G:\[redacted]DRIC\BPL10

RESTRICTED - POLICY AND COMMERCIAL

Mrs Weatherseed PS/PS(H)

From: **Mr Guinness CA OPU1-2**
Date: **10 May 1996**
Copies: **Mr Holden PS/SofS**
Mr Hockley SpAdv
Mr Griffiths PS/CE
Mr Jarrold DHCR
Mr Garland FPA
Mr Staniforth FPA NHSP
Mr Dobson FPA FPS
Dr Harding EOR3
Mr Hurst EOR1
Dr Rejman CA OPU2
Mr Murray EOR3
Mr Paley FPA FPS2
Mr Pudlo CA OPU2

BIO PRODUCTS LABORATORY (BPL)

Purpose of Submission

1. This submission is largely for information, though any comments which PS(H) has at this stage would, of course, be welcome. It:-

explains why decisions are needed about the future of BPL;

sets out the options for the future of BPL, and informs PS(H) which of these are currently being considered more fully, with the help of the Department's Major Business Case Team.

Background

What is BPL?

2. BPL, which is managed by the National Blood Authority and located near Elstree, Hertfordshire, was set up in order to meet the Government commitment to self sufficiency in blood products, in particular in coagulation factors - primarily Factor VIII - from voluntary unpaid donors in England and Wales. BPL has for some years been able to meet the clinical demand for its products. (Clinicians have been free to purchase products from other suppliers.) It employs around 470 staff with an annual turnover of around £50 million.

3. After blood has been collected, most of it is split into three parts - red cells, platelets and plasma. The amount of blood collected is driven by the clinical demand for red cells. BPL takes all the plasma collected in England and Wales (apart from small quantities collected for clinical use) - about 580 tonnes - and fractionates it to produce

coagulation factors (notably Factor VIII for haemophilia), albumin, and immunoglobulins. BPL have spare capacity and could fractionate about 700 tonnes of plasma at present, which could rise to 1000 tonnes with some further capital investment.

4. BPL pays the Blood Transfusion Service for the plasma and sells its products to NHS and independent hospitals in England and Wales. It also exports surpluses where it can. Not all the available plasma is turned into the full range of products because BPL cannot sell the full amount, in part because of its position as part of the NHS. This severely affects BPL's financial performance. A successful fractionator makes and sells as many products as possible.

5. NHS hospitals are not bound to buy BPL's products. There are alternative commercial suppliers of plasma-based products, which use plasma from paid donors in the USA and elsewhere. Prices in the UK are low by international standards - the NBA believes strongly that this is as a result of BPL's presence in the market, though the arrangements for setting prices in different European countries vary - and some commercial companies will not supply the UK market for this reason. There is, however, one aggressive competitor (Alpha) which is determined to more or less match BPL's prices on coagulation factors. More recently, recombinant coagulation factors have come onto the market. The effect of this is considered later.

6. Scotland has its own Plasma Fractionation Centre (PFC), which also fractionates plasma from Northern Ireland. It fractionates about 84 tonnes of plasma a year. The PFC forms part of the Scottish National Blood Transfusion Service, and the PFC neither pays for the plasma it fractionates, nor charges for the products it supplies to NHS hospitals in Scotland. It does, however, charge non-NHS customers and sells some products to the NHS in England and Wales, in competition with BPL.

7. Over the years there have been substantial changes.

- Originally there was a shortage of plasma, which led the BTS to develop plasmapheresis (removing plasma from the blood and returning the rest of the blood to the donor). There is now more than enough plasma to make the volume of product which BPL is able to sell in a free market.

- Between 1986/87 and 1995/96 the clinical demand in England and Wales for Factor VIII (which represents over 50% by value of all BPL's sales) grew from 80 million iu (international units) to about 140 million iu, an increase of 75%. BPL's market share increased from 37% to 58% during this period. This share is now being eroded by the entry of recombinant product into the market and is forecast to be 56% in 1995/96.

- The price of Factor VIII has fallen from 39p/iu to 24p/iu in 5 years.

- Use of albumin in the UK has historically been lower than in other countries, but some other countries are now reducing their usage towards the concept of optimal use of human derived products.

- BPL are now able to produce an intravenous immunoglobulin. This is an expanding market, although there is a lot of difference of views on the indications for use of IvIg.

- The private sector has paid for blood and blood products since 1984 on the basis of cost-recovery. DH determined levels. Cross charging for blood products in the NHS was introduced in April 1989. The level of reimbursement to RTCs for plasma was set by DH and the cost of products charged to hospitals was determined by bulk negotiation. In April 1991 charging was extended to blood as part of the "Working for Patients" White Paper philosophy. Since 1994 the prices of plasma and the resultant blood products have been under the control of the NBA.

Funding History

8. BPL exists to make the best use of the blood donor's gift, and to secure self-sufficiency, not to make money. However, with the introduction of charges to the NHS for BPL products in 1989/90, BPL has been operating on a commercial basis. The following table shows that DH has nonetheless had to subsidise BPL in all but one of the years since it was founded,as well putting in capital investment. Of course, if BPL had not existed, and capital investment had not been made, expenditure would have been incurred to obtain the products which BPL makes. This might or might not have been greater than the sums set out below, plus the cost to the NHS of buying the sort of products which BPL makes, whether from BPL or its competitors. It is impossible to know.

BIO PRODUCTS LABORATORY

	Revenue £000	Capital £000	Total £000
1984/85	4,535	17,000	21,535
1985/86	3,268	13,915	17,183
1986/87	6,807	14,818	21,625
1987/88	8,864	8,056	16,920
1988/89	10,444	4,089	14,533
1989/90	12,885	7,924	20,809
1990/91[1]	13,524	3,640	17,164
1991/92[2]	13,002	3,428	16,430
1992/93	1,629	947	2,576
1993/94	5,765	2,744	8,509

1994/95	(806)	2,164	1,358
1995/96	5,231[3]	2,000	7,231
1996/97 (forecast)	3,131[3]	5,890	9,021

[1] This was the last year in which BPL products were supplied free of charge to the NHS

[2] BPL received transitional funding to purchase stocks of plasma and for setting up charging systems

[3] Capital charges of £4.4 million and £4.8 million have to be paid in these years.

9. It can, of course, be argued with some justification that this presentation of the facts is unfair to BPL. They take all the BTS plasma at a fixed price. They might improve their financial performance if they took in less plasma, or paid the price for it which a commercial fractionator would be prepared to pay, given that they had to buy all of the BTS's plasma. That would transfer the problems to the BTS, which would have to raise the price which hospitals pay for red cells etc. But the longer-term problems of BPL would have to be addressed in any event.

10. The constraints of public funding, and the rules governing "not-for-profit" organisations make it difficult for any publicly funded organisation, however efficient, to operate effectively in the market. Such organisations find it particularly difficult to compete with commercial competitors which are structured and financed flexibly in order to meet the requirements of the market in which they operate. There are also considerable problems over investing in new technology.

Future Prospects

11. Recombinant Factor VIII is taking an increasing share of the Factor VIII market everywhere. In the UK the recombinant share rose from 1% in 1993, to 4% in 1994, 10% in 1995 and a projected 20-30% in 1996. Up to now, the recombinant product has been significantly more expensive than the plasma-based product. Its sales pitch has been that it is safer (which is true in the sense that there are known - and probably unknown - infectious agents which are not destroyed in the fractionation process, although the known but not fully destroyed viruses are thought to be of little importance for most patients). Its market penetration has been more rapid than was expected as recently as 2 years ago. The future is uncertain and will be determined by 2 factors - the relative price of recombinant Factor VIII as compared with plasma derived Factor VIII, and any major episode of infection in the UK or abroad resulting from the use of plasma derived Factor VIII.

12. The established markets for albumin are stable or declining. Demand in the Third World is increasing, but the market is highly competitive and prices are low..

There are some other products of fractionation for which plasma is at present the only source, but they would not require anything approaching current available volumes of plasma. Enabling BPL to produce these products would also require further investment, and it would be some time before any return was achieved.

13. BPL is capable of substantially increasing its production of immunoglobulins, so there is a potential for building up exports, particularly if BPL can produce a liquid IvIg, rather than its current freeze-dried product. But precisely how well BPL would do in a highly competitive commercial market is difficult to determine. Exports will also take time to build up because of the need for the product to develop a track record and the necessity to license the product in each country in which it would be sold. The ultimate potential could only be achieved using ALT tested plasma (see Appendix 1, section 2 for a note on ALT testing).

14. If BPL cannot match the amount of plasma they buy to the quantity of products which they can sell profitably, their long-term future looks bleak. Clearly, before any final decision is taken, work will be needed to set the future of BPL in the context of the uncertainties of the market.

15. These factors have led to a situation where there is a surplus of plasma and where BPL's prospects seem likely to decline. In 1995-96 BPL budgeted almost to break even, but ended up with a deficit of nearly £6 million. For 1996-97 the latest forecast deficit is again £5-6 million (to which has to be added an unacceptable level of internal and external debt). We have allocated them £3.1 million and are currently considering urgently a request for additional funding arising from the level of debt. Operating as BPL does in a commercial marketplace, these forecasts are inevitably very difficult to make but the advent of recombinant Factor VIII makes it certain that, if nothing is done, the situation will only get worse. What is more we are constantly in danger of being accused by BPL's commercial competitors of distorting the market by our "subsidy".

Previous Ministerial Decisions

16. These issues are not new. In November 1993 the NBA, following a study by Bain and Co, presented three options for the future of BPL :-

(i) **The sale of BPL and the use of a contractor to fractionate plasma.** The NBA did not favour this option as it would mean increased costs to the NHS and would be politically unattractive.

(ii) **Improving the current system.** The NBA considered that there were substantial improvements that would secure the short-term future but that in the long term a declining service was inevitable.

(iii) **An alliance of some sort with the private sector**. This was the preferred option. Under this option NBA would retain ownership of BPL but management would be contracted out and overall control would be shared. The contractor would take in plasma, fractionate it and give plasma

products back for the NBA to market. Any plasma products not taken up by the NBA were to have been sold by the commercial contractor. It was argued that this arrangement would allow BPL to :-

- increase the range of products
- sell all surplus products overseas
- improve manufacturing efficiency by operating at full capacity (ie by fractionating paid as well as unpaid plasma)
- use surplus plasma.

17. These proposals were put to Ministers in early 1994. They decided that:-

- as proposed by NBA, BTS should restrict plasma collection to the level recoverable from whole blood so as to minimise surplus
- BPL should not be sold off
- NBA should progress to tender and detailed discussions with commercial blood product manufacturers with a view to entering an alliance if an acceptable deal could be struck.

18. In July 1994 the NBA considered offers of partnership from Alpha, Armour, Immuno, Cutter/Miles (now Bayer) and Baxter, shortlisted the last two, and recommended the Cutter/Miles option. The NBA also formally requested ALT testing of blood donations in order to fully exploit the export market, potentially valued at £10 - £14 million and because it was a precondition set by potential commercial allies.

19. The question of ALT testing was referred to the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) in October 1994. MSBT concluded that ALT testing would add nothing to public safety.

20. Ministers decided in January 1995 to reject both proposals due to concerns over likely allegations of privatisation and the risk

products back for the NBA to market. Any plasma products not taken up by the NBA were to have been sold by the commercial contractor. It was argued that this arrangement would allow BPL to :-

- increase the range of products
- sell all surplus products overseas
- improve manufacturing efficiency by operating at full capacity (ie by fractionating paid as well as unpaid plasma)
- use surplus plasma.

17. These proposals were put to Ministers in early 1994. They decided that:-

- as proposed by NBA, BTS should restrict plasma collection to the level recoverable from whole blood so as to minimise surplus
- BPL should not be sold off
- NBA should progress to tender and detailed discussions with commercial blood product manufacturers with a view to entering an alliance if an acceptable deal could be struck.

18. In July 1994 the NBA considered offers of partnership from Alpha, Armour, Immuno, Cutter/Miles (now Bayer) and Baxter, shortlisted the last two, and recommended the Cutter/Miles option. The NBA also formally requested ALT testing of blood donations in order to fully exploit the export market, potentially valued at £10 - £14 million and because it was a precondition set by potential commercial allies.

19. The question of ALT testing was referred to the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) in October 1994. MSBT concluded that ALT testing would add nothing to public safety.

20. Ministers decided in January 1995 to reject both proposals due to concerns over likely allegations of privatisation and the risk of destabilising the supply of blood from voluntary donors, but thought that the options could be reconsidered in two years' time.

The Issues

21. The main issues involved are:-

(a) Financial What ways forward provide the best value for money? If BPL continues to lose money, should this be made up through a central subsidy or through increased charges to the NHS, either for BPL's own products or for the red cells, platelets, etc which hospitals get from the BTS?

(b) Ethical Should we be seeking to maximise the use of the donor's gift of blood, even if this does not represent best value for money?

(c) Safety and Security of the Blood Supply and the Supply of Blood Products Do any of the possible ways forward constitute a possible threat to the safety or security of the blood supply or the supply of blood products? If so, how significant is the threat, and what could be done to reduce or remove it?

(d) BPL's Purpose Would it be acceptable for BPL to move beyond its original purpose of fractionating BTS plasma - for example, fractionating paid plasma or unpaid plasma from other sources; making products which are not based on plasma? (Ministers agreed in 1992 that BPL could undertake contract fractionation for third parties provided the plasma came from voluntary unpaid donors, but they have never obtained any contracts to do so, and in 1992 (before the NBA was set up) there was none of the furore which appears to surround anything the NBA proposes.) What changes would require amendments to the Regulations which set out BPL's functions?

(e) Privatisation Ministers have so far been very wary of anything which might appear to be the first step on the road to "privatising the NHS".

The Options

22. OPU and NBA have given some preliminary consideration to the available options. In view of the deteriorating financial position, and the fact that Ministers have not previously been able to consider a full range of options, we have included all possible options, including those which Ministers have previously rejected. We have concluded that the following options merit more detailed exploration.

(i) Keep BPL as it is now, looking at the consequences for either central funding or the price of BPL products or of red cells, (this is essentially the baseline option) but considering whether there is any scope for "downsizing" (which may mean simply employing fewer staff) or fractionating plasma from other sources under contract.

(ii) Keep BPL as it is now, but allow ALT testing to increase the potential for exports.

(iii) Diversification into products which are not plasma-based.

(iv) Commercial partnership.

(v) Disposal, either with a contract to fractionate all or a specified quantity of BTS plasma, or without.

23. We have considered other options, which we do not think should be explored

further, namely:-

(a) Keep BPL as it is now, but return to a system of fully central funding (i.e. supplying products free to the NHS).

(b) Partnerships with other not-for-profit fractionators.

24. Appendix 1 gives more detail on the options which we consider should be explored further and Appendix 2 on those which we do not.

Next Steps

25. OPU have consulted the Department's Major Business Case Team and EOR are currently working with NBA/BPL on a draft option appraisal which will identify the key factors which will affect the financial outcome and any gaps in our knowledge which need to be filled. They will be examining the assumptions underlying NBA's financial projections as set out in the Appendices, and exploring the impact of alternative assumptions. EOR will be reporting back to the Major Business Case Team shortly and the next steps will be discussed on 20 May. We aim to put forward a full submission before the recess.

Conclusion

26. PS(H) is asked to note the work in hand and comment if he wishes. He has accepted an invitation to visit BPL on 18 July.

K J GUINNESS
EH 303
ext GRO-C

RESTRICTED - POLICY AND COMMERCIAL

APPENDIX 1

OPTIONS WHICH APPEAR WORTH PURSUING

1. Keeping BPL as it is now

1.1 The baseline option is to continue to subsidise BPL as we do now. It is included because it is the baseline option, although it does not appear attractive, since it is precisely the current system which is in crisis, and the prospects for improvements in the market do not look good. NBA projects that what would otherwise be continuing losses of £7 - 9 million a year (including capital charges of around £4 million a year) could be reduced to £3 - 4 million a year by 1999-2000, and a small profit earned by 2005-6 if exports of IvIg take off.

1.2 One potential problem about subsidising BPL is that we are open to accusations of unfair competition from BPL's competitors. A case has already gone forward to OFT on predatory pricing in respect of high purity Factor VIII. Such accusations will become more likely if they too see shrinking margins and/or if BPL moves out of its traditional territory. This might be alleviated by cutting the price BPL pays for plasma and transferring the "subsidy" to the blood service.

1.3 It could be argued that BPL could reduce its losses by increasing its prices. Whether this would indeed be the effect, or whether BPL's losses would increase, would depend on the response of its commercial competitors.

1.4 An alternative to continued central funding would be for the NBA to reduce the price which BPL pays for plasma to such a level that it broke even, and cover more of the cost of the BTS through increasing the price which hospitals pay for red cells, platelets, etc. NBA estimates that prices would have to rise by nearly 6%. However, one of the stated objectives of the reorganisation of the BTS is to bring red cell prices down. Increasing them would therefore be difficult.

1.5 Another possibility might be contract fractionation of plasma from other sources. We might look first to Scotland, because of the overall surplus capacity in the UK, though the closure of PFC would be likely to be difficult for Scottish Ministers to accept. Beyond that, BPL could seek contracts to fractionate plasma from unpaid donors in other countries, returning the finished product to the country of origin. Unfortunately, currently there is an excess capacity for fractionation of such plasma and some fractionators, for example in France, have already closed. BPL were granted permission to seek such contracts in 1992, but none has been forthcoming. Similarly, but more controversially, BPL could seek contracts from commercial companies to fractionate plasma from paid donors. NBA estimate potential income at around £1.5 - 2 million a year, but have doubts about whether they could achieve any long-term contracts without a commercial partner because essentially these are package deals done between commercial companies.

1.6 There would undoubtedly be concerns under both these options as to whether BPL

could guarantee to avoid any possibility of cross-contamination between "foreign plasma" and BTS plasma, though there is now little difference in safety between imported paid plasma derived blood products and those from unpaid donors, since both are subject to the same tests and viral inactivation procedures and the MCA could provide reassurance..

1.7 These options also raise the question of the purpose of BPL. Is its prime purpose to meet the needs of the NHS, or is it a facility which we should use to make profits for the NHS, if necessary in competition with commercial providers?

2. Keep BPL as it is now, but allow ALT testing to increase the potential for exports.

2.1 Some European countries are at present obliged to import blood products, though, as regards coagulation factors, how long this situation will last in the face of the rise in recombinants is a matter for debate. Self-sufficiency is considered a national rather than an EU concept (despite the Commission's entreaties) and so countries do not feel any particular need to buy plasma or products from unpaid donors, but, in a situation where there are plenty of suppliers, will buy at the cheapest price, so long as there are no safety concerns. Also they prefer not to buy BPL products because BTS blood is not ALT tested.

2.2 ALT is an enzyme produced by the liver. Its level is increased where there is damage to the liver. Prior to the existence of a specific test for hepatitis C, some countries introduced ALT testing as a surrogate test for hepatitis C (then known as non-A, non-B hepatitis - NANB hepatitis). Some of the early studies suggested that this was a helpful test, although following the introduction of this test in the US, there was no reduction in the amount of NANB hepatitis transmission by blood. In the late 1980s DH commissioned an investigation of the use of ALT, as well as another test (anti-HBc) on a sample of the UK donor population. These results showed no correlation between NANB hepatitis and a raised ALT. Many individuals with a raised ALT had either recent increased alcohol intake or were obese. For these reasons ALT was never introduced into the UK Blood Transfusion Service.

2.3 In 1989 a test was discovered for hepatitis C, which was improved over the next two years prior to routine introduction into the UK Blood Transfusion Service in September 1991. There was an opportunity at that time for those countries which were using ALT testing to abandon it, since the primary reason for doing the test had now gone away. However, it can be very difficult to convince the public that it is sensible to stop doing a test ostensibly for the safety of blood. In early 1995 the American Food and Drug Administration (FDA) decided to stop insisting on ALT testing, but suggested that, if a donor were tested and found to have a high ALT, it would be appropriate not to use the blood from that donation.

2.4 Several European countries, in particular Germany, continue to insist upon the ALT test. This is despite the fact that blood products are governed in the EC by a Directive, EEC/89/381, and the guidelines emanating from this do not state that ALT testing is a requirement. Although the German action can be considered as a restriction

of the free market, no one is prepared to take the Germans to the European Court. The insistence on ALT testing is not claimed under a public health derogation.

2.5 The problems with the introduction of ALT testing are not just the actual cost of the test (estimated by the NBA in September 1994 at £1.06 million per annum). It would lead to the exclusion of some blood donors (around 8,000 according to the NBA's original estimate), who would need to be told that although they were probably healthy their blood could not be used. Such action could, itself lead to the problems. Additionally, these donors would need to be replaced, especially as red cell demand is rising steadily. There would be controversy over the introduction of a test solely for the purpose of encouraging exports. There might in future be other tests not required for UK purposes that would need to be introduced if BPL were to retain these markets.

2.6 Other parts of the UK have up to now opposed the introduction of ALT testing. We have always had universal testing across the whole of the UK.

2.7 On the other hand, although ALT testing and exports are controversial, they must be set against the prospect of using plasma to help patients rather than burning it, particularly if exports can be made profitable. NBA projects the value of ALT testing as £5 million, rising to £10 million, a year.

3. Diversification

3.1 BPL have been considering producing monoclonal Anti D which is not produced from plasma at all. (There is an increasing demand for Anti D, and declining availability of plasma from donors with the necessary antibodies.) This may be an option for improving BPL's financial position but it clearly raises issues about BPL's purpose. Would Ministers be content to see BPL competing with the private sector in this way?

3.2 BPL has to date invested around £1 million in this development. They estimate that the worldwide potential from the development of the product is around £40 million - possibly very much more depending on its licensed indications. It will, however, require capital and revenue investment of the order of £10 million to achieve the stage of licensing the initial product over a timescale of between 5-10 years from investment to payback.

4. Commercial Partnership

4.1 The idea here is that a commercial partner would invest capital in BPL, and commit themselves to purchasing and exporting all BPL's surplus. BPL would continue to own all the assets and use revenue from the sale of surplus protein to repay the capital over time. This could be interpreted by the media as the sale of plasma for commercial gain, even though the profits would go to BPL and hence to the NHS. Commercial partners previously considered all insisted on ALT testing, and the fractionation by BPL of plasma from paid donors. BPL's processes might also need to be modified to match those of their commercial partner and some of BPL's products might need to be

sacrificed, including the newly-developed intravenous immunoglobulin Vigam-S. BPL and the commercial partner would be competing for the UK and other markets.

4.2 Thus, this option has potential financial advantages, and might be a halfway stage to disposal of BPL as a going concern, but it compounds the problems associated with ALT testing and fractionating plasma from paid donors (see options 5 & 6) by introducing a clear commercial element, which could give rise to accusations that the Government was privatising part of the NHS.

4.3 The option remains open at present, though almost certainly not on such favourable terms as were available 18 months ago (when the "net present value" to BPL on a 15 year discounted cash flow was £127 million). NBA are, of course, unable to pursue this option with a potential partner at present, as Ministers' stated position is that they have rejected it. There are other potential suitors for the potential partner, so the option may not always be available.

5. Disposal

5.1 BPL could be sold, either with a contract to fractionate all or a specified quantity of BTS's plasma, or without such a contract. Financial considerations aside, the former looks preferable.

5.2 Under this option BPL would be sold with a contract with the new owners either to take all BTS plasma or all the plasma they needed and BTS could supply at a price which would be fixed in the contract for a period of time. This would relieve DH of any immediate worries about BPL, but would clearly be privatisation. ALT testing would almost certainly be required as a condition of contract. We would also have to ensure that we could cope if, for example, the company which bought BPL folded.

5.3 Whilst a straightforward sale would appear simple, this would raise obvious questions about whether BTS could get any income from its plasma, to keep red cell prices down, and about the supply of blood products.

5.4 The National Blood Authority (Establishment and Constitution) Order 1993 sets out the following functions which are relevant to BPL:-

- the preparation of plasma fractions and other products of therapeutic, diagnostic and other purposes;

- research and development in plasma protein fractionation and for other purposes.

By Direction the NBA "shall not close or alter any of its laboratories or transfusions centres without the approval in writing of the Secretary of State".

5.5 Whilst the NBA is not required by statute to carry out the functions currently performed by BPL, a total withdrawal by NBA from functions set out in its Establishment

and Constitution Order would seem likely to require an amendment to that Order.

APPENDIX 2

OPTIONS WHICH DO NOT APPEAR WORTH PURSUING

1. Moving to Full Central Funding

1.1 By making plasma-based products available free of charge to the NHS commercial competitors would be eliminated from the market and the move to recombinant products could be slowed down, extending the useful life of BPL, although ultimately it is unlikely that a solution to the plasma surplus will be found. This option would also be in line with the policy of encouraging self-sufficiency, and would bring England into line with existing Scottish practice as regards blood products.

1.2 Clinicians would (rightly) perceive this option as a device to prevent the use of recombinant Factor VIII and protect BPL. The Department would run the risk of being accused of promoting a "less safe product".

1.3 The manufacturers of other plasma derived products would also complain, saying that this was a denial of clinical freedom, the reason which the Department has used for many years to justify the sale of commercial blood products in England. However, a policy which entailed taking the NHS out of the market by supplying the NHS with NHS-made products free of charge might be less vulnerable to challenge on the basis of unfair competition than one based on continued subsidy, provided prices in other markets were perceived as fair.

1.4 The consequences for red cell prices would need to be considered. In Scotland red cells, etc are provided free. Could we carry on with charging for red cells, etc whilst not charging for blood products?

1.5 The option is rejected on the grounds that moving away from the general principles on which NHS bodies in England deal with one another and with alternative suppliers is unacceptable. There is also the problem that BPL could not supply the total demand for Factor VIII.

2. Partnerships with Other Not-for-Profit Fractionators

2.1 It might be possible to construct collaborations with the Dutch or the Swiss not-for-profit fractionators. Any such deals involving specialisation would require significant changes within the organisations and quite possibly the introduction of ALT testing (certainly with the Swiss). However, given the longer term threats to the European fractionators, even if collaborations were viable they are only likely to defer BPL's problems for about 5 years.

2.2 The chances of this option providing a solution to BPL's problems appear too remote to merit further consideration.