Witness Name: Alice Mackie
Statement No.: WITN2189001
Exhibits: **Nil**
Dated: 21 February 2019

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF ALICE MACKIE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 5 November 2018

I, Alice Mackie, will say as follows: -

Section 1: Introduction

1. My name is Alice Mackie. I was born on GRO-C 1956. I have been married to Robert Mackie since 6 June 1981. We have one son.

2. My husband Robert Mackie has Severe Haemophilia A with less than one percent clotting factor. To my knowledge he was diagnosed with haemophilia A when he was under a year old and his family has a history of haemophilia. When Robert was a young child, he was given fresh frozen plasma but only for serious bleeds. Then later he began to

be given Cryoprecipitate (Cryo) for bleeds. Until he was about 13 years of age all of Robert's haemophilia treatment was at the Edinburgh Sick Children's Hospital in respect of bleeds. Then his haemophilia care was transferred to the Royal Infirmary of Edinburgh (RIE), Lauriston Place, Edinburgh.

Section 2: How Affected

3. Before 1979 I do not know what Robert was treated with. In 1979 Robert was being treated with Cryo then by 1980 he was being treated with both Cryo and Factor VIII. From February 1981 he has only received Factor VIII. He has been treated with Scottish National Blood Transfusion Service (SNBTS), Protein Fractionation Centre (PFC) produced Factor VIII on every occasion except once. On the 7th June 1981 at 03.45 he received 960 units of Armour product, Batch Number U17609. At the time of being given this American Factor VIII he initially refused it and informed the nurse on duty that he did not receive American products that he has only had Scottish Factor VIII but he was told *"That is all there is – take it or leave it"* and since we were going on honeymoon, he just took it. Unfortunately, he took a severe adverse reaction to this product. His face was swollen, he had a fever and he had a rash on his face, arms and body, and we had to stay in the hospital for the rest of the night. In July 1981 bloods were taken from Robert for routine investigations, which it seemed included *"in particular liver function tests and Australia antigen screen."* Because he had received Armour product. He was ill for some considerable time after this infusion, so much so, he later had to visit his GP. I can recall one

year later he was still fatigued. This is the only time Robert has received commercial Factor VIII until he began using Recombinant. He also was given BPL Factor VIII (after 1987) due to the reactions he was taking from Heat-treated Scottish product, but took a reaction to that too. I thought it was connected to the processes they put the "safe" Factor VIII through to kill the HIV/AIDS virus but Dr Ludlam told us it was because he was allergic to Albumin. After this incident Dr Ludlam issued Robert with a letter to ensure that he did not receive anything other than Scottish Factor VIII if attending another hospital for treatment, the letter said to give Robert only SNBTS Factor VIII and not any other product. We at first thought it was because of the reaction from the Armour product, but learned from other haemophiliacs attending Edinburgh that he issued the letter to other patients at his centre. It is odd that Dr Davies preferred to keep Robert on Cryo and Dr Ludlam preferred to keep him on SNBTS Factor VIII, it now makes me wonder if research was the reason behind these decisions.

4. Since Robert began attending the RIE he was under the care of Dr Davies until the end of 1979 and then Dr Ludlum took over as his consultant, but when attending hospital for routine appointments or just for treatment, he was seen by not only Dr Ludlam but by other doctors. If it was just to collect Factor VIII for home treatment it would be a nurse that we would speak to and she would order the Factor VIII. Sometimes the Factor VIII was delivered to the Haemophilia Centre at Ward 23, sometimes we would go to Blood Transfusion Service (BTS) to collect it ourselves.

5. The Haemophilia Centre at Ward 23 consisted of a small room off of Ward 23. When I first began attending with Robert in 1979 the centre was like an "open house", by that I mean that needles, syringes, cotton wool etc were on a trolley in the treatment room, if there were no supplies left you just went to a cupboard and got more of what you required, a cinbin was also kept on the trolley. If Robert had to speak to or be examined by a doctor it would either be in front of other patients in the centre, or in the corridor. I can remember him with his shirt tucked up under his chin and a doctor examining his chest/side at the same time as the visitors to Ward 23 were walking past. The first time I encountered this I could not believe it, but the haemophiliacs just seemed to accept that that was how they were treated.

6. When Robert first began to take Factor VIII, he asked Dr Ludlam (and other doctors) if there were any risks from taking this product and was told that haemophiliacs could perhaps get hepatitis, but it was not a problem, it might mean that he could turn a bit yellow for a day or two but then it goes away – nothing to worry about. Before getting married he again asked Dr Ludlam if there could be any risks to myself or any future children from him taking blood products and was again told that there was nothing that we should worry about, there was nothing he could pass on to me, he asked this question specifically because I read in the information leaflet about the risk from hepatitis from blood products, and since it was specifically mentioned asked again, just to be sure. Throughout the following years I would read the package inserts, not every time, but regularly. There was always the mention of Hepatitis

(but this had already been discussed with Dr Ludlam) but there was never any mention of HTLVIII/HIV/AIDS during the time before heat-treatment of the Factor VIII when it was made "safe". Even after the end of 1984 at the beginning of heat-treated product the package insert still did not warn the patient of the risk or potential risk.

7. In 1983 everything suddenly changed. We turned up one day to find notices on the wall stating, "All blood spillages must be reported." The new instructions were that cinbins had to be used and the cupboards containing the syringes, etc were now locked and you had to see a member of staff for any equipment. The treatment room was even clean. The whole atmosphere and attitude of the staff changed during this time; Suddenly (around 1983/84) a new treatment room was added, it was small but gave some privacy. A nurse specifically for the haemophilia centre began working, haemophiliacs had never had a nurse specifically for them before. By now blood was being taken from Robert as often as he would allow. When we asked what tests were being done, I was told it was just routine testing. I never asked when on my own, always with Robert in attendance, so there was no reason that patient confidentiality could be a reason for not saying the truth. About the beginning of 1984 they began weighing Robert but this did not last for long, since Robert was not always prepared to have this done, but when we moved to Ward 45 the procedure began again. When we asked why this was necessary so often, we were told this was a new procedure.

8. Robert was given HIV/AIDS from SNBTS Factor VIII, produced at the PFC, Edinburgh, with known Batch Number 023110090 between March and May 1984. May being the first date given for Roberts seroconversion (this is confirmed in correspondence from Dr Ludlam to Dr Wensley (Manchester Royal Infirmary) on 17 September 1987 during Roberts legal proceedings, where it states his last seronegative result was on the 27th March 1984 and the first seropositive on 29th May 1984, we also have this date written in Roberts medical records dated 28 April 1989 when Dr Ludlam was requesting formal HIV reports, however, we also have correspondence from Dr Ludlam on 14th March 2003 stating *"We tested earlier stored samples and found that the last sample that was negative for HTLVIII was 27th March and the first positive result was 13th August 1984."* I do know that Dr Ludlam had Roberts serum samples tested on 12th January 1984, 1st February 1984, 14th March 1984, 9th May 1984, 13th August 1984 and 21st November 1984. There is no mention of 27th March 1984 or 29th May 1984. What I would like to know is what sample came back positive and when did Dr Ludlum receive the positive result and where is the report since it is not in Robert's medical records that I have in my possession (2 separate copies).

9. Before reading Robert's medical records it did not really matter the specific date of his seroconversion, but because the infected batch number 023110090 is for some unknown reason written differently in Robert's treatment sheets I now would like to know. The unusual way of writing the infected batch number stands out because in Roberts Factor

VIII Treatment Record Sheets it is the only batch number to be written out in full. Not only in the treatment record sheets (which is the information that the patients return) but also in the Record that is kept by the nursing staff when issuing the Factor VIII to the patient. Every other batch number in Roberts treatment record sheets (for about 5 more years) is abbreviated i.e. 540, 0350, 0070 whereas the "infected" batch number should have been written as 0090 it was written as 023110090. From this infected batch Robert became part of The Edinburgh Haemophiliac Cohort (which also includes two uncles and one cousin) who are classed by Dr Ludlam as a *"Unique Group"* or *"of special value"* and he may also have been infected with *"an unusually virulent strain of HIV"* but maybe the fact that Robert is part of the *"cohort of haemophiliacs who have become one of the most extensively studied group of HIV infected individuals in the world"* where *"A great deal has been learned from the careful study of these unfortunate individuals."*

10. Robert kept asking every doctor or nurse he came into contact with at the Haemophilia Centre if there were any risks to him with taking Factor VIII and he was always told there were no problems and nothing to worry about. Then he began to hear about something in America about some illness that was killing people, we did not know what it was, but for some unknown reason he began asking about it. By 1983 he was continually asking since he had begun to hear about deaths. Along with Dr Ludlam he asked Dr Tucker, however, we later discovered (2003) that whilst Dr Tucker was telling us that he knew nothing of the

"disease" and that he did not know what we were speaking about, he was taking blood from Robert for an AIDS Study and carrying out skin tests into what he informed us was to do with reactions to Factor VIII but was in fact in relation to the AIDS Study being carried out on him. We did ask Dr Tucker when we saw him at Borders General Hospital but all he would say to us was *"I was only doing as I was told"*. (This we discovered from documents released under Freedom of Information). The last blood sample we have evidence of in Robert's medical records regarding this AIDS Study is in November 1984 and the blood sample was taken by Dr Tucker himself. Because of the amount of times Robert was asking about how safe the Factor VIII was he eventually got branded a troublemaker by the staff because he was discussing it with other haemophiliacs. He got told if he did not stop frightening other patients with his questions he would be barred from the hospital. This was at a time when we did not read newspapers, only listened to the radio, and there was no way we would have had access to any medical journals, but then again it was also at a time when we believed that doctors told their patients the truth, and would have let us know of any risks – old or new.

11. Many years later we spoke to another Edinburgh HIV/AIDS infected haemophiliac and he told us that because he kept hearing Robert asking if the Factor was safe, he began asking the same question. He said he did not know exactly why, but thought that if Robert was asking, there must have been a reason. Sadly (as he said) he now knows the

reason. We also had a Hepatitis C haemophiliac patient who said that his parents wished they had listened to Robert instead of the doctors.

12. Even when 1984 arrived, every time we went to the hospital Robert was still asking and still being told the same thing – no problem, nothing to worry about, don't know what you are talking about.

13. In December 1984 Robert received a letter from Dr Ludlam inviting him to attend a meeting which was being held in the (Little Theatre) Lecture Theatre at RIE. Robert and I both attended this meeting along with other haemophiliacs, including family members. At this meeting I can recollect Dr Ludlam and Dr Forbes (Glasgow). At this meeting Dr Ludlam stood up and explained about HTLV III and how it could be transmitted, that it was known to be transmitted by blood products and possibly sexual contact and that there had been a problem with a batch of Scottish Factor VIII and some patients had been infected with HTLV III from it. At this meeting it was stated that if you were HTLV III positive you should use condoms and use rubber gloves and aprons when taking treatment and cleaning up spillages (these would be supplied by the centre). He then went on to tell us about Heat Treatment and that Scottish Factor VIII was now safe to use since the heat treatment killed the HTLV III virus.

14. At this meeting there were Robert's uncles, cousin and other haemophiliac friends and we all left believing that those who had received the "infected" batch and were positive had been informed by Dr Ludlam personally before this meeting took place, after all, what idiot

would hold a large meeting to tell those attending that they were infected and had a fatal and sexually transmissible disease? Therefore, we all thought (incorrectly) that the group of haemophiliacs beside me, along with Robert were all negative. Robert, his uncles and one cousin and haemophiliac friends (which were really an extended family), all left the meeting saying to each other *"Have you been told you have this?"* and each one saying *"No, thank God!"*. I left the meeting thinking the same thing *"Thank God Robert is not infected with this thing."* Seems according to Dr Ludlam, I was the idiot in not understanding what he said. Several years later, we learned that not all the people who attended the meeting were HIV positive. Some were negative and not all the HIV positive patients were at the meeting. We learned this through friends and relatives. We have since learned though Freedom of Information requests that according to Dr Ludlam it was up to the patients to *"realise that they have received a contaminated batch and know they have developed HTLV III"*. If the patient did not *"realise"* then according to Dr Ludlam they *"did not wish to know."* Surely it was Dr Ludlam duty of care to inform his patients individually and face to face as soon as he himself received their test results that they had received the infected batch and that they were infected and not leave it up to them to *"realise"*? Should Dr Ludlam not have informed the patients before this meeting took place? Even after this meeting, was it not the responsibility of Dr Ludlam to contact the patients and inform them as soon as possible?

15. None of us realised that this meeting was to tell us that they had been infected but had not yet been informed of this fact, that this was the way in which Dr Ludlam had chosen to inform his patients that they were infected with a sexually transmissible and fatal disease. I believed that this meeting was just to inform us of what had already happened to some haemophiliacs and the impression given at this meeting was that everything was fine now, there was no risk from HTLV III since the Factor VIII was now being heat treated and everyone sitting next to us was fine since Dr Ludlam had not informed them that they had this disease. It also turns out the only reason he held the meeting was not to inform his patients of their infection, but because the media were going to publish an article in a newspaper about a group of Edinburgh haemophiliacs who had become infected. I cannot say often enough how stupid I now feel in not realising – but then again, I should not have had to "realise" should I? Even after this meeting took place, at no time did Dr Ludlam, Dr Tucker or any other doctor or nurse mention the word HTLV III or HIV or AIDS. Even if they were afraid of how Robert would have reacted, surely someone should have informed me. They could have mentioned it to me when I was on my own when collecting Robert's home treatment. I cannot understand why I was not informed. Dr Ludlam put my life and our son's life at risk by not telling me or Robert. I am so angry at this fact. I was not at risk from Robert when dealing with his treatment because we were always very careful even before AIDS appeared. I can recall that in 1986 Robert cut his hand very badly on a can and I cleaned his wound without using protective

gloves. I was also the person who would sometimes mix his Factor VIII when Robert was unable to, or clean up spills which occurred during his treatment, through all of this I was never issued with gloves or aprons. Also, when Robert went fishing his friend had to remove a fishing hook from his hand and he could easily have become infected through contact with his blood.

16. Whilst we were at the above meeting our son was with my mother and sister and when we told them what the meeting was about, the first thing my sister asked was *"Is Robert OK? Has he been told he has it?"* I told her that he is alright, he is not one of the ones who have been told they are positive – How stupid could I have been?

17. Since Dr Ludlam informed us at the meeting that the Factor VIII was now being heat treated to kill the 'virus' and the product was 'safe' to use, Robert continued taking Factor VIII but also continued to ask the doctors at the haemophilia centre if Factor VIII was safe to use. He was always told that everything is safe and there is nothing to worry about. He eventually stopped asking, and we still did not receive disposable gloves or aprons, so assumed everything was fine.

18. The Haemophilia Centre was moved from Ward 23 to Ward 45 in 1985/86. This ward was at the other end of the hospital. The centre had its own reception, treatment rooms and consulting rooms, along with its own nursing staff. If you were an in-patient you still went to Ward 23.

19. From December 1984 to January 1987 I never heard the word AIDS mentioned in front of myself or Robert by any member of staff, we used

to hear other patients attending tell all the jokes about AIDS or discussed in general, but I never really took any notice.

20. By the end of 1986 Robert was healthy, we were getting ready to change our lives, he had been offered his "dream" job as a ghillie in the North of Scotland. To us, everything was falling into place, all our plans seemed to be coming to fruition. We could not have been any happier. We had everything planned. Then (unfortunately) 1987 arrived.

21. We received a letter from Dr Ludlam requesting Robert attend a meeting at his office in January 1987. (This letter was unfortunately destroyed by our solicitors) We somehow knew when the letter arrived that something was not quite right, there was no indication in the letter what the meeting was to be about, but I just knew that something was wrong because I could never recall Robert being given an appointment to see Dr Ludlam in his office. I could not understand why we were not just to go to Ward 45 as normal. As usual, I went with Robert to this meeting. When we arrived at his office he was not there yet, so we were told just to go in. I could not believe the number of files that were lying everywhere, I could not understand how he could find anything, I remember thinking that it would drive me mad having to work in this room. When he arrived and saw me sitting with Robert, he asked me to leave the room, when Robert said no Dr Ludlam left us for 5 minutes to discuss it. On his return Robert still insisted I stay. Dr Ludlam did not look too pleased at this decision. There was no lead into what Dr Ludlam said next. He just came out with three questions *"Have you used intravenous drugs, had sex with any men or had sex with any*

other woman?" Robert replied *"No"* to each question. Dr Ludlam then said to Robert *"You're HIV positive"*. He then went straight on to ask us what precautions we were taking and we told him that we were not taking any specific precautions since we were trying to have another child. He told us to use condoms as this was a sexually transmitted disease and not to have any more children. He then went on to tell us not to tell anyone, including our own families, including Roberts haemophiliac relatives (Two Uncles and One Cousin were told the same, not to tell anyone) because of the stigma and discrimination attached to it. Robert asked what the prognosis was and Dr Ludlam replied *"I have more chance of dying from a heart attack than you have of dying from AIDS"*. Robert also asked how many haemophiliacs had been infected and he said *"Just a few"*. He never looked us in the face, he just looked down at the paper in front of him and was writing in what I took to be Roberts medical notes. Robert did ask how he had become infected but Dr Ludlam did not answer this question, what he did tell us was that he had met the donor, and that he was a homosexual who was now dead. He told us that Roberts infection was just *"one of those things"* and that it *"could not have been avoided"*. Robert was not told the date he was infected, or when the test was carried out and we thought that Dr Ludlam had just received the results, he was not offered any treatment, offered or given counselling nor was a test offered to either myself or our son, at this point it never crossed my mind that I could have been infected. I was under the impression that the test had just been carried out and the results just returned to Dr Ludlam. Dr

Ludlam did ask Robert if he wished to change consultants but Robert decided to stay with Dr Ludlam because we were under the impression that he did not know of any risks to Robert before he became infected, as he had already told us *"It could not have been avoided"*. If we knew then what we know now he would have requested another doctor. Had Dr Ludlam been more open and prepared to talk at this meeting perhaps we would have asked more questions, but I just felt that he wanted it over and done with and us out of his office. I do not know if he was afraid of our reaction, perhaps not everyone took the news with calm. Thinking on it, 30 years later I feel that it was not something that Dr Ludlam wanted to discuss, perhaps it was with me being in the room, or perhaps he just felt uncomfortable giving bad news. At the time it never crossed my mind that in December 1984 we were told that the Factor VIII was free from HTLV III due to heat treatment. At this meeting we were also informed that any treatment required in relation to Roberts positive status would be carried out at the Haemophilia Centre. Some people will say that when you are told upsetting/bad news you forget everything that is said, well I can assure you that I remember it all. To me it is not something that I will ever forget.

22. The advice given was what was said at the meeting with Dr Ludlam in January 1987, which was really nothing. There was at the time no counselling given after this meeting and definitely no support offered – just a sense of, you have this thing that will eventually kill you, but so what! We really had to find out everything ourselves. By this time there were booklets on a table at Ward 45 which I began to read.

23. You cannot imagine the journey home after that, the silence going was bad enough, but the silence going home again was the worst thing ever, everything and anything was going on in my mind. I kept going over what was said, and how little I knew about HIV/AIDS. The silence was unbearable, what could we say to each other? (Nowadays I wonder how other haemophiliacs who were informed on their own without their partners being with them managed to go home and inform their wives/partners that they had HIV/AIDS). I know how I coped – In silence. When we arrived home, I cannot say what Robert was thinking, all I know is that I went upstairs and cried. At the time (1987) the little that I did know of HIV/AIDS was that you got ill quickly and died.

24. Regarding Hepatitis, we received a letter from Dorothy G Chapman, Clinical Assistant, RIE on 20 February 1990 stating *"A new blood test has recently become available for assessing hepatitis and we would like to evaluate its usefulness. If the early promise of the new test holds good it is likely to be very valuable for evaluating both the suitability of blood donors as well as the safety of Factor VIII and IX concentrates. We wish, therefore, to review case records to assess if and when individuals have had hepatitis or been jaundiced. We also want to relate the blood test results to the use of different forms of treatment."*

25. The above only states a new blood test for hepatitis, and that they just wanted to look at Roberts medical records, it does not state Hepatitis Non-A Non-B or C. It does not state that a new form of Hepatitis has been discovered, therefore we were led to believe that it was a new test for either Hepatitis A or B, up till then we had never heard of Hepatitis C

(Non-A Non-B). There was a questionnaire which was included with the letter but Robert never returned it.

26. What was said to him at a meeting at Ward 45 with both Dr Ludlam and Dr GRO-D in May 1993 was that he needed to have an endoscopy and a liver biopsy to tell if he had Hepatitis C. Robert agreed to the endoscopy but later cancelled this appointment as he thought it too risky and flatly refused the liver biopsy as he knew that poking about and taking a slice of anything inside a severe haemophiliac was not really a good idea. He was never at any time told that there was a blood test that could be done to tell him the results. There was no discussion as to how serious Hepatitis C was or could become, and again no offer of counselling to cope with yet another, what we now know as, serious and possibly fatal disease. We were both trying to cope with Robert being infected with HIV/AIDS and what we definitely knew was a fatal disease, so when Hepatitis C came along, I do not think we really bothered much about it but this was because we were more worried of how to survive HIV/AIDS and did not know at the time just how serious Hepatitis C was, or that it could lead to liver failure and death or that it could have a serious impact on his HIV/AIDS status. Robert still refuses any type of procedures which would involve any risk to him bleeding.

Section 3: Other Infections

27. I am not aware of whether my husband has any infections other than HIV and Hepatitis C

Section 4: Consent

28. Robert is one of the group of haemophiliacs who were being studied/researched on in relation to AIDS from 1983 by Dr Ludlam and his staff without his knowledge or consent before they became infected, and enabling Dr Ludlam to state in publications that they were studied for AIDS before, during and after infection. This research was being carried out on Robert at a time when according to some March 1984 was too late in the day, at a time when it was known that HIV/AIDS could be transmitted via blood products.

29. Robert did not at any time between 1980 and 1987 give consent for an HTLV III or HIV/AIDS test to be carried out on him. At no time did a doctor or nurse say to him that they were/wanted to take blood specifically for an AIDS test, all the bloods that were taken from him was to our knowledge for "routine" blood tests, tests related to his Factor VIII levels. However, more and more blood began to be taken from Robert. In the 1980s the blood was drawn into syringes and then put into smaller vials, and it got to the point that they were taking at least a 50ml syringe full, sometimes more. I began to get concerned about so much blood being taken at one time and asked what it was all for, and if they took much more, he would need a blood transfusion. They never said what it was for – they would just ignore me and continue what they were doing. This conversation happened on a regular basis.

30. In January 1983 Dr Ludlam asked Robert if he would be prepared to donate Factor VIII free plasma at BTS. This was the first time FVIII free

plasma was requested, previously (as with other select haemophiliacs) it was just a pint of blood. This donation was given around March 1983 at the same time Dr Ludlam decided to include Robert in an AIDS Study. What I fail to understand is why anyone would request blood (FVIII free plasma or not) from a haemophiliac at a time that it was thought possible that haemophiliacs could be infected with HIV/AIDS. What was this donation used for?

31. In 1985 Dr Ludlam wrote to me and asked if I would give blood for research purposes (unfortunately this letter was destroyed by our lawyer along with other papers). When I attended the haemophilia centre Sister Philps (now the haemophilia centre permanent nurse) began to take blood for this, we began asking questions regarding what it was for and she told us *"genetic"* purposes. We thought it strange at the time as Robert and I are not blood relatives and I asked her why the blood was needed since Robert and I are not linked genetically and I am not connected via haemophilia. She looked very sheepish and flustered and had trouble finishing off the withdrawal of blood. I now think that this is how Dr Ludlam tested me for HIV without us knowing. We have since found out under the FoI (in a document entitled "Interim Report on Survey of HTLVIII Antibody in Haemophiliacs in UK – 27 September 1985") that spouses were also being tested for HIV at four UK haemophilia centres, with Edinburgh being one of the participating centres. Sister Philps left the Haemophilia Centre about Mid-1986, and Staff Nurse Reynolds took her place, she was then joined by Sister Jones later that year. I cannot recall the year for moving the centre was

1985 or 1986, but I do know it was before Robert was informed of his positive status.

32. As with HTLV III testing, Robert was never informed of being tested for Hepatitis C, he never gave consent for this test, in fact he was never told that there was a specific blood test for Hepatitis C and it was never explained to him/us what exactly Hepatitis C was or indeed how serious it could become.

Section 5: Impact

33. When Robert was told that he was infected with HIV, "normal" life stopped and we began a life full of lies, deceit, secrecy, more secrecy and lies and in a way a life of loneliness and isolation. This is also the point in which Robert had to turn down the job offer to become a ghillie because he would have had to explain to his employer (who did not know he was a haemophiliac) and every person he ghillied for that he had HIV/AIDS because of the potential risk.

34. You cannot separate Robert's life from mine, what happened to Robert also happened to Robert, myself and our son, we are a family. What Robert has gone through we have all went through in one way or another (and still are), every little piece of it.

35. Before 1984 Robert was a fit and healthy person, he played all types of non-contact sport such as Tennis and Golf but his passion was for fly fishing which entailed a lot of walking and exercise. He could walk for miles and not get any bleeds into his knees and ankles (although many years later Dr Dennis did tell him his problems with his knees nowadays

was due to him *"using them too much(?))"*. Robert was always active, never being able to sit in one place for long; he really liked the outdoor life. His only ill health was 1981/82 due to the Armour Factor VIII but he built up his strength and health again.

36. Roberts working life consisted of many things including looking after the big cat section in Edinburgh Zoo (lions, tigers etc). It seems that even this part of his life was comparative to a non-haemophiliac, and very active. Today, he does not have the energy to do anything, he is always tired but not depressed, only very angry, and has great difficulty walking a yard never mind for miles. Unfortunately, he is still more interested in outdoor activities than computers or television and this can make life a lot more difficult to cope with.

37. The consequences of what happened to us after Robert was told of his +ve status are vast and difficult to tell in this statement. Before being told, we were a happy family, everything to look forward to, but "normal" life just seemed to stop. As I said before, we began to live in fear, uncertainty, worry and most of all secrecy and lies, which in itself is a very difficult thing to deal with.

38. We learned our first lesson very quickly. We had (previously) arranged to go and stay for a few days with family, we thought that since we were living under their roof, we had better tell them of Roberts +ve status so we could not be accused of anything in the future. After all, these people were family, people whom we thought would be caring, kind and understanding. Well, when we did tell them, we were asked to leave

their house because they did not want us to "infect" their children. That episode only emphasised what Dr Ludlam told us *"do not tell anyone, including family"*. Well, from that point on we lived as a family of three (two adults and one (at this time) very young child). Because of this, the closeness we previously had with our families has gone and is something that can never be fixed. We could not face my family because of all the lies we had to tell because we had never told any of them that Robert had contracted HIV, and Roberts family because we were afraid that the rest of them would react the same way as we had already been subjected to. We decided just to keep to ourselves, so we just ended up staying away, not visiting or going to family gatherings. Our son missed out, he grew up without the closeness and friendship of family because we chose to isolate ourselves, he suffered in this way more than we did, nowadays, he has aunts, uncles and cousins but really only in name (all that is except one aunty and uncle who would still take care of him if needed.) As for the family we visited – they soon discovered that there were another 3 family members infected.

39. When we got home, we were so angry and upset that this disease could cause such a reaction from family that we decided to write to the Haemophilia Society (of which we were not members) in late January 1987 asking if we had a case against anyone for Robert's infection. They replied on 10 February 1987 telling us that they thought that *"there is no guarantee what so ever that action against a health board or an individual doctor would be likely to succeed."* At this time, I have to say that we had not heard of haemophiliacs taking any legal action against

the government in Scotland, and were also unaware of any legal action being taken in England and since we were not members of the Haemophilia Society we did not get any information regarding what was happening in England. At this time, we really did not know how many haemophiliacs had become infected because Dr Ludlam had in 1987 informed us that not many haemophiliacs had become infected. After the letter we received from the Haemophilia Society we decided that we would to see a lawyer to see where we stood, even this was difficult to do since no one wanted to go up against the Medical Profession or Government. By April 1987 we did eventually find a firm prepared to look at our complaint, Lindsays in Edinburgh was about the 6th firm we asked. At the same time, we spoke to Roberts uncles and cousin and advised them to go and see a lawyer and take legal action (which they did). We then went to see a haemophiliac friend who we knew also to be infected and advised him to go to see a lawyer.

40. Because of Roberts mum learning of her brothers and nephew being infected we thought that it only right that we tell her about Robert. I think she knew before we told her. She never again spoke of it unless we said something to her. I do not know if she really understood the seriousness at the time, but a few years later she did.

41. Although Lindsays took Roberts case, they had great trouble finding a doctor prepared to deal with our case. In October/November 1987 we were sent by Lindsays to Dr GRO-D of Manchester Royal Infirmary for a medical report on Robert regarding his infection, at the time of his medical by Dr GRO-D we did not know that Dr GRO-D was one of the

doctors who were included in the HIV litigation being taken by English haemophiliacs, I do not know if Mr GRO-D knew of this, but I suppose to him it did not really matter, as long as he was able to give a medical opinion – today I do not know how he would have been able to give a non-biased opinion, since he knew Dr Ludlam I would hardly think that he could (but that is my thoughts retrospectively). Robert had a medical and bloods taken, I also gave blood for my first HIV test, which was negative. I do not know if this test result was sent to Dr Ludlam or not, but I did not give permission for him to do so. During the Scottish HIV litigation, we did not have contact with English haemophiliacs. During this litigation I had my first encounter with full blown AIDS. It was in August 1988. We were at Ward 23 to collect Factor VIII one evening. Robert, being Robert had a look to see if any haemophiliacs were in-patients. (He always checked whenever he was at the hospital to see if anyone was in and that they were being treated okay and if they needed anything – he has always done this – even before I met him). His closest friend was in a side-room. When he saw Robert, he started to shout at us *"The have murdered us Robert, they have murdered us."* When the staff heard him shouting, we were told to leave, we could still hear him shouting when we were getting into our car in the car park. He was in such a state. Robert did not understand what he was shouting, but we spoke of it for a long time afterwards, even after he died. Sadly, this was the last time we saw him. I do not want to say what he looked like, but I will never forget it, and it made me more afraid than ever.

42. In May 1991 we discovered that Dr GRO-D was a participant in the HIV litigation in England, we also discovered from the "Opinion for The Scottish Haemophilia/HIV Litigation Group" that the QC who was writing this opinion for our (and other) lawyers had not been given any access to details evidence available to the solicitors and counsel who had dealt with the English claims. In particular he had no access to the many thousands of documents obtained on discovery in the English proceedings (cf. Re HIV Haemophiliac Litigation, Court of Appeal, 20 September 1990); nor did he have the benefit of a consultation with any expert witness. His view was to accept the offer. In July 1991 Robert signed to accept the payment. At the time we were pressured by Mr GRO-D into accepting the offer. He put the fact that haemophiliacs were dying and if Robert tried to take it to court, he would probably be dead before the case was heard. He also told us that if we did not all accept then no one would be paid. Again, we listened to someone we should have trusted. We did return to Lindsays a few years ago to ask if we could get the paperwork from Roberts case, but he said that because it was longer than 10 years it had been destroyed.

43. We then had another death in August 1990, his illness was completely different to the previous. Then in 1992 we had two more deaths in our "group" and one in 1993. Each one different, each one more frightening than the last. The reality that it was getting closer to home began to hit. One of the hardest to accept was in 1994 when one uncle died in the next bed to his brother who was also ill with AIDS. Before he died, he told us that he could not take any more, that he could not cope with

having AIDS – he just gave up. A couple of months later his brother died. By now we were unable to actually go into the funeral service, we began paying our respects by waiting outside, it was just so heart breaking. It even got to the point that when we were at funerals we felt as if people were looking to see who looked the sickest and would die first. It was horrible, Robert and his cousin joked about it at their uncles, but underneath they were not laughing. Then by the time 1996 came his cousin died. That was it, we could take no more. The thing is, when someone is dying from AIDS, they never seem to die the same way, there is always some difference in the illnesses they take and their bodies all deteriorate differently, by this time the death toll that we knew of in the Edinburgh group was 9. That was just too much for Robert, that was when he started to change, he began to become distant. This is when the drinking and rebelling against life in general began. He came up with this idea in his head that if he could get both our son and myself to hate him enough, we would not miss him when he died, he was fed up seeing the sadness in the families left behind. Now that we are all older, he now regrets this, but you cannot take back the past, the three of us missed out on a lot of family things as Robert was unable to attend school events with our son, unable to be there for his birthdays and lots of other memorable parts of our sons life, all because he did not want to get too close to him just to die, as I said, he tried to distance himself from us as much as he could. Unfortunately for him (lucky for us) his plan did not work, only now he feels that he has to make up for what he did in the past, and I am afraid you cannot change the past.

44. It was about this time that I stopped opening my front door to anyone. I also began to ignore the ringing of the phone. Eventually, as Robert's health deteriorated, I turned it off completely. You can find in Roberts medical records comments from Dr Dennis regarding phoning Robert at home and getting no answer and therefore assuming Robert was out. What she never noted was that I had informed her many times that did I not answer the telephone so it was pointless the hospital phoning for any reason. This was not just for the hospital but also for anyone. That is why my mum and I would write to each other regularly, it was easier to speak to her that way.

45. From 1996 we began to live without plans. The only "plan" we made was to tell my sister (in 1990) because we had to put into place plans if both Robert and I were to die. That is the only person outside Roberts family that knew. Then a couple of years later I asked her to tell my mum because I could not, she was so upset that we did not tell her ourselves or sooner, or believed in her enough to know she would understand, it also answered a lot of questions as to why we stopped visiting, this upset me even more. My dad, well he is a different story. We never told him, in fact no-one needed to tell him. He found out one evening at his work. He was security at the WGH and saw Roberts name somewhere next to the word HIV/AIDS. He put two and two together and came up with the right answer. He is the person who gave me the MRC magazine in which Dr Ludlam speaks about the Edinburgh Haemophilia Cohort. I never asked, but still think he managed to connect Robert, his infection and the Edinburgh Cohort, which was

more than I did at the time. He never mentioned the fact that he saw Roberts test results until many years later. It did make me wonder what else he saw that he should not have.

46. Robert has always been very wary of doctors all his life even though the medical profession has been a large part of it. Perhaps we should have been more wary, because before Dr Ludlam began at the haemophilia centre, we were told that he was "hired" more as a scientist than a doctor. The fact that he chose to accept Dr Ludlam and his advice regarding treatment (Factor VIII against Cryo) was a big step for him. At the beginning (1980) I can remember him always saying that he preferred to stay on Cryo, but Dr Ludlam informed him that they were not making Cryo for haemophiliacs any more so he just went with the Factor VIII. From 1982 he was treated by prophylaxis. This form of treatment continued until 1985 although we now know that prophylaxis for haemophiliacs should have stopped by 1983. The reason was that he was busy at home decorating, carpet laying etc because he was independent, and would do anything that needed done, if he had known of the high risks from FVIII we would have asked someone else to do all the "heavy" work, and he would not have had the recurrent bleeds in his elbow or any bleed that would have required treatment. His infection from FVIII only emphasised why he would not seek medical help if he needed it. It got to the point that I was terrified of when Robert would get ill. Up until the late 1990s his health was not always good, he had his off days and illnesses, but he would never attend the hospital unless he had to because of something not clearing up, or GP because the doctor

as far as we knew did not know of Robert's status because we had instructed the hospital that he was not to be told. This was because we lived in a small town and the doctor's receptionist was our next-door neighbour. Again, secrets. We managed to cope well enough, by that I mean that we struggled through, and I do not think the haemophilia centre doctors were happy at treating Robert for things other than haemophilia, this again was a reason we tried to keep away. They could never understand that Robert could not attend his GP about an infection but keep why he was so worried about the infection to himself. Apart from that Robert was never one to attend the hospital for "regular" appointments anyway. I will add here that he was not the most patient of patients – but it was soon to get a lot worse.

47. We still just got on with life. I tried to make our sons life as "normal" as possible, but after Robert's cousin died, he took to fishing all the time and then the drinking began. It was his way of coping. The staying away from us, of trying to make him look a bad husband and father. People did say nasty things about him, I would sometimes hear them pitying me for being married to a drunk, even our sons' friends' parents would pass comments not directly to me but our son would hear them, whether it was from the parents or his friends I do not know, but as we all know people can say very nasty things if they want. I eventually informed his school that his dad had cancer, this was the only way I could account for Roberts dad being ill. Cancer was something that people accepted, and perhaps made things easier for Robert during the rest of his schooling, I sometimes thought that he preferred to be with his friends'

parents rather than have to spend time at home. But then because of all the secrets and lies I had to keep, along with all the tension at home with one thing and another I just had to accept what was thrown at me and since I thought he was too young to know what was really wrong I just had to accept how things were. People can be so cruel!

48. People did talk, even family members would talk, the ones that did know what was wrong and the ones that did not. I thought that the ones that knew would have understood why he was like he was, but they seemed to be the biggest critics, always running him down because he drank so much, and behaved the way he did. We did not see them very often, perhaps a couple of times a year, but eventually it was better not to see them at all. So, we just continued to live in our own secret world. By this time, I was really on my own, having to cope with not only Robert and our son but also trying to keep family members from making upsetting remarks in front of Robert and our son. When Roberts uncles and cousin began to get ill and die, the rest of his family all said to me that if I needed any help looking after Robert, just let them know, they would always be there – that also did not happen. When Robert did get ill, they all disappeared. I have to add here, that today thinking back on things I do not really blame them. At this time Robert was not the easiest person to get along with, he just seemed to be festering.

49. Nowadays Robert requires 24-hour care. He needs help with everything from getting out of bed to going back into bed. He cannot be on his own because of the panic attacks he still takes. He does not really go out on his own because of the panic attacks and his quick temper. He cannot

be left on his own because he again panics if I am not there with him. If I do go out I have to ensure that someone is with him. If he goes out without me I have to make sure that someone is with him.

50. Myself, I seem just as bad as Robert. I panic if I do not know where he is. I panic if I am in crowds or busy shops. I panic if I am anywhere noisy. Before all this I used to be a very timid person, now I am the complete opposite. I have learned that I have to shout for the medical profession to listen.

51. We still do not go out much in the daytime. All our outings are in the evening or during the night. We do not eat in restaurants, or in cafes because of Roberts temperature problems and because we both tend to panic if they are too small or busy. We both still have panic attacks, but I am learning to control them.

52. During all these years I was only offered a HIV test once at the RIE (because of GRO-C and never was I offered a Hepatitis test. At no time after this did anyone offer me a test to check that I was still negative for both HIV and Hepatitis C.

53. I was not offered a test to find out if I had been infected with HIV before or after January 1987 by Dr Ludlam or by any other doctor or nurse at the RIE. I did get tested in Manchester in October or November 1987 by Dr GRO-D during Robert's medical for his legal case, I do not know if he contacted Dr Ludlam about my test result (without my knowledge or consent). However, I eventually got tested at the haemophilia centre in February 1989 and received the results in March 1989. The only reason

I was tested by the centre was because we had heard that TB was one of the infections which AIDS patients seemed prone to so in December 1988 Robert asked Dr Ludlam if he was at increased risk of TB and he *"responded in the affirmative."* Since, Robert and so many family members were infected with HIV, we asked Dr Ludlam about having our son vaccinated for TB. Dr Ludlam suggested that our son would need an HIV test first. Rather than him being stressed Dr Ludlam said that it would be easier for our son if he gave me the test first. GRO-C GRO-C but I cannot understand why I was not offered a test after Robert tested positive in 1984, or when we were informed in 1987 that he was infected. GRO-C GRO-C However, it does make me ask the question now regarding the "genetic" blood sample I gave in 1985 if it was a "secret" AIDS test carried out by Dr Ludlam. This ties in with documents released under FoI regarding testing spouses/partners. It also brings me to a questionnaire Robert received through the post around this time which asked questions about our sex lives, this questionnaire was said to be in connection with the Factor VIII, but after reading FoI the questions on the form were the same vein as the ones mentioned in documents in which a doctor states that he thought the questionnaire was "unethical and immoral". Unfortunately for me, I tore the questionnaire up in disgust after reading the questions.

54. I received HIV and Hepatitis C tests at the WGH in 2004. Dr Rae advised me that it would be a good idea to get myself tested. Thankfully both came back negative, but I am still at risk.

55. Robert will not attend hospitals or doctors, but there is no way he will ever be an in-patient again. This is because the last time he was in hospital, albeit a long time ago (1994 RIE) he was treated deplorably. They did not feed him and I had to ask for the medication he required, his bed was never changed or made and I even had to ask for water for him to drink. I have panic attacks at the thought that Robert will die – I know everyone dies, but even after all these years I am afraid that he will die the same death as his uncles, cousin and friends. After almost 20 years I still have nightmares about the way they all died.

56. Since Robert began to speak out about being infected with HIV/AIDS his friends tell us that they now think they understand why he was like he was. During the 'bad' years they could not understand why he did what he did, why he did not care about anything or anyone. The things he would say to them, the risks he would take.

57. My own siblings have accepted things are as they are. The sister I informed of early on still tries to be supportive, but she also understands that we still prefer to be on our own.

58. Roberts siblings have accepted things too. They also now accept Robert for who he is now. Since he has changed a lot over the past 30-odd years, however he is still not a person to forgive easily and is still distant with some.

59. My biggest sorrow is not being able to have any more children. Dr Ludlam told us in 1987 that we could not. But at least we were lucky in that we had our son (just) before HIV/AIDS became known.

60. It has been good for Robert to be able to speak to others about his infection. He does not have to live with so much secrets and lies anymore. To him it is all out in the open. Me, well, I have always been in the background where this catastrophe is concerned. I still find it hard to speak to anyone about his infection and the devastation it has had on my family. Perhaps when this inquiry is over I will not be afraid anymore.

61. Even though the last 30-odd years have been hard on me I still would do it all over again if it meant that I still had Robert by my side. I suppose it is as they said during our wedding ceremony *"For better, for worse, for richer,* for *poorer, in sickness and in health – till death do us part".* I perhaps did not get all the good bits but I would accept them again if it meant being with Robert.

Section 6: Treatment, Care and Support

62. After being told that he had been infected the doctors and nurses who saw Robert at the haemophilia centre did not mention HIV/AIDS, except once in 1987 when he was given an information sheet about a trial of AZT for HIV, but as it was a trial Robert was very wary and refused the treatment. Friends and family began taking this treatment at some point,

and they died. We were later informed by Dr GRO-D (WGH) that this was probably due to the high dosage used in the trials so if Robert had begun AZT he probably would not be here now. As for speaking to other infected patients, the word HIV/AIDS were not allowed to be mentioned in the waiting room either between ourselves or with other patients. It was as if it did not exist – if we did do not speak about it – it was not there.

63. The whole situation was very weird. After we were told of Roberts infection the words LAV/HTLVIII/HIV/AIDS was never mentioned again by his doctors (except in relation to AZT above) for many years it was as if it was a taboo subject at the Haemophilia Centre, in fact it was a taboo subject as we were told never to mention or speak about AIDS in the haemophilia centre in front of other patients. Perhaps they were right in that because when we moved to the RIE at Little France another patient (not haemophiliac) overheard Robert and myself say something about AIDS, he turned around to the person he was with and went on about it only being drug addicts and homosexuals who had AIDS and they should not be allowed into the hospital beside other decent patients. I did complain to the receptionist and sister at the time because of what and how he said it upset me and made me so angry.

64. The first mention of counselling was via a letter from Dr Bernadette Auger and someone called Alison Richardson (we now know who she is, but not then) on 24th November 1988 inviting Robert to a meeting with other "infected" haemophiliacs, wives/partners/parents were not invited to this meeting. By this time, we had decided we were in this

together, there would be no secrecy between us and Robert did not think he would be comfortable sitting in front of a group of people who perhaps he did not know with a doctor and a stranger, since he did not know who Alison Richardson was. He also did not attend since he did not know who else might be at the meeting. I partially blame this on Dr Ludlam telling Robert not to tell anyone.

65. Robert did go to see a psychiatrist/psychologist (but I had to be with him since he would not go on his own) for a short time. This was after he began his treatment at the WGH. Dr Tait informed us that we were both suffering from Post-Traumatic Stress Disorder.

66. Robert's health began to deteriorate, and I can recollect Dr Dennis speaking to Robert about seeing Dr GRO-D at the WGH in about 1998 but Robert still did not trust the treatment, also since it would mean him going to the WGH Infectious Diseases Unit he refused. By January 2000 his health deteriorated so bad that he did not know what was going on around him. For the past few years he was beginning to just sit in a chair, first in the living room where he sat (or what I would say "slouched") he never even went to bed, then for some unknown reason he moved to kitchen. He sat on a chair in the kitchen just looking out of the window or door, not eating or drinking liquids (unusual for Robert since he could never get enough tea). He just sat there, never speaking, just staring outside (when he could lift his head up long enough). He did not have the strength to do anything. He lost a lot of weight and I cannot recall Robert taking any Factor VIII because he was literally just sitting there not moving. He could hardly get up enough strength to walk to the

toilet, never mind have a shower. This was the time I told our son that his dad was dying of cancer. I used the word dying specifically so that he could perhaps (how can I say) get used to the fact? Even though he was now an adult I still wanted to protect him. I was unable to tell him the truth. Perhaps I was afraid how he would react to me keeping something so serious from him, or perhaps I had just gotten used to the secrecy and lies. I know I should have told him before I did, but I was afraid that if I said AIDS to our son, I would have to accept just how ill his dad was.

67. By the end of 1999 Robert was extremely lethargic, sleeping somewhere between sixteen and twenty hours a day (sitting up) and he was always sweating. January 2000 arrived, and I eventually got Robert to agree to see Dr GRO-D at Ward 45. He cannot even recall being there, never mind what was said. Dr GRO-D explained to Robert his CD4 counts etc and exactly how bad he was. He explained all about the "new" medication that HIV/AIDS patients now took, and that if he did not start to take medication he would die, at this point he told me he would be lucky to see six weeks. Of course, Robert did not hear any of this and was still reluctant to take medication. It was also the fact that we would have to attend the WGH Infectious Disease Unit that was putting Robert off. We again had a meeting with Dr GRO-D around March, at this meeting he explained again to Robert just how ill he was, that he would die if he did not begin medication, they thought he could perhaps have pcp. By now I did not think Robert would have been able to make any decisions on his own therefore I discussed with Dr GRO-D that if he

just gave us the medication, he recommended then I would discuss it again with Robert when we got home, and it would then be up to him if he wanted to take them. The fact that we would have them at home would mean that if he changed his mind they were on hand. At this meeting I was told that Dr GRO-D would listen to any concerns I had in relation to the medication and made it all sound good. On leaving the meeting with Dr GRO-D I felt a bit more positive about Roberts health if I could persuade him to begin anti-viral medication. A couple of days later Robert began his HIV/AIDS medication.

68. Originally, he was put on Combivir and Efavirinez along with Amitriptyline for his "night" sweats but he did not really take the Amitriptyline for long. The medication did not help in regards to the amount of sleeping he did and did not help the sweats. Now I had a problem having to wake him up to make sure he took his medication at the right time. This medication achieved two things: one, it helped Robert to get stronger and begin to know what was happening around him again, but the downside was that he took a psychotic reaction to one of the tablets (Efavirinez). By June his medication was changed to Stavudine, Lamivudine and Efavirinez. But he also became anaemic which a transfusion was suggested but since Dr Ludlam had told him in the past that he was allergic to Albumin he refused, and since Robert had a history of transfusions and Dr Ludlam thought it likely if he did need red cell transfusions that he would be at very high risk of quite bad reactions, it was put on hold and he began taking Folic Acid. We still did not like going to the WGH IDU but got used to it, except when I

complained to Dr GRO-D who commented in Robert's notes that I did not like the clientele at the hospital which was and still is not true. I was actually afraid, this was because one the patients approached me when I was outside on my own and put a knife to my throat, luckily for me Robert came out and the person walked away, luckily for him Robert did not notice what he was doing. I was also sometimes afraid in the waiting room when listening to some of the other patients (male and female) speaking since what/how they were speaking was something I was not used to, I admit that I was afraid every time I had to go to the WGH and on top of that we were both stressed out regarding Robert's health. However, there were a lot of patients who I would speak to, the ones who did not threaten or speak of violence. In fact, we learnt a lot from them regarding treatment and side-effects and how other medication interacted with Roberts medication. However, after I complained about the threats (and Dr GRO-D wrongly writing in Roberts notes) a security camera was installed at the waiting room. But we also changed our day to a Friday since it was quieter.

69. As Robert became more active, I began to notice a difference in him. He began to drink again but stopped again very quickly and has not drank alcohol since the middle of 2000) and fish again. However, that was not my worry, Robert began to take bad panic attacks so could not be left on his own. I could not go out of the house without Robert being with me and holding my hand, and if anyone looked at me (in what he thought was the wrong way) he would be aggressive to them. He just had this manner about him, that if looks could kill. I could not speak to

anyone, do anything, go anywhere without Robert being there. He began to do the same with our son and life at home became unbearable, he was afraid that we were in danger, that if we were on our own, we would be attacked, he knew in his head his thinking was not rational but he could not help it. He was never aggressive with us but was with everyone else, one day when he was fishing someone parked in the wrong place and obstructed an entrance to a farmers field, and he went crazy, his friends had to try to calm him down before he seriously hurt the person. It got that the two of us would only go out in the evening, when there was no-one about. We even had a barbeque in December at St Mary's Loch at midnight in the snow, it was the only way I could calm him down and get him to settle a bit. We would drive to the middle of no-where and just sit in the car. It all began to rub off on me, I began to take panic attacks, I began to isolate myself even more than previously. I never went out except to do grocery shopping. I never spoke to anyone. I spent all my days in the house alone with Robert who was by this time stomping about the house like a caged animal. When our son had any friends in the house. I was always on edge in case Robert got something stupid into his head. My life during this time was bad. I could not ask my sister for help since I did not want her to know how bad things were. I could not ask Roberts family since they had abandoned us a long time ago. I could not sleep because he did not sleep at night, also the responsibility of taking his medication on time (every 12 hours) was mine, so even if I did want to sleep I could not until after his medication, I tried to work out the best time for it, and I decided that if he was sleeping in the morning it was better to leave him as long as possible before waking him, so I decided 12 noon and 12 midnight (since we were always awake at midnight), and after 19 years I am still awake until at least midnight. He cannot recall any of what happened during this time. We could not keep living like that, sometimes I wished it would all end it was that bad, that I really could not take it anymore. I began to inform Dr GRO-D and staff at the haemophilia centre about it continually, but no-one took any notice. This went on for 10 or 11 months. The things he would say to the doctors during his appointments was to me fantasy. I can recall him telling a doctor at the western that he was close to his family – the brother and sisters who had not seen him for months on end. He would come out with some things that could be classed as criminal in what he said and they always looked at me to see my reaction, I just agreed with Robert because I thought that if he said enough someone would listen to me. It never happened. In November Dr GRO-D took Robert off Efavirinez. It seems that he decided it could cause disturbed sleep, produce nightmares and have on rare occasions a frankly psychotic effect. When it was suggested to Robert about changing this medication, he was reluctant, but truthfully, I do not think he was able to think straight at the time, the decision should have been taken away from him there and then, because he did not know what was happening. He did not know that he was acting the way he was. When he stopped taking the Efavirinez I noticed straight away the difference. He was still everything above but it did not get any worse. Eventually it settled a little, not a lot, but at least some.

70. During the months Robert was on Efavirinez he was causing havoc at the haemophilia centre. He again did not know he was doing anything wrong, but the problem here was that we attended the centre more and even though he had changed the medication he was still aggressive. When we had to attend the WGH he would stay outside until the doctor saw him. At the RIE he would walk up and down the waiting room (which was small) or the short corridor just outside. He never had any patience and when we had to attend hospitals it was even worse. He did not like being in others company, even just to sit next to them. It got that even visiting the Haemophilia Centre was stressful, but by this time I thought I had learned to hide all the strain. However, I do recall a staff nurse at the centre asking me if Robert hit me. I actually joked about it since it was the exact opposite. Reading in his medical records I got the impression she did not believe that he did not hit me (this is upsetting because I know Robert would never have hit me). Perhaps the fact that by now the staff were also afraid of him because he just looked frightening and aggressive gave her this opinion. By now our son had left home. His story is not mine to tell, so I will say no more about him. The side-effects did not seem to stop. We were still going out at night. Still going to places that was in the middle of nowhere. We still did not speak to anyone. We still lived in isolation, and then we decided to run away – by that I mean we moved home. It was both our decision. I think we both thought that if we moved somewhere else things would be

different, but that did not work. We just took all our worries and problems with us, including Robert's aggression.

71. The fact that life did not settle was only emphasised when on 24th March 2003 Robert had to attend a meeting with Dr Ludlam and Staff Nurse Shea because of Robert's behaviour in the centre. Even though his medication had been changed a few years ago Robert only settled a bit. Because he always paced up and down in the waiting room, the other patients did not like it. I could in some way see their point, I perhaps became complacent and began to accept Roberts behaviour as normal. The fact that things had to reach this point before the staff at the centre acknowledged the real problems Robert had with the tablets makes me angry. I kept on telling them for years and no one listened. We have now moved to the (new) RIE but Robert still goes outside until he is to be seen by the doctor, and unless another patient speaks to him, he is not allowed to speak to them because he then gets accused of annoying or frightening them. Robert is still aggressive and quick tempered but his aggressiveness has calmed down a bit.

72. Robert did receive Sofosbuvir and Ledipasvir Tablets to "clear" him of Hepatitis C. During the time he was taking this medication he began to complain about pains in his right leg and left ankle. He knew it was not a bleed he had, but whenever he mentioned it to the staff at RIE they just kept putting it down to arthritis, but the pain just got worse over the months. It got so bad that he could not stand. I was continually telling nursing staff at the RIE but they did not take any notice of what I was saying. It was not until I actually shouted at them down the phone that

they decided to give him an x-ray. Why is it that I now have to raise my voice to be heard? When we got the result at the centre, we found out Robert had been walking about with a fractured leg. We went home after dealing with that only to receive a phone call first thing the following morning asking for Robert to go to the centre immediately – it seems he also had a fractured left ankle. It turned out that his HIV/AIDS medication was responsible. It now seems that anything that is wrong with Robert be it his eyes, ears, teeth/gums, is now put down to either his Immune Disorder or Hepatitis as the cause. Doctors still have problems deciding how to treat Robert when something is wrong, because they do not know if it is HIV/AIDS, Hepatitis or Haemophilia. The medications he takes for his HIV/AIDS causes problems with other medications. His haemophilia causes bleeding problems with certain medications. He has perhaps "cleared" the Hepatitis virus but still suffers the side-effects of having had it. It is all just a mess!

73. We did discover (from Dr GRO-D) that the "sweats" he took were probably related to his Hepatitis C and not HIV/AIDS. But even after hepatitis treatment the sweats still do not stop. These are not just "normal" sweats. They can happen at any time. They are especially bad during the night, but can cause us problems during the day. It can be -5°C outside and we can have all the windows and doors in the house open. Nowadays it can also go the other way, it can be very warm outside but the heating is on at the highest.

Section 7: Financial Assistance

74. We received payments from the Macfarlane Trust, (now SIBSS) but this just goes towards helping pay the extra bills. It covers the extra cost of food that has to be thrown away because just cooking it has made Robert feel ill, or he is not well enough to eat anything. It also goes towards the extra heating/electricity bills. It pays for the disability appliances we require, extra bedding and a mattress around every 6 months, for the extra washing and washing machines we can go through, for extra clothes for Robert. The fact that neither Robert (because he is HIV/AID positive) and myself (because I am married to Robert) were unable to get any kind of life insurance, and since I do not work, I am a full-time carer to Robert, I have no pension to help me. I am now of an age that employers will be looking at my age and recent past employment (which does not exist) against someone who is younger and knowledgeable in what is required for work. Robert worries continually about how I will cope when he dies.

Section 8: Other Issues

75. We requested Robert's medical records which we received in March 2003. This request took some considerable time (months) and every time I phone the hospital the records were either at the Legal Department or with Dr Ludlam. Eventually they arrived and I began to

read through them but found no mention in his records of anything related to HIV/AIDS after Robert became infected in 1984. The only thing that was related to AIDS was an AIDS Study which Dr Ludlam carried out on Robert from March 1983, it seems that the circumstances leading up to Roberts infection of AIDS was not like we were led to believe – that AIDS in haemophiliacs did not just appear out of the blue. We discovered that an AIDS Study was being carried out on him from March 1983, this AIDS Study was (it seems) the beginning of many years of research being carried out on Robert without his knowledge or consent. You cannot imagine how angry I was reading this. I could not believe what I was seeing. How could this not have been mentioned during the legal case Robert had taken in 1987? I did write to Dr Ludlam on 7 March 2003 asking about dates of testing for HIV/AIDS or any related illnesses, when he tested positive for HIV/AIDS or any related illnesses and the batch number he contracted it from. We also asked the date he began testing him for Hepatitis C and when he first tested positive. At the end of this letter I informed him that there were notes missing from his records and asked him if he could forward them. We did get a reply (answers elsewhere in this statement) and he sent me a couple of blank pages which were meant to have HIV test results. I have since learned that Dr Ludlam kept a "separate" file on Robert which contained all his HIV/AIDS medical notes, but even after requesting them in 2003 he did not give us them or tell us he had them. Roberts medical records have been requested more than once, but we still have not had access to the separate file and noted that the treatment sheet which contained the batch number written out differently was taken out of his notes. You cannot imagine how upset and angry we both were. I mean really angry!

76. Then late 2003 when we were at an appointment with Dr Ludlam I asked about the AIDS Study which was carried out on Robert in 1983 and 1984 and all he said to us was *"That's all in the past."* (although this is not what was written in Roberts medical notes – it states that we discussed the matter). This was a meeting in which we had with Dr Ludlam to try and calm things down as there was no patient/doctor respect or trust. This all stemmed from Robert asking doctors about risks and doctors telling him everything was alright – nothing to worry about. How could we trust them again? This included not only doctors but nurses, which again did not make things easy.

77. Due to the breakdown of patient/doctor trust that had occurred between Robert and Dr Ludlam, Robert wrote a complaint to the General Medical Council (GMC) in around November 2003 regarding his care and treatment. This case ended in April 2005, with the words *"The Case Examiners concluded in this case that whilst, the allegations were serious, there was no realistic prospect of establishing that Professor Ludlam's fitness to practice is impaired to a degree justifying action on registration."* This goes on to say *"... and the fact that an individual Dr cannot be said to be responsible for maintenance of medical record files no impairment of Professor Ludlum's fitness to practise has been found and the GMC will not be taking action on his registration."* However, it seems that they were wrong on the point *"responsible for maintenance*

of medical records" since Dr Ludlam had the files in his possession but failed/refused to give us them.

78. Due to the above GMC complaint Robert was informed by Dr Ludlam that he considered it appropriate to review the arrangements of Robert's care at the Haemophilia Centre. We had a meeting on 4 February 2004. The options we had were:

    a. Mr Mackie is referred to another Haemophilia Centre (This was either Glasgow, Newcastle or Borders General).

    b. Mr Mackie continues to be seen at the RIE, but a consultant at another Haemophilia Centre becomes responsible for his care.

    c. Professor Ludlam's colleague, Dr Horn, is asked to consider taking over the care of Mr Mackie.

79. Since Glasgow and Newcastle were not an option a meeting was arranged at the Borders General Hospital. Unfortunately, the haematologist at the Borders General Hospital turned out to be Dr Tucker (one of the doctors who took blood from Robert for AIDS Studies and also carried out skin allergy tests in relation to AIDS. I did ask Dr Tucker at the time why he did not tell us he was taking blood for an AIDS Study and he told us *"he was only doing as he was told"*. This was then translated in the minutes to read *"Dr Tucker advised that documents relating to any investigation have all sorts of signatures on them that at the time Professor Ludlam was the consultant in charge and his team were therefore working under his direction. He advised that he was currently party to the GMC investigation and had no right to*

be given information. He might be called as a witness but that would be a separate process in any involvement in ongoing care." The result of this meeting regarding Robert's treatment at BGH was Dr Tucker refusing to treat Robert. However, he did arrange for Robert to collect his FVIII treatment from Blood Transfusion at the hospital since we could not go to the RIE and at this time Robert had no haemophilia doctor.

80. In the end, Dr Horn (reluctantly) agreed to see Robert for his check-up appointments.

81. I have to say that the GMC investigation was biased in that Dr Ludlam received all the correspondence we wrote, but we were never allowed to see what replies he gave to the GMC. I did write and request under FoI after the case ended and was informed that I would have to get permission from Dr Ludlam before I was able to get access. I never bothered!

82. We then wrote to the Crown Office in Edinburgh and in February 2004 we received a letter telling us that after receiving report from Strathclyde Police (Stephen Heath was the investigating officer) in connection with allegations concerning the infections of haemophiliacs with Hepatitis C and HIV. Crown Counsel consider that there is insufficient evidence that any criminal offence has been committed. So, the case was closed.

83. Because we had amassed a lot more information about Roberts infection we decided to ask the GMC to look at Roberts case again. In December 2006 we wrote to Sir Graeme Catto (GMC) requesting a

review of Roberts original case. This was at the same time that the Penrose Inquiry was being held and in April 2007 we received a letter from GMC informing us that *"public interest will not be served by the GMC conducting parallel investigations in relation to matters that are likely to be covered during the course of the public inquiry."* We wrote objecting to this and received a reply in August 2007 informing us that the President has decided it is appropriate to lift the stay of the rule 12 review in relation to complaint against Professor Ludlam. The case investigation by the GMC proceeded, however, I do feel that the fact that Professor Ludlam and his legal team were allowed to see all our correspondence with the GMC but we were not allowed to see what his replies were made the case against him all in his favour. Anyway, on 15 January 2008 we received a letter telling us that the original decision not to refer the allegations to a Fitness to Practise Panel should stand. The decision was in the light of:

(a) The inevitable difficulties in investigating events of so long ago;

(b) The lack of clear applicable standards at the material time; and

(c) The lack of any realistic prospect on the known information that a Panel would now find that Professor Ludlam's fitness to practice is impaired.

Again, we would have been unable to get any more information ourselves under FoI since we would again have had to ask permission from Professor Ludlam.

84. In December 2007 Mike Pringle MSP approached Mr Charles Winstanley, Chair, Lothian NHS Board, asking if Robert could get access to the medical records that Dr Ludlam held on him. We still never received any acknowledgement of these "separate" records.

85. Then on 6th December, Mr Pringle MSP wrote to Mr David Strange, Chief Constable, Lothian and Borders Police Headquarters, Edinburgh, forwarding a letter which both Robert and myself and one other person wrote, again about Dr Ludlam. This letter was forwarded to Detective Chief Superintendent Iain Livingstone of the Criminal Investigation Department.

86. This investigation was carried out by Det Sgt Kavanagh. The result was nothing we did not expect. However, no one has yet explained what the following means:

87. *"It is a well-established principle of Scots Law that an accused can only be prosecuted if there are 2 sources of evidence that an offence has been committed and 2 sources identifying him as the perpetrator. In this case there was insufficient evidence to prove any allegation against Professor Ludlam and that is why no proceedings have been instructed."*

88. Since we received a copy of Robert's medical records in 2003, we began to look into Roberts infection with HIV/AIDS more closely. What we discovered only made me sadder and angrier than I already was. The fact that Robert was still suffering after-effects from his medication did not help any. So, after I read the words *"AIDS Study"* in Roberts

medical records, we decided we would do some research of our own. Our anger (and I suppose my disappointment) is also built on the fact that we were foolish enough to trust the one person in all this who knew of the risks but simply refused to inform us – Dr Ludlam. We found out that Dr Ludlam chose to ignore the risks not only to Robert, myself and our son all for the sake of his own non-consensual scientific research and his own personal kudos, but also the other haemophiliacs under his pastoral care who have since died. Robert took so much care in his younger life to enable him to lead a normal life and Dr Ludlam took it all away.

89. When we began looking into Robert's infection, we did not imagine that we would find what we did. We started by requesting information under the FoI to the Scottish Parliament, and then hospitals and other places in which we thought that there might be relevant information. Before we received anything from any other sources, I looked through the microfiche held in the Library. What I saw really opened my eyes. I found research which had been carried out on a group called the Edinburgh Haemophilia Cohort. This was when I discovered that Robert was part of this cohort. In it there were dates of birth, deaths and FVIII doses. I managed to work out from this information the other people who were included in this research. Then I found a letter published in the Lancet in May 1983 in which a Dr Gordon, Chairman of NIH AIDS Working Group, USA. Dr Gordon writes *"that these two hypotheses could be distinguished by study of "similarly treated haemophiliacs in a geographical area into 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."*

90. Dr Ludlam answers this what I would term "cry for help" by offering his Edinburgh Haemophiliac Cohort 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. It seems that Dr Ludlam had begun his research on a group of haemophiliacs under his care beginning 1983 at least one full year before they had become infected.

91. The above exchange appears to suggest that Dr Ludlam was fully aware of the value to scientific endeavour of his Edinburgh patients and that Robert along with others were of value to him as a publishing scientist and potentially to global public health. Indeed, he later published on the very question raised by Dr Gordon in the Lancet, June 1984.

92. From this point on the evidence of non-consensual research carried out on this group of people from Edinburgh just grew and grew and research on this cohort continued until at least 1998. There is also mention in these research papers of the patients "donating" blood samples. I can assure you at no time did Robert "donate" any blood samples. This group are also used as Thesis subjects in which samples

from haemophiliacs from the Edinburgh Haemophilia Cohort are used in this paper. Did these patients know that their samples were being used? More importantly who gave this person the samples, and where did he get them from?

93. At the same time I was looking at research papers, I began to receive documents under my FoI requests. What I began to read regarding what was known about HIV/AIDS before the Cohort became infected was unbelievable. Everything I was led to believe from Dr Ludlam was questionable. What he knew and what had been discussed between other haemophilia centre doctors. What research was carried out not just on Robert and Cohort but all haemophiliacs. We have the MRC discussing haemophiliacs as the perfect subjects for research along with their partners/spouses. We even have the NIH discussing how great the UK were at keeping records and how valuable they were to research. The evidence of what was known before HIV/AIDS infection in Robert just kept on growing. As for the research on hepatitis, this just seemed to be as bad as HIV/AIDS. I could continue on and on about the non-consensual research being carried out on Robert regarding HIV/AIDS. The Inquiry team have collected my research documents and I would like the opportunity to give a further detailed statement regarding these. I have included a brief summary of my research below.

94. I provided a statement to the Penrose Inquiry and can provide a copy of that statement to this Inquiry.

95. The following is a summary of some of the non-consensual research carried out on my husband Robert Mackie. At no time did he give consent for any research to be carried out on him. At no time did he give consent for blood to be taken for research. At no time did he give consent for HTLVIII/HIV/AIDS testing. At no time did he give consent for Hepatitis C testing. At no time did he give consent for any of his stored serum samples to be given to any other person in relation to research.

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

Then in **May 1983** there is the matter of 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.**

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".**

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

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 into **the study of haemophiliacs who have received no American Factor VIII preparations.**

What we also discovered by reading his medical notes is that the "infected batch" **batch number 023110090** is the only batch number to be written out in full in **ALL** of his treatment record sheets, this information is gathered from his treatment record sheets from 1980 until he started receiving recombinant Factor VIII, this number is written out in full several times until after he complained of a very bad sore throat in April 1984 which would not get better (this it seems was his sero-conversion), thereafter the batch number is abbreviated to **0090.**

Another AIDS Study blood test is again carried out in June. We have evidence that HTLVIII (AIDS) tests were carried out in the UK on Factor IX patients, the results known by February 1984 with patients testing positive for HTLVIII, therefore we know that it was possible to test before June 1984 – **Perhaps this is the reason why Batch Number 023110090 was abbreviated to 0090 after my sore throat as it was possible to test for AIDS by the time I began receiving the infected batch.**

On **24 May 1985** Dr Ludlam applies for Ethics Approval entitled **Study of Immune Function and HTLVIII Infection in Haemophiliacs treated exclusively with NHS Factor VIII/IX Concentrates.** – This application contains 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 we did not know his AIDS status until 1987. How he did not know anything about his studies/research in which he was carrying out and there is no record of my giving consent in my case notes.

You may well ask how blood (up to 30mls) was taken for this research without our 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**".

Following on from the Ethics request in May, he then writes to The Medical Adviser on **25 June 1985** formally reporting the infected batch to Committee of Safety of Medicines in this correspondence he states "**Although some of the patients realise they have received a contaminated batch and know that they have developed anti-HTLVIII, other patients do not know of this and do not wish to know"**

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 consultants **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, the fact that Robert was continually asking Dr Ludlam and other treating doctors if everything was all right and the answer that always came back was "that there was no problem".

On 3 August 1985 another research paper is published in which it is 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**". Had Robert not been receiving prophylaxis throughout 1982 to 1984 it makes me wonder if he would have become infected.

Dr Ludlam also carried out an AIDS test on me without her knowledge or consent under the guise of "Genetic research". When I 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 I am not genetically related to my husband 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.

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

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

He states 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 Hematology, April 1988)

Also in 1988 he states

"... 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)

then by 1990 he publishes

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)

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). 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.** (Medical Research Council News, September 1990)

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)

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)

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)

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)

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

If Dr Ludlam became interested in AIDS area of investigation 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 his patients. Why did he think it necessary to carry out research on his cohort for **at least 15 years without informing them?** I find this **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.**

At **no time** was Robert ever informed that Dr Ludlam was carrying out **AIDS research on him from March 1983** – at a time when he was asking Prof Ludlam (along with other doctors) of the risks of taking Factor VIII, and they all **denied** any problems with Factor VIII. Nor was he informed as stated by Dr Ludlam in 1985 when applying for Ethics Approval that he knew all about his research, and that he gave his consent (**considering we were not informed of his HTLVIII status until 1987 I cannot see how he could have given consent into research into a virus he did not know he had**). At **no time** did he "**donate**" blood for **research** as stated in published research papers. The list is just endless.

Perhaps the MRC Working Party on AIDS, October 1983 gives the answer to why he deemed it necessary to keep his research and his positive status to himself (but not it seems to the rest of the scientific world). At this meeting it is 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** **<u>before</u>** **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. …**

Because of Dr Ludlams failure to inform patients of the risk of this known **fatal** disease – **16 haemophiliacs** became infected from this one batch of Factor VIII at a time when their infection **could have** and **should** have been avoided.

I feet that haemophiliacs at the Royal Infirmary of Edinburgh would have been better served if their consultant had informed them all of the risk of AIDS instead of using them as guinea-pigs for non-consensual research and scientific kudos for at least 15 years - **I find this absolutely unacceptable and outrageous.**

Statement of Truth

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

Signed GRO-C

Dated 1 March 2019