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

John O. Agwunobi, M.D.
Assistant Secretary for Health
Office of Public Health and Science
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Agwunobi:

The Advisory Committee on Blood Safety and Availability (ACBSA) is grateful for your support of our previous recommendation for the establishment a comprehensive system for biovigilance in the United States. The recent change in our charter, with a broadening of oversight to include transfusion and transplantation safety, fits the strategic objectives recommended by ACBSA.

We appreciate your input at our recent meeting on May 10 and 11, 2007 and will take on your challenge for us look forward and aid in developing the best possible systems to promote the public health in those matters under our purview.

During our May 2007 meeting held in Washington, DC, ACBSA heard presentations on the status of safety systems for transfusion, tissue banking and transplantation from major blood collectors, accrediting agencies and practicing physicians. The Committee was impressed by the number of common issues facing these activities and the opportunity for process improvement.

The following statements contain our answers to the questions you presented to ACBSA regarding our thoughts on specific aspects of a biovigilance system.

Whereas the Assistant Secretary for Health accepted the Committee's August 2006 recommendation to pursue Biovigilance by expanding the role of the Committee's oversight in its new charter and by establishing a PHS Biovigilance Task Group, the Assistant Secretary requests additional input from HHS ACBSA. The Committee responded to questions posed by the Assistant Secretary in the following statements:

1. **Is there an opportunity to lay out a process for transfusion and transplantation safety for the future?**

   Yes, there is a need to develop processes to enhance quality improvement in transfusion medicine and transplantation.

2. **Is there scientific evidence to support a need for a master strategy?**

   While surveillance evidence is limited, reports of infectious disease transmission and errors substantiate the need for a master strategy for safety. Noting that the benefit-risk profile differs between transfusion, tissue and transplant recipients, all patients treated with these modalities have potential for acquiring life-threatening infections if infectious disease screening is flawed or emerging, unknown diseases evolve unchecked over time.

3. **What should be the scope (rubric) of a master strategy?**

   I. Recipient Outcome Surveillance (Biovigilance System)

      a. Identify all donors using common identification numbers, linked to biological products that are uniquely identified

      b. Mandatory adverse event reporting process for tissue, organ, and blood therapy through appropriate mechanisms to designated public health authorities and to recipients and donors.

      c. Timely and efficiently trace all biologic products to the clinical user, recipient and donor

d. Recognize transmissible events resulting in adverse outcomes, including:
   i. Infectious agents
   ii. Malignancies
   iii. Toxins

e. Build communication and education network to disseminate data to users

II. Develop informatics to support surveillance, process improvement and evidence-based research

III. Include other strategic plan elements as needed, such as:

a. Donor recruitment
b. Donor screening
c. Research coordination
d. Emergency Preparedness

4. **What are areas of commonality with blood products, cord, progenitor cells and bone marrow, tissues and organs?**

Key elements in common with transfusion required for ensuring high quality include:

a. Donor recruitment - availability
b. Donor screening and eligibility
c. Collection
d. Infectious disease testing
e. Transportation
f. Storage
g. Processing
h. Labeling
i. Traceability
j. Good Manufacturing Practices / Good Tissue Practices
k. Outcomes analysis
l. Adverse event reporting

In addition to these commonalities, there is a need to evaluate the differences.

5. **How best should this be done with the stakeholders? How do we begin?**

HHS should convene a forum of stakeholders to include public health agencies, accrediting agencies, manufacturers, clinicians, consumers and end users. HHS should be responsible for implementing a master strategy with appropriate resources based on input from stakeholders.

6. **What are the resources needed? What are the estimated costs?**

See number 5

We look forward to further progress on this important matter. We feel that this will evolve into a product that all will appreciate and enthusiastically endorse. Please let me know if you need additional input from me or the Committee on this any other matter under our purview.

Sincerely,

Arthur W. Bracey