DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

January 28, 2008

Donald Wright, M.D. M.P.H.
Acting Assistant Secretary for Health
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. Wright:

The HHS Advisory Committee on Blood Safety and Availability met in Washington, DC on January 9 and 10, 2008. The Committee heard from a number of authorities regarding current risks of transfusion, available testing strategies and supplier capability for developing new tests. We also heard reports on systems designed to inactivate a wide range of potential blood-borne pathogens including toxicity data, clinical efficacy data from clinical trials and ongoing European experience as well as a summation of a recent Canadian consensus conference of pathogen inactivation. The Committee felt that further development of these systems and a move toward implementation is warranted. The Committee's resolution follows.

"The Advisory Committee on Blood Safety and Availability (ACBSA) finds that accumulating evidence for the efficacy and safety of pathogen reduction warrants a commitment and concerted effort to add this technology as a broadly applicable safeguard which additionally would provide a reasonable protection against potential emerging infectious diseases. This would result in a pro-active, pre-emptive strategy that would broadly render most known agents non-infectious and prevent emerging agents from becoming transfusion risks. To achieve this goal, government, industry, blood organizations and public stakeholders need to work in concert to commit the required financial and technical resources.

In particular, the Committee finds that:

a) Despite the overall safety of the blood supply based on credible scientific assessments, unmet needs exist to further reduce known infectious threats to blood transfusion recipients from infectious agents including bacteria, viruses, parasites, and prions.
b) The well-established strategy of implementing donor screening and testing subsequent to the identification of infectious agents of concern to blood safety has inherent limitations including the possibility for widespread transmission of disease before a new agent is recognized or can be interdicted by specific methods.
c) The cost and complexity of agent-specific screening and testing is itself becoming a barrier to further blood safety innovations. At the same time, business models do not appear to favor continued aggressive investments in blood safety technologies.

d) The anticipated high costs of pathogen reduction technologies would likely be offset through the gradual elimination of some current blood safety interventions that would be rendered redundant.
e) Because the agents of variant Creutzfeldt Jakob Disease (vCJD) and other prion diseases cannot be inactivated in blood components, techniques to detect and remove these infectious agents need separate consideration.

Pathogen reduction offers the following potential benefits:

1. reduction of current risks of known infectious agents,
2. protection against the risk of emerging infectious agents including shielding the nation from introduction of biological threats into our blood supply,
3. avoiding obligate blood recipient infectious risk before emerging infectious diseases are detected and new assays are developed,
4. increase the availability of blood supply by avoiding unnecessary loss of blood donors as an undesired outcome attributable to false-positive infectious disease tests and non-specific donor screening strategies,
5. avoidance of the need to develop new screening assays for emerging and/or localized infectious agents, and
6. mitigation of non-viral threats associated with blood transfusion, such as transfusion related acute lung injury (TRALI), bacterial contamination, graft versus host disease (GVHD) and human leukocyte antigen (HLA) alloimmunization.

Based on these findings, the Committee recommends that the Secretary:

a) Adopt as a high priority the urgent development of safe and effective pathogen reduction technologies for all blood transfusion products and implementation as they become available;
b) Provide resources to overcome current barriers to development and validation of pathogen reduction technologies;
c) Ensure adequate safety monitoring of pathogen reduced blood products post- marketing using an active national hemovigilance system, and
d) Ensure that other efforts to improve blood safety and availability are not compromised by these efforts.

I hope that this recommendation provides a clear sense of the Committee's stance on this important subject. The adaptation of pathogen reduction will bolster our nation's blood safety capability. I would be happy to answer any additional questions you may have regarding the recommendations. The Committee stands ready to aid in efforts or act as a forum for further deliberation in order to move forward on pathogen inactivation.

Sincerely,

Arthur W. Bracey, M.D.