



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

AUG 14 2007

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

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

Dear Dr. Bracey:

It was a privilege to meet with the Advisory Committee on Blood Safety and Availability (ACBSA) at the May 2007 meeting. I appreciate the leadership you provide to the Committee and the thoughtful discussion of the proposed questions regarding the need, opportunity, and the scope of a master strategy for transfusion and transplantation safety.

It is apparent from the response to the questions that there is both an opportunity and a need to develop a process to enhance quality improvement in transfusion medicine and transplantation. As the Committee noted the benefit-risk profile differs for transfusion, tissue and transplant recipients, however all patients treated with these modalities have the potential for acquiring life-threatening infections. This risk increases if good laboratory, manufacturing, tissue, or transplantation practices are not followed. The Committee also noted that there needs to be a mechanism to detect and monitor emerging, unknown diseases which may be transmitted by transfusions or transplantations.

The scope of a master strategy is very consistent with the previous recommendations made for biovigilance to include all transfusion and transplantation modalities. The Department and its operating divisions are working with the private sector concurrently with internal discussions to move forward on these recommendations. Some activities, such as biovigilance partnerships have already been initiated with both AABB and the United Network of Organ Sharing (UNOS) using HHS resources.

Please express to the Committee my appreciation for their service and valued recommendations. I look forward to the advancements in transfusion and transplantation safety which will be realized in the near future.

Sincerely,

A handwritten signature in black ink, appearing to read "John O. Agwunobi", is written over a horizontal line.

John O. Agwunobi
Assistant Secretary for Health