NQA/7/11

1. Dr Scott
2. Dr McIntyre

... Herewith for your information a note of the recent meeting of the CBLA R & D Committee, along with the agenda and papers.

I leave it to you to decide whether further circulation to CSO or Group D is appropriate.

GRO-C

A E BELL
10 November 1983

Room 25
Extn GRO-C or GRO-C

NOTE OF MEETING OF CBLA CENTRAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN BLOOD TRANSFUSION HELD AT ELSTREE, 7 NOVEMBER 1983

I attended this meeting as SHHD observer. Dr McClelland was present as a member. Dr Clark attended as DHSS observer in place of Dr Walford (whom I was told was in India).

The meeting commenced at 11.30 am and continued till after 4.00 pm, with a break for lunch. Having regard to the considerable cost of such a meeting one cannot at this stage be fully convinced as to its value. Most of the members are very able, and some quite distinguished, and it will be interesting to see what the future attendances are like.

The following notes relate to agenda items:

Item 3.1 Dr Lane reported that it had been ascertained that there was no procedural obstacle to BTG funding an enterprise such as BPL.

Dr Thomas (who had not been present at the first meeting of the Committee) expressed considerable interest in budget sources. This led to a discussion of the need for funding clinical trials of new products. (This is a problem that Dr Cash has discussed in the past). It was agreed to be unsatisfactory to have to rely on MRC to fund such trials. Dr Lane mentioned that the income from the BPL RIA test was £560K per annum with manufacturing costs of £170K. He reckoned that £350K could be allocated for development work from this source (I don't know what happened to the other £40K) if the Treasury could be persuaded not to take account of this income in making its revenue allocation.

It was agreed to make a strong recommendation to the CBLA that development funds were needed and should be provided for such work as clinical trials. I asked that it be noted that this was a UK problem not limited to BPL.

Dr Lane mentioned that next year the CBLA would be funded as a health authority and not as at present direct from the Treasury. He pointed out that health authorities usually had an R&D budget.

Item 3.2 It was reported that the CBLA had been informed that there was no suitable genetic engineering expertise available at Porton. However Dr Clark said that CAM R would be able to carry out production developments if they were given a clone. Professor Bloom doubted this, saying that CAM R did not have the kind of expertise necessary to cope with glycolisation and carboxylisation steps. Dr Luzzatto agreed and pointed that the separation between cloning and further development was not clear cut.

With regard to genetic engineering of coagulation factors Professor Bloom considered that the NHS would be 3 years behind Genentech. Dr Luzzatto stressed the importance of the science and production technology being brought together. He mentioned that many parts of the factor VIIIC structure had already been solved, but without publication because of commercial interests. It was agreed that Dr Rizza should discuss this with Professor Charles Brownlea of Porton who had an association with his unit in Oxford. It was also agreed that Dr Lane should take up with PHLS (after clearance from CBLA through Dr Harris) the question of identifying exactly what Porton could be expected to do.

Item 4. Paper 83/3 from the Working Group on AIDS was the focus of discussion. With regard to recommendations a.-d. on page 2 of the Working Group minutes it was reported that DHSS was considering distribution of the AIDS leaflet to special clinics, and noted that there were financial considerations - the present distribution had been funded from the publicity budget of the BTS. It was said that the Health Education Councils had been approached and that contact with Gay Societies should be left for local consideration. With regard to the content of the leaflet some doubt was expressed as to whether the message was being got over and it was mentioned that Dr Gunson and Dr Walford intended to consider a revision before the next print. (With Dr McClelland on the AIDS Working Group, chaired by Dr Gunson, I think we can rely on there being consultation with Scottish interests).

The discussion on surrogate tests for AIDS centred mainly on anti-HBc screening and Dr Fraser said that Bristol was going to carry out another 10,000 screens prospectively but in this case excluding the prison population. Of the 75 positives reported in the minute (page 2) 48 were prisoners but it was not known what the total prison population was.

Dr McClelland commented on the ineffiency of HBc screening, which was only a surrogate marker identifying a sociological group. Dr Gunson pointed out that HBs/Ag was also a very inefficient screening test. It was noted that HBc was the only screen seriously considered and that the others (page 3 of the minute) were not at present sufficiently promising. Dr Tedder thought that HTLV might be a rare opportunistic infection in homosexuals.

With regard to transfusion practice in relation to AIDS it was considered that non-A, non-B hepatitis provided a useful model for pilot trials because of its short incubation period. Small pool apheresis was suggested as a potentially significant strategy, within transfusion practice, in combating AIDS. It was commented that the development of filtration plasmapheresis offered a cheaper prospect than the present generation of machine plasmapheresis.

With regard to treatment to eliminate micro-organisms it was reported that dry heat treatment was disappointing for factor VIII, compared with the success of wet heat for albumin. Dr Lane said that small quantities of heat treated factor VIII were available from BPL, without stating the technology employed. Professor Bloom welcomed the potential availability of a British heat treated factor VIII, which haemophilia directors would prefer to use on virgin haemophiliacs rather than US products. Incidentally Dr Lane commented that he saw no need for a loss in yield from heat treatment greater than 10%.

Again the plea was made for funds for clinical trials [though I am not clear in this case where the great cost arises]. Professor Bloom also mentioned the possibility of doing pharmacokinetic studies on "old" haemophiliacs.

It was noted that Professor Bloom was a member of the MRC Working Party on AIDS and should therefore be brought on to the CCRDBT Working Group. Professor Bloom mentioned the membership of the MRC Working Party chaired by Dr Tyrell, and presumably known in SHHD who it was reported had a representative. One of the members is a Professor Murray of Edinburgh. It was noted that Professor Bloom was the only "blood" specialist on the MRC Working Party and recommended that there should be a transfusion representative. I understand that Dr Harris is taking this up with the MRC.

Item 5. This concerned the use of Scottish anti-CMV in a trial conducted in Sheffield. This arose from a request to PFC for anti-CMV for a particular patient who was critically ill, leading to a proper trial with full protocol under the control of one Colin Brown. In considering the source of plasma for anti-CMV, ie likely to be high risk donors, it was noted that this was a therapeutic and not a prophylactic trial, and any risks were believed to be justified.

Dr Lane said that he had supplies of CMV IgG but was refraining from using it because of his findings of non-A, non-B transmission with I/V IgG (see item 7 and letter in Lancet, also Dr Cash's reports on different downstream technology employed in PFC and BPL.) Dr Lane could reprocessed his serum using pepsin and pH4.

Overlapping with item 7 Dr Thomas stated authoritatively that there was plenty experience of I/V IgG without problems.

Item 6. This related to the abortive exercise started off by the MRC Blood Transfusion Research Committee when Dr Cash met great difficulty in getting trials of albumin V crystalloids off the ground. There was reference to the collaborative exercise between the SNBTS and Dr John Settle with regard to the use of modified SPPS for burns treatment.

Item 8. Dr Thomas came back to his earlier questioning about the funds available to the CCRDBT and questioned the functions of the Committee in the absence of any capacity to draw on funds. This ground had been coveredat the first meeting and while Dr Thomas' points were valid they did not break any new ground. Since he is a member of the parent CBLA he might have been expected to have the answers rather than the questions. There appeared to be a tacit agreement that the viability of the Committee without access to funds was questionable, but that it should be given a chance.

Item 9. It was hoped to have the next meeting before the March meeting of CBLA, and Tuesday, 28 February 1984 was tentatively agreed.

GRO-C

A E BELL
9 November 1983

Room 25
SAH