Mr Cranston / ~~see me I think we should open a file on this~~
1. Mrs Angus
2. Tell & BF for Mr Murray's return. NRLS/1

Dr McIntyre
Mr Macniven
Mr A J Murray, O/R

COMPENSATION ARRANGEMENTS FOR PARTICIPANTS IN TRIALS OF PFC PRODUCTS

I met Dr Ludlam at Royal Infirmary, Edinburgh on 24 March in response to his letter to me of 12 March (copy attached). The following points were made, and I stressed that the Department were at pains to be candid in this matter.

The Minutes of the Haemophilia Directors/SNBTS Directors Meeting of 9 February do correctly report the Department's position; but since they could not serve as a definitive statement of this, discussion of them is not directly to the point. Mr Murray's letter of 6 February to Dr Cash states the Department's position.

The arrangements now agreed extend to those participating for non-therapeutic purposes in trials of FVIII. These participants naturally enjoy exceptional public sympathy. Participants who receive FVIII for reasons of treatment as well as trial are not included.

Consequently the next aim is to extend the arrangements to participants in non-therapeutic trials of other PFC products, and this is in hand; Dr Cash has presented a "shopping list". But I remain concerned about Dr Cash's interpretation of Mr Murray's letter. I suspect that he reads it as extending the arrangements to all participants in clinical trials of FVIII, whether they receive the product as treatment or not. This appears to me just wishful thinking. Mr Macniven will wish to give further attention to the point in view of the meeting scheduled for 31 March. Mr Kernohan's letter of 14 January to Treasury mentions just six volunteers to be covered by the arrangements!

Product licences are unlikely to be issued in the foreseeable future. Dr Ludlam inclined to believe that the Secretary of State must be seeking to evade his responsibilities. I replied that the Secretary of State was inescapably saddled with his responsibilies, but was free to determine the context within which they would be assessed and interpreted, and was also reluctant to add to the heavy load of Medicines Division, DHSS.

Some general discussion of the life insurance position and other issues followed and it was clear that in Dr Ludlam's mind his patients' anxieties about AIDS bulked large. I pointed out that money as compensation for participants in trials represented only a small facet of this much larger problem, and I took the liberty of mentioning that any generous no-fault compensation scheme might attenuate the present zeal of PFC and SNBTS to provide very safe products.

Dr Ludlam had previously seen Mr Murray's letter of 6 February to Dr Cash; it was a response to a letter of Dr Cash to Mr Murray and he asked for a copy of Dr Cash's letter which I have sent to him. Dr Ludlam is to consider his position; I indicated that the immediate prospects of extending the arrangements to participants in clinical trials in general seemed to me poor, because the issues there transcend those of SNBTS and its products.

DR J M FORRESTER
25 March 1987

Room 25
SAH