



Department of Health and Human Services  
Advisory Committee on Blood Safety and Availability  
1101 Wooton Parkway, Suite 250  
Rockville, Maryland 20852

October 2, 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 September 19-20, 2005 in Bethesda, MD to discuss to continue discussions on two current issues. The first issue access and availability to IGIV products. The Committee felt this remains an **URGENT** issue.

The Committee makes the following two recommendations to the Secretary:

After new input from patients, medical professionals, distributors and manufacturers, the committee remains highly concerned that persistent disruptions in access to IGIV, which include a progressive shift to treatment in a hospital, continue to compromise quality of care for many patients. In particular, we believe the transfer to a hospital may impair continuity of care by their usual medical provider and may add otherwise unnecessary cost, logistical complexity and nosocomial infectious risk. We further are concerned that a change to hospital outpatient reimbursement to ASP + 8% effective January 2006 will further aggravate an already difficult situation and that this shift will not be sustainable.

We therefore recommend that the Secretary take immediate steps to:

1. Increase reimbursement for non-hospital IGIV therapy to a level consistent with current market pricing.
  - a. Consider reclassifying IGIV as a biological response modifier.
  - b. Consider declaring a public health emergency to address the short-term problem.
2. Modify the current plan to change hospital outpatient reimbursement to ASP + 8% in January 2006 in such a way as to prevent any sudden and large decrease in reimbursement.

3. Reexamine whether the current IGIV supplies are meeting patient needs.
4. Work with Congress to establish a long term stable and sustainable reimbursement structure.

The second item was the need for coordinated strategy plan for ensuring blood safety and availability. The Committee's recommendation is:

Blood is a critical element of modern medical care, and ensuring an adequate supply of safe blood is a national responsibility. Although there have been dramatic improvements in blood safety and availability in the United States in the last two decades, the Committee finds that there are compelling needs for improvement in some areas:

- Minimizing disruptions in the supply of and access to blood products and their analogues,
- Meeting the product development needs for patients with rare disorders,
- Timely funding to ensure appropriate utilization of new technologies,
- Integrating presently fragmented systems for monitoring blood safety and availability,
- Aligning reimbursement and funding policies with product approvals and other decisions intended to optimize blood safety and availability,
- Modifying reimbursement policies as needed to sustain access to blood products and their analogues for all patient groups (e.g. IGIV),
- Reassessing policies and their related interventions based on evaluation of their impacts,
- Intensifying efforts to influence clinical practices related to blood transfusion and alternative therapies, based on scientific evidence,
- Accelerating responses to threats (e.g., patient /specimen/unit misidentification) for which there are available interventions,
- Utilizing formal risk communication strategies targeted to blood donors, patients, and care providers to enhance scientific comprehension and public trust,
- Pursuing opportunities to enhance public health in the management of blood donors,
- Promoting comprehensive disaster planning including sustaining the inventories necessary for an effective crisis response,
- Establishing a proactive, prioritized, and goal- oriented research agenda,

- Utilizing formal assessment tools more routinely in policy development and decision making,
- Further clarifying the respective roles of government agencies and the private sector in management and oversight of the blood system,

Therefore the Committee believes that the Department should develop, in collaboration with stakeholders and interested parties, a strategic plan for increasing safety and availability for blood products and their analogues. This plan should include a review of the process of policy and decision making for blood issues and its integration with broader public health policy making.

Such a plan should encompass:

- Structured process for policy and decision-making,
- Integration of blood system within the PH Infrastructure,
- Surveillance of adverse events related to blood donations and transfusions,
- Risk communication,
- Error prevention in blood collection centers, transfusion services and clinical transfusion settings,
- Donor recruitment and retention,
- Clinical practice standards for transfusion,
- Strategic research agenda,
- Disaster planning,
- Stable and sustainable reimbursement ,
- Funding for promising new technologies.

Respectfully,



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

Cc: J Holmberg