"When were the risks from Factor VIII first known?"

1. The first report of three haemophiliacs with an opportunist pneumonia (subsequently associated with AIDS) was published in the USA in July 1982 and UK Haemophilia Centre Directors agreed to gather more information. By early 1983 the possibility that AIDS might be transmitted by an infectious agent was established as a plausible theory. Blood donors in high risk groups were asked not to give blood from August 1983, but otherwise little positive action could be taken because of a lack of knowledge of the causative agent. Not until 23 April 1984, with the statement from the US Secretary for Health notifying the isolation of the AIDS virus, could it be said that conclusive evidence was available.

2. In the meantime, Haemophilia Centre Directors encouraged their patients to continue to use Factor VIII because in their view the risk from bleeding episodes outweighed the risks from AIDS. Where haemophilia is not treated at all death can also result (eg cerebral haemorrhage) and serious disabilities can arise. The Haemophilia Society itself was still recommending that haemophiliacs should continue to treat bleeding episodes as late as May

1985, while recommending the use of heat-treated materials wherever possible ("Haemofact" No 7 dated 22 May 1985).

Self Sufficiency

3. A major plank of the haemophiliacs' court case is that the government failed throughout the 1980s, to achieve its own (1976) target of self-sufficiency in blood products, thus exposing haemophiliacs to the extra risks of imported Factor VIII (from US and other paid donors) instead of the relatively safe home product (from volunteers). At face value this assertion is true, but there are several comments to make.

i. Crucially, no one could have predicted in the mid-1970s how rapidly and how far the demand for Factor VIII would grow, as a result of the take-up of home therapy and the revolution it brought about in the treatment of haemophilia. If a new factory had been commissioned by another government in 1976, when demand for Factor VIII stood at 16 million international units (miu's) p.a., it would have been hopelessly inadequate today. By about 1980 the demand could be more accurately assessed and the new factory at Elstree has sufficient capacity. Construction began in 1983 using a "design and build" concept for early

completion.

ii. Apart from increasing manufacturing capacity, the drive to self-sufficiency has required an enormous increase in the level of plasma collection while retaining total commitment to the voluntary donor principle. In the area of blood donation, safety has always been an overriding consideration. The achievement of the NBTS in the last decade,in delivering this increase while continuing to meet the requirements for blood for blood transfusions, should not be under-rated.

iii. In the mid-1970s the main concern was hepatitis infection (AIDS was of course unknown) and all blood donations were being tested to screen out the most virulent type B hepatitis. Self-sufficiency was perceived as desirable but not as the matter of life-and-death it has become since AIDS; this would have affected the assessment of the priority to be given to committing resources to this aim.

iv. Self-sufficiency is also dependent upon whether clinicians prescribing for haemophiliacs will choose to exercise their clinical freedom in

favour of the domestic product. Many prefer imported commercial Factor VIII even today, and BPL maintain that they cannot capture all the market.

v. Heat treatment against HIV also reduces the Factor VIII yield from plasma.

Heat Treatment

4. The first widely available heat-treated Factor VIII was only manufactured in the USA in [October 1984] and was immediately available in this country on a "named patient" basis before licensed products became available. The Department believes that there was no delay in introducing heat-treated Factor VIII from Elstree once the method had been perfected. It was necessary to ensure that the treatment was effective against HIV, and did not in itself introduce other toxins. It must also be stressed that heat treatment leads to loss of Factor VIII, and efforts had to be made to keep this loss to a minimum. Early heat-treatment methods were extremely poor in terms of Factor VIII "yield"; so were very wasteful of plasma. All Factor VIII manufactured at BPL from April 1985 was heat-treated. From October 1985 all Factor IX from BPL was heat-treated, and BPL produced an 'all-new' heat-treated Factor VIII known as Factor 8Y. At all times clinicians treating haemophiliacs

could exercise their clinical freedom in prescribing the product(s) available,

Testing Of Blood Donations.

5. A test for antibodies to the AIDS virus was first produced in the USA in March 1985. Following a thorough evaluation of the available screening tests, all blood donations given in the UK were tested on an individual basis from October 1985. A conscious decision was taken to undertake the full evaluation, and to introduce testing in Genito Urinary Medicine Clinics at the same time (October 1985). This was to prevent people at high risk of HIV infection from presenting at blood donor sessions to be tested.