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To: Dr. J. E. Pennington Ref: JB 88-253 May 20, 1988

Patient Initials: GRO-A Age: 67 years (at the time of receiving Koate-HT) Date of Birth: GRO-A 1920

Mild hemophilia A with a Factor VIIIc level of 13 IU per/dL.

On August 8, 1987 this patient developed a severe elbow bleed. Between August 11th and August 16th, 1987, he received 66 vials of Cutter Koate-HT lot number 50S021. Thus a total of 18,480 units of Koate-HT were administered.

On December 21st, 1987, the patient was admitted with a diagnosis of hepatitis. He was jaundiced and initially a diagnosis of gall stones was considered. His AST was 1032 IU per liter (normal range below 40 IU per liter), bilirubin was over 340 micromoles per liter (normal range 5 to 17 micromoles per liter), and alkaline phosphatase was 191 IU per liter (normal range 20 to 160 IU per liter). On December 22nd he was found to have positive HBsAg, negative HBeAg, negative HBeAb and negative HBsAb with a positive IgM antibody against HBcAg, the latter indicating an acute hepatitis B. On January 26th, 1988, the patient still had positive hepatitis B surface antigen. By March 29th the hepatitis B surface antigen had disappeared. He[±] was positive for hepatitis B surface antibody and on March 30th had normal liver function tests. He has recovered clinically and there are no evident sequelae.

GRO-C - Rousell