(K)

Reference .....

Mr Harley

BLOOD PRODUCTS LABORATORY: POSSIBLE TAKE-OVER BY INDUSTRY

I think it best if I confine my comments on the possible take-over of BPL by Beechams to purely technical and medical comments, although I do have major worries also about many other aspects of the proposals, as, I think, you yourself have.

1. The principal medical worry is presented by Beecham's intention to import plasma for fractionation. Unless it were Beecham's intention to process such plasma in an entirely separate plant or with complete duplication of all facilities in a single plant, it would be impossible to prevent contamination of the UK material with imported hepatitis viruses.

I must emphasise that 90% of all post-transfusion (and blood-product infusion) hepatitis in the USA and elsewhere is caused by non-A, non-B hepatitis viruses which (unlike Hepatitis B) cannot, at present, be detected by testing donor blood. This form of hepatitis can be rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage. It can also result in a chronic carrier state, thus increasing the "pool" of these viruses in the community.

In my view, the Department has a moral obligation to ensure that any collaboration with industry does not increase the health hazards, not only to recipients of blood products, but to the community as a whole.

2. If the DHSS did not agree to Beechams fractionating imported plasma other than in a separate plant etc, Beechams would probably feel constrained to obtain the necessary extra volume of plasma by buying it in the UK. That is, it is likely that the company would establish plasmapheresis centres in this country for paid donors and thereby seriously undermine the voluntary donor principle in the UK.

3. I have just visited PFC Liberton with colleagues from HS2. Although we have no formal information about its capacity to expand production, it was conveyed to us informally that Liberton had a substantial capacity for expansion, notwithstanding staffing difficulties etc. If Liberton were to take on $\frac{1}{4}$ - $\frac{1}{3}$ of the England and Wales fractionation requirements in addition to meeting Scottish needs, UK vulnerability in the event of Beechams pulling out would be reduced and the price of Beechams (or imported) products might be kept down. My impression from that meeting was that the Scots are very willing to consider UK fractionation as a whole and that, having provided the DHSS (through the SHHD) with detailed schedules of their products and performance since commissioning of the plant, anticipate expanding production by an agreed amount for the benefit of England and Wales. Perhaps, therefore, we should be very cautious before asking Beechams to provide totally for the requirements of England and Wales when we may not need it to do so.

4. I have just seen the tables on cost-benefit analysis prepared by FB. I think the paragraph 4 note to table 1 may underestimate the requirement

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of FFP for "self-sufficiency" for England and Wales. Dr Lane has said that he would need 500,000 litres FFP to meet anticipated demands for products. Each litre of FFP is made up of 5.6 "donations" of plasma (0.18 litres plasma per whole blood donation). Therefore there is a requirement for (500,000 x 5.6) FFP donations = 2.8 million FFP donations. Previously Dr Lane has given the FFP requirement as nearer 400,000 litres of FFP which is equivalent to 2.2 million donations. In the FB table, the anticipated need for FFP has been taken to be only 1.6 million donations.

I cannot comment on the figures arrived at for the equivalent 80/81 commercial value for FVIII and PPF because I'm not sure what prices have been used. However the minimum qunatities under consideration by FB should have been

FVIII : 90 m iu

PPF : 6,900 kg

and other albumin fractions.

Perhaps Mr Brechin could confirm that these were indeed the sort of figures on which the calculations were based and if not, what figures were used. I should add that the projected requirements for FVIII, which were based on advice given to the Department earlier this year, may have to be revised in the face of very recent evidence which indicates that UK clinicians are coming under pressure from various quarters to step-up the dosage regime for the home treatment of haemophilia.

GRO-C

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cc

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