DL/JN

11 October 1989

Mr E G Jones Legal Adviser North Western Regional Health Authority Gateway House Piccadilly South Manchester M60 7LP

Dear Mr Jones

HEPATITIS C

About 18 months ago, before the Hepatitis C test was available, we embarked on a study of the use of two surrogate markers of possible Hepatitis C infection in blood donors. The use of these surrogate markers have become a requirement for all recognised blood banks in the USA and the purpose of the study was to assess the effect of introducing similar tests in this country. Three Regions were participating in the study which was co-ordinated by Dr Gunson.

When the Hepatitis C test became available some months ago, Dr Gunson approached the manufacturers and asked them to provide test kits to examine serum from the 9,000 donors in the study and we are still awaiting the final analysis of all the results. Approximately 20 donors from this Region were found to be positive in the Hepatitis C test and we will be taking steps in due course to withdraw them from our donor panels and provide appropriate counselling.

After this somewhat lengthy preamble, I come to the point of this letter. One or more donations from each of these donors carrying Hepatitis C has been issued to patients in the past. It would be very valuable to undertake a "look back exercise" and to examine surviving recipients of their blood for their Hepatitis C status. In order to do this, it would be necessary to place the relevant information before the patient in order to obtain their consent to giving a sample. I am concerned that by admitting to a patient that he or she has received a unit of blood which may be contaminated with Hepatitis C virus, we may lay ourselves open to litigation even though there was no way of detecting the viral contamination at the time when the blood was issued from this Centre to the hospital. In other words, providing a patient with the information that he or she has received a potentially contaminated unit of blood gives them the necessary ammunition to take action against us on the grounds of product liability.

I would welcome your comments.

Yours sincerely

DR D LEE Director