

FOURTH WRITTEN STATEMENT OF RICHARD GUTOWSKI

Witness Name: Richard  
Gutowski

Statement No.: WITN5292109

Exhibits:

WITN5292110-WITN5292116

Dated: 13/03/2023

INFECTED BLOOD INQUIRY

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## Section 1: Introduction

I, Richard Gutowski, will say as follows: -

- 1.1. I am a retired Civil Servant. My date of birth and home address are known to the Inquiry.
- 1.2. This is my fourth statement to the Inquiry. My first statement [WITN5292001], dated 10 May 2022 addressed the destruction of Department of Health (DH) papers and was in response to a Rule 9 Request from the Inquiry dated 29 January 2021. My second statement [WITN5292016], dated 11 May 2022 addressed matters arising from Rule 9 Requests dated 1 November 2021 and 14 February 2022. My third statement dated 19 May 2022 addressed matters arising from a Rule 9 Request dated 18 February 2022.
- 1.3. I then gave oral evidence to the Inquiry on Friday, 10 June 2022.
- 1.4. In this fourth statement I respond to a fourth Rule 9 Request dated 30 January 2023. This Rule 9 Request relates to the involvement of external medical consultants from Dianthus Medical Limited (Dianthus) in the production of the report entitled "Self-Sufficiency in Blood Products in England and Wales. A Chronology from 1973 to 1991" (hereafter referred to as "**the Self-Sufficiency Report**") [NTHT0000053].
- 1.5. I understand that the Self-Sufficiency Report was published in February 2006. I was Team Leader (Grade 6) in the Blood Policy Team from 9 June 2003 until December 2004, when I moved to the MHRA. After December 2004, I was not involved with any work on the Self-Sufficiency Report.

- 1.6. My first and second statements set out my involvement in what led to the Self-Sufficiency Report, see, especially, paragraphs 4.38 to 4.65 of my second statement [WITN5292016].
- 1.7. In my oral evidence on Friday 10 June 2022 I was questioned by Counsel to the Inquiry about the Self-Sufficiency Report. The relevant evidence is at pages 109 to 128 of the transcript [INQY1000214].

## **Relevant chronology and response to the Inquiry's further questions**

- 1.8. I set out below a chronological account of my involvement in the Self-Sufficiency Report. I have sought to answer the Inquiry's further specific questions at the appropriate stage in the chronology. In doing so, I have repeated references to some of the documents discussed in my earlier statements and in my oral evidence. I emphasise, however, that this statement is not the totality of my evidence on the issue of the Self-Sufficiency Report and reference should be made to my earlier statements and oral evidence.
- 1.9. With regards to the specific issues raised by the Inquiry in this Rule 9, I do have some limited recollections of the events, particularly since reviewing the documents. However, I am conscious that my active recollections remain limited / patchy and, given the passage of time, I remain heavily reliant on the written records when those records are not complete. I continue to do my best to assist the Inquiry.

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1.10. As I explained at paragraph 4.3 of my second statement, before I joined the Blood Policy Team, an internal review of the Department's commitment to self-sufficiency had been commissioned in 2002 by Yvette Cooper (when she was PS(H)).

1.11. In my first statement, I referred to Charles Lister's email of 10 June 2003 [DHSC0020720\_081]. By this date, I had taken over as Team Leader and Charles Lister had left. His email explained that Peter Burgin (who I now understand was a DH official (on temporary promotion to Grade 7) with no prior involvement in blood policy) had been tasked to review documents from 1973 to 1985 to address how the Department implemented policy of UK self-sufficiency in blood products; the developing understanding of the seriousness of non A, non B hepatitis; the extent to which problems at BPL delayed self-sufficiency; and whether self-sufficiency would have led to fewer cases of hepatitis C in haemophiliacs. Charles Lister said that before Peter Burgin's report could be made more widely available it needed,

*"- 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."*

1.12. A few days later, on 12 June 2003, Zubeda Seedat forwarded to me an email that Peter Burgin had sent to Charles Lister on 24 December 2002 [WITN4505402]. Mr Burgin had said in that earlier email that he was attaching the final draft of his report.

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- 1.13. The Inquiry has now provided me with a copy of Peter Burgin's statement to the Inquiry [WITN7485001]. In that statement, Mr Burgin explains that while preparing his statement he was able to retrieve from his computer the document that he emailed to Charles Lister on 24 December 2002 (hereafter referred to as "**the 2002 draft report**") [WITN7485005]. The report was titled, "*England and Wales Self-Sufficiency in Blood Products: a Chronology from 1973 - 1985*". It ran to 21 pages and annexed a chronology of events.
- 1.14. On 15 December 2003, I minuted John Hutton's Private Secretary about the background to the Self-Sufficiency Report and its progress [LDOW0000350]. I explained that, "*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.*"
- 1.15. In terms of when action was first taken to progress the 2002 draft report, on 1 March 2004, I emailed my Head of Division (Grade 4), Gerard Hetherington about next steps [DHSC6259005]. As I explained in my oral evidence (INQY1000214, page 119), nothing had happened on the report since June 2003 due to staffing pressures and the huge amount of other work my team were involved in. My email said,

*"I would like to bring someone in to finish off the Report in the sense of producing a chronology, cross-referencing the documents referred to and clearing it with those consulted during its production. In addition we need to produce an Executive Summary which could be published. It would also be useful if at the same time someone ie Hugh Nicholas, could produce a subsid[i]ary report on the issue of when NonA, NonB, and Hepatitis C was first identified and what decisions were taken at the time and for what reasons. This would give us an extra degree of confidence in our line that we dealt with Hepatitis C as soon as we became aware of it."*

It seems apparent from this email sent on 1 March 2004 that it had not been determined at this stage that the whole report would be published; we were thinking in terms of creating and publishing an Executive Summary of the report.

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1.16. I note that, save for the point about a chronology, the next steps that I suggested were the same as Charles Lister had said were required in his email of 10 June 2003. As to the reference to a subsidiary report on the issue of hepatitis C, I explained in my oral evidence (INQY1000214, page 120) why I thought this was required.

1.17. I have not been shown any written response from Gerard Hetherington to my email, although it is apparent from my subsequent email (sent on 6 May 2004) that I had discussed the issue with him and that he must have agreed to the instruction of a medical writer to redraft the report. In my email of 6 May 2004, I 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 th[e]y 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. Unfortuna[t]ely 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.” [DHSC5336358].*

1.18. The Inquiry asks whether I asked Dianthus to “redraft the Report in a more robust form” and if so what I meant by requiring it to be in a more robust form. The wording, “...redraft the Report in a more robust form” comes from the email set out above, rather than any instruction to Dianthus. In my previous evidence to the Inquiry, I have addressed what I meant by this phrase in my email to Gerard Hetherington:

(1) In footnote 9 of my second statement [WITN5292016], I explained that,

*“On review of the documents available to me, it is my recollection that we decided to instruct a medical writer to address the outstanding drafting issues that Charles Lister had identified in his email to Zubeda Seedat dated 10 June 2003 .... This is what ... I*

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*mean in my email dated 06 May 2004 ... when I say "...redraft the [Self Sufficiency] Report in a more robust form";*

- (2) During my oral evidence on 10 June 2022 at pages 121 (line 20) -123 (line 25) of the transcript [INQY1000214] I said this:

*"Q. Could we then turn to DHSC5336358, please. It's an email from you to Gerard Hetherington again and there's lots of details about your team, but if we turn over the page to the end of the email, we have this is final paragraph:*

*"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 they are able to take on the work."*

*Just pausing there, what did you mean when you said it needed to be redrafted in a more robust form?*

*A. What I meant there was to redraft -- rather than redraft it, actually pull together into a stronger form for it to be published. Because when we first got the Burgin report, it wasn't in a format that was okay to put out into the public domain. It needed to be pulled together. I didn't use the word "robust" there in the sense of trying to strengthen up any of the conclusions that were -- or to undermine any of the conclusions that were reached.*

*Q. Just in terms of the redraft, that might have suggested that you were seeking substantial changes to the report rather than finalising it or something like that?*

*A. No, I think a better use -- a better word would have been to "finalise" the report rather than "redraft". That's bad drafting on my point -- on my part, back then.*

*Q. Then if we carry on in the paragraph:*

*"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. Unfortunately 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."*

*Why did you think -- why were you considering using the medical writing firm to assess whether the decisions made stood up?*



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*A. Because I -- if I recollect, I was advised that this particular company had the expertise of doing this type of work.*

*Q. It might seem somewhat unusual for a writing consultancy, a medical writing consultancy, to also address matters of substance. Do you have any recollection of your thinking or the discussions you had about that?*

*A. I don't, I'm afraid. My main concern at this point is just to get somebody in to do the work, given the very strong steer we'd been given from Melanie Johnson."*

I would re-iterate that my reference in the email to Gerard Hetherington to "...redraft[ing] the Report in a more robust form" was in effect shorthand for the tasks that Charles Lister had set out. It was not intended to convey a process of amendment (in either direction, strengthening or undermining) to the substantive conclusions of the report, rather that there needed to be detailed referencing for the statements made in the report. I cannot say one way or the other whether I used the language of "robust" in any instructions to Dianthus or meeting with them, though I refer to the agreement with them below. If I did use language similar to "robust" with Dianthus I am confident that it would have been in this same sense.

- 1.19. There is an exchange of emails between Dr Adam Jacobs of Dianthus and me between 14 May and 8 June 2004 [WITN5292110]. That exchange shows that Dr Jacobs came into DH to discuss the work with me; and subsequently gave a quotation for the work (see email of 14 May 2004). I asked Dianthus to draw up the terms of an agreement (emails of 19 May 2004). On 7 June 2004, I emailed indicating that two copies of the agreement signed by me on behalf of DH were in the post. The agreement was signed by me on behalf of DH on 7 June 2004 and Dr Jacobs on behalf of Dianthus on 9 June 2004. Since it is clear that Dr Jacobs had drafted the agreement following our meeting, the agreement is likely to reflect the tasks as we had discussed at the earlier meeting. Under the agreement, Dianthus was contracted to **"...provide the services of one or more of its medical writers to the Department of Health to improve the quality of referencing in a report of hepatitis C and blood transfusions"** (emphasis added) [WITN5292057]. The written agreement therefore corresponds with what I have set out above, *i.e.* that the material

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task was one of the backing up / referencing for the conclusions in the report, this having been a weakness in Mr Burgin's completed first draft as originally identified by Charles Lister. The continuing email correspondence between me and Dr Jacobs from June 2004 confirmed that the work would be undertaken by either or both of Dr Jacobs and his colleague, Dr Shanida Nataraja, and would begin on 23 June 2004 with a target completion date of end of July 2004 [WITN5292110].

1.20. The Inquiry asks me a series of questions about the agreement.

a) How did you come to appoint Dianthus Medical Ltd to undertake the work? Why was this organisation selected for the work?

As far as I can remember, we had to move forward with completing the work identified by Charles Lister in order for the Burgin Report to be in a fit state for publication. Charles Lister's note to Zubeda Seedat dated 10 June 2003 detailed what work he felt needed to be done. Paragraph 4.40 of my second statement [WITN5292016] explains this especially as qualified by footnote 9. I had no reason to disagree with this assessment by Charles Lister. I have a recollection of some discussions with colleagues within the Health Protection Division to try to identify a company competent enough to undertake the task, and I think we would have moved towards this solution once it was clear that Dr Hugh Nicholas could not do the work himself. I cannot recall precisely with whom I had those discussions. It was a question of checking with colleagues if they knew of a suitable firm and my recollection is that during the course of those discussions the name Dianthus Medical came up. I then went to Gerard Hetherington for clearance. As the May – June 2004 email correspondence shows, I arranged a meeting with Dianthus to determine whether they were able to do the work and the likely costs. Following those discussions, I clearly felt they were able to do the work and at a cost that was acceptable and for which I could get clearance.

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b) Prior to the signing of this agreement, what was discussed, and with whom, about the task that was to be completed?

As I have explained above, I discussed the need to progress this work, which was a Ministerial commitment, with my Division Head, Gerard Hetherington. I know I would have had to discuss the work with Gerard Hetherington because his clearance was required. Funding was very tight at the time and would have needed approval. I recall that the funding came from project money. I cannot specifically recall exactly what was agreed between Gerard Hetherington and I in relation to any terms of reference. However, I believe that we would have agreed that the nature of the work should be as per Charles Lister's email. As to instructions to Dianthus, I have referred to the meeting I had with them as mentioned in the contemporaneous email exchanges with Dr Jacobs. From general experience, I would have thought it likely that in addition to the discussions in the meeting, there would have been some written terms of reference or instruction, given the need to justify the spending of public money. However, the materials made available to me from DH records do not include any written terms of reference or instructions and I cannot rule out the possibility that the meeting I held with Dianthus, followed by the short written agreement was thought sufficient. Although I cannot recall the detail, my recollection is that relevant divisional policy files were made available to Dianthus because, although my memory is hazy, I have a recollection of them having to sign some sort of confidentiality clause to be able to access these files. Unfortunately, I do not have sight of any written instructions from me on this point or memory of the detail of any discussions to assist further.

c) Was a written "brief" or instructions provided by you (or, to your knowledge, anyone else within the Department of Health) prior to

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Dianthus Medical Ltd commencing the work about what amendments or additions were to be made to the report?

I have addressed this in answer to the previous question.

d) What was your understanding of the task that you had asked Dianthus Medical Ltd to complete?

I covered this in answer to the previous questions and in paragraphs 4.40 and 4.41 of my second statement [WITN5292016] where I said as follows:

*“4.40 In terms of others who had input into the report, on 6 May 2004 I emailed the director of my Division, Gerard Hetherington, and recorded our agreement that we should “...pursue appointing a medical writer to redraft the [Self Sufficiency] Report in a more robust form” [DHSC5336358]. I can see that within the same correspondence, I explained that I had hoped that Dr Hugh Nicholas an experienced Senior Medical Officer in the Department, might be able to assist with this redrafting process, but he did not have the necessary capacity at that time due to commitments on other projects. I have set this email out more extensively below in addressing the timescales involved in work on the report.*

*4.41. On 7 June 2004, I signed an agreement for medical writing services provided by Dianthus Medical Limited. This agreement provided for Dianthus Medical Limited providing “the services of one or more of its medical writers to the Department of Health to improve the quality of referencing in a report of hepatitis C and blood transfusions” [WITN5292057]. I have also seen a briefing for a Parliamentary Question dated 23 May 2006 which records, in response to the question “Who undertook the review?”:*

*“A DH official (Peter Burgin) was employed for three months to undertake the review of papers. A draft report was submitted to the Blood Policy Team in January 2003. The report was completed by Medical Consultants from a company called Dianthus Medical Limited. The company specialises in medical writing, statistical consultancy and clinical data management services. The consultants that assisted were Dr Shanida Nataraja and Dr Adam Jacobs.”*

*[WITN5292062 (pg 24)]*

1.21. The Inquiry asks whether I supplied Dianthus with the list of things that Charles Lister had noted were required before the report could be made

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*“more widely available”*. I cannot say whether we gave Dianthus the list from Charles Lister verbatim; whether we went through it in a meeting, or it was in written instructions. One way or the other, however, I believe that the thrust of what needed doing, as originally set out by Charles Lister, would have been communicated to Dianthus.

1.22. The Inquiry asks whether I sent Dianthus the December 2002 draft report [WITN7485005]. I do not specifically recall personally providing Dianthus with a copy of Mr Burgin’s draft report from December 2002. However, clearly either I or someone on the Blood Policy team must have provided them with the 2002 draft version of the report for them to work on.

1.23. The available materials include a subsequent email that Dr Nataraja sent me on 20 July 2004 [WITN5292111]. She said she had spoken with *“David last week about the status of the Hepatitis C project”* (this was likely a reference to David Reay, an Executive Officer in my team).

*“I was sorry to hear that your mother passed away last week. Please accept our condolences.*

*I spoke with David last week about the status of the Hepatitis C project and thought that I would send through an update for you on your return to the office. I have identified 145 of 160 references for the text in the report. Of these 10 or so references cannot be found in the specified binders or are reported to be located at the solicitors office, and I have provided David with a list of these references in the hope that he will have more luck in tracking them down than I have had. I have ordered a further 20 or so references from the British Library and expect that the library will forward these to you when they become available. I have also proofread the report, correcting it for punctuation, spelling, and grammar. Of the remaining 15 statements in the text for which I have failed to find an appropriate reference to support them, I have addressed some of these issues by re-wording the text or removing them [al]together, on the advice of David, and plan to address the remaining issues in the same manner.*

*There are a number of issues that still need to be addressed before I can submit the first draft of the report:*

*1) There are sections of the report that could be re-written and/or re-structured for clarity, such as the section on the development of*

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*understanding on the long-term health consequences of Hepatitis C. Do you want me to modify the report in this manner?*

*2) There is additional information that could be included in the report, such as the availability of surrogate and first/second generation Hepatitis C testing, and the rationale for the Government not implementing these test[s] when they became available. Do you want me to include this extra information in the first draft of the report or merely indicate in the text where this information could be added if necessary?*

*3) There are sections of the report that are repetitive and this repetition could be removed by subtle changes to the structure of the report and the insertion of appropriate cross-references within the text. Would you like me to address this issue?"*

Dr Nataraja said Dianthus had billed for 16 of the 20 days quoted and asked for a meeting to discuss how to address the issues she had raised.

- 1.24. The DHSC disclosure made available to me does not include any reply to Dr Nataraja or any record of a further meeting with Dianthus in response to this email. I cannot now recall whether I met Dr Nataraja at any stage, she may have been at the earlier meeting I had with Dianthus. But I cannot recall, one way or the other, whether I met her in response to this email. As is apparent from the opening paragraph of Dr Nataraja's email, this was occurring in the period immediately after my mother had died. I would have taken some compassionate leave at this time. I am simply unable to recall whether I responded to this query or whether David Reay may have done so in my absence (the email reflects that Dr Nataraja and David Reay had liaised on the project the previous week). In any event David Reay would have brought me up to speed on the discussions in my capacity as Team Leader. The second paragraph of the email recaps what has been done so far, which is what we expected. The list of things that Dr Nataraja then described as "*a number of issues that still need to be addressed before I can submit the first draft of the report*" were somewhat more substantive in nature not mere referencing. However, they were about structure, clarity, avoiding repetition and in some respects adding further information. The Inquiry will have seen

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from the version of the report returned by Dianthus on 4 August 2004 (see further below) that their draft did include some reference to surrogate testing for HCV and first/second generation Hepatitis C testing (*i.e.* to point 2 in Dr Nataraja's list). That may suggest that I or someone in the team (again possibly David Reay if I was absent) responded positively to the invitation in relation to the additional issues numbered 1) to 3) in Dr Nataraja's email. However, I cannot be more positive on this as I do not actively remember it and I have not seen correspondence or emails confirming the point. I would only add that, on its face, the "further issues" outlined by Dr Nataraja and numbered 1) to 3) do not read as in any way untoward or inappropriate. To my current reading they appear sensible suggestions for improvement to the report, the emphasis being on improving clarity and structure, cross-referencing, avoiding repetition and offering further information.

- 1.25. I am asked by the Inquiry whether I gave any additional instructions of what Dianthus were tasked to do. I do not recall giving Dianthus any additional instructions. No documents as far as I am aware show that I did. However, as I have set out above, it may be that I or someone in my team approved the suggestion for further improvements (cross-referencing, restructuring, removal of duplication and inclusion of some further information) as proposed in Dr Nataraja's email of 20 July 2004.
- 1.26. On 4 August 2004, Dr Nataraja emailed me with, "...*the first draft of the report as an electronic version*" [WITN5292112]. She attached a Word document file titled, "*BurginReportRevWed.doc*". From searches of the DH's database, my advisers have identified the document that was likely to have been attached [WITN5292113]. The document was a draft report dated 4 August 2004 that ran to 38 pages (hereafter referred to as "**the August 2004 draft report**").
- 1.27. The title of the August 2004 draft report had been amended from the 2002 draft report to cover the period 1973 to 1991 (the 2002 draft report covered

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the period 1973 to 1985). I cannot say now why this date was amended although I note that: (i) the suggestions from Dr Nataraja in her 20 July 2004 email had included reference to the introduction of HCV testing (which had occurred in 1991) and (ii) even Mr Burgin's draft report of December 2002 had contained a number of references to developments between 1985 and 1991. In a further development, the August 2004 draft report included a list of abbreviations; an executive summary; and a list of references. Against several of the references was written the words, in green highlight, *"To be ordered from the library"*. This seems to correspond with what Dr Nataraja said about references in her earlier email of 20 July.

- 1.28. On 1 September 2004, I emailed Gerard Hetherington and my Branch Head, Dr Ailsa Wight (Grade 5) [DHSC6258608]. I said, *"... we have just received the report we commissioned on this whole issue and we could attempt to finally nail this long running saga"*. I assume that I was referring to the August 2004 draft report. I discussed this email at paragraphs 45 to 52 of my first statement [WITN5292001], (and explained at paragraph 47 what I meant by *"nail this long running saga"*). I was also asked about this document more generally in my oral evidence (INQY1000214 p.124). My email was silent about whether further work was required on the draft. I said,

*"The key is how we take this forward. Do we react to a Lord Morris question or a make a proactive move. Do we release the Executive Summary of the Report or just the Conclusions or the Report itself. We will need to engage MHRA because of the licensing issues.*

*Can we therefore meet to discuss handling."*

- 1.29. In a Health Protection Divisional Update regarding Blood Policy dated 15 September 2004 (to which I referred in my second witness statement at paragraph 4.29), it was recorded that, *"...the consultant has now produced a first draft of the report, which concludes that the Department acted reasonably at the time in terms of known infectivity of blood"* [DHSC5042710]. This update was reproduced verbatim in the 29 September 2004 update, to which the Inquiry has referred me [DHSC5349579].



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1.30. As I noted at paragraph 2.10 above, I had previously told Gerard Hetherington that I wanted to get Dr Hugh Nicholas, a DH medical civil servant, “... *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*” [DHSC5336358]. Dr Nicholas had not been able to undertake the work on Mr Burgin’s draft report earlier in 2004. However, having received the revised version from Dianthus, I assume that I must have asked Dr Nicholas to help review their draft report. I say that because I can see from the documents that on 22 September 2004, Dr Nicholas emailed me attaching detailed comments on the August 2004 draft report [WITN5292114]. The reason I went to Dr Nicholas was that he was a Senior Medical Officer (SMO) in the Health Protection Division and he would have had medical expertise to provide input into the report, something which I did not have. I did not have the clinical or technical expertise and I would not have felt comfortable to make any judgement on the substance of the report in the medical areas, in particular. Hugh was at this time my Branch’s “go to” medical civil servant and, as I have indicated, I had first wanted to consult him when I started work on this project as I explained in my 1 March 2004 email to Gerard Hetherington. Dr Nicholas copied his email to Gerry Robb and said he had also copied in “Denise”. This is I believe a reference to Denise O’Shaughnessy who was another SMO who joined the Health Protection Division halfway through my time there. I think she joined to help Dr Nicholas with the Hepatitis C strategy.

1.31. Dr Nicholas attached a Word document file titled, “*SELSUFFIC.doc*” which was his comments on the August 2004 draft report [DHSC0041232\_006]. Dr Nicholas’ note set out general comments on the draft and suggested specific amendments. In opening, he said,

*“1. This is a helpful report, and the amassed references should prove a useful resource. However, further work will need to be done if it is proposed to make the report public (under a DH imprimatur) in any way in the future, and care should taken if quoting from the report in its current state. Whilst the drafting by the authors is OK from their perspective and the information available to them, it is not always*

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*written in a form which could be used by DH – e.g. their various speculations on what DH policy may have been (when we should know), and it might be difficult to attribute to DH some of their more intuitive views.*

*2. I have looked at this with the idea that DH may wish to publish the document (? As its own rather than under the names of the authors). One thing that frequently seems to be missing, is the actual views of the Department in this. Also there is little on where DH was obtaining its expert advice at the time, but this might become clearer if I knew more about the various committees and working groups referred to in the report (see below)."*

- 1.32. A week later, on 29 September 2004, I emailed Dr Wight [DHSC5041563]. As set out at paragraph 4.28 of my second statement [WITN5292016], I told Dr Wight that we recently commissioned further work into the allegations about self-sufficiency and the report was being "*peer reviewed*". In my oral evidence to the Inquiry, I was asked by Counsel to the Inquiry and by the Chair what I meant by "*peer reviewed*" (INQY1000214, p.127-128). I said I thought that my reference to "*peer reviewed*" referred to the medical consultancy firm's work. Having now seen Dr Nicholas's email and comments (which were not available to me when I made my previous statements or when I gave oral evidence), I think it more likely that in referring to peer review, I was reflecting that we had gone to Dr Nicholas for comment on the August 2004 draft report, rather than Dianthus peer reviewing Mr Burgin's draft report.
- 1.33. On 4 October 2004, I emailed the Head of Customer Service at DH, Linda Percival, (copied to Dr Wight, Gerard Hetherington and Zubeda Seedat) about various items of Private Office correspondence [DHSC0041333\_004]. As set out at paragraph 4.30 of my second statement, I said, "*...we have just concluded a review of documents at the time and the preliminary conclusions reached are that the Government at the time acted reasonably and a public enquiry is not warranted.*" [WITN5292016].

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- 1.34. Dr Nataraja emailed me on 8 October 2004 [WITN5292115]. I assume from the content of her email that I must have sent her Dr Nicholas' comments, although I have seen no record of this. Dr Nataraja said,

*"...I have made some changes to the report in line with Hugh's comments. I have yet to compile a table of all the different committees and working groups involved, and their responsibilities, but can do this at a later stage, if necessary."*

- 1.35. Dr Nataraja attached a Word document file titled, "*BurginReportFinal.doc*". Again, using searches on the DH's database, my advisers have identified the document that was likely to have been attached [WITN5292116]. While this had a similar layout to the August 2004 draft report, it was dated 8 October 2004 (hereafter referred to as "**the October 2004 draft report**"). Having compared the August 2004 draft report and the October 2004 draft report the changes made seem to be consistent with changes having been made by Dianthus to address the comments made by Dr Nicholas.

- 1.36. On 26 October 2004, I emailed Robert Stock of the Scottish Executive [DHSC0038529\_072]. I said "*... the report into self sufficiency we commissioned has now been peer reviewed, and I will be going to the Minister next week on how to make the findings public.*" I gave further detail of this correspondence at paragraphs 54 to 57 of my first statement [WITN5292001].

- 1.37. As I explained at paragraph 4.56 of my second statement [WITN5292016], despite the indication that a ministerial submission was imminent, the available papers do not suggest that a submission was put to Melanie Johnson before I left the Blood Policy Team in December 2004.

- 1.38. From documents that I have been shown that post-date my time in blood policy, some five months later, on 12 May 2005, Zubeda Seedat emailed Peter Burgin a copy of "*the final draft copy of the review of papers on self-sufficiency in blood products*" [DHSC5368830]. She attached a copy of

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the October 2004 draft report [WITN7485007]. The Inquiry asks whether the document that was attached [WITN7485007] was the first draft of the report produced in September 2004. My understanding from the documents is that this document is in fact the copy of the report emailed to me by Dr Nataraja on 8 October 2004 referred to in this statement as the October 2004 draft report (i.e. from the papers, what appears to have been the second of the two drafts submitted by Dianthus which incorporated amendments made by Dianthus following the comments of Dr Nicholas).

1.39. Zubeda Seedat said that Dr Frank Hill (UKHCDO), Jane Martin and Dr Terry Snape (BPL) and the NBA Chief Executive would be sent a copy and asked to comment on factual accuracy and that they were considering sending it to Professor Zuckerman and Dr Craske. Peter Burgin provided some brief comments by reply dated 16 May 2005.

1.40. On 27 May 2005, my successor, William Connon, wrote to Dr Snape with a copy of the draft report and invited his comments by 10 June 2005 [DHSC0020720\_015]. On 20 July 2005, William Connon put a submission to Caroline Flint with a copy of the draft report [DHSC0006259\_020]. He said,

*"13. Due to a number of pressures, there has been a long delay in finalising the report. A draft report was submitted to the Blood Policy Team in January 2003. However there were a number of outstanding issues which had to be resolved before the report could be finalised and submitted to Ministers.*

*14. There were a number of unsubstantiated statements in the report which had to be checked for accuracy, we had to draw up a lengthy list of references to the report and include an executive summary. In 2004, officials commissioned consultants to analyse the papers and finalise the report. We have also had to consult with colleagues in the devolved administrations, BPL, National Blood Service and some clinicians. The draft may be subject to some minor amendment to reflect comment from clinicians which we have just received. However, this will not alter the main findings of the report."*

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- 1.41. Finally, I have been shown a briefing for a Parliamentary Question dated 23 May 2006 [DHSC0004232\_078]. As I said in my second statement at paragraph 4.41, the briefing recorded, at page 24,

*“A DH official (Peter Burgin) was employed for three months to undertake the review of papers. A draft report was submitted to the Blood Policy Team in January 2003. The report was completed by Medical Consultants from a company called Dianthus Medical Limited. The company specialises in medical writing, statistical consultancy and [clinical] data management services. The consultants that assisted were Dr Shanida Nataraja and Dr Adam Jacobs” [WITN5292016].*

- 1.42. Finally, the Inquiry asks me a number of sub-questions about who made the changes between different versions of the report, who was responsible for deciding on those changes, and what my own involvement was and the evidence I relied on to make changes. In that regard, the Inquiry has also referred me to Mr Burgin's statement at paragraph 3.25 onwards [WITN7485007] [1/91 at 109ff]. I should first of all repeat what I said in my introduction that there are limits both to my memory and to the documentary record. However, I can say that:

- (1) To the best of my knowledge and belief, I do not think that I personally made changes to the report;
- (2) I am sure that I would not have made changes to the report in relation to explanations of the development of medical understanding or other issues in the medical field;
- (3) As far as I understand it, and to the best of my knowledge and belief, the changes between the 2002 draft report and the August 2004 draft report would have been made by Dr Jacobs and / or Dr Nataraja of Dianthus. As per Dr Nataraja's email of 20 July, there may have been liaison with my team. Dianthus raised the possibility of some re-writing or restructuring for clarity, inserting more information revealed by the underlying papers and removing repetitive parts. It may be my team gave the go ahead for that kind of change to be made and that these were incorporated by Dianthus in the version they provided in August 2004.

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(4) Further changes then appear to have been made because I asked for input from Dr Nicholas on the August 2004 version of the report. It seems clear that these were passed on to Dianthus who then put forward further amendments to the report in the October 2004 draft report, dealing with Dr Nicholas's comments.

Statement of Truth

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

**GRO-C**

Signed.....

Dated...13/03/2023.....