



Via live presentation- Washington, DC

July 13, 2006

To The Blood Products Advisory Committee:

In the 1970s and 1980s, liver transplantation in patients with hepatitis B, in the absence of immunoprophylaxis or with short-term immunoprophylaxis, was associated with disastrous results. The recurrence rate was approximately 80%, while the mortality rate was as high as 55% within 60 days post-transplant. Those who survived experienced a high rate of allograft loss, and the retransplant results were similarly dismal. Consequently, transplantation for hepatitis B was contraindicated in many centers during this period.

However, the prognosis has significantly improved over the past 20 years with the utilization of Hepatitis B Immune Globulin (HBIG) as standard of care to prevent HBV recurrence in HBV-positive liver transplant patients. Well documented in the medical literature is that the recurrence of HBV has been markedly reduced to approximately 20% with HBIG immunoprophylaxis. With the combined use of antiviral regimens plus immunoprophylaxis, the recurrence rate has further decreased to less than 5%.

Several recent clinical studies designed to identify the optimum HBIG/antiviral combination regimen have demonstrated that there was a high likelihood of recurrence of HBV if the HBIG regimen was discontinued post-transplant, thus pointing to the need for indefinite HBIG immunoprophylaxis to optimally prevent recurrence of HBV in liver transplant recipients.

In conclusion, the use of HBIG immunoprophylaxis in patients following HBV liver transplantation has clearly and dramatically improved clinical outcomes. It is in the best interests of the liver-transplant community, including both clinicians and patients, for there to be specific language in the product labeling to provide guidance on the appropriate use of HBIG to prevent recurrence of HBV in liver-transplant recipients. Therefore, we respectfully request that the Advisory Committee vote to approve the use of HBIG to prevent recurrence of HBV in this patient population.

Sincerely,



John Fung, MD, PhD
Chairman, General Surgery
Director, Transplantation Center
Cleveland Clinic

Linda Sher, MD
Associate Professor of Surgery
USC School of Medicine
Los Angeles, CA