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PSG81/7

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NOT FOR PUBLICATION

POLICY STEERING GROUP FOR THE REDEVELOPMENT OF BPL

MINUTES OF THE FIRST MEETING HELD ON 24 AUGUST 1981 AT DHSS, HANNIBAL HOUSE, ELEPHANT AND CASTLE, LONDON, SE1

PRESENT:

Mr Smart - (Chairman) Mr Armour Dr Dunnill Dr Gunson Mr Harley

Mr Hibbert Dr Lane Dr Walford } Secretariat

IN ATTENDANCE:

Mr Bench - DHSS Works Group Mr Hilton - DHSS Finance Division

Introduction/Terms of Reference - PSG81/1

Nr Smart explained that the PSG's primary purpose was to act on behalf of the Joint Management Committee for the Central Blood Laboratories in planning the redevelopment of BPL. Its objective was to redevelop the Laboratory as quickly as possible in order to save NHS expenditure on commercial blood products. This would require members to devote considerable time to the task ahead. Outside experts would be called in as necessary.

BPL's Terms of Reference - PSG81/2

2. The draft terms of reference, to be considered by the Joint Management Committee, were noted. The Group emphasised the importance of an early decision on the long-term management arrangements for the Central Blood Laboratories.

Financial Provision for Redevelopment - PSG81/3

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- 3. Mr Harley explained that there were two possible sources for capital funding - additional money from the Treasury, or "top slicing" health authorities. The pattern of expenditure set out in PSG81/3 was not rigid, and the possibility of moving sums forward if the time-scale were compressed would be considered.
- 4. The Group agreed that the target time-scale for redevelopment should be three years. The rate of technology change was such that too long a redevelopment scale would put the investment at risk.

Protein Fractionation Technology Working Party - PSG81/4

- 5 Dr Dunnill confirmed that the Working Party's report remained valid, though for a finite period. He asked that all Members be supplied with the Appendices in full. Data were not yet available about the potential capacity of PFC, Liberton to fractionate a proportion of English plasma.
- 6. Dr Walford explained that the PFC trials were set for late Autumn; but for a two-week period only. They would centre on the production of SPPS from which it should be possible to extrapolate potential plasma protein fraction production levels. The Scottish Home and Health Department would readily co-operate with the PSG regarding information about any aspect of PFC's work.

7. It was agreed that Dr Lane and Mr Hibbert should discuss the design implications for BPL of a 24-hours-a-day processing system.

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Increasing the Supply of Plasma to BPL - PSG81/5

- 8. Dr Gunson confirmed that his Working Party's initial calculations showed that BPL would be required to fractionate 500,000 kg of fresh frozen plasma to produce sufficient Factor VIII to enable the NHS to be self-sufficient in blood products in the mid-1980s. The Working Party was currently refining its costings before reporting to the Advisory Committee on the NBTS on 28 September. It was also looking at intermediate levels between that required for self-sufficiency and that which could be reached without increasing substantially the number of whole blood donations currently taken by the NBTS. Subject to the Adivsory Committee's views, RHAs would be consulted about the level of plasma they could provide, and the phasing of the increased input. Dr Lane stressed the need to bear in mind the potential for increasing the yield from ffp. He hoped for a 20% improvement over the next two years.
- 9. The Group agreed that whilst the target capacity of BPL must recognise RHAs' ability to provide the raw material, it would be a mistake to build too small a factory. Spare capacity must be built in. A multi-stream operation was preferable so that different streams could be brought on as the supply of plasma increased.

Project Management

10. Mr Armour suggested that Gordon Collins (currently Project Manager for BPL's short-term upgrading programme and the conversion of the Harkness Building for the BGRL) should be made Project Manager for redevelopment. He had a proven track record, and was fully versed in NHS procedures. Points of detail, particularly regarding his accountability within the RHA, would need to be resolved. He would be freed of other RHA work, though would complete the short-term upgrading programme and the Harkness conversion. The RHA would not provide design expertise.



- II. The Group discussed briefly the options for project management, including the combination of project management with a design/building commercial package. It was agreed that
 - 1. Mr Armour should set out the RHA's proposals;
 - 2. Mr Bench should describe the options open to the Group; and

3. Mr Hibbert should prepare a note on what might be done in industry.

Mr Harley would co-ordinate these and prepare an options paper for the next meeting of the PSG.

Capricode - PSG81/6

12. The Group noted Mr Bench's paper. Mr Bench confirmed that projects could be "fast-tracked", and that Departmental approval stages need not necessarily delay projects, provided that a clear submission was put forward from the outset.

Involvement of BPL Staff/Release of Minutes to the Staff Side

13 The Group recognised the potential contribution of BPL staff. It was agreed that when the Group's work had progressed slightly more, and the proposals for the long-term management of the Laboratory were known, representatives of the PSG should visit BPL to discuss redevelopment with the staff. In the meantime, Dr Lane and Mr Armour would keep staff in touch with development through the Joint Consultative Committee. In view of this, it was agreed that minutes of the PSG would not be released to the Staff Side, but that the Chairman would submit regular reports to the Joint Management Committee.

Questions for the Group's Consideration

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14. The Group discussed broadly the following points:-

1. Should BPL be planned to meet all or only part of NHS demand for blood products?

The general feeling was that the Laboratory should be planned so as to be able to meet the target for self-sufficiency, but regard would have to be had to Regions' estimates of likely plasma supply.

2. Should it built on a flexible, modular basis, permitting colonisation of modules as required as had been done at the plant on Long Island?

This was agreed. Modules could be equipped as and when necessary.

3. What is the recommended technology?

The advice of the Protein Fractionation Technology Working Party was accepted ie cold ethanol precipitation.

4. What about the effect of the development of genetic engineering techniques?

It was pointed out that even if Factor VIII could be genetically engineered, BPL would still have a major role in producing other products (notably albumin), and it was sensible to make use of the available raw material. The Group asked whether DHSS would permit the redeveloped BPL to produce genetically engineered material in direct competition with industry. This was an important consideration in whether the design should recognise that there might be a requirement to change to large-scale fermentation at some time in the future.

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5. Is single shift working contemplated or two or three shifts? What would be the effect on capital building costs and on revenue?

Dr Lane pointed out that the Laboratory worked on a 16-hour day basis, but that only specific parts of the process required shift working. It was agreed that Dr Lane and Mr Armour would seek the staff views informally at the next Joint Consultative Committee.

6. <u>Should it be a single building</u>, a series of isolated buildings, or inter-connected units?

It was agreed that the differences in quality of environment required in different parts of the plant (eg air conditioning, clean processes), dictated a series of separate buildings. There was a case for at least two separate production lines, both as a contingency and to assist in maintenance work.

7. Can it be phased so some parts come on stream before the whole factory is commissioned?

It was agreed that this was not essential if the time-scale were suitably short (two years from approval to build to completion).

8. The role of PFC, Liberton and its effect on target capacity.

Dr Walford suggested that, subject to the result of PFC's shift-working experiment, it may prove uneconomical to divert resources to Liberton to enable it to fractionate English plasma. PFC's capacity was so small compared to that required to reach self-sufficiency in England and Wales as to be within the acceptable "margin of error" for assessing BPL's capacity.

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9. <u>What consultation should there be with the Medicines Inspectorate</u> and Health and Safety Executive?

It was agreed that the Laboratory had to be designed to meet good manufacturing practice, and that the Medicines Inspectorate could offer invaluable advice. However, the Group had to recognise the limited manpower resources of the Inspectorate.

10. How is the architect's brief to be prepared, and how soon can it be completed?

It was agreed that Dr Lane, Mr Hibbert and Dr Dunnill could usefully start preliminary work before the appointment of a Project Manager to co-ordinate preparation of the brief. Assuming agreement on project management arrangements at the next meeting, and that a decision on the long-term management of the Central Blood Laboratories would be forthcoming, a target date for the completion of the brief would be the end of 1981.

11. What use hight be made of existing buildings?

The Technology Working Party suggested that existing buildings could be used for support services (eg storage) only.

Date of Next Meeting

15. This will take place on Wednesday 30 September at 2 pm in Room 87, Hannibal House.

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