Northern Regional Health Authority
National Blood Transfusion Service
Regional Transfusion Centre
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Our Ref. XRH^1201/HLL/pk

Your Ref.

30th April 1991

Mr I Vickerman
Executive Director, Human Resources
Northern Regional Health Authority
Benfield Road
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Dear Mr Vickerman

Re: Hepatitis C Testing

At the end of 1990 or early 1991 I was asked by the National Directorate when the Northern Region Blood Transfusion Service could start Hepatitis C testing. At that time I gave a start date of 1st April 1991. Subsequently Dr Gunson, the National Director informed me that some Transfusion Centres were not able to start testing until September 1991. Eventually a start date of 1st July was circulated. I took this to mean the date by which all units of blood and all blood components transfused to patients in the Region would have been tested. I made plans accordingly and aimed to start testing in April, giving time for all stocks to be tested, including frozen products which have potentially, a 6 month shelf-life.

Shortly before the date when we intended to start testing, the Procurement Directorate started a comparative evaluation of Second Generation test kits for Hepatitis C testing. This round of evaluation, initially between the two kits available in this country was then extended to include two other kits, including one from a firm that has not previously supplied test kits to the UK market.

I suspected that this extended comparative trial would not be completed quickly and even the initial trial of Second Generation tests would not have been completed before we were due to start testing.

Subsequently a revised starting date for Hepatitis C testing was circulated. This suggested September, although it was not clear whether this meant that September was the time to start testing or the time by which all units of blood for transfusion should have been tested. This represents about a 3 month difference for this Centre.

I therefore decided to continue with our original plans to start testing in April so that all units for Transfusion were negative by 1st July 1991.

This action appears to have upset Dr Gunson considerably and it may be that through his contacts at the Department, questions will be asked of the RHA as to why I did not follow Dr Gunson's instructions.

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My prime reason for not delaying the start of testing, relates to Product Liability and the risks of litigation. Product Liability means that if anyone is harmed by a transfusion, the person concerned does not have to prove negligence, merely that the product caused harm. The degree of culpability relates to whether or not it would have been possible to have provided the product free of that defect.

In this instance I felt that we would have no defence whatsoever. We had stated that we could start testing in April, and we had all the means for testing at our disposal. We would only be delaying testing to enable a comparative test to be carried out between Second Generation kits. An evaluation of the first generation kit had already been performed.

With no mitigation available to us we would have become fully liable for all damages and publicly we would have been shown to have failed to carry out a test for dubious reasons relating to comparative tests, an element of which could be seen as an attempt to bring down the costs by increasing competition in the market. This is a perfectly acceptable action, but not at the expense of postponing testing by several weeks, possibly by as much as four or five months. Finally of course, Dr Gunson does not have executive authority, and any defence suggested on the lines that the National Directorate take responsibility would in my view have been spurious.

As a footnote on the role of the National Directorate, it is interesting to see that they have asked Ernst and Young to define a new role for the National Directorate, which can then be put forward to the Department.

Yours sincerely

GRO-C

H L Lloyd
Director/General Manager

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