THE PENROSE INQUIRY

44 Drumsheugh Gardens • Edinburgh EH3 7SW
Tel: 0131 528 5221
www.penroseinquiry.org.uk

Dr Graeme Alexander
Consultant Hepatologist
Cambridge Hepatobiliary Service
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 2QQ

24 October 2011

Dear Dr Alexander

PENROSE INQUIRY – TOPIC C5

Thank you for your letter dated 11 October 2011. We are delighted that you are able to assist the Inquiry with our investigation of Topic C5.

I can confirm that we do not require you to comment on Topic C5 (a).

We would be grateful if you would provide us with a written report addressing the questions set out in the **attached** schedule.

When preparing your report, you may find it helpful to look at the Inquiry's Preliminary Report (published September 2010). I have **enclosed** a hard copy of the Preliminary Report for your information. An electronic copy of the Preliminary Report can be found on the Inquiry's website at http://www.penroseinquiry.org.uk

Before finalising your report, it would be helpful if you could submit it in draft form. This will allow Lord Penrose and counsel to the Inquiry to raise any points for elaboration or clarification. We would hope that a draft report could be provided to the Inquiry by **Friday 04 November 2011**. Please advise if that timescale is likely to present a problem.

As you are aware, the public hearings in respect of this matter are scheduled to take place between 13 December and 16 December 2011. I note that you are unable to attend on 13 December due to other commitments. I have asked our Witness Liaison Manager, Margaret Fraser, to contact you as soon as possible to make arrangements for your attendance.

Should you have any questions/queries in respect of this matter, please do not hesitate to contact me, either by telephone or email (details below).

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

Yours sincerely

Gemma Lovell

Direct Dial: [redacted]
E-mail: [redacted]

Schedule
Issues in respect of which a statement is sought

It is in relation to Topics C5 (b) and (c) that a statement is sought from you at this stage. We would be grateful if you could provide us with a statement addressing the following matters:

(b) The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products;

(c) The information given to patients who might have been infected, or who were found to be infected, and their families.

Sections of Preliminary Report which may assist when preparing your statement

Chapter 4 "The experiences of patients and their families" in particular paragraphs 4.65 to 4.111 which deal with the information given to patients.

Chapter 6 "Hepatitis 1974 to 1981"

Chapter 7 "Hepatitis 1982 to 1985"

Chapter 9 "Hepatitis 1986 to Date"

Snapshots and Landmarks

The Inquiry has identified the following years as landmark dates in the story of NANB hepatitis/hepatitis C: **1974, 1985, 1991 and 1995**.

By the early 1970s it was recognised by medical scientists and practitioners that factor concentrates were associated with a risk of transmitting hepatitis (at that time only two types of hepatitis were known to exist – hepatitis A and hepatitis B). However, the increased risk of clinical illness was generally thought to be insufficient to outweigh the advantages of using cryoprecipitate and concentrates in the clinical treatment of haemophilia patients.

In **1974** Prince et al suggested that a substantial proportion of cases of post transfusion hepatitis were caused by neither hepatitis A virus nor hepatitis B virus. They suggested the existence of an additional hepatitis virus or viruses which became known as 'non A non B hepatitis'.

In **1985** Hay et al published the results of the Sheffield study. This study showed that there was cirrhosis in 12% of haemophilia patients with chronic NANB hepatitis. The study by Aledort et al (also published in 1985) was also important in developing knowledge about the severity of the virus. From this time onwards there appears to have been a growing awareness that NANB hepatitis was a potentially serious and

progressive disease which could lead, over time, to cirrhosis of the liver, hepatocellular cancer and death.

In **September 1991** a screening test for hepatitis C was introduced throughout the UK for all blood donors.

In **April 1995**, as part of the HCV look-back exercise, the Chief Medical Officers of all four UK Health Departments issued letters to GPs and hospital consultants with guidance on hepatitis C. The letters advised that cirrhosis could develop in 10-20% of people infected with the virus but that it might take 20-30 years to develop and might not be recognised clinically.

Matters to be included in the statement

Anti-HCV testing

We know that an anti-HCV screening test for blood donors was introduced UK wide in September 1991 and that anti-HCV tests had been available for some time prior to this.

When was the first anti-HCV test used in the UK? What type of test was used initially? Who carried out the early tests? Who would have had access to these early tests? What was the correct approach to using the first generation tests?

HCV Look-back

What was your involvement in the HCV look-back exercise?

How useful do you think the look-back exercise was?

What do you think was achieved?

Would you have done anything differently in hindsight?

A screening test for anti-HCV in blood donors was introduced in 1991 but the formal UK look-back programme did not begin until 1995. Could you explain why the look-back exercise did not commence earlier.

Communication of results and implications of diagnosis

What was your practice in relation to telling your patients the results of anti-HCV positive tests in (a) the early days of anti-HCV testing; and (b) from 1995 onwards? Did your practice change over the period? If so, why did it change?

What should clinicians have been telling their patients about the disease and the implications of a positive diagnosis in (a) 1974; (b) 1985; (c) 1991 and (d) 1995?