Witness Name: Ron Feakes
Statement No.: WITN7302001
Dated: 16 November 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF RONALD JAMES FEAKES

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 11 October 2022.

I, Ronald Feakes, will say as follows: -

I. Preliminary observations

i. Before answering the questions raised with me by the Inquiry I think it would be helpful to make some preliminary comments that I think are relevant to my written answers. I retired from Baxter Healthcare Limited in 2009. The questions raised by the Inquiry require me to try to recall detailed events, often involving complex medical and scientific matters, from around 40 years ago. I have had only a few weeks to consider the questions and try to recall information. I have tried my best but have found this very difficult. In respect of many of the questions I either have no direct knowledge or no recollection. Where I think I can provide answers I have done so. Whilst my answers are the best that I can give at this time, they may not be accurate as I may have forgotten or confused matters as a result of the passage of time.

ii. The Inquiry's request for a written statement refers to the US company, Baxter International Inc (and its subsidiaries, which it identifies as Travenol Laboratories and Hyland Laboratories/Division) referring to them as

"Travenol/Baxter (US)" and the UK companies including Travenol Laboratories Ltd and Baxter Healthcare Ltd, referring to them as "Travenol/Baxter (UK)". I will try and distinguish between the individual companies in the US and the UK as best I can recall, though I may not be exact in my terminology.

iii. The UK based companies, principally Travenol Laboratories Limited ("Travenol UK") and Baxter Healthcare Limited ("Baxter Healthcare") where I was employed, had a wide product portfolio including intravenous solutions and intravenous administration sets (the plastic tubing used in hospitals to administer blood or IV solutions to a patient) and blood collection systems (for example Fenwal™) used by the UK Blood Transfusion Service. These non-blood products were manufactured by the UK based companies. The oversight of manufacture of products in the UK was the major part of my job from around 1978. Whilst I had some oversight of regulatory matters because the Regulatory Department reported to me from around 1981 to 1993, after 1993 I had no involvement in regulatory matters at all.

iv. In relation to blood products specifically, the UK companies I worked for had a different role from the US based companies like Hyland Laboratories. In respect of blood products, the UK companies were responsible for the sale and distribution of the blood products and acted as a point of liaison with the UK regulators. They did not develop or make blood products. I was not involved in the sale and distribution of blood products, but as far as I was aware, it was a relatively small part of the UK based companies' day to day business. I have been asked to consider 59 questions, many with sub questions, and to consider 37 documents. I have read the documents provided to me by the Inquiry and considered the questions diligently over many days and have done my best to answer them in the limited time the Inquiry has provided for my statement to be prepared. Where questions seem to me to be unclear I have tried to identify what I think is the point being raised and answered on that basis. Unfortunately a number of questions ask for information that, because of my role and the work undertaken by the companies I worked for, I have never had the knowledge to answer. There are also subjects and events about which I have no recollection.

v. For ease of reference, the questions raised in the Rule 9 Request are included below in **bold** and *italics* before my responses.

Section 1: Introduction

1. Please set out your name, address, date of birth and professional qualifications.

1.1 My full name is Ronald James Feakes. I was born on GRO-C 1948. and my address is known to the Inquiry.

1.2 I was a Licentiate of Royal Society of Chemistry (LRSC) and subsequently I became a Member of the Royal Society of Chemistry (MRSC) until I retired from Baxter Healthcare.

2. Please set out your employment history, including the various roles and responsibilities that you have held throughout your career, as well as the dates. Please consider, in particular, the document enclosed at NHBT0000487_006. Please set out the timeline of your work with Travenol Laboratories Ltd and Baxter Healthcare Ltd, including:

(a) ***The positions you held from time to time; and***

(b) ***The responsibilities that each of those positions entailed.***

2.1 The dates I set out for various roles I have held are approximate and given to the best of my memory.

2.2 In terms of the names of the companies I worked for, these are given to the best of my recollection. I understand Baxter Laboratories Limited changed its name to Travenol Laboratories Limited in 1972 and then changed its name again to Baxter Healthcare Limited in 1988. In answering this question I have referred to page 89 of the transcript of 24 September 2021 [INQY1000147] and statements provided to the Inquiry on the corporate structure of the companies I worked for given by Susan O'Reilly and Bo Tarras-Wahlberg.

2.3 On 15 August 1966 I joined Baxter Laboratories Limited in Thetford in the UK as a Laboratory Chemist. Over the following nine years or so I held various positions in the Quality Department of the company.

2.4 Baxter Laboratories Limited changed its name to Travenol Laboratories Limited. I do not recall exactly when this happened but I have reviewed

pages 88 to 90 of the transcript of 24 September 2021 [INQY1000147] and I think it is probably correct that this happened in or around 1972.

2.5 In 1975 I became Quality Control Manager for the manufacturing plant in Castlebar, Ireland, but I cannot recall which company in the group was responsible for the plant. In 1978 I returned to Thetford as Director of Quality for Travenol Laboratories Limited. In this role I managed the Quality organisation associated with manufacturing in Thetford and Nelson in the UK.

2.6 In 1981 I became Director of Quality Assurance for Travenol UK, based in Thetford. I am not certain, because I have not kept a record of my employment, but I believe at this time I also became responsible for Scientific Affairs which later became the Regulatory Department. This was the first time I had had any involvement with the licensing and regulation of products.

2.7 In 1986 I became Director of Quality Assurance (UK and Ireland) and the Quality Department in Travenol's manufacturing facilities in Ireland was added to my responsibilities.

2.8 As Director of Quality Assurance (UK and Ireland) I had oversight of the Quality and Regulatory compliance and procedures of Travenol in the UK and the manufacturing plant in Ireland to ensure that manufacturing processes and products complied with both company requirements and those of the regulatory authorities, in the UK and Ireland.

2.9 As noted in document [NHBT0000487_006] my role in 1986 required that I was a "Qualified Person " and was named as such in the Travenol Laboratories Limited and Baxter Healthcare Limited manufacturing Licenses. I believe that the “requirement” for a company to have "Qualified Persons" was introduced to harmonise the UK with EC practice, and I believe that I would have been named as a "Qualified Person" when I returned from Ireland in 1975.

2.10 Travenol Laboratories Limited changed its name to Baxter Healthcare Limited. I do not recall exactly when this happened but I have reviewed pages 88 to 90 of the transcript of 24 September 2021 [INQY1000147] and I think it is probably correct that this happened in or around 1988.

2.11 In 1990 I was appointed Technical Director for Baxter Healthcare Limited. At this point the technical development of products and processes relating to manufacturing in the Thetford plant was added to my responsibilities.

2.12 In 1993 I was appointed General Manager for Manufacturing for Baxter Healthcare Limited and was responsible for manufacturing at their UK facilities in Thetford and Nelson. From this date I no longer had oversight of the Regulatory Department and therefore no further involvement with blood products.

2.13 In 1996 I was appointed European Director of Quality Systems with responsibility for the Quality Assurance function in several Baxter plants in Europe. These would have included the Quality Assurance functions in the UK and Ireland, but not regulatory responsibilities.

2.14 In 1997 I was appointed Vice President of Quality Assurance for the manufacturing facilities in Europe associated with the two Baxter Healthcare Divisions (IV systems and Renal). There was a separate Vice President of Quality Assurance who had responsibility for other products including blood products; blood products were not within my responsibility.

2.15 In 2005 I was appointed Vice President of Quality Shared Services and Compounding (Europe).

2.16 In 2009 I retired from Baxter Healthcare Limited.

2.17 As noted above, between 1981 and 1993, the manager of the Scientific Affairs / Regulatory Department for Travenol UK (and then Baxter Healthcare) reported to me. The Regulatory Manager in the UK managed a small team consisting mainly of pharmacists.

2.18 In relation to products manufactured by the UK companies this team was responsible for:

(a) Compiling information relating to stability data on products, manufacturing process details, quality testing details, product safety data.

(b) Collating the information in to a file for submission to the regulatory authorities in the UK and Ireland in order to obtain product licenses.

(c) Responding to requests from the licensing authorities in the UK and Ireland if more data or information was required.

(d) Liaising with UK and Irish regulatory authorities and maintaining existing product licenses.

2.19 For products not manufactured by in the UK, this team was responsible for:

(a) Liaising with the US business, (which I will call Hyland Laboratories or Hyland) in order to obtain the initial information related to the product for the purposes of applying for product licenses in the UK and Ireland and any additional information required to respond to any requests from the licensing authorities.

(b) Liaising with UK and Irish regulatory authorities and maintaining existing product licenses.

2.20 In my role as Director of Quality Assurance from 1981 until 1990 and then as Technical Director until 1993 I was not directly involved in the day to day detail of regulatory matters relating to any of the company's products, including blood products, and so my direct knowledge is limited. It is on this basis that I have attempted to answer the Inquiry's questions.

3. Please set out your membership, past or present, of any committees, associations, parties, organisations, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

3.1 I have not held any memberships of any committees, associations, parties, organisations, societies or groups, relevant to the Inquiry's Terms of Reference.

4. Please confirm whether you have provided written or oral evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or

hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports that you provided

4.1 I have not been involved in or provided written or oral evidence in the circumstances stated.

5. Please describe the relationship between the US company, Baxter International Inc (and its subsidiaries, Travenol Laboratories and Hyland Laboratories/Division) and the UK companies Travenol Laboratories Ltd and Baxter Healthcare Ltd. In particular, please describe what roles the UK companies undertook, and what matters were reserved to the US companies.

(a) ***You may be assisted by the summary given by Counsel to the Inquiry in the Transcript of 24 September 2021 p.88-90 [INQY1000147]. Please provide any corrections or comments that you wish to provide on that summary.***

For ease of reference the respective companies will hereafter be referred to as "Travenol/Baxter (US)" and "Travenol/Baxter (UK)", unless otherwise specified.

5.1 I have reviewed pages 88 to 90 of the transcript of 24 September 2021 [INQY1000147]. I was employed by Baxter Laboratories Limited, then Travenol Laboratories Limited and then Baxter Healthcare Limited between 1966 and 2009. I do not know the corporate history of the US companies or the UK companies. I think it is probably correct that Baxter Laboratories Limited changed its name to Travenol Laboratories Limited in 1972 and changed its name again to Baxter Healthcare Limited in or around 1988. I cannot comment further on the history of the companies as set out in the extract from the transcript.

5.2 As noted already neither Travenol UK or Baxter Healthcare was a manufacturer of blood products. However they did manufacture a range of other products including, intravenous solutions and intravenous administration sets (the plastic tubing used in hospitals to administer

blood or IV solutions to a patient). During my period of employment the UK companies were involved in importing and selling products, including blood products, in the UK.

Section 2: Knowledge of risks associated with blood products

6. ***When you were working at Travenol/Baxter (UK) in the 1980s, what did you know and understand about:***

(a) ***The risks of infection associated with blood and/or blood products generally; and***

(b) ***The risks of transmission of hepatitis (including HBV and what was later identified as HCV). What, if any, were the sources of your knowledge? How, if at all, did those sources and your knowledge change over time?***

6.1 Prior to 1981 I had no involvement with the blood products sold and distributed by Travenol Laboratories Limited and I do not recollect having any knowledge concerning the risks associated with blood or blood products generally or specifically concerning risks of transmission of hepatitis.

6.2 After I became Director of Quality Assurance in 1981 I became aware of information associated with blood products including infection risks, which came from a variety of sources, including conversations with colleagues, scientific literature and the media.

6.3 I cannot recall what I knew and when I knew specifically about risks of infection or where that information came from. I remember it became apparent that blood products could potentially transmit HIV and be a risk to people receiving them. I recall there was a lot of information in the media generally, including a government advert on the TV with a grave stone mentioning AIDS.

6.4 I do recall that the US company developed new processes to reduce the risk of transmission of viral agents and I had conversations with colleagues in the UK who were more directly involved in the blood product side of the business informing me about what was being done, for example heat treating the blood products and then, later on, the use

of solvent/detergent and monoclonal technology. I would not have had these conversations with colleagues in the UK every day. There were regular communications between colleagues in the US and the UK companies about the technology being used to improve the products.

7. What if any steps were taken to ensure that:

(a) ***NHS bodies and/or clinicians purchasing and/or using Travenol and Baxter products were made aware of the risks of hepatitis?***

(b) ***Patients treated with Travenol and Baxter products were made aware of the risks of hepatitis?***

7.1 The steps I was aware of were to provide Data Sheets and these, and other product information supplied with the product, included warnings of risks. These materials were principally directed towards clinicians and other healthcare professionals. Patient Information Sheets, including warnings of risks, were also prepared though I think that legislation requiring these documents came much later, towards the end of the 1990s.

8. What was your knowledge and understanding of HIV (previously known as HTLV-III) and AIDS, and in particular the risks of transmission from blood products, during your time working at Travenol/Baxter (UK)? What were the sources of your knowledge? How did your knowledge and understanding change over time?

8.1 It is hard to recollect with accuracy what I and colleagues in the UK knew and when we knew it in relation to matters that took place almost forty years ago. Please see my answer to question 6 above, where I have explained the extent of my knowledge and understanding in relation to both hepatitis and HIV.

9. How and when did you first become aware that there might be an association between AIDS and the use of blood products?

9.1 Please see my answer to question 6 above.

10. To your knowledge, what enquiries and/or investigations did Travenol/Baxter (UK) carry out in respect of the risks of transmission of HTLV-III/HIV/AIDS, prior to 1985? What was your involvement in such enquiries and investigations?

10.1 Research and development in relation to blood products was not generally part of the UK company's role and I was not aware of or involved in any such enquiries or investigations being carried out. I was aware some products were involved in clinical trials but I have no recollection of the detail addressed in question 33 and I had no involvement in that work.

11. When did you become aware of the risk of HIV and AIDS transmission by Travenol/Baxter products specifically? What was your source of knowledge?

11.1 Please see my answer to question 6 above, where I have explained the extent of my knowledge and understanding in relation to both hepatitis and HIV.

12. What if any steps were taken to ensure that:

(a) ***NHS bodies and/or clinicians purchasing and/or using Travenol products were made aware of the risks of HTLV-III, HIV and/or AIDS?***

(b) ***Patients treated with Travenol products were made aware of the risks of HTLV-III, HIV and/or AIDS?***

12.1 Please see my answer to question 7 above, where I have explained my understanding of how risks were communicated to clinicians and other healthcare professionals and then at a later date to patients via patient information leaflets.

Section 3: Blood supply, donor pools and screening

13. What did you understand, during the time of your employment with Travenol/Baxter (UK) about:

(a) ***From where Travenol/Baxter (US) obtained plasma for use in blood products sold in the UK;***

13.1 At some point in the 1980s, I do not recall exactly when, I became aware of a difference between how blood was collected in the UK and US, namely that donors in the US were paid for their donations.

(b) ***The extent to which Travenol/Baxter (US) obtained plasma for use in blood products sold in the UK from prisons in the United States;***

13.2 I cannot recall being aware that plasma was obtained from prisoners in the US.

(c) ***The extent to which Travenol/Baxter (US) used plasma obtained from homosexual donors not only for the production of Hepatitis B immunoglobulin but also for the production of Factor VIII and IX concentrates (as described in the expert witness report of Dr Donald Francis) [CGRA0000404];***

13.3 I have read [CGRA0000404] as provided by the Inquiry to me. I cannot recall previously being aware that blood products manufactured by Hyland Laboratories used plasma that came from any specific sector of the population.

(d) ***The size of the plasma pools used in producing blood products sold in the UK;***

13.4 I do not recall having any knowledge of the size of plasma pools used. I am not aware that employees in the UK, including the Regulatory Department over which I had oversight, had detailed or specific knowledge about the size of plasma pools.

(e) ***The association (or otherwise) between the size of the plasma pools and the risk of the blood product infecting a patient with hepatitis and HIV/HTLV-III;***

13.5 I do not recall any discussion about the association between the size of the plasma pools and the risk of infection.

(f) ***The testing and selection procedure undertaken by Baxter/Travenol (US) when selecting donors. In particular, please consider the document enclosed at SHPL0000409_130. To the best of your knowledge, what was the "Travenol Philosophy" of methods used to ensure the safety of blood donations used for the creation of blood products?***

In respect of each of these matters, please explain the sources of the information you obtained on these matters, and how your knowledge of them changed over the years.

13.6 Donor selection procedures and other methods used to screen blood donations were as far as I have any knowledge, managed and overseen by Hyland. If required for product registration in the UK then these details would be included in the product licence application.

13.7 Document [SHPL0000409_130] notes a pre-registration application meeting held between regulatory staff from Travenol Laboratories Limited and representatives of the DHSS. It records what information was expected to form part of the product licence applications and I expect that this information would be supplied by Hyland Laboratories and submitted as part of the formal product licence applications.

13.8 I have no familiarity with or recognition of the phrase "Travenol Philosophy" and do not have any specific knowledge of what, "the Travenol Philosophy" of methods used to ensure the safety of blood donations used for this blood product – and all other blood products" were.

14. Did you have any concerns, in the 1980s, about the source of plasma used in the blood products that Travenol/Baxter (UK) were importing and selling? What steps, if any, did you take to address any such concerns.

14.1 I do not recall having detailed knowledge in respect of the source of plasma used in the blood products imported.

15. Please consider the memorandum of Travenol Laboratories Limited regarding HIV screened diagnostic products dated 5 January 1986 (printed

on 6 January 1987), enclosed at SHPL0000226_003, into which you have been copied. The memorandum explains that there was a lack of supply of screened product and that whilst it would be possible to stop supplying "all but screened product, this would naturally result in a loss of sales." Please explain, to the best of your ability and recollection:

(a) ***When was screening for all blood products manufactured/marketed by Travenol/Baxter (UK) implemented?***

(b) ***Considering that Travenol/Baxter (US) had jointly produced a diagnostic test for detecting HTLV-III antibodies in 1985 [SHPL0000226_073 and SHPL0000226_086], why was there a lack of supply of screened products in January 1986?***

(c) ***What decision was taken regarding the possibility of ceasing the supply of all but screened product on this occasion? Who was responsible for taking this decision and why was this decision made?***

(d) ***Was any assessment made of the risk of transmission of HIV by the supply of unscreened product? If so, what level of risk was identified and how was this information used in the decision-making process?***

(e) ***What were your views on this matter at the time?***

(f) ***To the best of your knowledge, when and in what circumstances did Travenol sell unscreened products following the introduction of HIV screening tests?***

15.1 I have reviewed [SHPL0000226_003]. The date of the memorandum looks wrong and I think the correct date is 5 January 1987. The subject line of the memorandum is "HIV Screened Diagnostic Products" (emphasis added) and the memorandum refers to Laboratory Division. I am not sure what the relevance of these products is to the Inquiry because these are diagnostic products for laboratory use and not used by patients or used in any treatment.

15.2 The products concerned were manufactured and supplied by a US based company called 'Dade'. I do not recall any information that explains the lack of availability of some screened products from Dade. I do not know

what happened regarding the recommendations made by Trisha Bowcott.

16. ***Please consider the enclosed letter from D Barrow dated 5 March 1986, into which you were copied [SHPL0001037_001]. Why was ALT and HTLV-III screening considered "mandatory" for "marketing reasons" whereas it was not yet required at a regulatory level? To what extent did the risk of transmission of infection to the consumer contribute to the policy that screening was mandatory?***

16.1 I have read the Telex concerning Hemofil HT sent by D. Barrow, on which I was copied, and in which he stated, "that although ALT and HTLV-III screening is not yet a regulatory requirement, it is mandatory for marketing reasons…". If I recall correctly, Hemofil HT was subjected to a heat process during manufacture to reduce the risk of potential viral transmission.

16.2 I cannot recall why Mr Crossman and Mr Tate were requesting that products made available in the UK and Ireland were only manufactured from screened plasma.

Section 4: Product warnings and labelling

17. ***Please describe the mechanism by which users of Travenol/Baxter blood products in the United Kingdom would be provided with information about those products, including warnings about the potential risks associated with them. In particular, was this information limited to the data sheet, leaflet and packaging provided with the product, or was other literature also supplied? (Please answer with particular reference to variants of Hemofil and Proplex.)***

17.1 Please see my answer to question 7 above, where I have explained my understanding of how risks were communicated to clinicians and other healthcare professionals and then at a later date to patients via patient information leaflets.

18. ***Please explain the process by which the wording of the data sheet, leaflet and packaging, and any other relevant literature, was determined. In particular, please explain:***

(a) ***Your personal role in that process;***

(b) ***The role of any other officers or employees of Travenol/Baxter (UK);***

(c) ***The respective roles of Travenol/Baxter (UK) and Travenol/Baxter (US).***

18.1 I had no role in developing or approving the wording of Data Sheets, leaflets or packaging. For blood products, all of which were developed and manufactured outside the UK, the literature supplied with the products was initially drafted in the US. As part of the product registration process the UK Regulatory Department reviewed these Data Sheets, to ensure they complied with current registration requirements, before including them in the documentation for review by the regulatory authority.

19. To whom was the information in the data sheet, leaflet and packaging (and any other relevant literature) directed? In particular, did Travenol/Baxter (UK) intend or expect it to be read by (i) clinicians, (ii) patients (or parents of patients), and/or (iii) both clinicians and patients (or parents of patients).

19.1 Please see my answer to question 7 above, where I have explained my understanding of how risks were communicated to clinicians and other healthcare professionals and then at a later date to patients via patient information leaflets.

20. Please consider the following documents and answer the questions that follow:

- ***SHPL0000283_005, p.10 and 24: proposed data sheet and carton label for Hemofil, accompanying the application for a variation to the UK licence made on 30 November 1984;***
- ***SHPL0001013_004: carton label for Hemofil-HT, expiry date June 1988;***
- ***SHPL0000963_002: data sheet for Proplex, revised February 1983;***
- ***SHPL0001049_034: data sheet for Proplex, revised October 1984;***
- ***INQY1000147: Transcript, 24 September 2021, p.148-149;***
- ***INQY1000148: Transcript, 28 September 2021, p.22-25.***

(a) ***What involvement, if any, did you have in the preparation of the warnings contained in these documents?***

(b) ***To the best of your knowledge, were the Proplex data sheets used with products sold in the UK? If not, are you aware of any differences in the wording of the warning labels?***

(c) ***Why was it that none of the warning labels referred to the risk of infection with HTLV-III/LAV/HIV or the risk of AIDS?***

(d) ***Did you have any concerns at the time that there should have been such a warning? If so, please explain those concerns and any actions that you took about them.***

(e) ***Do you have any concerns now that such a warning should have been included?***

20.1 As noted above, in my various Quality Assurance related roles, between 1981 and 1993, I had ultimate responsibility for the work of the Scientific Affairs / Regulatory Department in the UK. This department, which was a small team consisting mainly of pharmacists, was managed by a Regulatory Manager who reported to me. This department understood the products and the related science more than me. I did not have any involvement in the preparation of the warnings.

20.2 The labelling and Data Sheets for these products was initially drafted by the US team and then provided to the member of the UK Regulatory Department who was working on the product licence applications.

20.3 The Regulatory Department team member reviewed the Data Sheet and liaised with the US if changes were required. I recall a lot of the regulatory applications relating to these products during this period were dealt with by Ivan Bryant.

20.4 If Ivan had questions relating to the licensing of these products then I believe he would discuss it with the Regulatory Department Manager at the time.

20.5 As mentioned above, whilst I was employed by Travenol UK and Baxter Healthcare I recall the main focus of the business was intravenous solutions, intravenous administration sets, blood collection systems, and renal dialysis products. The sale of blood products was as I recollect, a smaller part of the day to day business.

20.6 I have reviewed the transcripts of 24 and 28th September 2021 [INQY1000147 and INQY1000148]. I had forgotten until I had read the transcripts that Proplex had been licenced in the UK.

20.7 I note the Data Sheets for Proplex as provided by the Inquiry were printed in the US by "Hyland Therapeutics Division, Travenol Laboratories, Inc.". I am unable to say whether or not there were any differences in the wording of the warnings used in these documents and any Data Sheet prepared for products licensed and sold in the UK.

20.8 I cannot comment on the warning information provided to me by the Inquiry and the text of the warnings in respect of the risk of infection with HTLV-III/LAV/HIV or the risk of AIDS. My role did not involve me considering what warnings were required in relation to these products.

21. What steps would Travenol/Baxter (UK) have had to take had it wished to add a warning about AIDS (or the viruses causing AIDS) to the blood products that it sold in the United Kingdom in the 1980s? In particular:

(a) ***Would it have been necessary to obtain the approval of Travenol/Baxter (US)?***

(b) ***Would it have been necessary to obtain the approval of the UK Licensing Authority?***

(c) ***Would you have expected Travenol/Baxter (US) and the Licensing Authority to agree to such a proposal? Please identify any difficulties that may have arisen.***

21.1 Travenol UK and Baxter Healthcare complied with its regulatory obligations within the UK market when considering what information had to be provided with its products. It was these regulatory obligations that determined what the business did with regards to warnings. My UK colleagues liaised with colleagues in the US if changes to warnings were required. However, information regarding any warnings for the UK was provided in accordance with and in a format that the UK regulatory authority approved.

21.2 I recall that the regulatory team generally considered that the UK regulatory authority did not necessarily just accept the information that had been provided to the US FDA. The UK regulatory authority frequently required further information, sometimes this was because

technology and scientific knowledge and techniques had progressed and as a result US colleagues were asked to conduct additional experiments and testing. This may have resulted in delays in the provision of information.

Section 5: Licensing

22. ***Please describe, in broad terms, your experience of applying for and obtaining product licences for blood products in the UK in the 1980s. Please include an account, in broad terms, of how Travenol/Baxter (UK) would go about applying for a licence (including any meetings that may be held), and your role in that process.***

22.1 As noted above, in my various Quality Assurance related roles, between 1981 and 1993, I was responsible for the Scientific Affairs / Regulatory Department for the UK company. This department, which was a small team consisting mainly of pharmacists, was managed by a Regulatory Manager who reported to me. However, as I have explained above I had no direct involvement in applying for and obtaining product licences for blood products in the UK.

22.2 The Regulatory Department prepared the product licence applications for all products, including blood products, to be marketed in the UK and this team liaised with the UK regulatory authority in order to obtain the product licences.

22.3 In broad terms I recall that a request to licence a product initially came from the Marketing Department to the Regulatory Department. A Regulatory Officer, usually a pharmacist, was assigned to the project. A product licence application was prepared with the information for each section being collated. In the case of blood products, the primary information came from colleagues in the US. A starting point, on products manufactured and already placed on the market in the US, was usually a review of the files sent to and approved by the FDA. If the Regulatory Officer required clarification or additional information then dialogue took place between him or her and their US counterparts. If it was a particularly complex application there could be meetings with personnel at the UK regulatory authority, who would eventually deal with the application, to ascertain what additional data may be required. Once the UK Regulatory Officer was satisfied that

all of the required information was available the application file was sent to the regulatory authority for review and approval.

23. In your view and experience, how stringent, how effective, and how efficient was the licensing process in the UK, and did this change over time? How did the UK compare to other countries in your experience?

23.1 I did not have any direct contact with the relevant authorities. However I never considered the process to be adversarial. Those working for the UK regulatory authority were doing their job and my recollection is that it was a very effective process.

23.2 Between 1981 and 1993 I had overall responsibility for the Regulatory team that dealt with product licensing in the UK and Ireland. My recollection of the Irish regulatory authority is that they were not as well-resourced as the UK regulatory authority.

23.3 As I have already noted above, at 21.2 I recall that we generally considered the UK regulatory authority did not necessarily just accept the information that had been provided to the US FDA. The UK regulatory authority frequently required further information and as a result the business needed to conduct additional experiments and testing.

24. Please describe the division of responsibilities and labour between Travenol/Baxter (UK) and Travenol/Baxter (US) in applying for UK licences. How effective was the relationship between Travenol/Baxter (UK) and Travenol/Baxter (US) when it came to licensing matters? Please describe and explain any difficulties or tensions that arose.

24.1 I believe I have already answered most of this question in answering questions 22 and 23.

24.2 I think the relationship between the UK companies (Travenol UK and Baxter Healthcare) and Hyland in the US in relation to licensing matters was effective. I do not recall any significant difficulties or tensions in relation to the licensing of blood products.

25. Were there any specific individuals that Travenol/Baxter (UK) had relationships with at the DHSS, and how would this impact Immuno's applications?

25.1 I assume the reference to Immuno in this question should in fact be to Baxter Healthcare.

25.2 A member of the UK Regulatory Department submitted a file to the regulatory authority. An assessor was assigned by the regulatory authority to review the application and this may have necessitated an exchange of questions and information. I cannot recall any specific individuals at the DHSS with whom the Regulatory Department had a relationship.

26. Please consider the following documents and answer the questions that follow:

- ***DHSC0105556_028 (in particular p.7): Report of Dr Fowler and Dr Purves on the application to vary the Hemofil licence;***
- ***PRSE0004496: Letter sent to DHSS by Travenol Laboratories Ltd dated 9 May 1983;***
- ***DHSC0003951_006: Minutes of the Committee on the Safety of Medicines ("CSM") Biologicals Sub-Committee, 14 September 1983;***
- ***INQY1000147: Transcript, 24 September 2021, p.140-147.***

(a) ***What role, if any, did you have in preparing either the application for the variation to the licence or the letter of 9 May 1983. Please provide any evidence that you may have on how the letter was prepared and who was responsible for it.***

(b) ***Do you consider that the following remarks made by the CSM Biologicals Subcommittee were justified in regard to the letter of 9 May 1983: "Promotional letter making unjustified claims on improved safety margins in respect of infection and AIDS were seen by the Sub-Committee and strongly deprecated"?***

(c) ***In your view, was the letter of 9 May 1983 consistent with the legal and professional obligations of Travenol/Baxter (UK) in respect of the advertisement and promotion of unlicensed products in the UK? Please explain your answer.***

(d) ***Are you aware of any further steps being taken either by the Licensing Authority or any other body in respect of the letters complained of by the CSM Biologicals Subcommittee?***

(e) ***Are you aware of any steps taken by Travenol/Baxter (UK) in response to the criticism that it received from the CSM Biologicals Subcommittee on this matter?***

26.1 I have read the documents listed above. I had no direct involvement in these issues. I do not recall previously having read a product licence application for Hemofil.

26.2 I do not recall the criticism received from the CSM or what specific actions were taken with respect to it.

27. Please consider the exchange of correspondence that you had with Patrick Rafferty in May and June 1990 [SHPL0000293_141 and SHPL0000293_142].

(a) ***Please explain the position and role held by Patrick Rafferty.***

27.1 Patrick Rafferty was Medical Director for Baxter Healthcare. To the best of my recollection he reported to John Adey who was the Managing Director.

(b) ***To the best of your knowledge, why was Dr Rafferty writing to you about this issue?***

27.2 As outlined in his memorandum to me, dated 21 May 1990, Dr Rafferty had discussions with many Haemophilia Centre Directors where he had received a number of enquiries concerning monoclonally purified Factor VIII, which was an unlicensed product in the UK, and which he believed may have been an improved product from those that were currently available. Dr Rafferty was seeking advice on how he should proceed in any future discussions with Haemophilia Centre Directors whilst complying with any appropriate regulatory requirements.

27.3 I think that I shared Dr Rafferty's request with either David Galliford or Ivan Bryant, in the Regulatory Department, for the up to date restrictions on how to respond to questions from clinicians in relation to products which were unlicensed in the UK. I think it likely that Ivan Bryant prepared a draft response for me in order that I could reply to Dr Rafferty. I would have done this as part of my general practice because I relied on his knowledge and expertise in this area.

27.4 I note SHPL0000293_142 is not signed. I usually signed my memoranda and so this document may be a draft of the response. However I believe I sent Dr Rafferty the memorandum as drafted.

(c) ***Please explain the reasons for the views that you expressed in your letter,***

27.5 The views expressed in the response to Dr Rafferty reflected what was permitted under the UK regulations and industry code of practice at the time.

(d) ***Do you recall whether Dr Rafferty followed the advice that you gave in this letter?***

27.6 I do not recall any information that led me to suppose that Dr Rafferty did not follow my advice.

(e) ***How seriously did you take the prohibitions on advertising and promoting unlicensed products that you referred to in your letter? In your knowledge and experience, how seriously did Travenol/Baxter (UK) and Travenol/Baxter (US) take those prohibitions? Was there any tension within or between the companies in this regard?***

27.7 In my position, being responsible for Quality and Regulatory, I took all prohibitions on advertising and promoting unlicensed products very seriously. I have no reason to think that my approach wasn't widely shared.

(f) ***In your knowledge and experience, how seriously did other companies selling blood products in the UK market take the prohibitions on advertising and promoting unlicensed products? Please provide any relevant examples that help explain your answer.***

27.8 I have no information concerning competitor companies' approaches to advertising and promoting unlicensed products. I was not involved in sales or distribution.

(g) ***Please provide any evidence that you can provide about the formal complaint received by Baxter from the Department of Health in early 1988 concerning the promotion of Gammagard in late 1987, to which you referred in the letter.***

27.9 I do not have and cannot recall the specifics of the complaint received from the Department of Health concerning the promotion of Gammagard on a stand at an ISBT meeting.

(h) ***Are you aware of any other complaints or actions taken by the Department of Health (or any other body) in respect of the promotion of unlicensed Travenol/Baxter blood products?***

27.10 I note the document provided by the Inquiry however I do not recall other complaints or actions taken by the Department of Health or other bodies regarding the promotion of unlicensed Travenol UK or Baxter Healthcare blood products.

(i) ***Please provide any additional context or evidence about the exchange that you consider may assist the Inquiry. (You may wish to refer to the discussion about this correspondence that took place between Counsel to the Inquiry and the Chair on 28 September 2021, p.6-13. INQY1000148)***

27.11 I am not able to offer any additional context or evidence about the exchange on this subject.

28. Having regard to both the letter of 9 May 1983 and your exchange with Dr Rafferty, and any other relevant examples of which you know:

(a) ***Please explain how a company that believed an unlicensed product might provide a greater degree of safety to patients could communicate that position to the Licensing Authority or doctors, health bodies and patients in the UK?***

(b) ***What level of evidence was required to support such a claim, and how would such evidence be presented?***

(c) ***In your view, was an appropriate balance maintained between protecting the integrity of the licensing system and the safety of patients in the UK? Were there any changes in legislation or practice in your experience that shifted that balance in your experience?***

28.1 As I have noted in my response to question 2 and in respect of my responses to other questions above, my responsibilities whilst at Travenol Laboratories Limited and then at Baxter Healthcare Limited were for a wide range of devices, systems and products. Whilst I understand the focus of the Inquiry's questions relate to blood products, in terms of my work whilst at Travenol UK and Baxter Healthcare, my recollection is that blood products made up only a relatively small part of the range of products being supplied to clinicians and hospitals. The majority of my work and knowledge focused more on products manufactured in the UK rather than on blood products. The consequence is that some 40 years later I now have very little recollection of work that related to the licensing sale and supply of blood products.

28.2 As the Inquiry can see from (NHBT0000487), by 1986 there was both a "Q.C. Manager" with a supporting team and a "Regulatory Manager" and regulatory team with appropriate expertise and knowledge to ensure the company met its regulatory and legal obligations. Whilst I was in my roles as Director of Quality Assurance and then Technical Director from 1981 to 1993 there was a Regulatory Manager reporting to me. Whilst I had oversight of this work which included the licensing of blood products, I have limited direct personal knowledge to draw upon or relevant expertise and experience that could assist the Inquiry. In broad terms my experience was that the licensing system in the UK worked well and I do not recall any changes in legislation that made any changes to the integrity of the system or patient safety.

29. In general terms (and insofar as you have not already answered these questions), how did Travenol/Baxter (UK) approach the sale of unlicensed blood products within the UK? How did the unlicensed nature of the product affect knowledge of and demand for such products?

(a) ***A Department of Health document dated 14 November 1989 recorded that Travenol/Baxter was able to supply approximately 2 million international units of unlicensed product (thought to be a reference to Hemofil-M) each year [DHSC0002412_077]. How was such a level of sales achieved?***

(Please also refer to the questions on Gammagard set out below.)

29.1 As noted above as far as I know, Travenol UK and Baxter Healthcare ensured that it complied with all relevant regulatory and legal obligations in respect of the supply of products. Unlicensed products were only supplied at the request of a clinician.

29.2 In my experience, the knowledge or awareness of unlicensed products frequently resulted from a clinician going to an event, attended by practitioners from outside the UK, and so becoming aware of a product being licensed and used outside the UK. In my experience clinicians, particularly if they were focused on a single disease state such as haemophilia, communicated with one another about treatments.

30. ***Please see this example of an order form [SHPL0000405_029], which includes the statement 'I understand that Baxter Healthcare Ltd., do not hold a product licence for this product and I take full responsibility for the use of this product in treatment of the patient(s) named below'.***

(a) ***Was this statement, or words to that effect, a prerequisite of Travenol/Baxter (UK) order forms for unlicensed products?***

(b) ***How did Travenol/Baxter (UK) communicate the risks of its unlicensed products to clinicians? Did you have any concerns about that process either at the time or subsequently?***

30.1 As noted above I do not have direct knowledge about how unlicensed products were supplied to clinicians. However, my recollection is that the completion of the form [SHPL0000405_029] was a prerequisite for the supply of any unlicensed products.

30.2 In respect of question (b) I cannot offer more information than given in my answer in respect of question 27 above.

31. To the best of your knowledge, did NIBSC test unlicensed blood products that were imported into the UK? If so, how did Travenol/Baxter (UK) engage in this process?

31.1 See my answer to question 28. This is not something about which I have direct knowledge or recollection.

32. Do you recall any instances of research relevant to the risks of HCV, HIV and other infections posed by products supplied by Travenol/Baxter (UK) being withheld from publication or dissemination to the Licensing Authority or doctors and patients?

32.1 No.

33. A meeting with representatives of Travenol/Baxter (UK) and Dr Geoffrey Savidge and Gill Harrington at St Thomas' Hospital on 16 September 1987. This was recorded in an internal Travenol/Baxter (UK) memorandum dated 16 September 1987 [SHPL0000596_059]. You did not attend the meeting. The meeting was to discuss a clinical trials exemption application for Hemofil-M. Insofar as you are able to do so from your own knowledge and experience, please answer the following questions.

(a) ***What was Dr Savidge's role in making this application? Did he have any wider relationship with Travenol/Baxter (UK) or Travenol/Baxter (US)? If so, please describe the nature of that role and whether or not he receive remuneration for it.***

(b) ***Do you know why you did not attend the meeting? Would you have expected to attend meetings of this nature?***

(c) ***The memorandum contains a note of a discussion on the "anticipated problems that would be encountered in our introduction of a non-heat-treated FVIII preparation, especially now that heat-treatment is the universally accepted viral inactivation process." Please explain what, in your understanding, those problems were and how Travenol/Baxter (UK) sought to overcome them. Were the concerns about such***

problems realised? Did the problems inhibit the licensing of a safer product?

(d) ***What do you understand Dr Savidge to have meant by his reference to "politically motivated inertia ('delaying tactics') on the part of the DHSS, similar to that displayed when heat-treated products were introduced." Did you share his concerns, or have any experience of the DHSS employing such tactics in the licensing process? If so, are you aware of why the DHSS took that approach?***

33.1 I cannot answer this question from my own personal knowledge and do not have any recollection of the events and opinions described in this document [SHPL0000596_059]. I did not generally attend meetings or get involved in the day to day activities of the Regulatory Department.

34. Please provide any further evidence that you consider to be of assistance to the Inquiry in respect of the licensing regime in the UK, including in respect of the provisions made for the sale of unlicensed products.

34.1 I cannot provide any further information in respect of the licensing regime in the UK other than that which I have already provided.

<u>Recall/Withdrawal</u>

35. Please consider internal Hyland correspondence dated 03 June 1985, which communicates the withdrawal of 'non-treated' Hemofil and Proplex from the US market, enclosed at [CGRA0000363].

(a) ***Do you know if an equivalent step was taken to products in the UK market?***

i. ***If it was not, please explain (to the best of your knowledge) why there was no such withdrawal.***
ii. ***If it was taken, please state to the best of your knowledge when the recall was instigated and completed.***

(b) ***Was the decision in respect of the UK market one for Travenol/Baxter (UK) or Travenol/Baxter (US)?***

(c) ***What, if any, role did you play in that withdrawal?***

(d) ***Do you know if hospitals and haemophilia centres in the UK were compensated for the withdrawn product?***

(e) ***To the best of your knowledge, did doctors, hospitals and haemophilia centres in the UK co-operate with the recall of products?***

(f) ***How, if at all, were products recovered from patients to whom they had been distributed?***

35.1 For the reasons already given in answers to previous questions I do not have relevant knowledge and cannot recall any information about the withdrawal of either Hemofil or Proplex. I can only state in general terms what I understood to be the general procedure within the company which was that if a product was withdrawn from sale in one market, because of a product quality or potential safety issue, it was withdrawn in all markets.

35.2 If any of the subject product was in the UK, the distribution and inventory records for the product were reviewed to establish which customer had received the product and if any were still held in inventory. The UK regulatory authority would be notified of the product recall and the reason for it. Customers would be contacted and the reasons for recall explained. They would be asked to segregate any product they had for collection. It was normal practice to replace or compensate for the withdrawn product.

<u>Section 6: Interactions with the DHSS, Haemophilia Centres, UKHCDO and the Haemophilia Society</u>

36. Please describe, in broad terms, the relationship between Travenol/Baxter (UK) and the DHSS / Department of Health during the period in which you were employed by Travenol/Baxter (UK) and how, if at all, it changed over time. (Please note it is not necessary to repeat evidence already given about the relationship with those working on licensing matters.)

36.1 I do not recall contact with the DHSS / Department of Health. I had regular contact with the Medicines Inspectorate in respect of Travenol Laboratories Limited and Baxter Healthcare Limited's manufacturing facilities.

37. Please describe, in broad terms, the relationship between Travenol/Baxter (UK) and the Haemophilia Society in the UK during the period in which you were employed by Travenol and Baxter and how, if at all, it changed over time.

37.1 I do not recall having contact with the Haemophilia Society.

38. Please set out your recollection of any specific interactions or meetings with the Haemophilia Society in which you were involved during the 1980s and 1990s.

38.1 I do not recall any contacts with the Haemophilia Society or attending any meetings.

39. Please describe the sales/marketing policies or strategies of Travenol/Baxter (UK) with regard to haemophilia centres/haemophilia centre directors in the UK during the 1970s and 1980s. Please include a description of any arrangements which Travenol/Baxter (UK) had for visiting centres/directors and any financial or non-financial assistance or incentives provided to centres and directors.

(a) ***Please identify any particular haemophilia centre directors in the UK with whom Travenol/Baxter (UK) or Travenol/Baxter (US) had a close relationship in the 1970s and 1980s.***

(b) ***Please identify any haemophilia centre directors in the UK from whom Travenol/Baxter (UK) or Travenol/Baxter (US) sought advice or who provided consultancy services to Travenol and Baxter, or who undertook research for or with Travenol and Baxter during the 1980s and/or 1990s. Please provide details of the same in so far as you are able to do so.***

(c) ***Please describe, in broad terms, the relationship between Travenol/Baxter (UK) and the UK Haemophilia Centre Directors Organisation ("UKHCDO") and set out your recollection of any***

specific interactions or meetings with UKHCDO in which you were involved during the 1980s and 1990s. Please consider this document SHPL0000293_141 in answering this question.

39.1 I was not involved in sales and marketing activities. Interactions with haemophilia centres was not part of my day to day role and I do not recall any specific relationships with centres or their directors. I do not recall meetings or specific interactions with the UKHCDO.

40. How would Travenol/Baxter (UK) seek to persuade clinicians, hospitals and haemophilia centres to use its products? In particular:

(a) ***Who would be the main points of contact (e.g. clinicians or administrators, individual hospitals/haemophilia centres or Regional Health Authorities)?***

(b) ***What methods did Travenol/Baxter employ to achieve sales, and (insofar as you have not already answered this) how did this vary depending on whether the product was licensed or unlicensed?***

(c) ***What rules or codes of conduct applied? Were they followed?***

40.1 As noted already I was not directly involved and did not have responsibility for sales and marketing activities.

41. Are you aware of any differences in approach adopted by other pharmaceutical companies? Were you aware of any practices that were employed that you considered to be unethical or contrary to contemporaneous legal or professional standards?

41.1 I was not involved in sales and marketing and do not recall the actions of other pharmaceutical companies being discussed with me.

42. Are you aware of any incidents in which Travenol/Baxter (UK) offered financial or other inducements to clinicians, hospitals or haemophilia centres with the intention of increasing sales of their products? Please provide as many details as you are able to provide.

42.1 As already noted my roles were in relation to quality assurance and manufacturing. I had very little interaction with those responsible for sales. I am not aware of any incidents of inducements to individuals or institutions, hospitals or haemophilia centres.

43. Are you aware of any incidents in which other pharmaceutical companies offered financial or other inducements to clinicians, hospitals or haemophilia centres with the intention of increasing sales of their products? Please provide as many details as you are able to provide.

43.1 No.

Relationships with Pharmaceutical Companies

44. Please describe, in broad terms, Travenol/Baxter (UK)'s relationships with other pharmaceutical companies during the period in which you were employed by Travenol/Baxter (UK) and how, if at all, it changed over time.

44.1 I do not recall having any interactions with other companies in respect of blood products.

45. Several internal documents refer to a collaboration with Blood Products Laboratory ("BPL") regarding Hemofil M and Gammagard in the early 1990s, see for example, the documents enclosed at [SHPL0000293_140] and [SHPL0000293_128]. With reference to these, please explain in broad terms:

(a) ***What was the extent of the collaboration with BPL?***

(b) ***What was the motivation for this collaboration?***

45.1 I recall that during the early 1990s Baxter Healthcare Limited had discussions about developing a working relationship with BPL.

45.2 I think that BPL wished to utilise their fractionating resources and capabilities to provide various products from blood collected in the UK. My involvement was in relation to Baxter Healthcare's Regulatory Department providing support to BPL product licensing activity.

45.3 Additionally I recall that Baxter Healthcare was in discussions with BPL about modifications to Baxter Healthcare's Fenwal Blood Collection

System to enable BPL to improve efficiency in processing of frozen plasma and so increase their capacity in blood product supply. I cannot remember exactly when we were working to try and develop this product and machinery and whether this was contemporaneous with the discussions reported in these documents.

45.4 I was not involved in the commercial aspects of this collaboration.

Section 7: Gammagard

46. Please provide an overview of the approach taken by Travenol/Baxter (UK) to the importation, sale and marketing of Gammagard in the UK. Please explain what the product was and the patients for whom it was intended. Please describe the various efforts made to obtain a licence from the UK Licensing Authority, and your role in that process.

46.1 I would like to preface my answers to this section with the following background information. When initially reading through the request for a written statement, I realised that I had completely forgotten what Gammagard was. As I hope I have made clear the Regulatory Department was run by a manager who reported to me, they had a small staff, of mainly professionals, such as pharmacists, who were responsible for producing product licensing files for submission to the authority, and maintaining those files over the lifetime of the product's availability in the UK. My own involvement in the detailed day to day operation of the department was very limited. I will attempt to answer the questions raised in this context.

47. It appears from a Medicines Control Agency (MCA) memorandum from 1994 that Gammagard was never licensed for use in the UK, though it was supplied on a named-patient basis [MHRA0014242_013]. Is this correct? If so, please explain why Gammagard never received a licence, despite the various applications that were made. Was Gammagard licensed in other countries?

47.1 As far as I can recall, during my period of responsibility for the Regulatory Department, that is up to 1993, Gammagard was not licensed in the UK. The UK had a different regulatory regime and

requirements from other EU countries and from the US. I think Gammagard was licensed in the US. I do not have any recollection of the licensing application process for Gammagard.

48. Please see the attached memorandum from D. Galliford, dated 20 February 1987, sent to you, detailing the Gammagard licence application history [SHPL0000293_146].

(a) ***Why was this document sent to you?***

(b) ***In your opinion, why were the applications made by Travenol/Baxter (UK) found to be incomplete or insufficient to gain a licence?***

(c) ***Do you recall why the Gammagard project was restarted in September 1986?***

48.1 David Galliford reported to me and I think that the memorandum was sent to me in order to update me of the licensing status of Gammagard. This was not unusual but I have no recollection why this specific memorandum was written at this time.

49. Please see the attached letter from the CSM to Baxter Health Care Ltd in 1988 outlining why Gammagard was refused a product licence [SHPL0000812_014]. One of the stated reasons was "concern about the transmission of hepatitis C by this product".

(a) ***To the best of your ability and recollection, please explain Baxter's reaction to the CSM's decision. Was it expected?***

(b) ***At this time, were you aware of concerns that Gammagard could transmit HCV? Please explain how and when the association between Gammagard and HCV first became apparent to you and, to your knowledge, to Travenol/Baxter (UK).***

(c) ***Did Travenol/Baxter (UK) continue to supply Gammagard on a named patient basis notwithstanding the concerns about the transmissions of HCV? If so, why?***

i. What were your views on this matter?

ii. What steps were taken to make health authorities, doctors and patients aware of the possible link between Gammagard and HCV?

49.1 I have no recollection of these events and as already noted the detailed aspects of licensing and supply of Gammagard was not part of my day to day role.

50. Please see the attached internal Baxter memorandum from Ivan Bryant, dated 9 February 1989, into which you were copied [SHPL0000875_013]. At point 5, the memorandum notes that Baxter would have to detail "why no additional viral studies were performed"

(a) ***Please explain Ivan Bryant's position and role.***

(b) ***To the best of your ability and recollection, please explain why no additional studies had been performed.***

(c) ***Please contrast this document with a letter dated 12 July 1989 letter, enclosed at [SHPL0000812_009], in which Ivan Bryant stated to the CSM that the data provided demonstrates that Baxter, "consistently yields a safe product with respect to [Non-A Non-B hepatitis]"***

i. Were additional viral studies undertaken within 4-5 months? If so, what studies were undertaken and what were the results?

ii. Was Travenol/Baxter (UK) confident in the removal of HCV by July 1989? If so, why?

50.1 Ivan Bryant was a Senior Regulatory Officer, reporting to the Regulatory Manager. I recall that during the 1980's he was the Regulatory Department member who usually dealt with the registration of blood products in the UK.

50.2 Given the explanations already provided in respect of my role, the detail covered in this memorandum is not familiar to me. I have no recollection of these events and cannot provide any further information that might assist the Inquiry.

51. Please see the attached internal Baxter memorandum from Ivan Bryant, dated 29 June 1989, into which you were copied [SHPL0000812_023]. At point B, the memorandum states that presentations to the CSM on Gammagard should include updates on the "N.A.N.B. hepatitis/ALT database" and "HIV transmission database from both controlled and uncontrolled (post marketing surveillance) sources".

(a) ***What were these databases, and what information specifically was Baxter collecting in relation to HCV, ALT and HIV transmission?***

(b) ***To the best of your ability and recollection, please explain how much data Baxter held about the product once it had been prescribed on a named patient basis.***

51.1 I recall there were strict regulatory requirements on the provision of unlicensed products and Travenol UK and Baxter Healthcare was required to maintain records of each supply on this basis. I do not recall what the precise details were.

52. Please see the attached internal Baxter memorandum, dated 01 August 1989, into which you were copied, summarising the current status of the Gammagard product licence application [SHPL0000785_013]. At point 3, on page 2, the memorandum details why the licensing authority requested validated filtration to lyophilisation lag times, which was seen as "the likely source of viral inactivation, certainly for N.A.N.B. hepatitis based on known differences in manufacturing procedures and clinical usage". To the best of your ability and recollection, please explain Baxter's approach to viral inactivation of Gammagard following this meeting.

52.1 As I have explained, the detail of license applications was dealt with by others who reported to me and though I was copied into correspondence from time to time, I have no familiarity with the detail of licensing applications. I did not attend the meeting to which the memorandum refers or participate in the contacts with the DHSS or the CSM and so I am unable to provide any further information to assist the Inquiry.

53. ***Please see the attached internal Baxter correspondence, dated 26 June 1990, into which you were copied, concerning Gammagard's UK Registration [SHPL0000784_018]. Please answer to the best of your knowledge:***

(a) ***What was BPL's involvement in manufacturing/marketing Gammagard?***

(b) ***How was Gammagard virally inactivated and did this viral inactivation method change over time?***

(c) ***How confident was Travenol/Baxter (UK) in the reduction of risk of transmission by Gammagard in relation to HIV?***

53.1 I have read the document, which I see was copied to me, but I have no recollection of the matters discussed or the actions described in the document and I am unable to add any further information to assist the Inquiry.

54. ***Please see the attached internal Baxter correspondence, dated 28 September 1990, into which you were copied, concerning the Gammagard Viral Inactivation Protocols [SHPL0000783_045]. At point 1, it notes there were "delays in Hyland committing to perform additional viral studies, as required by the UK MCA".***

(a) ***How was work regarding Gammagard divided between Hyland and Travenol/Baxter (UK)?***

(b) ***To the best of your ability and recollection, please explain why there were delays.***

54.1 As already explained above, Baxter Healthcare did not manufacture blood products in the UK and I was not aware of research or development or testing of blood products conducted by Baxter Healthcare. The UK company was responsible for applying for the product licences for the blood products, interaction with the UK regulatory authority and sales and supply.

54.2 I have no familiarity with or recollection of the history of Gammagard's licensing application. I have read the document provided to me by the

Inquiry but I have no knowledge about the "delays" which are mentioned.

55. ***Please see the attached Baxter adverse event report of a patient who contracted HCV having received Gammagard in 1994 [SHPL0000741_072] and the Baxter product complaint summary for March 1994 [SHPL0000804_029]. To the best of your ability and recollection, please explain:***

(a) ***The process of reporting a case of transmission of HCV by Gammagard to Baxter. What information did Baxter require?***

(b) ***What would Baxter do once it had received this information?***

(c) ***Would Baxter communicate these reports to the licensing authorities?***

55.1 As noted above my role did not involve me in the management of, or response to, complaints in respect of blood products. Looking at the dates of the documents the specific complaint relates to a period when I had no involvement in regulatory matters. My colleagues within the Regulatory Department would take the necessary steps to inform regulatory authorities. I do not recall this particular event though my recollection is that there was an established and detailed protocol for reporting adverse events to the regulatory authorities.

56. ***The Inquiry understands that Gammagard was withdrawn worldwide on 21 February 1994. The following documents may assist by way of reference: [SHPL0001026_002] (a letter from Edward Gomperts to doctors providing drug withdrawal information concerning Gammagard); [MHRA0014242_013] (an MCA briefing note on Gammagard).***

(a) ***To the best of your ability and recollection, please explain how the recall decision was made. What was your involvement in this process?***

(b) ***In your opinion, could this, and should this, have happened sooner?***

56.1 I did not have any involvement in respect of product recalls at this time because by 1993 my responsibilities had changed. I was General

Manager with responsibility for manufacturing and I no longer had continuing oversight of the Regulatory Department.

57. Please see the attached MCA briefing note on Gammagard, dated 3 May 1994 [MHRA0014242_013].

(a) ***The note states that "between 20 August 1991 and 20 February 1994, Baxter UK supplied 8,883 vials for use in the UK on a named patient basis". To the best of your ability and recollection.***

- ***i. Do you think that this is likely to be an accurate figure?***
- ***ii. Were there limits on how much unlicensed product Baxter UK could import?***
- ***iii. How did Travenol/Baxter (UK) supply this quantity of product in this period (for example, how did doctors become aware of the product)? You may be assisted by the reference in the note that "some supplies were made in accordance with a DDX for the John Radcliffe Hospital in Oxford, the remainder were supplied under section 13(1) exemptions"***
- ***iv. Please provide an indication of how significant a quantity of Gammagard 8,883 vials represented.***

(b) ***Is the memorandum correct in its understanding that Gammagard products were recalled in the UK? How did that process work, and what was your role in it?***

57.1 I am unable to verify the figures quoted but I think it is reasonable to assume they would be accurate if the figures were derived from distribution information from Baxter Healthcare. Please note my answer in respect of 56 above in respect of product recalls.

58. Please see the memorandum sent by Dr Susan Wood of the MCA on 24 March 1994 in which she expressed her concerns about the possible public health implications of the named patient usage of Gammagard [MHRA0014242_019].

(a) ***Dr Wood stated that a company named Caremark had also been involved in the provision of Gammagard in the UK. Were you aware of this company? If so, please provide details of its role in providing Gammagard and any relationship that it had, to your knowledge, with Travenol/Baxter (UK) or Travenol/Baxter (US).***

(b) ***Do you think that the concerns raised by Dr Wood in the memorandum were justified either in respect of Gammagard specifically, or as a more general point about the use of the named-patient exemption?***

(c) ***Would you characterise the provision of Gammagard in the UK as an example of the "somewhat excessive use of drugs under a named-patient basis"? Do you think that this placed patients at risk and/or undermined the "credibility of the Licensing Authority"?***

58.1 I recall a company called Caremark, or some similar name, delivered medical supplies to patients at home. I do not recall when it operated or whether it was involved in delivering Baxter Healthcare products.

58.2 As I have already stated, by 1994 my role had changed but, as I have already stated in response to questions 29 and 51, the supply of unlicensed products was made on the basis of a clinician's request and the company kept records in respect of each supply.

Section 8: General

59. Please provide any further evidence that you wish to give and that you consider to be relevant to the Inquiry's Terms of Reference.

Statement of Truth

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

Signed: GRO-C

Dated: November 16th 2022