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Dr M LONNERS
Director

MC/JC

28 December 1989

Dr H H Gunson
National Director
The National Directorate
Gateway House
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Dear Harold

ALT testing of plasma from apheresis

Thank you for your letter of 22 December 1989 which arrived yesterday. I feel that I have to answer it without delay and raise the following points.

- i) Although we already carry out ALT estimations regularly, every three months, on blood samples from our haemapheresis donors, we would find it extremely difficult to comply with your request as from 29 January 1990. As you no doubt realise the departments of Biochemistry, Components Production and Data Processing would have to get in place the procedures for testing, record keeping, transmission of results, selection of plasma packs and issue, at a rate of throughput of 25,000 units a year. I am afraid I lack your optimism that this can be achieved within 21 working days.
- ii) The introduction of routine testing of all plasma donations will require an initial outlay of capital for buying or leasing back-up equipment, and revenue costs for additional staff. I can foresee difficulties in getting money without prior notification, in spite of the fact that the costs will be repaid by increasing the credit for the plasma delivered to BPL. As the CBLA has not given us any official notification about payment for ALT tested plasma, we are in no position to argue the case for additional (temporary) funds from the RHA at such short notice.

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Furthermore, it is not clear how much we are going to be paid for plasma with ALT over 90 iu/l. If this plasma is destined for R&D we may suffer losses even if only a small fraction of the plasma falls into this category.

- iii) Finally, I feel that you should have used the process of consultation before deciding on a date for implementation of this policy. Somehow, I find it strange to be bound by a unilateral agreement on a date which you have reached with Richard Lane without knowledge or participation of RTDs.

Consultants at NLBTC are fully supportive of the production of i.v. IgG by BPL. We have been asking for this product for more than 3 years. We were aware that Richard was trying to obtain a patent for i.v. IgG from the USA and that this would require ALT tested plasma. However, we had no knowledge that the introduction of i.v. IgG would be so imminent; we were given no warning of a possible date. In addition, when we discussed ALT testing of apheresed plasma, we were led to believe that there could only be 2 categories: (1) Normal ALT (2) Raised ALT. The 3 categories proposed will introduce additional complications which we had not anticipated.

With kind regards

Yours sincerely

GRO-C

DR MARCELA CONTRERAS
Director

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