Witness Name: Andrew Michael March

Statement No: WITN1369014

Exhibits: WITN1369015-63

Dated: March 2020

INFECTED BLOOD INQUIRY

EXHIBIT WITN1369060

TaintedBlood.info

In the late 1970s and early 1980s, 4,800 British haemophiliacs and many more others were infected with Hepatitis C through their NHS treatment. 1,200+ of those people were also infected with HIV, the virus that leads to AIDS. Of those 1,200, more than 800 people have already died. Hundreds more have died from Hepatitis C.

People are still dying

We are striving to bring to an end a tragedy, dubbed by Lord Robert Winston and reiterated by Lord Morris of Manchester as "*...the worst treatment disaster in the history of the NHS...*". Thousands of lives have been lost or destroyed, and thousands more left without their loved ones.

We will not stop until justice is done

We are fighting for closure, not only for the survivors but for those people who have been left behind. We all deserve answers as to why this has happened and we need to be able to live, not just exist. The people we entrusted our lives to have wronged us, but they have also grossly underestimated the will and strength of the survivors of this tragedy. Now we bring the fight to them.

To this day, the British Government has steadfastly refused to hold a public inquiry into this tragedy. Against overwhelming evidence, no fault has ever been admitted by either Government or the pharmaceutical companies who supplied the contaminated blood products. We start the process towards the end here.

'We Accuse' will find the truth

This document is produced by:
TaintedBlood PO Box 13421 Moseley Birmingham B13 3EF
0121 288 2361
campaign@taintedblood.info
http://www.taintedblood.info/

We Accuse…

Accusations from the taintedblood.info Group

We accuse the Government of GROSS MALADMINISTRATION for the systematic failure in attempting to achieve UK self-sufficiency in blood products between May 1975 and January 1986.

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We accuse the Medical Profession and Haemophilia Reference Centre Directors of CONDUCTING UNETHICAL RESEARCH and allowing it to dictate clinical need and we accuse BPL and the UKHCD of CONSPIRACY to CONDUCT NON-CONSENSUAL RESEARCH.

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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.

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We accuse the Government and the Department of Health of IGNORING WARNINGS and of FAILING TO TAKE ADEQUATE MEASURES against hepatitis viruses and in failing to do so, leaving the haemophiliac community wide open to infection at the advent of AIDS.

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We accuse the Government and the Department of Health of FAILING TO LEARN LESSONS in not rapidly introducing monoclonal-derived Factor VIII at BPL Elstree when it was considered and allowed-for in the plans for BPL in 1985/6 and that even now, the safest recombinant Factor VIII products are not being made available to all adult haemophiliacs within the UK, and that the same mistakes are being repeated: in placing cost concerns over and above patient safety.

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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.

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We accuse the Government and the Department of Health of THE IMMORAL AND UNLAWFUL EXCLUSION OF LIABILITY for future blood-borne pathogens, whilst KNOWINGLY WITHHOLDING HEPATITIS C TEST STATUS RESULTS and for MISLEADING the haemophilia community regarding the availability of the technology for the testing of patients and the screening of blood for hepatitis C, and whilst in full knowledge of this, bringing pressure to bear to prematurely 'settle' a *prima facie* Legal Action with a compromised and unsound legal process.

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We accuse the Government and the Department of Health of a COVER-UP regarding the contaminated blood catastrophe – in ATTEMPTING TO VANISH crucial evidence, and in allowing the shredding of documents leading to deliberate obfuscation by publishing a biased and incomplete account of the self-sufficiency fiasco.

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I. GROSS MALADMINISTRATION

In 1974, Dr David Owen, then Health Minister, decided that if enough money were to be invested, the United Kingdom could become self-sufficient in blood products and they would only need to be sourced from Britain and would thus be much more likely to be free from contamination. Dr Owen announced in the House of Commons that several million pounds had been allocated. (Source: BBC News. 'Haemophiliac HIV tragedy needless'. Friday, 3 August, 2001).

The World Health Organisation (WHO) had warned Britain NOT to import blood from areas with a high prevalence of Hepatitis - areas such as the United States. By May, 1975, the WHO had issued a resolution stating that each member country should be able to supply sufficient quantities of its own blood and blood products to meet clinical needs. Sadly, David Owen's initiative did not follow through, as there was considerable resistance from within the Department of Health against putting up the required money and the funding that had been apportioned-off for the protection of haemophiliacs was 'diverted to other purposes'. (Source: Former Health Minister, Lord Owen speaking on the BBC's "Face the Facts" programme in August 2001.)

Dr David Owen, in a Written Answer of March 1975, stated his intention that a pledged sum of money, some £500,000, (about half of which would be recurring) was to be allocated for increasing production at Blood Products Laboratory (BPL). These funds, however, ended up being used to increase donations in Regional Transfusion Centres (RTCs), leaving BPL Elstree short-changed. This misappropriation of funds demonstrates GOVERNMENT MALADMINISTRATION as the DHSS should have insisted on the extra money being allocated to its intended purpose – to increase production of Factor VIII with the aim of the NHS being self-sufficient. (Source: Written Answer Dr David Owen. Vol 887. 6th March 1975.)

In 1976, Dr Helen Dodsworth sat on a committee which was convened to advise the DHSS as to how much Factor VIII concentrate was needed to treat UK haemophilia patients. Dr Dodsworth stated that they found themselves buying large quantities of concentrate from America and that they had consequently infected many of their patients with HIV. She went on to say that this had happened despite the fact that their spokesman, Dr Tovey, had persuaded them that to treat their patients adequately it would be necessary to fractionate at least 80% of the blood that was donated. She explained that the Government had, at that point, decided that money was neither available for extending the fractionation unit at Elstree, nor for equipping the transfusion centres to separate yet more plasma from donor units.

Dr Helen Dodsworth's exact words were: "*So this is really why we found ourselves buying large quantities of factor VIII concentrate from America, and why we infected so many of our patients with HIV.*" (Source: Transcript of a Witness Seminar held at the Wellcome Institute for the History of Medicine, London, 10 February, 1998, (see pages 29-30): "HAEMOPHILIA: RECENT HISTORY OF CLINICAL MANAGEMENT". Transcript, edited by D A Christie and E M Tansey.)

I b. UNDERFUNDING OF THE LISTER INSTITUTE

In the early 1970's, it became more and more clear that the world-renowned Lister Institute of Preventative Medicine was experiencing considerable financial difficulty. The Institute's list of achievements was unprecedented in the field of medical science and we believe they were well-poised to go on to develop heat-treatment and a screening test for non-A non-B hepatitis by as early as 1978. However, by 1975, the Institute's Chelsea Laboratories were forced to close after repeated annual deficits and failure to secure adequate government funding. (Source: Lister Institute of Preventative Medicine. Scientific Heritage.)

In 1977, a DHSS Viability Study discussed the fate of the floundering research facility. In a DHSS letter, it was stated that *"The Department should not on financial grounds make a loan or grant to [Lister?*] and that the possible consequences of [Lister?] ceasing to produce sera and vaccines should be accepted."* (Paragraph 1, lines 3-5.) (Source: Recovered FOI Document. DHSS Letter. Dated 2nd February, 1977.) * Note: In the original source letter, (see Appendix, Chapter I), despite Civil Servants deleting the names within this released document, they have overlooked several instances of the name 'Lister' and we therefore know that this letter concerned the fate of the Lister Institute. The exact quotation above did contain 2 crossings-out, but is, however, from the same letter.

By 1978, the Lister Institute's Elstree Laboratory had to close due to repeated annual deficits and lack of government funding. (Source: Lister Institute of Preventative Medicine. Scientific Heritage.) We believe that the Government's INADEQUATE FUNDING of the Lister Institute, prevented the facility from going on to develop heat-treatment and a screening test for Non-A Non-B hepatitis - possibly by 1978. This could have helped stem the damage done by HIV and AIDS as we know that HIV is heat-labile and that heat-treatment processes would have covered against HIV, even if HCV (NANBH) and other hepatitis viruses had slipped through.

I c. NEGLECT OF BPL ELSTREE

In 1980, Dr David Owen, then Minister for Health, in an interview for ITV's "World in Action" said in relation to the condition and lack of funding at BPL Elstree, that no government had put enough money into BPL: "*Well, I don't think we've invested enough. I thought then, on the best evidence that I had, I think it was £500,000 that we found, was going to be sufficient. But what has happened is that although we have increased, as I gather at production, demand increased as well.*" (page 2, paragraph 4). Dr Peter Jones stated: *"What should have been put in is something more in the region of £25 million..."* (page 4, paragraph 2). (Source: Transcript of 'World in Action'. ITV. Dated 22nd December, 1980.)

The interviewing reporter, in their closing comment, made the following rather salient point: *"The Department says there's no money available. That means hospitals will spend millions more on imports, patients will risk the consequences of skid row blood and Britain will become increasingly dependent on the world blood market."* (Page 16.) (Source: Transcript of 'World in Action'. ITV. Dated 22nd December, 1980.)

In a letter from Blood Products Laboratory, Elstree, dated 4th July 1980, there was mention of the poor conditions and low staff morale at BPL Elstree. Consideration was given to the alternative of importing blood product requirements, but grave doubts were expressed over the quality of overseas production facilities. Some of BPL's staff had visited a fractionation plant in the USA, in which they found manufacturing conditions to be even worse than those at BPL. (Page 2, paragraph 1.) (Source: Recovered FOI Document. Letter, Blood Products Laboratory, Elstree. Dated 4th July, 1980.)

In a BPL letter to the DHSS in May 1981, we read further details of the appalling conditions: *"..likewise, there is inevitably an increased risk to the end product if high bacterial contamination is present in the laboratory environment, in process equipment and raw materials."* (Paragraph 2, line 11) (Source: Blood Products Laboratory Letter to the DHSS. Dated 22nd May, 1981.)

In November 1984, the Director of BPL visited the USA to discuss possible collaborative work on research and development into the preparation of genetically engineered Factor VIII. (Source: Recovered FOI Document. CBLA Minutes for the Fourth Meeting of the Central Committee for Research and Development in Blood Transfusion. Dated 9th November, 1984.)

By 1985, we read that the advance in technology of being able to produce Factor VIII in a laboratory through genetic engineering has been borne in mind whilst conceiving the redevelopment plans for the new BPL Elstree - due to be completed circa 1986. Ministers were aware of the intention that the plans for the redevelopment project at BPL were to be sufficiently flexible with regards to the new technology so as to allow for genetically engineered Factor VIII in the near future. (Source: Recovered FOI Document. Paper on Self-Sufficiency in Blood and Blood Products in the UK. Date unconfirmed. However, the FOI Document Itinerary supplied by the DOH suggested the date of 17th January 1985.)

We, therefore, pose the question: "What happened?" The redevelopment project at BPL Elstree was due to be completed in 1986. Even if we allow another 5 years for research and development, we should have seen the arrival of BPL monoclonal-derived Factor VIII by 1991. Instead, haemophiliacs have to wait until 1994 for the first licence to be granted to commercial companies and until 1998 for those patients under 16 years of age to be issued with recombinant – which should be weighed against Hyland (Baxter) commencing human trials with recombinant Factor VIII as early as 1987. (Source: Baxter Vaccines: Milestones 1941-2004.). Even today, we find that some adult haemophiliacs in the UK are still not receiving 3rd-generation recombinant; made entirely from non-human, synthetic materials.

We accuse the Government of GROSS MALADMINISTRATION for systematic failure in attempting to achieve self-sufficiency, for the under-funding of the Lister Institute, for neglect at BPL Elstree and for placing 'cost' above patient safety.

II. CONDUCTING UNETHICAL RESEARCH

In the early 1970's, Directors of UK Haemophilia Centres signed-up with commercial manufacturers of Factor VIII to receive imported products for use in trials. (Source: Haemophilia Centre Directors' Organisation (HCDO) Meeting Minutes 1974.) In 1982, in a letter to all Haemophilia Centre Directors, plans for future trials of clotting factor products were discussed and it was suggested that requesting exemption from clinical trials certificates in relation to individual products would expedite trials. (Source: Bloom Al, Rizza CR. Letter to All Haemophilia Centre Directors. Dated 11th January, 1982.)

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 licence was granted in May '82 and a trial was to be conducted at Oxford involving haemophilia A patients. (Source: Minutes of the 13th Meeting of UKHCD, University Hall of Residence, Owens Park, Manchester. Dated Monday, 13 September, 1982. Page 10, paragraph 2).

We believe that this trial of the hepatitis B vaccine was UNETHICAL. A direct test for the presence of Hepatitis B Surface Antigen (HB_sAg) had been in existence since 1968. (Source: Krever Commission Report (1997), Vol 3, Part IV, Chap. 27, page 753). The Medical Profession already knew that haemophilia A patients would have mostly 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.

The safety of the hepatitis B vaccine was later called into question in the July 1983 meeting of the Biologicals Sub-Committee of the Committee on Safety of Medicines (CSM). It was noted that although there was no evidence at that time of any risk from AIDS in the licensed vaccine material, the Sub-Committee recommended that the manufacturers provide ongoing data relating to the "*safety of the product in relation to AIDS*". (Source: CSM Sub-Committee on Biological Products, Meeting Minutes, agenda point 5.8. Dated 13th July, 1983.)

II b. 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. It should be noted that this was approximately 3 years after the advent of AIDS. The letter describes a new Factor IX product which had been dry-heated in order to inactivate viral agents including hepatitis and AIDS but that the new product could not yet be assumed to be safe from viral infection. (Source: Letter from BPL Product Services Department to Haemophilia Centre Directors. Dated 7th October, 1985. Page 1, paragraph 2.)

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. It would be more reassuring to read of trials involving life-saving medicines, but instead we always seem to see an emphasis placed upon 'infectivity'.

We, therefore, consider that this infectivity trial, being conducted in late 1985, in the wake of AIDS, constituted UNETHICAL research.

In a letter of 17th February 1984, from the Scottish National Blood Transfusion Service to the Department of Haematology in Cardiff, we learn of plans for clinical studies of wet heat-treated Factor VIII in haemophiliacs to be held in September 1984 – which was several years into the AIDS crisis:

"We are particularly keen to see part of this product is put into "virgin haemophiliacs" and would much appreciate the assistance of the U.K. Haemophilia Centre Director's Working Party on Hepatitis." (Source: Recovered FOI Document. Letter from Scottish National Blood Transfusion Service to Cardiff Haematology Department. Dated 17th February 1984).

II c. SPIKING OF FACTOR VIII WITH PATHOGENS

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. Antigen (of which viruses are a source), was added to the Factor VIII prior to the heating process. 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. (Source: Notes of the Haemophilia Reference Centre Directors Meeting, Blood Products Laboratory, Elstree. Dated 10th December, 1984.)

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 patients. The need for follow-up studies in Haemophilia Centres is indicative of this.

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. We know that the available techniques for testing the final concentrate – to demonstrate its safety from viral infection - were not adequately sensitive to identify infectivity, as it was known ***then*** that concentrates which had tested negative on virological investigation could still transmit viral infection in a patient.

II d. 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. Due to inconsistencies in the results of the tests that had already been conducted, a study of the haemophiliac population was proposed. It was stated that it "*would provide invaluable material to increase our knowledge of the disease.*" 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.*" (Source: Meeting of the Haemophilia Reference Centre Directors. 10 December 1984. Point a. Paragraph 2.)

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.

III. AIMING INFECTIVITY TRIALS AT CHILDREN

In July 1976, a collaborative trial took place between BPL Elstree and the Lord Mayor Treloar College, Hampshire. Factor VIII concentrates were supplied by BPL to be used in a prophylaxis trial. In the same month, an inspection of the production facilities at BPL Elstree revealed short-comings and in certain respects were found inadequate in terms of the Medicines Act. (Source: Recovered FOI Document. Blood Products and Plasma Fractionation Labs 1976. Collaborative Trials.) It should be pointed out that the Lord Mayor Treloar College is in fact a SCHOOL, according to the Oxford Dictionary definition, despite the use of the word 'College' in its name. In a paper by Dr A. Aronstam, et al, it states that the adolescent boys with severe haemophilia A, cited in his study, were in the age range 12-17. (Source: Patterns of bleeding in adolescents with severe haemophilia A. A Aronstam, et al. Br Med J. 1979 February 17; 1(6161): 469–470.)

In the Witness Testimony of one of our Mandated Members, who attended the Lord Mayor Treloar College in the late 1970's, they categorically stated that neither themselves nor their parents were informed of the trials, or of the risks involved in receiving Factor VIII concentrates. They also said that neither themselves nor their parents had heard of Factor VIII until they were 12 or 13; when they first attended the Treloar College. They recalled telling their mother over the phone, on their second day there, about being taught to administer the concentrates to themselves by intravenous injections. That phone call was the first that their parents had heard of the new Factor VIII concentrates.

In a letter from the Lord Mayor Treloar Hospital to the Public Health Laboratory Service (PHLS) in 1979, it was made clear that there was an intention from the PHLS of transfusing mild haemophiliacs with a questionable 'material' which would have caused the mild haemophiliac patients to develop hepatitis. The author of the letter strongly disagreed with the PHLS suggestion. (Source: Lord Mayor Treloar Hospital. Letter to PHLS. 14th May 1979).

III b. CIRRHOSIS IN CHILDREN

In November 1982, a prospective study of hepatitis in haemophiliacs who were first-treated with Factor VIII or IX concentrate was planned. It was stated in a draft of the trial protocol that the only sure way of assessing the risk of transfusion hepatitis associated with new brands of concentrate, was by use of chimpanzee inoculation experiments, or TRIALS of each heat-treated or ultra-violet light-treated product compared with an untreated product in a group of subjects – human subjects.

As a consequence of trials such as this, we read on Page 2, under 'Complications' that "*some children with cirrhosis have received concentrate for 6-7 years.*" (Source: A Prospective Study of Hepatitis in Haemophiliacs first treated with Factor VIII or IX Concentrate. Oxford Haemophilia Centre Prospective Study. Circa November 1982. Dr C.R. Rizza. Dr. J. Craske.)

It is disgraceful that these Physicians seem to find it acceptable that CHILDREN should have CIRRHOSIS.

In another trial protocol of March 1983, Dr Craske, Dr Rizza and Dr Bloom state that: *"You will see that the class of patients to be given these products are those who have had no previous treatment with factor VIII concentrate."*

In the same letter, the authors actively invite '*any approaches from commercial firms*' to notify Dr J. Craske. We would like to point out that Dr Craske had knowledge of the threat of AIDS to haemophiliacs from commercial concentrates from as early as September 1982. (Source: Craske J, Rizza C, Bloom A. Public Health Laboratory Service (PHLS) letter to Haemophilia Centre Directors. 22 March 1983.)

III c. RULES OF 'LIFE - SUPPORT THERAPY'

In trials involving infrequently treated patients, we believe that doctors surrender their protection under the rules of "Life-Support Therapy" if the majority of the haemophiliac subjects included in the trial are NOT severe haemophiliacs. (Source: Recovered FOI Document. Proposal: European Directive Note on Liability for Defective Products. Dated March, 1980.)

When a doctor treats a patient, without consultation, on the basis that they meet the criteria for research; such as qualifying as Previously Untreated Patients (PUPs), we believe that the physician compromises, or even contradicts their Hippocratic Oath by allowing research to dictate clinical need.

III d. HAEMOPHILIACS USED INSTEAD OF CHIMPANZEES

It was known in 1981 that there were very few chimpanzees available for research. The animal could only really be exposed once for an infectivity trial, and at a cost of £10,000 each, they could be considered 'expensive' in terms of research budgets. 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."* (Page 4, point 2, line 7) (Source: Dr Craske. UK Haemophilia Centre Directors' Hepatitis Working Party, Minutes. 24 September 1981.)

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.

The Oxford letter went on to recommend that the most 'clear cut' way of doing this was by administering those concentrates to patients requiring treatment who had NOT been previously exposed to large-pool concentrates. (Source: Bloom AL, Rizza CR. Letter to all Haemophilia Centre Directors. 11 January 1982.)

We know that this reference to Previously Untreated Patients (PUPs) or 'virgin' patients, usually meant either CHILDREN or infrequently-treated mild to moderate haemophiliacs; simply by definition of NOT having been previously exposed to concentrates.

By July 1985, we find that an INFECTIVITY TRIAL IN HUMAN BEINGS is being contrasted against an animal model involving chimpanzees. 11 out of 13 Previously Untreated Patients (PUPs) go on to develop non-A non-B hepatitis after being given commercial heat-treated Hemofil-T made from around 5,000 North American pooled plasma donations, collected in 1982, 1983, and 1984. (Source: Colombo M., Mannucci P.M. et al (1985) Transmission of Non-A Non-B Hepatitis by Heat-Treat Factor VIII Concentrate. The Lancet. Saturday 6 July 1985. 2(8445):1-4.)

CHILDREN USED INSTEAD OF CHIMPANZEES (CONT.)

Of the 13 patients, 9 of them were in the age range of between a 3 month old baby and 15 years of age. Five of these subjects were each only 1 year old babies. In fact, there were only 2 patients who were over the age of 18. On page 2, under the heading "Patients", it states that those who met the trial criteria "***gave their written informed consent***". (Source: Colombo M., Mannucci P.M. et al (1985) Transmission of Non-A Non-B Hepatitis by Heat-Treat Factor VIII Concentrate. The Lancet. Saturday 6 July 1985. 2(8445):1-4.) It should be remembered that 11 out of 13 patients in this trial went on to develop hepatitis.

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.

IV. IGNORING WARNINGS

As early as 1970, Dr J. Garrott Allen from Stanford University, California, wrote to the head of the Transfusion Service in the United Kingdom, warning them of the dangers of using pooled plasma from high risk ***paid*** donors in the United States. (Source: 1975, World in Action Documentary: Blood Money, Granada TV (1975).

Nevertheless, by 1972, commercial factor VIII started to be imported into Britain from the USA. Dr Maycock, in the same year, stated that commercial blood had been shown to be 10 times more likely of transmitting hepatitis than blood collected from unpaid sources. (Source: Maycock 1972).

Then in 1974, the World Health Organisation warned Britain not to import blood from areas with a high prevalence of hepatitis - areas such as the United States. (Source: WHO Warning. Sunday Times Scotland. Dated 20th August, 2000.). Dr David Owen, Secretary of State for Health, announced to the House of Commons that several million pounds had been allocated towards making the UK self-sufficient in blood products, but the initiative did not follow through, since there was considerable resistance in the Department of Health against putting in the money. It is at this point that we feel we could reasonably expect preventative measures to have been put in place.

In a DHSS memorandum of 20th February, 1976, the Minister of State is referred to as only recently having reaffirmed his aim of NHS self-sufficiency in Factor VIII, and it is pointed out that the alternative of buying commercial products is not only likely to be more costly, but that it also carried a higher risk of hepatitis. (Source: Recovered FOI Document. DHSS Memorandum, 20 February 1976, paragraph 1).

In the minutes of a meeting at the DHSS of the Expert Group on the Treatment of Haemophilia and Allied Conditions on 4th May, 1976, it was suggested that the money being spent on commercial concentrate might be better spent if it were used to further increase the output of NHS concentrate. (page 3, paragraph 2, lines 1-6) (Source: Recovered FOI Document. Minutes of the Expert Group on the Treatment of Haemophilia. Dated 4th May 1976.)

We believe that greater adherence to the push for self-sufficiency would have served to protect the blood supply from hepatitis and if some of these WARNINGS HAD NOT BEEN IGNORED, then the haemophiliac community, IN BEING SHIELDED FROM HEPATITIS and COMMERCIAL concentrates, would not have been left wide open to infection with HIV and AIDS in the early 1980's.

Between 1982 and 1984, Dr John Seale had been trying to alert Public Health Officials to the implications of the threat of AIDS. Dr Seale had written both to Mrs Thatcher and the PHLS to suggest blood transfusion policy changes. (paragraph 4) We believe this article demonstrates that both Margaret Thatcher and the PHLS were notified circa November 1982 about the threat of AIDS to the Blood Transfusion Service, yet THIS WARNING WAS IGNORED. (Source: Article in The Standard, by Alan Massam. 20th November 1984.)

In May 1983, Professor A. L. Bloom, in a letter to Dr Bolton regarding commercial Factor VIII from the USA, stated that: *"We are however taking steps to recommend that imported products from the U.S.A. at least meet with the new F.D.A. regulations."* (Line 8). This WARNING, that blood products from the US should meet the new post-March 1983 Food and Drug Administration (FDA) Regulations, was IGNORED. Physicians, instead, decided to carry on using the pre-March 1983 'high-risk' concentrates. (Source: Letter, Professor A L Bloom writing to Dr F. E. Bolton. Dated 23rd May 1983).

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. (Source: Recovered FOI Document. AIDS Background Paper II. Dated 31st May 1983.)

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. (Source: Recovered FOI Document. DHSS Letter. Med SEB. 'Action on Aids'. Dated 13th May 1983).

IV b. FAILING TO TAKE ADEQUATE MEASURES

In a letter to the DHSS from the National Blood Transfusion Service (NBTS), in 1977, it is clear that cryoprecipitate is no longer the product of choice for Haemophilia Centres. Instead, they favoured concentrates, with them being easier to administer. It is stated that the only solution that they had in sight to adequately treat the UK haemophilia population was to push wholeheartedly towards the phasing out of cryoprecipitate. (Source: Letter from the NBTS to the DHSS. Dated 14th July, 1977).

In the height of the AIDS crisis, the Biologicals Sub-Committee of the Committee on Safety of Medicines (CSM) recommended that *very little* was done about the threat of AIDS to haemophiliacs. The possibility of withdrawing factor VIII concentrates from the market and replacing them with cryoprecipitate was considered, but it was concluded that this wasn't feasible in the UK on grounds of supply. (Agenda Point 5.3) (Source: Minutes - Committee on Safety of Medicines (CSM). 13 July, 1983.)

The Committee also considered withdrawing US concentrates from the UK, but again, it was concluded that this was not feasible (in July 1983) on grounds of supply and they did not perceive the level of risk to justify consideration of such a serious solution. (Minutes Agenda Point 5.4) (Source: Minutes - Committee on Safety of Medicines (CSM). 13 July, 1983.)

In August 1983, a DHSS letter from Lord Glenarthur stated that there was still a quantity of Factor VIII stock made from high-risk, 'pre-March' 1983 plasma in the USA, and that some of it was already in the UK and more was in America awaiting shipment here. Lord Glenarthur went on to say that: *"We have to balance the risk of AIDS against the severe risks to haemophiliacs of withdrawing a major source of supply of Factor VIII which cannot be made good from elsewhere in sufficient volume."* (Source: DHSS letter from the Office of the Joint Parliamentary Under Secretary of State. Dated circa August 1983).

We believe this to be a prime example of FAILING TO TAKE ADEQUATE MEASURES to protect haemophiliacs. The FDA had introduced new regulations for the collection of plasma that excluded donors from high-risk groups – this was done for a reason. Any plasma intended for Factor VIII products was likely to have been collected up to 2 years previously and even as the FDA restriction came in (circa March 1983) the products available at that time could have been manufactured from high-risk, AIDS-implicated 1981-2 plasma. It should have been possible for cryoprecipitate to have been used instead of high-risk Factor VIII - at least until alternative arrangements could have been made, except the production facilities for cryoprecipitate in the UK were no longer adequate. (Agenda Point 5.3) (Source: CSM Minutes - Committee on Safety of Medicines. 13th July, 1983.)

In a letter from the NBTS to the DHSS in October 1985, quarantined stocks of pooled plasma for fractionation at Elstree were mentioned, and it was assumed that the heat-inactivation process would make safe the quarantined plasma. (Source: Recovered FOI Document. NBTS Letter to DHSS. Dated 29th October, 1985.)

We ACCUSE the NBTS of ASSUMING that BPL's heat-treatment process would safely inactivate any possible viruses in QUARANTINED pooled plasma. The NBTS FAILED TO TAKE ADEQUATE MEASURES to discard quarantined untested or virus-implicated plasma pools. The heat-inactivation process was hardly infallible as only 2 months later, several haemophiliac patients became HTLV-III positive after receiving Factor VIII which had allegedly being heat-treated. (Source: Recovered FOI Document. Letter DHSS Ref. Heat-Treated FVIII. Hannibal House. Dated 28th November, 1985.)

V. FAILING TO LEARN LESSONS

In November 1984, it was noted in the minutes of the fourth meeting of the Central Blood Laboratories Authority (CBLA), that there had been significant progress in the cloning of Factor VIII. (Source: CBLA Minutes for the fourth meeting of the Central Committee for Research and Development in Blood Transfusion. Dated 9th November, 1984).

By 1985, Ministers were not only aware that genetically engineered Factor VIII had been produced in a laboratory, but that prior to the completion of the redevelopment project at BPL Elstree the genetic engineering methods for producing Factor VIII had been borne in mind when ensuring that the plans of the new BPL were sufficiently flexible to allow for this in the future. (Source: Recovered FOI Document. BPL Paper on Self-Sufficiency in Blood and Blood Products in the UK. Dated circa 17th January, 1985.)

Product Liability legislation was due to take effect in March 1988 and by May, it was noted by Mr Keyes, of the Blood Transfusion Services Board (BTSB), that to continue with factor VIII concentrates might present Product Liability problems. At that time, the option, inter alia, of changing to monoclonal-derived Factor VIII was only considered. (Source: Lindsay Tribunal of Inquiry Report. Page 57.)

Consequently, it was not until 1994 that the first recombinant licence for Factor VIII was issued in the UK and only in 1998 did the Government announce the roll-out of recombinant for all children under 16 and Previously Untreated Patients. (Source: Haemophilia Society, Fact Sheet. Dated April, 2004. Dated April, 2004.)

V b. VARIANT CREUTZFELDT-JAKOB DISEASE: LANCET 1996

The publication of a key article in the Lancet in 1996 marked the threshold whereby senior Physicians and Ministers could reasonably have been expected to start to become aware of Variant Creutzfeldt-Jakob Disease (vCJD). (Source: Lancet 1996: 347: 921- 25. "A new variant of Creutzfeldt-Jakob disease in the UK".)

We believe that the technology for monoclonal-derived Factor VIII existed from as early as 1984. We ACCUSE the Department of Health and BPL of failing to learn any lessons from the years of hepatitis in the 1970's and from AIDS in the early 1980's. In failing to initiate and scale-up the production of genetically engineered Factor VIII from circa 1986, or certainly, within 5 years of this date to allow for research and development, we allege that not enough was done to protect the haemophiliac community from the threat of further blood-borne pathogens – in particular, the failure to introduce non-human-derived Factor VIII with haste.

In a Sunday Times article in September 2001, Alan Milburn said that "*where the system fails the lessons need to be learned.*" (Source: The Sunday Times, 30 September 2001.) In failing to learn these lessons, we find that batches of 8Y Factor VIII, [FHC0289] manufactured from vCJD-implicated donations dating back to **May 1990**, (some 4 years after BPL had made plans to allow for monoclonal), are being traced in an Patient Notification Exercise initiated by The Health Protection Agency, Colindade as of September 2004. We believe that the possible exposure of haemophiliacs to this 'theoretical' risk could most certainly have been AVOIDED if the Department of Health had ensured that monoclonal-derived Factor VIII had been developed at BPL from 1985 onwards. (Source: vCJD and Plasma Products. Tables of vCJD implicated batch numbers. Health Protection Agency, Colindale. Dated 7th September, 2004.)

To date, (February 2007), we find that the Department of Health and Consultant Physicians are still not using the safest products available to treat *all* adult haemophiliacs in the whole of the United Kingdom. Some older haemophiliacs are still having to use earlier forms of recombinant containing various blood-derivatives such as albumin, since third-generation, entirely synthetically-derived (non human) recombinant is not available to every haemophiliac in the UK.

The various systems that have been put in place for the treatment of haemophilia have had an extraordinary history of fallibility, perhaps mostly due to issues of cost.

Due to the failure to rapidly introduce monoclonal-derived Factor VIII at BPL Elstree, when it was considered and allowed-for in 1985/6 and due to the fact that even to date, the safest recombinant Factor VIII products are not being made available to all adult haemophiliacs in the UK, we ACCUSE the Government and the Department of Health of FAILING TO LEARN LESSONS and placing cost concerns over and above patient safety.

VI. PROCRASTINATION OVER WIDER HIV TESTS

In April 1984, the National Institutes of Health (USA) developed and patented a prototype screening test for HIV antibodies and, by May 1984, had solicited applications from various US manufacturers interested in the commercial use of the tests. (Source: Recovered FOI Document. Publication of a Paper in the Lancet on the Use of a Screening Test for AIDS. 20th August, 1984.) By July 1984, there was evidence of a diagnostic test in the UK for Antibodies to HTLV-III. In a letter from the DHSS dated 27th July 1984, it was stated: "*Since my minute of 6 July there have been further developments regarding the radio immunoassay for antibody to HTLV-III. Some 2,000 tests have been carried out on AIDS patients...*". If some 2,000 patients had already been tested, then the early diagnostic test must have been available prior to July 1984. (Source: Recovered FOI Document. DHSS letter ref. Diagnostic Test. Dated 31st July, 1984.)

By September 1984, it was announced in the Lancet that reliable tests for HIV existed and that they were already aware that 34% of tested English haemophiliacs had HIV. How did they know this so early on? We know that one of our Mandated Members is in possession of a letter from Coventry & Warwickshire Hospital in June 1983, where a Registrar in Haematology wrote to them asking if they and their child could attend the Walsgrave Blood Bank for a blood test. This letter suggests that a blood test was available for HIV or HTLV-III as early as June 1983. It is unlikely that this was just a serum-collecting exercise, as the letter goes on to offer the results by 11th July 1983, which was only 11 days later. (Source: Letter ref. Blood Test. M. D. Williams. Coventry & Warwickshire Hospital. 2nd June, 1983.)

In a meeting of the Haemophilia Reference Centre Directors in December 1984, there is further mention of the EARLY existence and availability of an antibody test to HTLV-III. However, Dr Craske, of the PHLS, advised that at that time, (December 1984), the reagents were only available on a "Research Basis". (Source: Recovered FOI Document. Notes of the Haemophilia Reference Centre Directors Meeting. 10th December, 1984.)

In a DHSS letter of 31st July 1984, reference was made to the formation of a note, the contents of which revealed the intention to 'FORESTALL THE PRESSURE' for the wider availability of a diagnostic test for HTLV-III due to the experimental nature of the arrangements for the development of the test at a Regional Transfusion Centre (RTC). (Paragraph 3) (Source: Recovered FOI Document. DHSS letter ref. Development of Diagnostic Test for HTLV-III. Dated 31 July, 1984.)

We believe that the NBTS and the DHSS were unduly PROCRASTINATING over the scaling-up of wider availability to GPs and STD clinics of the HTLV-III antibody test, since in a DHSS letter dated only 4 days earlier (27th July 1984), a discussion took place where it was revealed that the radio immunoassay for antibody to HTLV-III had already been used to test some 2,000 AIDS patients. (Source: Recovered FOI Document. DHSS Letter, Hannibal House. Dated 27th July, 1984.)

VI b. PROCRASTINATION OVER INTELLECTUAL PROPERTY

In an NBTS Advisory Committee paper of 13 August, 1984, a discussion took place regarding whether to pursue developing the UK's own isolates for a test for antibodies to HTLV-III. It was stated on page 1, point 2, lines 7-11, that a UK isolate had yet to be achieved, whilst 5 US pharmaceuticals were poised to start marketing HTLV-III (HIV) tests (late 1984). There seemed to be some reluctance in the NBTS to buy in the isolates of Dr Gallo for the test from abroad; perhaps due to cost implications or the availability of the isolates? Nevertheless, there appeared to be a chaotic scientific ownership 'race' for Britain to find it's own test, and meanwhile, the wider release to GPs and STD clinics of the urgently required tests were apparently FORESTALLED. (Source: Recovered FOI Document. Proposed Working Group of the Advisory Committee on the National Blood Transfusion Services. Ref. consequences to the NBTS of Screening for HTLV-III. Dated 13th August, 1984.)

In a draft question and answer briefing for officials later in August 1984, it was clear that a 'sensitive and specific' HTLV-III antibody test was available from abroad. The test, based on isolates of HTLV-III probably obtained from Dr Gallo in Bethesda, USA, had been made available to research workers in the UK on the basis of exchange. (Source: Publication of a Paper in the Lancet on the Use of a Screening Test for AIDS. Dated 20th August, 1984.)

We, therefore, ask the question as to how long the wider availability of the HTLV-III test may have been forestalled? We know from a DHSS Press Release that it was not until mid-October 1985 that routine screening of all blood donations for antibodies to the AIDS virus was in fact fully introduced, which was a whole 14 months after the above-mentioned August 1984 NBTS letter. (Source: Department of Health and Social Security Press Release (Ref. John Patten Announcement) 85/277. Dated 23rd August 1985).

VI c. DELIBERATELY WITHHOLDING TEST RESULTS

According to The Journal, Newcastle, UK haemophiliac patients, on reading their medical records had learned that they were surreptitiously tested for hepatitis C between 1990 and 1992, WITHOUT BEING INFORMED of the results. Haemophiliac patients have claimed that NHS Trusts had NOT SOUGHT PERMISSION for the tests to be carried out and as a consequence, cross-infection with Hepatitis C could have occurred, putting the lives of spouses in danger. (Source: *"GMC U-turn in Blood Tests Row"*. Unnamed Author, The Journal, Newcastle, 14 April 2003.)

In a PHLS letter of October 1984, two alternative strategies for the follow-up of haemophiliac patients who had received an HTLV-III-implicated batch were deliberated. The option of NOT INFORMING patients was considered in depth. Dr Craske knew that HTLV-III infection could be transmitted by sexual contact, yet there was clear evidence that he was still deliberating the option NOT TO INFORM PATIENTS. In an Appendix on page 5, Dr Craske does eventually state that the option of informing the patient was *"the only one tenable on moral and ethical grounds."* (Source: Dr Craske. PHLS Letter. Dated 23rd October 1984.)

However, this conclusion should not even have required such discussion, never mind arriving at it almost as an afterthought. This PHLS letter may well have had a detrimental knock-on effect, since, 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. (Page 1). (Source: Notes of the Haemophilia Reference Centre Directors Meeting, BPL Elstree. Dated 10th December, 1984.)

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. (Source: Notes of the Haemophilia Reference Centre Directors Meeting, BPL Elstree. Dated 10th December, 1984.)

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. (Source: Notes of the Haemophilia Reference Centre Directors Meeting, BPL Elstree. Dated 10th December, 1984.)

In March 1985, the Expert Advisory Group on AIDS gave consideration to the idea of conducting studies on samples collected from patients without consent:

"[Deleted Name] expressed his unease at 'freezer' studies being carried out on samples collected from individuals attending STD clinics who would not necessarily have given consent for such investigations to be carried out." (Page 4, point 12) (Source: Minutes of the Expert Advisory Group on AIDS. 1st March 1985.)

Then 4 months later, in July 1985, we are appalled to read in the minutes of the Expert Advisory Group on AIDS, (page 4) that in the case of an HTLV-III (HIV) positive test result, that the emphasis of the Advisory Group was placed upon *'infection control measures'* for the benefit of the staff, whilst clearly stating that it was not for the benefit of the individual's diagnosis:

"A positive result could be serious for an individual patient and the implications of tests taken as an infection control measure for staff and not for the benefit of the individual's diagnosis and treatment should be carefully considered." (Page 4, point 7.3.3)

We also read that the Expert Advisory Group on AIDS felt that it was acceptable to conduct Hepatitis B testing without always gaining the patient's consent:

"Patient's permission for hepatitis B testing was not always sought and, with a variety of tests being taken, it should not be necessary to inform the patient in all cases that these included a test for HTLV-III antibody. It was also agreed that the result of the HTLV-III antibody test should not be awaited before undertaking other tests which might be critical in the treatment of the patient. [Deleted Name] said that with hepatitis B it was now acceptable that other tests should be done while the result of the hepatitis B test was awaited." (See page 4, line 8.) (Source: Minutes of the Fifth Meeting of the Expert Advisory Group on AIDS. 30 July 1985.)

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.

VII. KNOWINGLY WITHHOLDING HCV TEST RESULTS

We can demonstrate that one of our Mandated Members was tested by the PHLS for Hepatitis C as early as 1989. This test was carried out prior to September 1991 when donated blood started to be screened. (Source: 'Testing for Hepatitis C Virus' E A Fagan. BMJ. 1991 September 7; 303(6802): 535–536.) This Mandated Member was SECRETIVELY TESTED 3 times PRIOR to the 'compromised settlement' of the UK HIV Haemophilia Litigation. This testing was carried-out WITHOUT DISCLOSING the results to the patient. (Source: HCV Test Results Certificate: H11142. No. 01886. Virus Reference Laboratory. Colindale. Dated 11th December, 1989.)

We feel that this is enough proof that haemophiliac patients were being surreptitiously tested without their knowledge and without their informed, written consent, prior to the culmination of the HIV Litigation, where the Government's liability for any future blood-borne pathogens was propitiously excluded in the terms of the 'compromised settlement'. This was secured whilst in full knowledge that hepatitis C was likely to be a considerable problem in the future.

It is for these reasons that we ACCUSE Government and the Department of Health of THE IMMORAL AND UNLAWFUL EXCLUSION OF LIABILITY for future pathogens whilst KNOWINGLY WITHHOLDING hepatitis test results.

VII b. A 'PRIMA FACIE' CASE

The Latin legal expression *prima facie* translates as "*on its first appearance*" or "*by first instance*" and is a legal presumption used to denote evidence that is sufficient, if not rebutted, to prove a particular position or fact when based upon what seems to be the truth when first seen or heard. In most legal proceedings, one of the parties has the burden of proof, which requires that party to present *prima facie* evidence of all facts essential to its case. (Source: Wikipedia.org).

In the July 1990 Public Interest Immunity Hearing, Mr Justice Rougier, as part of his judgment said: "*As to the facts, whilst stressing that I desire to express no opinion whatever on the ultimate outcome, the documents I have read which have already been disclosed to my mind* ***are sufficient to show that the plaintiffs can raise a Prima Facie case*** *if they can surmount the initial hurdle of showing that they are in the position to sue".* (Source: Mr Justice Rougier. Public Interest Immunity Hearing. Judgment 22a. Immunity Appeal Document, Page 36, paragraph 2.)

In the HIV Haemophiliac Litigation *Immunity Appeal* document of 20th September 1990, it was stated: "*It is not in dispute that some at least of the plaintiffs have been infected by HIV by Factor VIII concentrate obtained by the NHS from the USA and supplied to those plaintiffs. The plaintiffs have set out, in my judgment, a* ***prima facie case*** *to the effect that the Department knew or should have known of the risk to the plaintiffs from the use of concentrate obtained from suppliers in the United States; that practicable steps could have been taken by the Department to eliminate or to reduce that risk; and that if those steps had been taken the injury suffered by all or some of the plaintiffs would not have been caused to them. By* ***"prima facie case"*** *I mean no more than that the plaintiffs have alleged facts, which, if proved, could justify those conclusions.*" (Source: HIV Haemophiliac Litigation. Immunity Appeal Document. Court of Appeal (Ralph Gibson and Bingham L.JJ. and Sir John Megaw). 20th September, 1990).

In September 1990, Lord Justice Gibson held that the haemophiliacs' right to proper presentation of their case overrode the right to Public Interest Immunity, and that the plaintiffs had "*a good arguable claim in law based upon common law negligence.*" Lord Justice Gibson said that it was *very likely* that the documents in question would contain material that would lend substantial weight to their claim: *"The plaintiffs need the documents for the proper presentation of their case in order for them to obtain the necessary expert evidence directed to the explanations for that failure which the documents will reveal. It seems to me to be necessary for the fair and proper disposal of the case that there should be known to both sides the actual grounds for the various decisions which led to the continued use of imported and other blood products capable of infecting a patient with HIV".* (Source: Court Of Appeal Judgement Re: HIV Haemophiliacs Litigation, Court of Appeal (Civil Division), 20th September, 1990.)

It should also be remembered that Lord Owen, in 2002, stated the following in relation to the haemophiliacs' situation: *"I have no wish to go to court, but I have no doubt whatsoever that if someone starts to take serious legal action, the Government hasn't got a leg to stand on."* (Source: James Meikle, Health Correspondent, The Guardian, Monday, August 19, 2002).

We accuse the Government and the Department of Health of THE IMMORAL AND UNLAWFUL EXCLUSION OF LIABILITY for future blood-borne pathogens, whilst KNOWINGLY WITHHOLDING HEPATITIS C TEST STATUS RESULTS and for MISLEADING the haemophilia community regarding the availability of the technology for the testing of patients and the screening of blood for hepatitis C, and whilst in full knowledge of this, bringing pressure to bear to prematurely 'settle' a *prima facie* Legal Action with a compromised and unsound legal process.

VIII. ATTEMPTING TO VANISH CRUCIAL EVIDENCE

Lord Owen said that in 1988, he had been unable to give evidence of his personal view that the source of donors was unreliable because his private office papers had "*for some inexplicable reason been pulped*". (Source: James Meikle, Health Correspondent, Guardian, Monday, August 19, 2002.) We claim that there has been a cover-up, as in September 2003, in an article by Ian Johnston in the Scotland on Sunday, (about the NHS knowing about lethal blood for 9 years), Brian Adam, SNP MSP said: *"There is certainly prima facie evidence of a cover-up. I cannot accept that the health community did not know what was going on in the light of this."* (Source: Ian Johnston on Hepatitis. Scotland on Sunday. 7th September, 2003.)

Then, a letter dated 1 December, 2005, Sir Nigel Crisp, replying to Lord Jenkin's enquiry as to why documents recently requested under the Freedom of Information Act (FOI) pertaining to contaminated blood were allegedly shredded in the early 1990s, stated that it was believed that an inexperienced member of staff may have mistakenly marked the files for destruction. (Source: Sir Nigel Crisp. Letter dated 1st December, 2005.)

In February 2006, Lord Warner, (Minister of State, Department of Health), in reference to the 600 HIV Litigation Papers stated that: *"Officials at the Department of Health have established that these documents related to the minutes and papers of the Advisory Committee on the Virological Safety of Blood between 1989 and 1992.* ***These papers were destroyed*** *between July 1994 and March 1998. A decision, most probably made by an inexperienced member of staff, was responsible for the destruction of these files."* (Source: House of Lords Written Hansard, 27 February, 2006: Column WA26)

VIII b. MISSING OR DESTROYED SIGNED 'WAIVERS'

More recently, we have reason to believe that there has been a shredding exercise as late as 2003. We have been privy to e-mails that indicate that MSPT2 (Macfarlane Special Payments Trust No. 2) files for many of our Mandated Members (which were meant to contain, amongst other documents, the signed waivers from May 1991) were still being stored within the archives of the Department of Health in 2003 when Mr Charles Lister left.

According to our sources, it is known that Mr Lister did not think that the files had been consigned to a warehouse and he seemed quite sure that the documents would still be within the DoH, as he had stated that these files were regarded as patients' records and had to be kept safely.

When several of our Mandated Members wrote to the DoH in September 2006, requesting copies of their waivers, the following reply from Mr Edward Goff was issued: *"Nevertheless, we have expended a great deal of time in an attempt to trace the applications and waivers, and although we were able to find some, it would seem that many of the applications were inadvertently destroyed. We can do no more."*

We, therefore, QUESTION whether there is a small chance that Mr Lister's successor, Mr Richard Gutowski, had ACCIDENTALLY MARKED THE FILES FOR DESTRUCTION, sometime after 2003? We know from a House of Lords Written Hansard of 15th May 2006, that the grade of official who can make an order for the shredding of documents within the Department of Health is required to be in Payband IP2, Executive Officer Grade or above. (Source: House of Lords Written Hansard, 15th May 2006, Column WA5, Ref. HL5511).

VIII c. RECOVERY OF MISSING 600 DOCUMENTS

It is of no surprise that 3 months after the release of the DOH Self-Sufficiency Report that we read that 12 big lever-arch files have turned up. In a House of Lords Hansard the following is stated: "*My Lords, the files that* ***have turned up*** *came from the archives of more than one firm of English solicitors. Given the substantial volume of documents passed to the department's solicitors - I am told that there are no fewer than 12 big lever-arch files and the fact that what they have is a small fraction of the material that has been held in solicitors' archives...*" (Source: House of Lords Hansard, 24 May 2006: Column 826)

VIII d. DELIBERATE OBFUSCATION: SELF-SUFFICIENCY

In February 2006, the Department of Health released a report into Self-Sufficiency in Blood Products in England and Wales, A Chronology from 1973 to 1991. The report came out of the opinion held by Ministers that the infection of haemophiliacs could have been avoided had the United Kingdom achieved self-sufficiency in blood products; a policy Government initiated in 1975. The destruction in the late 1980s and early 1990s of many documents relating to this issue (that were being held by the Department of Health) could have aided the accuracy and impartiality of the 2006 report into Self-Sufficiency in Blood Products. We would also assert that the review conveniently **omits important correspondence** between Government bodies in the timeframe 1973-79 and instead concentrates more on efforts to address the failings highlighted in the Medicines Inspectorate report of BPL Elstree, which, had it been a normal company, would certainly have been closed down. Due to Crown Immunity, however, the Government avoided the closure of BPL and they continued to process blood products in a condemned facility.

In an accompanying Press Statement we find that conclusions are frequently presented as facts, rather than opinions; whereas the Department of Health report itself concludes that "*The information gathered during this review has been at times contradictory and incomplete, but the following conclusions can be 'inferred'.*" (Source: Department of Health Press Statement. 'Review Published on Infected Blood Products'. Dated 27th February, 2006.)

Moreover, the report was a review **focusing upon "surviving" documents** from 1973; when a decision was made to pursue self-sufficiency for England and Wales through to 1991; when a validated screening test for hepatitis C was introduced in the UK.

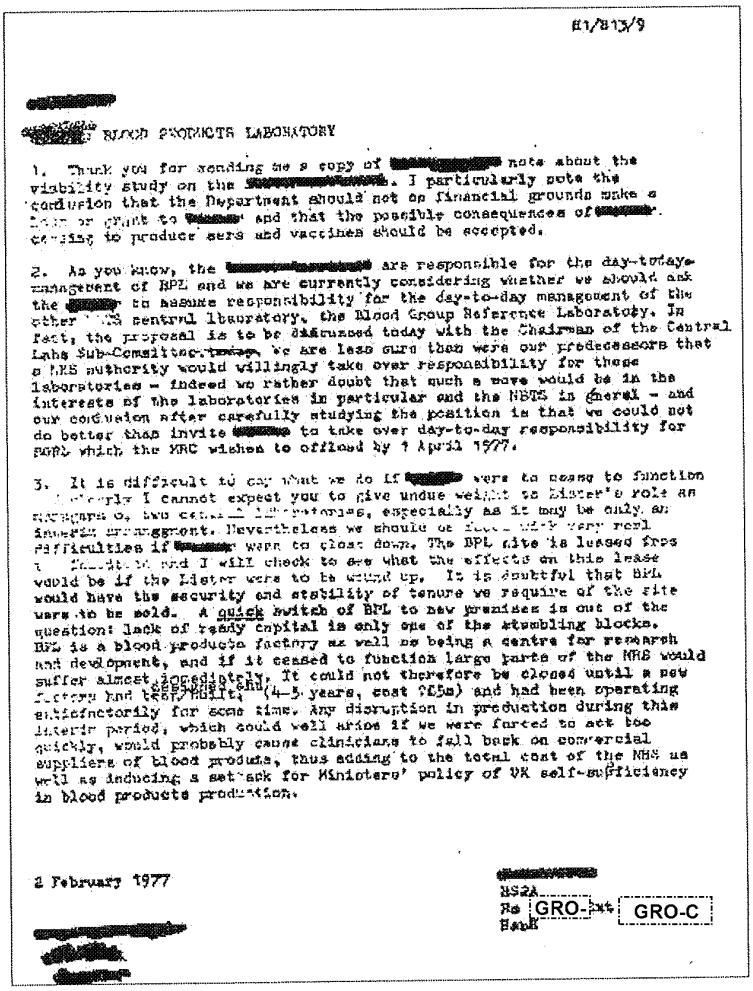
We should add further, that the Haemophilia Society condemned the DOH Self-Sufficiency Report as *"an attempt to gloss over the details of a medical disaster that left a generation of people with haemophilia infected with life-threatening viruses"*. (Source: The Haemophilia Society. Press Release. Dated 28th February, 2006.)

It is for these reasons that we ACCUSE the Government and the Department of Health of a COVER-UP and ATTEMPTING TO VANISH crucial evidence, leading to deliberate obfuscation by publishing a biased and incomplete Self-Sufficiency report.

APPENDIX

SELECTED SUPPORTING EVIDENCE

Chapter I:



B1/813/9

[redacted]

[redacted] BLOOD PRODUCTS LABORATORY

1. Thank you for sending me a copy of [redacted] note about the viability study on the [redacted]. I particularly note the conclusion that the Department should not on financial grounds make a loan or grant to [redacted] and that the possible consequences of [redacted] ceasing to produce sera and vaccines should be accepted.

2. As you know, the [redacted] are responsible for the day-to-day management of BPL and we are currently considering whether we should ask the [redacted] to assume responsibility for the day-to-day management of the other [redacted] central laboratory, the Blood Group Reference Laboratory. In fact, the proposal is to be discussed today with the Chairman of the Central Labs Sub-Committee [redacted]. We are less sure than were our predecessors that a NHS authority would willingly take over responsibility for these laboratories - indeed we rather doubt that such a move would be in the interests of the laboratories in particular and the NBTS in general - and our conclusion after carefully studying the position is that we could not do better than invite [redacted] to take over day-to-day responsibility for BPL which the MRC wishes to offload by 1 April 1977.

3. It is difficult to say what we do if [redacted] were to cease to function properly I cannot expect you to give undue weight to Lister's role as [redacted] laboratories, especially as it may be only an interim arrangement. Nevertheless we should [redacted] very real difficulties if [redacted] were to close down. The BPL site is leased from [redacted] and I will check to see what the effects on this lease would be if the Lister were to be wound up. It is doubtful that BPL would have the security and stability of tenure we require of the site were it to be sold. A quick switch of BPL to new premises is out of the question: lack of ready capital is only one of the stumbling blocks. BPL is a blood products factory as well as being a centre for research and development, and if it ceased to function large parts of the NBS would suffer almost immediately. It could not therefore be closed until a new factory had been built (4-5 years, cost £5m) and had been operating satisfactorily for some time. Any disruption in production during this interim period, which could well arise if we were forced to act too quickly, would probably cause clinicians to fall back on commercial suppliers of blood products, thus adding to the total cost of the NHS as well as inducing a setback for Ministers' policy of UK self-sufficiency in blood products production.

2 February 1977

[redacted]
HS2A
Rm [redacted] GRO-C
Hath

Recovered FOI Document. DHSS Letter Ref. Lister Institute. Dated 2nd February, 1977.

(See Point 1.)

BLOOD PRODUCTS LABORATORY

National Blood Transfusion Service

Director:
R. S. LANE, MD MRCP MRCPath.

Telephone: 01-953-6191

Dagger Lane,
Elstree,
Borehamwood,
Herts WD6 3BX.

22nd May, 1981.

[redacted]

Department of Health and Social Security,
Hannibal House,
Elephant and Castle,
LONDON, SE1 6TE.

Dear Diana,

Proposed Inspections of Regional Transfusion Centres by Medicines Inspectors.

Thank you for your letter of the 19th May, 1981. I assume from the wording that my presence at this meeting is not required in particular and I have asked [redacted] if he will represent me at this meeting and he has agreed. It is appropriate that he should fulfil this role since he bears the main brunt of raw material input at this laboratory and this will increase with time.

I am sure you are aware that the views of this laboratory and those represented by [redacted] are not in agreement and that the NBTS Regional Transfusion Directors are anxious to conform with the standards required by BPL through the use of "closed" blood and plasma collection systems. I am not impressed or confused by arguments suggesting that it is possible to fractionate contaminated plasma in open systems and produce products which are acceptable for therapeutic use within the normal regulatory definitions. I don't believe that we should be fractionating bacterial proteins which we cannot recognise or control and which conceivably can contaminate the final product without our knowing; likewise, there is inevitably an increased risk to the end product if high bacterial contamination is present in the laboratory environment, in process equipment and raw materials.

Medicines Division will have to make a choice, but I see little room for compromise since their attitude towards the aseptic practice has been vigorous in the industrial sector and should not relent with the inclusion of Crown services. [redacted] will pursue this line since this laboratory's products must have the same assurance as those issued by the Pharmaceutical industries in this country and the United States.

I doubt that any of this comes as a surprise to you.

Kindest regards,

Yours sincerely,

[redacted]

[redacted]

P.S. [redacted] informs me that he will be away for approximately two weeks from 7th July and a further two weeks during August. They may assist you in finding a date for the meeting.

Blood Products Laboratory Letter to the DHSS. Dated 22nd May, 1981.

(See paragraph 2, lines 5-7 and 11.)

SELF-SUFFICIENCY IN BLOOD AND BLOOD PRODUCTS IN THE UK

1. The case for self-sufficiency in blood and blood products which is expected to be attained when the newly built Blood Products Laboratory is processing 450 tonnes of plasma has not substantially changed since Ministers agreed it in 1981.

2. In the first place Ministers are committed to the WHO recommendation that member states should be self-sufficient. It is ethically unacceptable for developed countries to rely on blood products obtained from people in less well developed countries who may suffer from inadequate nutrition. Both these and donors elsewhere are paid for their donations and for that reason may fail to reveal adverse circumstances which would normally render their donations clinically unacceptable.

3. The case of AIDS is apposite in illustrating this dilemma. There is no test at present to screen donors for evidence of infectivity. Groups at high risk of AIDS in the USA are known to be drug abusers who need funds to support their addiction. There is evidence in both the US and the UK that Factor VIII produced in the USA has transmitted AIDS to haemophiliacs. It cannot be guaranteed that AIDS-infected volunteer donors in the UK can be excluded from giving blood, but most volunteers from high-risk groups would be likely to observe the request not to donate. Only one UK donor, whose earlier donations were used in blood product manufacture, is now known to be suffering from AIDS.

4. It should be noted that AIDS is not the only transmissable agent; hepatitis is still an important infectious hazard for recipients of blood and blood products and again emphasises the advantages of a population of volunteer donors.

5. Between 50-60 per cent of the Factor VIII required to maintain the 4,500 haemophiliacs in the UK has to be imported as BPL are currently only able to manufacture sufficient for 40 per cent of them. The cost of commercial Factor VIII is held down in the UK because of the availability of the UK product. A much higher price is charged by commerical interests in West Germany for instance. However if there is a move to market commercial heat treated Factor VIII, (as there may be if research confirms the hypothesis that the AIDS agent is heat labile) then the costs of imported Factor VIII will probably escalate in the UK.

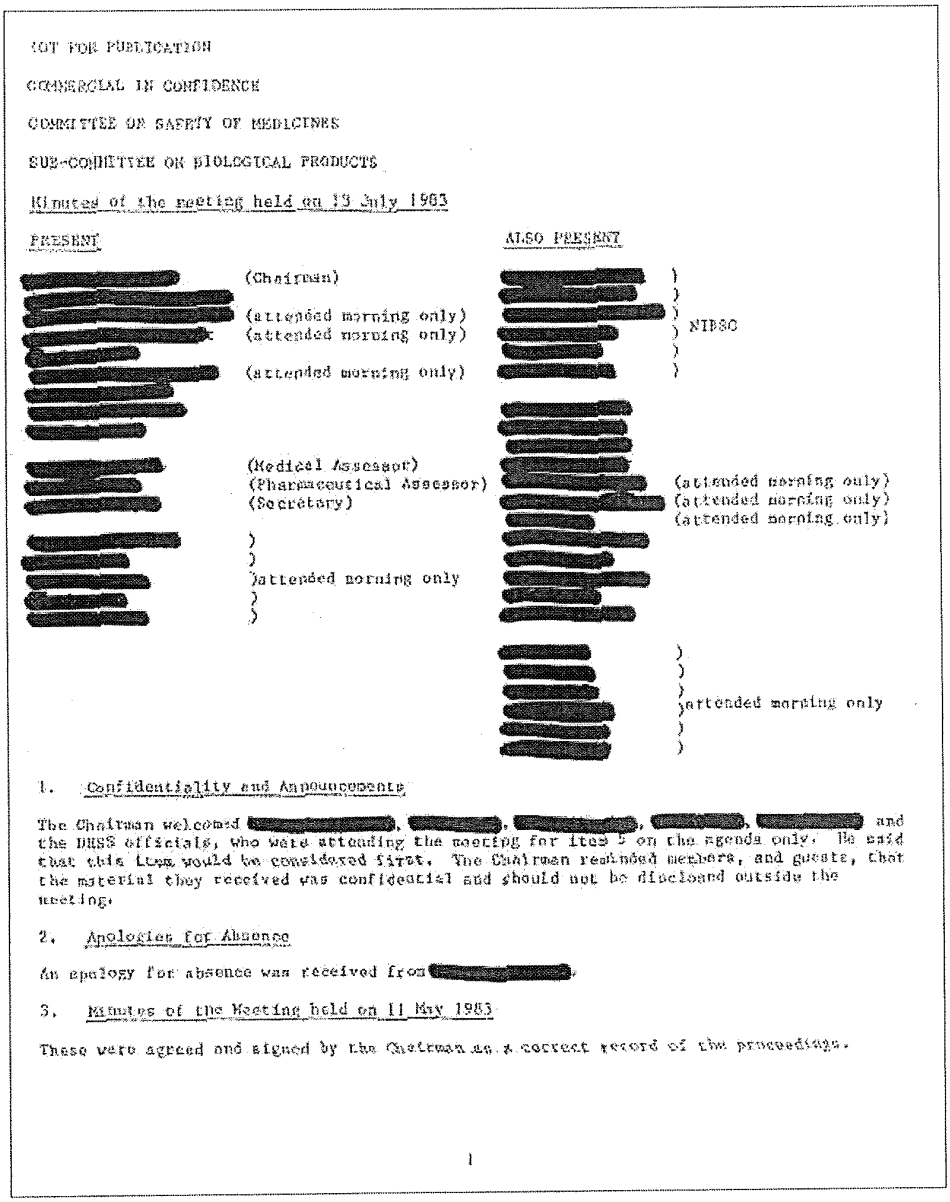
The economic argument for becoming self-sufficient in blood products is a convincing one in that a cost benefit analysis showed in 1980 that for the expenditure of £25 million, the outlay would be paid back in terms of replacement of imported commercial products within 3 years of opening the new unit. The same argument holds for an expenditure of £35 million, with reduced running costs - the break-even period is again 3 years of commencing production.

7. Ministers will be aware that Factor VIII, the most significant blood product, has been produced in the laboratory by genetic engineering methods. As far as any prediction can be authoritative in this highly complex and commercially secretive field, it is considered that it will take up to five years at least for this product to be available on a commercial scale. Even then its cost may be high compared to that obtained from human plasma. This possible development has been borne in mind and the plans for BPL are sufficiently flexible to allow the refining of such products from genetically engineering source material when available in the future.

Recovered FOI Document. Paper on Self-Sufficiency in Blood and Products. Date unconfirmed, however, the FOI Document Itinerary supplied by the DOH suggested the date of 17th January 1985.

See Point 7.

Chapter II:



NOT FOR PUBLICATION

COMMERCIAL IN CONFIDENCE

COMMITTEE ON SAFETY OF MEDICINES

SUB-COMMITTEE ON BIOLOGICAL PRODUCTS

Minutes of the meeting held on 13 July 1983

PRESENT

[redacted] (Chairman)

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] (Medical Assessor)

[redacted] (Pharmaceutical Assessor)

[redacted] (Secretary)

[redacted] attended morning only

ALSO PRESENT

[redacted] NIBSC

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] (attended morning only)

[redacted] attended morning only

1. Confidentiality and Announcements

The Chairman welcomed [redacted] and the DHSS officials, who were attending the meeting for item 5 on the agenda only. He said that this item would be considered first. The Chairman reminded members, and guests, that the material they received was confidential and should not be disclosed outside the meeting.

2. Apologies for Absence

An apology for absence was received from [redacted].

3. Minutes of the Meeting held on 11 May 1983

These were agreed and signed by the Chairman as a correct record of the proceedings.

1

CSM Sub-Committee on Biological Products, Meeting Minutes. Dated 13th July, 1983.

Page 1.

4. Matters arising from the minutes

The Sub-Committee noted the CSM's advice on applications previously seen by the Sub-Committee.

5. Acquired Immune Deficiency Syndrome

The Sub-Committees' consideration of the question of AIDS and licensed blood products was augmented by the following expert advisers:

[redacted] Professor of Haematology Welsh National School of Medicines, Cardiff and Chairman of the Haemophilia Centre Directors Committee;

[redacted], Consultant Virologist, PHLS;

[redacted], Director of the Communicable Disease Surveillance Centre PHLS;

[redacted] Director, Regional Blood Transfusion Laboratory, Manchester, DHSS Adviser in Blood Transfusion;

[redacted], Consultant Virologist, PHLS.

Consideration was given to the current information available on incidence and epidemiology, aetiology and related factors. Strategies for limiting or eliminating risks from blood products were examined, together with possible practical measures.

The following conclusions were reached:

5.1 The cause of AIDS is unknown, but an infectious aetiology seems likely. A previously unrecognised or new agent may be responsible, but repeated exposure to, or reactivation of, known agents, (eg CMV, EBV) may be involved. Heightened susceptibility may be an important factor, e.g. immunological deficiencies induced by unusual sexual practices or exposure to blood products. Based on the clinical evidence, transmissibility of the supposed agent(s) appears to be low, requiring intimate contact or introduction into the tissues.

5.2 Patients who repeatedly receive blood clotting factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small. The risk appears to be greatest in the case of products derived from the blood of homosexuals and IV drug abusers resident in areas of high incidence (eg, New York and California); and in those who repeatedly receive concentrates in high dosage. Balanced against the risks of AIDS (and of other infections transmitted by blood products) are the benefits of their use: in the case of haemophilia they are life-saving.

5.3 The possibility was considered of withdrawing clotting factor concentrates from the market and replacing them with cryo-precipitate. It was concluded that this is not feasible in the UK on grounds of supply.

5.4 The possibility was considered of withdrawing US preparations from the UK. It was concluded that this is not at present feasible on grounds of supply. Moreover, the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign suppliers of clotting factor concentrates. This should

2

CSM Sub-Committee on Biological Products, Meeting Minutes. Dated 13th July, 1983.

Page 2 (see points 5.3 and 5.4)

reduce markedly, although not eliminate, the risks to recipients of these products, and the Sub-Committee strongly supports this aim. The Sub-Committee was also informed that the UK Haemophilia Centre Directors have adopted a policy for use of US Factor VIII in order to minimise risks as far as possible.

5.5 It is advisable that all clotting-factor concentrates derived from US plasma sources and intended for use in the UK be prepared only from material manufactured from plasma collected after new regulations were introduced by the FDA on March 23rd 1983. These regulations were introduced specifically to minimise the likelihood of collecting blood from affected donors. This step is recommended notwithstanding the possibility that its practical value may be relatively small. It cannot, however, be taken until supplies of post-March 23rd material can be assured. It is recommended that close contact is maintained between the Licensing Authority and Supplies Division with the aim of introducing this step immediately it becomes feasible.

5.6 The introduction of products treated in ways likely to inactivate viruses is a promising future development. At present no such products are available in the UK but it is known that manufacturers are working upon their development. When licence applications are received it is important to examine not only possible improvement in the safety margin but also the clinical effectiveness of material treated by heat or by other means. Thus, for example, treated material could possibly induce reactions in recipients which could render them more susceptible to infectious agents.

5.7 The Sub-Committee learnt that manufacturers were producing advertising material for use in the UK which appeared to make unjustified claims concerning the safety of heat-treated Factor VIII. It is advised that this should be stopped. It is feared that unlicensed material could be used on a named-patient basis, despite the fact that its safety and effectiveness had not been established or considered by the Licensing Authority.

5.8 Hepatitis B vaccine was considered. At present there is no evidence of any risk from the material licensed in the UK, and it was concluded that the licence should remain unchanged, i.e. for use in high-risk groups only. Such groups have a clear risk of hepatitis B, which is a serious and potentially fatal disease. The position should, however, be kept under close observation. It is recommended that the manufacturer be asked to provide ongoing data relating to the safety of the product in respect of AIDS. It is understood that ARVI have recommended that the PHLS undertake surveillance of recipients of Hepatitis B vaccine, and such a study has been planned by the PHLS; the Sub-Committee supports this recommendation. The currently licensed vaccine, manufactured by MSD, has been subjected to three separate inactivation processes, and it is recommended that any new vaccines derived from human blood should be licensed only if subjected to similar stringent treatment.

5.9 Both immunoglobulins and albumins were considered. At present there is no evidence of risk from these products, and no action was though to be justified; however, the position should be kept under close observation.

5.10 Many groups, inside DHSS and outside, are professionally involved in the AIDS question. The Sub-Committee recommends that the DHSS makes sure that adequate arrangements are maintained to ensure coordination of activities between these groups. The PHLS, through its Communicable Disease Surveillance Centre is

3

CSM Sub-Committee on Biological Products, Meeting Minutes. Dated 13th July, 1983

Page 3. Agenda Point 5.8

Our Ref: MP/KS

7th October 1985

To: Haemophilia Directors, England & Wales

INFORMATION SHEET : OCTOBER 1985

DRIED FACTOR IX CONCENTRATE ; HEAT-TREATED

As from this month, a new Factor IX concentrate (type 9A) is now replacing the unheated product type IE(1). General named patient issue will begin over the next week or so. If you wish to receive a supply of Factor IX concentrate, it is essential that a list of named patients to be treated with this product be sent to Dr T Snape, Head of Quality Control, BPL, as soon as possible. In addition please telephone the Packing and Despatch Section (extension 271) with your product requirements for the first issue. Further supplies can be obtained on request either by telephone or by using the postcard enclosed with each delivery, but only to those clinicians who have submitted patient listings.

This new product, containing a nominal 600 iu per vial has been dry heated at 80°C for 72 hours to inactivate viral agents (including hepatitis and AIDS viruses) but it cannot yet be assumed to be free from viral infection. (see also enclosed data sheet).

The conditions of heating have little effect on the factor IX, II, and X content or solubility of the concentrate. Preliminary studies indicate that the in-vivo recovery and half-disappearance time from the circulation of factor IX activity are unaffected.

A study of factor IX infusions into dogs (using this product) in doses of 100 units per kg indicate that there is no risk of disseminated intravascular coagulation.

Clinical trials at specified Haemophilia Centres are now in progress to gain evidence of reduction or elimination of viral transmission, particularly NANBH virus transmission. Further assurance is sought over freedom from risk of viral transmission. If you have under your care, suitable patients who would be able to participate in a clinical trial, the enclosed protocol should be used only for this purpose. (Please see the enclosure for further information on its use).

In accordance with the regulatory requirements, the product should be issued by clinicians on a named patient basis until a product licence has been granted. It is expected that output of the 9A concentrate from the date of first issue will entirely meet the demand for heated factor IX concentrates (for use in the treatment of patients with congenital deficiency).

For any further information, please contact:

Product Services Department, BPL.
01-953-6191 x 200.

F9//10/85

Letter from BPL Product Services Department to Haemophilia Centre Directors. Dated 7 October 1985.
See paragraph 2, beginning 'This new product' and see Paragraph 5, beginning "Clinical trials".

Letter Ref. "Virgin Haemophiliacs":

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE
Headquarters Unit
Ellen's Glen Road
Edinburgh EH17 7QT
031-664 2317

JDC/EP/RH

17th February 1984

[redacted]
Department of Haematology
University Hospital of Wales
Heath Park
[redacted]

Dear [redacted]

A note to confirm our conversation last Friday at NIBSC.

We hope to have sufficient wet heat treated factor VIII for limited clinical studies by September 1984. We are particularly keen to see part of this product is put into "virgin haemophiliacs" and would much appreciate the assistance of the U.K. Haemophilia Centre Director's Working Party on Hepatitis.

For your interest I enclose the analytical profile of the last batch of this product.

Kindest regards.

Yours sincerely

[redacted]

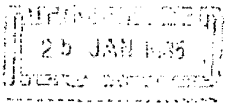
Enc

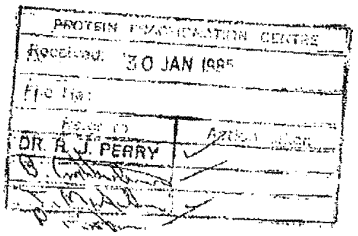
Letter from Scottish National Blood Transfusion Service to Cardiff Haematology Department. Dated 17th February 1984.

Notes of the Haemophilia Reference
Centre Directors Meeting, Blood Products
Laboratory, Elstree 10/12/84

Present:

Prof. A Bloom (Chairman)
Dr R S Lane (BPL)
Dr T Snape (BPL)
Dr M J Harvey (BPL)
Mr P Prince (BPL)
Mr N Pettet (BPL)
Dr J K Smith (BPL)
Dr P Kernoff
Dr P Jones
Dr C Ludlam
Dr F Preston
Dr E Mayne
Dr H Gunson
Dr A Smithies (DHSS)
Dr J Cash
Dr I Delamore
Dr P Mortimer (PHLS)
Dr J Craske
Dr C Forbes
Dr C Rizza
Dr G Savage
Dr R Tedder (Middx Hosp.)
Dr I Temperley





Agenda

In addition to the previously circulated agenda, an aide-memoir was tabled by the Chairman. This covered several points for discussion at the meeting.

Item 1 Introduction to the meeting

The Chairman outlined that the resulting publicity surrounding the events in Newcastle and Australia, and the continuing work on HTLV III, has precipitated todays meeting.

Item 2 (i) HTLV III antibody screening

Dr Tedder reviewed the current situation by saying that the Gallo cell line was available for investigation although the USA had made the isolates difficult to obtain. The British isolate required an organisation to handle the bulk virus culture: Porton (PHLS) and Wellcome are the only ones

Recovered FOI Document. Notes of the Haemophilia Reference Centre Directors Meeting. 10 December 1984.
Page 1.

Spiking of Factor VIII with Live Antigen:

The alternatives to dry heat, ie heat in solution or virus inactivation by detergent offered additional prospects for a safer product.

Dr Smith stated that the priority had been given to Factor VIII, although Factor IX was capable of being heat treated. However the problem of potential thrombogenicity was causefor concern and no HT-Factor IX would be issued even for clinical trial before animal experiments had confirmed safety.

The present stock of Factor VIII is being considered for heat treatment. Not all batches were suitable and these would remain available as non HT product.

Current work is directed to making available limited supplies of a heat treated product to April 1985, when it is expected that all batches will be heat-treated. A new product of higher Specific Activity is already being prepared which will withstand more severe heat-treatments and other treatments designed to inactivate hepatitis viruses as well as HTLV III.

Dr Lane remarked that in order to determine the effectiveness of the heat-treatment, spiking of Factor VIII with antigen was required prior to heating. The present methods used by the NHS and commercial companies may still leave an active antigen. BPL would therefore be looking for follow-up studies during 1985 with Haemophilia Centre support.

Dr Lane advised that HT material in large quantities could not be available before April as equipment had to be ordered. These had now been placed for all the required plant.

The Chairman commented that "CDC type evidence" for BPL HT batches was important. BPL would need to obtain this evidence in support of their marketing of the product. It was accepted that with limited trial facilities available, the NHS producers were in competition with commercials for trial studies.

Dr Lane advised that it was too soon to be precise on the yield losses involved, with heat treatment. Users should not assume that the higher purity product meant a higher loss yield. Observed losses so far for the standard heat-treated product were similar to those found by commercials.

Dr Craske in response to Dr Lane, advised that it was too soon to know whether the Aids implicated batch of NHS Factor VIII had caused seroconversion.

Recovered FOI Document. Notes of the Haemophilia Reference Centre Directors Meeting. 10 December 1984.

Page 8. See paragraph 5: "Dr Lane remarked".

MEETING OF THE HAEMOPHILIA REFERENCE CENTRE DIRECTORS - 10 DECEMBER 1984

1. Background

So far three patients with haemophilia are known to have contracted AIDS, two of these have died. About twenty four other cases are known to have persistent generalised lymphadenopathy (PGL). Some eight hundred haemophiliac patients have now been tested for HTLV III antibody. The incidence of antibody to HTLV III in haemophiliac patients overall is of the order of thirty five per cent. However seventy five per cent of patients with severe haemophilia have the antibody. Of four thousand haemophiliac patients some two thousand can be considered to be severe the remainder being moderate and mild cases.

2. As you know I was invited to the above meeting held at CBLA headquarters and arranged to discuss the implications of AIDS for haemophilia patients. We can expect a letter from the Directors to the Department with a statement of their policy decisions. A letter will also be sent to all Haemophilia Centre Directors advising of the decisions taken by the Reference Centre Directors. The following main issues were discussed:

a. Testing haemophiliac patients for HTLV III antibody

Directors would like to test all haemophiliac patients in order to establish their antibody status. [redacted] thought that provided they were not overwhelmed by all specimens at once they could test most of these patients. They would need additional resources to do this.

Inconsistencies in the results of the tests reveal that a study of the haemophiliac population would provide the invaluable material to increase our knowledge of the disease. [redacted] has developed the same test as [redacted] using the Gallo isolate obtained with his permission through Professor Weiss. 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. However I was told that little support has been given to the relevant section of the Virus Reference Laboratory while working on a shoe string. It may be appropriate to ask PHLS to treat testing as a priority.

b. Dealing with haemophiliac patients

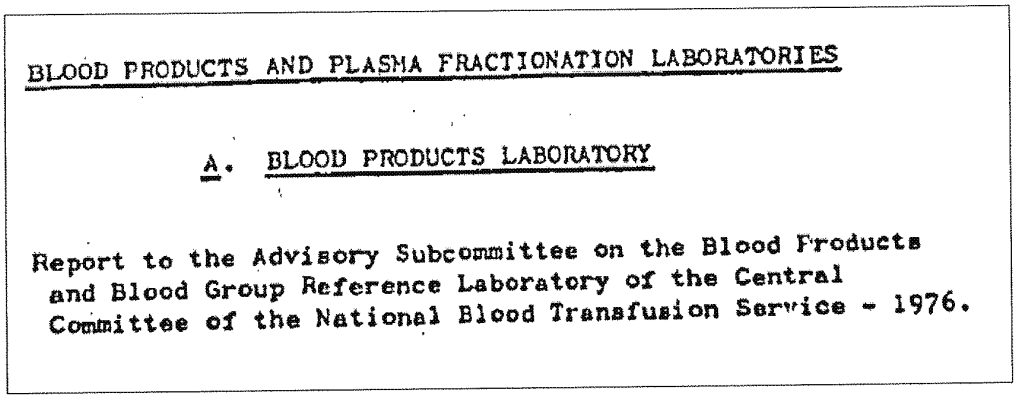
It was agreed that all haemophiliac patients should be counselled to use barrier methods of contraception in order to protect their heterosexual contact. Patients who asked for their HTLV III antibody test results should be informed of them otherwise it is up to individual Directors to decide whether or not they wish to tell the patients their results.

1

Meeting of the Haemophilia Reference Centre Directors. 10 December 1984.

See Point 2a, paragraph 2. "Testing haemophiliac patients"

Chapter III: School Trial - Lord Mayor Treloar



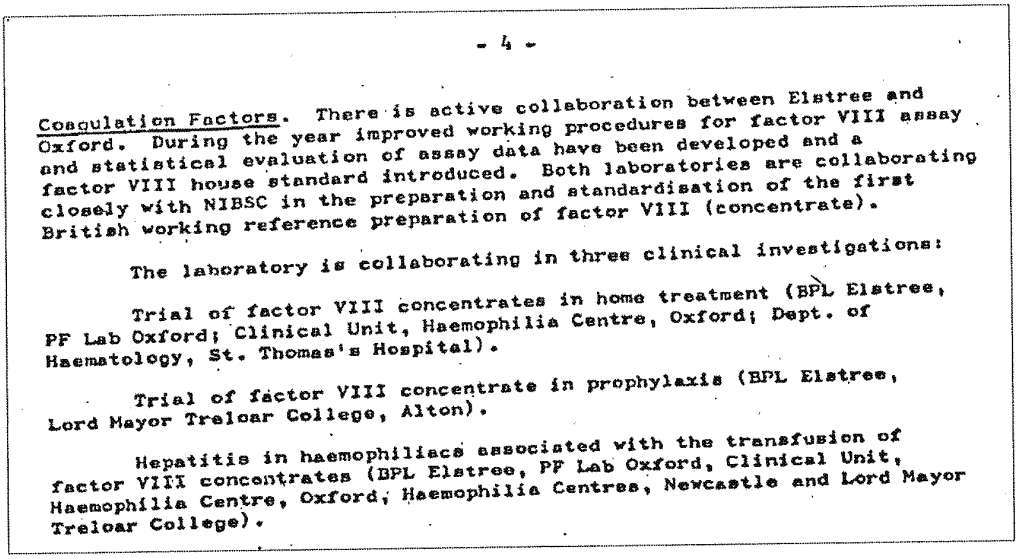
BLOOD PRODUCTS AND PLASMA FRACTIONATION LABORATORIES

A. BLOOD PRODUCTS LABORATORY

Report to the Advisory Subcommittee on the Blood Products and Blood Group Reference Laboratory of the Central Committee of the National Blood Transfusion Service - 1976.

Recovered FOI Document. Blood Products and Plasma Fractionation Labs 1976. Collaborative Trials.

Page 1. Letter Heading.



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Coagulation Factors. There is active collaboration between Elstree and Oxford. During the year improved working procedures for factor VIII assay and statistical evaluation of assay data have been developed and a factor VIII house standard introduced. Both laboratories are collaborating closely with NIBSC in the preparation and standardisation of the first British working reference preparation of factor VIII (concentrate).

The laboratory is collaborating in three clinical investigations:

Trial of factor VIII concentrates in home treatment (BPL Elstree, PF Lab Oxford; Clinical Unit, Haemophilia Centre, Oxford; Dept. of Haematology, St. Thomas's Hospital).

Trial of factor VIII concentrate in prophylaxis (BPL Elstree, Lord Mayor Treloar College, Alton).

Hepatitis in haemophiliacs associated with the transfusion of factor VIII concentrates (BPL Elstree, PF Lab Oxford, Clinical Unit, Haemophilia Centre, Oxford, Haemophilia Centres, Newcastle and Lord Mayor Treloar College).

Recovered FOI Document. Blood Products and Plasma Fractionation Labs 1976. Collaborative Trials.

Page 4.

HAMPSHIRE AREA HEALTH AUTHORITY (TEACHING)
NORTH HAMPSHIRE HEALTH DISTRICT

Director:
A. ARONSTAM, M.B., M.R.C.Path.
Basingstoke 3202 Ext. 0256
GRO-C

TRELOAR HAEMOPHILIA CENTRE
LORD MAYOR TRELOAR HOSPITAL
ALTON
Telephone No. 82811 Ext. 253 & 211

14th May 1979.

[redacted]
Public Health Laboratory.
Withington Hospital,
MANCHESTER M20 8LR

Dear [redacted]

We have not had any cases of hepatitis following N.H.S. Factor VIII. As far as your suggestion about transfusing mild haemophiliacs with this material is concerned, I totally disagree with this concept. I do not wish any of my mild haemophiliacs to develop hepatitis in any form and therefore adopt the policy of either using D.D.A.V.P. or Cryoprecipitate.

Yours sincerely,

[redacted]

Letter to PHLS from Lord Mayor Treloar Hospital. Dated 14th May 1979.

Oxford 'Chimpanzee' Letter:

OXFORDSHIRE HEALTH AUTHORITY

OXFORD HAEMOPHILIA CENTRE

575

Churchill Hospital,
Headington,
Oxford OX3 7LJ.

11th January, 1982

To all Haemophilia Centre Directors

Dear Colleague,

You are no doubt aware that at least 4 commercial companies are about to introduce preparations of factor VIII and possibly factor IX that have been processed in an attempt to reduce the risk of transmitting hepatitis B and non-A non-B. As far as we know the products have been subjected to a heat treatment process such as pasteurisation after removal of the bulk of fibrinogen but other methods such as treatment with B-propiolactone and UV light or differential adsorption-elution may be used. Although initial production batches may have been tested for infectivity by injecting them into chimpanzees it is unlikely that the manufacturers will be able to guarantee this form of quality control for all future batches. It is therefore very important to find out by studies in human beings to what extent the infectivity of the various concentrates has been reduced. The most clear cut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large pool concentrates. Those patients are few in number but a study along those lines is being carried out at Oxford to determine the infectivity of factor VIII concentrates produced by the Plasma Fractionation Laboratory, Oxford and Blood Products Laboratory, Elstree. This study shows that it is possible to demonstrate infectivity using quite small numbers of previously untreated patients. It is very important also to find out as soon as possible whether the manufacturing methods used to reduce the hepatitis risk has resulted in a product with undesirable characteristics such as high content of denatured protein, reduced factor VIII recovery in vivo, reduced factor VIII ½-life in vivo, increased incidence of factor VIII antibodies or of immune complex disease.

Although there is no doubt that the introduction of 'hepatitis-safe' products would constitute a major advance we hope you will agree with us that their use on a 'named patient' basis would be undesirable and might seriously hinder controlled studies in the future. There are several reasons for thinking this:-

1. The best way of assessing efficiency and observing recovery of activity, side effects etc., is by properly conducted clinical studies. Since a number of products are likely to be introduced in the next few months a core of 'at risk' patients will be needed for this assessment. It is for the treatment of such patients that producers will make their products available. If patients at risk are treated on a 'named patient' basis they will be unavailable for clinical trials and the results will be of anecdotal value only.

Bloom AL, Rizza CR. Letter to all Haemophilia Centre Directors. 11 January 1982.

Page 1. (See lines 8-15 and 18-20.)

Oxford 'Chimpanzee' Letter: (Cont.)

2. For the purposes of a Product Licence the manufacturers are required to set out to the Regulatory Authority in the U.K. the evidence of product efficacy and safety and details of processing, batch to batch reproducibility toxicity tests etc., which help to ensure quality control. In addition there would be a requirement for samples of each batch or batch protocol to be submitted if requested to the Regulatory Authority for assessment at NIBSC. Manufacturers could be liable if subsequent batches failed to meet the original product protocols and import of such products could be prohibited. Although it will not be possible for the Regulatory Authority to check infectivity of batches as an ongoing control, measurement of total protein, clottable protein, factor VIII antigens and activity ratio etc., will help to ensure that the materials have been properly processed. Even if factor VIII concentrates are subjected to similar pasteurization processes as those used to sterilise albumin and other simple plasma protein fractions they may not withstand denaturation to the same extent. Formal trial of efficacy and on-going monitoring of quality control is thus important.

3. Use of a product on a 'named patient' basis is often justifiable but by-passes these regulatory controls which have been established in the interests of patients.

We are therefore writing to let you know that the Hepatitis Working Party are discussing plans for Clinical Trials of these products as they become available and will if necessary request exemption from a clinical trials certificate in respect of individual products in order to expedite trials. We hope that the companies concerned will collaborate in these trials and will offer appropriate supplies of their concentrate as well as financial support.

Unfortunately there is insufficient time available to air these problems at the next meeting of the Haemophilia Centre Directors but if you have any observations we would be most grateful to learn of them as soon as possible.

With all best wishes,

Yours sincerely,

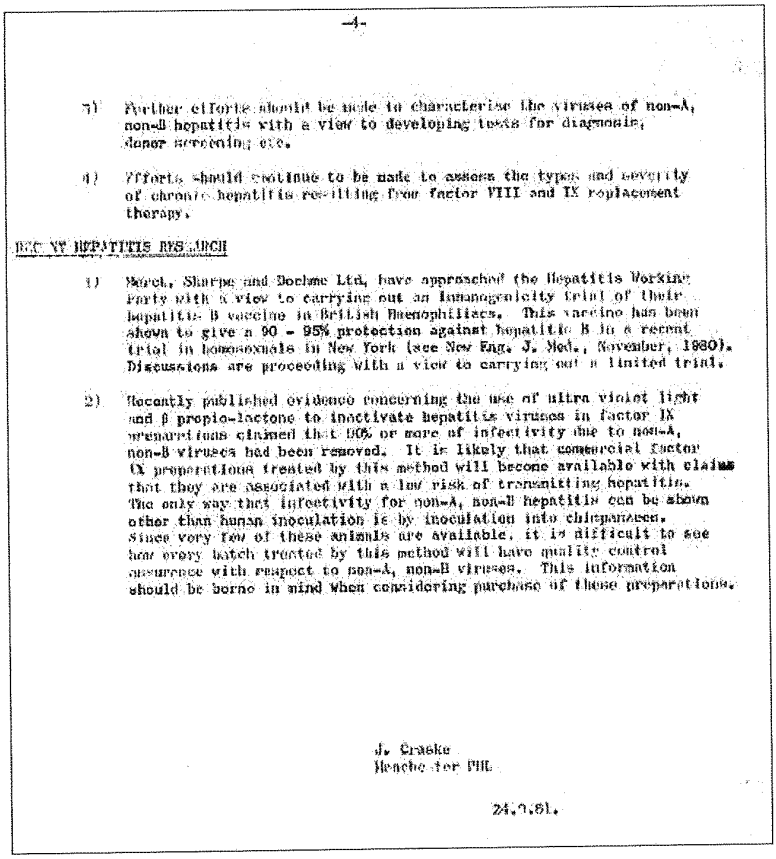
GRO-C GRO-C

A.L. Bloom C.R. Rizza

Bloom AL, Rizza CR. Letter to all Haemophilia Centre Directors. 11 January 1982.

Page 2. (See point 2. Lines 7-11 and lines 16-17)

Chimpanzees - Few Animals Available:



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7) Further efforts should be made to characterise the viruses of non-A, non-B hepatitis with a view to developing tests for diagnosis, donor screening etc.

8) Efforts should continue to be made to assess the types and severity of chronic hepatitis resulting from factor VIII and IX replacement therapy.

NEW VT HEPATITIS RESEARCH

1) Merck, Sharpe and Dohme Ltd, have approached the Hepatitis Working Party with a view to carrying out an immunogenicity trial of their hepatitis B vaccine in British Haemophiliacs. This vaccine has been shown to give a 90 - 95% protection against hepatitis B in a recent trial in homosexuals in New York (see New Eng. J. Med., November, 1980). Discussions are proceeding with a view to carrying out a limited trial.

2) Recently published evidence concerning the use of ultra violet light and β propio-lactone to inactivate hepatitis viruses in factor IX preparations claimed that 90% or more of infectivity due to non-A, non-B viruses had been removed. It is likely that commercial factor IX preparations treated by this method will become available with claims that they are associated with a low risk of transmitting hepatitis. The only way that infectivity for non-A, non-B hepatitis can be shown other than human inoculation is by inoculation into chimpanzees. Since very few of these animals are 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. This information should be borne in mind when considering purchase of these preparations.

J. Craske
Member for PHL

24.9.81.

Dr Craske. UK Haemophilia Centre Directors' Hepatitis Working Party, Minutes. 24th September 1981.

(See point 2, line 7).

Chapter IV:

Prifysgol Cymru
University of Wales

Ysgol Feddygol Cymru
Welsh National School of Medicine

Department of Haematology
University Hospital of Wales
Heath Park, Cardiff CF4 4XN
Tel. Cardiff 755944
Ext. 2155

Strictly Confidential

Professor A. L. Bloom

Dr. F.E. Bolton,
Deputy Director,
Regional Blood Transfusion Service,
Royal Infirmary,
Edinburgh EH3 9 HB

23rd May, 1983

Dear Frank,

Many thanks for your letter and for your suggestions about AIDS. This question has been discussed several times amongst those concerned with haemophilia treatment and was the subject of a special meeting of the Haemophilia Reference Centre Directors recently. Most of the recommendations which you suggest have in fact been incorporated by the Haemophilia Reference Centre Directors. We have not laid down hard and fast regulations since the date of treatment will depend upon local circumstances. I do not think that anyone is complacent about the situation but I think that we all agree that it would be counter-productive to ban the importation of blood products at this moment. We are however taking steps to recommend that imported products from the U.S.A. at least meet with the new F.D.A. regulations. Your comments about the use of cryoprecipitate and N.H.S. factor VIII concentrate have been incorporated into our advice although at the moment we are not rigidly differentiating between cryoprecipitate and N.H.S. concentrate as far as severely affected patients are concerned at any rate. I think that this is implied in your recommendation number 2. With regard to determs of home treatment for new patients this is a matter for further discussion. The Haemophilia Society have expressed concern that we are not expanding the home treatment programme with sufficient vigour and this whole question will no doubt be on the agenda of the next Reference Centre and Haemophilia Centre Director's meeting. No doubt you are already aware of the recommendations made at the recent meeting of the Blood Transfusion Centre Directors.

With all best wishes,

Yours sincerely,

A.L. Bloom

c.c. Dr. C.R. Rizza

Letter, Professor A L Bloom writing to Dr F. E. Bolton. Dated 23rd May 1983.

(See lines 6-9.)

PAPER II

ACTION ALREADY TAKEN BY RELEVANT AUTHORITIES OUTSIDE THE DEPARTMENT

1. Action by Regional Transfusion Directors

At their meeting on 18 May the Regional Transfusion Directors agreed to prepare an information leaflet on AIDS which would be available to donors to read at donor sessions and could be sent to donors phoning in with enquiries. (Directors asked if the Department would pay for the printing of such a leaflet and this has been agreed with Information Division. A draft has been circulated for comment).

The Directors further proposed to make an approach to the Medical Gay Society (an association of homosexual doctors) to enlist their help in the dissemination of information on AIDS to homosexual groups. The Society's initial reaction has been favourable.

Directors were adamant that there would be no direct questioning of donors about their sexual habits nor about the presence of symptoms such as night sweats, weight loss etc.

2. Recommendations of Haemophilia Reference Centre Directors

At their meeting on 13 May 1983, the Haemophilia Reference Centre Directors agreed that on the evidence available and because of the benefits of treatment, no restriction should be placed on the use of imported Factor VIII concentrate other than to continue with the present policy of using only NHS material for children under the age of 4 years and for mild haemophiliacs.

3. New Regulations on Donor Screening by the Food and Drugs Administration (FDA) in the USA

As from 23 March 1983, FDA regulations have required that:

i. Educational programmes be instituted for potential donors from defined high risk groups asking that they refrain from donation. (High risk groups are defined as: persons with symptoms and signs suggestive of AIDS; sexually active homosexual or bisexual men with multiple partners; Haitian immigrants, intravenous drug abusers and sexual partners of individuals at increased risk of AIDS).

ii. All plasma donors to receive information on AIDS.

iii. Plasma taken from a donor in a high-risk group should be labelled to indicate that it should only be used in the preparation of albumin, PPF, globulin or for non-injectable products. (NB: the use of such plasma for albumin, PPF etc production is extremely dubious. If an infectious agent is involved, there is no means of knowing that the heat treatment, to which these products are subjected, will inactivate it - DW).

iv. The donor's medical history should include specific questions designed to detect possible AIDS symptoms eg night sweats, unexpected weight loss etc.

Recovered FOI Document - AIDS Background Paper II. Dated 31st May 1983.

Point 2.

[redacted]

ACTION ON AIDS

I refer to a letter to you from [redacted] of CDSC on 9 May (of which I was shown a copy) recommending that American FVIII concentrate should be withdrawn from use because of the risk of transmitting AIDS.

In my view this suggestion is premature in relation to the evidence and unbalanced in that it does not take into account the risks to haemophiliacs of withdrawing a major source of their FVIII supplies.

Perhaps the situation is best put in perspective by a statement which was drafted to appear in the minutes of the meeting of the Directors of Haemophilia Reference Centres which I attended today:

> "Many Directors have until now restricted their use of FVIII in young children (under the age of 5 years) and in mild haemophiliacs to NHS materials and we consider that it would be circumspect to continue with that policy.
>
> There is not sufficient evidence to restrict the use of imported FVIII concentrates in other patients in view of the benefits of the treatment but the situation will be kept continuously under review by means of a surveillance system which has been instituted and by means of regular meetings of the Reference Centre Directors.
>
> The Directors welcome the fact that the Regional Transfusion Directors would be meeting to consider steps which could be taken to avoid bleeding donors who might be in a category thought capable of transmitting AIDS." (NB: this statement is not for publication until the minutes have been formally circulated; the wording may not be precisely that of the final form.)

With regard to the Working Party on AIDS which [redacted] has proposed, I suggest that Prof. [redacted] also be invited to represent haemophilia centre directors.

[redacted]
MED SEB
Room GRO-C HAITH
Ext GRO-C

13 May 1983

cc [redacted]

Recovered FOI Document. DHSS Letter. Med SEB. 'Action on Aids'. Dated 13th May 1983.

Paragraphs 1 & 2.

4. Matters arising from the minutes

The Sub-Committee noted the CSM's advice on applications previously seen by the Sub-Committee.

5. Acquired Immune Deficiency Syndrome

The Sub-Committees' consideration of the question of AIDS and licensed blood products was augmented by the following expert advisers:

[redacted], Professor of Haematology Welsh National School of Medicine, Cardiff and Chairman of the Haemophilia Centre Directors Committee;

[redacted], Consultant Virologist, PHLS;

[redacted], Director of the Communicable Disease Surveillance Centre PHLS;

[redacted], Director, Regional Blood Transfusion Laboratory, Manchester, DHSS Adviser in Blood Transfusion;

[redacted], Consultant Virologist, PHLS.

Consideration was given to the current information available on incidence and epidemiology, aetiology and related factors. Strategies for limiting or eliminating risks from blood products were examined, together with possible practical measures.

The following conclusions were reached:

5.1 The cause of AIDS is unknown, but an infectious aetiology seems likely. A previously unrecognised or new agent may be responsible, but repeated exposure to, or reactivation of, known agents, (eg CMV, EBV) may be involved. Heightened susceptibility may be an important factor, e.g. immunological deficiencies induced by unusual sexual practices or exposure to blood products. Based on the clinical evidence, transmissibility of the supposed agent(s) appears to be low, requiring intimate contact or introduction into the tissues.

5.2 Patients who repeatedly receive blood clotting factor concentrates appear to be at risk, but the evidence so far available suggests that this risk is small. The risk appears to be greatest in the case of products derived from the blood of homosexuals and IV drug abusers resident in areas of high incidence (eg, New York and California), and in those who repeatedly receive concentrates in high dosage. Balanced against the risks of AIDS (and of other infections transmitted by blood products) are the benefits of their use; in the case of haemophilia they are life-saving.

5.3 The possibility was considered of withdrawing clotting factor concentrates from the market and replacing them with cryo-precipitate. It was concluded that this is not feasible in the UK on grounds of supply.

5.4 The possibility was considered of withdrawing US preparations from the UK. It was concluded that this is not at present feasible on grounds of supply. Moreover, the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign suppliers of clotting factor concentrates. This should

2

CSM Sub-Committee on Biological Products, Meeting Minutes. Dated 13th July, 1983.

Page 2. (See Agenda Points 5.3 and 5.4)

NATIONAL BLOOD TRANSFUSION SERVICE

NORTH LONDON BLOOD TRANSFUSION CENTRE
OEANSBROOK ROAD
EDGWARE, MIDDX
HA8 9BD
Telephone: 01-952 5511

Dr. M. CONTRERAS
Director

29th October 1985.

[redacted]
Department of Health and
Social Security,
Hannibal House,
Elephant and Castle,
London SE1 6TE.

[redacted]

Dear [redacted]

Thank you for your letter of 25th October.

Fortunately for us, we were able to start anti-HTLV-III screening unofficially from the 23rd September 1985. Since we rarely have the luxury of too much blood gathering dust in the 'fridge and since our supplies of fresh frozen plasma get snapped up very quickly our only stored material is cryoprecipitate. We have been storing serum samples from donors for several months now and we are going through the records of our cryoprecipitate stocks to check which stored donors samples correspond to the stocked material. In addition we will be able to test those cryoprecipitate donors who return to give further donations so this problem is in hand.

Naturally we cannot comment on quarantined stocks of pooled plasma for fractionation at Elstree but assume that the heat inactivation will cover that aspect.

Yours sincerely,

[redacted]

Recovered FOI Document. NBTS Letter to DHSS. Dated 29th October 1985.

(See final paragraph.)

IN CONFIDENCE

HEAT TREATED FACTOR VIII

CMO will wish to know that there is some hearsay evidence that haemophiliac patients are seroconverting to become anti HTLV III positive despite being given heat treated Factor VIII.

This could be because:-

1. They have seroconverted some months after having received a non-treated product (the use of heat treated Factor VIII only became common at the beginning of 1985)

2. Certain heat treated products are not being subjected to sufficient inactivation. There is considerable variation between the methods used by the commercial firms and in particular the Protein Fractionation Laboratory in Liberton in Scotland introduced on a short term basis a very quick method which they thought might inactivate the virus, at the beginning of this year. I believe that it is this latter which may be implicated in the information I have received.

   The Blood Products Laboratory at Elstree were rather late starters in heat treating their Factor VIII but are probably now producing the safest product in the world. There is good evidence that the prolonged and high temperature treatment,
   is inactivating the non-A non-B agent. It has been apparent for some time that commercial heat treated Factor VIII does not inactivate this agent.

Whether or not the heat treated product is transmitting HTLV III will take some time to disentangle. We have scrupulously observed in all our answers to POs that heat treatment should inactivate HTLV III. This note is just to emphasise the need for continuing to do so.

[redacted]

28 November 1985

[redacted]
Room 102/a Hannibal House
Ext GRO-C

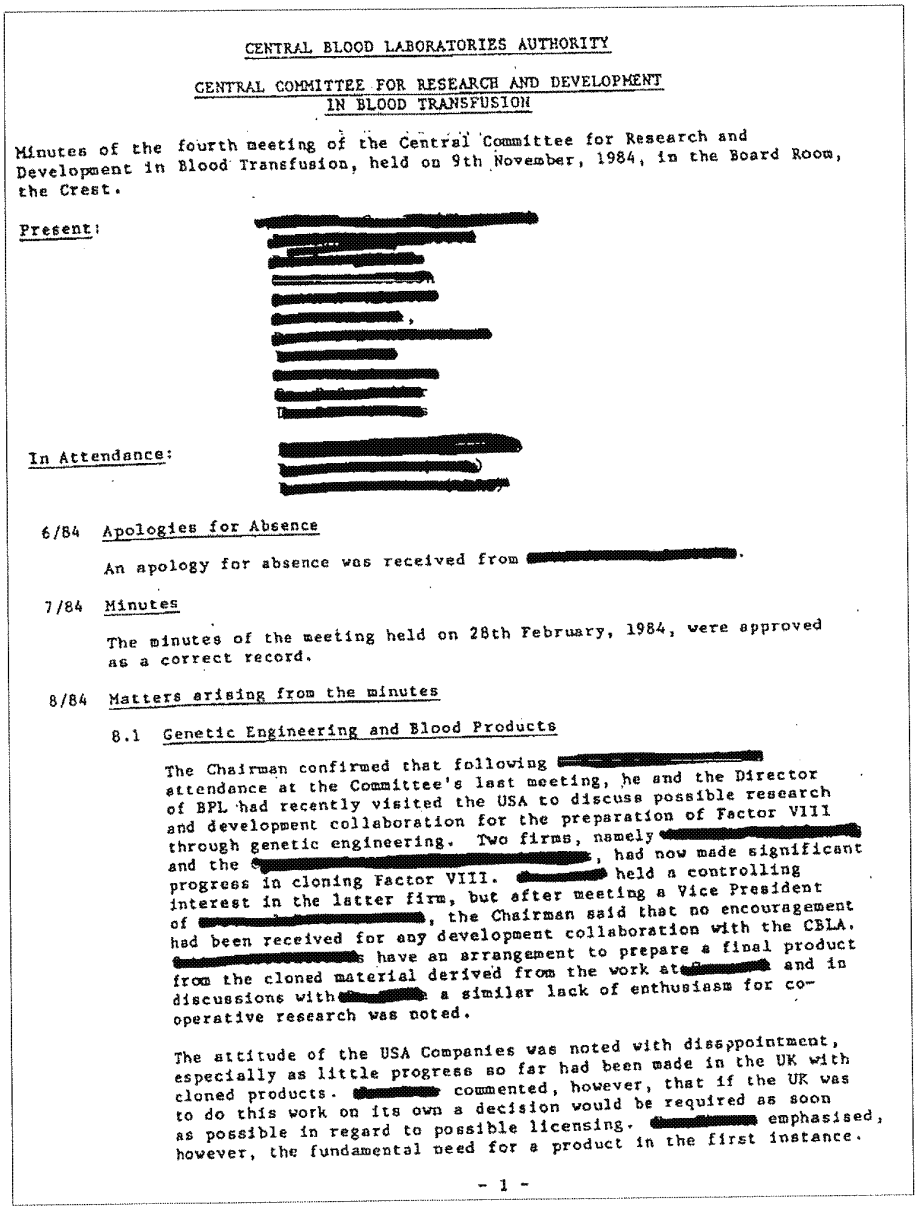
cc

[redacted]

Recovered FOI Document. Letter DHSS Ref. Heat-Treated FVIII. Hannibal House. Dated 28th November, 1985.

(See points 1 and 2 and paragraph 2 of point 2.)

Chapter V:



CENTRAL BLOOD LABORATORIES AUTHORITY

CENTRAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN BLOOD TRANSFUSION

Minutes of the fourth meeting of the Central Committee for Research and Development in Blood Transfusion, held on 9th November, 1984, in the Board Room, the Crest.

Present: [redacted]

In Attendance: [redacted]

6/84 Apologies for Absence

An apology for absence was received from [redacted].

7/84 Minutes

The minutes of the meeting held on 28th February, 1984, were approved as a correct record.

8/84 Matters arising from the minutes

8.1 Genetic Engineering and Blood Products

The Chairman confirmed that following [redacted] attendance at the Committee's last meeting, he and the Director of BPL had recently visited the USA to discuss possible research and development collaboration for the preparation of Factor VIII through genetic engineering. Two firms, namely [redacted] and the [redacted], had now made significant progress in cloning Factor VIII. [redacted] held a controlling interest in the latter firm, but after meeting a Vice President of [redacted], the Chairman said that no encouragement had been received for any development collaboration with the CBLA. [redacted] have an arrangement to prepare a final product from the cloned material derived from the work at [redacted] and in discussions with [redacted] a similar lack of enthusiasm for co-operative research was noted.

The attitude of the USA Companies was noted with disappointment, especially as little progress so far had been made in the UK with cloned products. [redacted] commented, however, that if the UK was to do this work on its own a decision would be required as soon as possible in regard to possible licensing. [redacted] emphasised, however, the fundamental need for a product in the first instance.

- 1 -

CBLA Minutes for the fourth meeting of the Central Committee for Research and Development in Blood Transfusion. Dated 9th November, 1984.

(See point 8.1)

7th SEPTEMBER 2004
VCJD IMPLICATED BATCH NUMBERS

Table 1: Products where the likelihood of a recipient surpassing the threshold dose for public heath purposes is HIGH[1,2],
THESE BATCHES SHOULD BE TRACED. THE INDIVIDUAL RECIPIENTS CONSIDERED 'AT-RISK' OF VCJD FOR PUBLIC HEALTH PURPOSES, AND SPECIAL PUBLIC HEALTH PRECAUTIONS TAKEN

Factor VIII				Factor IX				Antithrombin			
Brand name	Vial Size [IU]	Batch Number	Release date	Brand name	Vial Size [IU]	Batch Number	Release date	Brand name	Vial Size [IU]	Batch Number	Release Date
8Y	500	FHB4116	26.06.92	9A	600	FJ40092	24.05.90	Antithrombin*	500	ATA4535*	20.12.96
8Y	500	FHB4189	14.04.93	9A	600	FJ44139B	08.07.93				
8Y*	500	FHB4419*	21.07.95	9A	600	FJ44308	18.06.94				
8Y*	500	FHB4547*	01.11.96								
8Y*	500	FHB4596*	06.05.97	Replenine	500	FJM4327	10.10.94				
				Replenine	500	FJM4437	27.11.95				
3Y	250	FHC0083	13.05.90	Replenine*	500	FJM4596*	23.04.97				
3Y	250	FHC0263	18.12.90	Replenine	500	FJM4625	07.07.97				
3Y	250	FHC4237	09.03.94								
				HT DEFIX (SFC)	276	3502-7021C	14.09.87				
Replenate	500	FHE4437	21.09.95								
Replenate*	500	FHE4536*	04.09.96								
Replenate*	500	FHE4546*	17.10.96								
Replenate	1000	FHF4625	19.07.97								
High purity FX	500	FHH2990	17.11.91								
High purity FX	500	FHH4054	06.05.92								
26 'PFC'	250	0101-7032D	02.08.87								
26 'PFC'	250	0104-7051D	14.07.87								
Total		16		Total		8		Total		1	

[1] All products implicated to date including batches previously notified to consignees(*)
[2] All products manufactured in UK; products manufactured by the Protein Fractionation Centre, Scotland are designated 'PFC'. All other products manufactured by Bio Products Laboratory

vCJD and Plasma Products. Tables of vCJD implicated batch numbers. Health Protection Agency, Colindale. Dated 7th September, 2004.

See text at the top of the table.
See column 4, 'release date', row 7 for an example of an early vCJD-implicated batch (23.05.90).

Chapter VI:

[redacted] HTLV III

AIDS - DEVELOPMENT OF DIAGNOSTIC TEST FOR ~~EACH-TLVIII~~

I thought it might be helpful if I recorded the main points made at the meeting which Miss Edwards, Dr Barnes, Dr Haveney, you and I attended on 31 July to discuss the paper you circulated with your minute of 27 July.

It was agreed that Ministers should be made aware of the arrangements to screen all blood donors at North West London RTC to start in October. A note might also include a reference to the need to find funding to scale up production of the test reagent. We agreed that Mr Parker's suggestion that the Supply RLG might be the most appropriate source of funding should be pursued.

The note might also need to deal with the question of publicising the research in such a way as both to take credit for Government support for development of the test and to make it clear that the arrangements at the North West London RTC were experimental, ie to forestall pressure for the immediate availability of the test throughout the blood transfusion service and more generally through GPs and STD clinics.

We discussed the need for a group to advise the Department about the development of the test and saw parallels in the arrangements which had been set up in relation to the development of hepatitis B testing ie that the initial interest lay with MED SEB but as the need to develop service wide provision grew transfer to MED IMCD. There were particular problems, however, in relation to the test to be made available for blood donors on AIDS because, in addition to the implications for screening widely for AIDS, eg through STD clinics, there was the problem of tracing people who had received contaminated transfusions. It was agreed that initially advice should be made available through a Sub-Group of the Advisory Committee on the National Blood Transfusion Service and that it would be helpful if the membership of any group included an expert on STD services, eg CMO's consultant adviser. The need to set up a group should be mentioned in the note to Ministers and the interest in the creation of new advisory groups kept in mind. The terms of reference of the group would need to cover the following:

The application of the test

Follow-up of cases with contaminated blood tranfusions

Implications for blood donors

The implications for cases identified by the test as possibly carrying AIDS

The wider use of the test.

It was agreed that HS and CHD together with medical colleagues would consult on the drafting of the submission which should originate from the HS/MED SEB side of the House. It was for consideration whether the submission should also deal with the blood donor leaflet and paper also to the HEC leaflet on AIDS which is in preparation.

CHD would look at the arrangements for contact tracing for STD patients to see if they could be applied to AIDS patients.

[redacted]
CHD
B1213 AFH
Ext GRO-C

31 July 1984

-77
483 cc:
One pair given minute of 27 July + [redacted]

Recovered FOI Document. DHSS letter ref. Diagnostic Test. Dated 31st July, 1984.

(See paragraph 3.)

Coventry and Warwickshire Hospital
Stoney Stanton Road-Coventry CV1 4FH
Telephone 0203 24055

Our Ref: MDW/SD
Your Ref:
Date: 2nd June 1983

Dear

I am sure you are aware of the recent publicity about Acquired Immune Deficiency Syndrome (AIDS) and the possible risk of this occurring in haemophiliacs using Factor VIII concentrate.

We would like to monitor all our haemophiliacs because of this and would therefore be grateful if you could attend the Blood Bank, Walsgrave Hospital on JUNE 30th between 9 - 9.30 a.m. for a blood test.

We shall then be able to see you with the results of the test in the Haematology Out-patient Department, Coventry & Warwickshire Hospital on JULY 11th 2.30p.m.

If there is any problem with the above dates could you contact Ext. 5001 at Coventry and Warwickshire Hospital.

Yours sincerely.

GRO-C

Dr M.D. Williams.
Registrar in Haematology

To re-order master L/811

Letter ref. Blood Test. M. D. Williams. Coventry & Warwickshire Hospital. 2nd June, 1983.

Dr Abrams

AIDS - DEVELOPMENT OF DIAGNOSTIC TEST FOR HTLV III

Since my minute of 6 July there have been further developments regarding the radio immunoassay for antibody to HTLV III. Some 2,000 tests have been carried out on AIDS patients, patients with the extended lymphadenopathy syndrome, homosexuals attending STD clinics, haemaphiliacs and others. The findings shortly to be published, confirm the presence of detectable antibody in 28 out of 29 (96 per cent)AIDS patients 104 out of a 117 (88 per cent) patients with extended lymphadenopathy syndrome 60 out of 288, homosexual patients attending STD clinics (20 per cent) who were apparently otherwise healthy barring their "normal sexually transmitted disease".

At the beginning of October it is planned to start screening all blood donors at North West London RTC. Whilst the latter trial will be a research project we need to plan ahead for an anticipated extension of the screening test to all blood donors and to others at risk to the disease. Attached is a paper setting out some of the many problems that will need solving as a consequence of being able to detect the antibody in carriers.It is proposed that the Department should invite a group of experts to provide guidance so that health authorities can be advised accordingly.

[redacted]

27 July 1984

[redacted]
MED SEB
Room 1025A Hannibal House
Ext GRO-C

copies

[redacted]

Recovered FOI Document. DHSS Letter, Hannibal House. Dated 27th July, 1984.
(See paragraph 1, lines 1-4.)

INFORMED CONSENT (Item 4)

10. The field evaluation proposed by [redacted] and [redacted] would not require consent of the participants because the sera would not be able to be identified with the donors.

11. [redacted] and [redacted] recommended that when tests for blood donations were introduced blood donors should be informed that their blood would be tested for AIDS. This could be by informing them through leaflets sent with their call up cards or providing leaflets at the donor session. They thought that a lot of donors would not be prepared to give blood if they knew it was going to be tested for AIDS. Efforts would have to be made to recruit more donors. It was agreed that Departmental legal opinion should be sought on the need to inform or for informed consent of blood donors.

12. [redacted] expressed his ~~dis-ease~~ unease. at 'freezer' studies being carried out on samples collected from individuals attending STD clinics who would not necessarily have given consent for such investigations to be carried out. It was pointed out that such studies provided invaluable information about the spread of the disease for which there was no other way of finding out. It was agreed that the manner in which these studies should be conducted should be given further consideration.

4

Minutes of the Expert Advisory Group on AIDS. Dated 1st March 1985.

See Point 12.

7.3.3 The question of patient consent to HTLVIII testing was discussed. A positive test result could be serious for an individual patient and the implications of tests taken as an infection control measure for staff and not for the benefit of the individual's diagnosis and treatment should be carefully considered. The BTS would be informing blood donors, who were volunteers, that the test was being done on their blood donation. However, in the context of the diagnosis and treatment of a patient it was agreed that a general clinical approach should be adopted. Patient's permission for hepatitis B testing was not always sought and, with a variety of tests being taken, it should not be necessary to inform the patient in all cases that these included a test for HTLVIII antibody. It was also agreed that the result of the HTLVIII antibody test should not be awaited before undertaking other tests which might be critical in the treatment of a patient. [redacted] said that with hepatitis B it was now accepted that other tests should be done while the result of the hepatitis B test was awaited. These tests should be handled in a high risk laboratory and no additional precautions were required.

7.3.4 Specific points on the text of the paper would be made direct to [redacted]. It was suggested that the term 'genito/urinary medicine clinic' should be used in preference to 'sexually transmitted disease' clinic, and Paragraph 10 concerning the employment of HTLVIII antibody positive individuals needed to be strengthened. The Chairman said that the covering letter would include a statement that the test would be available to doctors generally.

7.4 Screening of blood donations for anti HTLVIII in Regional Blood Transfusion Centres - report by the Working Party of Regional Transfusion Directors - EAGA(5)6

7.4.1 [redacted] tabled an amendment to item 3 on page one of the report. The working party of the Regional Transfusion Directors Committee recognised the pressure to introduce routine screening in the BTS as soon as possible. Regional Transfusion Directors were therefore being advised to make arrangements with their respective RHAs for the introduction of routine screening, and familiarising themselves with the kits recommended by the PHLS study, whilst the NBTS evaluation was proceeding. The evaluation within the BTS had begun, 6000 specimens were being tested each in two centres, at the rate of 600 tests a day. An analysis should be available in September which would give estimates of the specificity of the kits and their ease of use. The working party considered it possible to commence screening of blood donations in October 1985 and recommended that the introduction of the tests should take place throughout the UK over the shortest period practicable. On receipt of a confirmed positive result for HTLVIII antibody, the donor would be sent a letter by the Centre and an appointment arranged for the donor to be interviewed by a doctor trained in counselling. The donor would be asked for the name and address of his family doctor and efforts made to ensure that the donor received further medical advice and obtaining his consent for the results of the test to be reported to his family doctor.

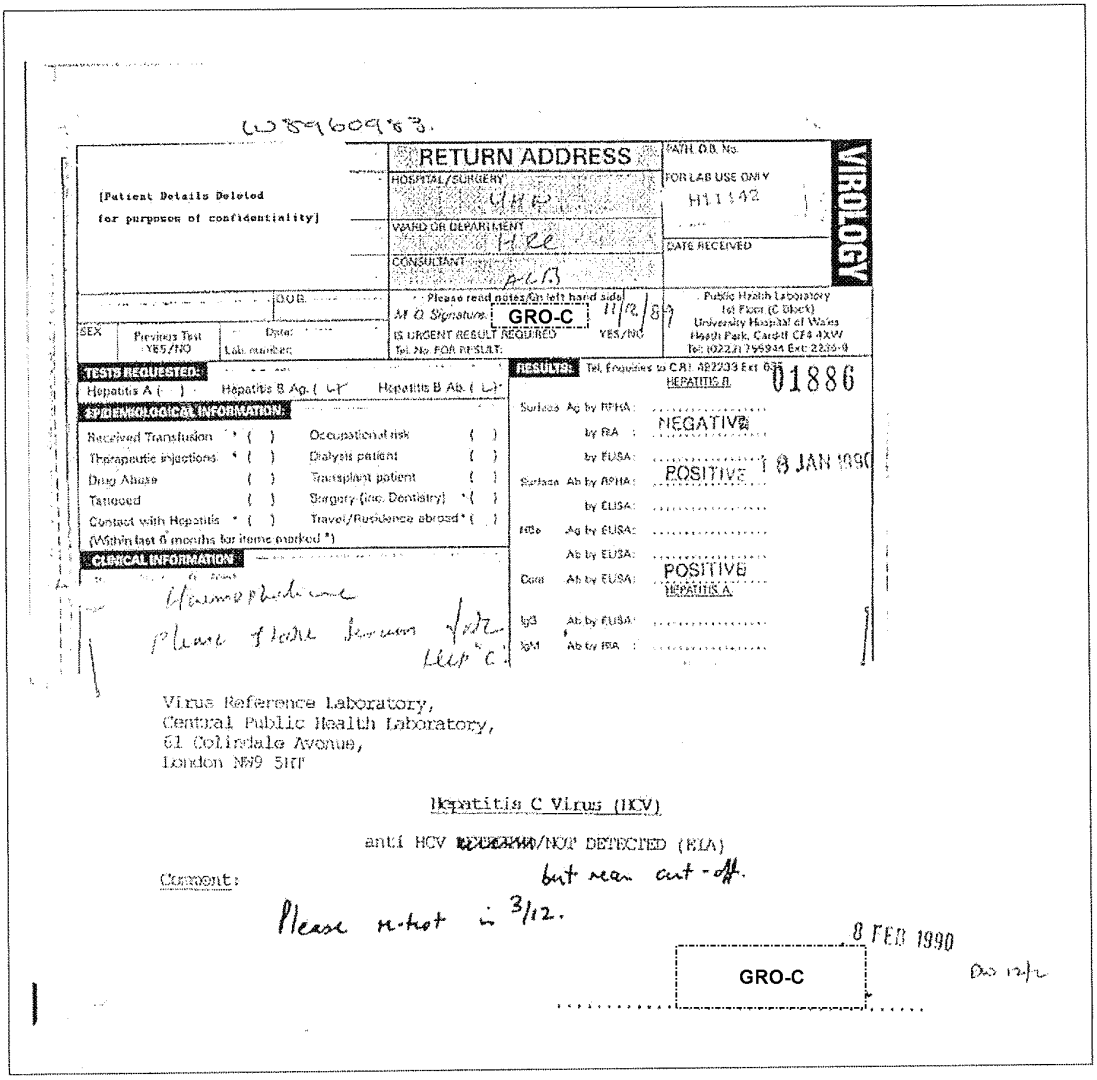
7.4.2 [redacted] said that the Department would be writing to Regional Transfusion Directors asking them to make arrangements for screening with RHAs. The exact introduction of testing would be a matter of co-operation between Regional Transfusion Directors, but some pressure might need to be brought to bear where Regions were not making the necessary funds available. Members agreed that the screening test should be introduced simultaneously throughout the BTS and that a date for the introduction should be set for all centres to work to. This would also provide an opportunity for publicity, which could be linked with advice to blood donors and the general public.

4

Minutes of the Fifth Meeting of the Expert Advisory Group on AIDS. Dated 30th July 1985.

See paragraph 1, point 7.3.3 (whole paragraph).

Chapter VII:



W35960983.

RETURN ADDRESS

[Patient Details Deleted for purposes of confidentiality]

HOSPITAL/SURGERY: UHW

WARD OR DEPARTMENT: Hse

CONSULTANT: Pcb

PATH. O.D. No.

FOR LAB USE ONLY: H11142

DATE RECEIVED

VIROLOGY

DOB

SEX

Previous Test YES/NO

Date:

Lab number:

Please read notes on left hand side

M.O. Signature: GRO-C 11/12/89

IS URGENT RESULT REQUIRED YES/NO

Tel. No. FOR RESULT:

Public Health Laboratory
1st Floor (C Block)
University Hospital of Wales
Heath Park, Cardiff CF4 4XW
Tel: (0222) 796944 Ext 2230-9

TESTS REQUESTED: Hepatitis A ( ) Hepatitis B Ag. ( ) Hepatitis B Ab. ( )

EPIDEMIOLOGICAL INFORMATION

Received Transfusion *	( )	Occupational risk	( )
Therapeutic injections *	( )	Dialysis patient	( )
Drug Abuse	( )	Transplant patient	( )
Tattooed	( )	Surgery (inc. Dentistry) *	( )
Contact with Hepatitis *	( )	Travel/Residence abroad *	( )

(Within last 6 months for items marked *)

CLINICAL INFORMATION

Haemorrhage

Please note serum for Hep C.

RESULTS Tel. Enquiries to C.R.I. 492233 Ext 635

HEPATITIS B 01886

Surface Ag by RPHA:

by RIA: NEGATIVE

by EUSA:

Surface Ab by RPHA: POSITIVE 18 JAN 1990

by ELISA:

HBe Ag by EUSA:

Ab by EUSA:

Core Ab by EUSA: POSITIVE

HEPATITIS A

IgG Ab by EUSA:

IgM Ab by RIA:

Virus Reference Laboratory,
Central Public Health Laboratory,
61 Colindale Avenue,
London NW9 5HT

Hepatitis C Virus (HCV)

anti HCV [redacted]/NOT DETECTED (ELA)

Comment: but near cut-off.

Please re-test in 3/12.

8 FEB 1990

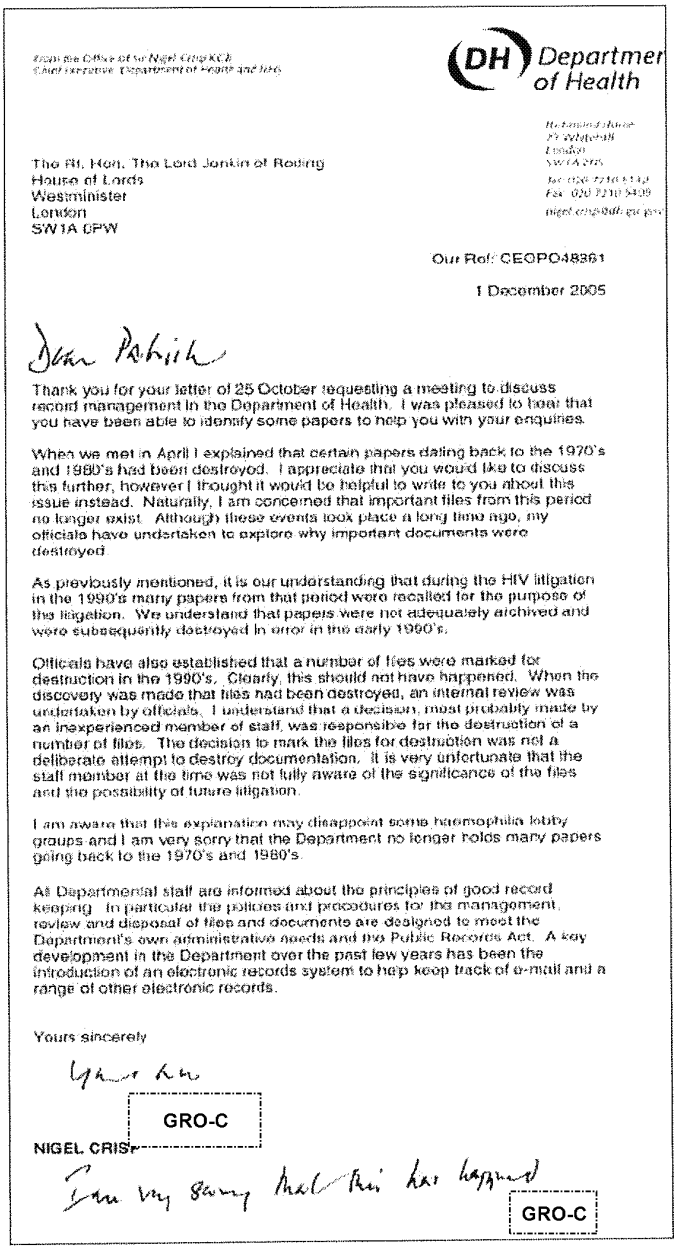
GRO-C

Dec 12/2

HCV Test Results Certificate: H11142. No. 01886. Virus Reference Laboratory. Colindale. Dated 11th December, 1989.

See 2nd column, 'Return address', row 4 for the 1989 date.
See the comment (bottom centre) of the test certificate for early Hepatitis C (HCV) test reference.

Chapter VIII:



From the Office of Sir Nigel Crisp KCB
Chief Executive, Department of Health and NHS

DH Department of Health

Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 020 7210 5342
Fax: 020 7210 5409
nigel.crisp@dh.gsi.gov.uk

The Rt. Hon. The Lord Jenkin of Roding
House of Lords
Westminster
London
SW1A 0PW

Our Ref: CEOPO48361

1 December 2005

Dear Patrick

Thank you for your letter of 25 October requesting a meeting to discuss record management in the Department of Health. I was pleased to hear that you have been able to identify some papers to help you with your enquiries.

When we met in April I explained that certain papers dating back to the 1970's and 1980's had been destroyed. I appreciate that you would like to discuss this further, however I thought it would be helpful to write to you about this issue instead. Naturally, I am concerned that important files from this period no longer exist. Although these events took place a long time ago, my officials have undertaken to explore why important documents were destroyed.

As previously mentioned, it is our understanding that during the HIV litigation in the 1990's many papers from that period were recalled for the purpose of the litigation. We understand that papers were not adequately archived and were subsequently destroyed in error in the early 1990's.

Officials have also established that a number of files were marked for destruction in the 1990's. Clearly, this should not have happened. When the discovery was made that files had been destroyed, an internal review was undertaken by officials. I understand that a decision, most probably made by an inexperienced member of staff, was responsible for the destruction of a number of files. The decision to mark the files for destruction was not a deliberate attempt to destroy documentation. It is very unfortunate that the staff member at the time was not fully aware of the significance of the files and the possibility of future litigation.

I am aware that this explanation may disappoint some haemophilia lobby groups and I am very sorry that the Department no longer holds many papers going back to the 1970's and 1980's.

All Departmental staff are informed about the principles of good record keeping. In particular the policies and procedures for the management, review and disposal of files and documents are designed to meet the Department's own administrative needs and the Public Records Act. A key development in the Department over the past few years has been the introduction of an electronic records system to help keep track of e-mail and a range of other electronic records.

Yours sincerely

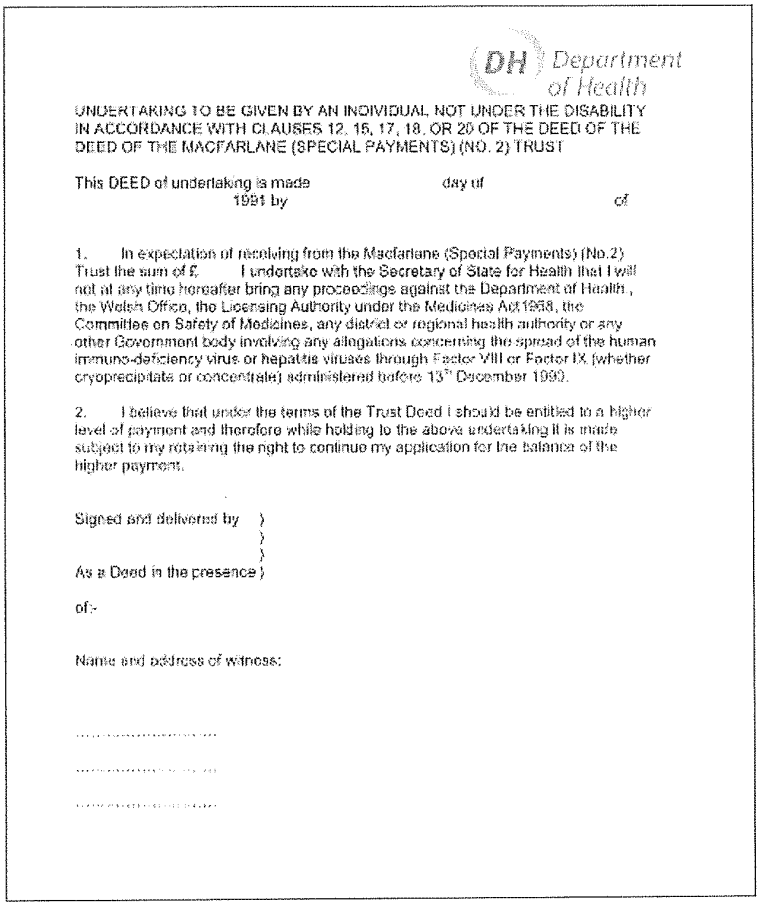
GRO-C

NIGEL CRISP

I am very sorry that this has happened

GRO-C

Sir Nigel Crisp. Letter dated 1st December, 2005. **See paragraph 2.**



DH Department of Health

UNDERTAKING TO BE GIVEN BY AN INDIVIDUAL, NOT UNDER THE DISABILITY IN ACCORDANCE WITH CLAUSES 12, 15, 17, 18, OR 20 OF THE DEED OF THE DEED OF THE MACFARLANE (SPECIAL PAYMENTS) (NO. 2) TRUST

This DEED of undertaking is made day of 1991 by of

1. In expectation of receiving from the Macfarlane (Special Payments) (No.2) Trust the sum of £ I undertake with the Secretary of State for Health that I will not at any time hereafter bring any proceedings against the Department of Health, the Welsh Office, the Licensing Authority under the Medicines Act1968, the Committee on Safety of Medicines, any district or regional health authority or any other Government body involving any allegations concerning the spread of the human immuno-deficiency virus or hepatitis viruses through Factor VIII or Factor IX (whether cryoprecipitate or concentrate) administered before 13th December 1990.

2. I believe that under the terms of the Trust Deed I should be entitled to a higher level of payment and therefore while holding to the above undertaking it is made subject to my retaining the right to continue my application for the balance of the higher payment.

Signed and delivered by)
)
)
As a Deed in the presence)
of:-

Name and address of witness:

.....

.....

.....

Example of one type of 'Waiver' from the 1991 Haemophilia HIV Litigation.

(See Point 1.)