

My full names are

IAN DONALDSON FRASER

and I am the Director of the
South Western Regional Blood Transfusion Service based at

The Regional Blood Transfusion Centre,
Southmead Road, Bristol, BS10 5ND. Tel. No. 507777.

The following hospitals are within the South Western
Regional Health Authority:-

Gloucestershire Royal Hospital.
Cheltenham General Hospital.
Bristol Royal Infirmary.
Frenchay Hospital, Bristol.
Southmead Hospital, Bristol.
Weston General Hospital.
Bridgwater Hospital.
Musgrove Park Hospital, Taunton.
Yeovil Hospital.
Royal Devon & Exeter Hospital.
Torbay Hospital.
North Devon Hospital, Barnstaple.
The Plymouth Hospitals.
Treliske Hospital, Truro.

The Regional Transfusion Service provide services to
these hospitals and also to the Royal United Hospital,
Bath (Wessex Regional Health Authority).

2. I have not been involved in the treatment of patients
with Haemophilia, I just arrange for products from the
Blood Products Laboratory to be issued to the various
hospitals in the region. I have not been involved in
purchasing commercial blood products. The Blood
Transfusion Service in the South West has been
responsible for the supply of cryoprecipitate since 1967
and the supply of Factor VIII from the Blood Products
Laboratory since 1977. The cryoprecipitate has been
made from blood collected within the South West Region
and has been issued to hospitals in the region and also
to Bath. The Transfusion Service has been responsible
for the separation of fresh plasma from blood donations
and this is sent to the Blood Products Laboratory (BPL)
at Elstree. I do not know whether the products that

were received back in the South West Region were actually processed from the plasma that was collected from the Region. I would assume that the plasma supplied by South Western Regional Transfusion Centre would have been pooled with plasma collected from other Centres in England and Wales. All the plasma received at Elstree was from the 14 Transfusion Centres in England and Wales. No foreign plasma would have been fractionated.

The Blood Transfusion Service has been sending plasma to Elstree for many years. The Transfusion Centre supplied as much cryoprecipitate as possible to the hospitals in the region and Bath but we were unable to supply as much Factor VIII that the region required. The District Hospitals purchased commercial Factor VIII to make up for the shortfall. During the late 1970's, the region only received approximately half the Factor VIII that it would require for the treatment of patients with Haemophilia from the BPL. Cryoprecipitate was used fairly extensively in the treatment of Haemophilia during the 1970's, however, if a patient required operative surgery, concentrated Factor VIII was used to cover these procedures. During the 1980's, haemophiliacs were able to inject Factor VIII themselves at home and cryoprecipitate was not requested very frequently from the District Hospitals although this product is still used for some patients with VW disease.

Patients with haemophilia in Gloucester and Cheltenham Hospitals have nearly always gone to the Oxford Haemophiliac Centre for their specialist treatment. The patients with haemophilia in Bristol and Bath tend to be referred to the Bristol Royal Infirmary, Haemophilia Centre or to the Bristol Children's Hospital. There are other Haemophilia Treatment Centres in Taunton, Exeter, Torbay, Barnstaple, Plymouth and Truro.

3. The South Western Regional Transfusion Service has not been directly involved in any research or links between Hepatitis and HIV and Haemophiliacs. Some research was carried out at the Haemophilia Centre at the Bristol Royal Infirmary by Dr. G. Scott and Dr. H. Daly.

The Regional Transfusion Centre introduced the HIV antibody test in October 1985 and it was agreed that the Transfusion Service would only test donors and not patients. The Regional Transfusion Centre has not been asked to carry out research into AIDS although it has sent off samples from the small number of donors who were found to have been HIV antibody positive to the Central Public Health Laboratory Service in London. The Public Health Laboratory Service in Bristol carried out the Patient Service Requirements and the two virologists concerned with this service have been Dr. A. Roome and Dr. O. Caul. The Public Health Laboratory Service is centrally co-ordinated and there are numerous laboratories throughout England and Wales. The Public Health Laboratory Service has carried out a considerable amount of research into AIDS and Dr. Philip Mortimer has carried out research in conjunction with the Blood Transfusion Service. The Public Health Laboratory Service Headquarters are in Colindale, London.

Tests for Hepatitis B were introduced nationally in 1972/73. This decision was made by the Committee of the Regional Transfusion Service Directors in England and Wales, the Chairman at that time was Sir William Maycock.

The decision in October 1985 to carry out HIV antibody testing followed a policy decision reached by the Department of Health in conjunction with the Regional Transfusion Service Directors. All 14 Centres in England and Wales and the 5 Centres in Scotland started the tests on the same date. The Regional Transfusion Service Directors Committee had no official status but observers from the Department of Health attended the meetings. Initially the Chairman was based at the Blood Products Laboratory, Elstree. However, in 1979 an Advisor to the Department of Health was appointed to advise on matters relating to Blood Transfusion Services and this person chaired the Directors Meetings until 1981 when he retired. He was then replaced by another Consultant Advisor who attended the meetings but the meetings were chaired by one of the Regional Transfusion Directors. The Committee Meetings discuss national matters relating to the Blood Transfusion Service. The Regional Health Authorities fund the Blood Transfusion Service.

In October 1988, a National Directorate was set up in Manchester and the first National Director was appointed (Dr. H. H. Gunson).

4. The Regional Transfusion Directors, at their quarterly meeting attempted to co-operate national policy although each Centre depended on their respective Regional Health Authority for funding any developments. The Directors of Haemophilia Reference Centres meet regularly and have also met with representatives from the Regional Blood Transfusion Service. In the South West Region matters relating to Haemophilia treatment may be discussed at the 6 monthly meeting of the Haematologists in the region.
5. The Regional Blood Transfusion Service in the South West Region attempted to produce as much cryoprecipitate as possible since this was the only main source of Factor VIII during the latter part of the 1960's and during the 1970's. The Transfusion Service appeared to be able to produce sufficient quantities of cryoprecipitate to look after the needs of the patients with haemophilia in the South West Region. In those days most of the treatment was carried out either as an in patient or an out patient. When Factor VIII became available as a concentrate from the Blood Products Laboratory and also from commercial sources, many Haemophiliacs began to receive treatment at home.
6. In the mid 1970's, I believe there was an attempt to form a National Blood Transfusion Service but this did not actually happen. In 1985 a further plan was sent to the Department of Health by the Regional Transfusion Directors in England and Wales suggesting that a nationally co-ordinated service be set up. In 1986 the Department of Health funded a Management Advisory Service to examine how the Regional Transfusion Services worked and a report was issued in 1987. Following this the National Directorate was set up in 1988. Each Regional Transfusion Centre is still funded by the Regional Health Authority. No central funding has yet been identified.

During the 1970's and early 1980's it was the responsibility of the Regional Health Authority to produce sufficient funding for the Transfusion Centre to obtain plasma to prepare cryoprecipitate and also to send fresh plasma to the Blood Products Laboratory.

7. England and Wales have not been short of Factor IX. This has been readily available from the Blood Fractionation Laboratory at Oxford.

Assessments for Factor VIII were made after consultation with our haematological colleagues in the South West Region. During the 1970's most of the haemophilia treatment was carried out in Bristol, Exeter and Plymouth. However, as more experienced haematologists have been appointed most of the hospitals in the South West region, and Bath, provide haemophilia treatment. We have always produced cryoprecipitate in sufficient amounts since 1967, however, Factor VIII was not produced in any reasonable quantity until the late 1970's. Before cryoprecipitate became available haemophilia patients were treated with fresh frozen plasma and then, before that was available, with fresh blood.

Assessments of the requirements for Factor VIII concentrate were made by the Haemophilia Centre Directors. However, they appreciated that they could only receive approximately half of their requirements from the Blood Products Laboratory and they purchased commercial products to make up for the shortfall. However, quite a number of Haemophilia Directors prefer to use commercial product rather than that produced by the National Health Service.

The BPL at Elstree gave Regional Transfusion Centres targets for fresh plasma collection which was based on the population of the region. These were first produced in the early 1980's and each Regional Transfusion Service had to negotiate with its Regional Health Authority for funding. The South West Regional Transfusion Centre almost always met its target although some Transfusion Centres had difficulty in producing sufficient plasma to meet their targets. During the early part of the 1980's the Blood Products Laboratory

would send Factor VIII, and other blood products prepared from fractionated plasma on a pro rata system so the more plasma that was sent to the BPL the more products the Transfusion Centre received. The pro rata system was abolished in 1984/85 primarily due to the fact that the Fractionation Laboratory was unable to fractionate all the plasma that it received. Each Centre was then provided with a quota of products which, in many cases, bore no relationship to the amount of plasma that was sent.

8. During the early 1980's each Transfusion Centre produced a plan for plasma (correspondence enclosed) so that the Regional Health Authority could identify funding for the development. The Regional Transfusion Service in Bristol has had no professional contact with Scotland with regard to blood and its products. The Scottish National Blood Transfusion Service is a national service. Their representatives would attend the meetings of the Regional Transfusion Service Directors and visa versa. In 1984 the BPL received some Factor VIII from Scotland and this was distributed to all RTC's in England.
9. The sizes of the donor pools for Factor VIII were in the order of 5,000 litres in the 1970's. I believe this was reduced to 1,000 litres when the new Factor VIIIY was produced in 1984.
10. Considerable efforts were made to increase the production of Factor VIII at the Blood Products Laboratory and the Regional Transfusion Service expected that the new factory would be finished in the early 1980's but it was not completed until 1986. I understand that the development was a joint Blood Products Laboratory and Department of Health project.
11. There was a fall off in the production of Factor VIII during 1984 and 1985. These were mainly manufacturing problems and I kept the Haematologists in the region well briefed with regard to the shortages of both Factor VIII and albumin.

12. In late 1984/early 1985, the Blood Products Laboratory indicated they would in future be heat treating Factor VIII and it was fully understood that it would give rise to a lower amount of Factor VIII for each amount of plasma fractionated and Transfusion Centres were warned that they would have to collect more plasma, therefore, plasma targets were increased. I believe I was told, in late 1984 or early 1985 when the Regional Transfusion Directors met, that heat treatment would kill HIV. We knew that albumin was pasteurised and, therefore, killed the Hepatitis B virus.

It was known by people working within the Blood Transfusion Service and also haematologists treating patients with coagulation disorders that there always was a risk of Hepatitis in the recipient from patients who received fresh frozen plasma or cryoprecipitate. In order to limit the chances of a donor carrying a virus we dissuaded donors who had a previous history of being jaundiced, or those who may have been in contact with a patient who is jaundiced, from donating blood. We appreciated, in those days, that there must be a Hepatitis virus that was related to jaundice. By 1972/73 the Hepatitis B test had become available and then we could start screening out our donors to find out who the carriers of the virus were and then remove them from our donor panel.

In the 1970's fresh plasma and cryoprecipitate had a shelf-life of between 3 and 6 months, at the present time both products have a shelf-life of 6 months. In the 1970's blood had a shelf life of 21-28 days as against 5 weeks now. Platelets have a shelf-life of between 3-5 days.

13. Albumin has been pasteurised, I believe, since 1983. This kills Hepatitis B virus. Non-A, Non-B virus has not actually been isolated but is now known as Hepatitis C virus. I assume that heat treatment will kill Hepatitis C. Hepatitis A is only very rarely is transmitted by blood. Hepatitis B is known to be transmitted by blood as is Hepatitis C.

14. It was early in 1983 that the risks of HIV as being a major disease problem were gaining recognition. The matter was discussed at the spring meeting of the Regional Transfusion Service in 1983 and the first AIDS leaflet for blood donors was printed and then made available in September 1983. In the South West region an AIDS information sheet was made available to Sessional Doctors in May 1983 indicating who were in the at risk group. A meeting was held, at the Transfusion Centre, of all Sessional Doctors the following month to discuss the whole problem of AIDS and blood donation.
15. The South Western Regional Blood Transfusion Service has not been involved in any research with regard to heat treatment of Factor VIII or Factor IX. The Blood Products Laboratory carried out all the research for the Transfusion Service in England and Wales.
16. In 1983 we began to appreciate the risk of Hepatitis amongst homosexuals and it was known that intravenous drug abusers carried a risk of contracting Hepatitis from sharing needles.
17. It was during 1983 we began to learn about the risk of homosexuals and their partners, the intravenous drug abuser and the bisexual person. Cases then were described of wives who were being infected by their husbands who were also homosexuals. The greater part of the infected population appeared to be mainly males although it was later shown in the mid-1980's that Africa, for example, males and females were both infected. The first AIDS leaflet for donors was prepared in September 1983.

When the first AIDS leaflet was introduced there was some initial reticence to send one of these leaflets to every blood donor since it was not appreciated, at that particular time, that quite a number of blood donors were, in fact, homosexuals. We thought that wide distribution of the leaflet would deter donors from coming forward and it would be difficult to question donors at donor sessions since these are often held in places where there is no specific area where

confidential discussions can take place. However, during 1984 we began sending AIDS leaflets directly to donors when sending them appointment cards and we introduced a large notice stating the at risk categories in order to deter donors from entering into the session. During 1982 and 1983 we were attempting to increase the number of donors in order to increase the amount of plasma that we were sending to Elstree and we were worried, in 1983, that we might deter donors from attending and, therefore, we would not reach our plasma targets.

We did not provide any written advice to clinicians on the risks associated with blood but numerous meetings were held throughout the region indicating the risks of getting AIDS and in 1983 and 1984 there was considerable literature on the subject, particularly in the British Medical Journal, Lancet and New England Journal of Medicine.

18. Although in 1982 it was becoming apparent there could be a link between blood and the development of AIDS, it was clear that by 1983 there was a definite link. Numerous papers and letters were written to the British Medical Journal and the Lancet and the New England Journal of Medicine, mentioned in Page 72 of the Statement of Claims, and the letter by Peter Jones, on Page 73, were given wide publicity.

The Transfusion Service were cautious in approaching donors asking direct questions about their sexual activities since we did not wish to offend the donor population. We appreciated there was a risk but we were not aware, in 1983, as to its extent. We were attempting to increase our donor panel and did not wish to deter donors from attending.

The Blood Transfusion Service tried to act in unison over these matters, however, we were caught in a difficult situation in that we were being asked to produce more of our own blood products but we were deterring donors over the AIDS issue. Unfortunately, a lot of donors thought that they could actually catch the AIDS virus from donating blood.

19. When the AIDS leaflet was produced in 1983 it was becoming apparent that quite a number of donors were actually homosexual. Some of these volunteered the fact to us confidentially, either by letter or by telephone, or during the blood donation session. When the latter applied their blood was not used. Some donors denied being homosexual. In 1983 the promiscuity of homosexuals was not appreciated by the Blood Transfusion Service. The second and subsequent AIDS leaflet were far more direct in dissuading at risk people from donating blood.

20. This Centre introduced the screening of blood donors on 1st October, 1985, that was 2 weeks earlier than the date agreed by the Transfusion Service (i.e. 14th October, 1985). The test was introduced in order to familiarise the staff with the new test since we appreciated we would be doing approximately 180,000 of these tests each year.

21. I have reviewed the literature from paragraph of the Statement of Claim and it would appear to me to be correct. This Centre has never tested for antigen.

22. We use the Wellcome test. My recollection is that the tests were introduced in June 1985 not April 1984. We did not undertake surrogate testing although the Blood Transfusion Services in the U.K. did discuss the possibility of introducing anti-Core tests and a case was made to the Medical Research Council for a preliminary study but this was unsuccessful. I did know that some surrogate tests were being introduced in the U.S.A. It was early in 1985 that I heard that Wellcome were working on a screening test for AIDS.

23. I do not remember receiving any advice regarding the various testing kits from the Department of Health. The Department of Health, however, did set up a special laboratory at the Manchester Regional Blood Transfusion Centre in order to evaluate kits for HIV antibody

testing and also to set up a central register for positive donors. We submit monthly results of all our screening tests and indicate the number of tests carried out, the number that were positive, the number of sample repeats and our quality control results. The Scottish Transfusion Centres also send their data to Manchester. As far as I remember this was set up in October 1985.

The tests for HIV antibody are very reliable.

24. I knew about the risk of Hepatitis for the treatment of patients with Haemophilia with fresh plasma, cryoprecipitate and Factor VIII. However, it was a risk that the patients would take since there was no alternative treatment. Since I have not dealt with patients with haemophilia I do not know if the risk of contracting hepatitis was actually pointed out to them.
25. I kept myself abreast of developments on Hepatitis and AIDS via meetings, both nationally and internationally, and publications in the Medical Journals.
26. I was appointed as Director of the Transfusion Service in 1979 and do not have any documentation prior to that date. I have Minutes of Meetings and correspondence with my colleagues, both at the Regional Transfusion Centres and the Department of Health. Factor VIII batch numbers would be recorded in the patients notes and these would be needed to follow up in the case of any adverse reaction.

In 1984, our donor records were computerised.

So far, just over 800,000 HIV antibody tests have been carried out on donor blood in the South West Regional Transfusion Centre and 5 donors have been identified as being HIV antibody positive. Fortunately, no patient has received any blood donated by these donors prior to introducing the HIV antibody test in October 1985.

SIGNED:
Ian Donaldson Fraser
M.D., FRCPE, FRC.Path.

DATED:

WEST MIDLANDS