

Dr Diana Walford CBE
Principal
Mansfield College
Oxford
OX1 3TF

Our ref: GM
Your ref: DW

23 December 2010

Dear Dr Walford

Penrose Inquiry – Topic Number B1 – HIV/AIDS – Higher Risk Donors – Request for witness statement

I understand that you will have been contacted by Mr Patrick Hennessy of the Department of Health in connection with the Penrose Inquiry's request to receive a written statement from you in relation to your former role at the Department of Health.

Lord Penrose would be grateful if you could provide a written statement of evidence to the Inquiry in respect of the issue and matters set out in the schedule below. I enclose a copy of the Preliminary Report of the Inquiry, including a disc of documents referred to, and it may assist you when preparing the statement to have regard to Chapter 8 of the Preliminary Report, and also the enclosed supplementary paper containing a narrative of events in relation to this issue.

I also enclose a supplementary disc (marked '22/12/10 B1 AIDS Leaflets etc') containing documents which are referred to in the accompanying supplementary paper but which are not referred to in the Preliminary Report. The disc contains 46 documents and I hope you will be able to identify them all on the disc. If there is any difficulty with this please let me know.

While you may derive some assistance from the Preliminary Report, the Report may not include all material relevant to the matters in respect of which a statement is sought, in which case you should include in the statement any material which you consider relevant to these matters, whether contained in the Preliminary Report or not.

While it is a matter for you as to how best to structure the statement, the Inquiry would find it useful if, in general, matters could be set out in chronological order. If the statement is lengthy, it may also be helpful to consider inserting sub-headings. It would

A19327

be helpful for you to provide the statement in draft form in the first instance, as follow up queries may arise which may require amendment of the first draft.

While the Inquiry understands that providing a statement is not a straightforward process, and you will have many demands on your time, it would be appreciated if a response could be provided as soon as possible and preferably within **four weeks** of the date of this letter.

I should be grateful if you would please acknowledge receipt of this letter.

Yours faithfully

Gregor Mair

A19327

Schedule

Issue in respect of which a statement is sought

HIV/AIDS

The efforts made to discourage “higher risk” donors from giving blood (by the dissemination of information, including leaflets); whether these efforts went far enough and began early enough.

Section of the Preliminary Report which may assist when preparing the statement

Chapter 8: “HIV and AIDS”

Matters to be included in the statement

1. In relation to preparation of the UK leaflet in 1983, it was said that “progress was slow”. Was that so and, if so, why was it slow?
2. What were the issues about distribution?
3. Does Dr Walford wish to comment on the attitude of the general media at that time to these issues (see, for example the material referred to in footnote 11 of the Supplementary Paper)?
4. It appears to have been considered in both Scotland and England towards the end of 1983 that the leaflet required revision. What in particular led to this view?
5. In February 1984, what was the new information which made Dr Walford feel that the advice might “seem too lax” (DHF.001.5266)? There is a study from this period referred to in paragraph 8.72, but there had been information implicating transmission by blood and blood products since at least 1983 (see paragraphs 8.18 to 8.22 of the Preliminary Report).
6. The revision process appears to have been lengthy. Does Dr Walford wish to comment on the time taken? (see, in particular, footnote 16 of the Supplementary Paper).

Supplementary Paper

Narrative in relation to Topic B1 – Efforts made to discourage Higher Risk Donors

1. As narrated in paragraph 8.21 of the Preliminary Report, a leaflet was produced in March 1983 for blood donors in the USA. Contrary to what is stated in the paragraph, the leaflet emanated from the American Red Cross. It was entitled “An important message to all blood donors”. The relevant section of the text is quoted in a decision of the Canadian Supreme Court, Walker Estate v York Finch General Hospital 2001 SCC 23:

Some persons may feel in excellent health but have viruses or other infectious agents in their blood that could cause illness in persons receiving a transfusion of their blood. If you think any of the following information pertains to you, please do not donate blood today:

1. Acquired Immune Deficiency Syndrome (AIDS). This newly described illness of unknown cause is believed to be spread by intimate personal contact and, possibly, by blood transfusion. Persons with AIDS have reduced defenses against disease and as a result may develop infections such as pneumonia, or other serious illnesses. At this time there is no laboratory test to detect all persons with AIDS. Therefore, we must rely on blood donors’ health histories to exclude individuals whose blood might transmit AIDS to patients who will receive that blood.

The Office of Biologics of the Food and Drug Administration has identified groups at an increased risk of developing AIDS. These groups are –

- Persons with symptoms and signs suggestive of AIDS. These include severe night sweats, unexplained fevers, unexpected weight loss, lymphadenopathy (swollen glands), or Kaposi’s Sarcoma (a rare cancer).
- Sexually active homosexual or bisexual men with multiple partners.
- Recent Haitian entrants into the United States.
- Present or past abusers of intravenous drugs.
- Sexual partners of persons at increased risk of AIDS.

...

What Should I Do?

A19327

If you believe that you may be carrying one of the above-mentioned illnesses, or if you are an individual in a group at increased risk of developing AIDS, we ask that you refrain from donating blood at this time. You may leave now without providing an explanation. Or, if you prefer, you may proceed to be deferred confidentially, without further questioning, by the health history interviewer.¹

2. As narrated in paragraph 8.28 of the Preliminary Report, on 24 May 1983, at a meeting of the SNBTS coordinating group, Dr McClelland tabled a draft leaflet he had prepared.² The leaflet stated:

What is AIDS?

It is a disease called (A) (I) (D) (S)
acquired immuno deficiency syndrome

which is thought to be caused by an infectious agent, perhaps a virus. So far, the cause is unknown. It is a rare disease, but it can have serious consequences.

.....

Who can get the disease?

AIDS has been occurring, particularly in the USA, in certain people who are apparently susceptible to the disease:

- 1) Homosexual men, particularly those with multiple partners;
- 2) Drug abusers;
- 3) Sexual contacts of people with AIDS – women can be infected if the males are bisexual;
- 4) Haitian immigrants to USA;
- 5) Haemophiliacs - who may be more susceptible or may become infected by their use of blood products which may have come from a blood donor with AIDS;

Most (but not all) cases have occurred in the homosexual male population. Why this should be so is not yet known. A small number of young children have been affected.

.....

Can it be Transmitted by Blood Transfusion?

¹ <http://sec.lexum.umontreal.ca/en/2001/2001scc23/2001scc23.html>

² Leaflet is SNB.003.7153; this is deduced from the handwritten note in the top right hand corner which reads "Item 15 of 24.5.83". The leaflet was entitled "AIDS AND BLOOD TRANSFUSION Some background to the recent publicity"

It appears it can. This might cause the disease in people who are not normally at risk. It may have infected clotting factors that caused AIDS in Haemophiliac men in USA.

We have not had any definite cases of AIDS in Haemophiliacs in UK. If the clotting factor concentrate (factor VIII) can be infected, then cases could occur in UK because much of the factor VIII is imported to UK from USA.

The disease cannot be taken lightly.

Those getting AIDS may die, because they are more susceptible to serious infections and cancer due to their impaired immune system.

The Blood Transfusion Service is therefore concerned to try and stop any chance of infection spreading by blood transfusion.

We want to ask people who may be at risk from the disease to avoid giving blood until we have a suitable screening test. Many donors will remember we did this with hepatitis until we had screening tests for the hepatitis virus.

Whose Blood Could be a Risk?

All our information about at risk groups comes from the USA. However, until more is known about the cause and spread of AIDS, we would ask the following groups to refrain from donating blood:

- 1) Homosexual men;
- 2) Women who continually have multiple sexual partners;
- 3) Partners of bisexual men;
- 4) Anyone who abuses drugs;
- 5) Anyone who has been in contact with a case of AIDS.

We hope that if we take precautions now, we can prevent the problem of AIDS which has become serious in USA.

Remember it is a rare disease but an important one.

3. As narrated in paragraph 8.33 of the Preliminary Report, leaflets were discussed at the meeting of the SNBTS directors on 14 June 1983. Dr McClelland had amended his leaflet.³ The new text appears to have included the following, with changes of substance now italicised:

What is AIDS?

³ Revised leaflet appears to be SNF.001.3397, dated "June 1983". Some background to the change may be reflected in a Press Release from SHRG dated 21 May 1983 – SGH.002.6759

It is a disease called (A) (I) (D) (S)
Acquired Immuno Deficiency Syndrome

which is thought to be caused by an infectious agent, perhaps a virus.

.....

Who can get the disease?

AIDS has been occurring, particularly in the USA. *The following groups appear to be at risk.*

- 1) *Men who have multiple partners of the same sex;*
- 2) *Intravenous drug abusers;*
- 3) *Haitian immigrants to USA;*
- 4) *Haemophiliacs - who may be more susceptible or may become infected by their use of blood products which may have come from a blood donor with AIDS;*
- 5) *Recipients of blood transfusion;*
- 6) *Sexual contacts of people at risk to AIDS.*

.....

How can it be Transmitted by Blood Transfusion?

If a blood donor happened to carry the agent responsible for AIDS it is possible to transmit the disease to those not usually at risk. For example, factor VIII (the clotting factor extracted from plasma for treatment of Haemophilia) could have become infected and caused AIDS in a few cases of Haemophilia in USA.

We have not had any definite cases of AIDS in Haemophiliacs in UK. If the clotting factor concentrate (factor VIII) can be infected, then cases could occur in UK because much of the factor VIII is imported to UK from USA.

The disease cannot be taken lightly.

Those getting AIDS may die, because they are more susceptible to serious infections and cancer due to their impaired immune system.

The Blood Transfusion Service is therefore concerned to try and stop any chance of infection spreading by blood transfusion.

Whose Blood Could be a Risk?

All our information concerning at risk groups comes from the USA. However, until more is known about the cause and spread of AIDS, we would ask people *in any of the high risk groups described above* to avoid giving blood until we have a suitable screening test. Many donors will remember we did this with hepatitis until we had screening tests for the hepatitis virus.

We hope that if we take precautions now, we can prevent the problem of AIDS which has become serious in USA.

Remember it is a rare disease but an important one.

4. This leaflet appears to have commenced circulation through the SHRG network in June 1983. This was not entirely intentional.⁴ Meanwhile, work continued on the UK wide leaflet, though “progress was slow”.⁵ The NBTS version had said that a person in “any of the high risk groups of developing AIDS ...should not give blood even though they are in normal health”. That had been amended to ask that anyone who thought they might have the disease or be at risk from it should refrain from giving blood. But Mr Fowler’s first reaction had been that that wording was too strong, so further revision might be required.⁶ A meeting took place on 6 July, involving the Minister of State for Health and the Under Secretary of State.⁷ Further revision occurred. Debate ensued about appropriate methods of distribution.⁸ Ministers appeared keen on a “low key” approach. When it was suggested, however, that the leaflet

cannot be seen as a leaflet which you read and then change your mind about giving blood⁹

intervention from a medically qualified civil servant noted that this was “precisely” the aim of the leaflet.¹⁰

5. As narrated in paragraph 8.47, a UK wide leaflet was produced and distributed from 1 September 1983.¹¹ It stated:

What is AIDS?

.....AIDS is probably caused by a virus, but this is not known for certain.

⁴ See the 2 memos SGH.002.6755 and SGF.001.0960. The former also makes clear that a number of steps were felt to be required before a leaflet could be published and distributed.

⁵ See memo of 28.6.83, SGH.002.6752.

⁶ See SGH.002.6732 – Memo of Dr Bell dated 6 July 1983.

⁷ Kenneth Clarke and Lord Glenarthur. See minute of meeting DHF.001.4580 and ensuing memo DHF.002.0412.

⁸ DHF.001.9912 and DHF.001.9913.

⁹ DHF.001.9914

¹⁰ DHF.001.9915. This appears to have been Dr Oliver – see SGH.002.6736.

¹¹ It was called “AIDS and how it concerns blood donors” SGH.002.6675, with accompanying Press Release for Scotland, SNF.001.0416. Publication of the leaflet was announced in the media; the tone of the coverage varied (compare The New Scientist DHF.001.4689 and The Sun DHF.001.4690).

Who is at risk from AIDS?

Most of the information about AIDS has come from the USA where approximately 1,500 patients have been found to be suffering from the disease up to the middle of 1983. Certain groups of people appear to be particularly susceptible; these are:

1. Homosexual men who have many different partners
2. Drug addicts, male and female, using injections
3. Sexual contacts of people suffering from AIDS

It has also been found in a number of immigrants to the USA from the island of Haiti. Patients with AIDS also seem more likely to have suffered, at some time, from various other diseases such as hepatitis B, syphilis or other sexually transmitted diseases.

.....

Can AIDS be transmitted by transfusion of blood and blood products?

Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital. However, in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease.

How can the risks be reduced?

At present there is no screening test the Transfusion Service can use to detect people with AIDS. So, until there is and until more is known about this disease, donors are asked not to give blood if they think they may either have the disease or be at risk from it.

6. As narrated in paragraph 8.50, the UK Working Party on Transfusion Associated Hepatitis¹² discussed leaflets at its meeting on 27 September 1983. In relation to the lack of a uniform method of distribution

Dr Lane presented the fractionator's view that a variable approach did not provide material of uniform specification, but Dr Mitchell pointed out the problems associated with any infringements of the integrity of the donor.

¹² Minutes now available - (A17942 for the moment). Copy on disc accompanies this paper.

7. As narrated in paragraph 8.63, the leaflet was discussed at a meeting of the (Scottish) Haemophilia and Blood Transfusion Working Group on 14 November 1983. It was felt generally that “the leaflet had not been particularly useful”.

A few donors had responded by declaring that they were homosexual but the problem of how to screen out those who might present as donors in spite of the leaflet remain(ed)”.

8. At the SNBTS Directors meeting on 8 December, Dr McClelland agreed to produce a revised leaflet. It was envisaged by some in England that his redraft would assist in the revision of the leaflet for the United Kingdom.¹³ As at 14 February 1984, it appeared to medical personnel in the Department of Health that the current advice to donors could seem “too lax”.¹⁴

9. At the National Institute for Biological Standards and Control (NIBSC) meeting on 9 February 1984, Dr McClelland explained the three main strategies for minimising the risk of infection. These were (1) avoidance of high risk donor communities (such as prisons, known homosexual areas etc) (2) detection of clinical abnormalities by examination and careful questioning and (3) exclusion of the high risk donor, or his blood, always allowing an “escape route” for the donor who is deemed unsuitable.

10. As narrated in paragraph 8.78, by 13 March 1984 Dr McClelland had produced a revised text.¹⁵ The text was still being revised in June 1984.¹⁶ At some point in 1984, a Scottish leaflet called “Important message to blood donors” was produced, probably the product of this process.¹⁷ It explained what AIDS was, including that it was frequently fatal and could be transmitted by blood or blood products, and stated

For the present therefore, it is important that those who belong to certain groups, who have an above average risk of contracting this condition, should not donate. These groups are:

¹³ Letter of 3 January 1984, DHF.001.5119

¹⁴ See memo at DHF.001.5266 which, from other material, emanated from Dr Walford.

¹⁵ This is likely to be SGH.001.0499, which has “item 3b of 13/3/84” on it in separate typescript.

¹⁶ The text as it stood at the meeting of 12 June 1984 is attached to the minutes of the meeting of the Directors on that date – SGF.001.0150, with the last page, 0155, being the leaflet. The position in England regarding revision of the leaflet is set out in various memos – a submission seeking authority from Ministers for revision of the leaflet was sent on 10 August 1984 (DHF.002.2192; submission is 2193-4) and approved on 16 October 1984 (memo DHF.002.2208 and docketed leaflet DHF.001.5849). The main change was to include all practising homosexuals as being in the high risk group (DHF.002.0040 at 0041). Publication of the revised leaflet was then held up until it could be discussed at a meeting of the Working Group on Aids on 27 November (see DHF.002.2233, dated 3 December). The English leaflet produced in January 1985 is DHF.001.8919. Thus, the revised version of the 1983 leaflet did not appear until January 1985 (see Circular which refers to the 2 editions, DHF.001.8929, and memo explicitly recording regret at delay, DHF.001.7438). A view that this was undesirable is also recorded in SNB.012.5019 and SNB.012.5017.

¹⁷ SGF.001.0932. This leaflet is referred to in the Scottish Health Education Group leaflet, “Some facts about AIDS” (SNB.004.9329) which bears the date “12/84”. It is recorded as issued in August 1984 in SNF.001.3381 at 3385. But by 17 December 1984, Dr McClelland was recognising that the leaflet required to be revised again – his letter of that date to Dr Cash, SGH.001.0343.

- residents of or visitors to certain areas such as Chad, Haiti and Zaire
- sexually active homosexual men
- present or past abusers of intravenous drugs
- sexual partners, male or female, of any of the above people

11. As narrated in paragraph 8.108, on 29 November 1984, by which time it had been discovered that a batch of PFC Factor VIII had been responsible for infecting the patients referred to as the Edinburgh Cohort, Dr Cash wrote to Transfusion Directors, summarising actions required in relation to the leaflet, including that donors had to sign a statement that they had read the AIDS leaflet and, to the best of their knowledge, were not in one of the risk groups.

12. As narrated in paragraph 8.111, a leaflet referring to blood donation and produced by the Terrence Higgins Trust was in circulation at the end of 1984. At the SNBTS Directors meeting on 11 December 1984, this leaflet was referred to and it was thereafter circulated among the Directors.¹⁸

13. When screening of donated blood was introduced in October 1985, as narrated in paragraphs 8.122 to 8.139, a new leaflet was given to donors in Scotland explaining that their blood would be tested and they were asked to sign a form indicating that they understood the new message.¹⁹ The leaflet stated

PLEASE REMEMBER

It is essential that although we are introducing HTLV-III testing you **MUST NOT** volunteer to give a blood donation if you are or have been:

1. A practising homosexual or bisexual man.
2. A drug abuser, either man or woman, who injects drugs.
3. Resident in or a visitor to central African countries.
4. A sexual partner of people in these groups.

14. In England at this time, the standard leaflet said that those in the high risk groups **MUST NOT GIVE BLOOD** (capitals as in leaflet).²⁰ The high risk groups were said to be:

1. Homosexual and bisexual men
2. Drug abusers, both men and women, who inject drugs
3. Haemophiliacs who have been treated with blood products
4. Sexual contacts of people in these groups.

¹⁸ Leaflet is SGH.001.0346, as is apparent from the typewritten note on it and the Minutes of the following meeting, on 27 February 1985, where the topic was again discussed (SNB.002.3507).

¹⁹ Draft of this is at SGH.002.6981. The final leaflet is SGH.002.7077.

²⁰ SGH.001.8292. A memo narrating the introduction of the new leaflet and of testing was prepared for the Advisory Committee to the National Blood Transfusion Service: SGH.001.8295.

15. By August 1986, South East Scotland had developed a Flashcard System, whereby a card to read was given to donors by a member of nursing or medical staff.²¹ The card read:

AIDS

PLEASE REMEMBER

1. ANY MAN WHO HAS HAD SEX WITH ANOTHER MAN SINCE 1977
2. ANYONE WHO HAS EVER INJECTED THEMSELVES WITH DRUGS
3. ANYONE WHO HAS EVER HAD A SEXUAL RELATIONSHIP WITH ANYONE IN THE ABOVE GROUPS

MUST NOT GIVE BLOOD

16. The co-coordinating group at its meeting of 19 August 1986 discussed the Flashcard and agreed that Dr McClelland would develop the idea further. There was a range of general information leaflets for donors, and the co-coordinating group thought that a wider based information leaflet was required.²² A draft had been prepared by Dr Gillon and it was agreed that it should be re-drafted after the meeting to convey a more succinct message to donors in the high risk groups.²³

17. As narrated in paragraph 8.193, it was agreed to withdraw AIDS leaflets with effect from 31 December 1986.

18. As at March 1987, SNBTS issued the leaflet "AIDS and Blood Transfusion – A Guide for Blood Donors".²⁴ The donor exclusion criteria were now in a separate document, which was given out at donor sessions. In South East Scotland as at May 1987 this was a "Health Check" leaflet, which set out those who "MUST NOT GIVE BLOOD".²⁵

There were seven categories:

1. Anyone who has AIDS or the AIDS antibody
2. Any man who has had sex with another man since 1977
3. Anyone who has ever injected themselves with drugs
4. Anyone who has lived in or visited Africa, south of the Sahara at anytime since 1977 and has had sex with men or women living there
5. Anyone who has had regular treatment with blood products since 1977
6. Any man or woman who has been a prostitute at any time since 1977

²¹ The card is at SNB.004.8150

²² See Minutes, SNB.004.0050.

²³ "AIDS and Blood Transfusion – A Guide for Blood Donors". The draft is at SNB.004.0059

²⁴ This is at SNB.004.0432

²⁵ Leaflet is at SNB.006.1161

7. Anyone who has ever had sex with a person in the above groups even on a single occasion.

19. These criteria were reproduced in a different style of leaflet in Glasgow and the West of Scotland.²⁶

20. There were also posters about AIDS produced by the Blood Transfusion Services. The Department of Health and Social Security recorded a suggestion in January 1985 that posters “would be useful”.²⁷ One undated and unattributed poster²⁸ sets out the criteria which should result in donor self-exclusion:

- A homosexual or bisexual man
- A drug abuser who injects drugs
- A sexual contact of any of these people

21. The possibility of introducing legislation to deter those at high risk from AIDS from giving blood was considered and rejected.²⁹

22. There is a chronology, dated 30 November 1984, which bears to summarise action taken, including distribution of leaflets, prepared by Mhairi Thornton of Edinburgh and South East Scotland Blood Transfusion Service.³⁰ The only date in it which appears erroneous is in relation to the 1983 UK wide leaflet. It is suggested that this was issued in December 1983. In fact, it was September 1983 – see footnote 11 above.

23. On this document someone has written a question which appears to focus the issue of how far this narrative reflects action at a national level. It is not clear if it does.

24. A further chronology appears at SNF.001.3399 and runs from 1 January 1985. It appears to have had appendices, but these are not now with the document.

²⁶ SNB.012.1270.

²⁷ DHF.001.8989

²⁸ SNB.006.1162.

²⁹ DHF.001.9388

³⁰ Found at SNF.001.3381