DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington DC 20201

MAR - 3 2009

Arthur W. Bracey, M.D.
Chair, Advisory Committee on Blood Safety and Availability
1101 Wootton Parkway, Suite 250
Rockville, MD 20852

Dear Dr. Bracey:

Thank you for your letter of July 2008 regarding the recommendations of the Advisory Committee on Blood Safety and Availability (ACBSA). Over the months since your letter, the Department and its operating divisions have developed some significant action plans to address the ACBSA recommendations.

While bacterial contamination of platelets remains an unresolved problem, testing strategies to improve bacterial safety and concurrently to permit extension of apheresis platelet dating to 7 days were addressed at the Food and Drug Administration's (FDA) Blood Product Advisory Committee meeting in September and discussion of options with the blood industry are ongoing. During the summer, the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) held a consultation on issues and priorities related to development of pathogen reduction technologies for blood components. A paper of those findings has been submitted for publication. In addition, the Blood Availability and Safety Information System (BASIS) is collecting data on the availability of platelets within the clinical facilities and reports are provided to senior leadership each week.

Consistent with the ACBSA recommendation for adequately controlled research on the effects of red cell age on outcome, NHLBI has established the Red Cell Storage Age Study (RECESS). This is a prospective, randomized, blinded superiority study on the physiologic effects and clinical outcome of transfusion with younger (<10 days) vs. older (>21 days) stored red blood cells (RBCs) in complex cardiac surgery. The study is expected to commence in 2009.

Grants submitted in response to NHLBI solicitation of basic research on the RBC storage lesion, including the development of animal models to improve our understanding of the changes which occur during storage recently underwent scientific review.

NHLBI is also supporting epidemiological investigation using large data bases collected in Sweden and Denmark (SCANDAT database) to study the effects of storage time on risks of some short- and long-term adverse outcomes after transfusions of RBCs. This study is underway and is being conducted by Scandinavian investigators in Sweden in

collaboration with NHLBI's Retrovirus Epidemiology Donor Study (REDS-II) investigators.

Collaboration is ongoing between FDA, Centers for Medicare and Medicaid Services, and Health Resources and Services Administration to collect data on tissues and organs as recommended by the ACBSA.

Please express my sincere appreciation to the entire Committee on the recommendations provided to the Secretary. We are excited that the action plan to support these recommendations has been embraced by the operating divisions. Updates on all these activities should be provided at an upcoming ACBSA meeting.

Sincerely yours,

Steven K. Galson, M.D., M.P.H.
RADM, USPHS
Acting Assistant Secretary for Health