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Dear Harold,

FACTOR VIII

Thank you for your letter of 10 May. I apologise for the delay in replying.

Jim Smith has already contacted us on this matter and Peter Foster has provided the data requested. No doubt Jim will present this data in a comparative format in due course and I would not wish to duplicate his efforts. I would however wish to make the following observations on this exercise.

- (a) FVIII yield from the Z8 process are significantly lower now compared with yields achieved when the process was originally introduced. Substantial efforts are now being made to bring process yield back into line with our expectations (280 IU/litre) are underway but we cannot assume that these efforts will be successful.
- (b) I believe that the implied option for BPL to implement the Z8 process (or for that matter PFC to implement the 8Y process) is neither viable or sensible as an operational option. FVIII processes are complex and invariably are designed to fit with other processing technologies within individual fractionation centres. Processes are intrinsically vulnerable to significant yield variations and history tells us that the transfer of a process from one centre to another represents a major undertaking with little assurance that product or process characteristics will be maintained. FVIII process technology is evolving rapidly - it would be unwise (in the short term) to attempt to transplant either the Z8 or 8Y process.

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- (c) There exists perhaps a more powerful argument for advocating a policy of no change. 8Y has now been substantially validated in naive patients with very promising results. Such studies are becoming major factors in the market place and to abandon 8Y in favour of Z8 (which has not been validated in patient studies) at this time would be quite irrational - even if there did exist a significant yield advantage.
- (d) 8Y is a good product of higher purity than Z8, PFC is planning the imminent introduction of a FVIII product of comparable purity to 8Y and which draws upon features of both 8Y and Z8 processes. Yield data from this process will emerge in due course.
- (e) The positive way forward for the UK at a time of considerable turbulence, market vulnerability and technological change is to foster strong collaboration links between BPL and PFC so that each Centre can benefit from the success and failures of the other. Advocating a policy of 'standard processing' between the two Centres is not possible at the present time or desirable. This situation may of course change in the fullness of time but should only be contemplated as part of a structured scientific/strategic development - not on the basis of a snapshot comparison.

I hope these comments are helpful.

With kind regards.

Yours sincerely,

R. J. PERRY  
Director

c.c. Prof J. Cash  
Dr. J. Smith  
Dr. R. Lane