February 9, 2007

John O. Agwunobi
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 met on August 30 and 31, 2006 in Crystal City, Virginia. Over the last year the Committee has been reviewing the current status of blood safety and availability within the United States and has made recommendations regarding measures to be taken. One of the areas of concern with which the Committee dealt was that of biovigilance of transfusion and transplantation products. The meeting was focused on the design, implementation and outcomes of biovigilance systems operating both within and outside of the United States. The consensus of the Committee was that biovigilance systems are important tools for improving outcomes related to transfusion and transplantation therapy. The Committee recognizes the complexity of launching a biovigilance system within the existing health care network of this country. Given the structure of our healthcare system, the development of a public-private partnership will be essential for the effective implementation of a biovigilance system. The Committee recommends that the Secretary move forward, emphasizing the important attributes in the following statement developed in our meeting.

The Committee recommends that the Secretary establish an inter-agency task group to develop an operational proposal for enhancing safety monitoring and developing a response system for blood products, cell and tissue products and solid organs in partnership with initiatives already existing or in development in the private sector.

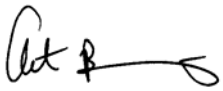
The task group should address the following issues:

- The effectiveness of the current system;
- The need for mandatory versus non-mandatory, and regulatory versus non-regulatory reporting;
- The scope of reporting with regard to product problems, medical errors and adverse events including recognized and novel events;
- Database centralization versus data sharing;
- Database governance, ownership and accessibility;
- Format and standards for data reporting including confidentiality;

- Funding mechanisms for a sustainable biovigilance system; and,
- Design and feasibility of suitable pilot programs that would provide additional value by enhancing transfusion and transplantation safety.

As the Department's Blood Safety Officer and leader of any of the government's blood safety initiatives, your support will be critical in making this system operative. We look forward to directives from you regarding this important topic and other topics on which you would like us to provide recommendations related to improving transfusion and transplantation safety.

Sincerely,



Arthur Bracey
Chairman, Advisory Committee
on Blood Safety and Availability