Glasgow and West of Scotland Blood Transfusion Service

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RM/GQ

25 August 1989

PROTEIN FRACTIONATION CENTRE
Received 31 AUG 1989
File No:

Professor JD Cash
National Director
SNBTS HQ
21 Ellen's Glen Road
EDINBURGH

Dear John

ORTHO CHIRON MEETING
LONDON 23 AUGUST 1989

At your request, Eddie Follett and I attended the meeting organised by Ortho Diagnostics in London. For ease of reference I attach a copy of the Agenda which was discussed. The meeting was attended by Dr Harold Gunson, Dr Marcela Contreras and Dr John Barbara.

Mr Davis of Ortho started the meeting by giving a statement concerning the recent release of the HBc antigenic material to Abbott Laboratories. Apparently Johnston & Johnston, who own Ortho, had contracted with Chiron to produce a test for alleged non-A, non-B hepatitis. Johnston & Johnston had put considerable money into Chiron and were anxious to recoup their commitment. For this reason Abbott Laboratories would not receive material until 1990 and it was unlikely that they would have any clinical trials done before the second half of that year. In exchange, Johnston & Johnston had extracted a Royalty from Abbott Laboratories and had ensured that Abbott would not develop any form of tests similar to that of Ortho. Johnston & Johnston recognised that introduction of a bead test by Abbott would mean a considerable loss of their American market but it was arranged that Abbott would at least be one year behind in the availability of any such test. The Royalty was designed to prevent any cheap tests being made available although it was recognised that other Japanese interests may come on to the market. Certainly Abbott cannot start clinical trials until at least July 1990.

A press release was tabled which had been given in Wall Street on Friday 18 August. Dr Gunson took charge of this and agreed to send photocopies to those present. I will send this when I receive it, if it does not catch up with this letter.

Ortho were keen to emphasise that there was no takeover or merger with Abbott Laboratories and that there would be some collaboration on blood banking and instrumentation.

Mr Davis then moved to the real purpose of the meeting and asked a number of questions. I will itemise these and indicate the responses given by the persons who were present from the Blood Transfusion Service:

1 Has any decision about blood testing been made? If not, how is it to be made and if any other information is required from Ortho Laboratories?

The answer was given that no decision had been made. That the decision would be subject to the advice of the National Advisory Committee on the Virological Safety of Blood. If the Advisory Committee were to make a recommendation, then this would go to Ministers in England and Scotland for a final decision. It was made clear by us that no decision was possible before the October 17 meeting which was to follow the Rome meeting which some Transfusion Directors were arranging to attend with their Senior Technical staff.

2 Mr Davis then moved to the position of 'What if a decision were to be made in favour of doing the test? What would be the time and events schedule? Would there be a simultaneous announcement or a phasing and would any preparation be needed?'.

We explained that <u>if</u> such a decision were to be made, then the UK would move in unity and that there would be a simultaneous announcement as happened with the HIV antibody testing. We explained that there would be other events and preparations not connected with the introduction of the tests, such as the arrangements for counselling of donors, the staffing and other matters which you have raised with the Management Committee of the CSA on the PES submission this year. Dr Gunson indicated that he had asked the English Transfusion Directors to put to him within the next 6 weeks, a submission for the likely costs in individual regions. Ortho indicated that they would be willing to run training seminars in various parts of the UK, so as to give individual Directors and their Senior Technical staff familiarisation with the technique. It was agreed that this could proceed at no commitment by the Blood Transfusion Service or HM Government so as to give Directors an opportunity to assess the likely cost implications <u>if</u> the tests were to be recommended and accepted. Dr Gunson indicated that individual Directors were free to take a small amount of kits from Ortho in order to get hands-on experience, just as was done with the introduction of anti-HIV testing.

I indicated that, whilst I was willing to host a meeting in the Glasgow Centre, there was little likelihood that the Scottish Transfusion Directors would wish to have any kits in the foreseeable future until a decision was made. A video tape had been produced by Ortho which would be made available to individual Transfusion Directors and their Technical staffs (I have since received a copy of this from Dr Marcela Contreras). Dr Gunson indicated that he would approach the Director of the National Procurement Directorate with a view to determining that, if the meeting on the 17 October made any recommendation, that the National Procurement Directorate might commission a number of laboratories to do an in depth study on donor prevalence for repeatable positives in the Chiron test. Ortho were obviously keen to know the total number of kits that might be needed but I did not commit Scotland to any such arrangements except, note, that the National Procurement Directorate would be a useful source of funding in the short term to give some hands-on experience of mass screening of blood donors.

3 With only 18 weeks left in the 1989 budget of Ortho, Mr Davis indicated that there were practical considerations on supply and pricing. In order to be an incentive to the BTS, it was suggested that if a decision was made soon ie by December, then the 1990 prices would be held at the 1989 level. Alternatively, the 1990 price would be up by about 6p-7p ie about £1.60 per test. Various options about combined sales and bundling of Ortho technology was discussed but this did not have much impact and early purchase options, looking one or two years ahead, were purely hypothetical as were ideas of lend-leasing etc. It was emphasised that Ortho needed to have a confirmatory test and they indicated that this would be available in time for the Rome meeting. We, in turn, indicated that we would be having a discussion after the Rome meeting in order that, by early October, the Advisory Committee would have reports from the Blood Transfusion Service on the latest, updated information so that the Committee might be able to make a realistic decision. Ortho indicated that of course, an early decision could save between £200,000-£400,000 per year. We were not entirely convinced by this argument. They indicated that the Federal Drugs Administration in the USA had not yet given approval to the test which was expected to be approved within the first 60 days of 1990. Thereafter, the USA would start testing on an individual blood bank basis. We were surprised at this and said that we did not understand why Britain was being asked to rush ahead of the United States since, in the past, we had tended to be somewhat behind the USA decisions.

Dr Gunson facetiously remarked that perhaps a start-up date of March 25 1990 would secure all of the 1989 pricing incentives.

4 Ortho then moved to the training needs and other associated back-up programmes. It was indicated that the Blood Transfusion Service would need some kind of turn-key system and that training was not a problem since most of the technology was well known to Blood Tranfusion Centres. They indicated that they would still wish to do a kind of road show for the appraisal of equipment, probably towards the end of September. We in turn indicated that there was a meeting of the British Blood Transfusion Society in Durham at which Ortho were demonstrating their equipment and that this would form a useful opportunity for Directors and others to see and discuss the arrangements. It was also agreed that we would have a meeting with Ortho on the afternoon of the last day when the meeting had finished ie Friday 22 September. At that time we would have returned from Rome and had the opportunity to discuss and think about the problems of donor counselling etc and perhaps be able to more clearly make recommendations to the Advisory Committee meeting on 17 October.

5 John Barbara presented the figures from the NE London Transfusion Centre studies and I presented some of the figures for Glasgow and Scottish figures, indicating a prevalence in the repeatable positive testing of the order of 1:150 to 1:200 blood donors. We again emphasised the importance of having a confirmatory test and it is likely that in Rome a test using the Western Blotting technique will be discussed, albeit the genetic basis of this will be the original isolation procedures described by Michael Houghton. John Barbara presented a lot of data concerning his studies at Edgware and I indicated that our studies were not yet complete but that we had been held up because of lack of kits from Ortho but we were rapidly coming to a conclusion on the tests and systems which had been agreed for the Scottish Blood Transfusion Service. Dr Gunson indicated that these results and his results must be available before the end of September. I indicated that we would be well on target for this but we had various things to do concerning the source of some materials and the history concerning some blood donors. We will be addressing this problem within the next few weeks and, of course, the Scottish Directors will receive a full report since we were asked by them to undertake these tests on behalf of the SNBTS.

6 The discussion then moved to what, if any, next steps needed to be taken. Ortho were keen to obtain information about forecasts and purchasing levels but we were naturally very reluctant to give any such forecasts on a basis that no decision had been made about the introduction of the test.

It was made abundantly clear that we could not pre-empt the decision of the Advisory Committee, that we were not representing the Advisory Committe and we were certainly not representing the various Departments of Health. There was a suggestion that a Working Committee should be formed and we indicated that perhaps informal seminars, such as is held by Wellcome Laboratories for the users of their equipment, might be a useful Forum, if and when the test were to be introduced. Again there was no commitment to the British Blood Tranfusion Services and Dr Gunson indicated that there was a Microbiology Working Party of the BBTS which might form a useful Forum for discussion. This was obviously premature and it was entirely up to Ortho to decide if such a Committee would be useful. He indicated that certainly Dr Supran at the DMRQC would be interested in having samples of low detectability to feed into some kind of National External Quality Assurance Scheme but that was for the future to decide.

In view of the comments in The Guardian, which I am sure you will have seen, and the press interviews with Dr Harold Gunson, I have written to you in some detail concerning the contents of the meeting that was held in London. I wish to stress that no decision was made that no Department of Health was committed to any decision in advance of the recommendations of the Advisory Committee which will make its own decision following the Rome meeting and taking account of all the scientific evidence which is being made available. I have discussed the contents of the meeting with Dr Brain McClelland and Dr Archie McIntyre.

Kind regards

Yours sincerely

GRO-C

Director

cc Scottish Directors
Dr A McIntyre, SHHD
Dr E Follett

Enc

NBTS/ORTHO DIAGNOSTIC SYSTEMS HCV MEETING

23RD AUGUST 1989

PROGRAMME

2.00	WELCOME	R.N. DAVIS
2.10	SUMMARY OF CLINICAL TRIAL DATA TO DATE	DR. J. BARBARA
2.25	TIMETABLE	R.N. DAVIS
2.30	PRICING AND PURCHASING ARRANGEMENTS	A.J. FOLLETT
3.00	FUTURE REQUIREMENTS AND START-UP DATES	P. SAVAGE
3.30	T E A	
3.45	INSTRUMENTATION AND SOFTWARE NEEDS	P. SAVAGE
4.00	TRAINING NEEDS	P. SAVAGE
4.15	FORMATION OF A NBTS/ODS WORKING COMMITTEE	A.J. FOLLETT
4.45	NEXT STEPS/DISCUSSION	R.N. DAVIS
5.00	C L O S E	