Rorer

Health Care Limited

E0000001

To: Dr M Rodell

From: Mr R B Christie Date: April 13, 1987

Subject: DR CRASKE - SECOND HIV ANTIBODY SURVEY Ref: RBC/EB/60

Copies to:

Ms A Bessler
Mr C R Bishop

I attach a copy of a recent letter from Dr Craske to Chris Bishop.

You will note that Dr Craske mentions Batch Y69402 which was the batch withdrawn here following discovery that the pool contained a donation from a subject who subsequently developed AIDS.

At the request of the DHSS, I am following up all patients who have been reported to me as having received this batch (including [redacted] I cannot readily identify the one that is quoted in Dr Craske's letter and propose to discuss it with him.

You will note that Dr Craske requests collaboration, including HIV antigen tests on Y69402, another heat treated unscreened batch and some of our current donor screened product. This independent work could be valuable but before I commit to this type of collaborative study, I would like to hear the reaction of yourself and other U.S. colleagues.

Regards.

GRO-C

R B Christie

Inter-office memorandum

ARMOUR003273

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Public Health Laboratory Service

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Public Health Laboratory
Withington Hospital
Manchester M20 8LR
Telephone 061-445 2416

2nd April, 1987

Our ref JC/PH Your ref

Mr. C.R. Bishop,
Armour Pharmaceutical Company Limited,
St Leonards House,
St Leonards Road,
EASTBOURNE,
Sussex BN21 3YG

R.B.C.
- 7 APR 1987

Dear Chris,

SECOND HIV ANTIBODY SURVEY

Thank you for your letter of the 26th March. This survey has now been analysed and the preliminary results are as follows, which I would be grateful if you would keep confidential:

38 patients were found to have seroconverted from being antibody negative in the first survey to being sero positive in the second survey.

After enquiry, detailed information about the types and batch numbers of therapeutic material used by these patients during the year prior to sero conversion was available in 29 patients. However, in all instances except one patient it was not possible to ascertain whether sero conversion was caused by unheated or heated concentrates.

This was because the time interval between the last sero negative test and the first sero positive was often very great (range 2 to 87 weeks, median 39, mean 40 weeks) and, therefore, if was not possible to say at what point sero conversion took place. In many instances the interval between the last treatment with unheated factor VIII and the first treatment with heated factor VIII was so short, the range 1 - 188 weeks, that either therapeutic material could have been responsible for the sero conversion.

One patient who had received no factor VIII for many years was found to be anti-HIV positive in June 1985, approximately 22 weeks after receiving 8,000 units of heat treated factor VIII obtained from two commercial companies, one of which was the Armour Pharmaceutical Co. Ltd. The patient received 2,000 factor VIII units of Armour batch Y69402.

We propose the following action:

1) The follow up of other patients who received the above batch of Armour and the batch of factor VIII from the other manufacturer to see if any more of the sero conversions can be identified, and to try and recover any used factor VIII from both types of material.

2) To confirm the above results with more sophisticated serology on suspect patients, and to compare the results with results of our studies on NHS unheated factor VIII about which we have quite a bit of information.

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3) I think we may study a further batch from each material as a control just to be sure that any sero conversions found are not due to confounding factors not related to the actual treatment of the suspect batch.

This is obviously a good opportunity to learn something from what is an unfortunate event. There is a possibility that we might be able to identify infected bottles by using HIV antigen tests, and I am looking at this possibility at the moment. Would it be possible to obtain some of the suspect batch of Armour identified above, and also any products from the heated material which you think might have been made from plasma not screened for anti-HIV during its manufacture?. We would also be happy to examine any of your latest products to see whether such screening might be of value as a quality control in manufacture of freeze dried concentrates.

I am really writing to ask the co-operation of your Company and of the other Company involved in this particular case, as few opportunities of this sort will arise in future and, therefore, it is important to obtain the maximum amount of information possible, so that further checks can be built in to the manufacturing process of your products.

Looking forward to hearing from you.

Kindest regards,

Yours sincerely,

GRO-C

J. Craske
Consultant Virologist