February 5, 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 January 25-26, 2005 in Bethesda, MD to discuss a variety of current issues, including the current status of bacterial detection in platelet concentrates, availability and progress toward seven-day platelets, identification of reimbursement issues associated with plasma and recombinant analogue therapy, and current and emerging pathogens – sharpening the health care approach for the 21st century to reduce the risk of transfusion-transmitted diseases.

The committee recommends to the Secretary the following unanimously passed resolutions:

Bacterial Blood Safety Initiative
The Advisory Committee on Blood Safety and Availability acknowledged the innovative regulatory pathway proposed by the United States Food and Drug Administration, allowing collection of post approval information on quality control tests to support applications for the approval of bacterial detection assays as release tests to reduce the risk of bacterial contamination of platelet concentrates and to facilitate the availability of seven-day platelets.

Whereas the approval process as proposed will require the capture of accurate information describing the extent of bacterial contamination of platelet concentrates, the capacity of diagnostic tests to detect this in parallel with the monitoring of the clinical safety/efficacy of screened concentrates; and understanding the requirement for post approval monitoring of bacterial contamination events may not persist beyond final approval,
the Committee recommended that the HHS Secretary request the cooperation of appropriate agencies with blood organizations and transfusion facilities to establish an ongoing program to:

- monitor residual bacterial contamination risk and generate summary reports;
- provide resources for surveillance of transfusion-associated sepsis; and
- make such additional recommendations as may be needed to maintain recipient safety.

Reimbursement of Plasma Derived Products and Their Recombinant Analogues

The Committee found that current reimbursement schedules for plasma derived products and their recombinant analogues for treatment of chronic conditions are not adequate to support optimal care of individual patients. Additionally, shortages in supply of these needed therapeutics have impacted the health care of these lifelong disorders. The Committee, therefore, recommends that the Secretary take steps to augment reimbursement of plasma derived products and recombinant analogues.

The committee endorses the following principles to guide such efforts:

- Plasma derived products and their recombinant analogues should be reimbursed at rates consistent with their true costs, including costs of distribution and administration;
- Reimbursement should be sufficient to ensure an adequate supply of these therapies;
- Individual products within product classes should be recognized as therapeutically unique;
- Equivalent reimbursement should be provided in different care settings; and
- The lifelong cost of treatment to the individual patient should be addressed in any pricing structure, including the extraordinary impact of co-payments.

Support of Policy of the Financial Burden for Patients with Bleeding Disorders

WHEREAS the committee is acutely aware of many challenges facing the bleeding disorders community;

WHEREAS the committee has been made aware that one of the foremost challenges to Access to Care is the 20 percent Medicare patient co-pay;

WHEREAS the cost of care for bleeding disorders can be as high as $8,000 per month per adult beneficiary, which far exceeds even the highest paid Social Security benefits;

WHEREAS supplemental coverage may not be obtainable or affordable for disabled qualified Medicare beneficiaries;

WHEREAS the committee is aware that the substantial cost of patient co-pay results in reduced access to quality care, impact on *choice* of product, provider and physician and significant personal financial and social consequences;

WHEREAS Medicare policy decisions are followed closely by third party payors;

The Advisory Committee on Blood Safety and Availability urges the Secretary of HHS to support any proposed policy and/or legislation to address the extraordinary financial burden for these patients.

Respectfully,

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