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26 November 1984

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Dear Brian

BATCH DEDICATION OF FVIII AND FIX

Thank you for your letter of 19 November.

Following our brief discussion of your proposals I would confirm that there is little doubt that we can do something at this stage on a selective basis since there is now approximately 36,000 vials of FVIII in stock at PFC and 11,000 vials held regionally. In general terms therefore, we have sufficient stocks to permit some manoeuvring and batch dedication even on a National scale.

Some cautionary notes and comments:

- (a) I believe that as a pilot study, we should calculate the period of dedication as 12 months - this will minimise the problems of outdating and disposal of batch ends in an under-use situation.
- (b) To extend a batch dedicating system both in time and patients would, I think, require an injection of fresh plasma to permit an acceptably short run-in time. Otherwise, a 2 year lead in time will be required if we are to avoid disrupting the presently well balanced supply/demand equation.
- (c) We should delay implementing this system until all SNBYS product has been heat treated. This is of course self evident but does give us a time frame within which we can plan the logistics (between now and January).
- (d) Not all batches are 1000 vials so this might be a bit disruptive in a long

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WATCH DEDICATION OF FAULT AND FIX

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term prospective planning exercise.

- (e) PFC is developing a heat treated product (wet heat with stabiliser) as you know. The timescale for the introduction of this product - which might reasonably be expected to eliminate all risk of viral transmission - is much shorter than the timescale for a National System of batch dedication. It would be inappropriate to embark on a complex and long-term exercise of batch dedication with an expectation of a non-infective product coming on stream in the short/medium term.
- (f) A batch dedication system effectively redistributes and decentralises the National Stocks and it should be made clear that any collaborative system which may be disrupted if wider supply/distribution problems emerge - for whatever reason. This event is unlikely but I believe the point is worth making.
- (g) Stocks of FIX are too low for any progress to be made in this area at the present time.

CONCLUSIONS

We can make a significant contribution to reducing patient exposure to donor plasma by implementing an annual batch dedication programme for a limited number of haemophiliacs (Haemophilia A). I would be delighted to sit down with you and discuss the logistics involved. I will ask Irene to contact your secretary to find a date.

With kind regards.

Yours Sincerely

R J PERRY
Director (Acting)

cc Dr J D Cash

The first part of the document is a letter from the President of the United States to the Congress. It is dated January 1, 1961. The letter is addressed to the House of Representatives and the Senate. It is signed by John F. Kennedy.

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