Witness Name: Mr. Clive John Collins

Statement No.: WITN7021001

Exhibits: 0

Dated: 2 September 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CLIVE JOHN COLLINS

I, Clive John Collins, will say as follows:

A. I provide this statement in response to a request from the Infected Blood Inquiry under Rule 9 of the Inquiry Rules 2006 dated 23 May 2022 ("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 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 many of the questions contained in the Rule 9 Request relate to events which happened more than 40 years ago and therefore about which I necessarily have limited recollection given the passing of time.

E. In addition, some of the events I am being asked about by the Infected Blood Inquiry happened before I joined or after I left Armour UK.

Section 1: Introduction

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

   My full name is Clive John Collins and my current address is: GRO-C GRO-C West Sussex, GRO-C England. I was born on GRO-C 1943. I have a B. Pharm degree from the University of London. In my working life I was a Member of the Royal Pharmaceutical Society of Great Britain ("RPSGB") and a Fellow of the British Institute of Regulatory Affairs ("BIRA").

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:

   a. September 1967 - October 1971: I was employed by Beecham Research Laboratories, Worthing, West Sussex initially in the Product Development Department to complete an apprenticeship and obtain membership of the RPSGB. In September 1968, I moved to the Production Department as Assistant Packaging Manager for Beecham's semi-synthetic penicillin products. I was initially responsible for the encapsulation department, then the antibiotic packaging floor and finally for the antibiotic sterile area. Unfortunately, I developed a chest allergy to ampicillin and had to leave the company;

b. October 1971 - October/November 1972: I was an executive at the Proprietary Association of Great Britain ("PAGB"), the trade association for proprietary medicine (i.e. over the counter medicinal products) manufacturers in the UK (based in Holborn, London), responsible for administering the PAGB's Code of Advertising Practice. Manufacturers were obliged to get prior approval for all proprietary medicines advertising e.g. in newspapers, magazines, on TV. It was my responsibility to sign off approval for all such advertisements. In carrying out this task, I had to review all potential new advertisements and TV scripts and films for compliance with the Code of Advertising Practice and general advertising regulations and to formally sign off approval. My role at PAGB also included drafting Manufacturers and Wholesale Dealers Licence applications for some member companies for them to comply with the requirements of the then newly introduced Medicines Acts 1968 and 1971. I was also asked to conduct a few informal inspections of company manufacturing and wholesale premises to advise on potential compliance/non-compliance with the new regulations;

c. October/November 1972 - September 1979: I was employed at Ciba-Geigy UK Ltd, Horsham, West Sussex initially as Assistant Manager, Quality Control and later as Assistant Manager in the Regulatory Affairs Department in the preparation, maintenance and renewal of the company's Product Licences, Clinical Trial Certificates, Manufacturers

and Wholesale Dealers Licences. For a time, I looked after the administration of named patient supplies as and when they arose;

d. October 1979 - October/November 1990: I joined Armour UK in Eastbourne, East Sussex as Regulatory Affairs Manager with responsibility for all products for applications, maintenance and renewal of the company's Product Licences, Clinical Trial Certificates, Manufacturers and Wholesale Dealers Licences and to provide regulatory input into various company products in-licencing and acquisitions and any development programmes as appropriate. My main liaison outside of the company was with the Department of Health and Social Security ("DHSS") and the National Drugs Advisory Board ("NDAB") in Ireland. I maintained this role until late 1986, when I began to head up a new European Regulatory Group for Rorer. From that time on, I had no further involvement with factor concentrates or other blood products;

e. October/November 1990 - October 1991: With the Rorer relocation to Chelmsford, Essex, I decided not to move and was offered a position by Johnson & Johnson US as Regulatory Liaison between the US company in Raritan, New Jersey, US and the company's affiliates in Europe assisting the European companies to obtain, maintain, renew their regulatory licences e.g. updating processing, stability data etc. and providing appropriate feedback to the US company;

f. November 1991 - September/October 1998: I became Regulatory Director for Shire Pharmaceuticals Development Company Ltd responsible for all the regulatory activities for both the development company and the marketing company Shire Pharmaceuticals Ltd. It was my responsibility to help investigate and report Adverse Reaction Reports ("ADRs") to the Medicines Control Agency ("MCA"). I looked after compliance of advertising material with the appropriate licence and the Association of British Pharmaceutical Industry ("ABPI") Code. I also had a significant role in acquisitions of products and companies in respect of the validity of the regulatory status of the products and companies in Europe after the flotation of Shire in the UK in February 1996; and

g. September/October 1998 - up to 2008: The two founders of Shire Pharmaceuticals Ltd asked me to help them with another 'start-up' company, Strakan Ltd. My role as Regulatory Director was initially to evaluate databases for products the company wished to in-licence for both marketing and clinical trial purposes. I was involved in the evaluation of contract manufacturing and wholesale facilities, the approval of marketing material for compliance with product licences and statutory requirements. I also oversaw Quality Control activities for the products both imported to and manufactured in the UK. Additionally, I conducted various inspections of potential suppliers of products.

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.***

   I was a member of the RPSGB from 1968 and from the mid-1980s a Fellow of the BIRA, for whom I lectured on European regulatory procedures at introductory training courses for regulatory personnel from both the UK and other countries.

   I was a member of the organising committees for two BIRA Annual Symposia.

   I also lectured on the same subject on the BIRA Post Graduate course at Cardiff University in the late 1980s. In addition, I lectured to the Spanish Pharmaceutical Association in Madrid and at a Drug Information Association meeting in Washington in the late 1980s both on the subject of European regulatory experience.

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 have not been involved with or provided evidence to any inquiries or investigations.

5. ***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.***

    a. October 1979 - late 1986: As Regulatory Affairs Manager, my primary role was to obtain, maintain and renew the company's Product Licences, Clinical Trials Certificates and Exemption Certificates, Manufacturers and Wholesale Dealers Licences in the UK and Ireland. It was my role to liaise with the DHSS and NDAB regarding the applications made and any updates or changes to licences or renewals of licences to all Armour products; and

    b. Mid-1982: In addition to the responsibilities discussed above I took over the above role for all Revlon Health Care products. My staff during this period comprised a junior executive and one, later two secretaries.

6. ***To whom did you report within Armour? Who oversaw, and/or was accountable for, your work and that of the Regulatory Affairs department?***
On taking up my role as Regulatory Affairs Manager at Armour UK, I reported to Mr Peter Lloyd who was then Technical Affairs Manager. Mr Lloyd oversaw my work and we agreed tasks, objectives, resources and timings. I later reported to the Medical Director, which was Ron Mann, then Lawrence Shaw, and later Peter Harris.

7. ***Please describe the role, functions and responsibilities of Armour's Regulatory Affairs department and identify by name the other individuals who worked within the department during the 1970s and 1980s.***

I note that the question refers to the 1970s and 1980s but I can only comment on what happened from when I joined Armour UK in October 1979 until 1986 when I left.

The Regulatory Affairs Department was responsible for the role, functions and responsibilities which I described in my responses to questions 5 and 6 above.

When I arrived in October 1979, the Regulatory Affairs Department comprised:

- An Assistant Regulatory Manager Mr William Tarbit; and
- A secretary.

To the best of my knowledge, other individuals working in the Regulatory Affairs Department in the 1980s were Dr George Overend and Simon Hince.

8. ***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 US to get information about safety of products and how to respond" (see p. 7 of INQY1000158). Is that correct?***

As far as I recall, the Medical and Regulatory Affairs Departments certainly had important roles to play in liaising with Armour US to get information concerning safety of products and in some circumstances to discuss what action(s) may be appropriate. In general, people at Armour UK would liaise with their counterpart(s) at Armour US.

9. ***Please set out your understanding of the role and responsibilities of the Director of Clinical Sciences (Mr Robert Christie) and how they interacted with the work of the Regulatory Affairs department.***

   I cannot recall exactly what the role and responsibilities of the Director of Clinical Sciences were but there was significant interaction with the Regulatory and Medical Affairs Departments at Armour UK.

10. ***Please set out your understanding of the role and responsibilities of the Medical Director (Dr Harris) and how they interacted with the work of the Regulatory Affairs department.***

    The Medical Director, Dr Harris, interacted with the Regulatory Affairs Department about many aspects of regulatory work including both safety and efficacy. For example, he would review draft submissions for new products, licence variations (with a clinical / safety aspect), clinical trial exemptions ("CTX"), named patient requests and ADRs. He would need to approve of these before any submission to regulatory bodies. Dr Harris and his Medical Affairs Department covered all medical issues pertaining to all Armour UK products that arose by whatever source. His role, as I understand it, was to advise on and evaluate problems, as well as to decide on appropriate courses of actions in respect of all medical aspects of Armour UK products.

11. ***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). Was that part of the responsibility of the Regulatory Affairs department?

The Medical and Regulatory Affairs Departments I believe did their utmost to keep up to date with scientific and medical knowledge in so far as it was possible. Those Departments would update Mr Bishop.

12. ***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 employed by Armour UK from October 1979. From the formation of Revlon Healthcare UK Limited in 1982, I was employed by that company. In January 1986, when Rorer acquired the Revlon Healthcare business, I was employed by Rorer UK.

13. ***When you were working at Armour in the 1970s and early 1980s, what did you know and understand about the risks of infection associated with factor concentrates and in particular the risks of transmission of hepatitis (whether hepatitis B or Non A Non B hepatitis)? What if any training from Armour did you receive on these matters?***

Prior to joining Armour UK in October 1979, I had no experience with blood products. Upon joining the company, I did review the company's Data Sheets and became aware that blood products produced from human plasma carried a potential risk of transmitting viral hepatitis. As far as I remember, when I joined the company in October 1979 there was no formal training programme in place

on these matters and I received informal training through my exchanges with my colleagues from the Technical, Medical and Information Departments.

Section 2: Licensing, relationship with the Medicines Division of the 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 concentrate 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?***
    b. ***How were decisions taken within Armour as to what information to include the product licence applications?***
    c. ***What involvement did you have in decisions as to the information to be included in the product licence applications? How were decisions taken within Armour as to what information to include on product labels, inserts and data sheets?***
    d. ***What involvement did you have in decisions as to what information to include on product labels, inserts and data sheets?***

a. Upon joining Armour UK in October 1979, all then- marketed Armour blood products were already registered and approved in the UK, i.e. they were all covered by product licences. I therefore had no part in their product licence

applications and subsequent registration process with the DHSS for those blood products.

However, I provided copies of the final Data Sheet for Factorate HP to the DHSS in November 1979 prior to the launch of this product in the UK [ARMO0000046]. Thereafter it was my remit to provide product technical information e.g. specification modifications, updated stability data, processing changes and all aspects that comprised a variation or change to the product particulars including data sheet and package leaflet modifications to the DHSS and seek DHSS approval of the same. Renewal of product licences was also my responsibility.

b. The information to be included in the product licence applications would be set out in the Notes for Guidance issued by the DHSS. Decisions as to how to complete specific product licence applications would be taken by the Technical, Medical and Regulatory Departments.

c. My function was to ensure that the information to be included in product licence applications was in compliance with the relevant DHSS Notes for Guidance and compliant with the labelling and package insert requirements for medicinal products. Decisions regarding what information to include on product labels, package inserts and data sheets would be taken by the Technical, Medical and Regulatory Departments. Any specific requirement of the UK regulators would also have to be included.

d. I or one of my regulatory colleagues would have provided input as cited above.

15. ***ARMO0000046 is a letter from you to the Medicines Division of the DHSS dated 21 November 1979, in which you attach the finalised data sheet text for High Potency Factorate and note that "it is not our intention to include the text of this data sheet in the ABPI Compendium". Why did Armour decide not to include the information in the ABPI Compendium?***

High Potency Factorate was a product used by specialist doctors in Haemophilia Centres and hospitals and not by General Practitioners. The ABPI Data Sheet Compendium was, I believe, provided by the ABPI to every doctor and pharmacist in the country at that time. Although I cannot recall the detail precisely, I suspect that a more targeted circulation of the Factorate Data Sheet was decided upon by my Medical Department and Marketing colleagues given that few General Practitioners and Pharmacists would have cause to refer to it.

16. ***Please describe, in broad terms, the kinds of interactions that you or your colleagues in the Regulatory Affairs department had with the Medicines Division of the DHSS.***

Most of my and my Regulatory colleagues' interactions with the DHSS Medicines Division were in written form i.e. letters and official forms but also telephone calls and, more rarely, face to face meetings. Occasionally, I or one of my colleagues might meet a Medicines Division official at a general regulatory or scientific meeting organised by an outside body.

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

I cannot recall that I or any of my Regulatory Department colleagues had specific interactions with any members or the secretariat of the Committee on the Safety of Medicines. I note that ARMO0000152 is a letter from Mr Christie, who was then, Director of Clinical Sciences, and not a member of the Regulatory Affairs department.

18. ***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 your colleagues in the Regulatory Affairs department had with NIBSC. (See by way of example, MHRA0000048).***

It was my understanding that the National Institute for Biological Standards and Control ("NIBSC") received samples of all Armour UK imported Factorate batches for specification testing as it saw fit and a review of test results provided by the company. I do not know precisely what tests they routinely conducted.

I do not recollect I or any of my Regulatory colleagues having any direct interaction with NIBSC scientists. I have no knowledge of the contents of MHRA0000048 which I note does not appear to have been authored by or sent to me.

19. ***Please set out:***

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

b. your involvement and that of the Regulatory Affairs department in Armour's applications for a "clinical trial exemption" in relation to Factorate HT.

a. If I recall correctly given that the question addresses events that happened more than 40 years ago, if a company wanted to investigate a new or significantly modified existing medicinal product in patients, an application for a Clinical Trial Certificate ("CTC") or Clinical Trial Exemption Certificate ("CTX") had to be made to the DHSS Medicines Division. Such an application would require full disclosure of all the technical aspects of the product including details of the active ingredient source and control, method of manufacture, quality control procedures and analytical methods, specification and stability data (which would be updated periodically), any safety data, any available data in healthy volunteers or patients as appropriate and applicable. CTC applications would need to set out clearly the objective of the clinical study proposed and a study protocol. Approval of the DHSS would be needed before any trial could commence.

If a company wanted to do a study on an existing product which had a modified process it could apply to the DHSS Medicines Division cross referring data from the original approved licence or CTC and so would submit a 'shortened' or abbreviated version of a CTC application. Such an application was referred to as a CTX.

For Heat Treated Factorate, much of the data approved at the DHSS for Factorate was still applicable e.g. source plasma collection, much of the basic processing etc, but the application required revised processing information, specification and stability data to be generated. There was a need to test the product in limited numbers of patients to provide assurance that the performance (quality, safety and efficacy) of the product in treatment was not compromised. Hence, an application for a CTX for Heat Treated Factorate followed.

It should be noted that in early 1985, as information was developing regarding AIDS and how it was transmitted, it was my understanding that Haemophilia Centre Directors would only accept heat treated products. No heat treated Armour Factorate or, if I remember correctly, any other manufacturers' products were approved for sale in the UK (but they were licensed in the USA) in early 1985. Therefore, the only way to provide them with heat treated factor concentrate was by the named patient supply. For both named patient supply and CTX applications, the demand from clinicians for heat treated Factorate created urgency.

b. My and my department's involvement was to ensure appropriate data was collated and submitted to the DHSS and to respond to any questions or queries that may have arisen from the DHSS assessors concerned.

I do not recall any details regarding the CTX for monoclonal Factorate.

20. ***Please set out your recollection of the discussions with the investigator on CTX 0231/0070A to which you refer in ARMO0000144.***

I do not have any recollection of the discussions with the investigator mentioned in my letter to the DHSS dated 17 April 1984 or of the identity of the investigator. Any such discussion with the investigator would have been conducted by my colleagues from the Medical Affairs Department. My function was to interact with the regulatory authority to notify a change in the original protocol submitted (as is apparent in ARMO0000144) i.e. to ensure the authorities were kept current of our activities in this regard.

21. ***What involvement did you and/or the Regulatory Affairs department more generally have in considering or following up reports of adverse reactions (in particular hepatitis) that were made to Armour (see, e,g., ARMO0000321, ARMO0000784, ARMO0000788, ARMO0000789, ARMO0000801, which were copied to you)?***

The Regulatory Affairs Department was not involved in the follow-up and consideration of the reports of adverse reactions. That was the remit of my colleagues from Medical Affairs.

Section 3: AIDS transmission

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

I cannot recall exactly when I first became aware of the possibility of HIV transmission by blood products but I suspect sometime in 1983. My and my colleagues' reaction would have been one of concern.

23. ***On 25 May 1983, Dr L K Fowler, Medicines Division of the DHSS, wrote to you requesting your response regarding "precautions" taken and "reports" received from Armour and Revlon Health Care Group, in response to the risk of AIDS transmission from Factorate. (See: ARMO0000118; ARMO0000757; ARMO0000119).***

    a. ***Was the telephone call between you and Dr Fowler on 25 May 1983 (referred to in his letter) the first interaction you or, to your knowledge, Armour had with the DHSS regarding AIDS and the risks of transmission from Factor VIII concentrates?***

    b. ***Dr Rodell's communication (ARMO0000757) referred to having received no reports indicating that any haemophiliac receiving Factorate exclusively had developed AIDS and added that "those haemophiliacs identified and diagnosed as having AIDS have been transfused with a variety of products, including concentrates and cryoprecipitate, from multiple sources". Armour's response (ARMO0000119), signed by Mr Tarbit and copied to you, stated that "we are not aware of any reports of AIDS or AIDS like illness arising anywhere in the world from the use of Factorate specifically", but did not contain the additional statement (set out in italics above) from Dr Rodell's communication. Why was that additional information not included?***

c. Mr Tarbit's letter implied that further information would be provided to the DHSS by him or by you when it was received from the USA. Was any such further information provided to the DHSS by Mr Tarbit or you (or others within Armour)?

a. Given the passage of time, I cannot specifically recall whether the telephone call on 25 May 1983 between Dr Fowler of the DHSS and myself was the first interaction with the DHSS regarding the risk of AIDS transmission from Factorate products.

b. I was not the author of the letter sent to the DHSS on 8 June 1983 (ARMO0000119) and therefore I cannot speak to why the additional information was not included.

c. It is unknown to me, given the elapsed time, if the implied further information was provided to the DHSS.

24. ***What further communications or interactions did you, or Armour's Regulatory Affairs Department, have with Dr Fowler or others within the DHSS, during 1983 and 1984, in relation to the possibility of factor concentrates transmitting AIDS and/or any measures being taken to reduce that risk? (See: ARMO0000266, ARMO0000267, ARMO0000271 and ARMO0000287)***

Again, I cannot recall what further communication or interaction took place between Armour UK's Regulatory Department or myself and Dr Fowler at the DHSS during 1983 and 1984 in respect of the possibility of factor concentrates transmitting AIDS. It is possible that my Medical Affairs colleagues and the

Director of Clinical Sciences had communications with Dr Fowler during this period.

25. ***What involvement did you have in Armour's decision-making regarding the proposal to fund research support into AIDS at the Royal Free Hospital (ARMO0000238)?***

I had no involvement in Armour UK's decision-making regarding the proposal to fund research support into AIDS at the Royal Free Hospital. I do not ever recall meeting Dr Kernoff or colleagues as referred to in the 7 April 1983 letter, of which I was not the author (ARMO0000238).

26. ***You were copied into a memo dated 16 May 1985 from Mr Christie to Dr Harris, which referred to "strong indications that before heat treatment, a significant number of batches of our Factorate may have contained sufficient challenge of HTLV-III virus to induce at least seroconversion when administered to haemophiliac patients" and "the need for us to agree a consistent reply to such reports"(ARMO0000391).***

    a. ***When did you first become aware of "indications" that Factorate may have led to seroconversion?***
    b. ***Was a "consistent reply" to reports of such cases agreed and if so what was that reply?***

a. As indicated above I cannot recall when I first became aware of indications that Factorate may have led to seroconversions.

b. I do not have any recollection about whether such a reply was ever generated or agreed.

Section 4: Viral inactivation

27. ***On 10 January 1985, Richard Landaburu, Revlon Health Care Group, wrote to you regarding Dr Alfred Prince's 'Studies of AIDS related viral infectivity: Assay of HTLV-III in infected plasma derivatives (Factor VIII and Factor IX) following heat treatment' (ARMO0000343). Why was this information being sent to you?***

I do not know why this information was sent to me because I do not specifically recall this letter (ARMO0000343). I generally recall that from time to time Dr Landaburu would provide me with information that might allude to changes to registered products particulars.

28. ***Later in January 1985 Dr Prince provided the results of his first study to Armour (ARMO0000356); his letter, which he copied to you, stated that "Disappointingly ... we were unable to show a >5 log kill as had been hoped. The most that can be concluded from the study is that the combined effect of lyophilization and heating inactivated >2.5-3.0 logs".***

    a. ***What was your understanding, at the time, of the implications of this study for the efficacy of Armour's heat treatment process?***
    b. ***What if anything was done by you or your colleagues in the Regulatory Affairs Department in response to Dr Prince's first study?***

c. In an internal memorandum (ARMO0000361) to Chris Bishop and Claudia Schott dated 11 February 1985, which was not copied to you, Dr Rodell suggested that the experiment "should be considered to be preliminary in nature". Were you party to any discussions with Dr Rodell, Mr Bishop, or others within Armour or Revlon about Dr Prince's first study? If so please set out your recollection of those discussions.

a. My understanding was that the study was flawed and would need to be repeated and thus at that point in time it had no specific implication for the efficacy of Armour's heat treatment process.

b. I do not recall but I believe that neither myself nor my colleagues from the Regulatory Affairs Department would have taken further action in response to the study.

c. I have no recollection of being party to any discussions with Dr Rodell, Mr Bishop or others within Armour US or Armour UK or Revlon regarding Dr Prince's first study.

29. ***Dr Prince conducted further studies which he reported to Armour during the course of 1985. His findings (PRSE0004828) were that "pasteurisation at 60° in the dry state had only a modest process efficacy for inactivation of HTLV-III/LAV"***

a. Did you receive a copy of this further study or otherwise become aware of it?

b. Did you understand the implications of the results as being that Armour's heat treatment process might not be sufficiently robust to inactivate HTLV-III?

c. Were you party to any discussions with others within Armour or Revlon about this further study or its implications? If so please set out your recollection of those discussions.

d. Were you aware that Armour took steps to prevent Dr Prince from publishing his results (see CGRA0000512)?

e. Was there a concern within the Regulatory Affairs Department that Armour's viral inactivation process was not sufficient and if so what steps were taken by you or your colleagues in light of that concern?

a. I am not aware that I received or saw a copy of this further study by Dr Prince.

b. Please refer to my answer to question a. above. I note that Dr Prince concluded that: "*it should however be stressed that our findings do not necessarily indicate that presently available dry heat treated products are unsafe with respect to transmission of AIDS*" (page 6 of PRSE0004828).

c. I do not recall any discussions within Armour UK about Dr Prince's studies.

d. I note that I was not the author or the recipient of CGRA0000512 and confirm that I was not aware of the discussions mentioned therein. I do not recall that any steps were taken to prevent Dr Prince from publishing his results.

e. Any viral inactivation studies were conducted in the US where Factorate was developed. Although my colleagues from the Regulatory Affairs Department and I were not directly involved in such research, I recall that the early years of the AIDS epidemic were a time of great uncertainty. The data covering revised specifications and analytical methods etc would have been provided to Armour UK by colleagues in the US.

30. ***On 19 December 1984 you had attended a meeting at the DHSS with Dr Duncan (ARMO0000337), at which you provided Dr Duncan with a copy of the available data from Dr Evatt of the CDC regarding viral inactivation work. Did you provide Dr Duncan or her colleagues with copies of Dr Prince's data? If not, why not?***

As reflected in ARMO0000337, I discussed Dr Prince's data with Dr Duncan at the 19 December 1984 meeting. I was unable to provide a copy of Dr Prince's report at the meeting because the study had not yet been completed by him.

Section 5: Batch Y69402

31. ***Please set out how and when you became aware of the possible contamination of Batch Y69402 and the steps that were taken by you, or your colleagues, in response to that information. You may wish to consider ARMO0000172 (letter from you to the Medicines Division dated 31 May 1985), ARMO0000417 (memo from you to Dr Rodell dated 15 July 1985) and ARMO0000394 (letter from Mr Christie dated 4 June 1985 and copied to you); ARMO0000398 (letter of 4 June 1985 from Mr Christie).***

I am not certain when I became aware that, as set forth in ARMO0000172, a donor whose plasma was incorporated into pools from which Factorate was prepared, had developed AIDS. However, it would have been shortly before my phone call to the DHSS on 9 May 1985 and my meeting with Dr Duncan and Mr Hewlett the following day. The phone call and next day meeting would indicate that Armour UK regarded the matter as serious and urgent. I and my colleagues obtained the available information regarding batch distribution and subsequent fate of this batch as a matter of urgency. My letter to Mr Woodhead of 31 May 1985 (ARMO0000172) details our findings and what actions we had taken.

32. ***According to a letter from the Medicines Division to you dated 3 October 1985 (ARMO0000179), in response to a letter which you wrote on 3 June 1985 (ARMO0000173) you agreed to confirm in writing that the follow-up of patients who received batch Y69402 would be maintained over several years.***

    a. ***Did you agree with the DHSS that the follow-up of these patients would be maintained over several years (you may wish to consider also ARMO0000178)?***
    b. ***What did you mean in your memo of 5 June 1985 (ARMO0000401) that you may have "fended off" the question of "long-term" follow-up on the basis of discussions that you and Mr Christie had had?***
    c. ***What did you envisage this follow-up would entail? Who would undertake the follow-up, what kind of information would be***

provided to Armour about the patients and what kind of information would Armour provide to the DHSS?

d. Did you or your colleagues take any steps to ensure that the patients in question were aware of an intention to follow them up over several years?

e. Were these patients in fact followed-up and if so how and for how long?

a. My letter to Mr Woodhead (ARMO0000173), dated 5 June 1985, said my Medical Department colleagues would endeavour to follow patients for two years or so. Any such follow-up would need to be done in conjunction with and with the cooperation of the relevant Haemophilia Centres Directors concerned. I note that it was Mr Bayntun from the DHSS in his letter to me dated 3 October 1985 who referred to a follow-up of "*several years*" (ARMO0000179). I do not recall any further discussions with the DHSS regarding the follow-up of those patients.

b. I do not recall what I meant by 'fended off' at the time (ARMO0000401) and only recall that I addressed this point with the DHSS by indicating to them that follow up would be two years or so (ARMO0000173).

c. I cannot speak to what the follow-up would entail because any follow-up would be undertaken by my Medical Department colleagues. The Regulatory Affairs Department would not participate in the follow-up. My colleagues from the Medical Affairs Department would correspond with the DHSS.

d. See my response to question c. above.

e. See my response to question c. above and my letter to the DHSS dated 3 October 1985 [ARMO0000178].

Section 6: Seroconversion from Factorate HT

33. ***Please describe:***

a. How and when you first learnt of possible HTLV-III seroconversion following the use of Factorate HT.

b. What action was taken (with your involvement or to your knowledge) in response to reports of HTLV-III seroconversion following the use of Factorate HT.

c. Your role and the role of the Regulatory Affairs department in considering and responding to this issue.

d. The extent to which you/the Regulatory Affairs department were kept fully informed of developments relating to this issue.

e. The role of others within Armour in considering and responding to this issue.

f. Your involvement and that of the Regulatory Affairs department in the decision of Armour to surrender its product licences for its Factorate concentrates.

a. I cannot recall when I first learned of possible seroconversion following the use of Factorate.

b. The matter came under the auspices of the Medical Department. These colleagues dealt directly with the Haemophilia Centre Directors and their staff and the DHSS Medical staff to follow up cases of seroconversion and associated actions. You will note that I am not copied on 14 of the 20 documents you cite in this section of your request for a written statement by me. I also note that several of the documents postdate my involvement with Armour UK.

c. As stated above, the Medical staff dealt with all matters related to this issue. My recollection is that the Regulatory Affairs Department was not involved.

d. I was not copied on most of the documents referred to above, as indicated in my response to question a. Further, my tenure with Armour UK's Regulatory Affairs terminated in 1986, so I am unable to comment on the communication that took place thereafter.

e. As stated above, the Medical Department dealt with all matters related to this issue and Regulatory Affairs would have no direct contact with Haemophilia Centre Directors or their staff. Given the specialised medical nature of the problem it was appropriate that my Medical Department colleagues dealt directly with the DHSS Medical staff.

f. I had no involvement with the decision to surrender the UK product licences for Factorate products. I had moved to my new position with Rorer some months before.

34. ***Please add any further comment that you wish to provide about matters of relevance to the Inquiry's Terms of Reference.***

Earlier this year, following the death of my wife at the end of March, the Inquiry kindly granted me an extension of time to respond to its request for a written statement under Rule 9. I was extremely grateful for the additional time granted.

I have first-hand experience with dealing with the decline of a loved one facing a serious and terminal liver illness and how this affects a family and loved ones. My wife had an autoimmune disease whereby her own immune system attacked her liver. The condition was diagnosed some 15 years ago and was well controlled (under the Kings College Hospital, London hepatology team) with relevant drugs and frequent check-ups. There is no cure. My heart therefore goes out to all those haemophiliac patients who have contracted AIDS and hepatitis, and their families.

The advent of Covid and in her case more particularly Covid immunisation, we believe stimulated her immune system and her condition worsened quite quickly with a number of hospitalisations. Her liver failure over the last 12 to 18 months of her life was, to say the least, very distressing not only for her but equally for myself and our family. I have therefore witnessed at first hand the appalling suffering serious medical conditions bring.

Looking at the much more recent Covid situation by way of comparison, I ask myself what would the case be for my wife if the Government had locked down earlier, locked down for longer, closed the airports and seaports early on.

However, they made their decisions based on the 'best' up to date advice they received.

I believe at Armour we did much the same and acted on what we believed was the best medical and technical advice we could get at the time. We did our level best to deal with the situation as it emerged. The virus was not identified until 1983. There were no tests for HTLV III in blood until 1985 and many reports in the earlier days were, if I recall correctly, conflicting and difficult to interpret.

My deepest sympathies go out to all those haemophiliac patients and their families.

Statement of Truth

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

Signed GRO-C

Dated 2 September 2022