

DRAFT

Mr M Harris HS1

From: Dr H Pickles
Med SEB/B

Date:

Copy: Dr Harris
Mr Hart
Mr Heppell
Mr Cashman HS
Dr Moore HS1A

CBLA

1. I still have difficulty with the proposals outlined in your draft submission of 21 October if all that Dr Lane has coming to him is a "severe reprimand". I have found Dr Lane devious and difficult and I would be less generous than you have been about his supposed scientific excellence. Like those RTD'S who were present when he informed the plasma supply working party that the figures had to be revised yet again, I am unable to accept at face value again any facts or figures from him. If Dr Lane is to remain at BPL and with his existing duties, then I would need to have defined carefully the limit of my own responsibilities in giving professional advice to HS.

2. PS(H) told us she would not be satisfied unless Dr Lane was sacked. I agree with you that this would not be the right response, and in any case I doubt whether it would be feasible to find grounds that would stand up in the event of a challenge. The

Chief Executive (who must carry some responsibility too, at least for the figures in this year's accountability review) could be invited to submit proposals for so marginalising Dr Lane at BPL that he becomes irrelevant to the main business. If Dr Lane then resigns in disgust, so be it.

3. I have several more minor points on your draft and these are attached. Overall, I am more critical of CBLA than you have been. Perhaps this just reflects my limited experience in dealing with them and the fact that those "mistakes" that have come to light during my time (the last 6 months) do not have ready explanations in terms of new safety requirements or new demands from us.

4. Can I repeat my request to be involved in future in any dealings with the Chairman and others at CBLA.

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DRAFT SUBMISSION ON CBLA

Please copy to CMO's Office
Do the Welsh Office need to be informed too?

Para 1. "The good news"

The processing is now at more than the capacity that was originally planned. Some would argue, with the late completion of the factory, the heat treated product has been late not timely. Do we only have Dr Lane's view on comparative yields, and are all these calculated in the same way?

Para 2.

These are annual demands, of course

Para 3.

Demand may not "go on increasing unless clinical practice changes"; demand will only go on increasing if clinical practice changes. The effect of HIV mortality is also relevant but will not have much impact in the next 3 or 4 years.

Para 4.

The maximum capacity of BPL is a very important factor. The NBTS may excell itself in a couple of years and produce plasma at the per capita rate of the Swiss. I have suggested to Dr Moore we should get CBLA to re-examine the arguments about all-night working: with foreign factor VIII being increasingly expensive this may now be economic, even if the surplus albumin does not find a ready market.

Para 5.

Are we clear what CBLA now believe to be realistic current net yields? 130 iu/kg was calculated when the process yield was said to be 140 iu/kg (making allowance for 7% loss from net weight). But more recently Dr Lane gave 145 iu/kg as the usual process yield.

Para 7.

These yields are also lower than we were led to believe were actually being achieved in the new factory. They had already started there at the time of this year's accountability review.

Para 9.

Individual batches have achieved process yields above 180 iu/kg, or so we have been led to believe.

Para 10.

Se my comment above re para 7. On the 12 July, the figures we were given were based on experience in the new factory. So there is no excuse for getting them wrong. Can anyone provide for me the true figures from commercial fractionators?

Para 14(b)

Isn't there a better alternative to "wind up", which could be ambiguous.

Para 16.

I dispute the first 2 sentences. Dr Lane has confessed to me that he has been deliberately over optimistic because he thought this is what we wanted and it would be good for staff morale. The best available estimates were not used at this years accountability review.

Para 20.

This ignores Dr Lane's current poor relationship with the RTD's , his lack of credibility in some circles and the difficulty some of us will have if we have to continue to rely on him in the future.