Birmingham Children's Hospital NHS
NHS Trust

DEPARTMENT OF CLINICAL & LABORATORY HAEMATOLOGY

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28th January 2007

Department of Health
5th Floor
Wellington House
Waterloo Road
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Dear Linda

Re: Paper titled "The safety of heat treated factors VIII"

This paper prepared by Dr Frances Rotblat and dated 4th March 1986, looks at the evidence available at that time that raised suspicions about the ability of some dry heat treatment processes in preventing HTLVIII (now called HIV) infection. At the time of the report 2 cases who seroconverted "after treatment with Armour material from a batch known to contain an AIDS donor" are acknowledged.

Armour Factorate heated treated at 60°C for 30 hours was introduced for use in UK patients from December 1984.

The April 5th 1986 Lancet page 803-804 contained a letter headed "seroconversion to HTLVIII in haemophiliac given heat treated factor VIII". The authors were W. Vanden Berg, J.W. Ten Cate, C Breederveld and J. Goudsmit (copy attached).

This letter does not identify the product or give the details of the virucidal treatment. These authors also refer to a publication in March from Gilbert White and colleagues, Lancet March 15th page 611-612 (copy attached). Their report is about a patient treated with heat treated factor VIII. Again the product is not identified.

The Birmingham Children's Hospital had introduced heat treated Armour Factorate in December 1984. Many of our patients were in a cohort study and we had stored sera and were aware of which haemophilic boys were HIV seropositive and HIV seronegative.

All HIV seronegative patients were being followed and regularly tested for HIV antibodies.

In the summer of 1986, an HIV seropositve test was reported on a previously HIV seronegative patient. The patient was retested and his HIV seroconversion was confirmed. This information was reported to Robert Christie at Armour Pharmaceutical Company and Frances Rotbalt at the CSM (Committee for Safety in Medicine). The Armour product was withdrawn from the UK market and the product no longer had a UK product license. The date of reporting this was September 1986.

We identified a further 3 at risk boys and 2 of these seroconverted late 1986/ early 1987.

Armour continued to market this product in Europe and North America. The Canadian Authorities were involved in a National Contract with Armour and this went ahead as the FDA did not remove Armour's product license in North America. There were further seroconversions in Canadian boys with haemophilia; a world Federation of Haemophilia meeting in Madrid (May 1998) (see attached abstract 197).

The Canadians had a National enquiry which reported in 1995. Since then there have been Criminal Investigations and a criminal lawsuit (Crown vs. Armour and others) is being heard in the Canadian Crown Court (started in February 2006). I have been providing statements and am scheduled to give evidence in February 2007. The paper you have sent to me would be of interest to the Canadian Authorities with regard to these legal proceedings.

My own patients (3 definite and 1 probable) who seroconverted to HIV on Armour Factorate brought a legal action in the USA and received an out of court settlement from Armour Pharmaceuticals. The information on these has been reported in a peer reviewed journal (copy enclosed).

If you think, I can help further please get back to me.

Yours sincerely

GRO-C

Frank G.H. Hill
Professor of Paediatric Haematology

Enc.