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Dear John

SUPPLY OF FACTOR VIII CONCENTRATE

The decisions on distribution taken a year ago should come to be reviewed about this time in light of available knowledge of the year ahead.

The plan of last year was that we should abandon "pro rata" in the absolute sense and revert to a pattern of distribution established in October 1981 so that a stockpile should accrue at PFC against expected lean times associated with renovation. With the exception of the South-East all regions have established a reasonable stock of Factor VIII.

QUARTER.

During 1982-83 PFC has continued to modify and improve the recovery process and has started to move toward a totally new packaging system. Issues have been of the order of 6 000 - 7 000 vials per month each containing an average of 270 IU/vial although the range of values has narrowed only slightly. From January 1983 we have trimmed back on the fill volume to accommodate the smaller vial and with the intention that 95% of all lots will have a value in the range of 200-250 IU/vial with a mean of 230 IU/vial. 2-5% will be above and 2.5% below this range.

During 1982 the quantity of material in process at PFC has, risen from 6 000 to 18 500 kg of plasma equivalent with about 12 000 kg equivalent being product in the final container ready to pass to labelling and issue. At present there are 8 460 vials at this stage. This product is not labelled and packaged because of storage bulk but represents the national stock and could be brought to issue very quickly if needed.

We/

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We are now at a stage of development where package redesign makes economic sense and a design is awaited. This will involve two trays within an outer cardboard sleeve. One tray will hold ten vials of Factor VIII and the other ten vials of water for injection. All printing will be on the outer sleeve but trays could be separated for storage at 4° and room temperature. Design study has included consideration of the dimensions of domestic refrigerators. This package will reduce the storage problem by about 70% of bulk volume.

I would like to propose that, for 1983-84, we start the year by issuing Factor VIII in the proportions of plasma received at FFC in October-December 1982. If this system had been used in that quarter the issue distribution would have been:

<u>Region</u>	<u>Plasma Input Kg</u>	<u>Age of Total</u>	<u>Possible Factor VIII Issue/Quarter</u>	<u>Per Month</u>	<u>Package Correction</u>
Aberdeen	672	6.2	424.7	141	140
Belfast	945	9.0	616.5	205	200
Dundee	686	6.3	433.4	146	150
Edinburgh	2233	21.0	1433.5	479	480
Glasgow	5615	52.1	3575.7	1191	1190
Inverness	611	5.4	390.5	130	130
<u>Total</u>	<u>10762</u>	<u>100.0</u>	<u>6284.3</u>	<u>2202</u>	<u>2280</u>

I propose that a distribution on these lines would be more equitable than previously and could be re-adjusted in October by using the plasma intake for the quarter June-August to calculate the adjustment on the same basis.

These proposals are on the assumption that plasma volume only is used in calculation. It is not practicable to use the HBTIS system of using regional yield to make a calculation on quality as well as quantity because it would be inequitable due to the difficult storage times. However I would propose that only 90% of the Fresh Frozen (18 hour) plasma should be applied since yield is known to be less for this category of plasma.

During 1983 we hope to reduce plasma storage time at FFC to about 15 days maximum but this may be difficult with intercurrent renovation also in progress.

The new packing should affect storage so that regional centres could hold larger stocks and I would like to see the product which is issuable but not issued from FFC transferred gradually to regional stock to create dispersal of the national reserve.

During/

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During the period from April 1982 to the end of January 1983 the mean net yield of Factor VIII per kg of plasma processed has been 250 IU/kg. This compares with the expected 300 IU/kg and actual 260 IU/kg for 1981-82 and indicates that the downward drift in plasma quality has not been arrested.

With kind regards.

Yours sincerely

JOHN G HATT
Scientific Director

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