Witness Name: Professor Charles Richard Morris Hay
Statement No.: WITN3289187
Exhibits: WITN3289188-189
Dated: 2 June 2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR CHARLES RICHARD MORRIS HAY

ON BEHALF OF THE UK HAEMOPHILIA CENTRE DOCTORS' ORGANISATION

I provide this statement on behalf of the UK Haemophilia Centre Doctors' Organisation (UKHCDO) and the National Haemophilia Database (NHD) in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 November 2022 to respond to a Rule 13 notification dated 1 June 2021 in relation to various criticisms of UKHCDO and the NHD from Witness W1210 and Witness W2368.

I provide a response to this Rule 9 request, on behalf of UKHCDO, in my capacity as Director of the National Haemophilia Database since 2002.

I, Professor Charles Richard Morris Hay, will say as follows: -

Section 1: Introduction

1. I am Charles Richard Morris Hay, Professor of Haemostasis and Thrombosis. My qualifications are MBChB MD FRCP FRCPath. I have been a Consultant Haematologist at Manchester Royal Infirmary since December 1993 and Director of the Manchester Adults Haemophilia Comprehensive Care Centre since December 1993.

2. I was Senior Lecturer in Haematology at Liverpool University and Director of the Liverpool Haemophilia Centre, Royal Liverpool Hospital 1987-1994.

3. I have been a member of the United Kingdom Haemophilia Centre Directors (later Doctors) Organisation Regional Committee and then Advisory Committee since 1987 and was Vice Chairman UKHCDO 1997 to 2005 and Chairman UKHCDO 2005-11. I have been Director of the National Haemophilia Database since 2002.

4. I have already provided my full Curriculum Vitae to the Inquiry [**WITN3289172**].

General comments:

5. I believe that most of the questions (as opposed to criticisms) raised by these two witnesses have been dealt with elsewhere for which reason I will not seek to explore those issues further in this response. I have therefore focused on the criticisms highlighted by the Inquiry in their Rule 13 notification and in the "*We accuse*" document submitted as an exhibit to the statement of witness W2368 [**WITN2368023**].

6. I set out below a brief historical background of UKHCDO and the National Haemophilia Database as an aid to understanding my response to the criticisms.

Section 2: Historical Background

7. UKHCDO came into existence in 1968, and in 1969 the National Haemophilia Database became operational when UKHCDO initiated the first data collection exercise.

8. Since that time, UKHCDO has existed as a membership organisation, exchanging information amongst its members and with haemophilia centres and publishing clinical guidelines. It has advised the Department of Health (DH) and/or NHS England (NHSE), from time to time, when requested, but there have been long periods of time when there was very limited dialogue between DH and UKHCDO.

9. Clinical guidelines are consensus documents, updated as the state of knowledge advances. UKHCDO guidelines are advisory only and may be adopted partly or in full or not at all, at the individual clinician's discretion. Similarly, UKHCDO may make recommendations in terms of treatment, but it cannot and did not direct clinicians as to which product to use as this was a matter for the discretion of individual clinicians. Moreover, until much more recently there was no central purchasing of blood or blood products and therefore UKHCDO could not dictate purchasing decisions of individual haemophilia centres.

10. UKHCDO did not make DH policy but regarded itself as an organisation advocating on behalf of people with bleeding disorders. UKHCDO advice was not always sought by DH and when provided was not always adopted. Examples of this include the following:

    (a) In 1996 UKHCDO published guidance [**WITN3289188**] recommending the introduction of recombinant factor VIII for all people with haemophilia A. This had not been solicited by DH, and the recommendation was not adopted in full by DH for a further 8 years.

    (b) UKHCDO advised DH orally at a meeting at Skipton House between David Gutowski for DH, myself (then vice Chair of UKHCDO) and Professor Frank Hill (then Chairman of UKHCDO) in advance of the inception of the Skipton Fund, that Skipton payments should be extended to widows whose husbands had died prior to the start of the scheme and warned that failure to do so would be unjust and would cause distress. The details of the scheme had just been presented to us for the first time and it was made clear that those details could or would not be changed and so our suggestions were not incorporated within the Scheme.

11. Although the minutes of UKHCDO meetings comment on discussions about clinical trials that some members may have been involved in as individuals, and which UKHCDO took a keen interest in, it would not be correct to conclude that these trials were conducted by UKHCDO. UKHCDO has never conducted interventional research and has only conducted observational or epidemiological research using the data routinely collected by NHD (or provided to it by others). Examples of interventional research would be clinical trials in which the person with a bleeding disorder was treated with a new or experimental treatment to establish the safety and efficacy of that agent or intervention. Non-interventional or observational research involves no change in treatment but merely observation of the natural history and outcome of the treatment of that condition as prescribed by the person's treating clinician.

12. The UKHCDO National Haemophilia Database was set up with an initial aim to establish the number of people affected by haemophilia and their clotting factor requirements and thereby to facilitate healthcare planning with the objective, amongst others, of achieving national self-sufficiency in the supply of blood and blood products. It was subsequently used to undertake epidemiological (non-interventional) research

based on collection of data about patients and their treatment. For many years, NHD was run without any external funding and was limited in its scope. It had one full time and one part time member of staff paid for by Oxford Health Authority. As haemophilia centres were not staffed to collect data and were not computerised, there were significant limitations on the amount of data that could be collected.

13. UKHCDO became a Charity in 1994. It then became necessary to form an associated limited company (UKHCDO Ltd), as the trading arm of the charity. UKHCDO Ltd took over the financial management of the NHD in 2006, after its move from Oxford to Manchester.

14. In 2002 the NHD moved to Manchester and from about this time the NHD increased its dialogue with and reporting to DH and subsequently NHSE and NHS Scotland and Wales. It has increased and formalised its pharmacovigilance function. The NHD has also established a long-standing dialogue with the European Medicines Agency (EMA) to discuss the role of databases in post-marketing pharmacovigilance. The UKHCDO/NHD has now conducted several post-marketing safety and efficacy observational studies on behalf of EMA and the manufacturers. NHD reports drug-induced adverse events to the manufacturers to enable them to satisfy their statutory obligation to investigate such events and report them to the regulators.

15. The NHD is accountable to the following bodies: the Information Commissioner, the Manchester Royal Infirmary Caldicott Guardian, NHS England (Scotland and Wales), the membership of UKHCDO and its committees, (particularly the Data Management Working Party (DMWP) and the Data Analysis Group (DAG)) as well as the Executive Committee and the board of UKHCDO Ltd. The DMWP is the governing body of the database. It includes the UKHCDO Executive, chairs of the working parties, a representative each from the Haemophilia Nurses Association, the Chartered Physiotherapists Association, the commissioners, the Haemophilia Society and representatives of people with a bleeding disorder. The DAG reviews and adjudicates on all requests to the NHD for data analysis and on all reports and publications. It was established in 2017, meets monthly, and has three representatives of people with a bleeding disorder and chairs from some UKHCDO working parties.

Section 3: Response to Inquiry Witness W1210

16. Witness W1210 has made a number of criticisms. The Inquiry has highlighted criticisms made in paragraphs 84 – 93 of the witness statement of witness W1210 [**WITN1210008**] as follows:

    The relevant section can be found at paragraphs 84-93 of witness W1210's statement. At paragraph 84 the witness states: "*I have conducted research to try and obtain data relating to the number of those infected by factor products that have died as a result of that infection. My requests for information and assistance have been refused or unhelpfully dealt with by the DHSC, UKHCDO, NHS England and others public bodies likely to hold such data*"

17. UKHCDO has done its best to address the data requests from witness W1210 in an open manner and can provide the email correspondence with the witness if that would assist the Inquiry. If we have not been able to provide full answers to his enquiries, it is because we are *unable* to answer and/or were in the process of collating information about these issues on behalf of the Inquiry. One of witness W1210's requests related to information concerning hepatitis C and HIV. UKHCDO had reservations about releasing this information into the public domain at that time, as it was likely to change with further data checking and as additional information was received from haemophilia centres. UKHCDO was particularly conscious that this information was being collated to assist the Inquiry, and we informed the witness of this at the time. An accurate figure for the number of people with bleeding disorders infected with hepatitis C was and remains unknown, as for a number of reasons the NHD does not hold comprehensive records. This has been explored in the evidence heard by the Inquiry.

    The witness goes on to discuss his "*deep concerns about the UKHCDO*" relating to the legality of its practices, "*particularly those in connection with data collection and sharing*". In these paragraphs the witness describes his concerns relating to funding of the UKHCDO by the Department of Health and the collection, processing and sharing of patient data without consent. The witness explains that the position on these issues has been misstated.

18. Two issues arise from this passage: the legality of data collection and sharing; and funding.

The legality of data collection and sharing.

19. I addressed the question of consent to data collection and sharing in paragraph 129 of my witness statement [**WITN3289039**] (pages 148-154) and in my oral evidence on 5 November 2020 [**INQY1000073**] (page 56 onwards). In summary:

    (a) Plainly, when the NHD started in 1969 the approach to data collection was very different from the current position. The Data Protection Act of 1998 (DPA 1998) changed the approach to data collection significantly. Prior to 1998 I believe that the view taken was that as UKHCDO/NHD were not conducting interventional research there was no need to seek specific consent to collect and retain data. For the avoidance of doubt, by interventional research I mean clinical trials involving any changes in treatment or procedures to test safety and efficacy.

    (b) In about 2000 the consensus view was reached within UKHCDO that people needed to be informed that data concerning them was being collected and held, and also the uses to which their data was being put and their rights under the DPA 1998.

    (c) UKHCDO/NHD received advice from the Information Commissioners Office (ICO) that consent to hold the data would be required if it was being shared with third parties or used for research, but that it was not required for reporting to the NHS.

    (d) Following some discussion within UKHCDO and with the ICO and in line with other disease registries, we opted for a system of consent whereby people were informed that information about them was held by the NHD and they could opt out. This was explained through leaflets provided to people with bleeding disorders or their carers. The information leaflets were revised at regular intervals. An example of the patient information leaflet is to be found at [**WITN3289088**].

    (e) In 2019, the evolving landscape in research regulation, implementation of the Data Protection Act 2018 (GDPR), and interactions with NHS Digital, led the UKHCDO to apply to the NHS Health Research Authority (NHSRA) for ethical approval for the UK National Haemophilia Research Registry (i.e. the National Haemophilia Database as used for the purpose of observational research). Approval for the Research Registry was received in April 2019. UKHCDO then began the process of seeking written consent from people registered with the

NHD for their data to be used for research (i.e. for their data to be included in the Research Registry). People registered with the NHD were given an age-appropriate information sheet and an opportunity to discuss any questions with their haemophilia centre. A consent form was signed and uploaded to the NHD if they agreed. By March 2020 (when progress was interrupted by the Covid-19 pandemic) the NHD had obtained written consent from more than 2000 individuals.

(f) More recently, NHD requested a review and were advised by the NHSRA Confidentiality Advisory Group (CAG) that they had reconsidered earlier advice to large disease databases in general. The NHSRA CAG realised that it was impractical to obtain consent from all members of such a large cohort of people, some of whom had been lost to follow up or who had died. This rendered the NHD eligible for exemption from seeking written consent to hold and use data in accordance with s.251 of the National Health Service Act 2006. Two applications for s.251 exemption were therefore made, one in relation to the NHS purposes for which the data is used and, separately, one for observational and epidemiological research purposes for the data. These were granted in September 2020 by the Secretary of State for Health. These exemptions are reviewed and renewed annually and were renewed most recently in September 2022.

Funding

20. I addressed the question of the funding of UKHCDO and the NHD in my witness statements at paragraphs 124.20 [**WITN3289039**, page 139] and 128 [**WITN3289039**, page 147] and in my oral evidence on 5 November 2020 [**INQY1000073**] (page 133-4). In summary:

    (a) UKHCDO is a membership organisation and has at times been funded by way of annual membership fees of £20 per member (for a few years from 1992 following the establishment of the constitution, but no longer charged). The running of the NHD was reliant upon the profits generated by the UKHCDO's annual general meeting (AGM) and membership fee. The AGM generated profits from income derived from the exhibition and (in common with other professional bodies) funding from pharmaceutical companies to assist with costs of organising and staging the AGM.

(b) Until its move to Manchester in 2002 the NHD was indirectly funded by Oxford Health Authority in that they paid the salary of an administrative assistant and a part time secretary. This arrangement was withdrawn by Oxford Health Authority when the administrative assistant retired in 2002, forcing UKHCDO to review arrangements for the database. After the move to Manchester the NHD was initially unfunded, and it was necessary to obtain short-term funding from all the pharmaceutical companies (by way of unrestricted grants) to re-establish the database on a stronger foundation, to bring the data up to date and to produce data that would be helpful for healthcare planning and that would attract central funding from DH and subsequently NHS England and other commissioners.

(c) In the past the DH has provided limited project-linked funding to support UKHCDO's involvement in national procurement and for specific projects. More recently, from 2007, the NHD has received regular funding from the commissioning bodies, NHS England, Scotland and Wales. The Inquiry has seen an example of the contract between UKHCDO Ltd and NHS England [**JEVA0000033**].

21. NHD also receives funding in the form of unrestricted grants from pharmaceutical companies to undertake observational research investigating the safety and efficacy of their products and the epidemiology and natural history of bleeding disorders and the outcome of treatment, and for software development. Unrestricted grants are unconditional grants given to undertake research over which the grant-giver has no control. UKHCDO characteristically reserves intellectual property rights, and both analysis and publication are conducted independently of the grant-giver. Some of these projects take the form of post marketing surveillance. Pharmacovigilance is an important aspect of the work of the database that has increased in scope and rigor over time.

Moreover, the witness explains why he believes "*the entire nature and setup surrounding the UKHCDO, its requirement to collect data on behalf of the Department of Health and the fact it is a private organisation is simply wrong*".

22. I am aware that in his oral evidence witness W1210 said that NHD had responded to him that "*We're a private body, we're not subject to FOI*" [INQY1000128] (page 141). I do not believe that UKHCDO/NHD responded to witness W1210 in these terms, but I am aware that it was explained to him that as a charity UKHCDO was exempt from

FOI requests. That said, UKHCDO generally did not invoke the exemption and provided him with what information it could.

23. UKHCDO disagrees with witness W1210's characterisation of UKHCDO as set out in the passage above.

24. UKHCDO suggests that clinicians involved in the care of people with bleeding disorders on a day-to-day basis and representatives of people with bleeding disorders are best placed to decide what questions should be addressed and therefore what data should be collected and how it should be interpreted and presented.

25. UKHCDO is of the view that it is very unlikely that information about people with bleeding disorders would have been collected over a prolonged period of time, in the way that the UKHCDO has done, if the NHD had been managed by the NHS or DH. Had UKHCDO not collected information and stored it in the NHD, these longitudinal data would almost certainly not have been collected at all and would not have been available to people with bleeding disorders and their relatives or to the Inquiry. So far as I am aware the longitudinal data held by the NHD is amongst the most comprehensive and reliable of any comparable database across the world. In some patients, the NHD record is the only historical record now available as hospital medical records have been destroyed in line with medical records policy.

26. UKHCDO also believes that there are advantages of UKHCDO and NHD being independent of the NHS and DH. UKHCDO's independence from the NHS allows the organisation to better advocate for people with bleeding disorders and ensures that it has the freedom to challenge or criticise decisions made by DH or NHSE.

27. The characterisation of UKHCDO and UKHCDO Ltd as "*a private organisation*" needs to be clarified. UKHCDO has been an association of NHS employees since its inception and a Registered Charity since 1994. Prior to 2002, the database operation was undertaken at the Churchill Hospital in Oxford. In 2002, UKHCDO decided to move the database to Manchester, where it was thought it would be better resourced, have better technical support and be able to develop. It was physically based at Manchester University NHS Foundation Trust (MFT), previously Central Manchester University Hospitals NHS Foundation Trust, and was initially staffed by NHS personnel. As the demands expanded, so did the staffing, office space and funding requirements. Since charities are not allowed to trade, and in common with most medical charities,

UKHCDO Ltd was formed as the commercial arm of the charity in 2006 to run the AGM and to manage and administer the NHD. MFT is the sponsor for research undertaken by the NHD, which is a supportive role, but MFT is not responsible for controlling the data and no payment is received from MFT. NHD has an agreement with MFT's Caldicott Guardian that they inspect the NHD at regular intervals to ensure that it is complying with data protection legislation and adhering to the principle of fair data handling (Caldicott Principles). This is an information governance inspection that is provided to all registered health and social care organisations that have similar agreements with MFT's Caldicott Guardian. MFT do not have access to, or any role in controlling or manipulating, the data within the NHD. MFT is not a data controller. The NHS also hosts the NHD fileservers, and all data communications are encrypted and transmitted within the NHS N3 network. The database is supervised by the Data Management Working Party of UKHCDO, a committee which has included representatives of people with bleeding disorders and a representative of the Haemophilia Society for at least the past 25 years.

28. The position of the NHD as a database managed by a learned society providing data independently to the NHS is not unusual. I list, below, some examples of the many disease databases and registries wholly or part-funded by NHSE but managed by learned societies or charities (and for which NHSE is therefore not the data controller):-

    - British Society for Blood and Marrow Transplant and Cellular Therapy Registry – custodian British Society for Blood and Marrow Transplant and Cellular Therapy

    - Cleft Research and Audit Network (CRANE) – custodian Royal College of Physicians

    - National Haemophilia Database (NHD) – custodian UK Haemophilia Centre's Doctors Organisation

    - National Intestinal Failure Registry – custodian British Association of Parenteral and Enteral Nutrition

    - UK Cystic Fibrosis Registry – custodian UK Cystic Fibrosis Trust

Further concerns are raised about the UKHCDO needing to be more transparent with patients and relatives, discussing patient data entries held by the UKHCDO which refer to "*Dr Craske's Research Work*", an entry that is "*confusing to patients and families*".

29. UKHCDO has made every effort to be as open as possible with people with bleeding disorders and their relatives and with the Inquiry about information held on NHD. People have access to the information that NHD holds about them as individuals or about their deceased relatives. Since 2003, NHD has supplied 818 individual data subject requests ("data extracts") for people with bleeding disorders and their relatives (correct at the time of writing), and has entered into sometimes lengthy correspondence with some individuals to help them understand the data provided and its limitations. The data extracts are sent out with a letter explaining what the extract means, accompanied in some complex cases by a further letter from me explaining a specific point. The extent of these extracts is extremely variable because the NHD is dependent on the haemophilia centres to submit data and in some cases, usually with mild bleeding disorders managed outside a haemophilia centre, NHD may hold no data at all. Since the digitisation of the paper archive (described below), further records have been sent to a number of individuals who had made data subject requests and received disclosure of available data prior to that digitisation.

30. Data generally available includes the electronic record and electronic and handwritten reports from which this record is derived. All records have been electronic since about 2001/2. Since the start of the Inquiry, the data from the paper archive have been digitised, including handwritten reports. This allowed the NHD to answer the Rule 9 statistical request made by the Inquiry but also permits a rapid response to request for data extracts. Data extracts are checked before being sent out to ensure that all data points concerning individuals other than the subject of the request are redacted.

31. UKHCDO/NHD try to be as helpful and as sympathetic as possible when dealing with data requests but can only supply the data that NHD holds, the extent of which varies considerably from one individual to another.

32. UKHCDO has developed a website (www.UKHCDO.org) which has evolved over the years but has always been open to the general public. This gives access to a contact list for all haemophilia centres, UKHCDO Clinical Guidelines, UKHCDO activities and working parties and the mission statement of UKHCDO. There is also a copy of the

patient information leaflets, which can be downloaded but which are also distributed in hard copy through haemophilia centres. A leaflet gives information on the database, its activities, the type of data collected and use to which the data is put. The funding of the database is also described, as are patient rights under the Data Protection Act. Contact details are provided for enquiries and subject access requests. The data points that are collected are separately listed on the website in full and are updated at intervals so that the details of the data collected are available for all to see.

33. People with bleeding disorders and representatives of the Haemophilia Society have had seats on the managing committee of the NHD, the DMWP, for the past 25 years at least. In 2017, UKHCDO established a Data Analysis Group (DAG) which has included representation from people with bleeding disorders since its inception. Currently, there are two people with bleeding disorders on the DAG, as well as a representative of the Haemophilia Society who has a bleeding disorder. The DAG is the committee that oversees the usage, analysis, interpretation and release of the data held by the NHD.

34. UKHCDO agrees that references to data held on the NHD as being attributed to *"Dr John Craske's Research work"* are likely to be confusing and concerning for people who are unaware of his work and for people who have not given consent for involvement in this research. Dr John Craske was a consultant virologist originally based in Poole, Dorset, and the local virologist who investigated a hepatitis outbreak at Bournemouth Haemophilia Centre. Subsequently, he worked in the Public Health Laboratory Service (PHLS) at Withington Hospital, Manchester. He worked with UKHCDO in the 1970s and 1980s to investigate the risk of transmission of hepatitis from blood products and subsequently the risk of HIV transmission. He chaired the UKHCDO Hepatitis Working Party until 1989 when Professor Preston assumed this role. He did not conduct interventional research or clinical trials on behalf of UKHCDO. His research, conducted in his capacity as Chair of the Hepatitis Working Party involved retrospective surveys and collating treatment data and liver function tests and virological tests for hepatitis B. Episodes of jaundice were also reported until the 1980s. My understanding is that those involved in this research at that time did not think that informed consent was necessary for retrospective surveys of routinely collected data such as this. The surveys are described extensively in the minutes of the Hepatitis Working Party, the AGM and Regional and Advisory Committees, all of which have been shared with the Inquiry. However, since only limited conclusions could be drawn from the basic data that was collected, very little of Dr Craske's UKHCDO research

was published. Dr Craske was also involved in interventional studies conducted independently of UKHCDO and for which full informed consent was obtained, as described in the methods section of the published report. Confusion may have arisen as to what was and was not done by Dr Craske under the banner of the UKHCDO. This is illustrated by two of Dr Craske's publications:-

35. Craske J, Kirk P, Cohen B and Vandervelde EM. Commercial factor VIII associated hepatitis 1974-75 in the United Kingdom: a retrospective survey. J Hyg. 1978, 80, 327-336. **[HSOC0000009]**

    This is the only publication which relates to Dr Craske's surveys conducted collaboratively with UKHCDO and the NHD. This was a retrospective survey of 371 people from 24 haemophilia centres who had been transfused with the same commercial factor VIII product (Hyland) thought to have been responsible for the hepatitis outbreak at Bournemouth Haemophilia Centre. New cases of hepatitis associated with this brand of factor concentrate were reported through the NHD. This was a non-interventional retrospective observational survey, which at that time was not thought by the people undertaking this work to require individual patient consent.

36. Fletcher ML, Trowell JM, Craske J, Pavier K, Rizza CR. Non-A non-B hepatitis after transfusion of factor VIII in infrequently treated patients. BMJ 1983, 287; 1754-1757. [**CBLA0001772**]

    This was an interventional clinical trial, conducted in Oxford, for which the subjects who participated gave full informed consent according to the methods section in the final, published, report. Although Dr Craske chaired the Hepatitis Working Party and Dr Rizza directed the NHD at the time, this trial was conducted independently of UKHCDO, its committees and database. There was of course enormous interest in the results of this trial, and it was discussed in UKHCDO meetings.

37. It should also be emphasised that all NHD's reports to outside bodies are of aggregated anonymised data. Indeed, mechanisms within the database ensure that the analysts never see patient identifiers because the data is pseudonymised before it is given to them.

At paragraphs 110-111, the witness describes that he believes many individuals were tested without their or their families' consent. He states: *"It is clear from evidence provided to me by those infected and affected that many patients were*

tested for HIV in 1984 and early 1985 without their knowledge or consent and that such non-consensual testing, on a mass scale, occurred in a joint collaboration between the UKHCDO, Dr Tedder and the Middlesex hospital. I am aware that the UKHCDO has also contended to the press that The Haemophilia Society were a party to this non-consensual testing."

38. UKHCDO agrees with witness W1210 that when HIV testing first became available in late 1984 and early 1985 many people were tested for HTLV-III (HIV), often from stored plasma samples, without pre-test counselling or specific consent being sought. UKHCDO cannot comment on whether the Haemophilia Society were aware of or involved in this practice. At this time there was no UKHCDO policy or guidance regarding pre-test counselling or consent for HIV testing. Decisions relating to pre-test information and consent were therefore made at the discretion of local haemophilia centre consultants. The concept of pre-test counselling and consent for HIV testing evolved as the full implications of a positive test result became clearer in 1986/7, and the General Medical Council first issued guidance recommending pre-test counselling and consent for HIV testing in May 1988.

39. On 14 December 1984, the UKHCDO AIDS Advisory document [**HCDO0000270_007**] recommended that people with bleeding disorders should be tested for HTLV-III and advised members that testing was available through Dr Tedder at the Middlesex Hospital and Dr Mortimer at The Central Public Health Laboratory Service, Colindale. The test was initially unreliable, and the implications of a positive result were not clear. Reflecting this uncertainty, the UKHCDO AIDS Advisory Document recommended that positive tests should be repeated. UKHCDO did not formulate a policy on pre-test counselling at that time although this AIDS advisory document did recommend that people should be informed of the result of the test.

Section 4: Response to Inquiry Witness W2368

40. The criticism has been made by a witness with Inquiry reference number W2368 in relation to her involvement in campaigning on haemophilia and contaminated blood.

41. At paragraph 12 of witness W2368's statement, reference is made to a document titled the ***'Tainted Blood Accusations Document'***. This document is an exhibit to her statement [**WITN2368023**]. The exhibit sets out numerous comments which are critical

of UKHCDO. The critical accusations are reproduced below in italics, as are our responses: -

Page 3 line 3**: "***We accuse Consultant Physicians, the HCDO and the PHLS of DELIBERATELY AIMING INFECTIVITY TRIALS at children and infrequently treated patients instead of always using expensive chimpanzees, thus nullifying the Physicians' protection under the rules of "Life-support therapy" since the majority of the patients involved in such trials were often NOT severe haemophiliacs with a life-threatening diagnosis."*

42. UKHCDO conducted no interventional clinical trials and had no influence over whether manufacturers used chimpanzees to screen batches of concentrate for non-A, non-B hepatitis.

Page 3: ***"***We accuse the PHLS, the Haemophilia Reference Centre Directors (HCDO) and the Department of Health of DELIBERATELY WITHHOLDING TEST STATUS RESULTS and we accuse the Department of Health and the NBTS of PROCRASTINATING TO FORESTALL the pressure to more widely release the early HTLV-III (HIV) test within the UK, leading to the avoidable cross-infection with HIV of the spouses and unborn children of persons with haemophilia. This inaction, tantamount to murder, caused the deaths of infants and family members."

43. UKHCDO was not involved in clinical management of patients. However, the UKHCDO position on informing people of their test results was very clear and set out in the 14 December 1984 AIDS Advisory Document [**HCDO0000270_007**]. Despite the uncertainties surrounding the interpretation of the early HTLV-III tests, it was advised that tested people should be informed of their results.

Page 9, lines 8, 13 and 17**. "***In the minutes of the 13th meeting of the UKHCD, we then read that there was to be a vaccine for hepatitis B available in the UK by September 1982. The license was granted in May '82 and a trial was to be concluded at Oxford involving haemophilia A patients. We believe that this trial of the hepatitis B vaccine was unethical. A direct test for the presence of Hepatitis B surface antigen had been in existence since 1968. The Medical Profession already knew that haemophilia A patients would mostly have possessed antibodies to hepatitis B yet we find

physicians conducting research on haemophilia A patients. We question whether any of the recipients were previously untreated patients."

44. I believe that the relevant document is to be found at [**CBLA0001619**]

45. Although this trial was discussed in a UKHCDO meeting, it was not conducted by UKHCDO. The trial was of interest to the membership because it aimed to demonstrate whether the subcutaneous administration of the vaccine, with minimal bleeding risk, was as effective as intramuscular injections, which were recommended by the manufacturer but which had a higher risk of bleeding in people with bleeding disorders.

46. The trial is described in a PHLS document dated 11 September 1984 [**CBLA0001884_006**]. This makes it clear that patients had been tested for hepatitis B surface antigens prior to immunisation and found to be negative.

Page 10: Conducting Unethical Infectivity Trials: *"In a letter from BPL to Haemophilia Centre Directors in October 1985, it is obvious that infectivity tests were being planned that year. The letter further states that clinical trials at specified Haemophilia Centres were in progress in order to gain evidence of the reduction or elimination of viral transmission, in particular Non A Non B hepatitis. Doctors with suitable patients under their care were encouraged to involve them in these clinical trials."*

47. The letter that is described in this criticism [**CBLA0002274**], was written and distributed by BPL, and UKHCDO had no influence over its contents.

48. Attempts were being made throughout the early eighties to make concentrates safer by eliminating or reducing viruses. These attempts were initially unsuccessful. In 1985, BPL introduced a new factor 8 concentrate (8Y) that appeared successful in non-human experiments. The efficacy of the viral inactivation methods used needed to be tested in humans to confirm whether or not the methods worked. The trials of BPL 8Y were conducted by BPL and a group of haemophilia centre directors, and the rationale, approach and informed consent are described in the resultant publications (for example, the article in the Lancet at [**PRSE0000044**]). Safety and efficacy trials are

mandated by the regulatory authorities and without such trials, products are not licensed.

49. The trials referred to in this criticism were conducted by BPL, with the support of UKHCDO and members of UKHCDO and it is true to say that UKHCDO encouraged their members to involve suitable patients in clinical trials, rather than using the same products on a named patient basis. Trial subjects were patients who required treatment, and who were faced with the choice of using a licensed product known to transmit hepatitis or a trial product treated to minimise or eliminate that risk. All patients gave informed consent.

50. These concentrates were unlicensed and therefore could only be used in the context of clinical trials or on a named-patient basis [at the discretion of the managing clinician]. Using the new concentrates only in properly controlled clinical trials rather than on a named-patient basis would allow information to be collated in a standardised way about whether the risk of hepatitis transmission was reduced or eliminated. This principle was discussed with Dr Richard Lane of BPL at a meeting of the UKHCDO Hepatitis Working Party on 19 January 1983 [**HCDO0000558**] in which he explained the importance of the proper evaluation of 'hepatitis reduced' concentrates by way of clinical trials rather than the use of the products on a named-patient basis.

Spiking of Factor VII with pathogens Page 11: *"In a meeting of the Haemophilia Reference Centre Directors in December 1984, Dr Lane discussed the spiking of Factor VIII with pathogens in order to determine the effectiveness of heat-treatment methods. Dr Lane went on to say that the present methods used by the NHS and commercial companies might still leave ACTIVE ANTIGEN and that BPL would therefore be looking for follow-up studies during 1985 with Haemophilia Centre support. It is disgusting to read in these Minutes that the Factor VIII concentrates which were 'spiked' with live antigen material, despite heating attempts, somehow found their way through to human patient. We allege that there was CONSPIRACY between Doctors at BPL and Haemophilia Reference Centre Directors to conduct NON-CONSENSUAL RESEARCH into the consequences of deliberately spiking Factor VIII with potentially life-threatening viruses. At that time, there was no effective way to know for sure if the heat-treatment process had adequately killed-off the antigen used to spike the Factor VIII."*

51. The relevant passage is to be found at [**CBLA0001948**] (page 8).

52. Dr Lane was an employee of BPL who provided information to a meeting that involved members of UKHCDO at the Blood Products Laboratory on 10 December 1984. The work referred to was undertaken by BPL and similar work was conducted by most other manufacturers.

53. The experiments described were pre-clinical, conducted in the laboratory to test the efficiency of the manufacturing process to eliminate viruses. These experiments involved spiking plasma from a test batch with measured amounts of various model viruses and then measuring how much virus was left at various stages in manufacture and viral attenuation. This enabled the effectiveness of each viral reduction step to be quantified approximately and to be modified if necessary. These test batches would then have been discarded and would *not* be administered to people with haemophilia. Dr Lane detailed the experiments as a surrogate of what might be expected if blood from infected donors was subjected to the same potential viral inactivation processes. This enabled viral attenuation methods to be optimised in the laboratory before being applied to plasma pools used for therapeutic materials in clinical trials and subsequently for routine use. Such spiking was not applied to therapeutic materials intended for administration to people with haemophilia. BPL and other manufacturers would be able to supply more detailed descriptions of these spiking experiments.

Page 12: Research dictating clinical need: "*In a meeting of the Haemophilia Reference Centre Directors in December 1984, the testing of haemophiliac patients for HTLV-III (Human T-Lymphotropic Virus type III - now termed HIV) was discussed. We are concerned to read that the Physicians were placing an obvious emphasis on research and not, however, on the welfare of their patients. The minutes go on to state "I believe a study of haemophiliac patients could be regarded as a research project now and Dr Mortimer could provide facilities for doing these tests." We believe that this is an appalling statement. People were dying from infection with deadly viruses, whilst here, we see the Consultants of the Haemophilia Reference Centre Directors Organisation engaged in CONSPIRACY to study haemophiliacs as a 'research project'. This is a clear example of research dictating and superseding clinical need. It is for these reasons that we accuse the Medical Profession and Haemophilia Reference Centre Directors of CONDUCTING UNETHICAL RESEARCH and for*

allowing it to dictate clinical need. We accuse BPL and the UKHCD of CONSPIRACY to CONDUCT NON-CONSENSUAL RESEARCH."

54. This passage appears to relate to a meeting including centre directors amongst others, which took place on 10 December 1984. There is a minute of this meeting at [**CBLA0001948**]. The passage quoted appears to be from a letter dated 12 December 1984 relating to this meeting, from Dr Smithies (DH) to Dr Abrams, [**DHSC0001117**] neither of whom were centre directors.

55. The entire haemophilia community, not least the people infected, were urgently seeking knowledge about AIDS and HIV in the 1980s. The only way to advance knowledge was to undertake research in parallel to attending to the clinical needs of people infected with HIV. In late 1984 an unvalidated [not fully evaluated and prone to false positive and false negative results] test for HTLV-III (HIV) became available and this was discussed at UKHCDO meetings so that clinicians were aware of the latest developments. Some clinicians sent samples to be tested with these early HIV tests.

56. The natural history and the prognosis of HIV and AIDS were not known and there was no effective treatment at the time. Under circumstances such as those it was important to collect whatever information was available, to learn more about HIV to improve patient care.

57. Any interventional research that was conducted was not conducted by UKHCDO.

Page 15: ***Haemophiliacs used instead of Chimpanzees.*** *"In the Minutes of the UK Haemophilia Centre Directors' Hepatitis Working Party, 24 September, 1981, it was stated that the only way that infectivity for Non-A Non-B hepatitis could be shown (other than by human inoculation) was by inoculation in chimpanzees. The minutes continue: "Since there are very few of these animals available, it is difficult to see how every batch treated by this method will have quality control assurance with respect to non-A, non-B viruses.""*

58. The relevant document is to be found at [**HCDO0000135_017**].

59. In an attempt to test the effectiveness of viral attenuation [reduction] in concentrates prior to administration in humans, several manufacturers administered selected batches of concentrate first to chimpanzees and tested the chimpanzees to see whether they developed abnormal liver function tests as a marker of whether the concentrate transmitted non-A, non-B hepatitis. The minutes of the Hepatitis Working Party state their opinion that it was unlikely that all batches of these concentrates would be tested on chimpanzees. The decisions about which batches of concentrate to test would have been taken by the manufacturers and not UKHCDO.

60. It was not known at that time whether this was an effective screening method or not. If the chimpanzees developed hepatitis, one could conclude that the material was infective. If they did not contract hepatitis, then one did not know whether the product was infective or whether it was just not infective to chimpanzees. Unfortunately, viruses are mostly very species-specific and using chimpanzees for non-A non-B screening was subsequently shown to be insufficient to confirm safety of a concentrate. Concentrates which did not transmit hepatitis to chimpanzees were shown to transmit hepatitis to humans and this was minuted as early as 1982 in the Hepatitis Working Party Minutes and subsequently published. (Non-A, non-B hepatitis and heat-treated factor VIII concentrate. Preston FE, Hay CRM, Dewar MS, Greaves M and Triger DR. Lancet 1985; 1:213. [**WITN3289189]**)

Pages 16 & 17: ***Children used instead of chimpanzees (cont)*** ***"****In January 1982, four commercial companies were poised to release heat treated Factor VIII. The infectivity of initial batches had been tested by injecting the product into chimpanzees, but it was stated in a letter from Dr C. R. Rizza and Dr A. L. Bloom, that it was unlikely that commercial manufacturers would be able to ensure this form of quality control in all future batches and that it was therefore very important to find out in studies of HUMAN BEINGS the extent to which infectivity had been reduced. We believe that this trial was UNETHICAL in that 8 of these patients were in the age-range of 3 months to 3 years old and would not even have been able to write. In the case of the 9 patients who were under the age of 18, their parents would have been required to give their informed written consent. Whilst the written informed consent of parents may have been obtained, we have to wonder if ANY parent would knowingly consent to hepatitis infectivity trials like this, especially if they were genuinely informed and cognizant of exactly what was involved. It is for these reasons that we ACCUSE Consultant*

Physicians, the HCDO and the PHLS of DELIBERATELY AIMING INFECTIVITY TRIALS at CHILDREN and infrequently treated patients, instead of always using expensive chimpanzees."

61. The relevant document is to be found at [**ARCH0001640**].

62. Dr Rizza and Professor Bloom wrote to members of UKHCDO to make them aware that concentrates that had been heat-treated to reduce the risk of hepatitis transmission were about to become available. Members were also made aware that some, but not all, batches of those concentrates would have been tested in chimpanzees before being made available for use in humans. The decisions about whether to test some or all batches of these concentrates in chimpanzees were taken by manufacturers and not UKHCDO. UKHCDO would not have been able to influence these decisions. UKHCDO's role was to make members aware of these developments.

63. These concentrates were unlicensed and therefore could only be used in the context of clinical trials or on a named-patient basis [at the discretion of the managing clinician]. In the letter from Dr Rizza and Professor Bloom, clinicians were urged to use the new concentrates only in properly controlled clinical trials rather than on a named-patient basis because this would allow information to be collated to investigate the manufacturer's assertion that the risk of hepatitis transmission was reduced or eliminated.

64. These trials were run by pharmaceutical companies and the inclusion criteria, approach to ethical approval and informed consent was the responsibility of the companies and treating clinicians rather than UKHCDO.

65. The methods sections of the published clinical trial reports indicate that ethical approval was granted before the trial commenced and that the trial subjects, or parents of trial subjects, gave written consent. Trial subjects were faced with the choice of using a licensed product known to transmit hepatitis or to use a trial product treated to minimise or eliminate that risk. Such clinical trials were conducted all over the world at that time and many were multinational. Clinicians from the United Kingdom were not unusual in participating in such studies, which were the only way in which to gain access to potentially safer products for their patients at that time. Although the objective of these studies was to reduce the risk of hepatitis, it later became apparent

that HIV was more susceptible to these methods of viral attenuation than hepatitis viruses and consequently, by chance, some people may have been spared HIV through their participation in such studies.

66. An example of such a trial is "*Transmission of non-A, non B hepatitis by heat treated factor VIII Concentrate." (Colombo M, Mannucci PM, Carnelli V, Savidge GF, Gazangel C, Schimpf K and the European Study Group. Lancet July 6th 1985, pp1-4)* [**HSOC0001563**]. This was a safety and efficacy study of a dry heated factor VIII concentrate conducted in 4 centres from four countries (Italy, France, Germany and the UK) in people who needed treatment but who were previously untreated with blood products. In the Patients and Method section of the paper it is recorded that the patients gave written informed consent. I note that 84% of the subjects developed hepatitis after treatment despite the concentrate having not caused hepatitis in chimpanzees, when administered to them. This illustrates that screening such concentrates by administration to chimpanzees was of no value.

Page 20: Ignoring Warnings. *"On 13th May 1983, in a meeting of the Haemophilia Reference Centre Directors, a decision was made that, on the evidence available, (and because of the so-called benefits of treatment), that no restriction should be placed on imported Factor VIII concentrate.*

The only exception was to continue with their policy of only using NHS material for children under the age of 4 and for mild haemophiliacs.

We challenge this decision and ask why the Directors of Haemophilia Reference Centres didn't try and do more to restrict or even ban imported Factor VIII? The Directors appear to have ignored the following warnings and developments:

- ***9 months earlier**, (September 1982), Dr Craske had been tasked by the HCDO with looking into reports of AIDS in 3 haemophiliacs from the USA and he suspected a link to commercial Factor VIII. (Source: Minutes of the 13th Meeting of HCDO. 13th September 1982.)*
- ***5 months earlier**, (January 1983), there had been an article in the Lancet by Dr Jones (also, HCDO), where AIDS was linked to common cell immunity in haemophiliacs.*
- ***2 months earlier**, (23rd March 1983), the FDA requirements on blood donations were introduced – this was still 2 whole months before this decision.*

- ***1 week earlier**, (6th May), the CDSC telephoned the DHSS to inform them that a 23- year-old haemophiliac patient in Cardiff was now showing symptoms of an AIDS diagnosis after having been infused with US Factor VIII. (Source: Recovered FOI Document. DHSS Letter. American Factor VIII. Cardiff Haemophiliac. Dated 6th May 1983).*

- ***4 days earlier**, (9th May 1983), the CDSC had written a letter recommending that American FVIII should be withdrawn from use due to the risk of transmitting AIDS. The DHSS definitely had sight of this CDSC letter by the decision of 13th May 1983."*

67. The relevant documents are to be found at [**HCDO0000003_008**] and **[DHSC0002227_047].**

68. The statement regarding the UKHCDO position on importation of concentrates as at 13 May 1983 is accurate. This issue has been addressed by several other witnesses to the Inquiry who were members of UKHCDO at the time in question. Although it was known that both UK and US-sourced concentrates transmitted hepatitis and AIDS virus, the extent to which they transmitted these viruses was unknown at that time and the suspicion was that non-UK-sourced concentrate was more infectious. Unfortunately, only about 40% of the factor VIII concentrate used in the UK at that time was of UK origin. Clinicians at that time had to balance the known benefits of factor VIII concentrates in terms of treating and preventing bleeding and in terms of life expectancy, with emerging knowledge about the risks of transmission of infectious diseases. These issues were discussed at the meeting of the Committee on Safety of Medicines, Sub-Committee on Biological Products, on 13 July 1983 [**ARCH0001710**] indicating that decisions were not taken by UKHCDO in isolation.

Page 29: Deliberately withholding test results. *"In the minutes of the Haemophilia Reference Centre Directors Meeting in December 1984, it was stated that any haemophiliac patients who enquired as to their HTLV-III antibody test status should be informed, otherwise it is up to the individual Centre Directors to decide whether or not to inform patients. We believe that this demonstrates that Physicians were testing haemophilia patients' blood for HTLV-III without consultation, a practice which denied the patient's rights concerning pre- and post-test counselling, and also in failing to*

inform the patients, the Consultants were taking away the person's right to protect others from infection. (In the Notes of the Haemophilia Reference Centre Directors Meeting on 10 December 1984, Dr P. Kernoff commented that "as some 70% of haemophiliacs were now positive, it may be considered ***irrelevant*** *if one tells or doesn't tell the results of testing." (Page 5). We believe that these Consultant Physicians should have given a strong line of advice to follow; that patients should not only have been informed, but also, that the patients had a distinct right to know. Dr Kernoff might have considered it "irrelevant", but we doubt that the intimates of the haemophiliac patients would have thought so. It is for these reasons that we ACCUSE the PHLS, the Haemophilia Reference Centre Directors (HCDO) and the Department of Health of DELIBERATELY WITHHOLDING TEST STATUS RESULTS and we accuse the Department of Health and NBTS of PROCRASTINATING TO FORESTALL the pressure to more widely release the early HTLV-III (HIV) test within the UK."*

69. It is acknowledged that in late 1984 and early 1985 many people were tested for HTLV-III (HIV), generally from stored samples, without their knowledge or consent. The witness refers to a meeting on 10 December 1984 chaired by Professor Bloom. This meeting took place at Blood Products Laboratory (BPL), Elstree. It included some haemophilia centre directors (members of UKHCDO), employees of BPL, representative of DHSS and expert virologists. The note of that meeting was written by Norman Pettet who was an employee of BPL at the time. It was not a UKHCDO meeting, and the account of the broad-ranging discussion does not reflect UKHCDO policy. The quoted view of Dr Kernoff in discussion was not shared by UKHCDO as an organisation (as can be seen from the recommendation in the AIDS Advisory Document of 14 December referred to below).

70. The meeting notes state "*A long discussion took place on whether persons found to be +ve were to be informed. Several differing views were expressed. It was agreed that each clinician would decide for each case depending on the facts of the case but in general to provide information if asked for*." [**CBLA0001948**] Later in the document it is stated "*The chairman summarised by saying that testing should be instituted as soon as possible, and that information on the test results, should not be given automatically but if asked for*." It is understandable that these statements would cause alarm for people with haemophilia and their relatives as expressed in the "We Accuse" document, however, this position did not become UKHCDO policy. At the end of the meeting the chairman (Professor Bloom) stated that the recommendations of the

meeting "*would be widely circulated*". The haemophilia doctors then had a UKHCDO meeting of centre directors only and formulated an AIDS Advisory Document which was issued and circulated to all members four days later on 14 December 1984 [**HCDO0000270_007**]. In that document under the heading "Antibody testing" the agreed UKHCDO policy is stated as follows: -

"*It is recommended that patients be HTLV-III Ab tested. Test should be repeated if positive. Ab positive people should be informed, reassured and counselled regarding transmission to spouses etc., including the possible use of barrier contraception.*"

71. This statement shows that the position of UKHCDO (including Peter Kernoff, who was a signatory to this statement in his role as one of the directors), communicated to members on 14 December 1984, was to inform individuals of a positive test result. The recommendation to repeat the test if positive was made because the test was relatively unreliable at that time.

Statement of Truth

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

GRO-C

Signed __ _____

Dated _____02/06/2023

Table of exhibits:

Date	Notes/ Description	Exhibit number
01/01/1997	Guidelines on therapeutic products to treat haemophilia and other hereditary coagulation disorders.	WITN3289188
27/07/1985	Non-A, non-B hepatitis and heat-treated factor VIII concentrate. Preston FE, Hay CRM, Dewar MS, Greaves M and Triger DR. Lancet 1985; 1:213	WITN3289189