



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

JAN 13 2005

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

Dear Dr. Brecher:

Thank you for your letter summarizing the activities and recommendations of the August meeting of the Advisory Committee on Blood Safety and Availability (ACBSA).

Since the Committee first recognized the importance of transfusion related acute lung injury (TRALI) as an issue in blood transfusion safety in 2003, there has been an increased awareness within the Department and the blood community. While we review the recommendations and determine appropriate action, I request that you continue to monitor progress by the scientific community and bring the topic to the Committee as needed.


The Committee's review of access to treatment for individuals with rare blood disorders was timely. Currently recommendations are being considered by several agencies within the Department. Specifically, the Food and Drug Administration is considering alternative pathways to the approval process for additional clinical indications and new product introduction. This issue will be discussed at a co-sponsored public workshop in June 2005.

I am also pleased by the continuing progress made by the blood community and the Department's agencies regarding the safety of platelet products and standardization of protocols for the detection of bacterial contamination. The recommendations are being carefully considered and we are hopeful that resolution can be achieved soon.

The Committee's discussion and recommendations made regarding hepatitis B virus mini pool nucleic acid testing have been extremely helpful to the Department and its Agencies in weighing cost and public health benefit. A status report on this issue should be available to the Committee at the next meeting.

Please express to the Committee members my sincere appreciation for their advice on these issues.

Sincerely,


Tommy G. Thompson