RSL/PP

22nd May, 1980.

Mr. J. Harley,
Department of Health and Social Security,
Hannibal House,
Elephant and Castle,
LONDON, SE1 6TE.

Dear John,

Revised Interim Forecast Capital Budget 1980/81.

I enclose for your attention the revised budget with introduction and explanation as requested by Tom Dutton. There are six copies.

The main budget still stands. This revision simply relates to the capital forecast as, I believe, was agreed.

Forecast requirements have been divided between actual building costs, plant and equipment and other equipment. Within the total set down for building, I have differentiated between those changes which would be retained in association with a newly developed BPL and those for which, at present, there is no immediate plan once the interim period is completed. It is in this last group, that the Minister wished expenditure to be limited to matters of absolute necessity. I believe this budget submission indicates that the Minister's wishes have been taken fully into consideration. There is nothing in this budget forecast that will not be retained for use during its normal life or will not serve its full worth in a functional sense during the interim term.

There are certain items indicated which require urgent decision and I hope this will be forthcoming.

Yours sincerely,

R.S. LANE.
Director.

c.c. Mr. G.M. Bailey
Mr. A.G.W. Bailey

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REVISED INTERIM BUDGET SUBMISSION 1980/81,
CAPITAL FORECAST EXPENDITURE

Introduction

This submission is based on the following requirements and assumptions:

(1) The existing laboratory will be run in a reliable safe and economic manner during the interim period i.e. until a new process laboratory is commissioned.

(2) High priority will be given during the interim period to establishing an efficient hand-over facility from the old to the new BPL. The requirements are:

(a) Major improvements in quality and quantity of raw material supply (fresh frozen plasma FFP) from NBTS.

(b) Modified technology for safe handling of the extra FFP and improvement in Factor VIII yield.

(c) Interim production target 30M in Factor VIII (equivalent 800,000 donations) by 1982/1983.

(d) Implementation of Medicines Division recommendations in documentation and environmental control where feasible in existing building. Upgrading of product steriliry testing and quality control.

(e) Stop-Gap developments - approved by Medicines Division. Albumin capacity improved to 225,000 containers per annum.

(3) Limited replacement of BPL equipment and plant and fabric to retain reliability and safety.

In attached proposals, maximum consideration is given to minimising expenditure on building modifications, plant replacement and extra equipment with limited use after a new BPL process facility is commissioned. To this end, it is assumed that:-

a new building will be available in 1984/85.

certain parts of the existing BPL will be retained for specific purposes.

the existing Virology Laboratory should be retained in the new BPL complex.

certain small parts of a new BPL complex should be commenced now since no economic or feasible alternatives exist during the interim.

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Interim Production Targets related to a handover facility.

FFP from 350,000 donations p.a. ⟶ 800,000 p.a. by 1983/84.

Factor VIII from 15m i.u. ⟶ 30m i.u. by 1983/84.

Albumin from 135,000 ⟶ 225,000 containers by 1982/83.

Anti-D from 75,000 ⟶ 150,000 x 100 µg by 1981/82.

Approximate forecast capital requirement over 1980/81, 1981/82 = £1.3M.

Foreign exchange equivalent of extra output.

	1980/81	1981/82	1982/83	1983/84	1984/85	TOTAL
Albumin			£1500K	£2700K	£2700K	£6900K
Factor VIII		£250K	£750K	£1500K	£1500K	£4000K
Anti-D		£750K	£750K	£750K	£750K	£3000K

Total product value = £13,900,000 at current exchange rate on U.S.A. imported product.

These production targets meet less than 50% of the annual use rate for Factor VIII and 65% of the estimated requirement for albumin (150g/1000 population).

The major constraint remains as deficient FFP supply.

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COAGULATION FACTOR DEVELOPMENT.

Functional content.

Improvement in fresh frozen plasma supply and use: elaboration of 30M i.u. Factor VIII.

(a) Receipt of plasma.

Modular Cold Store 5,000 cu. ft. required September 1980. To be retained in new BPL complex as ex-quarantine FFP Cold Storage.

Design stage.	£
Ready for immediate progression to tender. Cost. Complete + services	90,000

(b) Handling of packs

Teardown machine for bag opening Initial costs estimated required from September, 1980.	5,000

(c) Cryoprecipitate preparation.

Plasma crushing and thawing equipment	17,000

(d) Finished product handling.

Laminar flow cabinets (6)	7,000
Vial filling machine	25,000
Vial freeze-driers x 3.	210,000
Equipment (general) £500 - £5,000	15,450
up to £500	4,240
Class (1)/Class (2) vial filling and drying modification to CF Lab.	120,000

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LARGE FRACTIONS AND FINAL SOLUTIONS

Functional content.

(a) Machine and plant replacement

	£
Bottle washing machine (Dawson)	15,000
Auto-filling and closure machinery for albumin containers (estimate)	50,000
Heat treatment cabinet.	
Inactivation of Hepatitis B.	15,000
Stainless Steel vessels	7,000
General equipment £500 - £5,000	6,300
⟶ £500	2,650

(b) Step-over facilities. 25,000

(c) Stop-Gap and Technical Services.

Design stage., awaiting Captricode I & II approval.

April 1980 redetermined costs:

	£
Loading Bay	98,900
Cold Room	103,200
Stores	45,800
Technical Services	2,300
Packing & Dispatch	189,800
	£440,000

Estimated expenditure in 1980/81 £100,000

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TECHNICAL SERVICES

Functional content

(a) Plant replacement

	£
Finn Aqua + works pretreatment	52,000
Laminar cabinets (2)	2,800
Stainless Steel Benching	2,000
General equipment £500 - £5,000	1,600
⟶ £500	1,945

(b) Engineering

York Compressor Glycol Cooling and installation	78,000
General equipment ⟶ £500	250

TERMINAL PROCESS AREA

General equipment ⟶ £500	750
Freeze Drying equipment	1,125

BACTERIOLOGY

(a) Minor modification Buildings	3,000
(b) Equipment, steam autoclave	7,500
laminar flow cabinets	1,600
general equipment ⟶ £500	100

VIROLOGY

Hepatitis Laboratory upgrading	10,000
autoclaves	15,000
equipment £500 ⟶ £5,000	1,200
⟶ £500	300

LABORATORY CLEANING AND UNIFORM

Clothing lockers	15,000
Clothing	25,000

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ANALYSIS.

Revised Capital Budget Summary 1980/81 (Appendix (1))

Buildings

The following functional areas of BPL would be retained in the old building after commissioning a new factory on the site:-

(a) Extended loading bay and cold store would remain the principal raw material supplies' reception area. The cold room would be a secure store for frozen plasma pending Control release from quarantine.

(b) Packing & Dispatch would be retained as reagent chemicals reception and non-toxic chemical store.

(c) Large Fractions would be retained with some modification for use as a Pilot Laboratory. Support services - glycol cooling, technical services area and EF10/10 freeze-drying unit would be retained for pilot plant use.

(d) Modular cold room to be retained as ex-quarantine secure store for FFP serving a new laboratory.

(e) Virology Laboratory to be retained in full.

Equipment

All major equipment items except the York Compressor - Glycol Cooling system would be transferred to a new factory provided the interim period was less than 5 years. After 5 years, equipment would have paid for itself.

The York Compressor would be retained in situ to service the Pilot Laboratory area.

All minor equipment items would be transferred to a new factory area for continued use.

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Capital expenditure on interim modifications to BPL without redesignated functions to-date.

		£
(1)	Sterile filling and drying area in Coagulation Factor Laboratory	120,000
(2)	Bacteriology	3,000

Summary:

(1) Capital expenditure (1980/81) on buildings and building modifications is limited to £348,000.

(2) Capital expenditure on buildings serving only the interim period is defined as £123,000 of which £120,000 contributes significantly to the plasma supply programme.

(3) Stop-Gap has increased from £365,000 (July 1979) to £440,000 April, 1980, of which, it is estimated, £100,000 would be spent in 1980/81, the remainder in 1981/82.

(4) Bacteriology: The existing facility which houses the critical control process of sterility-testing final product is essentially derelict. No re-use of this area is envisaged and no economic case for major extension or modification can be made. For this service, it is essential that the interim period before rebuilding is as short as possible. (see Appendix (2)).

(5) Agreement is needed immediately to proceed with the following:-

Modular Cold Room Suite
Stop-Gap
Bottle washing machine
York Compressor
Finn Aqua Water treatment

(6) Without the modular cold room suite approval, the single pack programme for increasing plasma supply will be shelved. Improvements and modifications to Coagulation Fractions, Large Fractions and the Stop-Gap programme are compatible with the interim requirements of Medicines Division and are complimented by the improved Contract Cleaning Services, extra laboratory protective clothing and improved documentation.

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APPENDIX (2)

Provision of facilities for sterility testing and environmental control.

A client brief describing the minimum functional-design content of this facility has been presented to Architects and Consultants and the options appraised as follows:-

(1) Modification to existing department with extensions

(2) Modification, upgrading and extension of the Lister Bacterial Vaccines Laboratory providing Class I testing accommodation in an Envair Modular prefabricated suite

(3) Building a new custom-designed building

(4) Option 2 without the Envair modular suite

Conclusions

Option (1) Not feasible and extension of this area of BPL on an interim basis uneconomic and likely to compromise a new development.

Option (2) Outcome compromised by structural considerations in existing Bacterial Vaccines building.

Provision 406 m^2 12 months building and commissioning time.
Cost £414,000.

Option (3) Provision of new laboratory. Compatible with a Management Control Plan for the new BPL, thus could be a front-runner of the new laboratory.

Provisions: Full client brief specification in 369 m^2.
Cost £380,300.
Building time, 8 months, including commissioning.

Option (4) Outcome similar to Option (2). Least satisfactory accommodation of client's specifications in Bacterial Vaccines. Area 414 m^2.
Cost £380,800. Building and commissioning in 11 months.

Recommendation

Option (3) A new Microbiology Laboratory should be accommodated within the BPL redevelopment Management Control Plan at the earliest time with a view to construction in financial year 1981/82. April ⟶ November.

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