

File : Product Liability

MC/EH

3rd May 1988

Dr F Seymour
Director of Clinical and Scientific Services
North West Thames
Regional Health Authority
40 Eastbourne Terrace
London W2 3QR

Dear Dr Seymour

You asked me to send you a draft for a letter to District General Managers regarding record keeping of units of blood transfused in hospitals. I propose something along these lines:

The Director of North London Blood Transfusion Centre has informed me that some clinicians, especially those in theatres and intensive care units, are not complying with the DHSS Circular on 'Record Keeping and Stock Control Arrangements (HC[84]7)'. The circular states clearly that records "must permit the tracing of any unit of blood from collection to transfusion or disposal".

Dr Contreras has informed me that, when trying to investigate the ultimate fate of blood or blood components involved in suspected cases of transfusion-transmitted HIV or HBV infection, it has been impossible in some cases for her or her staff to know, with certainty, whether a specific unit of blood was actually given to a particular patient, since no entry was made in the patient's notes. On all occasions, the records in the blood bank were adequate but the fact that blood or blood derivatives were issued for a named patient does not necessarily mean that they were actually given to that specific patient.

You may not be aware that blood and blood derivatives are no longer considered a service, but a product and, in view of the new regulations on Product Liability of the Consumer Protection Act which came into force in 1988, I urge you to insist to surgeons and anaesthetists to enter in the patients' notes the donation numbers of all units of blood and blood components given to those patients. These regulations apply to whole blood, fresh frozen plasma, cryoprecipitate, red cell components, platelet concentrates, buffy coats, etc. They also apply to blood products, i.e. albumin, factor VIII, factor IX and immunoglobulins; in these cases, the name of the manufacturer and batch numbers should be entered.

With kind regards,

Yours sincerely

Dr Marcela Contreras
Director