

PRIME MINISTER

Tomorrow, at 3.00 pm you are seeing Robert Key, and colleagues about Haemophiliacs who are infected with the HIV virus. The colleagues are:

Sir Bernard Braine

Sir Geoffrey Johnson-Smith

Emma Nicholson

John Hannam

I attach some briefing for this meeting.

Virginia Bottomley will be coming.

GRO-C

IP MARK LENNOX-BOYD
21 November 1989

BRIEFING FOR MEETING ON 22nd NOVEMBER

BETWEEN THE PRIME MINISTER, AND ROBERT KEY'

BACKGROUND

Haemophiliacs with HIV infection.

1. Some 1200 haemophiliacs became infected with the AIDS virus (HIV) as a result of NHS treatment with coagulation products, (Factor VIII in particular), made from human plasma. This was in 1985 or earlier and before methods of preventing transmission of the virus by testing blood donations and heat treating blood products were generally available.
2. Those haemophiliacs who are HIV positive do not usually show clinical signs of illness; we think most will progress to develop AIDS but the timescale is uncertain. Up to 31st October 1989, 107 haemophiliacs with AIDS were reported to have died.

Haemophiliacs/HIV Litigation

3. About 600 haemophiliacs are now pursuing claims for compensation through the Courts. Action is being taken against the Department of Health, the Medicines Licensing Authority and the Committee on Safety of Medicines, the

Welsh Office and the Health Authorities. We believe that the various allegations of negligence can be successfully countered.

4. The Lord Chief Justice has assigned Mr Justice Ognall to deal with these cases. There have been three hearings before the judge: on 29 June, 24 July and 23 October 1989, and another is scheduled for 5 December. At the hearing on the 23 October 1989 the Judge ordered that the trial of preliminary issues take place on the 15 January 1990. The main hearing is expected early in 1991.

5. Amongst other things, the hearing on the 15 January 1990 might deal with the general question of whether or not some or all of the defendants had a legal duty of care towards the individual plaintiffs.

6. Because the Judge has set a date on 15 January 1990 on which the preliminary issues will be dealt with, the Department considers this matter to be sub-judice, (for background information, please see Annex A which deals with some of the issues raised in the litigation). Although the factual issues will not be dealt with at the hearing in January 1990, the possibility exists that evidence will be given and certainly the general liability of some or all of the defendants to the plaintiffs will be the subject of considerable argument.

7. Because of this we consider the questions should not be accepted which go to the issue of liability in these proceedings. These would cover e.g. such subjects as what action the Department took up to 1985 as regards screening blood donors, importing blood products, heat-treating blood products and arranging for self-sufficiency in blood products. Neither in our view should questions be accepted which go to the question of whether or not the Secretary of State is prepared to compromise the proceedings with an out of Court settlement.

Out of Court Settlement

8. We know the Haemophilia Society were advised around March 1987 against pursuing legal action. They are however pressing for compensation out of court, and have suggested that a settlement of £86m would be appropriate; this would average about £71,000 per case. Any out of court settlement of the litigation would carry with it a tacit admission of negligence and could set an unacceptable precedent by implying NHS liability for treatment which reflects the best available medical information at the time but turns out later to be wrong. The implication of liability could also undermine the medicines licensing system. The Licensing Authority (i.e. UK Health Ministers) and the Advisory Committees have been involved in a number of court actions. They have consistently denied liability and resisted any moves towards any out of court settlement. Any such move could encourage further litigation and

expectations of similar settlements. Constant litigation would be damaging to the integrity of the licensing system, could lead to over defensive licensing decisions and could lead to problems in attracting members to sit on advisory committees. For these reasons Health Ministers are not considering an out of court settlement. Legal advice is that it would be inappropriate to comment on whether the Government is prepared to consider compromising the court proceedings by offering an out of court settlement.

Ex gratia payment

9. An ex gratia payment would also present difficulties. No fault compensation schemes for medical accidents have been resisted since the Pearson Commission reported in 1978. The arguments for and against have not fundamentally changed. No fault compensation may overcome the perceived unfairness of treatment between those victims of medical accidents who are awarded damages after proving negligence and those who are not compensated because either they failed to prove negligence or because negligence was clearly not involved. However such a scheme would, in its turn, create unfairness between those who are disabled by a medical accident, who would then be compensated, and those who are equally disabled as a result of the natural progression of their disease who would not normally fall to be compensated under a no faults compensation scheme. It would be difficult to find convincing arguments for why haemophiliacs were thought

a uniquely deserving group.

Vaccine Damage Payments Scheme

10. This scheme is sometimes mentioned as a precedent for no fault compensation. However there are special factors surrounding vaccination.
11. Vaccination not only provides protection for the individual but is a safeguard for the public generally. This is in line with the World Health Organisation's aim to eliminate by the year 2000 seven specific diseases from the European Region. It is therefore public health policy to promote vaccination and the remote risk of injury resulting from it is recognised by the special scheme. These payments are not compensation and individuals retain the right to seek it through the Courts on grounds that negligence led to the vaccine related injury.

Macfarlane Trust

12. Following a campaign by the Haemophilia Society, the Government announced in November 1987 an ex gratia payment of £10m to meet the special needs of haemophiliacs with HIV and their dependents. The Macfarlane Trust was set up as a charitable trust in March 1988 to administer the funds. Up to 31 October 1989 the Trust has made over 1800 single payments totalling nearly £1m and implemented regular payments in more than 600 cases at a cost of nearly £1.2m.

13. The Trust was always intended to help in cases of genuine financial need. The Trustees do interpret "need" in a broad way and the Department has encouraged them in this view. However the haemophiliacs do not regard the "needs" based payments as an adequate response and they are pressing for compensation, without any "needs" assessment.
14. At a meeting with the Secretary of State for Health on 20 November, it was agreed that the £10m allocation to the Trust should be "topped-up" with a further injection of £20m. It was also agreed that the £20m would be front-end loaded to allow the Trust to give immediate help of £10,000 to each family unit affected thereby responding to requests for more substantial immediate help. This may require a change to the Trust Deed and the implications of such a change are being considered; this will be in consultation with the Trustees. This will raise the total provision to an equivalent average payment of £24,000 per case, and comparable to the better European schemes.

Compensation in Other Countries

15. Some countries have paid higher amounts and we understand Canada will shortly announce an out of court settlement equivalent to around £60,000 per case [still in confidence]. Others have made no special State provision, (see Annex B).

LINE TO TAKE

Haemophilia/AIDS Litigation.

16. Since court action by a number of haemophiliacs with the AIDS virus is now underway, it would not be proper to comment on the suggestion as to whether or not the Government defendants are prepared to compromise those proceedings with an offer of out of court settlement. Sympathy for the haemophiliacs has already been demonstrated by making an ex gratia payment to set up the Macfarlane Trust. However the deputation can be reminded of the Government's willingness to consider additional funding for the Trust.

2. In the meantime, haemophiliacs who are 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 for cerebral haemorrhage or liver disease. The Haemophilia Society itself was at first reluctant to accept the fact that haemophiliacs should continue to treat bleeding episodes.

"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.

1. 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