

Interoffice
Communication

CONFIDENTIAL



Berkeley, CA

CC: R. Galustian
Dr. H. Mayer
H. Wallrabe

Date February 6, 1987

Subject: Alleged seroconversion to HIV
Antibody Positivity
From M.M. Sternberg

To Dr. Risse

We have been advised by Mr. Ralph Galustian to provide you with the following brief:

For the last several weeks we received information that Dr. Mariani, a physician of Rome, Italy is claiming that three patients have seroconverted to HIV [AIDS Virus] antibody positive after having received heat treated Cutter's Koate^R and Konyne^R products. Acting in close contact and agreement with Mr. Jack Wood, Vice President of Cutter Biologicals in Europe, we sent Drs. Rousell and Mozen, from Research in Berkeley, to Italy for a thorough review of the situation. Prior to their visit we enlisted the support of Dr. Jay Levy, University of California-San Francisco one of the leading AIDS investigators and a consultant to us. Dr. Levy, after hearing the information that we had available at the time, categorically stated that the process developed at Cutter has been shown beyond doubt to inactivate HIV with a large margin of over kill.

On February 2, 1987, a meeting was held at the Hemophilia and Thrombosis Center of the University of Milano with Drs. Mannucci and Mariani, in the presence of Drs. Vanni and DeTomasi, from Sclavo our distributor in Italy, Mr. Jack Wood and Drs. Rousell and Mozen, from Cutter. The results of the investigation are as follows:

Two of the cases were hemophilia B individuals who received small amounts of Konyne HT interspersed with large doses of Hébulin from Immuno. In both cases there is no way Konyne could be unequivocally implicated, although there seems no doubt that seroconversion to HIV did occur, in spite of the patients receiving heat treated preparations.

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