The Advisory Committee on Blood Safety and Availability (ACBSA) met May 16-17, 2005 in Bethesda, MD to discuss:

1) Strategic actions for emerging infectious diseases to reduce the risk of transfusion transmitted diseases and its impact on availability.

2) An update on current status of bacterial detection methods as a released platelet concentrate procedure.

3) An update on current issues, including access and availability to IGIV products.

1) Strategic actions for emerging infectious diseases to reduce the risk of transfusion transmitted diseases and its impact on availability.

The Committee decided that numerous questions surrounding that needed to be resolved prior to making a specific recommendation and the issue was tabled until the next meeting.

2) An update on current status of bacterial detection methods as a released platelet concentrate procedure.

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.

3) An update on current issues, including access and availability to IGIV products.

The Committee found 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.

3) An update on current issues, including access and availability to IGIV products.

The Committee therefore urged 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.

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

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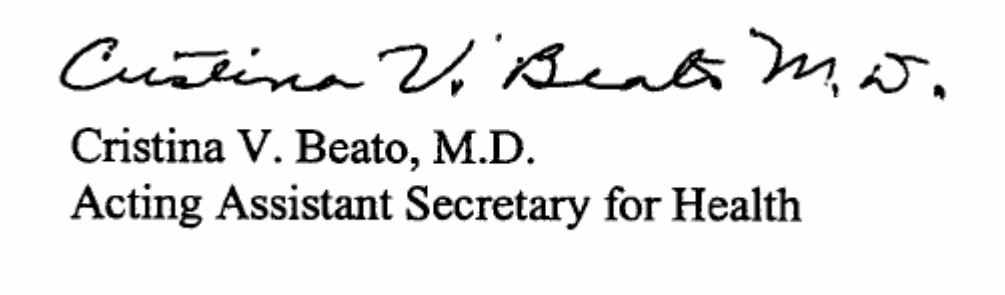

Cristina V. Beato, M.D.
Acting Assistant Secretary for Health

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Status of Immune Globulin Intravenous (IGIV) Products

In the last few months, the Department of Health and Human Services (HHS) and its agencies, the Food and Drug Administration (FDA) and the

We are working with stakeholders to further assess the evolving marketplace. At this time, we believe there is sufficient supply of IGIV for patients who need it. Under manufacturers' allocation processes, physicians might best serve their patients by communicating their supply needs directly to manufacturers and by ensuring that IGIV treatment is prioritized toward FDA labeled use and those diseases or clinical conditions that have been shown to benefit from IGIV based on evidence of safety and efficacy, and for which safe and effective alternative therapies are not available.

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It is a HHS goal to work with partners in the marketplace to help prevent or alleviate shortages of medical products, including IGIV. We are seeking additional information on the current availability of IGIV products. We are asking health care providers and patients who experience difficulty obtaining IGIV to report their experiences (e.g. denial of treatment, delay of treatment, forced reduction in dosage, etc.) by sending an email to FDA at CBERProductshortages@cber.fda.gov. Those without email access may call (800) 835-4709. Reports related to Medicare-related coverage and access to care should call 1-800-MEDICARE.

Last Revised: August 11, 2005