DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

AUG - 8 2005

Mark Brecher, M.D.
Chair, Advisory Committee on Blood Safety and Availability
1101 Wootton Parkway, Suite 250
Rockville, MD 20852

Dear Dr. Brecher:

Thank you for your letter summarizing the topics discussed at the May meeting of the Advisory Committee on Blood Safety and Availability. I am encouraged by the progress reports on standardization of protocols for the detection of bacterial contamination and the extension of platelet product dating. This is an excellent example of the private sector and the Department working together to increase product safety and efficacy.

The Committee's continued evaluation of strategies for vigilant detection and management of emerging or re-emerging infectious diseases is a necessary first step toward the goal of reducing the risk of transfusion-transmitted diseases. Your work has potential impacts on blood and blood products as well as other vital products such as bone marrow, progenitor cells, tissues, and organs. Please continue your discussions and deliberations on this important issue.

We have investigated the current status of IVIG highlighted in your comments. After extensive discussions we have concluded that at this time there are sufficient supplies available to patients. However, there do appear to be ongoing marketplace adjustments related to how manufacturers and distributors are managing their respective inventories, and we will continue to monitor the situation.

Our examination of the allocation process indicates that physicians and providers might best serve their patients by communicating supply needs directly to manufacturers and distributors. Review of the current utilization of IGIV also indicates that there is increased use of this product for off-label uses that may also be increasing pressure on supplies. Therefore, we believe that physicians should ensure that priority be given to IGIV treatment for FDA labeled uses and those diseases or clinical conditions that have been shown to benefit from IGIV based on evidence of safety and efficacy.

While HHS has no control over the prices manufacturers or product distributors may charge, the Centers for Medicare and Medicaid Services (CMS) will continue to monitor the average sales price on a timely basis, as mandated by Congress, to ensure that the reimbursement reflects 106 percent of manufacturers' average sales price.

Thank you for your dedication, and please express my appreciation to the Committee.

Sincerely yours,

Cristina V. Beato M.D.

Cristina V. Beato, M.D.
Acting Assistant Secretary for Health