[redacted] (04-07-80) July 1980

BLOOD PRODUCTS LABORATORY, ELSTREE

I visited BPL this week, not to inspect the factory but to attend a meeting of the technical committee.

It was apparent from the members of staff whom I met and who made a definite point of contacting me on the future of BPL that their morale is extremely low; worse than when the original inspections were being carried out. Staff are extremely worried about their future and cannot generate any confidence in the Department's handling of affairs in the absence of any real progress or change since the inspections were made.

Points I noted in my mind at the time were:-

1. Upgrading, as outlined in the Inspection reports and subsequent correspondence, must be implemented to ensure that production at current levels even is carried out to acceptable standards.

2. We must be reasonable and agree to production being expanded to handle the additional supplies of plasma which are being planned for by the Regional Transfusion Centres, but this can be agreed to only if the facilities are upgraded. Any increased production under present conditions will worsen the position further as any expansion will have to be met by the present one-shift working day and already the BPL is overcrowded and cannot cope adequately with the existing work load.

3. I am lead to believe that there will not be any co-operation from Regional Transfusion Directors in organising additional supplies unless there is a guarantee of additional finished products being returned to them. Hence BPL must be capable of processing any additional supplies of plasma made available; the plasma cannot be stockpiled.

4. The increase in plasma donations by Regional Transfusion Centres can only be built up progressively on an annual basis if adequate quantities are to be available for any new plant, say in 5 years time. The build-up must therefore start as soon as possible as it will be impossible to expect adequate supplies if the increased requirement is delayed until start up of any new facility. However, unless the BPL facilities are upgraded to a minimum acceptable standard required by Medicines Division then increased production cannot be approved.

5. Without increased production and associated upgrading of BPL then staff will become even more despondent with a real possibility that key staff will resign. Once this decline sets in it could be progressive and quite quickly we could see a situation where the BPL is unable to operate.

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The alternative will then be to import NHS requirements if such supplies are indeed available, and there are also grave doubts whether quality of overseas production will be acceptable. My experience of overseas plants generally leads me to believe that quality standards will be no better than those at BPL. Some of the Elstree staff told me that on recent visits to the USA they had visited fractionation plants in which the manufacturing conditions were worse than those at BPL.

6. It is commonsense to consider Elstree and Liberton as complementary manufacturing sites for the UK and not as two entirely separate situations, which appears to be the present policy.

Liberton does not have sufficient capacity to process English/Welsh requirements but it is capable of being brought up to an acceptable standard more quickly than Elstree. If it were up-graded quickly then some plasma for England could be processed there whilst short term upgrading at Elstree was being implemented. If additional plasma supplies were made available next year from Regional Transfusion Centres this could be one way of processing them more readily and may be give Regional Transfusion Directors an incentive to collect more plasma immediately.

Quickly reading through the draft submission I see there isn't any reference to provision for the appointment of additional key staff, which was one of our major recommendations.

Para 14, page 3, proposes a possible reduction in the £0.5m expenditure if a new plant could be built in substantially less than 5 years. Such a building development is practically impossible and should be discounted. In any case BPL must be upgraded in the immediate short term irrespective of long term intentions and the minimum requirements have been outlined elsewhere and presumably costed. The requisite financial approval for this expenditure is needed now.

Para 8, page 2 refers to cleaning, ie "thoroughly cleaned and to be cleaned regularly".

The cleaning specification which we agreed was the best that could be achieved in an unsatisfactory building. I stressed at the time that the perforated ceilings in the production areas were totally unsatisfactory, could not be cleaned on the upper surfaces where moulds were growing, they were gradually falling apart and this deterioration would be progressive, and our supplies came through the ceiling voids cooling pipes above the ceilings were also causing serious condensation problems. Superficial cleaning is inadequate in such a situation but the only alternative was to shut down production and install new ceilings and air systems. I advised continuation of production on the basis of a new factory being built and operative in about 5 years time. It is false and dangerous to imply that the revised cleaning programme has produced a safe system.

I also doubt if Training has had any real impact. On my recommendation some senior staff visited the Roussel and Roche factories to see industrial production but more training than this is required.

Para 13, page 3, refers to "safe handling by means of a new 1 litre pack".

I believe the pack size is incorrect as the packs concerned will be single donation packs (200ml approx). There are new packs developed by Travenol Laboratories USA, using a new design, new plastics material and specially designed equipment for opening them under clean conditions. This is a monopoly industrial development. I understand from Dr Lane that the machinery is being shipped here from the USA and has been tested but not under working conditions. How much is known about the new plastics material, what testing has been undertaken for stability, compatibility, leaching of extractives, shelf life, and how soon will the data be available to DRSS for evaluation.

These bags are to be used for fresh-frozen plasma only, whereas time-expired plasma will still be required and will need to be handled under different conditions at BPL as I understand that the Travenol bag opening machinery can only deal with the new plastics bags.

How are the existing conventional supplies to be handled for entry to the clean rooms. I suggested a process of alcohol spraying or dipping which has been developed by the Liverpool Regional Transfusion Centre in collaboration with Envair and which has been incorporated into the new aseptic facility at Liverpool Regional Transfusion Centre. I learned this week that the Health and Safety Executive has refused to approve the process due to possible explosion hazard. This decision may have to be contested but in the short term it could affect how Elstree and Liberton handle plasma packs as Liberton are using an alcohol bath already.

The so called 'safe handling' referred to in para 13 needs to be examined and will take time. It is an over-statement to claim that it will meet the majority of the Medicines Inspectorate's most urgent safety requirements as it deals only with the clean up of bags before handling in the clean room.

I attach manuscript notes from [redacted]

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4.7.80