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25 November 1985

Professor R Weiss
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Dear Robin

HTLV III INACTIVATION STUDIES IN BLOOD PRODUCTS

You will no doubt recall that we had some discussions some time ago regarding a collaborative study to evaluate the efficacy of FVIII heating regimes in inactiviting potential HTLV III contamination of products produced at this Centre. At that time you very kindly agreed that such studies were important and that you would be able to contribute to such studies by providing virus and residual infectivity assays. You will also doubtless recall that technical and Health and Safety Executive problems at our end delayed the initiation of such studies. Similar studies were, in the meantime, reported in the literature providing some measure of confidence in our heating protocols. As a consequence, the perceived importance of pursuing our original plans for a collaborative study diminished (I understand that you also moved your laboratory!). I now believe that these perceptions were a little premature since data was presented at the recent AIDS meeting in Washington which casts some doubt on the safety of heated coagulation factor concentrates and equally importantly, intravenous immunoglobulin preparations. The latter is a new development in the debate (I enclose some pre-prints - in confidence) and as the sole manufacturer within the UK of this product our ability to demonstrate its safety is of paramount importance. Bruce Cuthbertson has been vigorously pursuing an evaluation of our manufacturing process for the manufacture of IV IgG assay, using a range of model viruses which suggest that the inclusion of pH 4/mild pepsin treatment of our IgG product quantitatively inactivates virus. This is reassuring but in the current climate we need unequivocal evidence of inactivation of the real things in order to avoid an imminent crisis of confidence!

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We are now technically equipped (from the HSE perspective) to carry out the previous planned programme of work on FVIII but clearly we would now wish to extend these studies to include IV IgG. It is clear that both studies are a matter of urgency.

My reason for writing therefore is to ask if you could once again undertake to help us with this work. Needless to say, we would be more than happy to discuss our precise requirements with you and to provide any necessary funding.

I very much look forward to hearing from you at your earliest convenience.

With kind regards.

Yours sincerely

R J PERRY
Director

cc Dr J D Cash
Dr B Cuthbertson