



**Response to Questions Raised at the Inquiry
into
Contaminated Blood and Blood Plasma Products**

**3. The Discovery of Heat-Treatment Conditions for the
Inactivation of HIV in Coagulation Factor Concentrates**

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The Discovery that HIV Could be Destroyed by Dry-Heat Treatment

In their evidence to the Inquiry, in a section headed “Delays in Heat Treatment, Testing and Screening” (first submission from the Haemophilia Society, p. 24) the Haemophilia Society claimed that “*In May 1983 it was discovered that the HIV virus could be destroyed by exposing it to dry heat at 68 degrees centigrade for one hour.*” In support of this claim, the Haemophilia Society cited a USA Public Health Service press conference held in July 1983 concerning the “*Hyland Heat Process*”.

In order to assess the merits of the claim by the Haemophilia Society it is necessary to consider both the “*Hyland Heat Process*” and experiments that were undertaken on the inactivation of HIV which involved “*dry heat at 68 degrees centigrade.*”

The Hyland Heat Process

“*The Hyland Heat Process*” concerned the dry-heat treatment of Factor VIII concentrate at 60°C for 72 hours that was developed by the USA company Hyland-Travenol (also known as Baxter). Their product was called Hemofil[®] T and it is important to note that dry-heating was carried out at 60°C **not** 68°C as implied by the Haemophilia Society. Other relevant points to note are:

- in March 1983, Hemofil[®] T was licensed in the USA by the FDA.¹
- by September 1983, it was known that despite heat-treatment, non-A, non-B hepatitis was being transmitted by Hemofil[®] T.²
- in September 1983, a UK licence application for Hemofil[®] T was rejected by the Committee on Safety of Medicines (CSM) and the company was criticised by the CSM for making unjustified claims concerning safety in respect of AIDS.³
- in February 1985, it was reported⁴ that 18 patients who had been treated exclusively with Hemofil[®] T were HIV- negative, whereas 5 of 29 patients (17%) who had been treated over the same period with various brands of unheated Factor VIII concentrate from the USA were HIV-positive. Testing for HIV-infection had been performed in late-1984.² Although these results were encouraging, they did not prove that HIV had been inactivated by the heat treatment employed, as there was no evidence that the relevant batches of Hemofil[®] T were contaminated with HIV.
- in January 1986, a manuscript concerning inactivation of viruses in clotting factor concentrates was submitted for publication by Dr E Gomperts.⁵ This

review included data from five companies on the inactivation of HIV, but “*Data not available*” was indicated against Hyland-Travenol.⁵ Dr Gomperts worked closely with Hyland-Travenol and was lead author of a joint publication with the company,⁶ he would therefore have been expected to have been given any available data.

- results of experiments on the inactivation of HIV by dry-heat at 60°C were published by Hyland in 1986⁷ for a Factor IX concentrate (Autoplex[®]), which was used for the treatment of factor VIII-inhibitors, and in 1987⁸ for Factor VIII (Hemofil[®] T) and Factor IX (Proplex[®] SX-T) concentrates.
- a comprehensive review of dry-heat studies undertaken by Hyland contained no reference to any earlier data from the company concerning the inactivation of HIV.⁹

Dry-Heat Treatment at 68°C

At the time in question, the only company which subjected its Factor VIII concentrate to dry-heating at 68°C was Bayer (also known as Miles/Cutter). Heat treated Factor VIII concentrate from Bayer, known as Koāte[®]-HT, was licensed by the FDA in February 1984.¹

Experiments on the effect of heat treatment on HIV that had been added to Factor VIII concentrate were begun at the USA Centres for Disease Control (CDC) in spring 1984 and were completed in the late-summer of 1984 in collaboration with Bayer (Miles/Cutter).¹⁰

A summary of the findings was published by CDC on 26th October 1984¹¹ and led to the widespread introduction of heat treated concentrates during 1985.¹² Results from the studies were published in a peer-reviewed journal in August 1985.¹³

Neither of these published reports included results of dry-heat treatment at 68°C for one hour, as described by the Haemophilia Society. However, information on the effect of dry-heating Factor VIII concentrate for one hour at 68°C was given:

- on 2nd November 1984, in an oral presentation by a speaker from CDC¹⁴ at a conference in the Netherlands, at which SNBTS was represented.
- in September 1985, in a commercial brochure published by Cutter.¹⁵

Information on dry-heating at 68°C for one hour was included in a presentation by SNBTS to the Haemophilia Society in 1999.¹⁶

Sensitivity of HIV to Heat.

Evidence that HIV was relatively heat sensitive and could be inactivated by heating in solution (in 50% serum) was first published in January 1985,¹⁷ with a caution from the authors that “*The data cannot, however, be extrapolated to lyophilised products since our experiments were conducted in liquid medium.*”

Conclusion

The sequence of events described above suggest that the Haemophilia Society has confused data presented in The Netherlands by CDC in November 1984 with speculation in 1983 that the “*Hyland Heat Process*” might be effective against HIV. The effectiveness of dry-heat for one hour at 68°C was not reported widely and the claim by the Haemophilia Society may be based on information supplied to it by SNBTS in 1999.

Despite this confusion over dates, the claim suggests that the Haemophilia Society does accept that evidence of HIV-inactivation was necessary to justify the introduction of heat treated coagulation factor concentrates.

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