Witness Name: Richard Gutowski
Statement No.: WITN5292063
Exhibits: WITN5292064-WITN5292108
Dated: 19/05/2022

INFECTED BLOOD INQUIRY

THIRD WITNESS STATEMENT OF RICHARD GUTOWSKI

I, Richard Gutowski will say as follows: -

Contents

1. SECTION 1: INTRODUCTION 3

2. SECTION 2: PRODUCT LABELLING 5

Roles and Responsibilities 5

Range of Products 7

Size and Organisation of the Team 7

Decision-making processes 7

Interactions with Pharmaceutical Companies and Concerns 8

Risks Associated with the Use of Blood Products 10

Additional Comments 11

3. SECTION 3: HIV LITIGATION 11

Advice on whether the litigation should be fought, conceded or settled 13

Identifying documents during the discovery and disclosure process 31

PII Certificates 35

The terms of settlement 42

1. SECTION 1: INTRODUCTION

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 third witness statement to the Inquiry. My first statement dated 10 May 2022 addressed the destruction of Department of Health ('DH') papers and my second statement dated 11 May 2022 addressed a number of matters arising from Rule 9 Requests received from the Inquiry on 1 November 2021 and 14 February 2022.

1.3. In this third statement I respond to a third Rule 9 Request dated 18 February 2022, concerning the period when I was working in the Medicines Division (the 'Division') of the Department of Health and Social Security ('DHSS')/DH. The topics covered by this Rule 9 Request were: (i) product labelling and information on blood products and (ii) my involvement in the HIV litigation brought against DH and others in the late 1980s. Eleven additional documents were provided for me to review.

1.4. As with previous statements, I have done my best to answer the questions raised in the Rule 9 Requests from both my memory and the documents that have been made available to me. I would emphasise that the same limitations referred to in my earlier statements apply equally to this statement.

1.5. In my first witness statement, I explained that I joined the then DHSS as an Executive Officer in October 1973 and retired from the Civil Service in October 2011 as a Grade 6. I set out a summary of the different roles I held within the Department. As I have now been asked questions relating to my time at the Medicines Division (the 'MD') between 1984 and 1991, I feel it is important to clarify that my work in the Division at this time was at a junior level, firstly as an Executive Officer in the labelling/advertising job and secondly, on promotion to

Higher Executive Officer, I moved to set up the Litigation Unit. Initially, my role involved reviewing medicines advertising and product inserts to ensure compliance with relevant legislation.

1.6. The requirements for product labels were stipulated in legislation and the product licence for any given medicine. My role was to check the labels against set criteria such as the manufacturer's details, correct name of the product, the product licence number etc. I do not recall being involved in any decision-making as to what should or should not be included in product labels, leaflets or in advertising in terms of what the medicine should be used for and any relevant warnings or potential adverse reactions. I checked whether any information was missing and if there was an issue or complaint about a product not being labelled or advertised correctly, this would have been dealt with by assessors within the MD who had relevant qualifications and expert knowledge in this area.

1.7. I also wish to clarify my role in relation to heading up the new Litigation Unit which involved preparing the MD's defence in various court cases. I was asked to set up a new Litigation Unit to deal with various cases being brought against the MD. Apart from the HIV litigation, a case involving the drug Opren springs to mind. Ordinarily, with litigation in the MD, I would take instructions from senior colleagues and, working with departmental and external solicitors, I would help manage and pull together information required by the lawyers and otherwise act as a conduit or single point of contact for information and progress on various strands of litigation. In terms of the HIV litigation, I recall that other senior colleagues in DH and the Medicines Control Agency ('MCA') effectively coordinated this work across DH and my role was, primarily, to act as an administrator and source of information to senior colleagues as well as helping carry out specific litigation tasks allocated to the MD such as discovery and disclosure.

2. SECTION 2: PRODUCT LABELLING

2.1. I have been asked a number of questions by the Inquiry in relation to the period 1984 to 1991) on the issue of product labelling. In addressing this issue, as I have raised in my first statement, in fact I was working within the MD slightly earlier than 1984. It is apparent from the content of a letter dated 13 October 1983, that in fact I was part of the division from September 1983 [BAYP0000002_205].

Roles and Responsibilities

2.2. As I have previously explained, the team that I worked in within the MD had a number of functions and undertook a broad remit of work. This included the team providing scrutiny of medicines advertising and checking labelling and product inserts for medicines to ensure compliance with the relevant legislation. I am aware from the limited documents which I have seen that I did undertake some tasks in the area of product labelling, although given the passage of time and the lack of available documentation, I do not now have any clear recollection of this work.

2.3. Requirements were in place at that time in relation to the labels applied to medical products as well as any product information, leaflet or insert which would be included within the medicine packaging. However, there is a key distinction which I should make clear. The advice on labelling requirements (i.e. what the labels should contain), inserts or product information for medicines and medical products was undertaken by *medical assessors* (both within the UK and abroad if a product was manufactured in another country) and those awarding any product licence. There were also requirements which manufacturers had to follow to ensure that any product information and labelling complied with the Medicines Act 1968 and any other relevant legislation. As I recall it, this legislation sets out the required information that must appear on over the counter medicines, pharmacy medicines and prescription only medicines (the latter of which would include blood products).

2.4. I was not involved in making these decisions about the content of any labels or product information. Rather, the role undertaken by my team was purely administrative. It was our job to check that the medical product labelling and information in fact complied with the requirements that had been set on the advice of the medical assessors. In other words, our role was limited to ensuring that the labels and product information produced met the necessary criteria. We were not responsible for any decision-making in relation to labelling requirements for products, nor were we responsible for identifying any specific issues, concerns or risks in relation to product labelling and information.

2.5. Where any issues or concerns arose in respect of product labelling or information, these were raised through correspondence with the relevant manufacturer. In addition, meetings would take place if these were considered necessary. I deal with a number of these aspects further below in my statement.

2.6. In any event, the type of the work undertaken by the team in relation to product labelling is shown within the small number of documents which I have read in preparing this statement and referred to further below. The fact that there are a very small number of documents which relate to this issue during the time that I worked within the MD illustrates, I believe, the limited nature of my team's involvement in product labelling and the fact that the work which my team undertook in this area was essentially administrative in nature.

2.7. My name will however appear on documents in relation to labelling issues because, on the administrative side of the labelling work, I would have been a named point of contact. I note, for example, that in a December 1985 contacts point sheet, I am listed as the non-professional enquiries contact point in relation to Advertising, Labelling and Packaging [MHRA0005126].

Range of Products

2.8. The Inquiry asks me about the range of products that my team worked on and how much time was devoted to blood products. However, other than the correspondence regarding Koate with Miles Laboratories Limited over the period September 1983 and June 1984 (which the Inquiry has raised with me and which I deal with further below), I cannot now recall any details of the different products that my team reviewed for product labelling and information compliance nor what percentage of our time was spent specifically on blood products. I do now recall that Koate was a blood product created for haemophiliacs but only because it has been raised by the Inquiry. My team did not have any special role in relation to blood products. The administrative role we had applied across all licensed medicines.

Size and Organisation of the Team

2.9. Unfortunately, I cannot now independently recall much, if any, relevant information relating to the organisation of this team either in terms of its size, structure and who dealt with specific areas of work. I do seem to remember that my principal in this team was Jim Bewley and his Assistant Secretary was David Hagger and that my work spanned a number of areas such as advertising, labelling and product labelling. However, I do not directly recall whether I, or any others in the team, line managed specific members of staff. I am afraid that I cannot usefully assist the Inquiry any further in relation to this area of questioning.

Decision-making processes

2.10. Again, I have very limited recollection as to the team's decision-making processes given the passage of time of almost 40 years. Nevertheless, I seem to remember that labelling compliance was checked with reference to the accompanying product licence as a guide. This is because the product licence would set out the information required on the label and product leaflet. I cannot now recall the exact process that was followed when labelling was in breach of

the relevant requirements, but I believe that there was an enforcement unit within the MD or MCA which would investigate and prosecute if necessary. I was not, however, involved in that process.

Interactions with Pharmaceutical Companies and Concerns

2.11. The Inquiry has asked how my team interacted with pharmaceutical companies with regards to product labelling and has provided me with a number of documents to review in this regard. It also asks me how my team learned of concerns and what my team would do in addressing such concerns. I have already mentioned above that my team acted in an administrative role in regards to labelling requirements for products. However, where concerns arose, these were generally raised through correspondence or meetings with the relevant producer.

2.12. For example, the Inquiry has referred me to a letter dated 13 October 1983 from Miss Nelson, who was within my team at the Medicines Division, sent to Mrs Tatt at Miles Laboratories [BAYP0000002_205]. Within her letter, Miss Nelson refers to a conversation between myself and Mrs Tatt on 14 September 1983 regarding the over-sticking of labels for the Koate product. Miss Nelson was chasing for an updated sample label to be sent to us. Given the passage of time, I do not now recall this conversation or the subsequent letter. However, Miss Nelson's letter demonstrates the very low-level administrative nature of the work which I was involved in with respect to product labelling.

2.13. On 9 December 1983, Mrs Tatt wrote to me in respect of the Koate blood product referring to an earlier letter she had written to me dated 30 November 1983. I have not been provided with a copy of the 30 November 1983 letter, but I note that Mrs Tatt's letter of 9 December 1983 confirmed that, as from 1 February 1984, all Koate blood products for sale in the UK would be labelled in accordance with the Medicines Act 1968 and subordinate legislation relating to labelling [BAYP0000002_217].

2.14. On 10 February 1984, I wrote to Mrs Tatt, referring to an earlier letter I had sent to her dated 29 December 1983 (which I also have not seen) chasing for examples of the revised labels which had been in use for Koate since 1 February 1984 [BAYP0000003_207]. Again, this was a purely administrative issue. There is nothing within this correspondence to suggest that I was involved in determining the contents of the labels, only that they were correctly formatted and applied in line with the set requirements.

2.15. On 2 April 1984, Mr Dyos, the Managing Director of Cutter Laboratories (which was a division of Miles Laboratories) wrote to Mr Booth in the context of labelling the Koate product [BAYP0000003_213]. However, I cannot now remember Mr Booth; he may have been a member of my team but I cannot now be sure. Within this letter, Mr Dyos apparently provided copies of the final Koate label, carton and outer packaging artwork. The letter stated that as confirmed at a meeting which took place between Mr Dyos and Mr Booth on 29 March 1984, *"…the protracted delay experienced over the past months was caused mainly through F.D.A reluctance in approving the text originally submitted…".* "FDA" refers to the American government department of Food and Drug Administration. I would assume that they were the body responsible for setting the US labelling requirements given that this product was manufactured in the U.S. Further, the letter stated that "*…new batches are labelled in accordance with the requirements of the Medicines Act 1968 and subordinate legislation".* Again, there is no indication in this letter that the administrative team of which I was a part had any role in drafting or approving the contents of any product labelling or information.

2.16. On 8 June 1984, Mr Dyos of Cutter Laboratories wrote to me again, referring to an earlier letter I had sent to him on 16 April 1984. I do not have a copy of the letter I sent in April 1984. However, in his letter to me, Mr Dyos stated that I had provided written confirmation that I was content that the label, carton and outer packaging label for the Koate blood product were acceptable

[BAYP0000003_233]. I do not have any reason to doubt what Mr Dyos says in that letter, but would again clarify that in confirming my view that they were acceptable, I would have been simply checking that the labels met the criteria which had been set by others and were in line with the applicable legislation. I would not have been evaluating the content of the labels, or providing any direction or advice on the text.

2.17. I cannot now recall whether I or the team had any other interaction with other pharmaceutical companies in connection with the labelling of blood products other than Koate, and I have not seen any documents relating to the labelling of other products. I have seen reference within the documents to another blood product, produced by Armour, in connection with the HIV litigation work that I was involved in whilst I was at the MD [DHSC0007045_002]. I recall that this product was withdrawn in or around 1986. However, I cannot recall having any involvement in product labelling or information of products produced by Armour, or any other blood product.

2.18. Due to the amount of time which has passed, I am afraid that I cannot add anything further to assist the Inquiry in relation to product labelling and information. As is demonstrated by the limited documents relating to this issue, my involvement appears to have been in relation to administrative matters only and I was only an Executive Officer at this time.

Risks Associated with the Use of Blood Products

2.19. The Inquiry has asked if I am able to assist with product labelling in relation to the risks associated with the use of blood products. In particular, the risk of infection with hepatitis viruses or HTLVIII/HIV/AIDS.

2.20. As I have explained above, it was not the role of my team to set the requirements for the contents of product labels and information. Given, therefore, the administrative nature of my role, I am not best placed to assist

the Inquiry on this question. Nevertheless, to the extent that it is helpful, my working understanding of the position is that within a clinical or hospital setting, patients would not have routinely been provided with product labels or warnings. This information would be given to the clinician who would decide what, and in what form, information should be provided to the patient. This is different to a more typical pharmacy setting where patients would be able to directly see any warning labels or packaging information.

2.21. I do not recall having any direct concerns at the time about how any risks to patients were identified within product labelling or information in relation to blood products. I am afraid I can only repeat that warnings about risks and side effects and the like were a matter for the qualified assessors. Any issues I did have in connection with the *accuracy* of labelling (in the sense of not meeting the set requirements) would have been raised with the manufacturer, as can be seen from my exchanges with Miles Laboratories in relation to Koate as I have mentioned above.

Additional Comments

2.22. I have been asked if I have any additional comments relevant to the Inquiry's Terms of Reference in respect of the labelling, information and advertising of blood products in the UK in the 1980s. As noted above, subject to the sight of further relevant documents, I cannot now recall any details in relation to product labelling during the 1980s and I do not have anything further to add in this regard.

3. SECTION 3: HIV LITIGATION

3.1. The Inquiry refers me to the fact that there are numerous documents concerning the HIV litigation in which my name appears on the distribution list and a smaller number that were written by me. Examples provided to me by the Inquiry are:

a. The minutes of a meeting about the litigation on 6 July 1988, which I attended [DHSC0007045_002].

b. My note of the hearing before Mr Justice Ognall on 26 June 1989 [DHSC0007045_003].

c. A submission from Mr Canavan, dated 19 July 1990, to the Permanent Secretary on Public Interest Immunity certificates, which was copied to me among others [DHSC0004360_144].

d. Mr Canavan's minute to Mr Powell, one of the Departmental Solicitors, dated 7 September 1990, and the attached draft letter, which was copied to me among seven others [DHSC0043124].

e. A minute dated 7 November 1990, written by me to senior members of the MCA providing a litigation update [DHSC0046962_367].

f. A minute from David Burrage, dated 23 January 1991, which was copied to me, again amongst seven others [DHSC0020866_045].

3.2. As I explained in paragraph 8.5 of my first witness statement, during the period 1984 to 1991, I was located in the MD of DHSC/DH with responsibility for providing scrutiny of medicines advertising and product inserts to ensure compliance with relevant legislation. During my time in the MD it became the MCA which was an executive agency of DH. I believe this change occurred in or around 1989 but I cannot be sure. For completeness and to assist with the context of the questions raised with me, the MD/MCA took on much of the day to day work of the Licensing Authority ('LA') and the Committee on the Safety of Medicines ('CSM') and advised the LA on the safety, quality and efficacy of medicines as part of the licensing process before products could be placed on the market. Both the LA and CSM were created under the Medicines Act 1968.

3.3. In this context, I set up a new MCA Litigation Unit to assist with preparing the MCA's defences in various court cases. However, I should clarify that (despite the title 'Litigation Unit') I was the only member of staff in that unit and I reported

directly to the head of policy, being Mr Hagger and his successor, Mr Adler. This was essentially a coordinating or conduit-type role, whereby I would take instructions from senior officials in the MCA to feed into any necessary defences or pleadings and would liaise with internal DH lawyers who would then instruct the Treasury Solicitor's Department and Counsel as required. I would then provide any updates on casework back to my senior officials. Again, this role was primarily administrative in nature but very labour-intensive.

3.4. In the MD /MCA and in the context of the HIV litigation, I was one member of the overall DH policy and legal team with responsibility for defending the litigation. Much of the lead work on this litigation was undertaken by Mr Canavan and Dr Rejman and other officials who were within departments of DH with a more central coordinating role in the litigation as I explain below. I acted as a single point of contact for the MCA in the litigation and took instructions from senior officials, assisted with disclosure searches and fed views and updates back to those coordinating and making decisions on the litigation. At times, I may have offered views on the implications of proposed strategic approaches being taken or proposed, but I was still a junior (HEO) grade reporting to and taking instructions from senior officials and acting as a conduit in the litigation. Inevitably, the work on major litigation was time-consuming, both in terms of documentary work and meetings, and senior officials in the MCA did not have the capacity to dedicate significant amounts of time to such work. I would be expected to be involved at ground level and report back (and take instructions on) the points of significance and potential concern.

Advice on whether the litigation should be fought, conceded or settled.

3.5. I have been asked specifically if I advised on whether the litigation should be fought, conceded or settled. In summary, I had little, if any, substantive contribution to the strategic direction of the litigation. This was because, firstly, I was a relatively junior official within the MCA which was itself a minor stakeholder compared to DH and others. Secondly, my role was, essentially, to

act as a conduit or single point of contact to senior MCA policy colleagues and to pro-actively carry out or represent their instructions. Thirdly, senior policy colleagues within DH were primarily responsible for advising ministers on this litigation and coordinating the various stakeholders.

3.6. From what I can see of the documents, I must have first become aware of the HIV litigation around June 1988. For example, I am copied into a minute from Mr Wilson, the head of the MD to Mr Nilsson (senior lawyer in SOLC5) on 20 June 1988 [DHSC0007046_039]. That minute refers to a previous minute of 17 June and confirms that the "*Licensing Authority wish to resist*". That basic decision had already been taken at a higher level, I would assume. Consistent with how I have already described my role, I was asked to be the 'administrative focal point' in MD for the case. Mr Wilson's minute also stated that: "*Ministers will need to be informed. Given the range of bodies upon whom a writ has been served it would be sensible if one branch in DHSS took the lead on this. I hope Dr Moore will accept that HS should do so".* HS1 was a DH administrative division and Dr Moore was, I think, a Principal (Grade 7) within HS1A at this time. This shows the MD wanting the main Administrative Part of DH to take the lead co-ordinating the response to the litigation.

3.7. On 23 June 1988, Dr Moore provided a submission to David Mellor, the Minister of State for Health, setting out the details of the case. He made clear that:

> *"Treasury Solicitors have been instructed by our solicitors that the CSM, the Licensing Authority, and the Secretary of State wish to resist the allegation and they will acknowledge the writ accordingly"* [DHSC0007046_035].

Again, I think this reflects the decision to contest the litigation that had already been taken.

3.8. As part of this "*administrative focal point in MD*", on 27 June 1988, I duly prepared and sent an internal memorandum and paper on the HIV litigation to colleagues ahead of the June meeting of the CSM. This was copied to more senior members of the MCA and to Dr Moore [DHSC0003675_008],

[WITN5292064] and [WITN5292065]. I can see that I then attended a subsequent meeting with the legal and policy colleagues across DH on 6 July 1988, and that Mr Sturdy of the Treasury Solicitor's Department was present along with Dr Moore and Mr Powell [DHSC0007045_002].

3.9. Nevertheless, it remains clear from correspondence that the lead role was being conducted by more central and senior DH colleagues. This is clear from a number of documents in this era such as:

a A minute from Dr Rejman (MEDSEB) to Mr Powell, dated 14 June 1989, (which was not copied to me) [DHSC0004359_059]. This minute set out much of the context behind the litigation but also suggested a clear DH preference for presenting a joined-up approach to the litigation: "*10. …the Licensing Authority and CSM have only been named as defendants in one case… They are relying on HS1 to deal with all the other cases, where SoS is named in his capacity as head of DH. …12. I have informed MD of the present attempt at concerted action by the plaintiffs and would suggest you copy details to them".*

b A minute from Dr Rejman to Mrs Armstrong (SOLC5 and internal MD legal advisor) dated 22 June 1989 [WITN5292066]. This mentioned that Dr Rotblat, who was the senior medical assessor with responsibility for biological medicinal products (including blood), and I had been kept informed of the progress of the litigation and suggested that the MD may wish to be represented at the forthcoming hearing;

c A minute from Mr Arthur (HS1) to various policy and legal stakeholders, including me, dated 22 June 1989 [WITN5292067] and [WITN5292068]. This sought to coordinate the preparatory work of the defendants in advance of the hearing scheduled for 29 June and to take instructions on various points. Two paragraphs were allotted to me to follow up /provide instructions, other MD points were for Dr Rotblat and Mr Bewley;

d. A submission from Mr Hagger (MD) to Mr Mellor dated 26 June 1989 and copied to me amongst very many others [DHSC0043529]. Mr Hagger was the Grade 5 Head of my Branch, responsible for the branch's overall

remit i.e. (a) Committee on Safety of Medicines; (b) general administration of Medicines Acts; international aspects of medicine control and National Biological Standards Board. This submission complemented a submission from Mr Dobson the Grade 5 HS1 of the same date. and which provided, from the LA's perspective, further details on the duty of care argument (i.e. that any duty of care owed by the LA is towards the public in general rather than specific individuals). The submission concluded by asking The Minister of State to agree not to use the LA/CSM duty of care legal argument and that, as the HS1 paper suggested, that no fault compensation was not an option. I do not recall contributing to the drafting of this submission. But it is consistent with my recollection that where there were strategic decisions with policy implications to be taken on the litigation, this would done at significantly more senior level than my own;

e. A minute from Dr Rejman to Dr Pickles dated 13 July 1989 (to which I was not copied) [DHSC0006272_043]. This suggested greater cooperation and coordination between DH and the regions but also, seemingly, with the MD. I believe but cannot be sure that, by this time, Mr Canavan had taken over from Mr Moore in HS1; and

f. A handwritten note from Mr Canavan to Mr Powell dated 19 July 1989. This note provided direction to the Solicitor's Division regarding a number of matters such as directions, costs, discovery and PII [DHSC0006481_030].

3.10. The Inquiry refers to my note to Mr Hagger, dated 3 July 1989, and the fact that I attended the hearing on 27 June 1989 (I have seen other references to the hearing taking place on 29 June) [DHSC0007045_003]. I would have attended this hearing on behalf of the MD given that, at this stage, different defendants were involved, and to act as a point of contact for instructions, as well as to promptly report back on the outcome of the hearing to more senior officials. On substantive matters, it tended to be MCA senior officials who engaged with the substance of the litigation. This approach can be seen in Dr Rotblat's minute to

Mr Nilsson, dated 16 August 1989, in which she attached her comments on the statement of claim and her reaction to it [WITN5292069] (minute), [WITN5292070] (comments). By way of contrast, I merely forwarded these comments to Mr Arthur. Dr Purves, a senior assessor with the MCA, also sent his own observations on the statement of claim to Mr Nilsson on 30 August 1989 [WITN5292071] and [WITN5292072].

3.11. This distinction can also be seen from a note from Dr Rejman to the CMO dated 23 August 1989, which was copied to me, amongst several other officials [WITN5292073]. This note enclosed a briefing for the CMO for his meeting with Mr Mellor on the litigation and set out the attendance list for both the briefing with the CMO and Mr Mellor. I see that I am not on the attendance list but that Mr Hagger of the MCA was invited to attend the meeting with the Minister.

3.12. From the MD/MCA's perspective, much of the activity from around September 1989 through to October 1989 appears to have been focussed on the issue of the 'duty of care' argument on behalf of the LA and CSM and the implications of this on the HIV litigation. This work was driven forward by my senior colleagues in the MCA. The duty of care issue was raised as a specific item on an agenda for a meeting scheduled by Mr Arthur for 25 September 1989 for the various stakeholders [WITN5292074] and [WITN5292075]. It was also raised in a draft submission to be put to Mr Mellor by Mr Hagger, dated, I believe, 25 September 1989, which was copied to me [WITN5292076].

3.13. The thrust of that submission centred on whether a separate strand of litigation relating to the use of Valium and Librium could be used to advance a case that neither the LA nor any of its advisory committees owed a duty of care to an individual, as opposed to the wider public. I recall that this strategy was alluded to as far back as 26 June 1989 in the submission from Mr Hagger to Mr Mellor in paragraphs 5-8. The draft submission noted that this could be precedent setting with direct read across to the HIV litigation for the LA and the CSM. It was to be put to the Minister on page 10 of the submission whether he would

want the duty of care arguments deployed as a preliminary issue in those cases, and counsel briefed accordingly. I do not recall having a hand in the drafting of this submission, but I must have been aware of it. A further draft of this submission appears to have been produced around October 1989 [DHSC0006484_016].

3.14. On 16 October 1989, Mr Dobson (HS1) sent a minute to the relevant officials dealing with the litigation (including me) which set out growing ministerial unease on the current position of the litigation and Mr Mellor's feeling that the "*Department will lose on this whatever the outcome of the court case and would like to see what more can be done"* [DHSC0006279_025]. As a result, Mr Dobson suggested that it would be timely to review the current position to include options available regarding an out of court settlement and to schedule a joint meeting accordingly. This document highlights that the impetus behind an out of court settlement appeared to have originated at ministerial level, with HS1 coordinating and seeking to implement that political drive.

3.15. It appears from a further submission dated 17 October 1989, from Mr Wilson put to Mr Mellor (but through Mr Dobson), that the previous submissions on the duty of care issue had not been put to ministers as yet [DHSC0041034_021]. I was copied into this submission on the administrative side. I can see that I sent it to Mr Dobson via, I presume, Mr Arthur, for his comments [WITN5292077]. It appears that this was because a written opinion from leading Counsel had not yet been produced, and was to follow. In any event, this further submission sought the Minister's views as to whether to instruct Counsel to run the duty of care argument.

3.16. Legal advice was eventually received on 18 October 1989, suggesting that "*a duty of care ought to be denied and a preliminary issue tried on the point in both the HIV cases and the Valium action, and that he sees no reason in principle why both should not be heard together on this point".* Accordingly, an updated

submission was put to Mr Mellor by Mr Wilson on 19 October 1989, attaching leading Counsel's advice [DHSC0007038].

3.17. I note that I provided a contribution on behalf of the MCA to Mr Arthur in respect of a draft submission intended for Mr Mellor on 20 October 1989 regarding a potential out of court settlement [WITN5292078]. I suspect this draft submission eventually took the form of a final submission and advice paper sent to the Mr Clarke, the Secretary of State, Baroness Hooper, Minister of State (Lords) and Sir Christopher France, the Permanent Secretary, from Mr Dobson on 26 October 1989 [WITN5292079]. The contribution that I sent over made clear that, from the perspective of the LA and CSM, any out of court settlement would, from a precedent-setting angle, override the LA's and CSM's consistent and historic denials of liability. In addition, it would create unhelpful precedent by encouraging further litigation, promoting over-defensive licensing decisions and the reluctance of academics to sit on the CSM and other advisory committees. This note concludes by stating at paragraph 4 that: "*Officials would accordingly advise strongly against an out of court settlement in the HIV/haemophiliacs litigation".*

3.18. I do not recall whether I drafted this note or it was drafted by one or more of my senior colleagues, and I was sending it on their behalf. If it was the former, I was reflecting on what I had already understood to be the MCA's established position. In either event, on 24 October 1989, Mr Wilson sent a minute to Mr Arthur (copied to me, Mr Hagger and Mrs Armstrong) raising, more forcefully, the same issues [WITN5292080]. In this minute Mr Wilson made clear that he was aware of the paper I had sent the previous week, and that he wished to remain clearly involved: "*2. I note that you intend to circulate a further version taking account of the contribution on out of court settlements to Mr Gutowski sent to you last week. I would like to see a copy of that version".* This point is made more clearly when he stated, at paragraph 7 regarding wording relating to an out of court settlement: "*I assume that this will be rewritten in the light of our contribution on this subject".*

3.19. In this note, Mr Wilson went on to suggest alternative wording to the submission and provided views and comments on behalf of the MCA on the settlement options. He also noted the response of Mr Mellor, who "*has indicated that he does not favour taking it in the HIV cases, but would be willing to see the issue tested in the Valium/Librium situation".* Mr Wilson noted that Counsel had expressed doubts as to the consistency of such an approach and that it would be difficult to raise the argument in the Valium case but not in the HIV litigation. I do not recall what input, if any, I had into this minute.

3.20. I can see from Mr Dobson's final submission of 26 October 1989 to Mr Mellor (and copied to Mr Clarke, Baroness Hooper and Sir Christopher France) that many of Mr Wilson's comments and the MCA contribution that I sent to Mr Arthur appear to were taken on board [WITN5292079]. The submission noted that "*Our advice therefore remains that ministers should continue with the litigation and should not signal any readiness to provide additional funding, beyond the steps already in hand to allow greater flexibility to the trust".* While that was the headline advice, the annexed paper set out a number of potential settlement options. These included Option A: Out of Court Settlement, Option B: Explicitly Increasing Funding to the Macfarlane Trust, Option C: Ex-Gratia Payment, Option D: Commission of Enquiry and Option E: Publicise the Government's Position.

3.21. Separately, I note that on 26 October 1989, Mr Wilson took the lead on putting up a further submission to Mr Mellor (on the point regarding the consistency of running the duty of care argument in the Valium/Librium litigation but not the HIV litigation [DHSC0046945_060]. In the same document, Mr Dobson added his comments:

> "*(Subject to legal advice)*
>
> *I agree with the analysis above and suggest that Counsel's proposals at 4b and 4c offer a way of minimising the political difficulties of appearing*

to be evading legal scrutiny, while avoiding the potentially very damaging knock-on effects if the "questions of policy" issue is not run".

3.22. On 21 November 1989, Mr Arthur provided a background note to Mr Canavan and Virginia Bottomley (who had taken over as MS(H)) on the vaccine damage payments scheme and the family fund [DHSC0002471_041]. I am copied into this note, and it appears to have been produced in response to a request from Mrs Bottomley for that information in advance of a meeting with the Haemophilia Society on 22 November 1989. I am unclear on the exact context behind this note but I would infer that this might reflect growing ministerial consideration as to whether to settle the litigation by looking at other existing funds set up to administer ex-gratia payments.

3.23. By 22 November 1989 a ministerial direction on the duty of care argument and related public policy issues had still not been given and therefore Mr Wilson suggested to Mr Dobson that a further submission should be put to the Minister of State [WITN5292081]. I was copied in along with Dr Jones and Mr Hagger in MCA. The submission from Mr Wilson appears to have been put to Mrs Bottomley on 23 November 1989, although I am not copied into it [DHSC0046959_075]. The submission asks for the Minister to advise on whether, firstly, the duty of care argument should be run in both the HIV and Valium cases with regards to the LA and CSM responsibilities under the Medicines Act, secondly, the duty of care argument should be run in the HIV case with regards to the Secretary of State's responsibilities under NHS legislation and thirdly that allegations concerning questions of policy should be struck-out as non-justiciable. On 1 December 1989, it was the Secretary of State who, in fact, responded to say that:

"S of S has seen Mr Wilson's submission of 23 November. His view is that Counsel should argue all three points listed at paragraph 7 of the submission…".

3.24. In the event, Mr Justice Ognall did not allow a trial of the preliminary issues (see the Minute from Kate Lee reporting this to Mr Wilson on 7 December [DHSC0044644]. I see that at paragraph 3 of this minute, leading Counsel had advised that this was not worth appealing given that the chances of succeeding were "*slim*" and that it meant that the duty of care arguments could be freely deployed in related litigation without running into the "*public sympathy problem*" as would be the case in the HIV litigation.

3.25. Kate Lee's note suggested, on the back of Counsel's advice, "*So far as the open letter is concerned, the offer not to seek an order for costs if actions are discontinued now follows the precedent set in the OPREN case, and, viewed with the additional money made available to the McFarlane Trust, may be seen as a sympathetic gesture" (§6).* I now recall, looking at my minute to Miss Lee dated 12 December 1989 and copied to Mr Wilson and Mr Canavan, that I was "*uneasy*" about writing such an open letter on costs [WITN5292082]. I think that it was rare for me to raise issues of substance like this directly but my concern was actually that such a move would not be viewed "*sympathetically*" and could actually be seen as "*overly aggressive*" on the basis that:

> *"It could be argued that having given the Plaintiffs an additional ex-gratia payment, the Government were now squeezing for the action to be discontinued especially as the payment was outside the litigation ie that the Gover[n]ment was buying itself out of the litigation". (§3)*

3.26. I cannot now recall specifically whether I did discuss the contents of this letter with my senior officials (e.g. Mr Wilson) before sending it, but I am sure that I would have done given its content. I do, however, note in this regard that this position was reflected in Mr Wilson's submission put to Mrs Bottomley and Mr Dobson on 18 December 1989 [DHSC0046948_041]. This submission asked for a ministerial decision on whether to a) seek leave to appeal against the High Court decision not to hear preliminary issues and b) whether the Government should indicate that it will not seek any order for costs against the plaintiffs who withdraw from the action by a due date. In respect of a) the submission leant

heavily on Counsel's advice and at paragraph 5, stated that officials advised against seeking leave to appeal. In respect of b) Mr Wilson appears to reiterate the point that I had made with a variation: -

> *"8. Officials do not favour an open letter to plaintiffs which could be seen in the media as putting pressure on litigants, to deter them from seeking 'justice' because of high costs. However, they think that if such an offer were to be made in response to the Pannone Napier letter and confirmed in Court at the next opportunity (probably January) such criticism should be avoided and it could be presented as a positive step for Government to be helpful to those plaintiffs who wish now to withdraw (or who are being advised of the wisdom of doing so)". (original emphasis)*

3.27. I am unclear which officials originally suggested this course of action but the clear advice in the submission was that "*Officials accordingly favour a response to Pannone Napier as soon as possible, indicating that the Government will be willing to forego its costs in respect of plaintiffs who withdraw by a due date…*" (original emphasis). I note that Mr Clarke agreed to this advice on 3 January 1990, and I was one of the several officials copied into his Private Secretary's response [DHSC0004415_045].

3.28. The pre-trial procedural aspects of this litigation continued into 1990. I have seen a minute from Dr Rejman to Dr Pickles, dated 31 January 1990, and copied to me, providing an update on a hearing on 22 January 1990 [DHSC0003674_010]. I have also seen a draft submission to the Secretary of State from the CMO dated on or around 21 March 1990, giving the view of the Regional Medical Officers that the current approach should be reviewed and that "*If the haemophiliacs get wind that an influential group like the RMOs is in favour of a generous out-of-court settlement, we cannot expect them to call of [sic] proceedings, so this review has to be handled carefully".* This advice went on to state: "*It will be damaging all round if these proceedings get to court*" [DHSC0046942_150].

3.29. Officials leading on the HIV litigation further circulated Counsel's views as to whether or not a limitation argument should be run when responding to the statements of claim. On 22 May 1990, Mr Canavan circulated a draft submission around the interested stakeholders for comment, including MCA colleagues, [WITN5292082A]. I was copied into this note and can see a handwritten note replying, I believe: "*Viv – pl tell Mr Canavan I agree with the draft*". I am unsure who wrote this. The submission itself was put to Mrs Bottomley on 30 May 1990, and copied to the Secretary of State and suggested, out of the three options available, favouring option (ii) being not to take the limitation defence [DHSC0038699_023].

3.30. On 4 June 1990, I put up an updated submission to Mr Clarke copied to MCA colleagues and Mr Canavan on the subject of the Opren litigation. This was at the request of the Secretary of State's Private Office [WITN5292083]. As with the duty of care argument, there was potential read-across from the Opren litigation to the HIV litigation. As regards the limitation argument and therefore I stated:

> *"5…instructions will need to be given as to whether to pursue the*
>
> *limitations point or drop it. This needs to be viewed in connection with the limitation argument currently being considered in the HIV litigation where it is proposed not to run the point – Mr Canavan's submission of 30 May to Mr Davey refers.*
> *6. Counsel has been asked to advise as a matter of urgency. On receipt, officials will make a further detailed submission to Ministers".*

3.31. I would have cleared this submission with Mr Alder and other MCA colleagues before putting it up.

3.32. I note that on 6 June 1990, Baroness Hooper responded to the earlier submission on whether to take the limitation point in the HIV litigation: "*PS(L) has seen your submission to MS(H) of 30 May and feels strongly that we should*

not plead the limitation defence at all" [DHSC0046957_044]. Mrs Bottomley was inclined to reserve DH's position on the limitation defence (option (iii)) but wished to defer to the Secretary of State's legal expertise [WITN5292084]. On 25 June 1990, Mr Clarke's Private Office communicated the Secretary of State's decision on this: "*S of S has seen your minute of 19 June and Mr Canavan's minute of 30 May. S of S commented that we should certainly not abandon the limitation point and he favours option iii"* [DHSC0046957_026].

3.33. As the Inquiry will be well aware, Mr Justice Ognall made an intervention seeking to encourage settlement of the claim. Miss Bendall (SOLC5 – MCA) provided an update of a hearing for directions to me on 26 June 1990 (the hearing took place on the same date) [DHSC0004360_083]. This note was copied to Mr Rees and Mr Cox of the MCA and attached Mr Justice Ognall's note, which was handed out at the hearing [DHSC0046964_024].

3.34. By a minute dated 29 June 1990, I sent a copy of both documents to Mr Alder and other colleagues at the MCA as well as Mr Canavan [WITN5292085]. I set out my views on the potential impact of settlement on the LA's and CSM's legal position taken to date, namely, that, despite Mr Justice Ognall's views that "*Compromise does not necessarily betoken any admission of blameworthiness"*, any settlement would imply that the LA and CSM were legally vulnerable. This could have had an impact on current litigation (e.g. the Opren litigation) as well as future litigation resulting in thousands of potential litigants. Accordingly, I see that I expressed the view that "*No compromise solution out of court could be effectively ring fenced so as not to create a problem/precedent".* While I was emphasising these points, these were views that had already been expressed by senior colleagues. I reported that, because of the seriousness of this intervention, "*Leading Counsel has called for a conference at which he has asked for the attendance of a "senior civil servant".* Obviously, this called for senior level input. I offered to provide a suitable background briefing pack for senior officials in advance of this conference.

3.35. I recall that there was then inevitably intensified consideration of whether or not to settle the HIV litigation. On 2 July 1990 Mr Dobson circulated a draft submission to key officials (I note that I was not copied into this document), the submission being intended for Mrs Bottomley and Mr Clarke [WITN5292085A]. This submission sought to invite Ministers to review current tactics in the HIV litigation in light of a) Mr Justice Ognall's intervention, b) advice from Counsel and c) the RMO's submission which was critical of the Government's stance. This draft submission concluded at paragraph 11 that: *"[Officials believe that to offer an out-of-court settlement to this particular group, without any effective way of avoiding creating a precedent for other groups, would be the worst of all worlds. We therefore advise that Ministers should continue with their present tactics and fight on]".*

3.36. From an exchange of minutes between Mr Alder and Mr Dobson, dated 12 and 16 July 1990, respectively (and to which I was not copied), I can see that concerns were expressed by Mr Alder that the current draft submission had not properly considered LA/CSM and MCA views [WITN5292086] and [DHSC0044287_216]. Emphasising that he was now the MCA lead on this issue, Mr Alder expressed concern that the LA/CSM views had not been sufficient, taken into account, in which context he referenced my earlier minute of 29 June 1990. He was concerned that there was a misunderstanding or misinterpretation of Counsel's advice and the previous concerns raised by Mr Wilson regarding no fault compensation. On my reading of this note now, this supports my view that positions that I had raised or put forward were always done with the agreement and direction of senior officials in the MCA. It also makes clear, again, that decisions and discussions on settlement options were being driven at a senior level. This can be seen in the CMO's separate submission to Mrs Bottomley and Mr Clarke, dated 20 July 1990, which concluded with the line:

> *"I hope therefore, that for humanitarian reasons the Government will find some way to make an ex-gratia settlement to the infected haemophiliacs in relation to this unique tragedy"* [HSOC0017025_004].

I was one of twenty people that were copied into this minute, and probably the most junior to be copied in.

3.37. On 24 July 1990, Mr Heppell (Grade 2) submitted Mr Dobson's note on responding to the HIV litigation to the CMO, the Minister or State and the Secretary of State for their views on the current strategy and potential settlement options [DHSC0046964_003] and [WITN5292087]. Again, I was one (and among the most junior) of a long list of people copied in. The covering submission made clear that there were two choices; either defending the action but being ready to consider administering financial aid through the MacFarlane Trust or seeking settlement out of court. The covering submission recommended not to pursue an out of court settlement but rather to administer payments under the MacFarlane Trust. The submission noted a number of factors to be considered in this regard, such as the fact that the Government's legal arguments remained strong and indeed were actually reinforced by Mr Justice Ognall's intervention, but that there was strong public sympathy for the families concerned and political pressure to settle.

3.38. The attached HIV litigation paper drafted by Mr Dobson invited Ministers to agree:

> *"(i) work up with Counsel detailed proposals for communicating their decision to the trial judge, plaintiffs' solicitors, and the public;*
> *(ii) prepare a minute for Secretary of State to send to the Prime Minister;*
> *(iii) take advice of the Law Officers' secretariat."*

3.39. On 27 July 1990, Mrs Bottomley responded to the effect that she wished to maintain the present position otherwise conceding would "*have inevitable long-term implications for the Department*" [DHSC0046964_008]. On 31 July 1990, Mr Clarke indicated that he was "*…in favour of sticking to our legal defence and continuing to fight the action".* He also considered that: "*the decision should be communicated to the Judge and the Plaintiffs' solicitors in strict confidence. He would like officials to work up detailed proposals for this with Counsel and then to put up to him a handling submission before proceedings".* Nevertheless, he

did indicate that he was "... *content for officials to take advice of the Law Officer's Secretariat*" [DHSC0046964_007].

3.40. Again, it was officials from HS1 (later EHF1) who led on driving forward this work. In particular, I note that Mr Canavan on 3 September 1990, provided the two draft letters to stakeholders for comment as requested by Mr Clarke and coordinated comments from the stakeholders [WITN5292088]. This included comments supplied by Miss Bendall [WITN5292089]. Mr Canavan also requested that Mr Powell seek the views of the Law Officer's Secretariat by a minute dated 7 September 1990 [DHSC0043124].

3.41. Mr Dobson provided a further submission to the Secretary of State on 18 September 1990 [DHSC0020866_091]. This submission conveyed the advice of Counsel and of the Law Officers on handling in light of Ministers' earlier decision and sought instructions as to whether Mr Justice Ognall should be asked to step down from the case and provided updates on several other areas such as the PII appeal and continued pressure to settle from the Regional Health Authorities and RGMs. It seems, from a minute from Mr Canavan to Mr Powell dated 8 October 1990, that Mr Clarke gave approval to the sending of the letter to Pannone Napier regarding cost recovery. This minute recorded that it had been slightly updated to reflect the outcome of the PII appeal hearing and instructed Mr Powell to send it to the Treasury Solicitor's Department [DHSC0020866_116].

3.42. Assisted by the documents, I recall that on 7 November 1990 I wrote to senior MCA colleagues providing an update on various strands of litigation, including the HIV litigation [WITN5292090]. It seems from this minute that I anticipated that the new Secretary of State (Lord Waldegrave) might be inclined to change the policy on defending the HIV litigation and, as a result, it was another opportunity to proactively reinforce the view that the LA/CSM had robust legal arguments that they did not owe a duty a care. Counsel's advice had been received. I suggested that "*any 'deal' would have to include a discontinuance*

of all action against the LA and CSM". However, again, my input merely reiterated the consistent position taken by the MCA to date.

3.43. The announcement of the in-principle agreement was made by the Prime Minister on 11 December 1990 and by further statement by Mr Waldegrave. However, I do not have a recollection of the events leading up to this announcement which, I would suggest, reflects the fact that this was being conducted at a much more senior level than mine.

3.44. On 12 December 1990, Mr Canavan sent a minute to the various stakeholders updating them on the statement given by Lord Waldegrave with regards to settlement of the litigation, its funding and how the £42m would be distributed [WITN5292091]. I have searched my memory, but I cannot recall how this change of policy came about nor who most influenced it.

3.45. On 13 December 1990, I sent a minute to MCA colleagues (copied to Mr Canavan) setting out the outcome of a meeting I had attended with colleagues from EHF1 and the Medical Treatment and Effectiveness Programme to discuss the terms of settlement [DHSC0003963_015]. Consistent with the MCA's position, I explained that at the meeting I had,

> *"… asked for this paragraph [paragraph 4 of the draft] to be strengthened with a separate specific reference to the fact that the Licensing Authority and the Committee on Safety of Medicines have continually categorically denied liability and will continue to do so. This is an attempt to ringfence the LA/CSM from the 'deal' in order to discourage any future litigants who feel that as their injuries were drug induced they were also deserving of 'preferential treatment'. Do we want to pursue this?*

3.46. Looking at this minute now, I can see that I was reiterating what was understood to be the consistent MCA position on this and as I have set out in this statement. Nevertheless, I can see that I still wanted to check with senior officials whether

they wanted me to pursue this further. I have dealt further with the issue regarding the terms of settlement further below in this statement.

3.47. Dr Alder replied the same day, December 1990, and confirmed his instructions on this point which supported the suggestion that I had raised:

> *"While it may not be necessary in terms of strict legal clarity in the context of this particular document to include such a statement, I think it very important in terms of the LA/CSM's future position to do so. We hope that this is the end of the matter so far as HIV and contaminated blood are concerned, but it is not the end of this type of matter for the LA/CSM. It is therefore important that we make it crystal clear to potential future litigants that the LA/CSM position is absolutely the same as it has been"* [DHSC0003655_045].

3.48. In summary, as I have set out above, I think I was far too junior to have played any material role in whether the litigation should be fought, conceded, or settled. Much of my role, as a relatively junior official, was to act as the administrative point of contact for the MCA in the litigation; to obtain and share updates with MCA colleagues, and take instructions on various points. It was in that context that – as the Inquiry has pointed out – my name appears on a large volume of the internal minutes and submissions on the litigation. At times I ensured that the MCA and LA/CSM's particular positions were adequately and proactively protected but this was to ensure consistency across litigation and in accordance with the instructions of senior officials. As I believe the documents show, the main driving force on of the HIV litigation and its eventual settlement was senior HS1/EHF1 colleagues and their own seniors (taking into account the MCA's position) and upon the basis of ministerial direction and on the back of internal legal and external Counsels' advice.

Identifying documents during the discovery and disclosure process

3.49. The Inquiry asks what role I had in identifying documents during the discovery and disclosure process. I would have normally expected my role to have included searching for and identifying documents for disclosure in litigation. This would have been conducted in accordance with instructions from senior colleagues and search parameters identified and set by legal advisors. This is borne out in the relevant documents that I have seen.

3.50. For example, on 3 July 1989, I sent a minute to Mr Hagger and copied to other policy and legal colleagues across DH and MCA. This minute represented my note of a hearing that I attended in the judge's chambers on 27 June 1989 in respect of the HIV litigation [DHSC0007045_003]. I have set out in paragraph 3.10 the reasons why I attended this hearing.

3.51. I cannot independently remember whether other colleagues from DH were present, but I think that it was likely that they were given that my minute intimated that DH were represented at this hearing. In any event, senior DH colleagues were aware of developments [WITN5292092]. I note that this hearing appeared to have effectively marked the start of the discovery process across the various defendants and that it was a process led by legal advice:

> *"On the question of preaction discovery... Our Counsel's advice, after the hearing was that we should agree to discover voluntarily of those documents that we would have released anyway had there been a Court Order against us. He felt that tactically this would have the advantage of keeping our 'powder dry' for future use in an action which was likely to get very messy. The list of documents requested is attached at Annex B and Counsel has asked for site [sic] of them prior to the adjourned hearing. Once we have extracted the relevant papers I suggest an early meeting with HS1 to coordinate a uniform central Government line prior to the meeting with Counsel"* [DHSC0007045_003].

3.52. My reading of this note, therefore, is that Counsel was providing the tactical direction on this request but that there was a need for Mr Canavan to provide a uniform approach across the interested stakeholders. I suspect that I made the suggestion to meet with HS1 in the expectation that my senior colleagues would authorise that approach.

3.53. From a note I sent to Mr Hagger on 10 July 1989, and copied to others, it must have been the case that Mr Hagger asked me to attend this meeting as I duly attended the coordination meeting with Mr Dobson, Mr Canavan, Mr Arthur, Dr Rejman and Mr Powell. It was agreed at this meeting that "*On the question of disclosure the meeting agreed to follow the line of no pre-action disclosure without a Court Order on the grounds of the Licensing Authority and CSM's past precedent in this area*" [Iron-Pres-01705734].

3.54. It is clear that from this point onwards, much of the discovery/disclosure work was coordinated by HS1, and in particular Mr Canavan, with the input of legal advisors both internal and from the Treasury Solicitor's Department. For example, I note:

a. A minute from Mr Powell to Mr Canavan (copied to me) dated 17 July 1989, attaching a letter from Mr Desai of the Treasury Solicitor's Department requesting comments on various categories of documents sought by way of disclosure by the plaintiffs [WITN5292093]. It appears from a handwritten note from Mr Arthur to Mr Canavan and Mr Powell (copied to me) dated 19 July 1989 that "*Medicines Division were also consulted but had no comments*" [WITN5292094];

b. A handwritten note from Mr Canavan to Mr Powell (copied to me) dated 19 July 1989, in which Mr Canavan noted: "*It was agreed on 4 July that we would follow precedent and not disclose documents voluntarily. However, we would cooperate fully once a Court Order has been made… Work is already underway to identify and list relevant documents…*" [DHSC0006481_30];

c. A minute from Mr Arthur to Mr Canavan and Mr Powell (copied to me) dated 21 July 1989 which tends to indicate that Mr Canavan and Mr Powell were acting as the primary point of instructions and coordination on disclosure and the litigation [DHSC0006272_022]. It is also clear from a minute from Dr Rejman to Mr Powell, dated 21 July 1989, that Mr Powell was collecting information on document lists [DHSC0006481_020];

d. A minute from Mr Arthur to MCA, Aids Unit and HS1 colleagues dated 22 September 1989 attaching an agenda for a meeting set for Monday 25 September 1989 [WITN5292095]. One of the items on the agenda, paragraph 3, related to the arrangements for collection/storage of evidence (i) for the defence and (ii) which might be sought under Court Order for discovery by the Plaintiff's solicitors; and

e. A minute from Mr Brand (SOLB3) to Mr Canavan, Dr Rejman and Mr Desai dated 6 November 1989. This note sets out areas of responsibility and the officer dealing with responsibility for each area [WITN5292096]. I note that on the Solicitors' side, the area of discovery and inspection of documents was assigned to Mr Brand, with the other areas divided between Mr Powell and Mr Brand.

3.55. During this period, I would have been involved in the search for relevant documents and providing lists in accordance with the parameters and categories set out by legal advisers and an example of this can be seen from my note to Mrs Armstrong dated 5 October 1989, in which I provided an update on the disclosure work being carried out [DHSC0046937_037]. The nature of my work on discovery can also be seen from a note produced, I believe, by Kate Lee (SOLC5) dated 17 January 1990 [DHSC0007045_009]. This note recorded:

> *"C. Richard Gutowski to send down to Mark (by Friday?):*
>
> *1. 2 Policy files for scrutiny (cross check with HS1/lawyers for SoS);*

2. *List for discovery (check and then decide whether there is a need for Sol C5 to look through all the relevant documents – check perhaps with Peter Nilsson);*
3. *15 documents Richard Gutowski classifies as 'doubtfuls'.*

3.56. I note that I sent a minute to Mr Nilsson copied to Mr Hagger, Mr Powell and Mr Canavan among others, dated 14 February 1990 [WITN5292097]. This minute referred to the fact that DAC Solicitors (acting for the Health Authorities) wished to inspect the LA and CSM's documents based *"on the list attached to my minute of 29 January to Mr Bratton".* I enquired whether Mr Nilsson wished a solicitor should be present.

3.57. I also note a minute from Christine Bendall (SOLC5) to Mr Desai dated 10 May 1990, to which I do not appear to have been copied [WITN5292098]. This minute provides useful context, however, in showing that internal legal advisors were clearly providing oversight and guidance on relevant aspects of disclosure, including potential redactions, PII claims, handling, disclosure lists and inspections etc. This minute concluded by stating:

> *"Finally, you informed me that Richard Gutowski said that I had the List of Licences which are required to be disclosed as part of a schedule to the main Defences. I have now been able to check all of my documents and I cannot trace the list at all. I have asked Richard to send a copy direct to you".*

3.58. A minute dated 29 August 1990 from Mr Alder to various MCA colleagues (including, Dr Jefferys, Mr Hagger, Dr Wood and others), is also useful in terms of understanding the disclosure work that I was involved in [DHSC0003963_064]. It stated that *"In the current litigation involving the LA and CSM we were issued with a Court Order in October 1989 requiring us to disclose all relevant documentation to both our co-defendants and the plaintiff's solicitors. As a consequence we undertook a detailed search of our database*

and relevant gold and policy files and filed our list of documents in November 1989". This note recorded that, unfortunately, served disclosure lists were incomplete due to a missing file (which subsequently turned up) and that a supplementary search and list of documents would be required.

3.59. I am unclear, now, why Mr Alder sent this minute save as, perhaps, to communicate the gravity and importance of the issue but, again, it demonstrated that, often, important issues of disclosure in the MCA were directed by more senior colleagues. By a minute that I sent to Miss Bendall, dated 12 November 1990, I note that I appeared to have taken forward some supplementary searches in response to a letter from Pannone Napier dated 5 October 1990, and provided responses and relevant material [WITN5292099]. This was then forwarded to HS1/EHF1A colleagues (Mr Burrage and Mr Canavan) and Mr Powell as noted in a minute dated 21 November 1990 from Mr Burrage to Mr Canavan [WITN5292100].

3.60. I can see that, at times, I raised concerns about specific issues arising from the disclosure/discovery process. By a minute that I drafted to senior MCA colleagues (Dr Jefferys, Dr Wood, Mr Bewley) and copied to Mr Canavan dated 15 May 1990 I raised a specific issue regarding the form of undertakings required and the anonymisation of doctor and patient details [WITN5292101]. This is an issue that I deal with in more detail below regarding PII advice but I see from this note that I had raised a concern about revealing doctors' names in Yellow Card Data, and had asked my senior colleagues for confirmation as to the correct approach to be followed in order that Counsel could be duly instructed. In any event, Dr Wood responded to me on 16 May 1990 to confirm that this was the correct approach [WITN5292102].

PII Certificates

3.61. I am asked if I was involved in advising in respect of PII certificates. In this regard, I have read a submission dated 19 July 1990, from John Canavan to

Sir Christopher France to which the Inquiry has drawn my attention to. I was copied into that submission [DHSC0004360_144].

3.62. This submission invited the Permanent Secretary to sign an annexed PII certificate in order to withhold disclosure of certain categories of documents held by DH, the LA and the CSM. I am not an expert in such matters but I understand from this submission that the Permanent Secretary would have normally been asked to sign the PII certificate in circumstances where the documents spanned different administrations, such that it is inappropriate for a serving Minister to sign the certificate.

3.63. The submission recorded that Counsel has advised that "*nearly 600 documents in five categories can be protected from disclosure in the public interest*". The submission set out the interests that required protection, which included, broadly, material covering the inner workings and formulation of government policy and, in the case of the LA and CSM, the voluntary reporting system for adverse reactions (the Yellow Card system). The submission stated that the concern with the voluntary reporting system in particular was:

> *"...we wish to protect our voluntary reporting system for adverse reactions. This relies on the willingness of practitioners to provide information about their patients on assurance from the CSM that the information will not be passed on to others in a form by which they or their patients can be identified. The Licensing Authority and the CSM believe that if this confidentiality is breached doctors would be unwilling to submit further reports. This would jeopardise the monitoring of medicines in the UK and could lead to failure in identifying drug safety hazards with serious implications to the safety of patients".*

3.64. As a result, at paragraph 4 of the submission, it was considered that letters received by doctors detailing patients' reactions to Factor VIII would be important to the plaintiffs' case, but that their contents could only be released in an anonymous form with doctor and patient names redacted. Otherwise,

such disclosure would potentially breach confidentiality between medical practitioners and the CSM, potentially jeopardising future reports and the monitoring of medicines in the UK.

3.65. The submission then set out the process of making a claim for PII and the strength of the respective arguments over the various categories of documents. The submission is clear that this exercise was conducted by Counsel and advice was prepared by Counsel for the decision maker, i.e. the Permanent Secretary, in considering whether or not to sign the certificate. My understanding is that Counsel's view on the potential PII claim was given independently of any views expressed by departmental officials. In other words, this assessment provided an additional and independent level of scrutiny on any claim for PII.

3.66. Whilst I am copied into this submission, given the content and context of the advice, which is underpinned by Counsel's independent assessment, it is clear that I had no substantive involvement in respect of advising on the public interest immunity certificate. As I have set out in paragraph 3.60, above, I had however flagged up the concern about doctors' names and the need for redaction, a concern with which senior officials in the MCA agreed. Redaction of this information was clearly our conventional approach to protect the effectiveness of the system.

3.67. In terms of my wider involvement in this process, in accordance with my role as "*the administrative focal point in MD in this case"* as I have already referred to, I was copied into various letters from senior officials regarding the potential for a PII claim to be made in this matter. For example, I was copied into a minute from Ronald Powell to John Canavan dated 17 July 1989 which attached a minute from Mr Desai of the Treasury Solicitor's Department dated 13 July 1989 [DHSC0006272_033]. The minute of 13 July asked for Mr Powell's comments on which categories of documents a PII claim would be made, and, subsequently, Mr Powell wrote to Mr Canavan noting "*Precisely what objections*

to disclosure will be raised can only be given when the documents have been examined".

3.68. Mr Canavan wrote a handwritten response to Mr Powell on 19 July 1989. In this note Mr Canavan mentioned that:

> *"As regards Hansford, Medicines Div are considering what documents, if any, they would wish to withhold. From my own viewpoint the advice to Ministers is something we would certainly wish to withhold if this were possible under public interest immunity. For the others, I would like to reserve judgment until I know the scope of public interest immunity. There would be no point in trying to withhold items which could not be covered by that immunity. I think you were going to advise us on this question. I will come back by Friday with a response to your minute of 17 July"* [DHSC0006481_030].

3.69. I take from this response that I and MD/MCA were aware of the need to consider a possible PII objection to disclosure in this claim but also that any consideration of PII was at a very early or formative stage.

3.70. It seems as though no firm assessment on the categories to be withheld under PII in the HIV litigation had been reached by either DH or the MD/MCA even by 17 January 1990. I was present at a conference on the HIV litigation held at 2 Crown Office Row with Counsel (Mr Fenwick), Mr Desai, internal legal advisers and Dr Rejman. Dr Rejman produced a note of this conference on 18 January 1990 for Mr Canavan and copied to several recipients including internal legal advisors [DHSC0044876]. This note recorded:

> "*Mr Fenwick and the MCA Solicitors are to check through their records of the Opren case to determine what will qualify for exclusion under public interest immunity and require certificates from Ministers…there are other aspects which relate particularly to the Licensing Authority and the MSC".*

3.71. My reading of this meeting is that, in terms of any PII assessment, this would be effectively guided by the position that was taken by the MCA in the Opren

litigation but also that the special position of the LA and the CSM would need to be considered. In both cases however, it appears as though Counsel and instructed solicitors were advising on and driving this aspect forward; see similarly a letter from Mr Desai to Mr Canavan dated 10 May 1990, which was copied to me [WITN5292103].

3.72. This letter referred to the fact that a conference with leading Counsel had been arranged to discuss the question of PII. It was copied to Miss Bendall with the suggestion that we attend the conference. The letter also attached the note from Ms Bendall, to which I have referred at paragraph 3.57. Ms Bendall said that she had:

> *"...spoken to Richard Gutowski and suggested that he proceed to prepare the MCA's documents for inspection on the basis which we originally intended; that is by obscuring both the names of patients and their families and also of the doctors who appear in them... As you know, the MCA feels very strongly about protecting the identities of doctors who correspond with it in confidence either by a yellow card or by letter in the nature of a yellow card because it is felt that the whole system would be placed in jeopardy if practitioners thought that the fact of their communication could be made available to others"* [WITN5292104].

3.73. Clearly, from this note, Miss Bendall was alive to the issue regarding the need to protect the voluntary reporting system through a PII claim. I cannot now recall whether the issue of doctor confidentiality and the importance of protecting the voluntary reporting system was an issue that I had first suggested was necessary, or whether it came from others in the MD/MCA. Either way, however, as I have indicated, this was I think the standard MCA approach. In a minute dated 15 May 1990 from me to Dr Jefferys, Dr Wood and Mr Bewley in the MCA, I wrote:

> *"At our insistence, Counsel included a provision that the LA/CSM's documents be anonymised prior to discovery to remove any names of patients and doctors. <u>This is in line with our [policy] with regard to</u>*

anonymisation of Yellow Card data. Unfortunately, whilst agreeing to the removal of patients' names, the Court ruled that doctors' names should remain uncovered. This could mean that doctors and/or hospitals could be contacted by the Plaintiffs' Solicitors or Experts on the basis of letters sent to us in confidence. I have agreed with Sol C5 and Treasury Solicitor that this is unacceptable and that we will continue to remove the doctors' names and leave it to the Plaintiffs to challenge. If they do decide to challenge us at the next hearing set for 26th June we may need to defend our position with Affidavit evidence and possible a Minister's certificate. I would be grateful for confirmation that you agree this approach so I can instruct Counsel accordingly at a Conference arranged for 18th May" (my emphasis added) [WITN5292101].

3.74. My note therefore made clear that the proposed anonymisation of Yellow Card data was MCA policy and that I was acting in a way which was consistent with that policy. As I have noted at paragraph 3.59, above, by a minute from Dr Wood to me dated 16 May 1990 which responded to my request for instructions, Dr Wood confirmed a clear imperative that the identity of doctors reporting under the voluntary reporting system must be protected from disclosure. She also pointed to the need to maintain consistency in approach in applying this protection, despite the apparent lack of clarity as to when it had recently been applied and the circumstances in which it applied [WITN5292102].

3.75. I have re-familiarised myself with Counsel's (Mr Fenwick) advice on the claim to PII in the HIV Litigation dated 19 June 1990 [WITN5292105]. This was sent to me under cover of a minute dated 22 June 1990, from Mr Burrage to Dr Rejman and me [DHSC0006348_114]. The category of documents over which a possible claim for PII could be made, which interested the MD/MCA, was contained in item 6 on page two: "*The original unexpurgated versions of documents in or by which doctors and other supplied details of patients' illnesses and/or adverse reactions in confidence to or from the CSM and/or*

Licensing Authority". In this advice, Counsel goes on to state in respect of this category:

> *"The sixth category is one which has already been the subject of a claim for privilege in the Whooping Cough vaccine and Opren cases, although the claim was not eventually challenged in either case. The interest to be protected is that of our voluntary reporting system for adverse reactions, which is much envied but which depends on the willingness of medical practitioners to provide information about their patients in the cause of the improvement of medical knowledge, in the clear belief that the information provided will be kept in the strictest confidence and will not be passed to third parties in any form by which their patients might be identifiable*".

3.76. This advice analysed each of the document categories and provided merit-based advice on the prospects of a PII claim for each category. This reflected the fact that the Licensing Authority and CSM documents were but one aspect of an overall PII claim. In respect of this sixth category, Counsel noted that "*there is no doubt but that a strong claim should be made in respect of the documents in the sixth category".* I note that the advice mentioned that where documents were protected by PII, the DH was under a duty to claim the privilege and had no discretion in pursuing such a claim. I cannot now recall the extent of the material that was in scope of this PII claim, either on behalf of the LA/CSM or DH as a whole.

3.77. This advice appeared to have led directly to the submission from Mr Canavan to Sir Christopher France, on 19 July 1990, as I have described above. On the same day, Mr Canavan sent a minute to Mr Powell, Miss Bendall, Dr Rejman and me enclosing that draft submission and asking for comments [WITN5292106]. I cannot recall and cannot see a response from me with any comments. However, I note that the submission was put to Sir Christopher France and can see a handwritten note on the copy before me, I presume from

Sir Christopher France, which reads: "*I have signed, and am grateful for the careful way in which these papers have been prepared*" [WITN5292107].

3.78. I note from a minute from Dr Rejman to various legal and departmental colleagues on 1 May 1996 which was not copied to me, that Mr Justice Rougier gave judgment on the PII claim on 31 July 1990 [DHSC0006352_044]. This was subsequently appealed by the various plaintiffs and cross-appealed by the central defendants on 22 August 1990 with judgment given in the Court of Appeal on 20 September 1990 dismissing the cross-appeal and varying the order of Mr Justice Rougier so that certain categories of documents previously withheld under PII should be provided for initial inspection by Mr Justice Ognall and potential onwards disclosure to the plaintiffs. As far as I am aware, the variation of the Mr Justice Rougier order did not extend to the Yellow Card Data category.

The terms of settlement

3.79. In terms of any role in advising on the terms of eventual settlement, I should say from the outset that despite being copied into much of the correspondence on this issue, I had very little substantive involvement in it. I continued to be copied into relevant minutes on this, but the MCA were not significantly involved in the actual terms of settlement.

3.80. Under the heading 'Advice on whether the litigation should be fought, conceded or settled', above, I have already set out the one point on which I did have some input. This was in relation to whether MCA should insist on a specific recognition in the terms of settlement that the LA and the CSM had continually categorically denied liability. See my minute of 13 December 1990, to which I have referred at paragraph 3.45 above [DHSC0003963_015].

3.81. This was, as far as I can see and remember, the only substantive input that I had into the terms of settlement. I was the recipient, as the Inquiry refers me to,

of a note from Mr Burrage on 23 January 1991, which attached, for comment, the latest draft of the settlement agreement and the Macfarlane Trust but I cannot trace a response from me to it [DHSC0020866_045]. Moreover, despite my review of the relevant documents, I cannot find any input from me that related to a settlement term which restricted the ability of those receiving payments to bring separate legal claims for infection with HIV and hepatitis viruses. In any event, I do not believe that such an issue/term of settlement would have fallen in my, or the MCA's direct remit.

3.82. I note that most, if not all, of the remaining contemporaneous minutes, notes and correspondence at this time were being sent, at various times by Mr Burrage, Mr Dobson, Mr Powell, Mr Canavan and Dr Rejman. I was copied into most of this correspondence but provided no further substantive input. I note that this activity culminated in a submission to Mr Waldegrave from Mr Dobson on 18 April 1991, seeking authorisation to make a final offer to the solicitors for the plaintiffs in the HIV litigation and to start making payments to individual plaintiffs upon receipt of a letter of discontinuance [DHSC0105653_031] and [DHSC0002433_091]. In a response dated 22 April 1991, Mr Waldegrave approved both the final offer and for payments to be made to individual plaintiffs [DHSC0003662_080].

3.83. From my review of the relevant documents, what appears to be the final version of the settlement agreement (titled 'The Main Settlement Agreement') is dated 26 April 1991 [WITN5292108]. The terms of this agreement appear, at paragraph 4(2), to reflect the continued reliance by the LA and the CSM throughout the HIV litigation, on the legal argument that no duty of care existed from them to the plaintiffs and that there had been no consequential breach of that duty:

> *"4. (1) These payments are made on behalf of the First Central Defendants and not on behalf of any other Defendant and are made without any admission of negligence, breach of statutory duty or other*

liability. The First Central Defendant maintains its denial of any legal liability whatever.

(2) For the avoidance of doubt the Second and Third Central Defendants are not contributing to this settlement and firmly deny any duty of care owed to individual plaintiffs and any breach of any duty whatsoever".

3.84. The Inquiry raises the requirement in the final settlement terms that those accessing ex gratia payments should waive future claims not just for HIV infection but also HCV infections. I am confident both from my recollection and from reviewing the available documents that this was not an issue in which I was involved. It would not have been a focus for the MCA.

3.85. Unless it would assist the Inquiry, I have no further comments that I wish to make as to the conduct of the HIV litigation or its eventual settlement.

Statement of Truth

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

Signed _____ GRO-C _____

Dated _____**19.05.2022**_____