Witness Name: Mr. Robert Barrie Christie

Statement No.: WITN7500001

Exhibits: WITN7500002

Dated: 10th November 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF ROBERT BARRIE CHRISTIE

I, Robert Barrie Christie, will say as follows:

A. I provide this statement in response to a request dated 27 July 2022 from the Infected Blood Inquiry under Rule 9 of the Inquiry Rules 2006 ("the Rule 9 Request").

B. The Rule 9 Request asks that I provide details of any documents I hold that might be relevant to the Terms of Reference. I have read the Terms of Reference and confirm that I do not hold any relevant documents.

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

D. Whilst I wish to be of assistance to the Infected Blood Inquiry, I would like to note that the majority of the questions contained in the Rule 9 Request are about events which happened more than 40 years ago and therefore about which my memory is necessarily limited given the passage of time.

Section 1 : Introduction

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

   My full name is Robert Barrie Christie. My address is GRO-C, GRO-C, East Sussex, GRO-C England.

   My date of birth is GRO-C 1932 (i.e. I am 90 years old).

   I attended the School of Pharmacy at the University of Brighton. I am a member of the Royal Pharmaceutical Society and the Royal Institute of Chemistry.

2. ***Please set out your employment history, including the various roles and responsibilities that you have held throughout your career and the dates when you held them.***

   Here is the detail of my employment history as far as I recall:

   a. 1950: I went to work for Boots Pure Drug Company Limited for the two years practical experience that was necessary for my qualifications.

   b. From 1952 to 1954: I attended the School of Pharmacy at Brighton University.

   c. October 1954: I joined the Royal Army Medical Corps. I was first in charge of a pharmacy and medical store at the Military Isolation Hospital in Aldershot. I was next in charge of medical supplies at the Cambridge Military Hospital in Aldershot. I then moved to the Garrison Medical Centre, Blackdown Hampshire, and finished my military service there. At the Garrison Medical Centre, I looked after the health of the troops stationed there and of their families, in consultation with the Medical Officer.

d. October 1956: I left the army and joined Armour Pharmaceutical Company Ltd. ("Armour UK") as the Deputy Quality Control Manager.

e. Early 1957: I was promoted to Quality Control Manager within a few months of joining Armour UK.

f. Late 1957/early 1958: I was promoted to Manufacturing Manager. In this role, I was in charge of basic drug and surgical suture manufacturing.

g. Approximately 1960: I was asked to set up a research and development department and became the Research and Development Manager.

h. Mid-1960s: I became the Operations Manager for Armour UK. In this role, I was in charge of the entire factory.

i. 1970: I became the Clinical and Technical Affairs Manager. In this role, I was in charge of the Research & Development Department and was responsible for licensing products from other companies around the world.

j. 1975: I was promoted to Director of Clinical Sciences. In this role, I first became involved with blood products.

k. 1986: I was promoted to Clinical and Technical Affairs Director for all of Europe.

l. 1993: I was appointed a Board Director of Armour UK for Clinical and Technical Affairs.

m. 7 July 1997: I retired. Thereafter, for approximately eight or nine years, I worked as a consultant for Armour UK, first for three days a week and later for two days a week. While I was working as a consultant for Armour UK, I also consulted for some UK hospitals.

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

Throughout my career, I have been a member of numerous professional organisations. I do not specifically recall the dates or details of any particular professional involvement. I recall generally that I often worked on test methods and standards of analysis.

Examples of my professional involvement include:

a. I was a member of the British Institute of Regulatory Affairs ("BIRA").
b. I am a member of the Royal Pharmaceutical Society.
c. I am a member of the Royal Institute of Chemistry.
d. I served on two committees for the British Pharmacopoeia and was involved in preparing monographs for Albumin and Pancreatin.
e. I was a member of the Committee for Sutures of the British Standards Institute.
f. I was a member of the International Committee on Pharmaceutical Enzymes.
g. I was a member of the Haemophilia Society.
h. I was a member of the European Plasma/Pharmaceutical Manufacturers Group.
i. I was the company representative to the Surgical Sutures Manufacturers Association.

4. ***Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Cretzfeldt-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.***

I gave evidence in two proceedings involving HIV: R v. Armour Pharmaceutical Co., *et al.* in Canada and a civil case. I do not remember the details of the civil case. I did not prepare a written statement or report for either proceeding.

5. ***Please confirm whether you were employed by Armour Pharmaceutical Company Limited (the UK based company) or by Armour Pharmaceutical Company (the US company) or both or a different legal entity (and if the latter, please provide details).***

I was initially employed by Armour UK. There were various corporate changes over the years. I do not recall the details or timing of these changes. I was never employed by a US company.

6. ***Please describe your roles, functions and responsibilities at Armour Pharmaceutical Company Limited ("Armour") during the time that you worked there. If they changed over time please provide details.***

As far as I can recall, here are the details of the roles, functions and responsibilities:

a. October 1956: I joined Armour UK as the Deputy Quality Control Manager. I was responsible for the analysis and assessment of the quality of the products produced in the factory. I worked in an advisory capacity for the subsequent release or failure of the products, which was dependent on whether or not the products met specifications.

b. Early 1957: I was promoted to Quality Control Manager within a few months of joining Armour UK. In that role, I became responsible for failing or releasing products manufactured in the factory after analysis to quality specifications.

c. Late 1957/early 1958: I was promoted to Manufacturing Manager. I was in charge of basic drug and surgical suture manufacturing.

d. Approximately 1960: I was asked to set up a research & development department and became the Research & Development Manager. I worked to develop new products for the company.

e. Mid-1960s: I became the Operations Manager for Armour UK. In this role, I was in charge of the entire factory.

f. 1970: I became the Clinical and Technical Affairs Manager. In this role, I was in charge of the Research & Development Department and was responsible for licensing products from other companies around the world.

g. 1975: I was promoted to Director of Clinical Sciences. My earlier responsibilities continued. While I was in this role, I became responsible for licensing and registration of blood products in the UK.

h. 1986: I was promoted to Clinical and Technical Affairs Director for all of Europe.

i. 1993: I was appointed a Board Director of Armour UK for Clinical and Technical Affairs. In this role, my regulatory responsibilities increased.

j. 7 July 1997: I retired. Thereafter, for approximately eight or nine years, I worked as a consultant for Armour UK, first for three days a week and later for two days a week.

7. ***Please describe your roles, functions and responsibilities as Director of Clinical Sciences at Revlon Health Care (UK) Limited during the time that you worked there. If they changed over time please provide details.***

In my role as Director of Clinical Sciences, I was in charge of the Research & Development Department and was responsible for licensing products from other companies around the world. At some point, I do not specifically recall when, I became responsible for commercial licensing and registration of Armour products. While I was in this role, I became responsible for licensing and registration of blood products in the UK.

8. ***Please describe the role, functions and responsibilities of Armour's/Revlon's Regulatory Affairs and Medical Affairs departments and identify by name the other individuals who worked within the departments in a senior capacity during the 1970s and 1980s.***

As Director of Clinical Sciences, I was not part of the Regulatory Affairs or Medical Affairs Department. The Medical Affairs Department was responsible for all of the medical aspects of the company's products, preparation of literature and training of representatives. Dr. Peter Harris, Dr. Bill Munro and

Dr. Lawrence Shaw worked in the Medical Affairs Department in senior capacities.

The Regulatory Affairs Department handled communications with the Department of Health and Social Security ("DHSS") regarding drug registrations and applications. Beginning in late 1986, the Regulatory Affairs Department reported to me. Mr. Clive Collins worked in the Regulatory Affairs Department in a senior capacity.

9. ***Please describe the relationship between Armour Pharmaceutical Company Limited and Armour Pharmaceutical Company in the USA (please note that the companies are referred to below generally as "Armour").***

Armour UK and Armour Pharmaceutical Company ("Armour US") were affiliated companies. The two companies had a close relationship regarding clinical and technical issues relating to common products. Armour US provided data to Armour UK regarding individual products. Please note that because they were separate companies, I refer to them separately herein as Armour US and Armour UK.

10. ***On 4 November 2021, Mr Christopher Bishop, in his oral evidence to the Inquiry, stated that he would expect his medical and regulatory colleagues to keep up to date with scientific and medical knowledge and in turn keep Mr Bishop and his sales colleagues informed (see p. 20-21 INQY1000158). Is that correct? Which individuals or departments had the***

responsibility to keep up to date and to ensure that the sales and marketing colleagues were kept informed?

Yes, Mr. Bishop is correct. The Clinical Sciences Department and the Medical Affairs Department had joint responsibility for keeping Mr. Bishop and his sales colleagues up to date. The Medical Director and I were primarily responsible for this task.

11. ***Mr Christopher Bishop, in his oral evidence to the Inquiry, stated that it was the Regulatory Affairs department, along with the Medical Affairs department, that was "primarily liaising with Armour in the USA to get information about safety of products and how to respond" (see p. 7 of INQY1000158). Is that correct?***

Mr. Bishop is correct. In addition to the Medical Affairs Department, I was responsible for liaising with Armour US on clinical and technical matters.

12. ***Please set out your understanding of the role and responsibilities of the Medical Director (Dr Harris) and how they interacted with your role and responsibilities and those of the Regulatory Affairs and Medical departments more generally.***

As Medical Director, Dr. Harris was in charge of the Medical Affairs Department. The Medical Affairs Department was responsible for all of the medical aspects of the company's products, preparation of literature and training of representatives. Dr. Harris would have communicated regularly with the Regulatory Affairs Department and advised on medical aspects of products for the preparation of Product Licence Applications. Dr. Harris and I consulted on

all important aspects of product safety and efficacy. We also consulted on adverse events.

13. ***Was it part of your role to provide medical bulletins to staff (see, e.g., ARMO0000614_002, ARMO0000518_001, ARMO0000435 and ARMO0000656)? What was the purpose of the bulletins? How often did you provide them? How did you decide what to include in them?***

    It was part of my role as Director of Clinical Sciences to provide Medical Bulletins for staff. When information of particular interest regarding the treatment of haemophilia appeared in the medical press, Medical Bulletins were prepared and disseminated.

Section 2: Licensing, relationship with the Medicines Division of the Department of Health and Social Security ("DHSS"), and relationship with the National Institute for Biological Standards and Control ("NIBSC")

14. ***Please describe your role in the licensing process for plasma products in the UK, with particular emphasis upon the licensing of Armour's Factor VIII concentrates in the UK in the late 1970s and 1980s. In particular:***

    a. ***What involvement did you have in submitting applications for product licences, or for variations to product licences, or for renewals of product licences, for Armour's Factor VIII concentrates?***

       I was responsible for providing data for Product Licence Applications.

b. ***How were decisions taken within Armour as to what information to include in the product licence applications?***

I was involved in discussions regarding what to include in Product Licence Applications. Any decisions on what to include were made by the Regulatory Affairs Department.

c. ***What, if any, involvement did you have in decisions as to the information to be included in the product licence applications?***

I was involved in discussions regarding what to include in Product Licence Applications. Any decisions on what to include were made by the Regulatory Affairs Department.

d. ***How were decisions taken within Armour as to what information to include on product labels, inserts and data sheets?***

Decisions regarding what to include were strongly guided by the relevant regulations and input from the DHSS. It was the responsibility of the Regulatory Affairs Department to seek approval from the DHSS for product labels, inserts and data sheets.

e. ***What involvement did you have in decisions as to what information to include on product labels, inserts and data sheets?***

I was responsible for preparing the information to be included on product labels, inserts and data sheets. I consulted with the Regulatory Affairs Department and the Medical Affairs Department to ensure that the labels, inserts and data sheets accurately described the product and complied with government regulations.

f. ***Please describe, in broad terms, the kinds of interactions that you or (to your knowledge) your colleagues had with the Medicines Division of the DHSS.***

My colleagues and I consulted regularly with the Medicines Division of the DHSS, as needed on issues of product safety, efficacy and registration.

g. ***Please describe, in broad terms, the kinds of interactions you or, to your knowledge, your colleagues had with the Committee on the Safety of Medicines (see, e.g., ARMO0000152).***

I was responsible for providing information on serious or unusual adverse events from clinicians or medical staff to the Committee on the Safety of Medicines. (See Document ARMO0000152 for an example)

h. ***Please set out your understanding of the role of the National Institute for Biological Standards and Control ("NIBSC") in relation to samples sent by Armour for testing and describe, in broad terms, the kinds of interactions you or, to your knowledge, your colleagues had with NIBSC. (see by way of example, MHRA0000048).***

It was a requirement that samples of all injectable biological products be sent to the NIBSC for testing and release. Such products were not allowed to be sold until notification of release was received from the NIBSC. The Clinical Sciences Department sent samples of each and every batch to NIBSC. I cannot comment on Document MHRA0000048 because I had not seen it before and it does not appear to be an Armour UK document.

Section 3: Products provided on a "named patient basis" and clinical trial exemptions

15. ***Please set out:***

    a. ***Your understanding of the purpose and process of Armour applying for a clinical trial exemption;***

    Armour UK applied for clinical trial exemptions for clinical studies on new developments which would improve product safety and efficacy. Clinical Trial Exemptions allowed such studies to be completed rapidly and without the long wait for a Clinical Trial Certificate.

    The process was dictated by the regulations pertaining to applications for a Clinical Trial Exemption. It was handled primarily by my colleagues from the Regulatory Affairs Department.

    b. ***The nature and extent of your involvement in Armour's applications for a "clinical trial exemption" in relation to Factorate HT.***

    I obtained data from the United States for the application for a Clinical Trial Exemption and provided it to Mr. Clive Collins. The data showed the processes which were expected to demonstrate improved safety and efficacy.

16. ***Please set out, if possible, your understanding of the process by which Armour in the UK supplied products to Haemophilia Centres on a "named patient" basis.***

Clinicians made requests for named patient supply of products which they perceived would be safer or for which there was a shortage. I do not recall being

involved in communications with clinicians about named patient requests. I recall that named patient supplies were documented but I do not specifically recall who was responsible for such documentation. Batch numbers, potency, number of vials, date of supply, name of the doctor and name of the patient were all documented.

Section 4: Knowledge of, and response to risk Hepatitis

17. ***When you began working at Armour, what did you know and understand about:***

    a. ***the risks of infection associated with blood and/or blood products generally; and***

    When I began working at Armour UK, the company did not sell any blood products, so I had no reason to be aware of any risks associated with such products.

    b. ***the risks of transmission of hepatitis (including Hepatitis B and Non-A Non-B Hepatitis) associated with factor concentrates?***

    When I began working at Armour UK, the company did not sell factor concentrate, so I had no reason to be aware of any risks associated with such products.

    c. ***What were the sources of your knowledge? How, if at all, did they change over time?***

    Once blood products were available for licensure in the United Kingdom, I became aware of the risk of viral hepatitis associated with blood and blood products. Comprehensive information from Armour US and

published literature were the sources of my knowledge. Additionally, over time, I received feedback and information from clinicians, health authorities and other sources.

18. ***What, if any, training from Armour did you receive on these matters?***

I did not receive any formal training; I received on-the-job training by reviewing materials provided by Armour US and from published sources, scientific and medical meetings, clinicians and health authorities.

19. ***To the best of your knowledge, what was the state of knowledge within Armour more generally in the early 1980s about the risks of infection associated with factor concentrates?***

In the early 1980s, we were aware of the risk of non-A non-B hepatitis and hepatitis B from factor concentrates and the Factorate labelling warned of the risk of viral hepatitis.

20. ***What advisory or decision-making structures were in place at Armour to assess the risks of infection associated with the use of blood and/or blood products?***

Full information on the potential risks of using factor concentrates was issued to clinicians by the Medical Affairs and Technical Departments, but the assessment of the risks and benefits of treatment with factor concentrates was up to the clinicians who prescribed them.

21. ***What was your understanding of the nature and severity of:***

a. Hepatitis B and

b. Non-A Non-B Hepatitis;

and how did that understanding develop over time?

At the time we began distributing factor VIII concentrate, we understood that hepatitis B was a severe infection that could lead to serious illness and subsequent liver damage. We also understood that Infection produces antibodies which prevent subsequent infection.

Non-A non-B hepatitis was initially universally thought to be a relatively innocuous infection giving rise to flu-like symptoms and elevation of liver enzymes which resolved apparently without liver damage. In the late 1990s, this was found not to be true. Liver damage and predisposition to liver carcinoma was discovered in some patients.

22. ***What was your understanding of the nature and extent of the risks of hepatitis in Armour products specifically?***

We were fully aware of the risk of non-A non-B hepatitis and hepatitis B from factor VIII concentrates and the Factorate labelling warned of the risk of viral hepatitis. Much of our research was aimed at removing or reducing this risk, which was universal.

23. ***Insofar as you are able to do so, please provide a chronological account of the steps taken by Armour during your employment to reduce the risk of people being infected with hepatitis (in particular Non-A Non-B Hepatitis) in consequence of treatment with Armour products.***

Given the passage of time, I cannot specifically recall the chronology. I recall generally that much of our research was aimed at removing or reducing the risk of viral hepatitis by various heat treatments and eventually by use of monoclonal antibody purification followed by pasteurization to eliminate the risk of infection with non-A non-B hepatitis. I generally also recall that efforts were made to improve safety through donor selection and donor screening measures.

24. ***What if any steps were taken to ensure that:***

    a. ***NHS bodies and/or clinicians purchasing and/or using Armour products were made aware of the risks of hepatitis?***

       The risk of viral hepatitis through blood and blood products was universally known. The labelling for factor VIII concentrates also warned of the risk.

    b. ***Patients treated with Armour products were made aware of the risks of hepatitis?***

       Haemophilia clinicians were responsible to advise patients regarding risks and benefits of treatment and it was not ethical for Armour UK to communicate with patients about their treatment.

25. ***Please describe the steps that would typically be taken by Armour, and your own involvement in such steps, if it became aware of reports of suspected hepatitis or other adverse reactions or side effects. The following documents may be of assistance: ARMO0000151, ARMO0000152, ARMO0000160, ARMO0000265, ARMO0000355,***

ARMO0000321, ARMO0000322, ARMO0000784, ARMO0000788, ARMO0000789, ARMO0000327, ARMO0000801, ARMO0000342 and ARMO0000348.

When we were informed by clinicians of suspected hepatitis or any serious or unusual adverse reactions, these were reported in full to the Medical Assessor of the Committee on Safety of Medicines. A covering letter and the appropriate adverse reaction form (which was known as a "Yellow Form") were used. I was responsible for completing the report to the Medical Assessor (later the Adverse Reactions Monitoring Unit). Documents ARMO0000151, ARMO0000152 and ARMO0000160 are examples of such reports.

I was also responsible for asking clinicians to fill in the appropriate form (see Documents ARMO0000784 and ARMO0000789), following up with them as necessary (see Documents ARMO0000321 and ARMO0000355) and providing information obtained in that follow up to the Medical Assessor (Documents ARMO0000788 and ARMO0000801).

I would also notify the Medical Director of Armour UK and would share any reports of serious or unusual reactions with my colleagues at Armour UK (see Document ARMO0000322) and Armour US.

HIV and AIDS

26. ***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 such as factor concentrates during your time working at Armour? In particular:***

a. ***What were the sources of your knowledge?***

Comprehensive information from Armour US and published literature were the sources of my knowledge. Additionally, over time, I received feedback and information from scientific meetings, clinicians, health authorities and other sources.

b. ***When and how did you first become aware of the possibility of AIDS (or an agent causing AIDS) being transmitted by blood or blood products?***

When I initially read reports about a strange syndrome in gay men whereby they lost most of their immune function, there were many theories about its cause. Initially a virus was not suspected and I did not associate it with blood products. Later, it became known that this syndrome was transmitted by blood and blood products, but it was not known to be a virus. After a period of time, it was learned that the causative factor was a virus which eventually was isolated after considerable scientific research.

I first learned of the possibility of AIDS being transmitted by blood or blood products through an article in the Journal of the American Medical Association ("JAMA") in late 1982. I also recall hearing a report of an individual who developed AIDS after receiving a blood transfusion from a donor who developed AIDS. I had no direct information that AIDS was associated with Armour's plasma products at that time.

c. ***What was your reaction and the reaction of your colleagues in Armour in the UK when you became aware of this possibility?***

There was considerable concern that this unknown agent might be transmitted by plasma products.

d. ***How did your knowledge and understanding change over time? You may wish to consider the document at ARMO0000119 and its reference to the study seen in PRSE0001303 when addressing this question.***

We closely followed scientific and medical developments through reviewing scientific and medical literature and attending relevant symposia. Our knowledge evolved over time with those developments.

27. ***Did you see (or do you think it is likely that you would have seen) the following publications at the time?***

a. ***The 9 July 1982 MMWR (PRSE0003880).***

I would not have received the MMWR, but I may have been made aware of the contents by US colleagues. At this distance in time, I do not remember.

b. ***The 16 July 1982 MMWR (PRSE0000523).***

I would not have received the MMWR, but I may have been made aware of the contents by US colleagues. At this distance in time, I do not remember.

c. ***The article in Science, 13 August 1982, entitled "New disease baffles medical community" (RLIT0000200).***

It is likely I would have seen and read this article. The publication was in Armour UK's library.

d. The 24 September 1982 MMWR (OXUH0002848).

I would not have received the MMWR, but I may have been made aware of the contents by US colleagues. At this distance in time, I do not remember.

e. The Observer, 14 November 1982 (MDIA0000010).

No.

f. The 10 December 1982 MMWR (PRSE0003276).

I would not have received the MMWR, but I may have been made aware of the contents by US colleagues. At this distance in time, I do not remember.

g. The 7 January 1983 article in Science Journal "Spread of AIDS sparks new health concern" (RLIT0000233).

It is likely I would have seen and read this article. The publication was in Armour UK's library.

h. The article on 13 January 1983 in the New England Journal of Medicine entitled "AIDS and preventive treatment in haemophilia" (PRSE0002410).

It is likely I would have seen and read this article. The publication was in Armour UK's library.

i. The Observer, 16 January 1983, "Mystery disease threat" (DHSC0002223_085).

No.

j. The Lancet, 22 January 1983, "Acquired immunodeficiency syndrome" (SBTS0000315_021).

It is likely I would have seen and read this article. The publication was in Armour UK's library.

28. ***On 03 May 1983, in a memo from you and Mr Bishop to Mr Fitch, you wrote that the "potential problem of AIDS (acquired immune deficiency syndrome) and products of human blood origin has been identified since the early part of this year" (see ARMO0000244).***

    a. ***What was the basis for your position that the Mail on Sunday's statement "that screening in the United States is less stringent than in Britain" was inaccurate?***

    The basis of my statement was my knowledge of donor screening practices in the US and the UK.

    b. ***Please describe your interactions with Messrs Regier and Kjellman referred to on p.2.***

    I believe the interactions referred to on p.2 of ARMO0000244 were between Messrs Regier and Kjellman and Mr. Bishop and I was not involved.

    c. ***It might be suggested that this document indicates that your predominant concern was that of adverse publicity rather than patient safety. Please comment.***

    Our predominant concern was always patient safety.

    d. ***Did you receive and issue a "policy document" as suggested? (see BART0000863).***

    No. BART000863 is not a "policy document" and I was not the author of the document.

29. ***What, if any, steps were taken to ensure that:***

    a. ***NHS bodies and/or clinicians purchasing and/or using Armour products were made aware of the risks of HTLV-III/HIV/AIDS?***

    Information about the risks of AIDS developed and changed rapidly over time and the entire medical community was engaged in assessing information as it developed. NHS bodies and clinicians were well-informed of developing information. We had no special or unique knowledge regarding these issues.

    b. ***patients treated with Armour products were made aware of the risks of HTLV-III/HIV/AIDS?***

    Haemophilia clinicians were responsible to advise patients regarding risks and benefits of treatment and it was not ethical for Armour UK to communicate with patients about their treatment.

30. ***To your knowledge, what enquiries and/or investigations did Armour 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?***

    Given the passage of time, I cannot specifically recall investigations or enquiries undertaken prior to 1985. I do recall that we investigated all adverse event reports associated with AIDS and liaised with colleagues at Armour US about developing information.

Section 3: Blood supply, donor pools and screening

Plasma collection

31. ***What was your understanding of:***

    a. ***Armour's commercial relationship with Plasma Alliance and its impact on the location of plasma sourcing for Armour's UK operations.***

    Plasma Alliance was an affiliate of Armour US and Armour UK. No Plasma Alliance centre was located in an area identified as at high risk for AIDS (see Document ARMO0000252). Armour UK did not process plasma products, therefore plasma was not sourced in the UK.

    b. ***Plasma Alliance's risk reduction practices.***

    Plasma Alliance located its Plasma Centres in the Midwest and complied with all of the regulations and directives of the US Food and Drug Administration ("FDA"). Given the passage of time, I do not specifically recall the details of Plasma Alliance's risk reduction practices, but I do recall that Plasma Alliance introduced screening measures over time to respond to developing information about AIDS and new technologies, as discussed for example in Document ARMO0000266.

    c. ***Any other sources of plasma used by Armour. ARMO0000252, PJON0000040_001, ARMO0000266, ARMO0000264 and CGRA0000319 are provided by way of background.***

    I understood that Armour US purchased small amounts of plasma when necessary to address shortages. I do not know the details of any such

purchases. I am aware that Armour US never purchased plasma collected in prisons.

32. ***According to ARMO0000266, as at June 1983 Armour occasionally obtained plasma from FDA licensed centres other than centres owned by Plasma Alliance.***

    a. ***Do you know which other centres Armour obtained plasma from?***

       No.

    b. ***Did Armour obtain plasma from the Arkansas Department of Correction, which in 1984 was due to have its FDA licence revoked due to "serious deviations" including the use of HbSag reactive donors' plasma being "shipped for further manufacture" (see pp.2-3 of CBCA0000022_023)?***

       No.

Pooled plasma

33. ***Please set out your understanding of:***

    a. ***The plasma pool sizes used by Armour in its production of factor concentrate products.***

       Armour UK did not process factor concentrates.

       I understand that the plasma pool for each lot of Armour factor concentrate was made of plasma from an average of 1,540 donors. See Documents ARMO0000005 and OXUH0003867_006).

I also understand that the donor pool from which Armour obtained all of its plasma donations (i.e. the total number of donors with Plasma Alliance at any one time) was between 5,000 and 20,000 (see Document ARMO0000501).

b. ***The steps, if any, taken by Armour to reduce the sizes of the pools.***

I do not recall changes, if any, in the pool sizes for factor concentrates.

c. ***The risk of infection created by the use of pooled plasma. ARMO0000005, OXUH0003867_006, ARMO0000229, ARMO0000519, ARMO0000756, CGRA0000534, and ARMO0000004 are provided by way of background to assist you.***

I understand that the risk of infection varied depending on the virus at issue, the processing undertaken for the lot, the extent to which donors were screened and the inactivation treatment of the final product. I note that I was never responsible for decisions regarding the pool size for lots of factor concentrates.

34. ***On 05 March 1986, regarding a meeting with the DHSS which you attended on 03 March 1986, you stated in ARMO0000501 that:***

We were asked the size of our donor pool which was defined as between 5000 and 20,000 donors. Before screening 0.25-0.3% of donations were HTLV-III positive by the ELISA technique. If one accepts that the maximum virus contamination from a symptomatic AIDS case is likely to be 10^8 virus/ml, then at 0.25- 03% infected donors per pool, the maximum virus challenge will be 10^5. Our lyophilisation and heating process, which was defined as 60˚C for 30 hours, will inactivate 10^5.5.

a. ***Was your statement that "Our lyophilisation and heating process, which was defined as 60˚C for 30 hours, will inactivate 10^5.5", when compared to your estimate that "the maximum virus challenge will be 10^5" the basis for your position that Armour's large pool plasma was safe for use?***

Document ARMO0000501 appears to be an internal summary I drafted of a meeting with the DHSS I attended with colleagues and reflects my notes of what others stated at that meeting. Question 34.a mistakenly attributes a quote from the document to me. I therefore cannot comment on this question.

b. ***Please set out the reason for the high variability in the defined donor pool size.***

See my response to question 34.a above.

Section 4: Heat Treatment

35. ***On 12 August 1983, Armour applied for a Clinical Trial Exemption to conduct a one year study at various UK Haemophilia Centres, to: "use our specifically prepared Factorate product exclusively for an extended period of time in a number of previously untreated patients or in those who have received minimal treatment to determine if infectivity of the product has been eliminated." (see ARMO0000121).***

a. ***Please describe your understanding of Armour's efforts, prior to 1983, to develop virally inactivated products to reduce the risk of HBV and HCV.***

Armour UK did not make factor concentrates and was therefore not engaged in any efforts to develop virally inactivated products.

I was generally aware of research undertaken by Armour US to use heat treatment and other processes to inactivate non-A non-B hepatitis. I note that the hepatitis C virus was not identified until many years later.

I recall that a vaccine for hepatitis B was developed and offered to most patients with haemophilia.

b. ***Was the study referred to above undertaken? If so please provide details. If not, please explain why.***

I am not certain, but I believe the study may have been undertaken. I do not specifically recall being involved with the study referred to in Document ARMO0000121 and note that my name does not appear on this document.

36. ***In late 1984 or early 1985, Armour contacted Dr Alfred Prince, of the New York Blood Center, requesting an assessment of its heat treatment process. (see: ARMO0000356). Please set out your understanding of this study, and Armour's response (You may be assisted by CGRA0000512).***

I note that I was not a recipient of Documents ARMO0000356 and CGRA0000512 and I have no recollection of receiving them. My understanding is that Dr Prince's study was flawed and the results were unreliable. I recall learning that Dr Prince was unable to seed HIV or HTLV-III at a high enough concentration to leave residual virus.

37. ***In October 1986, Lofty Lucas met with the Edinburgh Haemophilia Centre Directors. In his note following the meeting, it was noted (at paragraph 14) that Armour stated that there was no laboratory evidence suggesting that Armo[u]r's viral inactivation process was not sufficient in inactivating HIV. Please set out your understanding of Armour's position in relation to informing those external to the company of the findings of the Prince study. (see: CGRA0000533).***

I understood that Armour US was unable to replicate Dr. Prince's findings and that, as mentioned above, his experiments were flawed and the results were unreliable. In those circumstances, it was not considered appropriate to inform others of the study results.

38. ***On 04 October 1985 you wrote a "Medical Bulletin" to the "plasma team" discussing recent developments in heat treatment for viral inactivation (ARMO0000435). Please explain what you meant when you referred to a study having an impact on a disproportionate effect on "the purchasing policies of haemophilia centre directors striving to achieve the safest treatment for their patients".***

I recall that the results reported in the Medical Bulletin (Document ARMO0000435) applied to a limited number of patients and a limited number of batches of factor concentrate. These results therefore could only be interpreted as preliminary (and indeed in the Medical Bulletin I said "from the limited numbers of patients and batches of material used, this letter must be regarded as a preliminary communication"), but might have been

misinterpreted as a definitive finding by those purchasing factor concentrates at the haemophilia centres.

39. ***Please consider the article in the Philadelphia Inquirer at CGRA0000523 and:***

    a. ***Set out your understanding of Armour's submission of viral inactivation data to licensing authorities;***

       It is my understanding that as part of its regulatory submissions the relevant Armour entity submitted viral inactivation data to all licensing authorities where sales of factor concentrate were planned.

    b. ***Set out any knowledge or recollection you have of the October 1985 meeting described in the article and of the decisions taken at that meeting;***

       I do not believe I attended the meeting described in the article (Document CGRA0000523) and therefore have no knowledge or recollection of the decisions taken at that meeting.

    c. ***Provide any further comment you have on the matters set out in the article.***

       I do not believe that the Philadelphia Inquirer was a publication that would have been considered authoritative for purposes of medical and scientific research. I do not recall ever reading the Philadelphia Inquirer. I also note that the article was published on 23 October 1995.

40. ***In early 1986, Meloy Laboratories performed an internal assessment "Infectivity Assay of Factorate Intentionally Seeded with LAV/HTLV III and***

Subjected to Heating in the Lyophilized State at 60°C for 30 hours, 60 degrees celsius for 60 hours and 68°C for 72 hours" (see: ARMO0000553).

a. ***Please set out your understanding of the study's findings, including (at p. 6) that: "Heating at 60°C for either 30 or 60 hours led to substantially less inactivation of virus contained in the less pure product (Factorate - Gen I), but the heat inactivation of virus contained in Factorate - Gen II under these conditions was only marginally less effective than heating at 68°C for 72 hours".***

   I recall generally that we were informed about the viral inactivation studies carried out by Meloy, but given the passage of time, I do not recall any details.

b. ***What if any impact did the study have on Armour's decisions and actions in the UK?***

   I do not recall.

The Rule 9 Request dated 27 July 2022 sent to me by the Infected Blood Inquiry jumps from Question 40 to Question 52. The Infected Blood Inquiry confirmed that this was a clerical error and that no questions were missing from the Rule 9 Request.

For ease of reference, I follow the numbering of the Rule 9 Request and therefore the numbering below jumps straight to Question 52.

52. ***If possible, please explain what version of Factorate (Generation I or Generation II) was marketed and sold as a heat treated product in the UK?***

Both Generation I and Generation II HT Factorate were marketed and sold in the UK.

53. ***On 12 March 1986, Armour's parent company Rorer received the final version of Professor Reinard Kurth's report on "Inactivation of LAV/HTLV-III in Blood Coagulants" as well as a letter from Professor Kurth, into which you were copied. (ARMO0000513). On May 14 1986, you were copied into a memo from Dr William Terry, which criticised the methodology of the Paul Ehrlich Institute's viral inactivation study on Factorate (ARMO0000530).***

    a. ***Please set out your understanding of both the Paul Ehrlich Institute's study and Dr Terry's response.***

    Given the passage of time, I do not recall the details of the study (Document ARMO0000530) or letter (Document ARMO0000513) and reviewing the documents does not refresh my recollection.

    b. ***What, if any, impact did they have on Armour's actions and decisions in the UK?***

    I do not recall.

54. ***On 27 March 1985, you wrote to Dr Frank Hill at the Birmingham Children's Hospital, noting your payment to the Hospital's research fund.***

    a. ***Please set out your understanding of the research undertaken at the hospital.***

This was a detailed follow-up of virgin patients who would be treated only with Armour heat-treated factor concentrate.

b. ***Please set out your understanding of Armour's scientific rationale for undertaking research at a children's hospital.***

In view of the fact that a high proportion of patients with haemophilia were already HTLV-III antibody positive, they could not be used in a study to assess possible HTLV-III infectivity of HT Factorate. Dr. Hill had patients who had never been previously treated and therefore were suitable for the study. Laboratory studies had indicated that heat treated factor VIII concentrate would be safer than unheated factor VIII concentrates. Because they were previously untreated, it was Dr. Hill's preference that they receive heat-treated factor VIII concentrate, which was hoped to be safer than unheated factor VIII concentrate.

c. ***Please set out your understanding of Armour's rationale for providing financial assistance to the hospital.***

Detailed testing and follow up of patients over a period of time and preparation of data for publication involved a considerable expenditure of the clinician's time and that of laboratory staff, the use of expensive tests and comprehensive follow-up. Therefore it was reasonable and common to provide financial assistance, which in no way could be considered excessive.

d. ***Please set out your understanding of whether this study resulted in those patients being treated by Dr Hill receiving heat treated Factorate as a preference over other blood products.***

I understood that the patients in a study of HT Factorate received only HT Factorate. Introduction of other companies' factor concentrates would have invalidated the results of the study. I cannot comment on what haemophilia treatment the patients received after the study concluded.

e. ***Please set out whether this arrangement was undertaken with the knowledge or oversight of any government or regulatory body.***

I do not specifically remember, but I recall that we had been asked by the DHSS to study HT Factorate. It was our practice that any study instigated by Armour UK would be performed in consultation with the DHSS. A study without a fixed protocol that was instigated by a clinician may not have been undertaken with government oversight. As can be seen from my letter to Dr Hill dated 27 March 1985 (ARMOUR002491) I was keen to keep the DHSS informed of findings made by clinicians in their research (ARMO0000370).

f. ***Please set out your understanding of any link between the use of Factorate at Birmingham Children's Hospital and the later seroconversions there (see: ARMO0000585 and ARMO0000592).***

On 29 September 1986, Dr. Hill reported two haemophiliacs who seroconverted to HIV-antibody positive following a long course of Armour heat-treated factor concentrate. This was reported to the DHSS and followed up as per the usual practice at the time. Because the seroconversions came after the patients had received a long course of Armour heat-treated factor concentrate, it was concluded that there was a possible association.

55. ***On 05 March 1986 you wrote to Dr Peter Harris regarding a meeting with DHSS attended by you, Dr Harris and Dr Rodell on 03 March 1986 (ARMO0000501).***

a. ***Please set out your understanding of why this meeting was held.***

Following our report to the DHSS of the seroconversions reported by Dr. Hill, a meeting was requested by Dr. Rotblat of the DHSS to discuss these events.

b. ***Was a common line of explanation agreed prior to the meeting taking place?***

Not that I can recall.

c. ***Was there any discussion or disagreement between Armour's UK branch, as represented by you and Dr Harris, and its US owner, represented by Dr Rodell?***

Armour US and Armour UK were affiliates and Armour US was not the owner of Armour UK. Dr. Hill's results were discussed between Armour US and Armour UK, but there was no disagreement.

d. ***In your memorandum you record that "Dr Betts requested detailed experimental methods for the virus inactivation studies. An outline summary is not sufficient. Dr Rodell agreed to provide this data." Was 'the Prince study' included in these discussions? If not, why not?***

The request was made for data presented in the specific study discussed at the meeting. Dr Prince's study was flawed and therefore not included in that discussion.

e. ***In your memorandum you record that Dr Rodell "elaborated" on a theory that the seroconversions of the Dutch patient and Dr Whitmore's patient may be "an antibody response to dead virus". Was this a position supported by any evidence at the time and if so what?***

The theory was one of many under investigation at the time, as the available data was limited and confusing.

f. ***You describe the atmosphere as "frank, open and helpful". How would you describe Armour's relationship with the DHSS more generally? (ARMO0000545 may be of assistance).***

In my experience, Armour UK always had a very good relationship with the DHSS.

Section 5: Factorate Heat Treated: AIDS transmission and withdrawal

56. ***On 1 May 1985, a "summary of findings" was produced into the market withdrawal of 10 lots of Antihemophilic Factor; it is noted in this report that:***

The 4th lot X57610 was shipped to (blank) where half was heat treated and half was not heat treated. I requested all correspondence from Armour to the firm's German and United Kingdom affiliates and any correspondence from those affiliates to Armour. As of this date, I have not received any of the requested correspondence. (see BAYP0005877).

a. ***Please set out the steps taken by Armour, if any, to reduce the risk posed by batches Y69402 and X57610/6, discussed in the***

document above, prior to notification of a suspected case of AIDS in a Dutch patient in February 1986 (see ARMO0000469)

I note that Document BAYP0005877 does not seem to be an Armour document. I do not recognise Document BAYP0005877 and as far as I am aware I never saw it. I do not recall and cannot comment on the circumstances discussed in that document.

57. ***On 16 May 1985 you wrote to Dr Harris regarding "Armour Factorate and seroconversion to HTLV-III positive". Please set out what you meant by your reference to a "consistent reply" (ARMO0000391).***

I believe I meant that the Medical and Clinical Departments should prepare any reply rather than the Marketing Department.

58. ***On 04 June 1985, you informed a number of Haemophilia Centres that heat-treated batch number Y69402 had incorporated plasma from a donor who subsequently developed AIDS. (see: ARMO0000393, ARMO0000394, ARMO0000395, ARMO0000396, ARMO0000397, ARMO0000398 ARMO0000399 and ARMO0000400) Please set out:***

   a. ***How and when you became aware of the possible contamination of this batch;***

      I believe I was advised by Armour US that Batch Y69402 included plasma from a donor who was subsequently diagnosed with AIDS.

   b. ***Your understanding of the risk this batch posed to patients; and***

I understood that this was a single donation to the pool and by dilution of the single donation and heat treatment the virus would have been inactivated. Therefore I believed there was a minimal risk to patients.

c. ***The steps that were taken by you, or your colleagues, in response to that information.***

In May 1985, we contacted all haemophilia centres who received the batch in question by telephone and followed up with written correspondence to notify them about the donation.

We consulted with the DHSS regarding follow up and then contacted the Haemophilia Centre Directors to specifically follow up and assess whether their patients developed symptoms of HTLV-III infection.

Documents ARMO0000393, ARMO0000394, ARMO0000395, ARMO0000396, ARMO0000397, ARMO0000398 ARMO0000399 and ARMO0000400 are examples of such follow up letters to clinicians which I sent in June 1985.

Thereafter, we continued to correspond with clinicians regarding their patients, including paying personal visits to them if data was not forthcoming, and to report back to the DHSS. See for instance my letter to Dr. Al-Ismail dated 12 June 1985 (ARMOUR002542) asking for follow up to be continued for some patients (WITN7500002).

We continued to keep the DHSS closely informed, see in particular my letter to Dr Rotblat at the DHSS on 22 August 1986 (ARMOUR004679) (ARMO0000812).

59. ***Your letters of 4 June stated that the Department of Health "would be very interested if all patients who have received this batch of material could be followed up for HTLV-III antibody conversion and/or any clinical or haematological signs of AIDS or pre-AIDS symptomology".***

    a. ***Who in the Department of Health had requested this follow-up (see also ARMO0000417)?***

    I do not specifically recall, but I believe it would have been Dr. Rotblat from the DHSS.

    b. ***Did you anticipate that clinicians would provide this information to you, or to the Department of Health directly, or both?***

    I anticipated that clinicians would provide the requested information to me.

    c. ***What information by way of follow up was provided to you?***

    The information that was requested, i.e. information regarding HTLV-III antibody conversion and/or any clinical or haematological signs of AIDS or pre-AIDS symptomology, was provided to me.

    d. ***Did you anticipate that the patients themselves would be told that they would be "followed up"? Did you take any steps to ascertain if that were the case?***

    This issue was at the discretion of the clinician. It would not have been ethical for me to interfere with relations between clinicians and patients.

60. ***On 17 July 1985 you wrote to Dr Whitmore regarding batch Y69402 and noted that: "Patient 1 is of particular interest. This patient is the first to show sero-conversion from HTLV-III negative to positive following***

administration of the batch of Factorate Heat Treated in question". (see: ARMO0000418).

a. ***Considering both ARMO0000402 and ARMO0000418, what was your view at the time regarding a causal link between batch Y69402 and the seroconversion of Dr Whitmore and Dr Ismail's patients?***

   I note that I said to Dr Whitmore (Document ARMO0000418): "the results for Patient 1 are of particular interest".

   At the time, I considered there was a possible link, but the information received from other centres regarding their patients treated with this batch gave rise to some doubt.

b. ***Please set out your understanding at the time of the implication of these seroconversions for the safety profile of Armour's heat-treated Factorate more broadly.***

   Because of the limited nature of the data, there was no basis to make a firm conclusion about the safety profile at that time.

61. ***In February 1986 at an AIDS conference held in Newcastle Dr Peter Jones expressed concern about the efficacy of Armour's heat treatment in inactivating HTLV III and referred to cases of seroconversion (see, e.g., ARMO0000469). Were you present at the conference? What was your reaction, and the reaction within Armour, when you learned about Dr Jones' comments? (You may wish to consider ARMO0000474).***

I was not present at the conference. Document ARMO0000474 summarises my reaction and the reaction within Armour UK to Dr. Jones's comments.

62. ***ARMO0000469 (a file note of 13 February 1986 copied to you) refers to discussions with you and Mr Bishop having confirmed "that this was a patient about whom we had previously been informed but the haematologist concerned (Dr Ten Cate) had wished to keep secret". Please set out when and how you learned about the Dutch patient. Is it right to understand from this document that Armour had previously done nothing in response to the information about the Dutch patient?***

I learned about the Dutch patient through a telephone call from Dr. Ten Cate on 18 February 1986, after which Dr. Harris and I visited him the same day to obtain further information on his patient (see Document ARMO0000474).

It is not right to understand from Document ARMO0000469 that Armour had previously done nothing in response to the information about the Dutch patient. The comment reflects that Dr. Ten Cate requested confidentiality while he investigated the situation and prepared an article, which he then published.

63. ***On 25 February 1986 Dr Jones wrote to Dr Harris (see ARMO0000489), expressing the view that "I do not think that the Armour material should be prescribed to previously untreated sero-negative patients and am particularly averse to its prescription for children".***

    a. ***Did you or, to your knowledge, Armour take any steps to ensure that Armour products were not prescribed to children or to previously untreated sero-negative patients? If not, why not?***

    We did not. It would have been unethical for Armour UK to attempt to interfere with the relationships between clinicians and their patients.

64. ***On 28 February 1986, you wrote to Dr Harris regarding a visit made to Dr Whitmore the previous day to follow up on two patients who had seroconverted to HTLV-III positive. "Patient 1" was given batch Y69402 on 5 February 1985 and on 6 May 1985 was found to be HTLV-III positive (had tested negative on 14 January 1985). "Patient 2" had mainly been treated with cryoprecipitate and was HTLV-III negative on 22 January 1985, after which he was treated with large amounts of Factorate HT throughout 1985. He was also given NHS Factorate on 12 December 1985 and then tested HTLV-III positive on 20 January 1986. (CGRA0000515)***

a. ***Please set out, if possible, your understanding of the actions taken by Armour, between the notification of potential seroconversions in July 1985 and your visit to Dr Whitmore in February 1986. (see CGRA0000514 and ARMO0000486).***

   In consultation with the DHSS, I followed up on the use of Factorate lot Y69402. I cannot comment on Document CGRA0000514 or the issues discussed therein. I was not at the meeting it addresses and the document was not copied to me.

b. ***Please set out, if possible, your reasoning for your stated "interpretation" that:***

   as he had no HTLV-III test between January 1985 and January 1986, and as he was exposed to blood products in the period 3 or more months prior to the negative test, he could have sero-converted within the accepted time for seroconversion. It could have been the NHS concentrate, or it could have been one of the bags of cryoprecipitate. It is unfortunate that he switched over to our Heat

Treated material during that year and nobody knows quite when he seroconverted, but it is by no means an unequivocal relationship to our product

My reasoning is stated in the quoted text. The patient had received cryoprecipitate and NHS concentrate, neither of which was virus inactivated. Therefore, it was not possible to relate the patient's seroconversion to any specific product.

65. ***In late August 1986, you wrote to the DHSS and to Dr Rodell regarding batch Y69402 (see: ARMO0000812) and noted regarding a patient that there was a "a five-year gap before he received batch Y69402 and he had tested HIV Ab Negative 3 weeks before he used the Armour product." Considering the combination of the number of seroconversions catalogued in ARMO0000812 what was your view, at the time, on the likelihood of Armour's heat-treated product being the causal connection between these?***

Because four patients out of six who received the batch did not seroconvert, and follow-up showed that those who seroconverted used other products, the likelihood of HT Factorate being the causal connection was possible but uncertain.

a. ***Had this view changed substantially from that expressed in February in CGRA0000515?***

No.

66. ***On 02 October 1986, you prepared an Aide Memoire (ARMO0000589) following the seroconversion of a number of children at Birmingham Children's Hospital (ARMO0000585). What was your reaction, and the reaction within Armour more generally, to the likelihood that children had been infected with HIV by Armour's heat treated Factorate?***

My reaction was one of great concern and I immediately reported the news of the seroconversions to my colleagues at Armour UK, Armour US and the DHSS. I recall that my colleagues and the DHSS responded very quickly to gather information and assess the situation.

67. ***In December 1986 you wrote to Harris and attached the article "Transfusion-Acquired Human Immunodeficiency Virus Infection Among Immunocompromised Persons" and commented on the median seroconversion time of 384 days which "means seroconversion times in excess of 18 months are possible" and as such "in view of the Frank Hill cases it seems that along seroconversion period after exposure to non heat treated material is still a possible explanation". (ARMO0000632). You then informed Dr Rotbalt at the DHSS and stated that "a long sero-conversion period after exposure to non-heat treated Factor VIII is still a possible explanation of Dr Frank Hill's recent experience" (ARMO0000637).***

    a. ***Was this theory of a long seroconversion period shared by anyone else at Armour in the UK or US?***

    I do not recall talking about the study discussed in Documents ARMO000632 and ARMO0000637 with any colleagues at Armour UK or

with anyone from Armour US, so I cannot recall what, if anything, anyone thought about it. I note that at the time, HT Factorate was no longer distributed in the UK.

b. ***Did this theory in any way impact your assessment in 1985 and 1986 of the risks posed by Armour's lower level heat treatment method?***

No. The time between exposure and seroconversion was one of multiple factors considered when attempting to assess causality.

68. ***On 18 February 1986, you were contacted by Dr Rotblatt [sic], Department of Health and Social Security ("DHSS") and confirmed that the "Dutch patient" was treated with Factorate HT. You promised to send further viral inactivation studies. (see CGRA0000520 and ARMO0000475).***

a. ***Please set out your understanding of what viral inactivation studies relevant to Armour products were supplied to the DHSS and when.***

I note that in Document ARMO0000475, Dr. Harris asks Dr. Swartz to send him viral inactivation studies for Dr. Harris to forward to Dr. Rotblat. I do not believe I was involved in supplying studies to the DHSS and have no specific recollection. I understand that all viral inactivation studies relevant to Armour's heat treatment would have been sent.

b. ***What did you mean by recording that "In the circumstances, I had to release to Dr Rotblatt [sic] some of the contents of the article prepared by Dr Ten Cate for publication"?***

Dr. Ten Cate specifically asked me not to divulge his report on the case as he was following it up and preparing a publication for a medical journal

and did not want information to be released prematurely. Because of the involvement of the DHSS, I had no alternative but to release some of the contents in spite of Dr. Ten Cate's specific request as indicated in Document CGRA0000520.

c. ***In what way was Dr Rotblatt [sic] "a valuable ally"?***

Dr. Rotblat was a direct contact within the DHSS with whom one could discuss issues of efficacy and safety.

d. ***Your memo records that "I am now obliged to report Dr Whitmore's patient". What was it that "now obliged" you to do so and why had you not done so earlier, given you had known about it for months?***

Dr. Whitmore had asked for confidentiality because he had some concerns about the patient's lifestyle and did not want the report to be publicised until he had investigated the issue. As is indicated in Document CGRA0000520, I was obliged to report the seroconversion to Dr. Rotblat because Dr. Whitmore had concluded his investigation.

69. ***On 27 February 1986, a meeting was held in Fort Washington concerning the seroconversion of haemophiliacs who used Factorate HT (see: CGRA0000519, ARMO0000496 and ARMO0000497).***

a. ***Please set out your understanding of Armour's supply of tested or screened plasma from 1986 onwards.***

In the spring of 1985, Plasma Alliance began screening plasma donations for HTLV-III. In June 1986 we conducted a voluntary exchange of any Factorate HT made with plasma collected before HTLV-

III screening was implemented for Factorate HT made from only screened donations.

b. ***Did Armour adhere to the policy of only supplying Factorate from individually tested donors?***

Yes.

c. ***Please explain your understanding of what was meant by the description of Armour's heat treatment process as "relatively satisfactory".***

I understood that heat treatment was effective and donor screening added an extra layer of safety.

d. ***The meeting envisaged that Armour might have to supply non-tested material "where potency and/or volume requirements demand". What was meant by potency and/or volume requirements?***

I cannot comment on what was meant because I did not attend the meeting.

e. ***Did Armour, to your knowledge, supply non-tested material in such circumstances? If so please provide details (including details of any clinicians who were "forewarned" and "agreed to this").***

I understood at the time that Armour UK was only importing tested material.

70. ***Please set out your recollection of the Recall Committee meeting held on 7 October 1986 (CGRA0000530) and how the decision to surrender the licence was taken.***

I do not recall the meeting in detail and cannot provide any information beyond what is stated in Document CGRA0000530.

71. ***Please set out your recollection of meetings with the DHSS in October to consider the position regarding Factorate (ARMO0000510, DHSC0003963_137).***

I recall that the meeting discussed in Document ARM00000510 addressed the issue of potential withdrawal of Factorate HT, which was deferred to three days later, when expert personnel from the United States would be present. Document DHSC0003963_137 appears to discuss the meeting held three days later. I recall that at that meeting, representatives of Armour US presented safety data and eventually a decision to relinquish the HT Factorate licence was made.

72. ***Looking back now, do you consider that Armour acted sufficiently promptly and appropriately in response to concerns about possible seroconversions from heat-treated Factorate? Please explain your answer. (The following may be of assistance: GRA0000585, CGRA0000514, CGRA0000519, CGRA0000517, CGRA0000520, CGRA0000515, CGRA0000520, CGRA0000514, CGRA0000518 p.4, CGRA0000519, ARMO0000501, CGRA0000570, ARMO0000585, CGRA0000530, CGRA0000531 and CGRA0000533 p.3).***

Yes. It was a time of great uncertainty and constantly evolving knowledge regarding the nature and severity of the AIDS virus and sensitivity of the virus to inactivation. There was great confusion about the reports of seroconversions, which occurred in only a handful of patients after many patients had received HT Factorate without seroconverting. Investigation of the seroconversions was exceedingly complicated – for example, patients received a number of different products, only some of which were heat treated and the amount of time to seroconversion was unknown. This made it difficult to assess whether the seroconversions were product related. Nonetheless, when the decision to withdraw the product was made, we immediately took steps to do so.

Section 7: Interactions with the DHSS, UK Haemophilia Centre Directors Organisation ("UKHCDO") and the Haemophilia Society

73. ***Please describe, in broad terms, Armour's relationship with the DHSS during the period in which you were employed by Armour and how, if at all, it changed over time. (See: CGRA0000570)***

We had regular discussions and consultations with the DHSS during the entire time I was employed by Armour UK. I found the DHSS employees to be professional and helpful. Their reactions to information were always fair and consistent.

74. ***Please set out your recollection of any specific interactions or meetings with the DHSS in which you were involved during the 1970s or 1980s (and in particular any interactions or meetings in which issues relating to the***

safety of blood products generally or Armour products in particular or licensing processes or risks relating to hepatitis or HIV were considered). (see ARMO0000287 and ARMO0000510

I recall that throughout the years, we met frequently with the DHSS regarding a range of issues, such as licencing, product improvement, adverse reactions, withdrawal of our licence for HT Factorate and subsequently regarding the development and licensing of our monoclonally purified product. Given the passage of time, I cannot specifically recall the dates or subjects of any specific meeting.

75. ***Please describe, in broad terms, Armour's relationship with the Haemophilia Society in the UK during the period in which you were employed by Armour and how, if at all, it changed over time.***

Individual members of the Regulatory Affairs, Clinical Sciences and Medical Departments were members of the Haemophilia Society, attended their meetings, and on occasion, gave presentations.

76. ***Please set out your recollection of any specific interactions or meetings with the Haemophilia Society in which you were involved during the 1970s and 1980s.***

I recall generally that I regularly attended meetings and took part in discussions, but I cannot recall any specific instances in detail.

77. ***Please:***

a. ***Describe Armour's sales/marketing policies or strategies with regard to haemophilia centres/haemophilia centre directors in the UK during the 1970s and 1980s. Please include a description of any arrangements which Armour had for visiting centres/directors and any financial or non-financial assistance or incentives provided to centres and directors. (see: ARMO0000282, ARMO0000286, ARMO0000236, ARMO0000268, ARMO0000282, ARMO0000369 and ARMO0000370)***

I was not responsible for any sales and marketing policies, strategies or decisions. I regularly visited most of the Haemophilia Centres and Directors to provide technical information and to arrange clinical studies. Clinical studies were appropriately funded.

b. ***Identify any particular haemophilia centre directors in the UK with whom Armour had a close relationship in the 1970s and 1980s.***

Armour UK had the same relationship with all Haemophilia Centre Directors.

c. ***Identify any haemophilia centre directors in the UK from whom Armour sought advice or who provided consultancy services to Armour or who undertook research for or with Armour during the 1970s and 1980s and provide details. (see: OXUH0001624_003, ARMO0000612, CGRA0000532, ARMO0000337 and ARMO0000370)***

Research was conducted with a number of Haemophilia Centres, including Oxford, Sheffield, Liverpool, Royal Free, St. Thomas, Birmingham Children's Hospital, Swansea and Thanet.

d. Describe, in broad terms, Armour's relationship with the UKHCDO and set out your recollection of any specific interactions or meetings with UKHCDO in which you were involved during the 1970s and 1980s.

I did not have any relationship with the UKHCDO and I am not aware of any relationship between Armour UK and the UKHCDO.

78. ***Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.***

The events addressed in this statement occurred over 30 years ago and I am now 90 years old. As such, my ability to recall particular events is limited. I do recall that our major objective at Armour UK was always to produce product of maximum safety and efficacy. As new technologies became available to us, we worked with maximum speed to implement them.

The onset of AIDS and its subsequent appearance in blood and blood products was an unexpected and unprecedented tragedy.

My deepest sympathy is extended to those patients who were infected with this dreadful disease and with hepatitis C and to their families.

Statement of Truth

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

Signed GRO-C

Dated 10th November 2022

Table of Exhibits:

Date	Notes/Description	Exhibit number
27 March 1985	Letter from Mr. Christie to Dr. Hill	ARMO0000370
12 June 1985	Letter from Mr. Christie to Dr Al-Ismail	WITN7500002
22 August 1986	Letter from Mr. Christie to Dr. Rotblat from the DHSS	ARMO0000812