Mr Knight

BLOOD PRODUCTS LABORATORY: INTERIM IMPROVEMENTS

1. Attached is a submission prepared by Mr Harley which recommends approval of capital expenditure totalling £1.3 million over the next 2 years, plus increased revenue of £0.1 million per year from 1981/2. The proposals would enable a substantial increase in production.

2. The 1980/81 costs can be met from money already set aside. Part of the cost in 1981/2 could only be met by increasing the centrally financed programme or displacing other expenditure (para 15).

3. Para 12 and the Appendix analyse costs and benefits. As noted thereon, I consider the assumption underlying Table 2 of the Appendix to be the more realistic (ie that RHAs would build up their plasma input, for the time being, only to the level which the present BPL could process). On this basis the pay-off from the proposed expenditure is very favourable.

4. In my view the real pay-off is more favourable still. Both Tables include in the costs column all the capital expenditure at BPL. But some of this is inevitable anyway - in our view over £1 million of the total £1.3 million (see paras 9-10). On this assumption the "net benefit" figures should all be much more favourable - ultimately £1 million more.

5. The recommendation in para 12 says that the success of the extra expenditure (ie the £0.3 million capital and £0.1 million revenue) would depend on persuading RHAs to increase plasma supplies. A few have already offered to do so. Others may not find it so easy, but I think we can be fairly optimistic about an increase of the order implied by the proposals. It will be the job of the reconstituted Co-ordinating Committee (now approved by the Minister) to sort this out, but it will take them some time. If we are to get our pay-off from the BPL expenditure we must get on with it, even though some risk is entailed, and I recommend that we do so.

6. An important factor here is that RHAs will in any case have to increase their input if we are to have a new BPL on any worthwhile scale. It will be much easier to increase gradually than attempt a sudden major increase when the new laboratory is ready.

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BLOOD PRODUCTS LABORATORY: SHORT TERM UP-GRADING

Purpose of paper

1. In December 1979 MS(H) considered a submission on the questions of the long term replacement of the Blood Products Laboratory (BPL) and its short term up-grading following a report by Medicines Inspectors. He asked for further consideration of the first question, which is in hand. He agreed in principle to short term measures to make the BPL reasonably safe for the time being but when he visited the BPL on 21 March added that, if the laboratory was to be replaced, short term expenditure should be kept to a minimum.

2. Officials have therefore reviewed, with the Director, the proposed short term measures, taking account of the possibility of increased production, which the original submission did not cover. They recommend acceptance of the Director's proposals for capital expenditure of £1.3m over this year and next, and increased revenue expenditure of £0.1m to come into effect over the same period. The capital figure includes the £90,000 already agreed to orally by MS(H) for increased cold store capacity. The expenditure recommended would allow a substantial increase in production with consequent savings on the purchase of commercial products. The new proposals and the resulting return are discussed in paragraphs 11-13 below. The paper first discusses the importance of the timing of a new BPL and the supply of plasma for it, and also considers what the effect would be of lower levels of expenditure which are not recommended.

Preliminary considerations

3. The timing of a new BPL (if agreed) is a major determinant of possible options for expenditure. Even taking into account the possibility that some form of collaboration with industry might reduce the construction time, we believe that the present laboratory will have to function for at least five more years.

4. The supply of plasma for a new BPL. In order to ensure an adequate supply of plasma for a new factory, the BPL ought to be in a position to begin accepting increased plasma supplies from the Regional Transfusion Centres as soon as possible. It will be necessary to encourage Regions to increase supplies, and they will expect to be able to offset the additional expenditure involved by the reduced purchase of imported commercial products.

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This requires an early increase in BPL production.

5. Officials have begun to discuss the implications of increasing plasma supplies with Regional Transfusion Directors and plan to discuss it with Regional chief officers. MS(H) has recently received a submission about the setting up of a new Advisory Committee on the National Blood Transfusion Service, to which he has already agreed informally. One of the tasks of the Advisory Committee will be to help coordinate future supplies. Officials would be grateful for authority to refer to Ministerial support for the necessary increase when they speak to the NHS about it.

Minimum expenditure

6. Officials consider that in certain circumstances it would be feasible to confine capital expenditure over the two years 1980/81 and 1981/82 to some £0.5m, and to make a small reduction in planned revenue expenditure. If, but only if, it were likely that a new laboratory could be operational in substantially less than the minimum of 5 years postulated in paragraph 3, the capital sum could be spent entirely on improving the reception and storage of increased supplies of plasma. But as there would be no increase in production (and for safety reasons the Director might well feel obliged to reduce production) it would be very difficult to get Regions to increase supplies. Processing of the plasma would have to wait until the new laboratory could undertake it, and it would tend to deteriorate during storage and become virtually useless for the production of Factor VIII after 12-18 months.

7. On present expectations of the time that will be taken to replace the BPL it would not make sense to limit the planned expenditure to this level, and we cannot recommend this option.

Expenditure to maintain present production

8. A number of steps have already been taken, within the expenditure planned prior to the present review, to improve conditions and procedures at the BPL. It has been thoroughly cleaned (as far as the present unsatisfactory building can be cleaned) and will now be cleaned regularly (by contractors) on the basis of a written specification. Operating instructions have been improved, proper job descriptions have been drawn up, and improved staff training has been started. MS(H) has agreed to the provision of 5000 cu.ft. of additional modular cold storage re-usable if the laboratory is

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redeveloped on the Elstree site). The main work of the short term up-grading of the buildings and equipment has however been held up while proposals have been reviewed.

9. Further measures covered by the planned capital expenditure of some £1.02m during 1980/81 and 1981/82 would result in considerably improved product handling and storage and would eliminate a variety of unsafe procedures which are unavoidable at present. Other safety measures would be covered by revenue expenditure. In many important respects, however, improvements would still fall well short of the safety requirements of Medicines Division. Moreover, although the improvements would allow for the storage of increased quantities of plasma, safety considerations make it doubtful if there could be any increase in production to encourage RHAs to provide more plasma.

10. What had been planned, therefore, was a simple maintenance job designed to keep the BPL operating at its present level, and in a tolerably (but still not wholly) safe state until a new laboratory could come into operation. It would have had the serious disadvantages that it could not be expected to have any significant 'pay back' in terms of increased productivity and that there would be no incentive for Regions to increase their plasma collection. The planned expenditure is the minimum which we regard as acceptable, but we consider it a second-best option.

Expenditure to increase production

11. A plan prepared by the Director of the BPL calls for capital expenditure during 1980/81 and 1981/82 some £0.3m greater than that already planned, and an increase of some £0.1m in revenue expenditure. The extra capital expenditure would be devoted largely to increasing the flow of plasma through the laboratory, the use of a new technology in its handling (single-donor 200 ml. packs instead of the present 5 litre multi-donor packs), and increased production. The additional revenue expenditure would go largely on improved staffing for increased production. The need to support increased production by increased supplies of plasma would mean an increase in expenditure by RHAs, though this would be off-set by a reduction in RHAs' reliance on imported commercial blood products.

12. The costs and benefits of the above expenditure have been analyzed using criteria recommended by the Treasury (see Appendix). On favourable assumptions about the build-up of RHA costs the proposed expenditure would be economically justified even in the unlikely event of a new laboratory being operational by 1983. On more severe assumptions the expenditure would still be justified

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provided a new laboratory were not commissioned before 1986/87, i.e the end of the five years mentioned in paragraph 3. Officials therefore recommend this proposal, but Ministers will wish to note that its success would depend on success in persuading RHAs to provide more plasma.

13. It must be strongly emphasized that this scheme would not provide a long term answer to present BPL problems concerning standards of safety, and that it would go only part of the way towards replacing current imports by BPL products. It is doubtful whether, even with further major expenditure, the scheme could be adapted to provide a long term solution. It is certain that it could not provide one without further major expenditure (though this does not of course preclude any possibility there may be of integrating the present building for some suitable use into a rebuilt BPL). While Medicines Division appreciate the need to keep up production and to encourage RHAs to increase plasma supplies, they have misgivings about increasing production even with BPL up-graded. These misgivings would be only partly relieved by the recruitment to the BPL of staff with production experience (particularly in pharmaceuticals), to which Medicines Division also attach special importance.

Meeting the proposed expenditure

14. Existing BPL estimates and forecasts included in our PES process provide for the following:

	(80/81)	81/82	82/83	83/84
Capital	(0.845)	0.175	0.220	0.220
Revenue	(1.969)	1.782	1.803	1.834

(All figures £'m at Survey 80 prices, except 80/81 at cash limit prices. Estimates for 82/83 and after must at this stage be regarded as provisional only; they are for the normal continuing needs of the BPL).

15. There is no possibility of increasing 80/81 expenditure limits. The additional capital expenditure of some £0.3m on the scheme outlined in paragraph 11 would therefore have to be placed in 81/82. Additional revenue expenditure would begin in 81/82. This extra expenditure cannot currently be accommodated within the spending plans for the Department's centrally financed services. Acceptance of the proposal in paragraph 11 is likely to mean that increased expenditure will have to be met by a cut in NHS capital and/or research.

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Decision required

16. Ministers are asked whether a revised programme of improvements to the BPL should be put in hand, at an additional capital cost of some £0.3m in 1981/82 and an additional revenue cost of some £0.1m starting in 1981/82 but enabling production to be increased with a resulting 'pay back'.

COST BENEFIT OF INCREASED PRODUCTION AGAINST INCREASED INVESTMENT

Investment appraisal by the use of Discounted Cash Flow is a management tool ideally suited to this type of exercise. Capital investment in early years plus a continuing revenue commitment is expected to show a cost benefit at some future period.

The tables below have been prepared by FA1 in consultation with FB3/4 and EAO. They show, for the first 4 years, the costs and the benefits accruing from a programme of investment in the BPL. Separate tables are provided which incorporate different expenditure assumptions: (1) a linear increase in input from RTCs over 3 years, from current levels to the target level for a new BPL, and (2) an accelerating increase only to the level required by an up-graded BPL.

Increased production and the consequential net benefit are expected to flatten out at the 1983/84 level. On Table 1 assumptions the analysis reaches a break-even point by 1986/87. On Table 2 assumptions the analysis shows a break-even point in 1982/83.

TABLE 1 (£m at forecast 80/81 out-turn prices)

	EXPENDITURE AT BPL AND RHA (REV + CAP)*	PRODUCTION TARGETS	VALUE OF EXTRA PRODUCTION †	NET BENEFIT	DISCOUNTED AT 7% ø
1980/81	0.85 (£500,000)	Factor VIII 15 miu Albumin 135,000 Anti D 75,000	-	-0.85	-0.85
1981/82	BPL = 700 1.908 1.208 = RHA	Factor VIII 17.5 miu Albumin 135,000 Anti D 150,000	1.0	-0.908	-0.85
1982/83	2.916	Factor VIII 22.5 miu Albumin 225,000 Anti D 150,000	3.0	0.084	0.07
1983/84	4.374	Factor VIII 30 miu Albumin 225,000 Anti D 150,000	4.95	0.576	0.47

* The sums shown include all capital costs (including those already planned: see paragraphs 8-10 of the paper) but omit baseline revenue expenditure (i.e revenue expenditure already planned). RHA costs are based on figures from NE Thames RHA.
† From current commercial cost of equivalent purchase of imported material.
ø Treasury recommended Test Discount Rate.

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TABLE 2 (£m at 80/81 out-turn prices)

	EXPENDITURE AT BPL AND RHA (REV + CAP)*	PRODUCTION TARGETS	VALUE OF EXTRA PRODUCTION †	NET BENEFIT	DISCOUNTED AT 7% ø
1980/81	0.85	As above	-	-0.85	-0.85
1981/82	0.967	As above	1.0	0.033	0.03
1982/83	1.742	As above	3.0	1.258	1.10
1983/84	3.28	As above	4.95	1.67	1.36

* † ø See notes to Table 1.