IN CONFIDENCE

CBLA 88/63

CENTRAL BLOOD LABORATORIES AUTHORITY

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6th October 1988

Mrs Edwina Currie MP
Parliamentary Under Secretary of Health
Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS

Dear Mrs Currie,

Re: CBLA's Annual Accountability Review: July 1988

There has been some doubt as to whom a reply to Lord Skelmersdale's letter of 25th July, which is acknowledged with thanks, should be addressed. However, I am advised by Malcolm Harris that you have assumed responsibility for blood products and I am accordingly submitting this commentary to you.

The team from CBLA found the Accountability Review stimulating and encouraging and I should like to express our appreciation of the courteous reception and constructive discussion which marked the occasion.

In response to the specific points raised in Lord Skelmersdale's letter I will attempt to comment on them seriatim, using his paragraph numbers.

(2) Production Targets:-

We are, of course, totally committed to the achievement of production targets at the earliest possible date. However, it must be stressed that no efforts, however dedicated and strenuous, will secure manufacture at full capacity until the contractors have rectified the defects in both services and equipment which are still, in a number of instances, far short of agreed specifications.

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(3) Research and Development

We shall, of course, be glad to discuss with Department of Health Officials how best current and projected research spending can be monitored. It should, I think, be appreciated that the R & D budget covers Process Investigation, external research and product development as well as internal research activities. A recent review established that 40% of the R & D budget is devoted to Process Investigation, leaving £664,000 to cover committed external research (which is never commissioned without the approval of the full Authority), product development and internal research activities. Details of the R & D budget and of subsequent performance are scutinised by the Authority at regular intervals and the Minutes of the R & D Sub-Committee are tabled at Authority Meetings; observers from the Department are present at those meetings and are always welcome to ask questions and make any observations which they deem appropriate.

(5) Product Yields

Efforts to improve product yields will continue as a matter of priority. The yields of Factor 8Y already exceed the yields of Factor VIII reported from private sector fractionators in the United States. However, in the longer term the law of diminishing returns will operate and a point will be reached at which yields of blood fractions will be maximal. We are also aware of the absolute necessity of eschewing any sacrifice of safety standards in the pursuit of yield, even though the achievement of the safest possible product may result in lower yields than would otherwise be feasible. Indeed, the trend of present viral inactivation requirements will result in lower yields rather than increased ones.

(6) Licensing

Our application for a Manufacturer's Licence will be submitted by the end of October this year and Product Licence applications will follow during 1989. A report on progress made in securing licences will be sent to you in January next year.

(7) Plasma Processing

We are reassured to learn that the National Blood Transfusion Service will be encouraged to meet the identified requirement of 540 tonnes of plasma per annum. We note that this is likely to represent the maximum obtainable supply and would suggest, should demand for Factor VIII increase beyond present estimates and should plasmapheresis not be able to close the gap, that the effective clinical use of available supplies of Factor 8Y should then be monitored on a continuing basis.

(8) New R & D Facility

The proposals for a new Research and Development facility will be submitted as soon as the Authority is satisfied that the plans are fully justified and realistically costed. We are much encouraged by the sympathetic support which we received at the 1988 Accountability Review.

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(9) Pay Structures

We shall in the coming months be submitting to the Department our proposals, arising from the current job evaluation exercise, for a new integrated pay and grading structure which we are convinced is essential if staff of sufficient quality to achieve the agreed objectives of CBLA are to be recruited and retained. Despite the overt differences between BPL process workers and other NHS staff we shall, of course, do our utmost to maintain such parallels with existing NHS structures as are possible.

(10) Management of NBTS
(11) Transfer Pricing

The Authority welcomes the plans for future management of the NBTS and for transfer pricing. We believe that both steps will further a constructive relationship between CBLA and both the providers of plasma supplies and the consumers of our products.

(12) BGRL Transfer

We confirm that the planned moves of reagent manufacture to the BPL (Diagnostics) Division at Elstree and of Blood Group Reference and research to Bristol can be costed separately. We regard the move of BGRL to Bristol as a desirable and cost effective project and a detailed justification will be submitted to the Department in due course.

We will also appraise the move of BPL (Diagnostics) to Elstree and will embrace in that report an evaluation of the possibility that this activity might be sold to the private sector.

(13) Revenue and Capital Requirement in 1989/90

We note the comments on next year's funding requirements and are glad to see recognition of the necessity of providing funds for recurrent minor capital/replacement projects which are essential in any factory if it is to continue operation at maximum efficiency.

(14) Other Items

We note the other matters which the Department may wish to pursue with us and remain ready for such discussion at any time.

In conclusion we shall continue to do our utmost to maximise the contribution to the NHS which we are confident that the new factory will make possible.

I very much hope that the pressure of Ministerial and Parliamentary duties will not be so onerous that a visit to the Blood Products Laboratory is precluded. The invitation which I extended to you in June 1987 is most cordially renewed and I hope that we shall be able to welcome you to Elstree soon.

Yours sincerely,

GRO-C

R D Smart
Chairman

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