THE PENROSE INQUIRY

Submissions made on behalf of the National Health Service in Scotland

March 2012

THE PENROSE INQUIRY

Issues to form the subject of Submissions to be made on behalf of the National Health Service in Scotland

1. Donor selection, donor testing, and tracing of blood donations in Scotland during the period 1974 to 1995.

2. The production, supply and use of blood or blood products in Scotland during the period 1974 to 1991.

3. The information given about the risk of AIDS (i) to patients (or their parents) before their treatment with blood or blood products and (ii) to patients who might have been infected and their families.

4. The circumstances in which the Edinburgh Cohort became infected with HIV including the testing of such patients for HIV and the information given to them about their infection.

5. The use of blood product materials in Scotland in the period between the introduction of NHS heat treated products in 1984 and the supply of NHS products sufficiently treated to inactivate Hepatitis C.

6. The information given about the risk of NANB Hepatitis (i) to patients or their parents before treatment with blood or blood products; (ii) to patients who might have been infected or who were found to be infected and in particular the apparent discrepancy between what a number of patients now recall and the evidence of Haemophilia Clinicians as to their practice at the material time.

10 February 2012

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INTRODUCTION

Before dealing with the Issues, it may be appropriate to make some preliminary observations in relation to the approach which it is respectfully suggested should be adopted in analysing the evidence, and in particular in reaching any conclusions from that evidence.

At a preliminary hearing of the Inquiry which took place on 31st March 2009, the Chairman stated that - "It is highly likely that it will be necessary to consider whether it would be appropriate to identify people who did or failed to do things that might have made a difference and to comment upon their actions and failure in the light of contemporaneous knowledge, not with hindsight but to focus upon what happened at the time having regard to the state of knowledge and understanding that existed". At other times during the course of the oral hearings the Chairman has animadverted upon the need to be wary of the dangers of viewing actions or decisions with what has been described as "the cruel vision of hindsight". In these circumstances it may seem otiose to issue yet another reminder about the dangers of - to paraphrase Lord Denning - "viewing 1980s events through 2012 spectacles", but this Inquiry is, unusually, dealing with matters which took place decades ago in a pre-internet era when medical and scientific knowledge was in many significant areas in its infancy. For these reasons it is especially important firstly to remind ourselves of the dangers of hindsight and secondly to seek at all times to view the actions or decisions in the context of their time and against the knowledge and understanding of the time, which was of course often an evolving picture. It is, it is submitted, particularly important to take an *ex ante* view when (1) considering events which occurred so long ago and (2) when the outcome had such grave consequences, many of which were not and could not have been foreseen.

The second preliminary matter must be the standard by which any action or decision is to be judged. Neither the Inquiries Act 2005 (2005 c.12) nor The Inquiries (Scotland) Rules 2007 (2007 No. 560) give much assistance. Section 2(1) of the Act provides that the Inquiry is not to rule on, and has no power to determine civil liability, with Section 2(2) providing that the Inquiry is not to be inhibited in the discharge of its functions "by any likelihood of liability being inferred from facts that it determines or recommendations that it makes". Rule 12 of the 2007 Rules sets out a procedure for the Chairman sending a warning letter to any person where that person may be criticised in the Report, the letter requiring to contain a statement of facts which may substantiate the criticism along with a reference to any evidence or documents which may support those facts.

Whilst it is by no means clear, one inference that may be drawn from these provisions is that the general purpose of the Inquiry (and the Report) is a fact finding exercise. The actions or decisions which have been the subject of scrutiny in this Inquiry may be broadly characterised as (1) clinical decisions by doctors in relation to the treatment of patients, (2) decisions of a significant research nature, (3) administrative decisions of the SNBTS and (4) decisions of the Scottish Home and Health Department or other organs of government.

In relation to the clinical decisions of doctors, it is submitted that, whilst this is not of course a litigation, the same principles must apply. In litigation the ultimate test remains whether the doctor has shown reasonable care for the safety of his patient.

Because of the lay person's lack of required understanding of medical science and clinical inexperience, they are rendered unable to balance the medical benefits and medical risks in both diagnosis and treatment, or to address the question of dissemination of information and disclosure of medical risks. This cannot be achieved without the assistance of medical expert evidence. Although Professor James has undoubtedly been of considerable assistance, his role is not that of expert witness. Whilst this matter will be addressed further in examination of certain topics, it is respectfully submitted that it is not for the Chairman to pass judgement on the clinical actions or decisions of the various physicians involved.

In the case of the purely scientific work carried out by the SNBTS at the Protein Fractionation Centre there has of course been some comment made by Professor Van Aken and Professor Leikola in this regard. However it is suggested that there would have to be very clear and unequivocal expert scientific evidence available to the Chairman before any sort of criticism could be made.

It is also suggested that the same principles do not apply to administrative decisions of the SNBTS and decisions of the SHHD. As a matter of logic it seems that the constraints that are necessarily present in relation to matters of scientific complexity do not present themselves in an appraisal of an administrative or political decision. However in so far as it is thought desirable at all to comment upon the actions and decisions of administrative bodies - and again it is submitted that the purpose of this Inquiry is largely a fact finding exercise - caution must be exercised. No doubt at certain times different decisions might have been taken. It may very well have been better if at certain times different decisions had been taken. Things might have been done differently but it is always necessary to recognise the range of decisions that is validly available to the decision maker acting in an administrative capacity. Unless there is clear and incontrovertible evidence that can only lead to a conclusion that a certain decision would have had to have been universally viewed as clearly wrong at the material time, then it is submitted that it would be inappropriate to express criticism.

As noted above, Section 2 of the Act makes reference to the making of recommendations. The question of recommendations is fraught with difficulties. Firstly there is the historical nature of this Inquiry. Many of the events happened decades ago. A great deal has changed since then. Secondly, there has been little or no evidence of the changes that have been effected over a substantial number of years. This was a matter which was raised with the Inquiry on a number of occasions on behalf of NHS Scotland. It is submitted that in the absence of evidence of the changes that have taken place, it would respectfully appear to be impossible to make recommendations. It would clearly be a superfluous exercise to make recommendations for change that had already taken place.

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