ITEM A

HIV/HAEMOPHILIAC LITIGATION - GENERAL BACKGROUND NOTE

1. Background to Haemophilia

Haemophilia is an inherited disorder characterised by absence or reduced amount of a blood clotting factor, normally Factor VIII.

Severe haemophilia may cause spontaneous bleeding into joints, or even the brain. Those less severely affected may have bleeding problems only following accidental trauma or operations.

The earliest form of treatment used either fresh whole blood or plasma. In the late 1960s cryoprecipitate was developed which provided an increased concentration of the missing factor. This was gradually superseded from the early 1970s by Factor VIII concentrate which could be readily used at home by patients. All these products were produced from human blood.

2. Self Sufficiency in Blood Products

In January 1975 Dr David Owen, then Minister for Health, committed the NHS to self sufficiency in the production of Factor VIII, a target expected to be reached in mid 1977. Funds of £0.5 million were allocated, half of which was recurring.

Between 1975 and 1977 NHS production increased from 3.2 million units to 12.8 million but demand increased from 8.2 million to 27.4 million units in the same period. The proportion of imported commercial product therefore remained the same.

The NHS production facility at Elstree was upgraded between 1980 and 1982 at a cost of £2 million. In 1981 Ministers approved the development of a completely new plant. This opened in April 1987.

3. Haemophiliacs with HIV

Some 1200 haemophiliacs have become infected with HIV in the UK through use of FVIII, both imported from USA and home produced. Over 200 haemophiliacs have been diagnosed as having AIDS, 143 have died. Around 1,000 individuals, (770 of them haemophiliacs, and the remainder are their partners and close relatives) are suing the Department of Health, Welsh Office, Medicines Licensing Authority and Committee on Safety of Medicines for damages. The main court hearing is set for March 1991.

4. HIV and AIDS

The state of knowledge of the cause of AIDS, the methods of transmission and the implications for haemophiliacs only developed over a period of time.

The first cases of what is now known as AIDS were reported in homosexuals in June 1981 in USA. In July 1982 3 Haemophiliacs in USA were reported with AIDS, although even in December 1983 only 1 in 1000 haemophiliacs in the US and Europe were infected. The first case of AIDS in a UK haemophiliac was reported in the Lancet of 19 November 1983. In May 1984 the virus causing AIDS (HIV) was isolated and accepted by most scientific authorities although the same virus had been reported 1 year previously when doubt was cast as to its relevance. In the latter part of 1984 and in 1985 tests were being developed to diagnose the presence of HIV.

Retrospective testing of stored blood samples has shown that the first positive HIV test in a UK haemophiliac dates back to 4 December 1979. It is possible that other haemophiliacs had positive tests at that time or even before. Both imported FVIII as well as UK product have been implicated in the transmission of HIV.

5. Government's position on litigation

The Plaintiffs allege negligence in that the Government did not achieve self sufficiency in blood products nor act quickly enough to prevent transmission of HIV in blood products, and in some cases that medical treatment was inappropriate. The Government does not believe that the measures taken and treatment provided for haemophiliacs were negligent or out of line with the state of medical knowledge at the time. The Government believes that the haemophiliacs were unwittingly infected with HIV, knowledge of AIDS then being in its infancy. The haemophiliacs have an undoubted right to take legal action, equally it would be wrong for the Government to defer to allegations which, as in this case, it believes are not well founded.

More generally, the NHS is experiencing an increased number of writs. This holds dangers of a move towards the practice of defensive medicine as seen in the USA.

6. "No Fault" Compensation

Some argue that "no fault" compensation would be the answer in tragedies such as this. "No fault" schemes, which the Pearson Commission rejected in 1978, would introduce unfairness between those disabled as a result of a medical accident, and those who are equally disabled through natural causes. "No fault" schemes tend to pay out sums smaller than court settlements, and sums already paid out by the Government through the Macfarlane trust are likely to be greater.

7. Government help for infected haemophiliacs

The Government has already recognised the special plight of infected haemophiliacs by payments totalling £34 million made available through the Macfarlane Trusts. In 1987 £10 million was made available to meet the special needs of the haemophiliacs and their families and a further £24 million in 1989 to provide payments of £20,000 to each infected haemophiliac. The Government has said that it will keep these sums under review to ensure that they are adequate to meet the needs of the infected haemophiliacs. Ministers must balance this need with all the other demands on the NHS.