Mr Harley
I'm content for you to sort this out,
but please agree your line with Finance. GRO-C

Reference Mr Dutton H/B13/6 42A
You are pursuing. GRO-C 26/11

Mr Harley

NOTE OF A MEETING HELD TO DISCUSS ENGLISH PLASMA FRACTIONATED BY PFC, EDINBURGH

I met with Dr Lane at BPL, Elstree on 14 November 1979 to discuss what was to be done with the 27,000 bottles of PPF fractionated by PFC from English plasma, which were currently being stored at PFC.

Dr Lane said that the product prepared by PFC was below BP standards for protein content and contained protein impurities which could prove a hazard to patients. Dr Lane explained that patients having repeated therapeutic plasmaphereses who had previously received replacement therapy with BPL plasma, might exhibit severe sensitivity reactions to the PFC product because of prior sensitization to certain of the proteins which were present as impurities in the Scottish product. This sort of hazard had occurred recently in England when a patient who had previously received many treatments with the BPL product, received instead a Commercial preparation of PPF. The patient suffered a very severe reaction to the commercial product and had to be resuscitated with several bottles of BPL PPF. Dr Lane feels that his position at present in relation to the Medicines Inspectorate's report is so vulnerable that he cannot afford to issue to clinicians a product about which he has grounds for concern in relation to patient safety.

I discussed with Dr Lane the options for utilizing the PFC product. Dr Lane said that either he or Dr Watt could re-process the Scottish product to produce pure albumin. He felt sure, however, that this would be construed as a 'slur' by the Scots. The alternative would be to let the Scots, use the product for patients in Scotland. They had already administered some of this material to patients and were quite content as to its safety. /I can confirm that this is so from a discussion which I have had with Dr Cash. Dr Cash also told me that they had measured pre-kallikrein activator levels in the product and that these were satisfactory. From what Dr Cash had said, I gained the impression that the Scots would be happy to use this material in Scotland./

Opinion

This has been a rather unhappy experiment in which there have clearly been technical problems experienced in Scotland. The 20,000 litres of plasma were sent to Scotland in the first instance, not because of they were surplus to BPL's fractionating capacity but because BPL was having problems with its cold storage. The experiment although for the most part unsuccessful, should, in my opinion be looked at as a pilot study to determine the parameters which would enable PFC to produce, from English plasma, a product acceptable for use in England. /The Scots/English product contains even less protein than the usual Scottish HPPS!./ Various technical lessons have been learnt from this venture but it remains to be determined whether PFC could, by their different method of fractionation, produce a product comparable to that produced by BPL. This has fundamental implications for any future coordinated UK fractionation effort.

I suggest that the practical solution to an embarassing impasse is to allow the Scots to use the England - derived product in Scotland, which they are apparently willing to do. The use of this product in Scotland can then be offset against the cost of processing the plasma. It may be argued that DHSS has invested £400,000 in Liberton and that they are now adding to that investment some 27,000 bottles of PPF without recouping anything. I suggest that the latter will be plasma (!) well spent if it succeeds in smoothing over

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relations between the two Directors and will be in tune with the new spirit of cooperation that appears to be emerging between SHHD and DHSS on the subject of UK plasma fractionation.

For the future, I think it important that all BPL and PFC blood products should be subject to Product Licensing (or its administrative equivalent) so that there can be no further dispute between the Directors as to what constitutes 'correct' product specifications. Each product will be prepared to its own licenced specifications and to BP or EP specifications as appropriate.

Action required

Will you please agree that the product prepared in Scotland from English plasma can be released for clinical use in Scotland?

GRO-C

DIANA WALFORD
Med SM4
Room 919 HAN H
Ext GRO-C

November 1979

cc
Dr Oliver
Mr Wormald ✓
Dr Tovey
Mr Dutton