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IN CONFIDENCE

January 7, 1981

Mr R Baker
Superintendent Medicines Inspector
Department of Health and Social Security
Medicines Division
Market Towers
1 Nine Elms Lane
Vauxhall
London SW8 5NQ

Dear Roger

The recent "World in Action" programme dealing with the problems of our Blood Products Laboratory at Elstree, raises a number of worrying questions. if the information disclosed about the outcome of visits of Medicines Inspectors to the Laboratory is based on fact.

It would appear, that Elstres was very heavily condemned by members of the staff of the Medicines Inspectorate, and according to the programme it is only the question of Crown Priviledge which is keeping it going. The principles at stake here are fundamental, I believe, since if things are as bad at Elstree as the programme suggested, then were the unit a commercial manufacturer like Travenol Laboratories, it seems likely to me that Licence to Manufacture would be withdrawn.

The two issues at stake are:

- The question of safety of patients and efficacy and safety of the product which is manufactured in the unit.
- The application through the continuing operation of Elstresof different standards for the approval of manufacture of medicinal products at a unit within the Health Service, and those commercial units outside of it.

We have discussed this matter before, and you will understand that I cannot simply sit by and see some of these things happening. I am in correspondence with my Member of Parliament concerning the implications of the "World in Action" programme, and I may get in touch with Members of the Opposition who were supportive of our development during the recent past, and I will probably take other steps through various contacts to get this issue raised further.

cont....

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I am writing to you to let you know that I am going to stir the waters somewhat on this matter, and I feel sure that if you have any comments you want to make to me you will contact me.

David and John will be with us in Thetford in mid January for a Medicines Inspection, and during the quiet moments which I hope we will have between issues during this inspection, I may mention this matter to them.

Yours sincerely
TRAVENOL LABORATORIES LIMITED

GRO-C

A W Barrell Managing Director