Whereas promoting the safety of the US blood supply is a principal activity of the Advisory Committee on Blood Safety and Availability, and inclusion of efforts to improve organ and other tissue safety and availability also need to be considered, we recommend that the Secretary coordinate Federal actions and programs to support and facilitate biovigilance in partnership with initiatives in the private sector.

"Biovigilance" is defined as a comprehensive and integrated national patient safety program to collect, analyze and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs. The program should be outcome driven with the objectives of providing early warning systems of safety issues, exchanging of safety information, and promoting education and the application of evidence for practice improvement.

Formation of a HHS and PHS Biovigilance Task Group would be an important step for identification of the vision, goals, and processes needed to advance these objectives. This Task Group should participate with private sector efforts, including the AABB Inter-organizational Task Force on Biovigilance, to advance public health in this effort.

The PHS task group should produce an analysis and operational proposal concurrently with the AABB Inter-organizational Task Force on Biovigilance and other private sector efforts to include:

- A gap analysis regarding the effectiveness of the current activities;
- 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 clinical 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;
- Potential for coordination with non-U.S. safety reporting systems;
- Funding mechanisms for a sustainable system; and,
- Design and feasibility of suitable pilot programs to determine the characteristics of a value-added system.