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Professor John D Cash
National Medical Director
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Dear John

PLASMA SUPPLY/ALBUMIN PRODUCT DEVELOPMENT - POSSIBLE EFFECT ON PRODUCT SUPPLY

I believe it is important to draw our collective attention to two emerging factors which together may conspire to lead to non-self sufficiency in albumin products in due course - unless avoiding action is taken.

1. Plasma Supply 87/88

I have become aware that there is a sustained reduction in blood donations being collected particularly in Edinburgh and Glasgow. I do not have any specific up to date data but I am led to believe that the downturn in donations is significant (5-10%). In response to this information I have assembled a half yearly plasma supply summary as follows:

	ABN	BEL	DUN	EDI	GLA	INV	TOTAL
Ap – Sept 6 Month Intake (All Plasma)	3276	6468	2654	6989	15512	1968	36868
Target (All Plasma)	3002	7232	2380	8336	15966	1960	38876
% Shortfall	+8.3	-10.6	+11.5	-16.15	-2.84	+0.4	-5.17

It is clear that there exists a shortfall in supply against agreed targets and assuming one can extrapolate to a full year's intake, this shortfall amounts to 5.17%. However, this shortfall has occurred predominantly within the quarter July-Sept and this shortfall may be a gross underestimate by as much as 100%. The WBTS has indicated to me that they are seeing a sustained 1500-2000 donation per month drop in intake which could amount to 5000 kg plasma per annum.

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Our Target for Fresh + Cryo/Cryo for 1st 6/12 = 7875

Comparative figures for 1986 and 1987 are as follows:

	1986	1987
Jan-Mar	20054.6	19671.3 (-2%)
Apr-Jun	19569.9	19205 (-1.87%)
May-Sep.	19681.7	17908.2 (-9%)

Directors may be aware of the reasons for this reduction in donor intake and may be able to advise that compensatory action is being taken to bring us on course for the remainder of the year.

2. Development of New (High Purity) Albumin Products

You will recall that the Directors agreed that PFC should further accellerate its efforts to develop a new albumin product (common product in 4.5% and 20% formulation) in the light of elevated aluminium (and other metal ion) contamination and high MW aggregates in our existing materials. We have now carried out the first large scale evaluation of a process designed to reduce aggregate levels to within pharmacopoeial limits (New EP), increase purity to ≥95% and reduce metal ion contamination by 10-20 fold over existing levels. The data from this experiment is not yet available but Peter Foster has outlined in the enclosed memorandum a number of scenarios which merit consideration in the context of supply and demand. Most importantly perhaps is the observation that an increased purity from 90% albumin to 97% albumin will alone result in product output loss of 7% since formulation is based on total protein content. Hitherto SPPS has contained 10% non albumin protein. Peter's subsequent scenario (3 to 5) are of course speculative, but nevertheless his proposal that we should base our planning on 5-10% decrease in yield does not seem unreasonable. Further large scale process experiements should permit a more accurate appraisal of yield losses - if any.

Against this background a number of SNBTS options can be considered:

1. Take no action and maintain supply of both SPPS and human albumin in their present form. This will leave us vulnerable to regulatory, pharmacopoeial and clinical criticism and market forces will undoubtedly force change. In addition the existing human albumin product consumes resources which are shared with IV IgG capacity.

2. Delay implementation of process modifications until yield losses can be reduced as close to zero as possible. Timescales for this are not yet available.

3. Collect more plasma as a matter of urgency.

4. Introduce new process as planned (approx April 88) and temporarily compensate for yield losses by processing plasma stockpile to provide a

period within which process refinements and improvements can be made (12-18 months). This will place considerable strain on processing capacity and almost certainly will require an extended working day.

5. For the immediate future seek only to remove metal ion contaminants and shelve plans for increased product purity. This will require a complete reappraisal of the process and will limit plans to increase IgG output.

6. Explore the possibility of different range of dose sizes eg 100 ml, 250 ml and 500 ml. This may reduce demand by tuning product range to specific requirements.

7. Launch a campaign to control inappropriate usage and restrict supplies.

We have an agreed objective for albumin product improvements and we should perhaps not be deflected at this stage. Accordingly I would suggest that a combination of 3, 4, 6 and 7 is required over and above the requirement to bring plasma input back on course.

In any event this topic requires urgent discussion by Directors and I would be grateful if you could arrange for discussion at an early date.

With kind regards

Yours sincerely

GRO-C

DR R J PERRY
Director

cc RTD's

Ps. I enclose a recent letter from Dr Hopkins on this topic.