might have been avoided had the UK achieved self-sufficiency in blood products.

2.7. I was therefore aware, at least in general terms, of the criticisms made by Lord Owen about self-sufficiency. The job description also said that campaigners had raised concerns about policy decisions taken at the time, so I would probably have been aware of the tenor of some of those criticisms. I did not, however, approach the work on the basis that the review was intended to be some sort of rebuttal to the accusations (if that is what is suggested by the Inquiry's question) nor was this the approach that I was instructed to take. Charles Lister was very straightforward and did not attempt to give any kind of steer about the conclusions that I should reach.

2.8. Further, on the issue of the remit of my review, the Inquiry refers me to an email dated 10 June 2003 (so, some six months after my review was completed) from Charles Lister to Zubeda Seedat [**DHSC0020720_081**]. He said,

> *"The remit for the work done by Peter Burgin was to review surviving documents from 1973 to 1985 to address a number of issues, chiefly:*
>
> *- how the Department implemented the policy of UK self sufficiency in blood products begun in 1973 (Lord Owen has said publicly that officials did not carry out his wishes);*
>
> *- to chart the developing understanding of the seriousness of non A/non B hepatitis (later identified as hepatitis C);*
>
> *- to examine the extent to which problems at BPL delayed the achievement of self sufficiency;*
>
> *- whether the achievement of self sufficiency would have led to fewer cases of hepatitis C in haemophilia patients.*
>
> *It was not set up to address Lord Owen's allegation, dating from the late 80s, that the papers from his period as a Minister had been "pulped". Unfortunately, none of the key submissions to Ministers about self sufficiency from the 70s/early 80s appear to have survived. Our 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 discovery process on the HIV litigation have since been destroyed in a clear out by SOL (there is an email from Anita James to me confirming this). This would have happened at some time in the mid 90s. I suspect that Lord Owen's allegation about pulped papers refers to the papers kept by Private Office which are never kept after a change of Government. They are either shredded or handed back to the relevant policy section. However, the fact that we can no longer find any of these documents - so can't say what Ministers did or didn't know about the state of play on self sufficiency - just plays into the hands of the conspiracy theorists."*

2.9. The Inquiry asks (Q5(a)) why my review did not seek to address Lord Owen's concerns that his ministerial papers had been *"pulped"* (which I now understand was Lord Owen's word). The answer is that I was not asked to consider this issue. At the time of my review, I was not made aware of Lord Owen's allegation that his papers had been destroyed. I do not recall that my briefings from Charles Lister ever connected Lord Owen's allegations about self-sufficiency with allegations about destruction of documents.

2.10. The Inquiry also asks (Q5(b)) why my review did not include consideration of how and when departmental documents from the relevant period were destroyed. Charles Lister told me that there were a limited number of documents available to me to review. I cannot remember him using the word *"pulped"* but he did tell me that some of the records had been destroyed. He

indicated that there was nothing untoward about this, but that an Executive Officer had *"inadvertently"* destroyed them when they should not have done so. I was not aware of the detailed history around the destruction of documents and it was not an issue that I was asked to address.

Section 3: My 2002 Document Review Report (titled *"England and Wales Self-sufficiency in Blood Products: A Chronology from 1973-1985"*)

3.1. I started the role in or around September 2002. The indication was that the task would take about two to three months to complete. I was allocated a locked office in Quarry House, a Departmental building in Leeds, to review the records which Charles Lister's team supplied to me. I recall that when I started work there were about eight boxes containing pink files which in turn contained papers such as minutes of meetings and inter-departmental notes. I was surprised to find no Ministerial submissions amongst the papers and I believe that I made that comment to Charles Lister or one of his team. After a few weeks, Charles Lister contacted me and said that *"a few more boxes have been found"* and they were also delivered to me to review. I think that there were two or three more boxes. I would not describe the amount of material as *"huge volumes of paper"* (compare Charles Lister's reference in his minute of 8 May 2002, about which the Inquiry asks at Q6(b)) and I therefore had enough time to review the material and draft the report.

3.2. I met with and interviewed certain key personnel (a task that the job description envisaged might be necessary). Charles Lister had provided me with a list of names. I recall that I visited Dr Terry Snape at home in Yorkshire to interview him. I also interviewed two haematologists, Dr Mark Winter and Dr Frank Hill. I also met with the Haemophilia Society and interviewed their Chair at the time, Chris Hodgson.

3.3. I noticed that Dr Jeremy Metters' (former Deputy CMO) name was prominent in the papers. I think I may have asked Charles Lister whether it was worth speaking to Dr Metters and he agreed that I should. I recall that I spoke to Dr Metters on the telephone. He was surprised to hear from me and asked me why I was calling. I explained to him what I was doing and said that I thought he

might have some papers from the time. I cannot now remember his response to my question about papers. He said he could not see any point in meeting with me. The conversation was very brief.

3.4. I also recall that I visited the Blood Products Laboratory (BPL) in Elstree. I cannot recall now who I spoke to, although the references section of the published Self-Sufficiency Report cited interviews that I apparently did with J Martin (BPL Marketing Director) and L Winkelman (BPL Research and Development Manager), as well as Dr Snape. The document said that I did these interviews in August 2002, but I think this must be a mistake. My recollection is that I started in September. I would have spent time reading into the papers before doing any interviews.

3.5. I recall that Charles Lister was fairly "hands off" and left me to get on with my work. I also recall that he was always very busy. I had very few face to face meetings with him, which was in part because he was based in Skipton House in London whereas I was in Quarry House in Leeds. I think I reported to Charles Lister on my progress roughly every fortnight, usually by telephone. It is possible that Charles Lister's team may have made some minor amendments to the draft report in the three months I was working on it. I have been shown an email dated 12 December 2002 from me to Charles Lister (copied to Zubeda Seedat) [**DHSC6700702**], which attached an early draft of my report [**WITN7485003**]. My email asked if he wished to meet me to discuss my work when I was due to be in London. I cannot recall receiving any response to my email.

3.6. The Inquiry asks me about the text of my 2002 Document Review Report. At 11:25am on 24 December 2002, I emailed Charles Lister (copied to my line manager in my next role, Miles Ayling, in case there was follow-on work) [**WITN4505402**]. I said,

> *"I attach my final draft of the report. I agreed with you that, subject to Miles' agreement, I will be available to brief Ministers on this when you*

> *are ready. It might be worth checking what I have written with one or two clinicians and perhaps Terry Snape (although as I said he was a bit shaky on dates). If there are any issues on which you want clarification or anything you want changing then again I am sure Miles will allow me to spend a little time on this.*
>
> *Thanks again for the opportunity to work on this - it was very interesting and I hope it is of some use (although since a lot of the papers were pulped I realise it may be more grist to the conspiracy-theory mill!"*

3.7. I no longer have access to my work email from 2002, but I have searched my work computer drive for any relevant files. I found a Word document with the root title *"edited draft of report.doc"* (i.e., the same title as the attachment I sent to Charles Lister) and which was last modified at 11:19 on 24 December 2002 (i.e., six minutes before I emailed Charles Lister). I exhibit a screenshot of the meta data [**WITN7485004**]. I believe that this is the final document that I sent to Charles Lister before my role finished. I exhibit a copy of the document found [**WITN7485005**]. All references in this statement to my 2002 Document Review Report are to this document as found on my computer (although my advisers have compared it with the version of my 2002 report provided by the Inquiry and the content appears to be the same [**WITN4505401**]).

3.8. The Inquiry asks (Q8) about the final sentence of my email to Charles Lister (*"…since a lot of the papers were pulped I realise* [my review] *may be more grist to the conspiracy-theory mill!"*). Some 20 years have passed since this email and I do not now remember writing those words. Doing my best to remember, I think that what happened was that in one of Charles Lister's briefings he told me that some people (he did not say who) believed that the destruction of documents was done deliberately and was evidence of a conspiracy. I think he asked me whether my report (through examination of the papers) had allowed any definitive conclusions to be made about what had happened and in doing so he may have referred to "conspiracy theories" but I cannot recall what they were (or even if he told me their nature). I think I recall that he said something like he hoped my report would put a stop to the theories. I emphasise that I did not feel that this was said in a way to put any pressure on me to reach a particular conclusion. My email comment in effect said that

the fact some of the documents had been destroyed meant those who believed in a conspiracy were unlikely to change their mind. This is also reflected in my report where I said, *"The information gathered during this review has been at times contradictory and incomplete"* (p.13). As I said above, I did not know which papers had been destroyed and I was not tasked to consider what was destroyed or how that came to happen.

3.9. I made no further edits to my report after my email to Charles Lister on Christmas Eve 2002. I had worked exclusively on the review, full time, since September (Q(6)(c)). I think that I formally left Charles Lister's team on 27 December 2002. I then had a couple of weeks off before I started a new role in January 2003 in Miles Ayling's External Gateway team, an area unrelated to blood policy.

3.10. My email of 24 December 2002 to Charles Lister anticipated that I might be asked to be available to brief Ministers about my report. I also said that I would be willing to clarify points or make amendments. I was not asked to do either. I recall a conversation with Zubeda Seedat either shortly before or shortly after I left Charles Lister's team. I think she asked me if I would be willing to field any further queries. I do not think at the time that I knew whether the intention was that my report would be for internal use only (although the job description referred to *"a report for Ministers"* [**WITN7485002**]) or would be published to the wider world.

3.11. I see from the documents that some six months after I left, on 5 June 2003, Zubeda Seedat forwarded to Charles Lister (not copied to me) a Parliamentary Question from Lord Clement-Jones about the outcome of any review into the circumstances in which files from Lord Owen's time went missing [**DHSC0020720_081**]. Richard Gutowski's first statement to the Inquiry says that by this time he had taken over as team leader of the Blood Policy Team and Charles Lister had left [**WITN5292001**].

3.12. On 8 June 2003, Charles Lister (by then at the Human Fertilisation and Embryology Authority) forwarded my email of 24 December 2002 (with the attached 2002 Document Review Report) to Zubeda Seedat (not copied to me) [**WITN7485006**]. He said, *"This is as far as Philip (sic) Burgin got."* I assume therefore that no changes were made to my report between my email to Charles Lister of 24 December 2002 and his email to Zubeda Seedat of 8 June 2003.

3.13. Two days later, on 10 June 2003, Charles Lister emailed Zubeda Seedat (copied to Richard Gutowski and Vicki King but not copied to me) about my report [**DHSC0020720_081**]. I set out the first part of Charles Lister's email above, at paragraph 2.8, when I discussed the remit of my review. The remainder of Charles Lister's email concerned next steps. It said,

> *"Peter Burgin's report nonetheless contains some useful stuff. However, before we make it more widely available it needs (I think):*
>
> *- An executive summary;*
>
> *- References added both to the documents quoted (eg quotes from published articles should be fully referenced) and to back up statements which otherwise remain unsubstantiated, eg paras 5 of page 9 states "at this time [1993] it was felt that there were dangers in absolute self sufficiency leading to a reliance on a sole supplier of blood products". It's no good putting this out unless we can say who felt this and in what context it was said. We should also be able to give Ministers the option of releasing documents that corroborate statements made in the report.*
>
> *- you may also wish to consider sending - with Ministers agreement – a final draft to some of the people consulted - eg Frank Hill, Terry Snape, Karin Pappenheim for comments on factual accuracy."*

3.14. Charles Lister's reply also provided a possible response to Lord Clement-Jones' Parliamentary Question:

> *"As to the PQ, one possible response is to say something like:*
>
> *'An informal review is being undertaken by the Department of Health to clarify the facts surrounding the drive for UK self sufficiency in blood products in the 1970s and 1980s. The review has been based on papers available from the time but has not addressed allegations that files from that period went missing. The outcome of the review has not yet been presented to Ministers.'"*

3.15. On 12 June 2003, Zubeda Seedat forwarded to Richard Gutowski (not copied to me) a copy of Charles Lister's email to her of 8 June 2003 (which itself included my email of 24 December 2002 with my attached report) [**WITN4505402**].

3.16. Some months later, on 5 November 2003, Jill Taylor emailed the Private Secretary (Robert Finch) to the then Parliamentary Under Secretary of State for Public Health, Melanie Johnson MP [**DHSC0004555_235**]. Jill Taylor's email referred to a letter from Lord Owen that sought an update on the self-sufficiency internal investigation. The then Minister of State for Health, John Hutton MP, had rejected a draft response to Lord Owen and asked officials for an explanation of Lord Owen's accusations. Jill Taylor noted that *"…all of this highlights the issue that the "Burgin" report has not been published"*. She referred to my report in inverted commas – this was of course almost a year after I had handed in my final draft to Charles Lister. I see from the papers that long after my work finished the term *"the Burgin report"* continued to be used internally as shorthand for what eventually became the Self-Sufficiency Report.

3.17. The Inquiry refers me to a draft submission from Richard Gutowski to John Hutton's Private Secretary (Tony Sampson) in response to John Hutton's request for an explanation of Lord Owen's accusation [**WITN5292006**]. The final, as sent, submission was dated 15 December 2003 [**LDOW0000350**]. In reference to my review Richard Gutowski said,

> *"6. A report was submitted to officials in the blood policy team earlier this year, however there are a number of outstanding issues which need to be resolved before the report can be finalised and submitted to Ministers.*
>
> *7. PS(PH) is aware of the background to this review. Earlier this year, officials agreed to conclude the review as soon as practicable. Unfortunately we have been unable to make any progress during the year."*

3.18. The final line of Richard Gutowski's submission suggested that no further work had been carried out since I sent my final draft report to Charles Lister. The Inquiry asks (Q7) what the *"outstanding issues"* were when I left my role in December 2002. As far as I was concerned, I had completed the task and there were no outstanding issues which I needed to resolve. I assume that what happened was that sometime after December 2002 others in the Department identified that further work was required. Indeed, this is what Charles Lister suggested in his email of 10 June 2003 (referred to at paragraph 3.13 above).

3.19. Some six months later, on 6 May 2004, Richard Gutowski emailed Gerard Hetherington (not copied to me) [**DHSC5336358**]. He said,

> *"When we last met Melanie Johnson she gave us three months to sort out the problem of accusations of self sufficiency of blood and the shredding of Lord Owen's papers.* ***We have a report produced - the Burgin Report - but it is not in form to be published or conclusions drawn from it. We agreed I should pursue appointing a medical writer to redraft the Report in a more robust form****. I am meeting Adam Jacobs from a medical consultancy next Friday to see whether thay (sic) are able to take on the work. Ideally I would have liked Hugh Nicholas to get involved in assessing whether the decisions made at the time stand up in the light of the knowledge at the time and the information available. Unfortunaely (sic) he is tied up with work on the Hep C Strategy and the Hep C Payment Scheme Application Form. If the Consultancy Firm feel that they are able to do the work the same question then applies, have we the money."* (emphasis added).

3.20. Also on this point, I have also been shown a draft supplementary Q&A briefing document produced by DH civil servants in response to a May 2006 Lords Starred Question from The Lord Jenkin of Roding (PQ09390, 21/03/2006). The briefing said,

> *"Who undertook the review?*
>
> *A DH official was recruited for three months (October 2002-December 2002) to undertake the review. The task was completed by independent consultants"* [**DHSC0041198_088**].

3.21. A further 10 months later, on 16 March 2005, I emailed Zubeda Seedat with a copy of the job description for the self-sufficiency review role [**WITN7485002**]. I

think that around this time in 2005 Zubeda Seedat called me to say that the Department intended to publish my report and had engaged a medical agency to tidy up the report and insert references. I do not remember any further details of what we discussed. I assume that she must have also asked me for a copy of the job description. As far as I can recall, this was the first contact that I received from Charles Lister's team since I left my role in late 2002 (save for a conversation with Zubeda Seedat that may have taken place shortly after I left, see paragraph 3.10 above).

3.22. Two months later, on 12 May 2005, I received an email from Zubeda Seedat [**DHSC5368830**]. I believe that this was the first time since my email to Charles Lister of 24 December 2002 that I was contacted in writing about the work that I carried out. The documents that I have seen do not suggest otherwise. Zubeda Seedat's email attached what she called *"the final draft copy of the review of papers on self sufficiency in blood products"* dated 8 October 2004 (hereafter referred to as the "2004 draft report") [**WITN7485007**] and a draft submission to Ministers [**DHSC5367051**]**.** Her email asked for my comments. She said that the attached 2004 draft report would be sent in confidence to key people to comment on factual accuracy (Dr Frank Hill (UKHCDO), Jane Martin and Dr Terry Snape (BPL) and the NBA Chief Executive) and that they were considering sending it to others who had been quoted in the report (Professor Zuckerman and Dr Craske).

3.23. I replied to Zubeda Seedat on 16 May 2005 [**DHSC5368830**]. I said,

> *"I am sure it is worthwhile asking the people you have identified (if they are still alive) to check the accuracy of the report in confidence. I know you haven't suggested this, but I would steer well clear of the Haemophilia Society. On the submission:*
>
> *page 3, first bullet point in para 12 - suggest RTCs and BPL*
>
> *On the report, the only thought I had is that the summary and conclusions overlap - do you need both? There is also repetition in the summary between the last para and the first para on page 4.*
>
> *Otherwise it looked OK to me."*

3.24. I was extremely busy in 2005, when I was working on the reconfiguration of the NHS, to tight Ministerial deadlines. Consequently, I gave the final draft report a cursory read only and my brief comments reflect that. I was also not in a blood policy role at the time. I believe that my comment about the Haemophilia Society related to the perceived risk of leaks at the time. My recollection is that the thinking within the DH was that sharing draft reports with patient groups was to be avoided to reduce the risk of unauthorised disclosures. The Haemophilia Society was the only patient group that I had met, which is why I referred to them only. It did not reflect any negative view on my part about Haemophilia Society – in fact, I had an extremely helpful meeting with them in November 2002 while working on the review and had no dealings with them before or since.

3.25. While preparing this statement I compared my 2002 Document Review Report which I sent to Charles Lister [**WITN7485005**] against the 2004 draft report which was sent to me by Zubeda Seedat [**WITN7485007**]. The 2004 draft report is materially different to my report. The title of the 2004 draft report was the same except that the period of the review had been extended from 1973 to 1985 (as it was in my report) to 1973 to 1991. The 2004 draft report also had added to it: a list of abbreviations; an executive summary; a list of references; and an expanded chronology of events at Annex A. In addition, there were aspects of the analysis that had changed. I set out examples in the table below:

2002 Document Review Report	**2004 draft report**
"The introduction of Factor VIII concentrate revolutionised the treatment of haemophiliacs and improved the outlook for the severely affected haemophiliac. Factor VIII activity was much greater in the concentrates and was much more predictable than cryoprecipitate." (p.2).	*"The introduction of factor VIII concentrate revolutionised the treatment of patient with haemophilia and dramatically improved the outlook for the severely affected haemophiliac [1]. It has been estimated that, when deaths related to viral infection are excluded from the analysis of mortality in patients with haemophilia, the life expectancy of these patients almost equals that of the general*

	male population [13]. Factor VIII activity was both much greater in the concentrates and much more predictable than in cryoprecipitate." (p.7)
[Not in my report]	*"There is therefore no evidence to suggest that the NANBH outbreak in the late 1970s and early 1980s could have been avoided had England & Wales been completely self-sufficient in blood products during this period. Domestically sourced blood products carried a risk, albeit a smaller risk, of NANBH transmission, and therefore it is likely that, over time, the majority of haemophiliac patients would have come into contact with contaminated product."* (p.11).
[Underlined text not in my report]	*"Tests for the HCV antibody were not introduced until 1991 [63, 64, 65], after the isolation of the virus in 1989 [24]. At this time, the knowledge that adequate methods of inactivating pooled plasma products were already available were thought to negate the need to introduce routine screening before it could be demonstrated that such screening would be cost-effective and lead to an increase in the safety of transfusion [66]."* (p.12).
[Not in my report]	*"In 1989, following the cloning of a complementary DNA representing a portion of the viral genome, Kuo et al. published data on the first HCV screening assay [65]. However, this test, the C100-3 antibody test, was found to be unreliable […]. If this test were to have been implemented, it was thought that the occurrence of false positives would result in*

	blood donors being given inaccurate information on their chances of having acquired HCV infection, whereas the occurrence of false negatives would result in donors who were infectious but still continuing to donate to the plasma pool." (p.12).
[Not in my report]	*"The Department regarded the achievement of self-sufficiency a priority. The reliance on expensive imported commercial material was seen to be costly: an estimated £6m per annum for the predicted requirements (275,000 donations) for the production of factor VIII. Furthermore, it seemed likely that, as the demand for plasma products increased, it would become necessary for commercial firms to establish paid donor panels in the UK. This was seen as a threat to the voluntary donor system on which the National Blood Transfusion Service (NBTS) was founded [88]."* (p.14).
"The production target for Factor VIII set for June 1977 was attained. However, as already outlined new opportunities in the treatment of haemophilia and associated disabilities had been developed which made further clinical demands for Factor VIII. In addition, the original estimate was based on numbers of severely affected haemophiliacs and did not include those who were moderately or mildly affected. There was still therefore a deficit which was continuing to be met by purchase of concentrate from commercial sources. The	[Underlined text not in 2004 draft report]

Department stated that England and Wales were still aiming for self-sufficiency."	
[Not in my report]	*"It is now known that it is an indisputable reality that very few counties are capable of completely satisfying their blood needs (i.e. becoming self-sufficient) without acquiring a proportion of blood from paid donors [158]."* (p.26)

3.26. The conclusions of the respective reports were as follows:

2002 Document Review Report	**2004 draft report**
*"**Conclusion***	*"**Conclusions***
The information gathered during this review has been at times contradictory and incomplete, but the following conclusions can be inferred.	*The information gathered during this review has been at times contradictory and incomplete, but the following conclusions can be inferred.*
The Government pursued the goal of self-sufficiency in Factor VIII during the 1970s and most of the 1980s, in line with WHO and EC recommendations. The primary aim of this goal was to reduce the reliance on expensive imported concentrate, although there is some evidence that in the late 1970s this was also linked to the risks of contracted hepatitis from imported concentrate.	*The Government pursued the goal of self-sufficiency in factor VIII during the 1970s and most of the 1980s, in line with WHO and Council of Europe recommendations. The primary aim of this goal was to reduce the reliance on expensive imported concentrate, although there is some evidence that there were also concerns over the possible threat to the volunteered-based donor system in England & Wales should commercial firms decide to establish paid donor panels in this country. In the late 1970s and early 1980s, these concerns were accompanied by fears of the risk of transmission of both hepatitis and HIV infection from imported factor VIII concentrate.*
In 1975 the Government allocated £0.5m, about half of which was recurring, to the NHS in order to increase plasma production. At the time this was thought sufficient to achieve self-sufficiency in Factor VIII by 1977. There is no evidence	

that there was subsequently insufficient funding for this, particularly when one considers the amount spent on the redevelopment of BPL. *However, the rapid growth in demand for Factor VIII due to home treatment in particular meant that the amount of Factor VIII produced was not enough to achieve self-sufficiency. This was despite the rise in production of NHS Factor VIII and the resulting increase in plasma collected by the Regional Transfusion Centres to support this. Therefore it was necessary to continue to import Factor VIII concentrate from abroad. This position continued until about 1990, when BPL were obliged to compete in the market place to supply clinicians.* *Although it is reasonable to suppose that the Government would have known of the risks of contracting hepatitis from blood products, this does not seem to have been the driving force behind development of policy, particularly in the 1970s. By 1983, it was thought that there were no differences in the levels of virus contained in the unheated BPL and commercial products.* *Moreover, the prevailing medical opinion in the 1970s and the early 1980s seems to have been that NANBH was not particularly serious and when set against the consequences of not having treatment for haemophilia (particularly cerebral heamorrhage) it was thought to be a risk worth taking.*	*In 1975, the Government allocated £0.5m, about half of which was recurring, to the NHS in order to increase plasma production. At the time, this was thought adequate to achieve self-sufficiency in factor VIII by 1977. However, the demand for factor VIII in the UK increased dramatically in the late 1970s. Clinicians were coming under pressure to step up the dosage regimen for the home treatment of haemophilia. This demand was expected to increase even further owing to a longer life expectancy of patients with haemophilia, the increased provision of home therapy, and the trend towards the use of factor VIII in bleeding prophylaxis. Therefore, despite the increase in both the plasma collected by RTCs and the amount of factor VIII produced by the NHS, it was still necessary to import factor concentrates.* *With the development of tests for hepatitis A and B in the 1970s, it became clear that other types of viral hepatitis could be transmitted by blood, and these were termed NANBH. Before 1989, potential blood donors could only be screened for NANBH using surrogate tests; however, these were perceived to be crude and inappropriate for use in the UK. With the cloning of a portion of the virus in 1989, the C100-3 antibody test became available. This was associated with a large number of false positive and negative results and, once again, was not approved for use in the UK. It was only in 1991 that a number of validated second-generation assays became*

Although commercial companies were experimenting with heat-treated Factor VIII as early as 1980, this could not be produced in sufficient quantities for the UK market. BPL developed their own product which was subsequently shown never to transmit NANBH and AIDS (unlike some of the commercial products which were available) and this was introduced as soon as possible. *The redevelopment of BPL was decided upon following the adverse report by the Medicines Inspectorate in 1979, and the realisation that the existing laboratory did not have the capacity to provide enough material for self-sufficiency."* (pp. 13-14).	*widely available and routinely used to screen potential blood donors for NANBH infection.* *The prevailing medical opinion in the 1970s and the early 1980s was that NANBH was mild and often asymptomatic. Therefore, as always, patients with haemophilia, their parents, and doctors were required to balance the improvements in quality of life and the dangers of bleeding against the risks of treatment. Research into NANBH was hindered by the lack of a definitive serological assay for NANBH, the reluctance of clinicians to perform liver biopsies and other invasive procedures in patients with a very high risk of bleeding, and the fact that, in the majority of patients, the chronic sequelae of NANBH only became apparent after more than a decade. Even in the mid-1980s, however, when it became apparent that NANBH was associated with long-term chronic sequelae, including liver failure, cirrhosis, and hepatocellular carcinoma, the consensus of medical opinion was that clinicians should continue using the concentrates. Patients, their physicians, and the Haemophilia Society all maintained that the improvement in quality of life and dangers of bleeding outweighed the potential risks of treatment. In an editorial in the British Medical Journal (BMJ), it was stated that early death from liver disease was viewed as a price that might have to be paid by a small minority of patients with haemophilia.* *In 1983, growing concerns over the safety of commercial blood products imported from the*

	US reinforced the need for both self-sufficiency in blood products and the development of an effective viral inactivation treatment at BPL. Although it was widely known that there was a risk of NANBH infection from imported concentrate, the Haemophilia Society appealed to the Government not to ban American blood supplies, claiming that, without the US imports there would be a sharp rise in deaths among patients with haemophilia. Furthermore, they advised their members not to stop treatment in response to concerns over potential risks. *Attempts to develop viral inactivation processes to treat blood products began in the early 1980s. Initially, a number of commercial companies experimented with different heat-treating regimens; however, these techniques resulted in a substantial loss in yield and therefore were not capable of producing concentrates in sufficient quantities for the UK market. In 1982–1983, further products were introduced; however, the viral safety of these had not been firmly established and, in fact, they were later shown to still transmit NANBH. In 1985, BPL developed a new, high purity product, designated 8Y, which was capable of maintaining satisfactory yield from fresh frozen plasma, had remarkable in vitro stability to heat in the absence of conventional stabilisers, and had a good record of safety in clinical trials. To date, 8Y has proved safe and has not been reported to transmit hepatitis or HIV.*

	The redevelopment of BPL was decided upon following the adverse report by the Medicines Inspectorate in 1979, and the realisation that the existing laboratory did not have the capacity to provide enough material for self-sufficiency. The re-development project comprised two main stages: the upgrading of the current facilities at BPL over a period of 3–4 years; and the development of a new laboratory with an increased capacity. Ministers agreed a short-term upgrading programme for BPL at a cost of £1.3m and £21m was allocated to the building of a new fractionation facility on the existing site at Elstree. In the early 1980s, the total cost of BPL redevelopment escalated; however, the project remained fully funded owing to the Government's commitment to self-sufficiency and thus the earliest possible completion date for the proposed redevelopment. Furthermore, the scheme was projected to pay for itself within 5–6 years of reaching full production. *Efficient operation of the unit required 3 times as much plasma as it was currently processing, and RTCs were held responsible to meet this increased demand. Errors in estimating both the amount of fresh frozen plasma stockpiled at Elstree during the mid-1980s and the net yield for factor VIII production at BPL led to difficulties in meeting factor VIII requirements. Even if the RTCs were capable of providing the necessary amounts of plasma to BPL, which they were struggling to do, it was thought unlikely that the factor VIII production at BPL would*

	exceed 70% of the total requirement nationally. *In the mid 1980s, when heat-treated factor VIII products were being produced both domestically and abroad, the risk of transmission of either NANBH or HIV from these products is minimal. Therefore, once again, the primary driving force for self-sufficiency became the cost saving predicted should the reliance on commercial products be reduced even further. By 1993, England & Wales produced 75% of the total requirement for factor VIII, but was still therefore still reliant on a certain amount of commercial factor VIII. This situation reflected a preference of some physicians for use commercial products over the BPL product. The continued use of commercial products therefore prevented the achievement of complete self-sufficiency; however, the Department was keen not to restrict the prescribing habits of clinicians, leaving them free to prescribe the product they considered most appropriate for the patient. At this time, it was also felt by groups representing patients with haemophilia that there were dangers in absolute self-sufficiency. This, they claimed, would lead to a reliance on a sole supplier of blood products, which was predicted to override clinical freedom, stifle new developments (many of which were from the commercial sector), and expose England & Wales to the possibility of inadequate volumes of product for effective treatment, and the risks to supply inherent in relying on a sole manufacturer.*

	About 3000 patients with haemophilia treated with blood products in the 1970s and early 1980s were infected with HCV and many with HIV. ***Available evidence suggests that during this period not only was the Government actively pursuing the policy of self-sufficiency, but NANBH was perceived as a mild, and often asymptomatic disease, and the advantages of treatment with factor VIII concentrates were perceived to far outweigh its potential risks. This view was supported by patients, their physicians, and the Haemophilia Society.*** *From the early 1980s, BPL attempted to devise an effective viral inactivation procedure. Progress was hindered by the heat sensitivity of factor VIII and lack of an appropriate animal model to investigate the efficacy of heat-treated products.* ***However, by the time it became apparent that NANBH was more serious than initially though, all domestic and imported concentrates were already routinely heat-treated and therefore conferred little risk of infection with NANBH or HIV."*** (pp.27-29) (emphasis added).

Section 4: The Self-Sufficiency Report, published in 2006 (titled "*Self-sufficiency in Blood Products in England and Wales: A Chronology from 1973 to 1991*")

4.1. The Inquiry refers me to the Self-Sufficiency Report, which I now understand was published on 27 February 2006 [**DHSC0200111**]. I only became aware that the final report had been published when in 2018 I was contacted by Departmental colleagues upon establishment of this Inquiry. At the time, I was seconded to the Paterson Inquiry. I am told by my advisers that the differences between the 2004 draft report and the published report were relatively minor and that the substance of the content was not materially changed. The Inquiry asks me to consider the following conclusions:

> *"Nobody acted wrongly in the light of the facts that were available to them at the time.*
>
> *• Every effort was made by the Government to pursue self sufficiency in blood products during the 1970s and early 1980s.*
>
> *• The more serious consequences of Hepatitis C, only became apparent in 1989 and the development of reliable tests for its recognition in 1991.*
>
> *• Tests to devise a procedure to make the Hepatitis C virus inactive were developed and introduced as soon as practicable"*

4.2. I wish to point out to the Inquiry that the quotation to which I am referred is not, as the question suggests, taken directly from the published report. I have been shown that it is in fact a quotation from a Departmental press release that was issued on publication day and which was accompanied by a comment from the then Parliamentary Under Secretary of State for Public Health, Caroline Flint [**DHSC0041198_088**]. The Inquiry's quotation of the DH press release is also incomplete. The press release included a fifth bullet point to the effect that self-sufficiency would have made no difference to Hepatitis C infection.

4.3. The Inquiry asks (Q9) to what extent do I agree with the conclusions set out in the quotation above now. As I have explained above, my involvement ceased

in 2002. Save for my very brief comments in my email of 16 May 2005 (see paragraph 3.23 above), I was not involved with either the 2004 draft report or the Self-Sufficiency Report published in 2006.

4.4. My general response therefore is that I am not able to comment on what was said in the report that was published. I am not an expert on blood policy and I am certainly not able to consider the validity of the conclusions above based on what is known now.

4.5. I do, however, offer the following comments on the bullet points above in so far as my 2002 Document Review Report was concerned:

a) *"Nobody acted wrongly in the light of the facts that were available to them at the time."*

This was not a conclusion that I drew in my report, after examination of the papers made available to me. As explained at paragraph 4.2 above, I understand that this is a quotation from the DH press release, rather than from the published Self-Sufficiency Report itself. This phrase did not appear in these terms in the published Self-Sufficiency Report, so it may have been an inference that someone drew from what was said in the published report. Given the report was subject to amendment and revision after my involvement finished, I am not in a position to venture a view about whether it was an appropriate inference to draw from the published Self-Sufficiency Report.

b) *"Every effort was made by the Government to pursue self sufficiency in blood products during the 1970s and early 1980s."*

My 2002 Document Review Report set out the steps taken by government to pursue self-sufficiency and the resources allocated, in so far as this was apparent from the available papers. I repeat the point that I made above about: (a) my understanding that this is a quotation from the press release, not from the published report and (b) given the

amendments made after my involvement finished and prior to publication, I am not in a position to venture a view about whether it was an appropriate inference to draw from the published Self-Sufficiency Report.

c) *"The more serious consequences of Hepatitis C, only became apparent in 1989 and the development of reliable tests for its recognition in 1991."*

My report said, *"the prevailing medical opinion in the 1970s and the early 1980s seems to have been that NANBH was not particularly serious and when set against the consequences of not having treatment."* (p.18). My report also said that tests were introduced in 1991 (p.4) but I did not consider the reliability of the tests that were available in 1991 or prior to 1991.

d) *"Tests to devise a procedure to make the Hepatitis C virus inactive were developed and introduced as soon as practicable"*

My report did not comment on the timescale for the introduction of Hepatitis C tests in the UK.

4.6. The Inquiry asks (Q10) whether I consider my report to be a complete account of the circumstances. I assume the Inquiry asks about my 2002 Document Review Report (given what I have said about my lack of involvement thereafter). As my report noted, the information provided to me was *"at times contradictory and incomplete"*. I was conscious that the documents that I had were incomplete and I understand that further documents have come to light since. My report cannot therefore be *"a complete account"* of the circumstances but presented a summary of the documents provided to me.

4.7. The Inquiry also refers me to a draft DH briefing pack produced in response to Lord Jenkin's Lords Starred Question (referred to at paragraph 3.20 above).

The Self-Sufficiency Report, published in 2006 (titled "Self-sufficiency in Blood Products in England and Wales: A Chronology from 1973 to 1991")

Lord Jenkin asked, *"whether DH's report, Self-Sufficiency in Blood Products in England and Wales… is a complete account of the circumstances leading to the infection of National Health Service patients with HIV and hepatitis C due to contaminated blood products"* [**DHSC0041198_088**]. The briefing pack said, *"The fact that self sufficiency was not achieved appears to have been linked to the increase in demand for clotting factors at the time, not to any failure to implement Ministerial initiatives."* The Inquiry asks (Q11) why "*the report*" did not consider what measures were or should have been taken to reduce demand. Since I found nothing about reducing demand in the documents that I reviewed, my report is silent on it. I cannot comment on why this was not considered in the later drafts or in the published Self-Sufficiency Report.

Section 5: Criticisms of the final report

5.1. The Inquiry refers me to Chapter 4 of campaigner Carol Grayson's dissertation, in which she critiques the Self-Sufficiency Report published in 2006 [**CGRA0000208**]. The Inquiry's questions proceed on the assumption that I was the author of the Self-Sufficiency Report. For the reasons I have explained, I was not and I am therefore not the right person to respond to the individual points of criticism made by Carol Grayson and referred to by the Inquiry.

5.2. I would, however, make the following points in relation to my 2002 Document Review Report:

a) My task was to review the papers available to me at the time, in late 2002, and produce a report for Ministers. I carried out this task within a short timescale (three months).

b) To assist me, I interviewed certain individuals, visited BPL and had a useful meeting with the Haemophilia Society. They offered to share documents, but I cannot now recall whether I received any from them.

c) I carried out my task in good faith. I did not *"choose a careful selection of extracts…to avoid showing successive governments in a negative light"* (Grayson dissertation), rather I reviewed and summarised faithfully the documents provided to me. If an issue was not apparent from the available documents and was not raised in any of my interviews, then it would not have been covered in my report.

d) I tried to draft my report in straightforward language to make it accessible (I myself was a lay person with no special expertise in this area).

e) My report was amended / redrafted in 2004. I understand that the Department employed an independent medical consultancy to *"redraft the* [my] *Report in a more robust form"* [**DHSC5336358**] and *"to analyse the papers and finalise the report"* [**DHSC0041198_088**].

f) I was asked to comment on the 2004 draft report, which I did in a very brief email and at a time of significant other work pressure. I understand

that other individuals (with specialist knowledge of blood policy and practice) were also asked to comment. The Department also *"consulted with colleagues in the devolved administrations, BPL, National Blood Service and some clinicians for factual accuracy."* [**DHSC0041198_088**].

g) I understand that the 2004 draft was subject to further, albeit more minor, amendment prior to publication in 2006.

h) I recognise that there was delay between the completion of my report in 2002 and publication of the Self-Sufficiency Report in 2006. I have set out some of the factual background above, in so far as it is apparent from the documents provided to me. I was not significantly involved after 2002 so cannot comment on the reasons for any delay.

5.3. During my career, I have been at pains to follow the evidence, even if this presents organisations, including the Department of Health, in an unfavourable light. My approach to the self-sufficiency report was no different to the investigations and inquiries that I worked on subsequently, since 2009. I have not shirked from criticising the Department in other reviews that I have done.

Section 6: Reflective questions / Other issues

Alan Milburn's oral evidence to the Inquiry

6.1. The Inquiry refers me to the transcript of Alan Milburn's oral evidence to the Inquiry [**INQY1000227**]. I have been reminded that he was the Secretary of State for Health at the time of my 2002 review. Alan Milburn told the Inquiry that he was not aware that Yvette Cooper had instigated the self-sufficiency review. He also told the Inquiry that he thought he might have felt at the time (i.e. when in office, up to June 2003) that a public inquiry was not necessary but that his view might have been swayed had he been aware of the outcome of the review.

6.2. The Inquiry asks (Q14) whether I was aware of a suggestion that the internal investigation into self-sufficiency delayed a public inquiry. I was not aware of any suggestion at the time about not having a public inquiry because I was doing my review. In any event, my 2002 Document Review Report was completed some five months before Alan Milburn left office, so could have been provided to him. I had also offered to make myself available to brief ministers.

Andy Burnham's speech to the House of Commons, 15 January 2005

6.3. The Inquiry refers me to an extract from Andy Burnham's speech to the House of Commons in which he stated,

> *"… 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."* [**RLIT0000771**].

6.4. I am asked (Q14) to set out my view on this statement. While working for three months in Charles Lister's team I did not experience anything like what Andy Burnham describes. More generally, I was surprised to hear Andy Burnham's views about civil servants, given that I am proud of my work as a seconded civil servant to the Hillsborough Independent Panel. I served alongside a very

talented and hard-working team of civil servants, mainly from the Home Office, who did not shirk from holding truth to power.

Charles Lister's statement to the Inquiry

6.5. The Inquiry refers me to Charles Lister's third statement at [**WITN4505389**], in which he said,

> *"I raised the question of how much I may have been affected by a collective mindset. I had in mind the concept of 'Group Think', and whether officials, experts and ministers alike were affected by group think when addressing this issue. When I now reflect on these issues, it is that concept which I ponder on rather than any sense of resistance from the civil service. It is the sense that when you work closely and collectively together, there is a risk of group mindset developing and the risk that you are not sufficiently open to challenge to the existing group views. It is of course impossible to say how much this impacted on our decision making."*

6.6. I had very limited contact with Charles Lister when carrying out this task, and certainly not enough to witness or develop the 'group think' to which he refers.

Statement

I believe tha GRO-C is witness statement are true.

Signed……

Dated……15.12.2022……