NOT FOR PUBLICATION STC Minutes 79(2)

NATIONAL BLOOD TRANSFUSION SERVICE
SCIENTIFIC AND TECHNICAL COMMITTEE FOR THE CENTRAL BLOOD LABORATORIES

Meeting at the Plasma Fractionation Laboratory at Oxford on Thursday, 7 June 1979

Present:

Professor P L Mollison (Chairman)
Dr P Dunnill
Dr H H Gunson
Professor D K Peters
Dr J Prydie
Mr R D Smart
Dr G Tovey

Directors

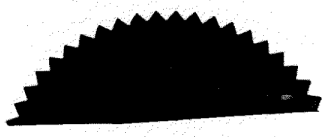
Dr A M Holburn
Dr R S Lane

Joint Secretaries

Mr T E Dutton
Dr Sheila L Waiter

In attendance

Mr J Harley
Dr J A Holgate
Dr R M Oliver



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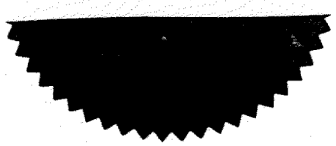

Apologies for absence were received from Professor Flute and Dr Wills.

Before the meeting members of the Committee toured part of the Oxford Regional Transfusion Centre to see the plasma production facilities and were later shown over the Plasma Fractionation Laboratory by Dr Bidwell. The Chairman thanked Dr Bidwell and Dr Gunson, on behalf of the Committee, for all the trouble they and their staff had taken to make the visit of the Committee as informative as possible. The Committee's appreciation was also conveyed to the Health Authority who had made most agreeable luncheon arrangements.

852[1]

35/158

Dr Bidwell was invited to say whether there were any matters during the years she had been connected with the Plasma Fractionation Laboratory which she felt she wished to bring to the Committee's attention. Dr Bidwell outlined the difficulties which she had encountered from time to time in running a production laboratory within the framework of the National Health Service, partly because of the apparent inflexibility of the NHS rules regarding staffing. Mr Harley explained that there was far more flexibility within NHS staff and pay structures than was generally appreciated and he was sure that if particular difficulties were referred to the Department they would be able to assist in solving them.

Dr Bidwell and Dr Lane provided figures showing the relative magnitudes of the output of PFL and BPL and described the differences in the range of products and processes. In addition to being the principal producer of Factor IX the PFL produced all the NHS Factor VIII used by the Oxford Region. PFL processed 100-200 litres of plasma a week for Factor VIII compared with BPL throughput of about 1800 litres of plasma a week.
Professor Mollison thanked Dr Bidwell who then left the meeting.

Minutes of the previous meeting STC Minutes 79/1

The minutes were agreed.

Revised Terms of Reference

Mr Dutton drew the attention of members to Mr Smart's suggestion at the previous meeting that the Terms of Reference were somewhat introspective. He had circulated proposals for amending them to his fellow Joint Secretaries prior to presenting them to the Committee. This had led to a suggestion for a further change of another aspect of the Terms of Reference on which it was proposed to seek the Chairman's views.

Future needs of albumin

Consideration of this item was postponed pending the preparation of a paper which Professor Peters hoped to write.

35/1-59

The development of BPL

Report by Mr Smart STC 79/4
Memorandum by Dr Lane STC 79/5

The Chairman proposed that in view of the need to consider these papers in relation to one another and also in relation to what Dr Holgate had to say about the visit of the Medicines Inspectors to BPL, consideration should be deferred until the next meeting. Mr Harley thought that it might be helpful, if this was what the Committee decided, if he were to prepare a paper containing the Department's appraisal of the options which appeared to be open to it, in the light of these papers and the Medicines Inspectors' report.

Mr Dunnill thought that further papers would not advance consideration of the problems facing BPL which were already well identified and the options were, in his view, also quite apparent. He wondered whether the better course might be for the Chairman to seek to see the Secretary of State and to express the Committee's disquiet that nothing was being done to put the defects at BPL right. Several members doubted whether there could be a useful discussion with the Secretary of State until the appraisal which Mr Harley proposed to cover in his paper had been carried out.
The Chairman suggested that members might wish to hear what Dr Holgate had to say before making up their mind on this question.

Visits of the Medicines Inspectors to BPL

Dr Holgate explained the arrangements made under the Therapeutic Substances Act to control the quality of biological products, based on the grant of licenses to manufacture or import. This Act had been repealed in 1975 and the provisions of the Medicines Act were substantially different. Although Crown privilege might have been claimed to exempt products made in NHS units it had been decided that they should comply with the same requirements as products made in industry, both as regards manufacturing environment and quality.

35/160

The visits by the Medicines Inspector were not yet complete and several more days would be needed at BPL. Dr Holgate had been present for much of the time. Serious deficiencies had however been found in practically all aspects of the laboratory examined so far, e.g. in documentation, quality control, environmental control, availability of pharmaceutical advice and in the schemes for training staff.

Although it might be some time before the Inspectors report would be available it was apparent that changes were needed at BPL and a decision might shortly have to be taken about what changes should be made in certain processes and whether some processes should continue to be carried out in the existing BPL premises. Many improvements could be achieved quite quickly by the institution of improved training programmes and the purchase of minor equipment and if suitable senior staff could be recruited to exercise closer control over manufacturing and quality control processes substantial improvements should ensue. There was however, a limit to the improvements which could be effected given the constraints of the existing buildings and plant, much of which was now very old.

Having identified the shortcomings Medicines Division was now considering how they might be remedied, because it was apparent that a licence would not be granted to a commercial company with similar shortcomings unless there was a commitment to improve the state of affairs.

After further discussion it was agreed that the Department should prepare a paper on the lines proposed by Mr Harley.

Dr Dunnill said that he still wished to reserve his position on the advisability of such a course since the need, as Dr Holgate had indicated, was for urgent action. Members felt, however, that it was unlikely that Ministers would give their consent to expenditure of the order of magnitude which might be necessary, until there had been a complete analysis of the situation. They would almost certainly want to see an

35/161

examination of the alternatives and a recommended course of action. Insofar as there was some uncertainty about the future pattern of organisation of the NHS there must equally be some doubt about the way in which the NBTS would be organised in future. Dr Tovey drew attention to the urgent need to let the Regions know where they stand, both in regard to the capacity of BPL in the short term and in the long term. It was apparent that many regions would be unable to produce the plasma required to support even the "stop gap" proposals without significant additional investment.

Mr Harley was invited to say what the alternatives were which could be put before Ministers since there seemed to be no other choice than to put money into BPL. He explained that one possibility was to make use of the fractionation capacity at the Protein Fractionation Centre, Edinburgh but Dr Lane said that it had never been envisaged that this Centre should process more than about 500 litres a week of plasma from England and Wales.

After further discussion it was unanimously agreed that it would be inadvisable to approach Ministers until a complete appraisal of the possibilities open and their cost effectiveness had been prepared, which the Department undertook to do in time for consideration by the Committee in September. Meanwhile, it was agreed that Ministers should be acquainted with the situation and told of the Committee's grave misgivings. Dr Tovey thought that it was important that Ministers should understand the concern which there would be amongst blood donors if they realised how much was currently being spent on commercial blood products. It was also necessary to decide to what extent there would be dependence on plasmaphereses in any future blood collection programme; Dr Tovey pointed out that this was only one aspect of the development which would be necessary in Region Transfusion Centres.

Dr Lane expressed the hope that there could be an early decision in principle on the development of BPL because thisradically affected the way in which the Laboratory would be run meanwhile.

Product Liability

The departmental paper was noted.

35/162

Progress with the acquisition of the Harkness Building

Mr Dutton explained that it now seemed fairly certain that this building would be made available to rehouse BGRL and the Department expected confirmation before the end of the month. The Department was also on the point of purchasing the freehold of the Lister, Elstree estate for the sum of £610,000.

Dr Gunson mentioned that there had been some concern expressed in Oxford about the effect of the move of BGRL on the already limited supply of serological technicians. Dr Waiter referred to the consultation which had taken place with the clinical interests in Oxford when this problem had been alluded to. While the move of the laboratory to Oxford would undoubtedly increase the problem to which Dr Gunson had referred, there would be some benefit to Oxford arising out of the move.

Dr Lane's proposal to replace the York compressors and to introduce improved containers and closures

Dr Lane said that there was a need to purchase a 3rd compressor at a cost of £40,000 for which there was no budget provision. There was also problems with servicing the other York compressors and the firm had given notice that spares would no longer continue to be available. The Committee agreed that there was no alternative but to maintain the full compressor capacity as long as the laboratory continued to function and they invited Dr Lane to prepare a short costed paper for consideration by the Finance Sub-Committee and possibly the Joint Management Committee.

Dr Lane referred to the defects in the existing bottle and closure for PPF which he had demonstrated on the visit of the Committee to BPL. He undertook to prepare a paper showing the advantages and costs of the changeover which he proposed, for the next meeting.

Any other business. No other business was raised.

Date of next meeting. Wednesday 26 September at 2.15 pm at the Department.

35/