THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 28 2004

Mark E. Brecher, M.D.
Chair, Advisory Committee on Blood Safety and Availability
Department of Pathology and Laboratory Medicine
University of North Carolina Hospitals
101 Manning Drive
Chapel Hill, NC 27514

Dear Dr. Brecher:

Thank you for your letter summarizing the activities of the meeting of the Advisory Committee on Blood Safety and Availability (ACBSA). The discussion of "methods to reduce the risk of bacterial contamination" is important to our efforts to balance safety and availability.

I appreciate the ACBSA recognizing barriers to the optimal implementation of bacterial detection in platelet products. Identification of needed data and reduction of the scientific data gaps are key in removing these barriers. The Department and its agencies, specifically the Food and Drug Administration, the Centers for Disease Control and Prevention, and the National Heart, Lung and Blood Institute of the National Institutes of Health, are carefully considering the recommendation made by the Committee and are currently working with the American Association of Blood Banks Task Force on Bacterial Contamination to ensure strategies are developed which will contribute to closing the data gap through carefully planned studies. It is my goal, that through cooperative strategic thinking, a plan can be developed that will reduce the risk of bacterial contamination while improving the safety and availability of both apheresis and whole blood derived platelets for patient care.

The Committee's comments on reimbursement at this meeting and at previous meetings indicate a continuing concern from the collector, provider, and user of blood and plasma products, including the plasma clotting factor analogs. The three recommendations of the ACBSA from April require more discussion. I am referring these recommendations to Dr. Cristina Beato, Acting Assistant Secretary for Health, and Dr. Mark McClellan, Administrator of the Centers for Medicare and Medicaid Services, for evaluation by their staff.

I continue to look to ACBSA for important and timely advice. I appreciate your dedication and service.

Sincerely,

Tommy G. Thompson

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April 19, 2004

Tommy G. Thompson, Secretary
Department of Health and Human Services
200 Independence Ave, SW Room 600
Washington, DC 20201

Dear Secretary Thompson,

The DHHS Advisory Committee on Blood Safety and Availability met April 7 and 8, 2004 in Washington, DC. The committee was charged to discuss the "Impact and Assessment of bacterial Detection on Platelet Product Availability". This topic resulted from recent national standards that have mandated by voluntary accrediting organizations (i.e. the American Association of Blood Banks - AABB and the College of American Pathologists - CAP) and the recent request by HHS to the AABB to delay such implementation (which was declined by the AABB – see copies of attached correspondence).

Because of my research/consultant support (but no equity interest) from a variety of companies with a stake in the outcome of such discussions, I chose to recuse myself as chair of the committee for this session and limited my participation to responding to factual questions in my role as a recognized expert.

The committee recommended:

Whereas the DHHS ACBSA recognizes the importance of methods to reduce the risk of bacterial contamination in both apheresis and whole blood derived platelets; and whereas the committee also recognizes the potential for limited availability of platelets, particularly whole blood derived platelets; and whereas the current five day shelf life of apheresis and whole blood derived platelets and restrictions on whole blood derived platelet pre-storage pooling have been identified as barriers to the optimal implementation of bacterial detection in platelets, the committee encourages dialog among the DHHS agencies, blood programs, and manufacturers to ensure strategies for:

- Facilitation of prompt development of technologies;
- The design and completion of feasible studies; and
- The satisfaction of licensing requirements to permit both the pre-storage pooling of whole blood derived platelets and extension of platelet dating.

I have attached 2 brief summaries of the discussions as printed in the America's Blood Centers Newsletter and the AABBs weekly report as they provide background to the committee's recommendation.

A second topic discussed related to CMS reimbursement for blood related products. The recommendations are as follows:

Recommendation 1:

Whereas a safe, available and affordable blood supply is an essential National resource; and, whereas the committee applauds Secretary Thompson recognition of the importance of sound policy of reimbursement, the DHHS ACBSA:

1) reiterates the recommendations of their January 28 & 29, 2004 meeting relevant to blood and blood products, including plasma-derived therapeutics and their recombinant analogs,
2) endorses the MMA Conference report statement,
" The Secretary is directed to compile and clarify the procedures and policies for billing for blood and blood cost in the hospital impatient and outpatient setting as well as the operation of the collection of the blood deductibles."
3) urges timely action in response to the above directive and the aforementioned recommendations of the committee.

Recommendation 2:

Whereas blood clotting factors are life saving biologic therapies; and whereas it is crucial that individuals with hemophilia have access to and choice of the full range of blood clotting factors available on the market; and whereas inappropriate reimbursement methodologies can have a significant and detrimental impact on Medicare beneficiary access to these therapies; and whereas a competitive bidding process under Medicare Part B (Sec. 1842 (o)(1)(C)) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) would not assure access to blood clotting factor; and
whereas Congress has recognized the unique access challenges facing beneficiaries who rely upon life sustaining plasma protein therapies through an exclusion of intravenous immune globulins (IVIG) therapies from competitive acquisition provisions of the MMA, the Committee recommends that the Secretary exclude blood clotting factors from competitive acquisition under the Exclusion Authority granted in Sec. 1847B(a)(1)(D).

Recommendation 3:

Whereas a competitive acquisition section of the MMA (section 302) contains language that may require the establishment of quality standards and accreditation bodies for blood products and transfusion medicine services; and whereas adequate federal regulatory controls and public and private standard setting and accreditation bodies exist and are effective, the committee requests that the Secretary should use his authority contained in the MMA to exclude all blood products and transfusion medicine services from the establishment of quality standards and competitive acquisition provisions of the MMA.

Respectfully,

Mark C Brecher MD

Mark E. Brecher M.D.
Chair, DHHS Advisory Committee on Blood Safety and Availability
Director, Transplantation and Transfusion Services, McLendon Clinical Laboratories
Professor of Pathology and Laboratory Medicine
University of North Carolina

cc: Christina Beato, MD; Jerry Holmberg, PhD; Lawrence McMurtry