Witness Name: Robert Mackie

Statement No.: WITN2190001

Exhibits: **Nil**

Dated: 17th October 2018

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF ROBERT MACKIE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 1 October 2018.

I, Mr Robert Mackie, will say as follows: -

Section 1. Introduction

1. My name is Robert Mackie. My date of birth is GRO-C 1950. My address is known to the Inquiry. I am married to Alice Mackie. We have one son. I have severe Haemophilia A. I intend to speak predominantly about being infected with HIV/AIDS. Although I have also been infected

with Hepatitis C I do not really have much information on my infection with Hepatitis C. I also do now know whether I have been infected with 'other' viruses during my lifetime through the treatment for my Haemophilia, though I suspect I may have been. I have been able, with the very considerable assistance of my wife, to undertake a good deal of research into the background circumstances which led to my infections. Below, I have tried to answer the questions put to me in the Inquiry's rule 9 request. In section 8 below, I have set out some of what I consider to be important material which provides information about how I came to be infected. It is very important to me that it is considered by the Inquiry in its investigation into why this happened to me and to others like me.

Section 2. How Infected

2. I suffer from haemophilia type A. My condition is considered severe. I was diagnosed with my original condition as a child.

3. Until my early teens I attended the Royal Hospital for Sick Children, Edinburgh and since then have attended the Royal Infirmary of Edinburgh (RIE) for my treatment, first under the care of Dr Howard Davies and then from 1979/1980 under the care of Dr Christopher Ludlam until about the end of 2003 beginning of 2004. At that time, I made an official complaint about Dr Ludlam and the circumstances of my infection with HIV/AIDS to the General Medical Council. For several years after that I really just had whatever haematologist would see me for treatment and for a while, I did not have any haematologist. I am now under the care of Dr Rodgers at the Edinburgh Haemophilia Centre. GRO-C GRO-C GRO-C Two of my uncles and one cousin have died of HIV/AIDS and one uncle died from Hepatitis C. GRO-C GRO-C

4. I learned at a very early age what I could and could not do in life which let me live a "normal" life before my infection with HIV/AIDS. During my early life, I cycled, ran, played golf, and tennis. I river fly-fished for brown trout and when in my teens I began salmon fly fishing, my fishing hobby involved a lot of walking. In fact, I took part in just about every non-contact sport you can think of – without using Factor VIII. If I did have a bleed, I mostly treated with bed rest. I was a very fit and active person up until the AIDS virus began to affect my health.

5. I GRO-C became infected with HIV/AIDS as a result of receiving Scottish National Blood Transfusion Services Factor VIII concentrate. It was produced at the Protein Fractionation Centre, Edinburgh and was part of the batch number 023110090. This information has been confirmed in correspondence from Dr Ludlam. I think that I received it at some point between March 1984 and May 1984. When I was informed of my infection by Dr Ludlam in 1987, May 1984 was the first date I was given as the date of my seroconversion. However, in 2003 Dr Ludlam told me that my seroconversion occurred in August 1984. I have to say here that, as far as I am concerned, no matter what the precise timing was from March 1984, I was given an infected product at a time when the risk of AIDS from blood products (Factor VIII) was well known.

6. I do not know when I was tested for HIV or AIDS. At no time did either Dr Ludlam or any doctor or nurse ever say to me that they were taking blood from me for an HTLV III/AIDS test. In fact during 1983 and 1984 I was continually asking both Dr Ludlam and other doctors at my haemophilia centre about any risks from Factor VIII and about this disease I had heard about in the news (AIDS). I was continually told that "there was nothing to worry about". At that time, I was informed by one doctor that if I did not stop asking questions and causing trouble I would

be banned from the hospital. This is because another patient who was present when I was asking questions began asking the same things. This patient (also infected with HIV and HCV) did tell me several years later that he did not know why he was asking but just knew that I was asking for a good reason. He did not know then, but does now. The first I knew of having been tested for AIDS was in January 1987 when I was told by Dr Ludlam that I had been infected with HIV for several years. This delay had put my wife, family and friends at risk. The question here that comes to mind is WHY was I never informed of either being tested or of my test result when the result was known.

7. A lot of the Factor VIII I received up until 1984 was given to me for prophylaxis due to my very active lifestyle at that time – which means that I did not really need the Factor VIII either for "lifesaving" treatment or for a specific bleed but only to prevent future bleeds. The fact that it was known by the end of 1983 that the more Factor VIII a patient received the more chance he had of contracting AIDS, makes me ask WHY I was given prophylactic treatment. The practice of prophylaxis should have stopped by that time due to the known threat of AIDS. If I had been warned during 1983 about the potential AIDS risk from my treatment (or indeed the risk of infection with other viruses such as HCV) it would have been very easy for me to alter my lifestyle to ensure that I did not require any treatment. I was not warned at all by Dr Ludlam or anyone else at the hospital, despite having asked about the risks generally and of AIDS specifically at that very time.

8. The circumstances in which I was informed of my HTLV III status in January 1987 are for both my wife and myself unforgettable and unforgivable. I received a letter inviting me to an appointment to see Dr Ludlam. This was in itself unusual, and the appointment was not at Ward 45 (where I would normally be seen) but in his office. When we arrived, we were told to wait in Dr Ludlam's office. When Dr Ludlam arrived, he

asked my wife to leave the room. When I refused, he left us alone to discuss her going. When he returned 5 minutes later and we insisted she was staying, he showed his displeasure. He then went on to ask me 3 questions; Have I used intravenous drugs? Have I slept with any other women? Have I slept with any men? Then he went on to tell us that I was infected with HTLV III and that he had met the donor of the infected blood donation, that the donor had been a homosexual man and that he was dead. According to Dr Ludlam, my infection with HTLV III was just one of those things that could not have been avoided. He then went on to advise us not to tell anyone about my status, not even our families,

GRO-C

When I asked what the prognosis was, he stated "*I have more chance of dying of a heart attack than you have of dying of AIDS.*" Dr Ludlam also asked if I wished for another doctor to treat me from now on, and since I believed that he was ignorant of the threat of AIDS and that it why he had not told me anything about the risks or about my infection sooner, I just decided to keep him as my treating consultant and that was really the end of the meeting. Dr Ludlam got up and left us sitting in the room on our own. I have to say here that this flippant remark from Dr Ludlam was given after he knew the mortality rate in haemophiliacs was high, in fact it was discussed in July 1983 about the predicted mortality being 100% in 25 months for haemophiliacs, meaning that since I was infected in May 1984 I was now out of time! We left Dr Ludlam's office believing what he said when he told us that "*It could not have been avoided*". No test was offered to my wife at this time, nor was there any counselling offered. We were left to go home, keep secrets and just live the rest of our lives with nothing ahead of us but lies.

9. What I cannot understand is why I was asked such questions when Dr Ludlam knew the batch that I was infected with, knew the blood donor, and more importantly knew that at least 15 other haemophiliacs

attending the RIE were infected with the same batch (as stated in numerous research papers).

10. At no time before this meeting did Dr Ludlam or his staff speak to me about taking blood from me specifically for a HTLV-III/AIDS test or inform me of being tested for HTLV-III. Nor was there any counselling offered before or after eventually being informed of the results. Nor was there any mention of a HTLV-III test for my wife at that time. At the above meeting there was also no mention of Dr Ludlam doing any research or studies on AIDS in which I was included. At no time during this meeting or before or after did he tell me that he would require extra blood to be taken from me during routine blood tests for his research. At no time during this meeting did he inform me that he had already taken 'extra' blood from me to carry out his research into AIDS in his patients who by 1987 were well known in research circles as the "Edinburgh Haemophilia Cohort". But, thinking back on it now, the research which was clearly being done explains the large amounts of blood being taken from me for my 'routine' blood tests over the years – at least 50mls. They were taking so much that my wife asked what they needed it all for warned that and if they took any more I would need a blood transfusion. No-one ever stopped to tell us, they just finished taking the blood and turned away. I trusted them all and did not question them when the blood was being taken.

11. I have since discovered that Dr Ludlam was not very forthcoming when informing me of my positive status. What he omitted to tell me was that he was aware (or at least should have been aware) of the potential risks to haemophiliacs from AIDS from as early as 1983. Of course, had he informed me of the risks, my infection with HIV would definitely have been avoided as I would have refused any kind of blood/blood product treatment, altered my lifestyle, and reverted to the way I treated a bleed when I was younger; by bed rest. This was all completely avoidable.

12. After the meeting with Dr Ludlam in 1987, my wife and I discussed where we go from here and decided that we would consult a lawyer. We eventually managed to get someone to help us to take legal proceedings against the Government and NHS. We had to go to Manchester for a medical and that is where my wife got offered an AIDS test. Thankfully, it was negative). It was during the course of discussions about our litigation that Dr Ludlam informed our lawyer and doctor in Manchester about the infected batch number which he stated had been 023110090, abbreviated to 0090 and claimed that 29 May 1984 was the date of my seroconversion. When checking my medical records subsequently, it is clear that this number is NOT abbreviated in this way in my treatment record sheets. Furthermore, Dr Ludlam also informed me later that my seroconversion date was August 1984 (as stated above).

13. In the early 2000s I requested a copy of my medical records. After some considerable time and being told by the hospital that Dr Ludlam had had them for some considerable time to take out all relevant information, they eventually arrived. My wife then read through them and was very upset when she discovered the words 'AIDS Study' on blood request forms in 1983. It seems that the circumstances leading up to my infection of AIDS were not as we had been led to believe by Dr Ludlam. It appears that he knew about AIDS in at least 1983 and that AIDS in haemophiliacs did not just appear out of the blue. This made us think that if the risks had been explained, my infection with AIDS could have been avoided. This was not what Dr Ludlam had told us in 1987. We later discovered that this AIDS Study which began in March 1983 was just the beginning of many, many years of research being carried out on me without my knowledge or consent. It was after this point that we began looking into the circumstances surrounding my infection. When reading my medical records, we discovered that the AIDS Study was the only mention in my medical records of my positive status. We also discovered when reading

through my treatment record sheets (which records batch numbers and vials of Factor VIII used) that the 'infected batch' is the only batch in ALL of my medical records which has its batch number written out in full. This is not only the position in the records which state the Date, Time, Reason for Treatment and Batch Number (which record was completed AFTER I returned my record treatment sheets to the hospital) but also in the Record of Batch Numbers of Factor VIII received at the ward from BTS, which I assume would have been completed on receipt of the Factor VIII at the ward. Why is this batch number written out in full?

14. We did ask Dr Ludlam at a routine appointment several years later why he did not tell us about his AIDS study in 1983 and he just said "*It is all in the past*" and changed the subject. I also asked Dr John Tucker and he said "*I was only doing as I was told.*"

15. When my wife read through my medical records, she found no mention of HTLV-III/HIV/AIDS anywhere. So, a letter was written to Dr Ludlam saying that there was no mention of HTLV-III or HIV/AIDS in my released medical records. We asked him if he had any information or paperwork in relation to my infection and if he could tell me when I was infected with HIV/AIDS. The letter he sent to me stated the Batch Number which infected me was 023110090 and that my seroconversion date was August 1984. I noticed that this was different to the date he told my legal team. He also sent a blank sheet of paper which was supposed to be some sort of blood test result. I have since applied again for a copy of my medical records and just received the same files (no HIV/AIDS information). I later discovered that Dr Ludlam keeps a separate file on me regarding my HIV/AIDS. Why did he not give me a copy of this file when I specifically asked for this information, and was this file kept for my medical treatment or was it to do with his research?

16. In December 1984 Dr Ludlam invited me to a meeting along with many other people, most of whom I did not recognise or know. The meeting took place in a lecture theatre at the 'old' Royal Infirmary of Edinburgh. GRO-C some haemophiliac friends (whom I did recognise) were there as well. I have since become aware that Dr Ludlam's position is that the purpose of this meeting was to inform us of our positive HTLV-III status. At the meeting, we were told that some people had been infected with HTLV-III by SNBTS PFC Factor VIII which they had received. Along with my wife and I, all the people at this meeting that I spoke to, thought that the people who had been infected had been informed before the meeting, so we all thought that we were all 'safe'. We would never have imagined that Dr Ludlam would use a meeting like that as the only means by which he was communicating to infected patients that they were infected. All we could say to each other after the meeting was "*Thank God I don't have it*". Turns out, we were all wrong, we were all infected. I have to say here that not all the infected attended the meeting and not all attending the meeting were infected. We all thought that those infected had been told individually by Dr Ludlam of their infection before the meeting and the meeting was to tell us that the risk had passed since we now had Heat Treated Factor VIII produced at the PFC.

17. I still do not understand how I was supposed to know that I had received the infected batch if I was not informed by any doctor in any manner be it face to face or by letter, or even to tell my wife whose life was also at risk. Other than at the December 1984 meeting, at no time after testing HIV positive in 1984 was the word HTLV-III/HIV/AIDS ever mentioned to me either by doctors or nurses, until the meeting in January 1987. No one stood in front of me and asked if I wanted to know the result of my HIV test. I did not even know I had been given one. Even after I was informed in January 1987, these words were not uttered by any of the staff at the haemophilia unit. It seems that I was not the only one not allowed to discuss it. All of the doctors seemed to be reluctant to discuss

it. I cannot recollect Dr Ludlam even mentioning it until I raised the topic of the AIDS Study several years later. Even then he avoided the subject. I have also learned that the meeting held in December 1984 in the lecture theatre was held not because Dr Ludlam thought it important or urgent to inform us of our infections (of which he had known for some time) but because the media had gotten information on the infection of HIV/AIDS in a group of haemophiliacs attending Edinburgh Haemophilia Centre and were going to publish the news.

18. I have asked the General Medical Council to investigate, and had a Police investigation into my infection with HIV/AIDS but get the same sort of reply in that 'It is all in the past, things were different then and he will not do it again'.

19. Attached to my statement is a brief summary of events from before, at the time and after my infection in 1984. This is included in section 8 below.

Section 3. Other Infections

20. I also have Hepatitis C but by the time I realised I had this I was too ill with AIDS to take it in. It was my AIDS consultant Dr Brettle in 2000 who told me. He said that some of my health problems could be because of me having Hepatitis C. That is when I can really say that I knew I was co-infected. But as I said, I do not really recall much of the years 2000 to 2003 since this was a time I was very ill with AIDS.

Section 4. Consent

21. I know I was tested without my knowledge or consent; the evidence is in my medical records. I was part of a research group and they did not tell us anything until it was too late. I feel that they used us for their own gain. After I received my medical records, I became aware of the research after reading the words "AIDS Study" in my notes. Then I decided to do my own research. We did research on Dr Ludlam's research.

22. I was used as a guinea pig, lab rat, for research by Dr Ludlam and his sidekicks as they are known. I know this because of published papers and medical journals. Some of these are detailed below. We are known throughout the world as a unique group – the "Edinburgh Cohort". A unique group from Edinburgh. I was researched on throughout my time at the Edinburgh Royal Infirmary, for how long I do not know. Perhaps I still am. I was infected from about March 1984 which according to the experts was a time when a group of Haemophiliacs ought not to have been infected with AIDS, certainly without being informed of the risks of AIDS to begin with. There was a large group of us. It worked out that approximately 50% of patients who received the infected batch became HIV+ and approximately 50% remained HIV-. 16-18 patients in all became infected, dependent on the research paper you read. I am still not at all happy about being used in this way.

23. We went to the library and read medical papers and basically Dr Ludlam had written articles about the "Edinburgh Cohort". I know that I did not knowingly take part in this, although it is stated that I "volunteered" my blood. I can categorically say that I did not knowingly give any blood donation for this research. My family and friends who were infected with HIV/AIDS and Hepatitis C are all dead, but I am not and I know for a fact that they did not know about the research that was being carried out on them either.

24. I remember the point when the hospital environment changed. All the chairs were taken away suddenly and replaced with new chairs. Historically up until 1984 the ward was not cleaned properly. There was blood on the chairs, floors and walls. There were blood spillages everywhere. I was always telling other patients to clean up their mess. Then all of a sudden, they started taking you to this small treatment room to speak with you instead of going into the corridor or in front of other patients or visitors to the main ward. Then my wife, who was friendly with one of the cleaners saw a dramatic change in how she acted towards her. When this cleaner saw us, she couldn't look at either of us. She started avoiding us, everything changed. To us, it was clear that the cleaners knew about the infection risk before we did. The staff changed as well. We actually got a Sister specifically for us. Up until then it was general ward staff and suddenly Sister Philips appeared. From then on haemophiliacs had their own nurses. It did change, you could feel the change. They were too professional from that point. No more banter. Just business. The staff started to take as much blood as they could possibly get from us. I do not know why.

25. We later discovered in our research on Dr Ludlum that two of the foremost researchers in the United States of America were called Dr Gordon and Dr Chernoff (National Institute of Health). They put out an SOS in a medical journal asking the medical world for help. What they really wanted was a group of patients "in some country where cases of AIDS have not yet been reported would be an immense help to public health workers worldwide. In this situation 'negative results' would be of great significance". Dr Ludlam replied to them saying that he had such a group of patients. How did Dr Ludlam know that his patients had 'negative results'? In the Spring 1984 this group of patients became infected. As Dr Ludlam's research states, he had this group of patients before they were infected, at the point of infection and after infection. That is why the Edinburgh Cohort is a unique group, because there is nobody else like us. That is why we are the most researched AIDS

patients in the world. Before this point, doctors were only coming into contact with patients who were already infected with AIDS throughout the world - after infection. They didn't see them until they became ill. What Chernoff and Gordon wanted was a group of patients before they were infected, when they were infected and after they were infected. Then they wanted to do research, from time zero. At least 50mls of blood is what the hospital would take from me at a time. It turns out that 30mls of that was for Dr Ludlam's research. My wife would keep asking them all the time "*Why are you taking all that blood?*" The syringe size was 50mls and sometimes they would take more than one. My wife would say "*He is going to need a blood transfusion if you take any more blood from him*". They never answered. Not once did anyone say that it was going towards research. Not one word was ever said. They took blood every time I went there. It got to the point I refused to give blood when I found out about the research. I still refuse to give them blood. I do not trust what they are going to do with it.

26. Over the years, I, along with other haemophiliacs, have given blood donations which were requested by Dr Davies. When I began donating this blood many years ago (1960s/70s), I did ask why it was so important and was told it was for heart operations, which I accepted until I questioned this one time and the reply was "*what have you been told?*" I said I had been told that it was for heart operations. I did not and do not know why that would be. The person just turned, laughed and walked away. I never did find out the true answer. However, it seems that our blood was worth a lot to someone because they flew at least one patient from the West of Scotland to Edinburgh and home again and this is not the only haemophiliac that I have heard this from.

27. I remember on one occasion that it was an Australian doctor who stood waiting whilst the blood was drawn and then walked away with it. I have

always wondered whether they were taken our blood to use it for a Hepatitis B vaccine.

28. The last request that I had for blood was in 1983 was from Dr Ludlam. It was for me to attend for plasmapheresis. There are two letters in my medical records that relate to Dr Ludlam requesting that I donate blood in 1983. On the 21st January 1983 he wrote to me requesting that I donate Factor VIII free plasma. I replied to this in a further letter, confirming that I would be happy to do so. I did donate this, but I was already infected at this point. Did I therefore donate infected blood for others or was this used for Dr Ludlam's research purposes?

Section 5. Impact

29. I am unable to find the words to describe the mental and physical effects of being infected with HIV/AIDS and Hepatitis C. It is ridiculous to be asked really. I think my wife would be better to describe the impact and effect of being infected has had on our family because I cannot remember most of it. What I can tell you is that my wife had a good job, she was earning a good salary. After I was told, it was thought I would have a maximum of 3 years to live in 1987 so my wife stopped working. 1987 went to 1989, then turned into 1999 and 2000. She never went back to work. My closest haemophiliac friend died from AIDS in 1988 and I seemed to be forever attending funerals after that until 1996 when the last died (all of them belonging to the Edinburgh Cohort). I have years that I cannot recollect. Perhaps she will be able to put into words what I cannot.

30. What I can tell you is that I have lived a life full of anger, lies and secrecy since being told of my HIV/AIDS status because Dr Ludlam told me how

important it was not to tell anyone – not even family - due to the stigma. I was mentally destroyed; I was physically destroyed. I lost the plot basically.

31. I do not accept or trust doctors, physiotherapists or anybody else to do anything to me. I will not let anyone near me. I do not trust the medical profession to go to them at all or have any sort of treatment. My faith in the medical profession has dwindled and gone.

32. As a new family man, we had plans, we had hopes and we had dreams. I was unable to take on the job that I wanted most in life – that of a Ghillie – due to the risks I would put prospective clients at and because of the high risks, I would have had to inform my employer and anyone else at risk.

Section 6. Treatment/Care/Support

33. Again, my wife is the person to ask this since she is the person who has dealt with my treatment, care and support over the past 30 years. Before that point it was always for the both of us to make decisions and do things together, but for a long time now it has just been my wife who is able to do that. She is also the person who takes care of me and supports me. If it was not for her I would not be alive today. It is her, not any doctor, nurse or specialist who has kept me alive this long. How she has achieved it I do not know.

Section 7. Financial Assistance

34. Again, it is my wife who has dealt with this on my behalf. A statement should be taken from her and she will be able to provide all the necessary details.

Section 8. Other Issues

35. I would like to give a further statement in due course highlighting relevant sections of my medical records.

36. I want the following to be recognised as it is very important to me:

The worst and saddest thing that this disaster has brought to me is that my wife has given up so much and made the ultimate sacrifices in her life. She has given up her right to have children and her career. She has perhaps not suffered physically, but has definitely suffered mentally not only by having to watch her haemophiliac family and friends die a most horrific death but now she has to watch me suffer the same fate. Even after my wife has made all these sacrifices, she is still with me after all these years – this most of all to me is the ultimate sacrifice.

8. Other issues

37. I wish to add the following which is just a brief summary of events from before, at the time of and after my infection which I would like to be included in my statement. It highlights the knowledge which Dr Ludlam should have known but chose to ignore and instead carry out non-consensual research.

38. In **March 1983** Dr Ludlam began his **AIDS Study**.

39. Then in **May 1983** there was a response by Dr Ludlam to a letter published in the Lancet in April 1983, from Dr Robert S Gordon of the

National Institute of Health, in America (Dr Gordon was Chairman of NIH AIDS Working Group) in which Dr Ludlam seems to be offering up myself, along with others under his care at the Royal Infirmary of Edinburgh as a candidate group for research/investigation to explore whether AIDS was caused by a transmissible agent such as a virus in blood products, or whether Factor VIII itself from multiple donors was inducing a mild immune disorder without the intervention of an infection.

40. Dr Gordon says that these two hypotheses could be distinguished by study of "similarly treated haemophiliacs in a geographical area to which AIDS has not yet been introduced". He concludes - "The resolution of this question by a timely investigation in some country where cases of AIDS have not yet been reported would be an immense help to public health workers worldwide. In this situation 'negative results' would be of great significance".

41. The above exchange appears to suggest that Dr Ludlam was **fully aware** of the value to scientific endeavour of his Edinburgh patients (myself included) and that I along with others were of value to him as a publishing scientist. Indeed, he later published on the very question raised by Dr Gordon in the **Lancet, June 1984**.

42. It is also known that Dr Amoz Chernoff of the National Institute of Health (and also a member of NIH AIDS Working Group) visited Scotland in 1983 and had preliminary discussions about the possible inclusion of me and my fellow patients into a study of haemophiliacs who had received no American Factor VIII preparations.

43. What we also discovered by reading my medical notes is that the "infected batch" batch number 023110090 is the only batch number to be written out in full in ALL of my treatment record sheets. This information is gathered from my treatment record sheets from 1980 until I started receiving recombinant Factor VIII. This number is written out in full several times but abbreviated between when receiving different batch numbers. Another AIDS Study blood test was again carried out in

June. We have evidence that HTLV-III (AIDS) tests were carried out in the UK on Factor IX patients, the results known by February 1984 with patients testing positive for HTLV-III. Therefore we know that it was possible to test before June 1984. Perhaps the fact that I reported with a very bad sore throat that would not get better just after taking treatment from batch 023110090 is how Dr Ludlam discovered I was positive.

44. On **24 May 1985** Dr Ludlam applied for Ethics Approval for a study entitled "Study of Immune Function and HTLVIII Infection in Haemophiliacs treated exclusively with NHS Factor VIII/IX Concentrates". – This application contained the following questions and answers:

"Will informed consent be obtained from all subjects? - YES

What information will be given to subjects/patients? – Patients and Controls are very well informed about our studies

How will consent be recorded? – Written in case notes"

If, as the ethics application form states, consent was obtained from all subjects, patients and controls are very well informed about our studies and consent will be written in case notes, how is it that I did not know my AIDS status until 1987, I did not know anything about his studies/research and there is no record of my giving consent in my case notes.

45. One may well ask how blood (up to 30mls) was taken for this research without my knowledge. It seems that according to this request these blood samples were taken "at the same time as blood for other routine blood tests to monitor their haemophilia and its treatment". This I take it is why at least 50mls of blood was being taken from me, the samples that my wife remarked would result in me needing a blood transfusion, as mentioned above.

46. Following on from the Ethics request in May, Dr Ludlam then wrote to The Medical Adviser on **25 June 1985** formally reporting the infected batch to Committee of Safety of Medicines. In this correspondence he stated: "Although some of the patients realise they have received a contaminated batch and know that they have developed anti-HTLV-III, other patients do not know of this and do not wish to know". How was I supposed to realise that I had received the infected batch if I was not told, and as I was not asked if I wanted to know the test results how does that mean that I did not wish to know?

47. Apart from the Ethics request where it states "informed consent will be obtained from all subjects", I do not understand why it was expected that patients had to realise that they had received this infected batch. Was it not the consultant's duty to inform the patients under his care of their status, that they were infected with not only a sexually transmitted disease, but also a FATAL disease? Also, we cannot forget the fact that I was continually asking my consultant and other treating doctors if everything was all right and the answer that always came back was "that there was no problem".

48. On 3 August 1985 another research paper was published in which it was stated: "The probability of seroconversion was independently related to the pre-existing low T-helper/suppressor ratio, the number of vials of the implicated batch transfused, and the total annual factor VIII consumption". It makes me wonder, if had I not been receiving so much factor VIII concentrate as prophylaxis, would I have become infected?

49. Dr Ludlam also carried out an AIDS test on my wife without her knowledge or consent under the guise of "Genetic research". When my wife was "donating" this blood we asked the Sister specifically what the blood was for, and she told us it was for Genetic research. When we queried this (due to the fact that my wife is not genetically related to me or haemophilia) she got very flustered and quickly left the room. It was

only many years later that we realised what this test was actually for. It was a test to see if she had become infected with HIV.

50. Research papers written by Dr Ludlam were then continuously published in the Lancet and other Medical Journals in which he mentions facts such as –

(a) "This small cohort of haemophiliac patients allowed us to study the antigen and antibody responses to HIV infection acquired at a known time from a single source. ... (BMJ, February 1988)"; and

(b) He stated in April 1988 – "The first cases of AIDS in haemophilia were reported in 1981 and shortly thereafter it became clear that the route of viral transmission was through the Factor VIII and Factor IX. ... I became interested in this area of investigation in 1983 ... It has been calculated that, for an anti-HIV positive haemophiliac in our cohort, the relative risk of developing symptoms is increased approximately 13-fold if he has the A1 B8 DR3 haplotype." (Seminars in Haematology, April 1988) How "shortly thereafter" did the route of transmission become "clear"?;

(c) Also in 1988 he stated:

"... Assessed immunologically since 1983 ... The Edinburgh cohort study is unique in at least three aspects. The patients had all been assessed before exposure to the virus; the period of exposure to infection has been defined with some precision; ... all are presumed to have been infected from the same source (probably representing a single virus strain) ... Information on the subsequent clinical course of these patients is thus of special value" (Lancet, May 1988)

(d) Then by 1990 he published:

"... Seropositive blood samples were donated by members of a cohort of HIV-1 infected haemophiliacs. ... The PBMCs used in these

experiments were donated during 1988 and 1989 by HIV-seropositive haemophiliacs who are believed to have been infected in 1984. Seropositive samples were collected by R Cuthbert and the staff of the Haemophilia Centre, Edinburgh Royal Infirmary". (Journal of Virology, February 1990). I did not "donate" any blood.

(e) Also in 1990 we find:

"... Here we examine serial samples from a cohort of haemophilia patients who became infected from a common source in 1984, ..." (Clin Exp Immunol., July 1990)

and

"In EDINBURGH we have had the opportunity to study a unique group of haemophiliacs who became infected in the Spring 1984 ... These haemophiliacs have been very carefully followed up, with close monitoring .. Detailed monitoring has allowed us to identify some factors which are predictive of clinical deterioration, and others that reflect decline of the patient's condition. ... Rapid progression to CDC Group IV disease is related to HLA type in this cohort (the haplotype A1 B8 DR3 is a marker of high risk). <u>This cohort of haemophiliacs has become one of the most extensively studied groups of HIV infected individuals in the world. ... A great deal has been learnt from the careful study of these unfortunate individuals."</u> (Medical Research Council News, September 1990)

(f) By the end of 1990 we read"

:... Five year longitudinal clinical and laboratory study. ... The early identification of individual patients who have a poor prognosis for HIV disease is an important objective. ... We previously described a unique group of haemophiliac patients infected with HIV from a single batch of Factor VIII concentrate used between March and May 1984. This led

inadvertently to the establishment of a cohort of individual patients with a common source of infection, whose times of HIV seroconversion were clearly recorded. Plasma samples collected at regular clinical follow up appointments ... information from this is uniquely homogenous cohort is of special value because its members were assessed immunologically before exposure to HIV and have participated in detailed follow up studies at regular intervals." (BMJ, December 1990). What he should have put here was that we had "unknowingly" participated.

and

"We have been studying HIV sequence change in a group of patients who became infected during 1984 ... The unusual circumstances surrounding the infection of these patients have permitted...." (Journal of Virology, December 1990). What are the "unusual" circumstances?

(g) By 1991 we are still finding published research on the Edinburgh cohort stating:

"... We have followed-up these patients since their seroconversion ... All 32 had been studied as part of an assessment of immunological changes in haemophilia during the two years before use of the contaminated factor VIII. ... Within the Edinburgh haemophilia/HIV cohort, which is uniquely homogeneous with respect to time and source of infection, we have now shown that the course of HIV-associated disease is related to at least two patient characteristics recognisable before exposure to the virus. ... We have now shown that individuals at risk of rapid disease progression can be identified in the earliest stages of infection and even before exposure." (Lancet, November 1991)

(h) And 15 years after the AIDS Study began we find the following:

"The two UK domestic plasma fractionators decided to manufacture different types of high-purity Factor VIII concentrates ... This offered us

an opportunity to compare the effects of these two products on immune function, survival, HIV disease progression and use of anti-retroviral drugs in a 3-year cohort study. ... believed that an insufficient number of patients with severe haemophilia A and HIV would agree to be randomized. For these reasons a prospective cohort design was adopted rather than a randomized trial. ... This difference was principally accounted for by the comparatively low CD4 counts of patients from a single centre, Edinburgh. The lower median CD4 count observed in the ion-exchange group at the beginning of the study was largely accounted for by comparatively low counts from a single centre, Edinburgh. Most of the HIV seropositive patients attending this centre had been infected from a single donor ... Half of these patients were reported to be either dead or symptomatic from their HIV within 4 years of seroconversion, which suggests that <u>they may have been infected with an unusually virulent strain of HIV</u> ..." (British Journal of Haematology, June 1998)

That half of these patients were reported to be either dead or symptomatic from their HIV within **4 years** of seroconversion suggested that they **may have been infected with an unusually virulent strain of HIV.** If this was the case, and it took Prof Ludlam almost 3 years to inform his patients of their +ve status, **I FIND THIS ABSOLUTELY UNACCEPTABLE.**

51. Dr Ludlam became interested in investigating AIDS in his haemophilia patients in 1983, then why did he not inform his patients of the possible risks of AIDS from Factor VIII/IX and ask their consent to carry out testing and research on them? Why did he not inform them of the risks which he thought the products were causing to them? Why did he think it necessary to carry out research on his cohort for at least 15 years without informing them? I find it totally unacceptable and outrageous that a doctor can carry out non-consensual research on a group of patients under what he calls his "pastoral care" and not be accountable for his actions. His research showed that his Edinburgh Haemophilia Cohort were infected with an unusually virulent strain of HIV – perhaps this is

also a reason why we were kept in the dark about the events which were taking place at the Royal Infirmary of Edinburgh from March 1983.

52. At no time was I ever informed that Dr Ludlam was carrying out AIDS research on me from March 1983 – at a time when I was asking Dr Ludlam (along with other doctors) of the risks of taking Factor VIII, and they all denied any problems with Factor VIII. Nor was I informed as stated by Dr Ludlam in 1985 when applying for Ethics Approval that I knew all about his research. Nor did I give my consent for that. Considering that I was not informed of my HTLV-III status until 1987, I cannot see how I could have given any such consent. At no time did I "donate" blood for research as stated in published research papers. The list of lies is just endless.

53. Perhaps the requirements for research discussed at the MRC Working Party on AIDS in October 1983 give us the answer as to why Dr Ludlam deemed it necessary to keep his research and my positive status from me, though not, it seems, from the rest of the scientific world. At this meeting the following was discussed:

"... the need to ensure the best use be made of the special combination of suitable patients for study ... The special features arising in relation to haemophilia were discussed and the possibility of identifying the role of imported Factor VIII concentrate used for UK patients was outlined. ... It was noted that attempts to detect such an agent [AIDS] in the US were being made in only a few centres, and it might be better to look for an agent early rather than in the later stages of severe disease. For this reason reliable identification of the early phases of the disease/infection was crucial. ... It was noted that blood product associated cases could enable some of these alternative hypotheses to be tested. ... The fact that the epidemic was lagging some three years behind that in the USA was considered an important factor ... This could enhance our ability to detect the emergence of AIDS and AIDS-related conditions in high risk groups. The underlying immunological and virological status of the high

risk groups before they encountered the "AIDS agent" could thus be defined. ... Further emphasis was given to the concept of identifying early phases of the disease for testing aetiological hypotheses. It was emphasised that at this stage national collaboration was possible and indeed essential on items such as an AIDS case-control study and active surveillance. This would need to be backed up by individual centres conducting cohort studies on patients in high risk groups etc. ..."

54. Because of Dr Ludlam's failure to inform patients of the risks of this known fatal disease – 16 haemophiliacs became infected from one batch of Factor VIII. Two Uncles, One Cousin and many haemophiliac friends have all died from AIDS contracted from this one infected batch at a time when their infection could and should have been avoided.

55. I cannot find the words to say how what is described as "The worst medical disaster in the history NHS" has affected my family, other than to say it has devastated **three generations**, and I do not wish for it to destroy the lives of future generations. The philosopher Santayana stated "*He who does not learn the lessons of history is condemned to repeat them*". I ask for this Inquiry to protect future generations of haemophiliacs by ensuring that the Government, the SNBTS and Haemophilia Consultants learn the lessons of the past to ensure that they do not repeat them in the future.

56. I feel that haemophiliacs at the Royal Infirmary of Edinburgh would have been better served if Dr Ludlam had informed us of the risk of AIDS instead of using us as guinea-pigs for non-consensual research for at least 15 years. Perhaps if he had acted more like a treating doctor than a scientist then at least 16/18 of his patients would not have been infected with HIV/AIDS and perhaps all of them would be here today to give their own statement to this inquiry.

57. It may be that I will wish to give a further statement to the Inquiry once my full records have been made available to me.

Statement of Truth

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

Signed GRO-C

Dated 27 February 2019