INFECTED BLOOD INQUIRY

BRENDON GRAY WITNESS STATEMENT

EXHIBIT WITN6984034

NOTES OF A MEETING AT NIBSC TO DISCUSS CUTTER PRODUCTS, THURSDAY, 19 MAY 1988

Present: Dr. Duncan Thomas - Head, Division of Blood Products)
Dr. Trevor Barrowcliffe - (Factor VIII))
Dr. Robin Thorpe - Head, Division of Immunology (Immunoglobulins)) NIBSC

Dr. John Marley)
Mrs. Joyce Boult) Bayer UK

A number of points were discussed and clarified as follows:

1. BATCH RELEASE PROCEDURE

No problems were seen from their side regarding samples they had received in the past. However, it was suggested that it is a good idea to telephone to check that any samples sent by courier have arrived. It takes about 2-3 weeks for Koate HT to be released, and up to 4 weeks for Gamimune N. Confirmation in writing should be sent notifying them that with immediate effect all communication concerning batch release should be with JMB at Newbury instead of Marie Tatt, Stoke Court.

Action: JMB

2. HEPATITIS

Our only legal obligation is to inform the Licensing Authority using the yellow card system if there is a case of hepatitis and Dr. Thomas suggested that we should also telephone Dr. Rotblat at the DHSS to inform her direct. Dr. Thomas would similarly appreciate being informed as the NIBSC would test their library sample, although he commented that they would be unlikely to find anything.

JMB commented that a batch had recently been recalled by Cutter US and it was agreed that details would be communicated to them in a letter giving the batch numbers, reason for withdrawal and any other relevant details.

Action: JM/JMB

3. KOATE HS

The information was given that the product licence application would be going to the CSM in July at the earliest and is currently being pharmaceutically assessed. Both Drs. Thomas and Barrowcliffe could be consulted by the DHSS for their opinions during the course of this.

Dr. Thomas wondered if we would continue to market Koate HT once Koate HS was licensed since we would be showing that the latter was potentially a safer product, although a poorer yield was obtained.

A sample of one batch has already been sent to NIBSC for reference and, although not mandatory at this stage, they would appreciate another to begin to get experience with the product.

continued/..

4. rDNA FACTOR VIII

Much interest was shown in this and it was hinted to them that a CTX application would be submitted this year. No batch release procedure is made a condition of a CTX approval although, again, an unofficial sample would be appreciated in order to begin communication on the product. Occasionally an investigator himself approaches NIBSC to test a batch of clinical trial material, but a company cannot do this.

5. GAMIMUNE

We were asked if the production and marketing of Gamimune had been stopped completely with the advent of Gamimune N. If so, they would appreciate being informed, as well as the Licensing Authority.

6. ANTI-RHO D

It seems that the reason a product licence application has begun to be drafted by Marie Tatt is because at one stage there was a chronic shortage of UK product. This is no longer the case and Elstree produces all that is needed.

COMMENT

It was appreciated by the NIBSC people that we had taken the trouble to introduce ourselves personally and explain how Bayer would be involved with Cutter products in the future. As new products come along they would be happy to discuss them with us.

JMB/ER
20 May 1988

cc: JM, RW

NOTE OF A TELEPHONE CONVERSATION WITH DR. ROTBLAT'S SECRETARY, 20 MAY 1988

CUTTER PRODUCTS

Meeting at the DHSS with Dr. Purves, Monday, 13 June 1988 at 9.30 a.m.

Dr. Rotblat will not be available on that date for discussions after the meeting with Dr. John Purves, but has said that she can be contacted later for help with any outstanding matters.

20 May 1988