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22nd February, 1984

Dr. J. Garrott Allen,
 Professor of Surgery,
 583, Salvatierra,
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Dear Professor Garrott Allen,

Dr. Anne Welch has asked me to reply to your letter of 7th December, 1983 concerning our letter published in the Lancet (19th November, 1983).

We began to investigate the heat treatment of labile clotting factors following reports that sugars could be used to stabilise proteins against heat denaturation (eg. Black et al, Biochemistry 18 : 5191-6, 1979; Gekko et al J. Biochem 90 : 39-50, 1981). We found that both FVIII and FIX (and other proteins) could be substantially stabilised against heat inactivation at 60°C in the presence of high concentrations of sorbitol (MacLeod et al, Thromb. Haemostasis 50 : 432, 1983). In subsequent studies of the behaviour of model viruses we have found that virus can also be stabilised to some extent in these solutions. We have not worked with hepatitis viruses but we are fairly sure that heating for 10 hours at 60°C in sorbitol will not give the same degree of viral inactivation that one expects from the pasteurisation of albumin solutions (60°C, 10 hours). However, the viruses that we have studied are stabilised to a lesser extent than the proteins and we therefore believe that a heating regime other than 10 hours at 60°C may be more appropriate where sugar stabilisers are used. We are still working on this aspect of the problem but it may interest you to know that we have prepared heat treated FVIII (60°C, 10 hours) for clinical evaluation and this has been found to be safe and effective in a small number of infusions.

I was interested to learn of your early publications on this topic and would welcome any comments or suggestions that you might have.

Yours sincerely,

DR PETER R. FOSTER
 R & D Manager