DRAFT – CONFIDENTIAL

PENROSE INQUIRY - PROFESSOR GORDON LOWE – REQUEST FOR WITNESS STATEMENT IN RELATION TO TOPIC B5

1. We note from Professor Lowe's letter to the Inquiry (in relation to the Reverend Black) dated 28 March 2011 that Professor Lowe "qualified in medicine in 1972, was appointed honorary NHS consultant in October 1985, and succeeded Dr C D Forbes as Co-Director of the Haemophilia Centre at the end of 1987". When did Professor Lowe first have responsibility for the care of haemophilia patients at Glasgow Royal Infirmary? From that point, did he discuss the risks of using factor concentrates (for example, infection with NANB hepatitis) with his patients?

1.1 I was a trainee doctor at Glasgow Royal Infirmary from November 1974 to September 1985. Firstly I was a Registrar in General Medicine in Professor E.M. McGirr's University Medical Unit, Glasgow Royal Infirmary, from November 1974 to December 1977. Secondly, I was Lecturer in Medicine and Honorary Senior Registrar from January 1978 to September 1985. During this period I developed a subspecialty interest in Thrombosis and Haemostasis, working under the direction of Dr. C.R.M. Prentice (Senior Lecturer, Honorary Consultant Physician and Haemophilia Centre Co-Director, until 1983 when he became Professor of Medicine in Leeds) and Dr. C.D. Forbes (Senior Lecturer, Honorary Consultant Physician and from 1983 Haemophilia Centre Co-Director, until 1987 when he became Professor of Medicine in Dundee). As part of my training I assisted Drs Prentice and Forbes in medical cover of the Haemophilia Centre from about 1976, together with other trainee doctors including Senior House Officers/Registrars in Medicine, Haemophilia, Haematology or Rheumatology.

1.2 From 1983 to 1985 I was seconded from the University Medical Unit to Professor D.H. Lawson's NHS Medical Unit at Glasgow Royal Infirmary, where I assisted Consultant Physicians in General Medicine and Diabetes.

1.3 In October 1985 I was promoted Senior Lecturer in Medicine and appointed Honorary Consultant Physician in the University Medical Unit. From that time I shared Consultant responsibility for the care of haemophilia patients at Glasgow Royal Infirmary with Dr. Forbes. However, Dr. Forbes as Haemophilia Centre Co-Director was in charge of the Centre's administration and policy and attended the meetings of UK Haemophilia Reference Centre Directors and other Haemophilia administrative bodies, until he moved to Dundee in 1987. I succeeded Dr. Forbes as Haemophilia Centre Co-Director from late 1987, initially with Dr. G.A. MacDonald, Consultant Haematologist, then following his retiral in 1990 with Dr. I.D. Walker, Consultant Haematologist.

1.4 From the time that I became Honorary Consultant at the Haemophilia Centre in 1985, I recall that only virally-inactivated factor concentrates were supplied to its patients by the Haematology/Blood Transfusion Department at Glasgow Royal Infirmary. However, I recall that the Centre's policy was to continue to advise all patients receiving factor concentrates about the risks of HIV and hepatitis, safe sex and care with blood and infusion equipment, and monitoring for these infections.

2. Did Professor Lowe discuss the relative risks of cryoprecipitate as opposed to factor concentrates with his patients?

2.1 I recall that Drs Prentice, Forbes and MacDonald's policy in the 1980s was to use cryoprecipitate, rather than factor VIII concentrate, for treatment of a small number of patients with moderate severity haemophilia A or von Willebrand's disease. This was because of the smaller blood donor pool and hence lower risk of hepatitis or HIV infection. This policy continued until the UK Haemophilia Centre Directors guideline on choice of blood products in May 1988 recommended that cryoprecipitate no longer be used for such treatment, unless the haemostatic efficacy of factor concentrates for treatment of von Willebrand's disease was in doubt. My colleagues and I would discuss these policies with patients where appropriate.

3. Could Professor Lowe describe his approach to the treatment of patients with mild haemophilia (both A and B) prior to 1986.

3.1 I recall that between about 1980 and 1986 Drs Prentice, Forbes and MacDonald's policy was to treat patients with mild haemophilia A preferentially with desmopressin (DDAVP), where appropriate and tolerated, or cryoprecipitate; and mild haemophilia B preferentially with fresh frozen plasma; because of the smaller blood donor pools compared to factor concentrates and hence lower risk of hepatitis or HIV infection.

4. When the possibility that AIDS was a blood borne disease which affected haemophiliacs became apparent (around December 1982) did Professor Lowe discuss the implications with his patients before continuing to use factor concentrate therapy?

4.1 Decisions on treatment policies from 1982 to 1987 were the responsibility of Drs Prentice, Forbes and MacDonald as Haemophilia Centre Directors. I recall that from 1983 the UK Haemophilia Society published many Bulletins and other publications on AIDS and Haemophilia, which were distributed to patients, partners and families attending the Haemophilia Centre for their information and education. In some of these publications, patients were advised to discuss any questions they had about their treatments with their Haemophilia Centre Director. While I was seconded to another medical unit for my clinical duties in 1983-85, I had relatively limited contact with patients with haemophilia, but during any such contacts I would discuss any questions they had about their treatments or AIDS and refer them to Drs Forbes or Prentice as appropriate.

5. Did Professor Lowe consider switching his patients back to cryoprecipitate? Did he discuss that option with his patients?

5.1 Decisions on treatment policies to 1987 were the responsibility of Drs Prentice, Forbes and MacDonald as Haemophilia Centre Directors.

6. When Professor Lowe became aware that pharmaceutical companies such as Alpha Therapeutics and Miles/Cutter had been granted a licence to sell heat treated factor VIII in the USA in February 1984 and that the products were available to clinicians in the UK on a named patient basis did he consider switching his patients to it? Did he discuss the relative risks of using unheated UK concentrate and heat treated commercial concentrates with his patients?

6.1 I have no recollection of availability of heat treated factor VIII concentrates in the USA in 1984. Decisions on treatment policies to 1987 were the responsibility of Drs Forbes and MacDonald as Haemophilia Centre Directors.

7. When did Professor Lowe become aware of the fact that a number of Edinburgh haemophiliacs (who later became known as the Edinburgh Cohort) had been infected with HTLV-III by PFC manufactured concentrate and that HTLV-III had therefore entered the Scottish donor pool?

7.1 I recall reading the Lancet paper reporting HTLV-III infection from PFC manufactured concentrate in patients with haemophilia in Edinburgh in 1985.

8. The Inquiry team is aware that from December 1984, all factor VIII manufactured by the PFC was heat treated. Factor IX was not heat treated by the PFC until October 1985. Did Professor Lowe continue to use PFC non heat treated factor IX after he became aware of the existence of the infection of the Edinburgh Cohort? Did he discuss the relative risks of using non heat treated PFC factor IX and heat treated commercial factor IX with his patients? Did he discuss the relative risks of using non heat treated PFC factor IX against the risks of non treatment with mild haemophiliacs?

8.1 Decisions on treatment policies from 1984 to 1987 were the responsibility of Drs Forbes and MacDonald as Haemophilia Centre Directors. From October 1985, when I became Honorary Consultant at the Haemophilia Centre, I recall that only virally-inactivated factor concentrates were supplied to its patients by the Haematology/Blood Transfusion Department at Glasgow Royal Infirmary. As I have noted in (3) above, I recall that Drs Forbes and MacDonald's policy was to treat patients with mild haemophilia B preferentially with fresh frozen plasma, rather than factor IX concentrates, because of the smaller blood donor pool and hence lower risk of hepatitis or HIV infection.

9. When did Professor Lowe start testing his patients for HTLV-VIII?

9.1 I recall that Dr. Forbes, as Haemophilia Centre Co-Director, arranged that all patients with haemophilia who had received blood products attending the Centre were tested for HTLV-III antibody from 1985. By October 1985, when I became Honorary Consultant at the Centre, I recall that the great majority of patients registered at the Centre had been tested.

10. In what circumstances were these blood tests carried out? When were blood samples taken from his patients? Were the blood samples taken with the intention of testing for HTLV-III? Who carried out the tests?

10.1 I recall that HTLV-III testing was performed as part of routine blood tests (clotting factor levels, blood counts, biochemistry including liver function tests, and hepatitis B tests) at clinic reviews. Dr. Forbes had arranged for testing to be performed at the Regional Virus Laboratory, Ruchill Hospital, Glasgow, where hepatitis B testing was also performed.

11. Did Professor Lowe tell his patients that HTLV-III tests were being carried out? Did he obtain consent from his patients before carrying out the HTLV-III tests?

11.1 I told any patients that I personally reviewed at the Haemophilia Centre that HTLV-III tests were being carried out on these blood samples. Before carrying out the HTLV-III tests I ensured that they understood the nature and implications of HTLV-III tests (e.g. from UK Haemophilia Society publications, letter about testing sent to all patients registered at the Centre by Dr. Forbes in early 1985, together with the UK Haemophilia Society publication, "AIDS and the Blood" by Dr. P. Jones).

12. Did Professor Lowe's practice in relation to obtaining consent and testing patients for HTLV-III change between 1984 and 1988?

12.1 My personal practice did not change between 1985 and 1988.

13. Did Professor Lowe's practice in relation to obtaining consent and testing patients for HTLV-III change from 1988?

13.1 My personal practice did not change from May 1988, as it already complied with the General Medical Council's recommendations that month that ".....each patient be given the opportunity, in advance, to consider the implications of submitting to such a test and deciding whether to accept or decline it."

14. What was Professor Lowe's practice in relation to telling his patients of positive test results? Did Professor Lowe inform his patients immediately upon receiving their results?

14.1 I recall that Dr. Forbes' policy as Haemophilia Centre Director was to inform patients of their HTLV-III results (positive or negative) at their next Clinic Review, usually within a few weeks of blood being taken.

15. What arrangements were made for patients about HTLV-III?

15.1 I recall that Dr. Forbes' policy as Haemophilia Centre Director was that patients with positive HTLV-III results should be informed by a Centre Consultant (himself or myself) at an appointment arranged at a quiet time at the Centre, to allow adequate time and privacy for discussion about the test result's implications. Post-test counselling was offered to patients and (with the patient's consent) families, e.g. by Mrs Patricia Wilkie or Mrs Miriam Guthrie; and with the patient's consent Mrs Wilkie or Mrs Guthrie were also present when some patients were informed of their positive HTLV-III test results. Patients were advised that, because a positive HTLV-III result indicated an increased risk of AIDS, they would be reviewed more frequently at the Haemophilia Centre, and by Consultants from the local Infectious Diseases Department (e.g. at Joint Clinics established at the Centre from 1986).

16. What did Professor Lowe tell his patients about HTLV-III?

16.1 I recall that Dr. Forbes' policy as Haemophilia Centre Director was to keep all patients at the Centre informed on current knowledge about AIDS and HTLV-III from 1983. This was by UK Haemophilia Society publications, letter and Dr. Jones' booklet in early 1985, and employing Mrs Patricia Wilkie as researcher and counsellor between 1985 and 1987. I followed this policy by informing any patients whom I personally reviewed about current knowledge.

17. At the UK Haemophilia Reference Centre Directors' meeting on 10 December 1984 [SNF.001.3850] there was a long discussion on whether persons found to be HTLV-III positive should be told. We note that there were several differing views expressed. Was Professor Lowe aware of what was discussed in relation to informing patients of test results?

17.1 I cannot recall seeing the minutes of the UK Reference Centre Directors' meeting on 10th December, 1984 around that time. However, I was aware through Dr. Forbes and others that there were around that time differing views across the UK (and in other countries) about whether persons found to be HTLV-III positive should be told.

18. Did Professor Lowe's practice in relation to informing patients of positive test results change between 1984 and 1988?

18.1 My personal practice did not change between 1985 and 1988.

19. Did Professor Lowe's practice in relation to informing patients of positive test results change from 1988?

19.1 My personal practice did not change from 1988.