

# Cutter



TO: Jan Peterson DATE: May 17, 1984

FROM: Milt Mozen COPIES TO: G. Mitra

SUBJECT: Synopsis of Jay Levy study on J. Levy

retrovirus inactivation in Koate®

On May 9, 1984, a press release was issued by the University of California San Francisco relating to the finding of a retrovirus, lymphadenopathy-associated virus (LAV)\*, having a major role in AIDS, and to the fate of a mouse retrovirus exposed to our process for the manufacture of Koate®.

These studies were under the direction of Jay Levy, M.D., UCSF Associate Professor of Medicine, and an investigator in the Cancer Research Institute. Dr. Levy reported these results in Toronto at a joint meeting of the American Society of Clinical Oncology and the American Association for Cancer Research. The studies with Koate were carried out in collaboration with researchers at Cutter namely, Dr. George Mitra, Mel Wong, and Dr. Milt Mozen and were designed to determine whether the retrovirus could survive the conditions used for preparing Koate®. The experiments were carried out by spiking human plasma with a mouse xenotropic type C retrovirus resembling LAV and then fractionating the plasma to Koate® and determining where the retrovirus migrated during fractionation and how much survived at each purification step. Additionally, the retrovirus was added at the final step of Koate® purification and its inactivation determined at various time points during Cutter's heating process of 68°C for 72 hours.

The results of these studies showed that fractionation without the heat treatment step caused only a small amount of retrovirus activity loss. This finding differs from the widely held opinion that a retrovirus could not survive such a process. However, when Koate® containing retrovirus particles was subjected to Cutter's heating process, no retrovirus were detected after 72 hours. However, retrovirus were still measurable at 48 hours.

We believe these findings are very significant. First, because they show that a retrovirus similar to LAV is more hearty than previously thought. Second, that the heat regimen adopted by Cutter is effective in totally inactivating this retrovirus. It is important to note that in this study only Cutter's heating conditions were tested, and it cannot be assumed that the heating conditions of all manufacturers would be similarly effective in eliminating retroviruses. Dr. Levy will soon be publishing these results.

\*LAV is believed by some investigators to be identical to the recently described HTLV-III.



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