TH

3

DEPARTMENT OF HEALTH & SOCIAL SECURITY
Alexander Fleming House, Elephant & Castle, London SE1 6BY
Telephone GRO-C
From the Joint Parliamentary Under Secretary of State

PO(6)4801/22

Clive Jenkins Esq
General Secretary
Association of Scientific Technical and
Managerial Staffs
79 Camden Road
London
NW1 9ES

5 Jan 1984.

Dear Mr Jenkins,

Thank you for your letter of 27 October in which you record a number of areas of disagreement with points which I made in my earlier letter. Let me deal with your paragraphs in numerical order.

Para 2. It remains the case that there is no conclusive evidence of the transmission of AIDS through blood products, although the circumstantial evidence is strong. These two statements in no way contradict one another as you will readily appreciate from an analysis of a similar argument which you use in paragraph 7. Whilst there is strong evidence to suppose that the hepatitis vaccine will not transmit AIDS, the evidence is not conclusive and cannot be so until a means of testing for AIDS has been devised. In both cases, the conclusive evidence awaits the development of a test which can identify the AIDS agent (or agents).

Para 3. There is no question of placing 'undue reliance' on the new Regulations introduced by the US Food and Drugs Administration. We take the view that any improvements in donor selection procedures, whatever their limitations, must, to some extent, improve the safety of the products. Therefore we feel that products which have been prepared from plasma collected in accordance with the new regulations may carry a small additional margin of safety - not simply from the point of view of the transmission of AIDS, but also for the transmission of other diseases.

Para 4. I find it difficult to see how you can reconcile the statements in your third paragraph with those in the fourth. If the FDA Regulations are as useless in improving the safety of products as you say they are, then surely it is of no consequence that the UK might become the "dumping ground" of products made from plasma collected before these regulations came into force!

We, on the other hand, take the view that were it possible to obtain sufficient supplies of the 'regulated' products to treat the UK's haemophiliacs, we would take the necessary steps to do so. Regrettably, we have established that at the present time this is not the case and that to insist on only 'regulated' products would be to pose an absolute risk to the health and safety of haemophiliacs. This known risk factor must be weighed against the potential risk to haemophiliacs of acquiring AIDS. Many of your members are in the business of 'risk assessment' in relation to work place safety; they will know that the balance of risks is often more finely drawn than it is in this case.

Para 5. With regard to the United Kingdom becoming self-sufficient in blood products, you are of course aware of the new laboratory at present under construction at Elstree which will enable England and Wales to become self-sufficient. At present however the existing laboratory at Elstree is capable of fractionating all the plasma currently available.

Should the situation arise where the plasma supply builds up beyond the fractionating capacity of the existing laboratory, we should need to examine whether any surplus capacity at the Protein Fractionation Centre could be used.

At present, however, PFC would not have the storage, filling and packaging facilities to handle a substantial amount of extra plasma, even if it were available.

Para 6. The statements made by the Haemophilia Society are a matter of fact. It has been necessary to quote from them in order to illustrate to those who are ill-informed on these matters, that to demand a total ban on the imports of US Factor VIII, so far from safeguarding the lives of haemophiliacs, would put them at greater risk.

Para 7. Concerning the MSD plasma derived hepatitis B Vaccine, the Department accepts that the standards of safety in the manufacture of the vaccine should ensure that there is no transmission of any putative agent causative of AIDS; yet acknowledges, with you and the medical research community in general the substantial scientific problems of conclusively proving this in the absence of a definite identified causative agent.

The Department also shares your view that we should not expect plasma derived hepatitis B vaccines to provide a long-term solution but rather should expect this to be provided by biotechnologically manufactured alternatives eg genetically engineered or synthetic oligopeptide products. We have reached this view not just because of the AIDS problems, but have taken note of the world-wide developments in biotechnology generally. To this end the Department is encouraging (under the auspices of the British Technology Group) a collaborative project involving a DHSS funded research group and the University of Uppsala, Sweden into synthetic vaccine production in general and including Hepatitis B work in particular.

I hope that, by answering your questions fully, I have been able to provide you with the necessary information with which to respond to your members' queries.

GRO-C

THE LORD GLENARTHUR