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DATE: May 14, 1986
TO: List
FROM: William Terry, M.D. GRO-C
SUBJECT: "Inactivation of LAV-HTLV-III in Blood Coagulants"

I have finally had the opportunity to carefully review the Paul Ehrlich Institute report, and while I think the data are interesting, the conclusions reached by Professor Kurth are overstated.

On page 14 the report states that, "Heating the lyophilized preparation (IP/HT) to 60° C for 10 hours with a residual moisture of about 1% led to a complete inactivation of at least 10⁶ ID₅₀/ml." The same results were obtained with preparations of Factor VIII-HP/HT and PPSB/HT. This conclusion is not valid because Professor Kurth failed to re-assay virus after it had been placed in product prior to lyophilization and again failed to assay post-lyophilization. Based on our experience, there is decreased viral activity caused simply by mixing virus into product. In addition, as he mentions, lyophilization alone leads to a reduction of virus titer by 2 to 3 logs. Since post-lyophilization data are not shown, the true starting point for the effectiveness of heating can only be estimated. If we use his own numbers, assuming there has been a decrease in 0.5 log from adding virus into the product and then an additional 2 to 3 log decrease caused by lyophilization, the maximum amount of virus available prior to heating is on the order of 3 logs. The only conclusion that can be reached, therefore, is that heating these products at 60° for 10 hours could lead to at least 3 logs of inactivation.

It is disturbing that post-lyophilization data are not presented, since the protocol sent to Eschwege required this as part of the experiment. To spend approximately \$120,000 for experiments that do not follow the required protocol and that are reported in a misleading manner does not seem to be in the best interests of the Corporation.

In summary, Professor Kurth's data demonstrate a 3 log reduction due to the heating step alone. While heating may lead to a greater reduction than this, it is not proven by these results, and the data are therefore no different from those attained at Meloy. I hope you find this information of some interest.

WDT:jp

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