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BRADFORD HEALTH AUTHORITY

BRADFORD ROYAL INFIRMARY

DUCKWORTH LANE
BRADFORD
West Yorkshire. BD9 6RJ

P.A.H.
RECD.
16 JUL 1986

Telephone Bradford (0274) 42200

Telephone enquiries on this matter should be made to

Ext. GRO-C

In reply please quote
LP/EB

Sent to BTS Ltd
18.6.86

Dr P A Harris
Medical & Technical Director
Armour Pharmaceutical Company Limited
St Leonards House
St Leonards Road
EASTBOURNE Sussex

13 July 1986

Dear Dr Harris

Thank you for your letter of 11 July 1986. We are returning a batch numbered A23004 to yourselves via the Blood Transfusion Service. I also enclose an AIDS update circular which is dated 30 June 1986.

It would appear that we have been issued bottles as late as late April from batch A23004. I am surprised and a bit disturbed at what appears to be acceptance by your Company to distribute material manufactured from donors that had not been screened for HTLV III antibody. I would have liked to have been informed by your Company prior to getting my information via the Haemophilia Information Exchange.

Yours sincerely

L PARAPIA
Consultant Haematologist

cc Mr C Bishop
Armour Pharmaceutical Co Ltd
St Leonards Road
Eastbourne Sussex

HEMOPHILIA
INFORMATION EXCHANGE

June 30, 1986

AIDS UPDATE

MEDICAL BULLETIN # 40
CHAPTER ADVISORY # 45

FACTOR VIII PRODUCT RETURN RECOMMENDED

Armour Pharmaceutical Company has recommended that their lots of heat-treated Factor VIII concentrate (H.T. FACTORATE) manufactured from plasma collected prior to donor screening for HTLV-III antibody be returned. Attached is a list of the lot numbers involved in this voluntary action.

This precautionary action is occurring because of as yet incomplete information suggesting that three patients who received lots of H.T. FACTORATE prepared from plasma unscreened for HTLV-III antibody have changed from a negative test to a positive test for HTLV-III antibody.

The occurence of a newly positive HTLV-III antibody test (referred to as seroconversion) suggests, if no other reason is apparent, that HTLV-III virus was transmitted by one or more of these lots. It should be noted, however, that none of the three patients has developed AIDS and seroconversion in other recipients of the lots in question has not been found.

NHF's AIDS Task Force appreciates Armour's effort in bringing these cases to public attention and for taking these strictly precautionary steps even though the facts are not clear.

Seroconversion in a patient using heat-treated concentrate could have at least five possible explanations.

1. The particular heat treatment process being used may not be completely effective at killing all infectious HTLV-III virus.

2. Seroconversion may have occurred due to immunization by killed virus.

3. Seroconversion may have passively occurred by receipt of immune globulin in factor concentrate (a phenomenon now well documented in recipients of of hepatitis-B immune globulin, but presumed very unlikely during routine treatment of hemophilia).

4. Seroconversion may only have occurred years after prior viral infection from a non-heat-treated product (this is well documented to occur in some blood transfusion recipients, and may well also occur with factor concentrates).

5. The patient may belong to another risk group for AIDS: (it is not rare for homosexual, bisexual men and IV drug users to deny these activities).

(OVER)

THE HEMOPHILIA INFORMATION EXCHANGE is made possible with funding from the Office of Maternal and Child Health of the United States Department of Health and Human Services

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While Armour's action is strictly precautionary, it demonstrates the correctness of NHF policy which has urged that the combination of HTLV-III antibody testing, the removal of groups at higher risk for AIDS from the blood donor pool and heat treatment all be used to protect clotting factor. We hope that multiple methods of protection lead to the safest possible system to protect those with hemophilia from AIDS.

Patients who have questions or concerns about this action or any other related matters should direct them to their treating physician or treatment center. Treaters should feel free to contact NHF's medical directorate or their regional MASAC representative.

AND, MOST IMPORTANT DESPITE THE CONCERN THAT MAY BE RAISED BY THIS ACTION INVOLVING THE RETURN OF PLASMA PRODUCTS, NHF REAFFIRMS ITS RECOMMENDATION THAT PATIENTS MAINTAIN THE USE OF CONCENTRATE OR CRYOPRECIPITATE AS PRESCRIBED BY THEIR PHYSICIANS. THE LIFE AND HEALTH OF PEOPLE WITH HEMOPHILIA DEPEND UPON THE APPROPRIATE USE OF BLOOD PRODUCTS.

Physicians: Please distribute this information to all providers who treat patients with hemophilia in your area.

Chapters: Please distribute this information to all chapter members.