

Tab 186

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Cutter



TO Dr. F. J. Celis
FROM J. Ryan
SUBJECT AIDS Impact on Cutter Biological

DATE October 6, 1983
COMES TO Dr. W. Schaeffler
Mr. J. Bjorth

AIDS continues as a major health concern in the U.S. The total number of AIDS cases in the U.S. is now 2,400. AIDS continues to increase in the homosexual and intravenous drug abuser groups. AIDS has been reported now in 16 hemophiliacs. The incidence in hemophiliacs has slowed down appreciably. This slow down is the only encouraging development in the AIDS situation. Publicity and political pressures have now caused the U.S. Government as well as other institutions to allocate substantial research dollars to determine the cause of AIDS. No cure is expected in the near future.

Although the link to human blood is not yet confirmed, there is a general belief that such a link exists. During the summer of 1983, collection of whole blood by the Red Cross was down by 15% because of the AIDS concern. This has since returned to normal as most of the "hysteria" surrounding AIDS has lessened.

Our Factor VIII sales have been dramatically affected by AIDS and we estimate the effect in 1983 to be reduced to \$8.7 million in Sales and \$3 million of Division Margin. The effect in the International Division is \$1.3 million in Sales and \$600,000 in Division Margin.

As reported earlier, Hyland was licensed with a heat-treated Factor VIII product earlier this year and remains the only licensed manufacturer in the U.S. market. We see an increasing sales penetration with their heat-treated product at a 15¢ per unit price compared to non-heat-treated at 9.5 to 10¢ per unit. Amour is expected to receive their heat-treated license in the U.S. in October and Beringwerke is expected to apply to the CoB for their heat-treated product in the near future.

Cutter's heat-treated Koates project suffered some delays due primarily to extra virus data required by the CoB. The license for the Cutter dry heat-treated process is now expected on March 1, 1984. Development of the wet process has been stymied. Licensure is not expected until February, 1984. Development of these processes has resulted in losses of product valued at \$700,000 and may be over \$1 million by year-end.

Our U.S. sales strategy for 1984 is to offer both a regular Koates at an average selling price of 9¢ as well as a heat-treated product at 12-15¢ per unit.

Beringwerke, Byland and Amour are licensed for heat-treated product in Germany. Cutter's sales of Koates in Germany are in even greater jeopardy with delays in licensure of the dry heat product. Once heat-treated AHF product is licensed in Japan, it will be virtually impossible for Cutter to sell non-heat-treated product in that important market. Italy and virtually all of the European markets for Factor VIII are turning to heat-treated product. Any further delay in licensure of the Cutter product will cause serious problems.

With the exception of a small effect in the blood bag sales, the AIDS effect on the Cutter Biological business has been limited to AHF. There still exists the possibility of effect on other plasma products. A team has been formed to study and evaluate "different AIDS Scenarios" and their report is expected by the end of November. We are in discussions with Ortho Diagnostics regarding a new "AIDS Screening Test" which may be approved by the FDA. Regulations may require that all our units of plasma be screened with such a test. The financial effect of this is not yet known.

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