



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