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BLH/5 vol 1

3574 Room 1208

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BLH/5

28 October 1981

Dear Ken

Thank you for showing me the paper prepared for your Blood Products Sub-Committee. I found it very interesting, particularly the 2 graphs. I have set out some comments below but would stress that these are very much my personal reactions. I have not cleared them with colleagues here in the Department. Please feel free to take them into account or ignore them as you think fit. Though there is nothing in them which could be regarded as confidential, please do not regard them (particularly the figures) as official DHSS estimates.

PRODUCTION FIGURES

I have not had an opportunity to check your figures against our files. They seem reasonably accurate except that it does seem that you have used UK figures for demand but England and Wales figures for production of cryo and Factor VIII. Should not your NHS production figures take into account the output of PFC, Liberton together with the cryo prepared by Scottish Transfusion Centres? I am sure that John Cash (Scottish National Medical Director) would be happy to provide figures.

FUTURE TRENDS

The juxtaposition of your first 2 sentences in paragraph 8 seems to make nonsense of their content. Are you perhaps saying that even relatively recent estimates of demand for Factor VIII by the early 1980s have proven totally inadequate? After all, if demand is 50 million international units why are we producing/buying 27.7 million?

TABLE 1 PAGE 9

I think it might be better to assume 100 mls of plasma per donation and a yield of 225 units per litre.

PROJECTED DEMAND/SHORTFALL/COST

The table in paragraph 10 does not seem to take account of cryo production. On the question of "cost of supplying shortfall" this is a particularly difficult area. I have seen some Companies quoting 12p per unit for Factor VIII equivalent to that produced by BPL. Since the cost is determined by so many market factors, it might be useful to give a range in column 4 say between 8p and 12p per unit.

INCREASING PLASMA SUPPLY

In 11(a) is it worth pointing out that above a certain level, this option would lead to the whole-scale discarding of red cells and might therefore be unacceptable? On 11(c) your figures relate to machine plasma-pheresis. Manual pheresis yields 200 ml (single) or 400 ml (double). Manual pheresis has some advantages particularly in terms of being cheaper to set up. It might be worth making the point that there is the choice between machine and manual. You might also mention the WHO recommendation that 15 kg is the maximum volume of plasma which should be collected from any one donor in a year.

Turning to 11(d) there is a possible correlation between the quality of plasma (which is determined by a number of things including how quickly it is frozen) and the yields which can be obtained from it. Aren't you in danger of raising false hopes if you mention the possibility of tripling the yield? As you will know, the current manufacturing processes involved in certain exceptionally high yield products would not be acceptable to the Medicines Inspectorate in this country.

I hope you find these comments useful. I have kept a copy of your paper but return this one because it seems that it contains the "originals" of your graphs.

Best wishes.

Yours sincerely

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