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8 January 1985

Dr Duncan Thomas
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and Control
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Dear Duncan

HEAT TREATED FVIII

Following our helpful discussion yesterday, I thought it appropriate to notify you formally of the prevailing policy at PFC (and therefore throughout Scotland) for the manufacture of heat treated FVIII. This is briefly as follows:

(a) That all FVIII issued from PFC has been subjected to heat treatment as from mid-December '84.

(b) PFC will be recalling all existing regional stocks of non heat-treated FVIII for heat treatment and reissue.

(c) Heating conditions at the present time are 68° C for 2 hours in the dry state. These conditions have been established on the basis that this was the best time/temperature profile which could be established for the existing product without compromising solubility characteristics and also in the knowledge that a joint CDC/Cutter study suggested that these conditions might provide 4-5 logs inactivation of HTLV III virus.

(d) The analytical specification of the heated finished product is unchanged and in-vivo characteristics (so far as is known) are identical to the unheated precursor.

(e) No significant deterioration has been detected as a consequence of heating.

(f) Plans are well advanced for the manufacture of a new product which is subjected to more extreme conditions of temperature and time. This will require modest reformulation before dispensing (addition of carbohydrate).

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I will arrange for samples of our heated products to be despatched to you for your routine assessment.

Dr Cuthbertson (Virologist) of this Centre is liaising quite closely with your Dr Garrett and has already sent a number of samples of product for reverse transcriptase assay including of course the batch of FVIII which has been implicated in the HTLV III sero-conversion episodes in Scottish Haemophiliacs. While I appreciate it is early days to be asking, it would be useful if we could invite you to consider putting this arrangement on a more routine basis in the future. Such a test would obviously not become a product release parameter but would nevertheless provide valuable information for both retrospective studies and prospective studies of product infectivity.

You also mentioned that you may, in the near future, gain access to live HTLV III virus with a view to establishing an antibody assay at your centre. As I explained, we are most anxious to carry out some viral inactivation studies to validate and establish efficacious heating protocols. We have a category 3 containment facility and I would be most grateful if you could indicate whether live virus might be made available to PFC in due course so that this work might proceed. You will be aware that HTLV III virus is becoming increasingly difficult to obtain. Meantime, we are proceeding with model viral inactivation experiments but I nevertheless feel that there is value in determining the heat lability of the infective agent itself.

Many thanks for a helpful discussion.

With kind regards.

Yours Sincerely

R J PERRY
Director (Acting)

cc Dr J D Cash
Dr D B L McClelland