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C13.

BLOOD PRODUCTS LABORATORY: REDEVELOPMENT

1. As Mr Finsberg knows, in April 1981 Ministers agreed that a Policy Steering Group should begin planning the redevelopment of the Blood Products Laboratory (BPL) at Elstree and that health authorities' capital allocations should be reduced to fund the redevelopment. The Steering Group have now reached the stage at which Ministerial decisions are required on

- a. the size of the new Laboratory;
- b. the scale of production;
- c. its cost.

PROGRESS MADE TO DATE

2. Redevelopment of the Laboratory has been approved in principle by the Treasury; the Treasury have also agreed that the project should be "fast-tracked" by using a firm that can provide a comprehensive service. The Policy Steering Group, after discussions with a number of potential contractors, commissioned Matthew Hall Norcain Ltd (MHN)\* to produce a detailed feasibility study. This study formed the basis of discussions with the Company which in turn have led to the preparation of a series of costed options described below.

OPTIONS

3. The Steering Group has considered a range of 3 options with regard to plant size. These are for a factory capable of handling:

- a. 200,000kg of fresh frozen plasma (ie large enough to deal only with a slight expansion in the present plasma supply);
- b. 275,000kg (which would generate sufficient Factor VIII, though insufficient plasma protein fraction, to meet current NHS demands);
- c. 400,000kg (the level of plasma required if England and Wales are to be self-sufficient in blood products by the mid-1980s).

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\*MHN is a subsidiary company of one of the UK's largest engineering contractors. It offers services covering all aspects of the design of a plant combined with those of a managing contractor who organises its construction, equipping and commissioning. MHN would be paid a fee (to be negotiated) for these services. The work on site would be carried out by sub-contractors and suppliers who would tender in competition for each of the many sub-contracts into which the work would be divided. In accordance with normal practice the Department requires that tenders should have been obtained for 70% of the work before construction begins and that the remainder should be covered by firm estimates. This is to provide some assurance that the final cost can be contained within the budget cost.

## PLASMA SUPPLY

4. Regional Transfusion Centres generate about 150,000 kg of fresh frozen plasma per year. This is rising steadily. RHAs have been consulted about their willingness and ability to produce 400,000 kg of plasma by the mid-1980s. Without exception, RHAs supported in principle the move to self-sufficiency and accepted the economics of producing more plasma to reduce expenditure on imported commercial blood products (at present estimated to cost the NHS about £10m a year). Several, however, doubted their own ability to reach Regional self-sufficiency targets without substantial extra investment in plasma collecting facilities.

5. The Steering Group, taking account of RHAs' views and with advice from the Advisory Committee on the National Blood Transfusion Service, think that it is likely that the NHS can generate sufficient plasma to sustain a factory of optimum size (see below). The capital and revenue costs of plasma collection have been taken into account in the investment appraisal in paragraph 12. It is undoubtedly preferable for England and Wales to be self-sufficient in plasma supplies (a principle previously endorsed by Ministers) but there are fall-back positions if there should be a shortfall from the NHS. It would be possible to make up any deficit by purchasing accredited plasma from a reliable source (eg the Swiss Red Cross) or, to make maximum use of the investment in the new plant, the new BPL could fractionate plasma on an agency basis for another health service. Both of these fall-back positions are feasible and have been endorsed in principle by the Policy Steering Group.

## SURPLUS PRODUCTS

6. The production process is such that whatever target capacity is chosen a considerable amount of raw material is generated (in paste form) from which could be manufactured quantities of certain products (immunoglobulins and Factor IX) surplus to NHS requirements. The unrefined paste itself is unattractive to <sup>British</sup> commercial interests who do not possess the technology necessary to process it into its final form. However, David Smart, Chairman Designate of the new Central Blood Laboratories Authority, using his position in the pharmaceutical industry, has investigated the demand for the products which can be derived from the paste and is confident that a substantial world market exists for their sale. The Steering Group have therefore <sup>costed</sup> the options described below on two bases. First, if such surplus paste were sold in "raw" form. Second, if additional facilities were provided to process the surplus paste into a saleable form. (It is envisaged that the products could be sold in bulk to pharmaceutical companies; the new Laboratory would not be involved in direct marketing). Ministers have agreed in principle that products surplus to NHS requirements can be sold and MS(H), when he visited the Laboratory on 1 July, told staff that he supported the sale of such products with an appropriate margin for profit provided that the income was retained by the NHS.

## COSTED OPTIONS

7. The range of costed options for the redevelopment at 1981 prices is as follows:

<u>CAPACITY</u>	<u>CAPITAL COST (INCLUDING FEES)</u>	
	(a)	(b)
<u>Fresh frozen plasma</u>	<u>Laboratory capable of of meeting NHS needs only (excess paste sold in 'raw' form)</u>	<u>Manufacturing all products which can be derived from plasma (excess products sold in finished form)</u>
200,000kg	£17.4 million	£18.6 million
275,000kg	£18.3 million	£19.6 million
400,000kg	£19.2 million	£21.03 million

## DESIGN CHANGES/CONTINGENCIES

8. The estimates above include no leeway for contingencies, for which the Policy Steering Group have suggested an addition of 2½%, or for design changes. On the latter, an essential part of BPL's role is to develop technological improvements in plasma fractionation and planning for the new Laboratory ought to be flexible enough to accommodate improvements which might emerge during the planning process. The Steering Group have suggested a 5% addition to cope with necessary design changes.

9. Although there is no reason to suspect that the Central Blood Laboratories Authority will exercise less than stringent control over its capital building programme, it would be prudent to build into the planning assumptions a margin of 7½% as requested. If used, this could add £1.5 million to the overall cost and this has been taken into account in the investment appraisal below; central planning assumptions will also allow for it. It is suggested, however, that the Authority should be told that the cost ceiling for redevelopment (including fees) is £21.03 million as it is an inevitable feature of large projects of this nature that if the planners are told that contingency money is available, it is used.

### PFC, LIBERTON

10. There is one other fractionation plant in the UK - the Protein Fractionation Centre at Liberton in Edinburgh - which was designed for continuous flow operation, and in which DHSS invested £400,000 in the early 1970s with the intention that it would be capable of fractionating English plasma. In the event, the plant has not been able to do so because shift-working arrangements have not yet been negotiated. SHHD estimates that if a continuous shift-system could be negotiated, an expanded PFC could handle up to 200,000 kg of English plasma for a further capital investment of £6 - £7 million of which some £4 million would be directly attributable to the cost of taking English plasma. Revenue costs, including transport and processing, would not be markedly higher than at BPL.

11. This option has been considered in depth by the Policy Steering Group who considered also the possible strategic advantage of 2 medium-size plants rather than 1 large factory (Elstree) and a relatively small one (Liberton). However, the strategic advantage (eg should an infection close down a production line) is off-set by the flexibility which the design of a factory of the size recommended for the BPL would permit (ie 2 production lines with scope for the introduction of a third if required). Given that the present BPL has to be redeveloped - it fails to meet current Medicines Inspectorate requirements and much of its fabric will not last beyond 1985 - it would be more expensive to build a smaller BPL (£18.6 million) and invest £4 million in PFC than to build a BPL capable of achieving self-sufficiency (£21.03 million). In any case, in the view of DHSS officials, it remains highly doubtful whether a shift-working agreement can be negotiated with staff at PFC without serious repercussions on pay of other groups in the NHS and the Industrial Civil Service.

## INVESTMENT APPRAISAL

12. An Investment Appraisal prepared by the Economic Advisers' Office is at flag B. It substantiates the Policy Steering Group's firm view that the new Laboratory should be planned to be large enough to fractionate enough products to enable England and Wales to be self-sufficient and should make maximum use of the raw material available to it by making surplus products for sale to industry.

### i. Pay back period

If built to schedule and commissioned by 1986, the 400,000 kg Laboratory should pay back the investment in the second year of full production. (At the lower production levels considered, the pay-back time does not differ markedly).

### ii. Cost over life of the investment

As Ministers will know, the "pay-back period" is less important in economic terms than the "overall project costs" taken over the life of the investment. The options described above have therefore been analysed taking into account that at the lower production levels the NHS would continue to purchase commercial blood products. On this basis the 400,000 kg factory emerges as the least expensive means of meeting the NHS demand for blood products.

At 1981 prices the cost of the new Laboratory would be £21.03 million.

## FUNDING

13. Ministers have already agreed to a preliminary pre-emption of £17m at 1980 prices (equivalent to £17.54m at 1981 prices) from health authorities' capital provision. It was stressed to the Treasury at that time that this was at the lower end of the estimates prepared by the Department's Advisers. A decision is now required whether the health authorities should bear the additional costs implicit in the investment appraisal now available.

## PATTERN OF EXPENDITURE

14. If Ministers agree that the Laboratory should be built large enough to make England and Wales self-sufficient in blood products, and that it should fractionate surplus paste, the proposed pattern of expenditure would be:

1982-83	£1.2 million
1983-84	£7.6 million
1984-85	£9.3 million
1985-86	£4.5 million (including £1.5 million contingency).

This can be met within cash planning assumptions for 1982-83 to 1984-85. As Ministers will be aware, assumptions have not yet been made for 1985-86.

15. The figures above are at 1981 prices. Planning assumptions, however, are in cash terms. It follows that if rising costs are not in line with cash factors some discrepancies will arise. This is a potential problem with any capital scheme once it is under way: it is a bridge we may have to cross if we come to it.

## DECISIONS REQUIRED

### 16. Ministers are asked whether

- i. officials may submit a Stage Two submission to the Treasury seeking approval to commence redevelopment of BPL at a size
  - a. capable of making England and Wales self-sufficient in blood products;
  - b. capable of extracting all therapeutic materials from the plasma it receives, and selling surplus materials to the pharmaceutical industry; and
  - c. at a planning cost of £21.03m with a contingency fund of £1.5m;
- ii. subject to receiving Treasury approval, the Policy Steering Group (or, if established by that time, the Central Blood Laboratories Authority) may be authorised to proceed with planning on this basis.

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