Witness Name: Alice Mackie
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INFECTED BLOOD INQUIRY

EXHIBIT WITN2189038

Minutes of the Sixteenth Meeting of the UK Regional Haemophilia Centre Directors Committee held at the Lansdowne Club, London on Monday 14th March, 1994.

PRESENT: Dr. B.T. Colvin - Chairman

Dr. A. Aronstam
Dr. H. Dasani
Dr. P.L.F. Giangrande
Dr. C.A. Lee
Dr. J. Leslie
Dr. C.A. Ludlam
Dr. E.E. Mayne
Dr. B.A. McVerry
Dr. G. Savidge
Miss R.J.D. Spooner
Dr. R.F. Stevens
Professor I. Temperley

1. Apologies

Dr. I.M. Hann
Dr. C.R.M. Hay
Dr. P.M. Jones
Professor F.E. Preston
Dr. A. Rejman

2. Minutes of the Fifteenth Meeting

There were no comments and the Minutes were approved.

3. Matters arising from the Minutes

Dr. Colvin said that he had written to Mr. David Watters as agreed and had received a warm reply.

4. Chairman's Business

a) Constitution and Charitable Status

Dr. Colvin said that Charitable status had been granted on the understanding that the HCDO Constitution document would be changed at the next AGM. This was agreed.

b) Comprehensive Care Centres

A list of Centres who had applied for designation as Comprehensive Care Centres or Haemophilia Centres was tabled. Dr. Colvin said that if less than forty severely affected patients were treated then applicants were listed as Haemophilia Centres unless they had specifically asked for Designation as a Comprehensive Care Centre. Dr. Savidge said that at his Regional Meeting he had asked his Health Authority to make a statement regarding the designation of Haemophilia Centres and had received a reply which might be of interest to Regional Directors. Dr. Colvin agreed to write to the Centres who had not yet applied for recognition with a closing date of 1st May. There was discussion about the next step to be taken and Dr. Mayne said that the purpose of the exercise was to designate Comprehensive Care Centres this being the only remit for the "Three Wise Men". Dr. Savidge thought that the designation should not only be based on the replies to the questionnaires but on proper audit and he suggested that a list should be drawn up by December 1994 which would give time for it to be used for the next financial year. Dr. Mayne and Dr. Colvin both stressed that patient numbers was not the only criterion to be considered by the "Three Wise Men". Dr. Savidge saw a problem in that forty patients were stated in HSG(93)30 and that this was what would count. Dr. Colvin said that he had received a letter from Dr. Jones raising the issue of the difficulties created for haemophilia care by large areas with small populations. Dr. Jones was concerned that Associate Centres would lose their status. Dr. Colvin had replied that such hospitals would not be stopped from acting under the supervision of their Comprehensive Care Centre. The Comprehensive Care Centres would keep records of the patients and the treatments given by the associated hospitals. Dr. Jones was also worried about the £20 subscription required from Haemophilia Centre Directors and whether it was right for the Directors of small Centres to be asked to pay this sum. It was agreed that designated Centres should pay a subscription.

ACTION: BC

c) Research and Publications

A document on Research and Publications prepared by Dr. Colvin had been circulated with the Agenda and discussion was invited by Dr. Colvin. Dr. Lee said that she wanted publications to contain the names of all those who had contributed to the work but to be attributed to the Organisation as a whole. She felt strongly that if people are asked to contribute data then their hard work should be recognised. After discussion it was agreed that the document prepared by Dr. Colvin would be accepted with minor amendment. Dr. Colvin would provide a fair copy for circulation to the Regional Representatives.

ACTION: BC

d) Continuing Medical Education

Dr. Colvin had received a letter from Professor

Flynn asking if the Directors had any educational programme for CME. Dr. Colvin had sent him a copy of the Agenda for the September 1994 AGM.

e) Hepatitis A Vaccine

Dr. Colvin had received a letter from Dr. Brenda Gibson asking for clarification of the policy regarding the vaccination of children and whether all children over one year old should be vaccinated. It was agreed that this was UKHCDO policy.

f) Dr. Bob Brearley had asked Dr. Colvin if the Haemophilia Centre Directors could nominate a speaker on the impact of recombinant F.VIII for the BBTS meeting later in the year and Dr. Colvin had nominated Dr. Christine Lee.

g) Dr. Colvin said that the Haemostasis and Thrombosis Task Force had been asked to send a representative to the BCSH General Haematology Task Force Working Group on Genetics. Dr. Colvin suggested that Professor Ian Peake should be asked to attend the meetings and this was agreed.

ACTION: BC

h) NEQAS

Professor Preston had sent out a questionnaire regarding testing of HCV positive blood samples and it had been agreed that they could be handled in Haemophilia Centre laboratories. A sample for inhibitor testing would therefore be distributed from a patient with haemophilia in the near future.

5. Financial Matters

a) Dr. Colvin said that Dr. Hay was not able to attend the Meeting and that therefore discussion of most of the financial matters should be deferred to the next meeting. Dr. Colvin said that satisfactory arrangements needed to be made to fund the activities of the HCDO. Dr. Ludlam said that the BSHT were awaiting a detailed application from the HCDO for funds which might be considered favourably if a specific item was requested. Dr. Mayne pointed out that the cost of running meetings wherever they were held was going up. Dr. Giangrande thought that £50 fee for copies of the report on the Annual Returns supplied to commercial firms could be increased. Dr. Ludlam suggested that the levy to Centres should be based on the numbers of patients attending those Centres. Dr. Lee suggested that Comprehensive Care Centres should pay a larger

ACTION: BC

fee in a similar manner to the NEQAS system. Dr. Colvin summarised the action to be taken.

1. He would ask Dr. Hay for a statement of the accounts.
2. He would apply to BSHT for financial support with particular reference to the new computer system.
3. The suggestion that Comprehensive Care Centres should pay a registration fee would be considered.

6. Annual Returns for 1992

The report prepared by Dr. Rizza and Miss Spooner had been pre-circulated to the Regional Representatives but most of the copies had failed to arrive in time for the meeting due to postal problems. Dr. Giangrande presented the report and outlined the contents. Dr. Lee suggested that Figure 1 should not be produced in the future as it was now meaningless to plot the NHS v. Commercial products. She thought it would be better just to produce a graph for the total amount of material used. Dr. Giangrande suggested that a pie chart should be produced in the future as an alternative showing the commercial brands of materials used. Dr. McVerry thought that the commercial firms might challenge the figures if they were shown in this way. After further discussion it was agreed that a graph should continue to be produced giving the total amount of factor VIII used annually and that a pie chart should be produced showing the amounts of the various commercial products. It was also agreed that the report on the 1992 Annual Returns should be sent out immediately to all the Haemophilia Centre Directors.

ACTION: RS

b) Review of Methods for Data Collection

Dr. Giangrande outlined the present system and the proposed new system for use in Oxford. He said that Oxford Haemophilia Centre had already spent £4,000 of their own money looking into the best way to improve their computing facilities. Dr. Leslie asked about security because he was concerned that the use of PCs for handling the data might be less secure than using the mainframe computer. Miss Spooner said that Oxford would ensure that the best possible security arrangements were made. Dr. Savidge said that he wanted full details of any proposed new system before he would agree to put his data into it. Dr. Giangrande said that he would like one or two other people representing the

Haemophilia Centre Directors Organisation to discuss the project with him and Miss Spooner. Dr. Savidge said that the new system must provide what the Directors wanted. Dr. Giangrande and Miss Spooner said that they understood that it would not be necessary for the project to go out to tender as the work would be done by staff in their own hospital. Dr. Ludlam said that he would like to see full details of the proposed system and would send his comments to Oxford and then leave it to them to make the arrangements for the new system. Dr. Giangrande said that Oxford would go ahead with implementing the new system for their own data irrespective of the decision of the Regional Representatives regarding the National data. Dr. Lee asked if a deadline had been set for removing the Haemophilia System from the Mainframe computer. Miss Spooner replied that at present no deadline had been given but it was very unlikely that the Health Authority would agree to Oxford Haemophilia Centre continuing to pay for use of the Mainframe computer for collating and analysing the National data after Oxford's own data had been transferred to the new PC-based system. After a discussion it was agreed that Oxford would produce a document for comment from the Regional Centre Directors and Dr. Giangrande would write to Dr. Colvin to ask if funding could be made available to help to pay for the cost of the upgraded system.

ACTION: PG

7. **Arrangements for the 1994 AGM**

Dr. Giangrande tabled the programme for the AGM which was agreed.

8. **Regional and National Audit**

Dr. Colvin said that he had sent out Margate's Regional Audit document to the Regional Representatives. Comprehensive Care Centres were responsible for audits within their Region. Dr. McVerry said that the small Centres in his Region did not see the need for the audits. Dr. Ludlam thought that audits need not be as detailed as for Comprehensive Care Centres.

Dr. Mayne asked if all the Regional Centres had been audited and all the reports received by the Directors. Dr. Ludlam said that the Chairman should have a list of the Centres audited and if the reports had been received. After further discussion it was agreed that Dr. Colvin would write to all the Regional Centre Directors to ask if they had been audited and received a report. The issue of confidentiality of audit

ACTION: BC

documents was also discussed and <u>it was agreed</u> that these are confidential reports. It would nevertheless be appropriate for Centres to use their <u>own</u> reports to assist purchasers if they so wished.

9. <u>Working Party Reports and Related Topics</u>

a) <u>Genetics Working Party</u>

Dr. Mayne said that the next meeting would be held on the following day (15th March, 1994). Professor Giannelli was coming to the meeting. The Working Party would be sending out a short questionnaire regarding Gene Tracking. They hoped to produce documents on :-

1. Guidelines.

2. Gene Therapy.

3. Organisation of Genetic Services, storage of samples, etc.

4. Genetics in von Willebrand's disease.

b) <u>Chronic Liver Disease Working Party</u>

Professor Preston sent his apologies as he was not able to attend the meeting and no report had been received. Dr. Colvin referred to a series of papers recently published on Hepatitis C and Dr. Lee reported that The Haemophilia Society had just held a meeting on the subject of hepatitis which was well attended. Dr. Savidge asked if interferon would be used to treat hepatitis C and wondered what would happen if the purchasers refused to pay for the cost of this treatment. Dr. Lee pointed out that interferon would be licensed from April. Dr. Colvin raised the question of liver biopsy, its cost and its value in selecting treatment.

c) <u>Paediatric Working Party</u>

<u>ACTION: BC</u>

Dr. Colvin said that if the protocol was now complete then The Haemophilia Society would like to use it to emphasise the need for prophylaxis. After discussion <u>it was agreed</u> that Dr. Colvin should write to Dr. Hill to ask for the protocol for distribution to all Haemophilia Centre Directors and to the Haemophilia Society. There was discussion of the study and the guidelines. Dr. Aronstam said that the World Federation of Haemophilia had a study which would be presented at the Mexico meeting. Dr. Colvin said that it was agreed that prophylaxis was indicated for selected children in the United Kingdom. He also raised the controversy about the use of portacaths and suggested a protocol regarding their use. <u>It was agreed</u> after discussion that Dr. Colvin should send his draft protocol to the Paediatric Working Party for consideration

ACTION: BC

d) <u>Adverse Events Working Party</u>

Dr. Colvin said that this item mainly related to inhibitors and presented a table giving information about new inhibitors detected in 1990-93. After discussion <u>it was agreed</u> that Dr. Colvin should try to prepare a letter for publication giving details of the incidence of inhibitors in the UK since 1990. He would also ask Professor Giannelli if he had samples from the two F.IX patients who had developed inhibitors. Dr. Savidge said that he had reported to the CSM a patient who had developed hepatitis A after receiving Alpha IX. This was probably a community acquired infection but was being investigated.

ACTION: BC

e) <u>von Willebrand's Disease Working Party</u>

Dr. Mayne said that the next meeting would take place on the 15th April, 1994. The Working Party would initially address the following items.

1. Diagnosis of von Willebrand's disease.
2. A booklet for the Haemophilia Society.
3. Guidelines on treatment.

Dr. Colvin said that he was concerned about the efficacy of 8Y in severe von Willebrand's disease. Several Centres had found that 8Y was not as efficacious as expected. Dr. Colvin said that Haemate P had been used instead of 8Y in the patients who developed problems and had been effective. Dr. Ludlam suggested that Dr. Mayne should write to all Centres asking for information about the failure of 8Y to control bleeding in von Willebrand's disease patients. <u>This was agreed</u>. <u>It was also agreed</u> that Dr. Colvin should inform BPL of the investigation.

ACTION: EM

f) <u>HIV Working Party</u>

Dr. Lee reported on the first meeting of the Working Party. She said that it had been agreed that the CDSC AIDS Report Form suitably amended would be used in the future for the reporting of AIDS cases by Haemophilia Centre Directors. Dr.

Giangrande would report to the AGM on the incidence of HIV and of AIDS. The possibility of getting data on CD4 counts had been discussed and a new form produced by Dr. Sarah Darby and Dr. Andrew Phillips was tabled for discussion. It was proposed that a MRC Project Grant should be sought. The Working Party wanted information on the numbers of partners who were HIV+. In response to her letter Dr. Lee had already received five protocols on HIV treatments from Haemophilia Centres. A report on the number of AIDS cases in haemophiliacs was tabled. <u>It was agreed</u> that this would be discussed at the next Working Party Meeting.

Dr. Mayne raised a problem on behalf of the Macfarlane Trust who were requesting financial support to do market research on the HIV+ haemophiliacs still alive. They needed constructive ideas about this. After discussion <u>it was agreed</u> that the Regional Directors would support the Macfarlane Trust in principle but that they could not provide financial support.

g) <u>Guidelines on Clinical Haemophilia Treatment</u>

Dr. Lee said that she would collate documents as they became available.

h) <u>Inhibitors</u>

Dr. Colvin summarised the Minutes of the first meeting of the Working Party. Liaison with the Genetics Working Party was proposed. BPL had asked for information regarding inhibitor patients. After discussion <u>it was agreed</u> that Dr. Colvin would send a copy of the table presented at the meeting to BPL but would tell them that it had not yet been submitted for publication.

<u>ACTION: BC</u>

10. <u>Date of Next Meeting of Regional Directors' Committee</u>

Monday 5th September, 1994 at the Lansdowne Club in London.

11. <u>1995 and 1996 Annual General Meetings</u>

This item was deferred until a later date.

12. <u>Any Other Business</u>

i) Dr. Mayne had written a paper regarding the declaration of interests which would be considered at the next meeting.

ACTION: RS

ii) Professor Temperley said he had sent a copy of the detailed report on the Outbreak of Hepatitis A among Irish Haemophiliacs in 1992 to Miss Spooner. After brief discussion it was agreed that Miss Spooner would send a copy of the Summary of the Report to the Regional Representatives and that a copy of the full report could be forwarded later on request.

The meeting closed at 3.00 p.m.

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