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ORTHO CHIRON TEST - Further Report

On the last day of the Durham meeting of the BBTS, Mr Barr and I attended a separate meeting with representatives from Ortho, Dr Gunson, Dr Contreras and John Barbara. This was to assess the impact of the Rome meeting which we attended on 14 and 15 September. Dr Gunson indicated that, in his view, the likely recommendation to the UK National Virus Advisory Committee meeting, to be held in London on 6 November, would be that testing should be introduced in the UK probably within the financial year 1990 ie sometime after 1 April 1990.

A meeting is being held in Manchester on 9 October to finalise the details of the report or reports to the National Advisory Committee. A number of English Centres are now carrying out small trials of the system for familiarisation.

Mr Davis of Ortho indicated that the FDA was likely to license the test according to the agreed timetable. We indicated that if the timetable was to slip then of course we would reserve our position, in that it was unlikely we would introduce a test which had not been approved by the FDA. Mr Barr and I indicated that there may be some batch to batch variation in the test results and if this was confirmed then this would be a disquieting observation.

Mr Davis was very keen to obtain such samples to be sent to the United States although these samples would be tested against a third batch of reagents to be used at the Ortho Wet Workshop in Glasgow on 27 September. Ortho were keen to say that whatever date was chosen or might be chosen they would require at least a lead-in period of a minimum of 90 days. When pressed about Ortho's ability to supply kits on a regular basis and to have at least two different batches in Centres at any one time, Mr Davis said that his Company was capable of mounting such a major requirement given the 90 day lead-in.

I asked if his Company was capable of supplying to a wide number of users and he indicated that France, Japan and Denmark were three major countries which had decided to adopt the test in the near future and their production capacity to meet their needs was already in hand.

Dr Contreras was hesitant at the speed of the proposed introduction of the test, especially since no account had been taken of how donor counselling would be effected. She still felt that some of the data presented at Rome and elsewhere was imprecise and that there were many grey areas of the interpretation of the results. Nevertheless, it was recognised that 1992 and the European Commission's requirements for blood and blood products was not far away and that member governments might well have to subscribe to the 'State of the Art' technology. Reference was made to the need for a confirmatory test. I attach a copy of a statement from Ortho that was issued at the Rome meeting.

GRO-C

Director

f:Ortho

28 September 1989