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June 1, 2005

Cristina V. Beato, MD,
Acting Assistant Secretary
Department of Health and Human Services
200 Independence Ave, SW
Room 716-G
Washington, DC 20201

Dear Dr. Beato,

The Advisory Committee on Blood Safety and Availability (ACBSA) met May 16-17, 2005 in Bethesda, MD to discuss "strategic actions for emerging infectious diseases to reduce the risk of transfusion transmitted diseases and its impact on availability" and an "update on current status of bacterial detection methods as a released platelet concentrate procedure." Prior to addressing those issues, the Committee obtained an update on current issues, including access and availability to IGIV products.

No recommendations were made at this time regarding strategies for reducing the risk of transfusion transmitted diseases in light of emerging agents. The Committee tabled until the next meeting any specific recommendation regarding strategies since numerous questions needed to be discussed and given careful consideration.

While the issue of IGIV is complex, the Committee heard comments from patients, clinical providers, manufacturers, distributors, and CMS. Based on discussions the Committee recommends to the Secretary the following unanimously passed resolution:

The Committee finds that:

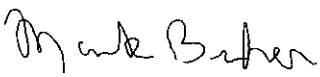
1. Since our prior recommendations of January 2005, there is a worsening crisis in the availability of and access to IGIV products that is affecting and placing patients' lives at risk (e.g., patients with immunodeficiency).
2. Changes in reimbursement of IGIV products under MMA since January 2005 have resulted in shortfalls in the reimbursement of IGIV products and their administration.
3. Immediate interventions are needed to protect patients' lives and health.

We therefore urge the Secretary:

1. to declare a public health emergency so as to enable CMS to apply alternative mechanisms for determination of the reimbursement schedule for IGIV products, and
2. otherwise to assist CMS to identify effective short and long term solutions to the problem of unavailability of and access to IGIV products in all settings.

The discussion on FDA position to require bacterial testing as a release criterion for platelet concentrations needed no recommendation. The manufacturers of various platelet collection and storage systems presented their approaches to FDA required testing and post market surveillance.

Respectfully,



Mark E. Brecher M.D.
Chair, DHHS Advisory Committee on Blood Safety and Availability

Cc: J Holmberg