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M E M O R A N D U M

TO: Mr. J. Watt
Dr. R. Perry

FROM: Dr. P. Foster

SUBJECT: Thrombogenicity Testing
of Coagulation Factor
Concentrate

DATE: 17th February, 1983

On 7th February a meeting was held between J. D. Cash, C. Prowse, J. Dawes and myself to discuss the need for a further animal (dog) study of this topic.

The motivation for this meeting stemmed from my view that in attempting to pasteurise factor IX concentrates we would need to evaluate any increase in thrombogenic potential which might result from the new procedures. The situation is complicated by the fact that we have a number of product options all of which may have different thrombogenicity/infectivity/yield profiles.

viz. (i) unheated DEFIX
(ii) unheated Supernine
(iii) heated DEFIX
(iv) heated supernine from unheated DEFIX
(v) unheated Supernine from heated DEFIX
also (vi) unheated FVII
(vii) heated FVII

If we adopt some form of heated Supernine we will also have the opportunity to review the processing conditions to maximise yield according to thrombogenicity potential rather than infectivity. Ultimately an animal test could be used to confirm procedures arrived at from in vitro tests (NAPTT, TGT 50).

A note of the meeting has been prepared by Dr. Prowse (appended). The proposals are:-

- (1) A dog colony be set up for this study.
- (2) Facilities at Bush Estate should be considered first (via PFC). If this is not possible other facilities could be pursued.
- (3) If the need for a study is agreed then the provision of finance, equipment and staff should be discussed by the appropriate Directors.

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