Spoke to Dr Walford 15.1.82. She will discuss with Mr Smart GRO-C 15/1

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Vol 2

DEPARTMENT OF HEALTH & SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-407 5522 ext GRO-C

13 January 1982

Mr R D Smart CBE
Director
Glaxo Holdings Limited
Clarges House
6/12 Clarges Street
LONDON W1Y 8DH

Dear David,

Thank you very much for your letter of 12 January conveying the extremely important news that Genentech have succeeded in producing genetically engineered human albumin. I believe your analysis of the situation is correct from the point of view of revenue implications, namely that it is unlikely that the synthetically prepared material would be any cheaper than that produced at the BPL.

I have no doubt at all that we must continue with our plan to rebuild BPL and that we should not be deviated from our course by this new development.

I do, however, agree that if Celltech can obtain a licence on reasonable terms a useful alternative UK source would become available. I would be very keen to pursue this matter with Celltech and would like to discuss with you how we could move this matter forward at an early date.

My secretary will be in contact with yours regarding our provisional date on the 19th January. I know that this clashes with your proposed visit to the West Country but if the bad weather persists that trip may be postponed.

With kind regards,

Yours sincerely,

GRO-C

E L Harris
Deputy Chief Medical Officer

c.c. Dr Walford
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12th January 1982.

E.L. Harris Esq., C.B., M.B., B.Ch.,
F.R.C.P., F.R.C.P.E.,
Department of Health and Social Security,
Alexander Fleming House,
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CONFIDENTIAL

Dear Ed,

Some information has come to hand which I think I should pass on to you without delay and with appropriate comments.

Last month, Richard Lawn and his colleagues at Genentech succeeded in the production of human albumin in bacteria and yeast using recombinant DNA methods. I understand that Genentech intends to deploy its resources (now by no means negligible) towards the introduction of this genetically engineered human serum albumin to clinical testing and large-scale manufacture.

It is difficult, at this point, to predict how long it will take Genentech to produce material of suitable purity and what price they will ask for it if they get clearance to introduce it to the market. There are obvious difficulties in the way in view of the fact that albumin from yeast will present problems in harvesting and it may even prove impracticable to get it to a sufficient standard of purity to satisfy reasonable clinical criteria, particularly since the dosages involved comprise many grammes of material. Stanford Research Institute in a recent paper suggests that the cost of producing human serum albumin by recombinant DNA techniques will be approximately equivalent to those generated by fractionation from donated blood. Kabi of Sweden contend that this is quite wrong and that Stanford has underestimated the cost of fractionated albumin. Whatever may finally turn out to be the truth in this matter, it seems to me that we have reached a point at which I ought to draw your attention to the possibility that genetically engineered human albumin may become available at about the same time, possibly even as early as 1985, as free supplies of Factor VIII from similar techniques are put on the market.

Until this point, we have tended within the Policy Steering Group to anticipate that Factor VIII produced by recombinant DNA techniques will become available during the 1980's but that this could be disregarded since Factor VIII produced by the conventional

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E.L. Harris Esq., C.B., M.B., B.Ch.,
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12th January 1982.

techniques designated for the Blood Products Laboratories of the Blood Transfusion Service can almost be considered as having been elaborated virtually at marginal cost in the process of providing the Blood Transfusion Service with its requirement of human serum albumin.

At the present time I do not believe that there is any organisation in this country which could produce human serum albumin by genetic engineering techniques unless a licence from Genentech were to be purchased. The validity of the patents needs examining and it might be worthwhile for consideration to be given to the acquisition of a licence by Celltech.

If commercial albumin becomes available, I suspect that the economic analysis of the role of the Blood Products Laboratory is altered only as regards its time-scale. An earlier paper suggests that a rebuilt BPL should be able to recover its costs within one or, at most, two years. Even allowing for any possible false comparison in the analysis made by S.R.I, it is doubtful whether genetically engineered human serum albumin will be available during the 1980's at less than 2/3rds the cost of the same product produced by conventional fractionation even if the former product can be isolated at appropriate purity during the decade. If that is the case, the arithmetic supporting the re-development of Elstree is merely moved 6 to 12 months further into the future; in the absence of BPL to provide conventional material, any commercial supplier would be able to offer his albumin and Factor VIII not on a basis of competition but on a basis of "take it or leave it - there is no alternative source". This might well result in a price which was not 2/3rds of that envisaged but at parity or an inflated level. It has been suggested that Genentech may try to produce the world requirement of albumin in their own U.S. plant; it seems unlikely that any government would wish to place itself in a position of strategic weakness by dependence on such a source of supply.

To summarise, I felt that the availability in posse of genetically engineered material should be drawn to your attention since it could make a difference to capital expenditure plans. However, I do not think that the revenue implications are altered substantially and would suggest that it could well be necessary to have a rebuilt BPL if the National Health Service is not to have a pistol held at its head, whether by American companies or even by a British company operating under licence.

If, however, Celltech could obtain a licence, on reasonable terms, for genetically engineered Factor VIII AND serum albumin, enabling the National Health Service to have an assured source of supply at a cost which was not inflated by opportunistic avarice, a great deal of capital expenditure could probably be saved.

With kindest regards,

Yours sincerely,

GRO-C