11195

Dr Walford
Copied to everyone except you! I will study Dr Lane's responses to date before pressing Dr Lane as suggested at X.

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2244

Mr Harley

BPL ELSTREE

GRO-C: S Godfrey

1. You will recall that on 9 April I sent you the report of the March 1981 inspection of BPL and advised that MD agreed the Inspector's conclusions and recommendations; you responded on 5 May. Mr Godfrey later copied to me Dr Lane's report to the STC/JMC commenting that the STC had noted the response, had accepted it as reasonable and that the JMC were expected to do likewise.

2. I must now seek your help in obtaining assurances from Dr Lane that his initial response has been followed up by positive action to remedy the deficiencies noted by the Inspector. Lacking suitable proposals and evidence of their implementation the position at BPL remains (with due respect to STC/JMC) unsatisfactory from our point of view. We fully recognise that a number of important deficiencies cannot be remedied short of major redevelopment. Nevertheless we are looking for improvements in the general standard of housekeeping and management - items which would probably not involve great capital expenditure. For example, remedial proposals are required for deficient procedures and for maintaining the processing area; there is the question of what action has been taken to deal with mould growth in production areas (3.12 of the report) and to stop water dripping from overhead pipes and causing mould growth in Room 217C (3.12 of the report); action is required to deal with any highly contaminated plasma or packs in poor condition.

3. In view of Secretary of State's concern that the NHS and industry should not operate to different standards we should be in a position to show that progress is being made. I should be grateful therefore if you would press Dr Lane to submit remedial proposals and to report progress on matters already resolved. We are very conscious that in dealing with commercial production any failure to provide a prompt and adequate response to our recommendations would have lead to early consideration of the need to suspend manufacturing.

4. When we have had an opportunity to consider BPL's proposals and report on progress already made we should be very willing to arrange another inspection during which any problems can be further discussed and advice given. We feel that the time has come to do some stock-taking so that we have a clearer picture of exactly where matters stand on the deficiencies set out in the March report.

GRO-C

J B BROWN
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Rm 1533
Ext GRO-C

25 September 1981

Copies: Mr Williams
Dr Griffin
Dr Thomas
Mr Chambers
Miss O'Carroll
Mr Baker
Mr Ayling
Mr Booth

PS. I understand that recent boards have been unable to recommend any of the applicants for the post of Deputy Director or Chief Engineer.

We are very concerned that more than 2 years after our main report forcefully recommended the need for these key posts, that recent advertisements and boards have failed to produce appointments. (See attached).

14/FL

8.9.3.10 Steps to be taken to establish the following key posts and appoint appropriate staff as :

* Factory Manager; with industrial experience of the manufacture of sterile pharmaceutical products and preferably blood products or biologicals processing.

Quality Controller; as defined in the Guide to Good Pharmaceutica Practice.

Microbiologist; to act as full time consultant and provide a fully integrated microbiological service.

* Engineer; with experience of clean rooms; clean air systems, filtration, to provide an engineering service and planned preventive maintenance throughout the laboratory.

8.9.4 Long term planning must take into consideration the following:

8.9.4.1 The present facility is totally unsuitable for manufacture of sterile products and incapable of being upgraded to the required standards.

8.9.4.2 The existing buildings would be suitable as, or could be adapted for use as:
in-process and control laboratories, research and development laboratories, office accommodation, warehousing, receipt and despatch, packaging.

8.9.4.3 A new factory-type manufacturing facility is required.

8.9.4.4 "Stop Gap Proposals", as described to us, should be proceeded with as quickly as possible to provide additional cold storage space, warehousing, goods receipt and despatch, container washing and preparation, but only if such a development can be incorporated into a new manufacturing facility. However, in proceeding with 'STOP GAP' there should be no intention of increasing production in the present facility as it is already overloaded and seriously deficient in standards.

WORKING PARTY ON PLASMA SUPPLY - AC(81)11 AND AC(81)18

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7. On behalf of members the Chairman thanked Dr Gunson and his colleagues for having prepared such an excellent and detailed document. Dr Gunson explained that as a result of further discussions with Haemophilia Centre Directors, the target plasma supply required to achieve self-sufficiency could be reduced to 435,000kg. This would produce 95 million iu of intermediate concentrate Factor VIII and 5 million iu of cryoprecipitate but would offer BPL sufficient scope to meet requirements for high-purity concentrate. It would also produce 200g of albumin (ppf) per 1,000 population. Dr Gunson emphasised how difficult it had proved to determine the total current albumin usage because there was insufficient information available about how much was being purchased by health authorities. One way to monitor usage would be to establish a central purchasing scheme in each Region.

8. Dr Gunson drew members' attention to Table 1 which set out the estimated annual cost to RHAs of providing plasma through whole blood collection and plasmapheresis, together with the commercial value of the products manufactured from the plasma. The Table did not take account of BPL's fractionating costs nor of the capital cost of redeveloping the Laboratory. Dr Lane estimated that the commercial value of the "other products" would be £4.5 million rather than the £2 million shown in the Table.

9. Miss Schofield stressed the need to ensure the donor's comfort and safety during plasmapheresis. Dr Gunson explained that the automatic process was safer and in addition took up less of the donor's time than the manual method. RTDs had prepared the Code of Practice for Automated Plasmapheresis of Volunteer Donors. An equivalent Code was required for manual plasmapheresis and he expected that a working group of Transfusion Directors would take this task in hand.

10. Members endorsed the report of the Working Group and asked that Ministers' agreement be sought to formal consultations with RHAs about plasma supplies. Mr Harley said it was envisaged that the UK's need for blood products would be met jointly by PFC Liberton and the redeveloped BPL and there would need to be further discussions between the Health Departments about the inter-relationship of the 2 fractionating facilities.

11. Discussing the future role of the Working Group, members agreed that the Group had an important part to play in the forthcoming discussions with RTDs and their Regions on the need to increase plasma supplies and also on the need for specific plasma. The Chairman asked the Group to keep abreast of world-wide developments in plasmapheresis. Members of the Committee were asked to contribute information to the Group.