Re: Your telex no. 2363 of Oct. 30, 1986 concerning the
HTLV-III/hepatitis statements for FEIBA IMMUNO, Vapour Heated (TIM 4),
PROTHROMPLEX, Vapour Heated (TIM 4), and KRYOBULIN, Vapour Heated (TIM 3)

We have discussed your proposal with Dr. Kaeser and Dr. Schwarz. Both of them do not agree to use a statement which diverges essentially from the wording generally adopted by our company world-wide. The statement agreed upon during our May meeting is already a commitment on our part, since we generally state that the transmission of HTLV-III will be prevented.

We do not see any connection with the Armour product which was heat-treated and prepared from unscreened material and caused sero-conversion. Our product is vapour heated and produced from HTLV-III negative plasma donations and we have provided data for HTLV-III inactivation in our preclinical study which shows a 10^6 reduction of HTLV-III already after 3 hours.

If we used a weaker statement such as proposed by IMMUNO Ltd. we might also run into difficulties at a later date, should it become necessary or appropriate to use a stronger statement. We will then not be able to provide further data on HTLV-III inactivation.

For the above reasons both Dr. Schwarz and Dr. Kaeser are of the opinion that we should leave the respective statements as agreed upon during our May meeting.

The statements should therefore read as follows:

"By careful selection of donors and plasma and the vapour heat treatment process, the transmission of HTLV-III can be excluded.

The above measures will certainly reduce the risk of transmission of viral hepatitis but this cannot be entirely ruled out."

Kind regards

GRO-C

Dipl.Dolm. I. Diernhofer
Head, Licensing Department