# AN APPRAISAL OF REDEVELOPMENT OPTIONS FOR THE BLOOD PRODUCTS LABORATORY

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1. In 1981 DHSS Ministers established a Policy Steering Group (FSG) whose objective was to plan the redevelopment of the Blood Products Laboratory on behalf of the Joint Management Committee for the Central Blood Laboratories. This paper sets out the results of the PSG's appraisal of the options for redevelopment. The report is set out according to the Department's guidelines for the approval of building developments under the revised Capricode procedures, (1) which are intended to make the choice between options as explicit as possible.

#### BACKGROUND AND DEFINITION OF OBJECTIVES

2. As was explained in the letter of 31 July/from Mr D Harris to Mr Prescott, in which Stage 1 approval was sought, the Blood Products Laboratory is essentially a pharmaceutical manufacturing unit which receives blood plasma from Regional Transfusion Centres and fractionates it into a number of products for use in the National Health Service. Increasing demand for blood products and the inability of the laboratory to comply with current pharmaceutical manufacturing standards has made it essential to consider a major and rapid redevelopment. In planning the redevelopment, the PSG has sought to secure the most cost-effective means of satisfying future NHS demand for blood products.

#### APPRAISAL OF OPTIONS

3. The PSG has been conserned with the clinical requirements of England and Wales. During the course of its studies, the group examined whether the Scottish fractionation centre, PFC Liberton, might economically fractionate a proportion of the English and Welsh plasma and thus reduce the capacity needed in the new EPL. However, the Scottish Home and Health Department estimated that an expansion and upgrading programme at PFC would cost £6-7 million, which £4 million would be directly attributable to the taking of 200,000 kg of English plasma. This is greater than the additional expenditure needed to build EPL large enough to handle all English and Welsh plasma. (2) In addition, lack of progress in negotiating a shift-work agreement at Liberton (to enable it to undertake the continuous production process for which it was designed) led the PSG to conclude that it would be unwise to anticipate any significant contribution from the Scottish centre.

(1) HN(81) 30 refers.

(2) Further details of capital exp

Released for disclosure.

ragraph 17 below.

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- 4. In principle there exists a spectrum of options for meeting future NES demand for blood products. These range from importing all requirements on the one hand, to complete self-sufficiency on the other. The option of buying-in all requirements has effectively been ruled out by the decision to redevelop BPL. The reasons underlying this were given in the correspondence between the Department and HM Treasury at the time of the approval in principle of the scheme. Briefly, these were:
  - a. The Government had already accepted the principle (enunciated at the 28th World Health Assembly) of self-sufficiency in blood products, at least in the long term.
  - b. A preliminary appraisal, using rather crude costings, had suggested that redevelopment of the BPL would justify itself in terms of savings on imported products.
  - c. If no redevelopment were to take place, the Medicines Inspectorate, acting under the terms of the Medicines Act 1968, would insist on its early closure.
- d. Some of BPL's products are not available commercially in this country. The present paper does not therefore focus in detail on the "no redevelopment" option, although the calculations presented later do show implicitly that this option is inferior to the recommended course of action.
- 5. Given that the Laboratory is to be redeveloped, the principal options concern
  - a. its geographical location
  - b. choice of fractionation technology
  - c. target capacity

A formal economic appraisal has been made of (c); this is described later in this report.

## LOCATION OF BPL

- 6. The present site at Elstree has a number of advantages over other possible locations. These are:
  - a. The site is owned by DHSS;
  - b. Outline planning permission has been obtained for a new laboratory. (The significance of this is described in paragraph 18 below, which discusses site values).

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- Staff with specialised training and experience are already available. A move to an alternative site would involve staff relocation costs and disruption of production (with a consequent increase in import costs) while staffing levels were built up and new staff were trained.
- Parts of the existing buildings (eg cold storage facilities) can be incorporated into the new Laboratory, so saving expenditure.
- Elstree is in a prime position for distribution to Transfusion Centres throughout England and Wales. (An internal study carried out by Glaxo Holdings Ltd showed the Elstree area to be in an excellent position for distribution of pharmaceutical products).
- The group examined the possibility of avoiding a large capital expenditure by transferring the Laboratory's operations to an unused pharmaceutical, or modified general purpose, factory. Enquiries regarding the availability of a suitable pharmaceutical factory were made through the Association of the British Pharmaceutical Industry. It appeared that few pharmaceutical companies had unused factories, and those which were available were in poor condition. In the experience of various members of the PSG, the cost of upgrading these factories to the manufacturing standards required under the 1968 Medicines Act would have been greater than that of starting from scratch.
- A number of senior Production Directors in the pharmaceutical industry were consulted on the possible conversion of a general purpose factory. In their view there would be no cost advantage in such a move since;
  - the necessary services were unlikely to be available in an unspecified building;
  - the design of a building for pharmaceutical manufacturing normally starts with the processes to be employed and the shell is then fitted to it;
  - an existing shell (the only part of an unspecified building likely to be of use) would probably be uneconomical to modify.

The PSG therefore abandoned this line of enquiry and concentrated on options for redevelopment on the existing Elstree site.

# FRACTIONATION TECHNOLOGY

The Scientific and Technical Committee for the Central Blood Laboratories set up a working party to evaluate the technological aspects of fractionation. The working party recommended that fractionation should continue to be centred on the method of cold ethanol precipitation. This has been accepted as the 62/25 basis for the planning of the redevelopment.

10. The working party, which was chaired by one of the country's leading biochemical engineers, also examined new scientific developments, particularly in genetic engineering. Genetic engineering of blood products would be a rajor breakthrough. While it is possible that a breakthrough might be made at any time, the odds are on genetically-engineered products being a decade or more away. It must also be borne in mind that even if one of the major products (such as Pactor VIII) could be produced in this way, there remain more than 10 other blood products to be derived from human plasma. Nevertheless, uncertainty about the rate of scientific development suggests the need for careful attention to the timescale over which the redevelopment is appraised; this is taken up later in the paper.

## CAPACITY OF LABORATORY

- 11. The appraisal of options which follows has been based on capital cost estimates prepared by Matthew Hall Norcain Engineering and on other data assembled at the Blood Products Laboratory.
- 12. The starting point is the forecast clinical demand for the main blood products in England and Wales. Forecasts of requirements in the mid-1980s have been made by a working party set up by the Advisory Committee on the NBTS, and are summarised in Table 1 below:

TABLE 1. ANNUAL REQUIREMENTS FOR BLOOD PRODUCTS

Albumin

10,000 kg

Factor VIII

100 million international units ·

Factor IX

15 million i.u

Immunoglobulin 200 kg

In addition there would be a clinical demand for other products such as specific immunoglobulins. These products are, however, common to all options. Since they would not affect the results of the appraisal, they have been ignored in the present paper.

13. These requirements may be translated into needs for plasma source material by applying figures for the yield of each type of product per kilogram of plasma. Table 2 shows BPL\*s target yields, ie those which are anticipated without major technological advances.

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## TABLE 2. BPL MET YIELDS PER KG PLASMA

Albumin

22.5 g kg (Fresh frozen and time-expired plasma)

Factor VIII

225 i.u per kg (FFP)

Factor IX

300 i.u per kg (FFP)

Immunoglobulin

3 g per kg (FFP/TEP)

Crude Fraction II & III

55 g per kg (FFP/TEP)

- 14. The information given in Tables 1 and 2 implies that some 400,000 kg plasma per annum, together with 50,000 kg from time-expired blood, would ensure self-sufficiency in albumin and virtual self-sufficiency in Factor VIII. The requirement for Immunoglobulin, Factor IX and other products could be met with small proportion of the total plasma supply. Although forecasts beyond the mid-1980s cannot be accurate, albumin is being used in an increasing number of treatments requiring plasma exchange. On Factor VIII, though the haemophiliac population is unlikely to rise substantially, the use of Factor VIII is changing markedly with a move towards prophylactic treatment. In addition haemophiliacs are now living longer and reaching an age at which, because of their condition, surgery is required on joints etc. In summary, while demand is expected to show some growth in the longer term, improvements in yield should offset such growth as takes place beyond the projections given in Table 1 above. The PSG therefore adopted these forecasts as the baseline for its consideration of the required capacity of the new laboratory.
- 15. In examining the capacity question, three levels of plasma supply were considered, viz 200, 275 and 400 tonnes of fresh frozen plasma per annum. The smallest laboratory represents a small increase on the present facility. The 275-tonne case would provide rather more than 60% of Factor VIII requirements and over 70% of Albumin, leaving the balance to be purchased as imports. The largest capacity would provide for virtual self-sufficiency in Albumin and Factor Each option could cope with NHS demand for Factor IX and Immunoglobin, with capacity to spare.
- 16. For each capacity level, two alternative designs have been examined. These are:
  - Option A: A laboratory designed only to derive sufficient products from the plasma to meet NHS needs.
  - Option B: A laboratory designed to fractionate the whole plasma resource to completion (irrespective of NES demand for the product) and with capacity to take on a new product line.

The following paragraphs set out the factors considered in the appraisal, and 62/27 explain the derivation of the data used in the analysis.

17. Capital costs. Estimates of the undiscounted capital costs of the redevelopment have been prepared by Matthew Hall Norcain Engineering, based on a feasibility study which they carried out on behalf of the Policy Steering Group. Budget costs are shown in Table 3 below. The figures include civil and building works, equipment, and the installation of power and controls. They do not include a contingency allowance.

TABLE 3. CAPITAL COST OF BUILDING AND EQUIPMENT, £ MILLION UNDISCOUNTED NOV 1981 PRICES

	Option A	Option B
200 tonnes	17.4	18.6
	18.3	19.6
275 tonnes	19.2	21.1
400 tonnes	17.6	_ · ·

The timing of these expenditures during the design, building and commissioning period is shown in the summary tables (Tables 5 - 7) below.

#### SITE VALUE 18.

The valuation of the existing site will not affect the choice between options for size and design of laboratory since the existing location will be required irrespective of the option selected. Site value is therefore not included in the summary tables below. However, for completeness the Group obtained a report from the District Valuer. The relevant value is the opportunity cost of the site, ie its value in its best alternative use. The Valuer pointed out that because the site is zoned as Green Belt land, it would be "of limited value in the open market as it could only be sold on the basis of its use for agricultural [or similar] uses". Accordingly, he valued the site, excluding buildings, at £60,000. If this amount were annuitised for inclusion in the calculations, the annual charge would be negligible compared with the capital and revenue costs involved. It should be noted that BPL is only permitted on the site because its development is believed by the planning authority to be in the national interest. The existing buildings would not be suitable for takeover by a pharmaceutical company.

#### BPL REVENUE COSTS OF PRODUCTION 19.

These have been extrapolated from BPL's 1981/1982 production costs. Costs have been assumed to rise broadly in proportion to the increase in tonnage throughput, though significant economies of scale are likely at the largest capacity. In this sense the profitability of the larger development is understated. 62/28

#### 20. COSTS OF PLASMA COLLECTION

The Working Party on Plasma Supply estimated that 200,000 kgs of fresh finter plasma per annum could be obtained by the conventional method of whole blood donation. Above this level, whole blood donation would be expensive, difficult to sustain in terms of an adequate supply of donors, and would involve an unethical waste of red cells. The preferred method of collection above this level would be by plasmapheresis, a technique (already in use in some areas) whereby a blood donation is taken, the plasma is extracted and the red cells are returned to the donor. Plasmapheresis may be carried out manually or by machine. For the purpose of the analysis we assume that plasma requirements above the 200,000 kg limit would be obtained by an equal usage of machine and manual plasmapheresis. The cost figures used are £40.65 per litre (1) when obtained from whole blood donation, and £49 when obtained by plasmapheresis.

## 21. COST OF COMMERCIAL BLOOD PRODUCTS

In the case of the 200 and 275 tonne laboratory, the NHS would have to supplement the products provided by BPL with significant purchases from commercial suppliers. In order to value this item, we have used the arithmetic mean of the prices quoted by a number of important suppliers. The prices used are shown below.

TABLE 4. COMMERCIAL PRICES OF BLOOD PRODUCTS (1981/2 price levels)

Albumin £1.75 per g
Factor VIII £0.065 per i.u
Factor IX £0.23 per i.u

Immunoglobulins £8.70 per g (intramuscular);

£26 per g (intravenous)

Fraction II & III paste £13 per kg

### 22. REVENUE FROM SALE OF PRODUCTS EXCESS TO MES NEEDS

This revenue helps to offset the costs described above. In Option A the laboratory is designed with no facility for processing excess material into finished products. This material is therefore sold to industry in its crude form (as Fraction II and III paste) at a very low price<sup>(2)</sup>. In Option B, BPL is capable of fractionating the whole of the plasma to completion. The revenue from sales of excess finished products is estimated at 'cost price', ie manufacturing cost at BPL plus a proportion of the cost of the plasma source material. Ministers have decided that

<sup>(1)</sup> One litre of plasma is approximately equal to one kilogram. Time expired plasma was costed at £13.55 per litre. (All prices on November 1981)

<sup>(2)</sup> The low price of paste reflects the considerable costs which industry would incur in processing it into immunoglobulins.

the Laboratory can sell at a profit, so that the revenue could be greater than that shown if market conditions permitted. As a rough correspondition of the figures used, Mr David Smart of Glaxo Holdings Ltd carried out a comercial assessment of the market for Factor IX and Immunoglobulin. Although Mr Smart tackles the issue in a markedly different way from that used in our analysis, he arrives at fairly similar figures for the combined value of Factor IX and Immoglobulin. Details are given in the Annex.

#### OTHER CONSIDERATIONS 23.

The items described above define the public sector effects of the redevelopment. A full cost-benefit analysis would also cover effects on the private sector, particularly those relating to the procedure of blood donation itself. Giving blood involves the sacrifice of business or leisure time, which can entail costs to society. When the donation is given in leisure time the benefits to the donor (eg satisfaction at being able to help others) will by definition exceed the costs, since the activity is voluntary. When donation takes place in working time the issue is less clear; some loss of production will occur, and the individual may value this less highly than his employers.

- The costing of blood donors: time therefore raises difficult issues which we are unlikely to resolve in the present appraisal. However, these issues would be of greatest importance if redevelopment were being contrasted with importing all NHS requirements - an option which has already been ruled out. Acceptance of some loss of time has been implicit in Ministers' decision to have a home-based Transfusion Service, and to accept the World Health Organisation resolution concerning self-sufficiency in blood and blood products. There is, of course, no intention of introducing payments to donors as an incentive to increase the amount of plasma collected.
  - Another consideration is the safety and efficacy of blood products. BPL's products are less likely than commercial products to transmit hepatitis to recipients because UK plasma, being obtained from healthy voluntary donors, is of high quality.
  - RESULTS OF THE APPRAISAL

The quantifiable factors involved in the proposed redevelopment may conveniently be summarised in tabular form. Tables 5, 6 and 7 present the results for the three alternative sizes of laboratory. These show the net cost of meeting NHS demand under each option; the superior option is that which satisfies demand at the lowest cost. The project life has been assumed to end in year 2000, when genetically-engineered products may exert a significant effect on the market. 62/3D The Tables show the Present Value of Cost for each option over this period using a 5% discount rate. As a subsidiary measure, we have also calculated cumulative net present values from the start of the project. When compared with the cost of commercial supplies, these show the discounted payback period, or how long the investment will be at risk.

- 27. A number of conclusions emerge from the figures presented.
  - i. The capital cost does not increase in proportion to the target capacity. An 80% increase in capacity gives rise to a cost increase of only 10-14% 1). This constitutes a source of scale economies for the redeveloped laboratory.
  - ii. In terms of the Net Present Value of Cost, for all sizes of Laboratory Option A is significantly more expensive than Option B. It therefore makes economic sense to design a BPL capable of fractionating the whole plasma resource to completion rather than one restricted to finished products for NHS requirements.
  - iii. The least costly size of Option B Laboratory is one designed to process 40 tonnes FFP, thus achieving virtual self-sufficiency in the principal blood products.
    - iv. The figures given in Tables 5-7 may be compared with the discounted cost of purchasing all NHS requirements from commercial sources (2). This gives the period over which the capital outlays are recouped in terms of savings on commercial purchases (all figures being appropriately discounted). All the Option B factories in fact pay back quickly within three years of commencement of production. The 400-tonne Laboratory is very marginally superior on this criterion.
- 28. On the basis of the analysis presented in Tables 5 7, the preferred course of action is therefore to design and build a 400-tonne Laboratory at a budget cost of £21.1 million, spread over the years 1982/3 to 1985/6.
- 29. EFFECT ON UNCERTAINTY
  In this section we examine the effect of uncertainty in some elements of the calculation.

<sup>(1)</sup> The precise figure depends on whether Option A or B is examined.

<sup>(2)</sup> Not shown in the tables.

- 30. One area of uncertainty at present concerns the supply of blood plasma from Regional Transfusion Centres. The transition to full self-sufficiency will involve Regions in a substantial increase in the quantity of plasma supplied to BPL. Initial soundings taken by the Department showed that some Regions doubted their ability to raise their plasma supply to the required level by the date of commissioning of the new laboratory. A large shortfall in supply would clearly undermine the case for the largest size of laboratory. However, the Policy Steering Group noted a number of considerations which ameliorated the position. These are:
  - i. the potential for Transfusion Centres to increase the amount of plasma obtained per donation;
  - ii. the possibility of making good any temporary shortfall by importing plasma. Quality of plasma could be guaranteed by contractual specification of sources and donors. At current prices foreign plasma can, in fact, be obtained at no cost penalty compared with UK plasma.
  - iii. the incentive of the recently-introduced system whereby BPL products are distributed to Regions pro-rata to their input of plasma.

The Group did not therefore consider that there was a risk of a significant shortfall in plasma supply.

- 31. Another uncertainty concerns the timing and cost of future technological developments, particularly in genetic engineering and tissue culture. In so far as this affects the investment, the uncertainty strengthens the case for those options which yield a positive NFV quickly, ie Option B with its capability for processing all plasma to completion, and the larger-capacity laboratory.
- To some extent. Paragraph 22 above refers to the PSG's clear view that there will be a continuing market for Immunoglobulins and Factor IX produced in excess of NHS requirements. It may be suggested that if revenue from these products were significantly lower than that shown for the largest size of Laboratory, then the cost advantage of the 400-tonne option over the 275-tonne option could decline or even disappear. However, a number of points need to be borne in mind. Firstly, if revenue were lower for the 400-tonne factory, then it could also be lower for the 275-tonne case albeit by a lower percentage. Secondly, BPL itself will have an effect on the pricing policies of pharmaceutical companies. The announcement of plans to build a small Laboratory would act as a signal to industry that the

market would bear an increase in prices, since the UK would be advertising its intention of being a long-term importer of blood products; import prices could then rise substantially. Following the agreement of Ministers that the new BPL may operate on a commercial basis, it could of course sell at a substantial profit if market conditions permit. On balance, the present assumption of current market prices for imported products and cost-price for surplus products is the most sensible that can be made.

- 33. A further consideration which is relevant to the cost difference between the 400 and 275-tonne options is the question of economies of scale in BPL production costs. As pointed out in paragraph 19 above, our estimates are based on a straight extrapolation of present BPL costs. Significant economies should be possible, and these will affect the largest option to a greater extent than the 275-tonne laboratory, counteracting any tendency towards a narrowing of the overall cost difference between the options.
- 34. A final point concerns the treatment of VAT. We have excluded VAT where it is readily extricable from the available data; in practice, this means that an adjustment has been made only to the shelf prices of commercial blood products. In so far as there is an element of VAT included in BPL running costs and in the cost of plasma collection (eg on equipment purchases) this will result in a slight overstatement of cost for all redevelopment options. Since the VAT component of BPL and Regional Transfusion Centres costs will be lower than the adjustment made to commercial prices, a true adjustment would be likely to place the largest option in a slightly more favourable light.

## CONCLUSIONS AND PREFERRED OPTION

35. The areas of uncertainty do not appear to affect the conclusion that an Option B Laboratory of 400-tonne capacity satisfies demand at the lowest cost. This is the preferred option for redevelopment.

Financial Year	RPL Capital Cost	RPL Revenue Cost	Plasma Supply Cost	Cost of Bought-in Products	Value of Excess Products	Ret Cost of option	Ret Cost dis- counted at 5% pa	Cimulative dis- counted Net Cost
OPTION A 1982/3 1983/4 1984/5 1985/6 1986/7 1987/8 1988/9 1989/90 1990/91 1991/2 1992/3 1993/4 1994/5 1995/6 1996/7 1997/8 1998/9 1999/2000	1.00 6.30 7.70 2.40 0 0 0 0 0 0 0 0 0 0 0	3.88 5.17 Years	6.27 8.81 1988/9 o	17.59 11.21 nwards: As 1		1.00 6.30 7.70 2.40 27.69 25.04 25.04 25.04 25.04 25.04 25.04 25.04 25.04 25.04	1.00 6.00 6.98 2.07 22.78 19.62 18.68 17,80 16.95 16.14 15.37 14.64 13.94 14.87 12.65 12.04 11.47 7.43	1.00 7.00 13.93 16.05 38.53 58.45 77.13 94.93 111.68 128.02 143.39 158.03 171.97 186.84 199.49 211.53 223.00 230.43
OPTION B 1982/3 1983/4 1984/5 1985/6 1986/7 1987/8 1988/9 1989/90 1990/1 1991/2 1992/3 1993/4 1994/5 1995/6 1996/7 1997/8 1998/9 1999/2000	1.10 6.70 8.20 2.60 0 0 0 0 0 0 4.00 0 0 -8.00	6.05 8.07 Tears	6.27 8.81 1988/9 o	17.59 11.21 nwards: As ]	-2.69 -8.16 -987/8	1.10 6.70 8.20 2.60 27.22 19.93 19.93 19.93 19.93 19.93 19.93 19.93 19.93 19.93 19.93	1.10 6.38 7.44 2.25 22.39 15.62 14.87 14.16 13.49 12.85 12.24 11.65 11.10 12.69 10.07 9.59 9.13 5.21	1.10 7.48 14.92 17.17 39.56 55.18 70.05 84.21 97.70 110.55 122.79 134.44 145.54 158.23 168.30 177.89 187.02 192.23

NOTES 1. APL capital cost shown in Year 1995/6 refers to equipment replacement.

<sup>2.</sup> BPL negative capital cost in Year 1999/2000 is allowance for residual values. It is assumed that in 1986/7 the amount of plasma input and EPL production costs are 75% of the level applicable in subsequent years. 62/3-However, actual output is assumed to be only 50% of a normal year, owing to "teething" problems. These notes apply also to Table 6 and 7.

ABLE 6. SUMMARY OF COSTS
Capacity: 275 tonnes FFP

£m, November 1981 prices

1983/4 1984/5 1985/6 1986/7 1988/9 989/90 1990/1 1991/2 1992/3 1993/4 1994/5 1996/7 1997/8 1988/9	1.00 6.60 8.10 2.60 0	4.91 6.55 Years	8.57 12.49 5 1988/9 o	15.59 7.16 Dwards: As 1	-0.08 -0.21 987/8	1.00 6.60 8.10 2.60 28.99 25.99	1.00 6.38 7.35 2.25 23.85 20.36	1.00 7.38 14.73 16.98 40.83
	3.80 0 0 0 -8.00		·			25.99 25.99 25.99 25.99 25.99 25.99 25.99 25.99 25.99 17.99	19.39 18.47 17.59 16.75 15.96 15.20 14.47 15.80 13.13 12.50 11.91 7.85	61.19 80.58 99.05 116.64 133.39 149.35 164.55 179.02 194.82 207.95 220.45 232.36 240.21
PTION B 1982/3 1983/4 384/5 1985/6 1986/7 1987/8 1988/9 1989/90 1990/1 1991/2 1992/3 1993/4 1994/5 1995/6 1996/7 1997/8 1998/9	1.10 7.10 8.60 2.80 0 0 0 0 0 0 0 0 0 0 0 0 0	8.07 10.76 Years	8.57 12.49 1988/9 onv	15.59 7.16 vards: As 19	-4.72 -12.04 987/8	1.10 7.10 8.60 2.80 27.51 18.37 18.37 18.37 18.37 18.37 18.37 18.37 18.37	1.10 6.76 7.80 2.42 22.63 14.39 13.06 12.43 11.84 11.28 10.74 10.23 12.39 9.88 8.42 4.52	1.10 7.86 15.66 18.08 40.71 55.10 68.81 81.87 94.30 106.14 117.42 128.16 138.39 150.06 168.70 177.32 181.84
					NPV	of cost	181.84	

TABLE 7. SUMMARY OF COSTS

Capacity: 400 tonnes FFP

ASO

Em, November 1984 prices

dinancial Year	BPL Capital Cost	BPL Revenue Cost	Plasma Supply Cost	Cost of Bought-in Products	Value of Excess Products	Net Cost of Option	Net Cost Dis- counted at 5% pa	Ourslat: Discour Net Co
OPTION A 1982/3 1983/4 1984/5 1985/6 1986/7 1987/8 1988/9 1999/1 1991/2 1992/3 1993/4 1993/4 1993/4 1995/6 1996/7 1998/9 1999/2000	1.00 7.00 8.50 2.70 0 0 0 0 0 0 0 0 0 0 0 0 0	6.63 8.84 Years 1	13.12 18.61 988/9 onw			1.00 7.00 8.50 2.70 31.94 27.78 27.78 27.78 27.78 27.78 27.78 27.78 27.78 27.78 27.78 27.78 27.78 27.78	1.00 6.67 7.71 2.33 26.28 21.77 20.73 19.74 18.80 17.91 17.05 16.24 15.47 17.22 14.03 13.36 12.73 8.63	1.60 7.67 15.79 17.79 43.79 65.49 106.23 142.93 176.79 176.79 208.99 222.93 249.67
OPTION B 1982/3 1983/4 1984/5 1985/6 1986/7 1988/9 1989/90 1990/1 1991/2 1992/3 1993/4 1994/5 1995/6 1996/7 1998/9 1999/2000	1.20 7.60 9.30 3.00 0 0 0 0 0 6.40 0 0 -8.00	11.41 15.21 Years 1	13.12 18.61 988/9 onwa	12.33 0.65 ards: As 198		1.20 7.60 9.30 3.00 29.02 15.99 15.99 15.99 15.99 15.99 15.99 15.99 15.99 15.99	1.20 7.24 8.44 2.59 23.87 12.53 11.93 10.82 10.31 9.82 9.35 8.90 11.87 8.08 7.69 7.33 3.49	1.20 8.44 16.89 19.47 43.87 67.80 79.96 100.27 119.36 148.36 148.36 166.8

## An assessment of the market for BPL excess moducts.

- 1. Market data for the production, sale and administration of blood fractions appear to be incomplete, on a country by country basis, and somewhat unreliable. The primary reason for this inadequacy is that most countries have both comercial and non-commercial sources of supply; the distribution mechanism is a dual one which is not monitored by the established market survey organisations.
- 2. The potential for any given fraction is probably best identified in most countries by calculating the number of patients who are, on a statistical basis, likely to require treatment. The incidence of Haemophilia A, for example, appears to be fairly constant at about 1 case per 10,000 males while Haemophilia B seems to occur with a frequency of approximately 1 in 40,000 males.
- 3. The approximate geographical split between various regions in their denand for blood fractions has been identified, as has the global break-down of the value of the fractions administered. The following are the results:-

### Regional demand for blood fractions.

•		% of total by
		value
Western Europe		41%
Central/South Pacific*	68.5	29%
North America		25%
Latin America (+Mexico)		4%
Middle East	•	1%

\*(Korea, Japan, Indonesia, Singapore, Hong Kong; Malaysia, Taiwan, Philippines)

Global d	emand	for	blood	fractions
	ру	valı	ıe	
Albumin/PPF	•		•	41%
IV Gamma globul	in			23%
Hyperimmune glo	bulin	3 .		14%
Factor VIII				13%
Immune serum gl	ropori	2		8%
All others				1%

4. In most countries (about 90%) either there is no indigenous source of non-commercial blood products or there is a shortfall which has to be met from commercial sources. This shortfall is met, in countries which can afford the hard currency, almost entirely by the export of surplus production from the United States. It is thus not unreasonable to take this "U.S. Export Sector" of the market as being that which could most readily absorb, given competitive prices and delivery schedules, any excess Elstree production. It may be necessary to get as close as possible to final packaged form in order both to compete and to maximise the return. It will be desirable, as soon as possible, to start building up a data base covering haemorrhagic disease incidence, demand for blood fractions, strength of competition and prices so that Elstree surplus can be offered at appropriate rates with neither delay nor the necessity for promotion which might be deemed inappropriate.

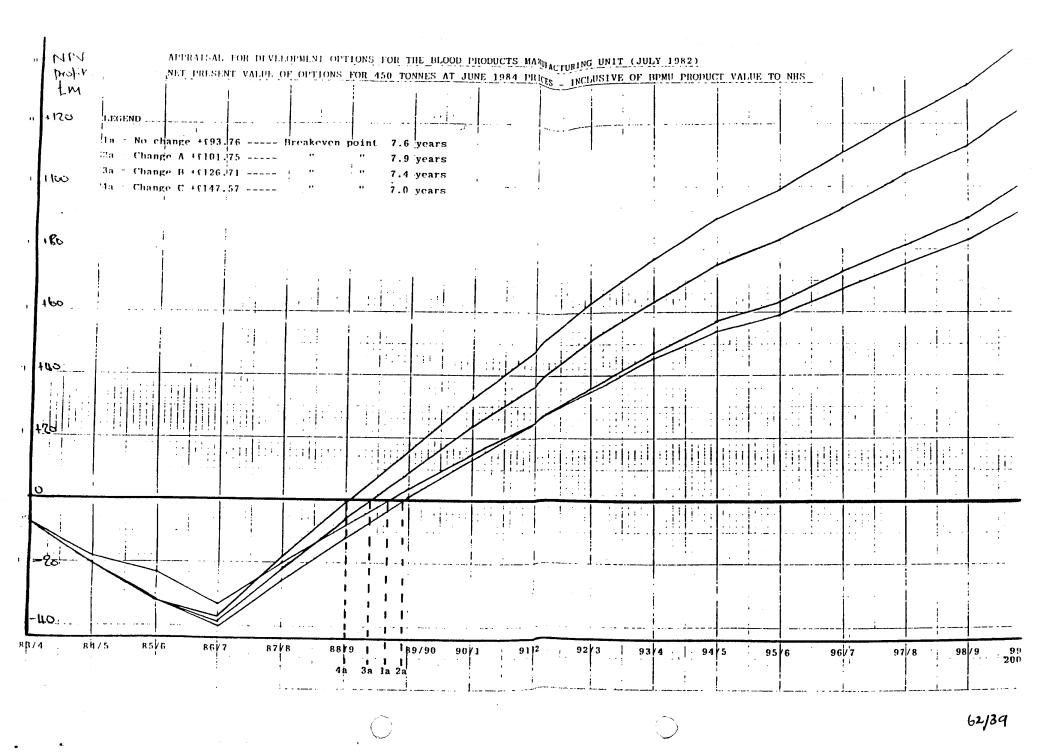
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5. The present US export of blood fractions (mainly to Europe) consumes about 1,200,000 litres of plasma (mainly obtained by plasmapheresis) per armin. The surplus availability of 1,200 tonnes per armin puts the times possible levels of Elstree production (200, 275 and 400 tonnes) into reasonable perspective. The 1,200 tonnes of US plasma will, after processing, provide:-

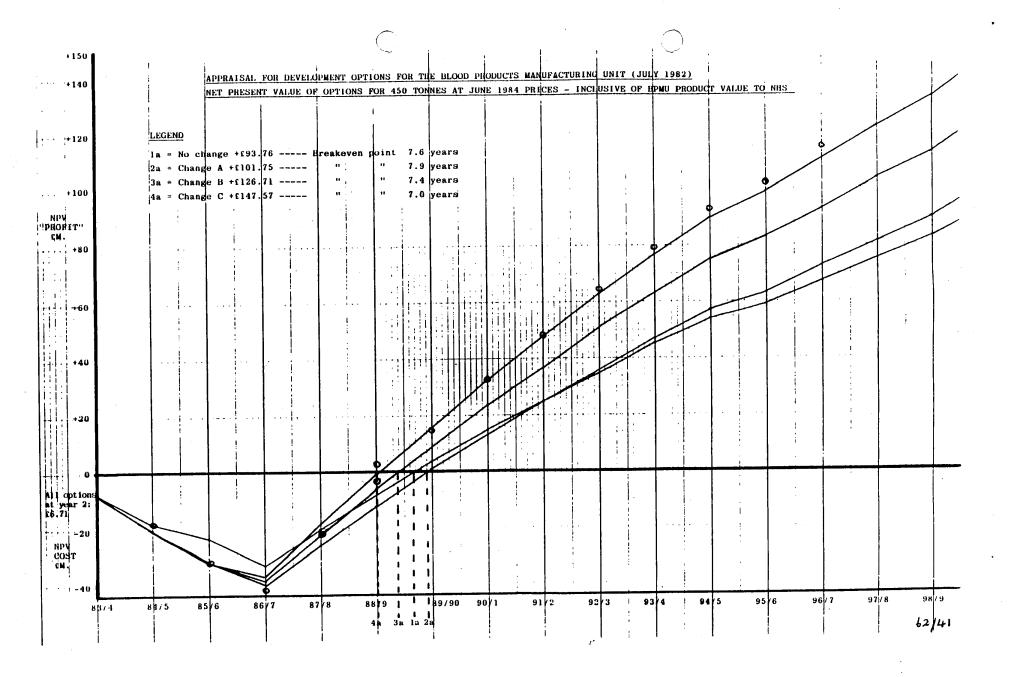
Albumin 27,000 kg
Factor VIII 240 m iu
Factor IX 360 m iu
Immunoglobulin (im/iv) 3,600 kg

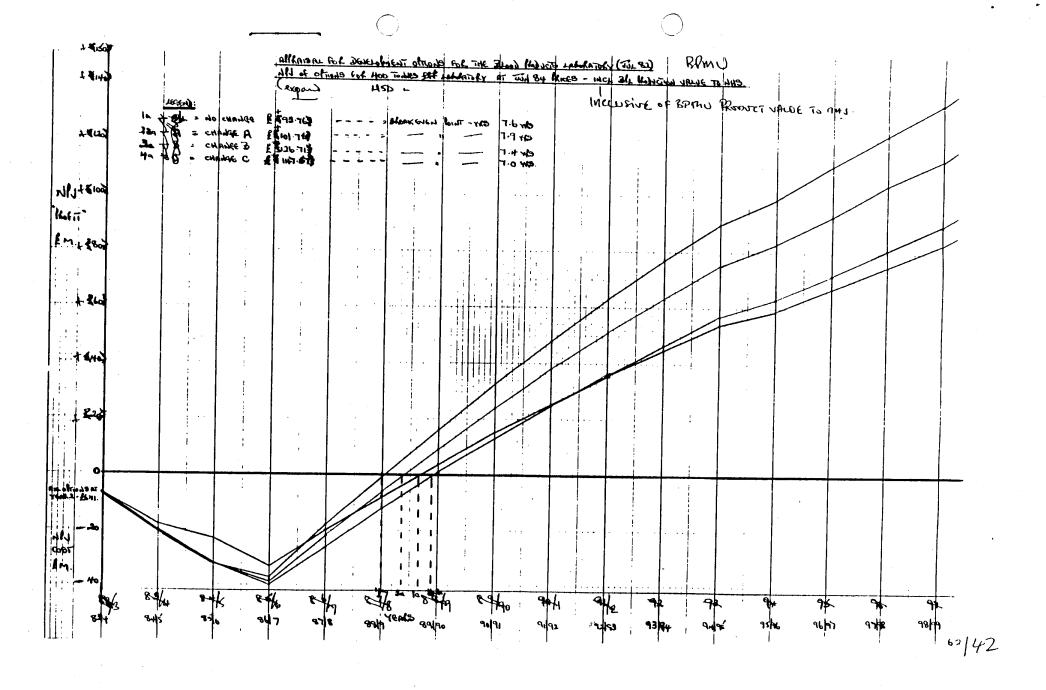
The identified Elstree surplus with the 400 tomme option is 105 m iu of Factor IX and 1,150 kg of immunoglobulin.

- 6. With a population of 49 million in England and Wales, NHS requirement for Factor IX is 15 m in per annum. We should, by extrapolation, therefore require to fulfil the entire demand in markets with a total population of 343 millions to absorb all the Elstree surplus (of a total European population of 473 million).
- 7. Although the analysis has used Elstree cost to project the value of sales of Factor IX, a very robust basis when one compares Elstree cost(£0.13/iu) with commercial price (0.27/iu), it is doubtful whether the market has the capacity to absorb the surplus, even at cost. It should be possible, however, to sell enough Factor IX to make a contribution and, in so doing, to force commercial competitors to increase the prices of their other products in compensation. This in return, would enhance the revenue sparing value of the Elstree production of other fractions. If one made a reasonable commercial judgement, it should be possible to sell at least double the NHS requirement for at least £0.15/iu = £4.5 million.
- 8. However, the picture is quite different when immunoglobulins are considered. The present estimate of the NHS requirement for immunoglobulin for 1985/86, made by the Director, is 200 kg (about 50% for intramuscular use and 50% for use intravenously). Intravenous immunoglobulin is sold for three times as much as is the intramuscular form (£30 v. £10 per g). The global analysis of blood fractions by value indicates that the value of intravenous gamma globulin accounts for 56% of the value of the albumin market. This suggests very strongly that the NHS demand is likely to rise to a value of approximately £11.5 million before long, providing a further £8 million of revenue sparing effect if Elstree can supply enough of the intravenous material. Even if the NHS demand is slow to develop, it should not be difficult to sell 1,150 kg of intravenous material at a minimum of £10 per g, also realising £11.5 million.
- 9. There is thus an identifiable £16 million of realisation which could be obtained by sale of production surplus to NHS requirements.



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APPRAISAL OF REDEVELORMENT OFTION FOR THE BLOOD POURTS LABORATORY (JULY SZ)
EFFECT OF VALUE OF BIL PENETTON FOR MAS NEEDS ON VARLOUS OFTIONS AT JULY STANGE אנדמפד אנד מפד מהישהעב JANE CF LADACIAL of Design HET COST of other العدينين المحصن الما YERR. TO NHS 192 P3 1.00 1.00 1.00 1-00 ≾-७। 6.71 183B4 2.00 6.00 17.59 12.00 10.93 BH185 12.00 €0.€£ 5.44 3.30 अधिक 6.30 < 21 327 11 94 9.82 32.85 78 bk 33.26 34.707 (16.37) (12.83) 20.02 88/12 18.33 534-707 (16.37) (12.22) 18.33 *38/3*9 34-707 (16.397 (11.63) ( 3.83) 18.33 39/90 1 34-707 K16-377K 11-087K 14-917 18.33 1969 くる4.707く16.377く10:35米、25146 91/92 18.33 34.707(16.37)(10.05)(35.31) 92193 18.33 く34-707(16-37)く9:57米45:08) 93194 18.33 <34-707 (16 37) < 9 117 < 54 A) अमेरिक् 18.33 (34.70) (9.03) (4.79)(58.98) 75/96 i 25.67 くさいてんだい のうかんしょう メイクト・チェン 18.33 196/97 く34-70×16-137×17-187)くてくいと i 8915P 18.33 <34.707 (16.37) < 7.50) (82 W) <del>19</del>199 : 18.33 (34.70) (25.54) (11.14) (93.76) 7 1 79/2000 7-16 NPI (NET PRESENT JOLUE) (93-76) : 9 i

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The mention from history productions 1. 2.4 20 Entirement at 3,132 (64.5) FROTOR VIII 100m is a foode per is · 15m in & 2003 to in FRICTOR XI 10.555 kg = \$ 1.75 pmgm Ridder immoviedaciones (in) 100 kg & E870 page 0.87 in here to father a 2.60 30.92 وم اعلى الاردية ويسهديد الله في الم المرابية المرابية المرابية PROJETION EHILTIANL FROM 1987/88 FOR HOD TOMBED FFI - citiEn 3. Frictor VIII 10 miles a forché pe me at 1984 PRICES בולב לו לו לו ביו ביו ביו ויקוויונד אוב ביבו ואבונו ואפולדו למציעות בילן ביל אונו ביו וא לו לו ביצועות בילן ביל אונו ביצועות ביל לו ביצועות ביל לו ביצועות ב son in a tock from FR 258 1111 5,000 kg & \$1.75 pg gm 2.76 LIMUZIA

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