

December 17, 2012

Howard Koh  
Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
HHH Building  
Washington, DC 20201

Dear Dr. Koh

I am writing on behalf of the Advisory Committee on Blood and Tissue Safety and Availability, that met on December 6-7, 2012. The new Committee members appreciated your personal remarks at the swearing-in ceremony. All of us welcomed your opening remarks and charges to the Committee. The purpose of the meeting was to discuss policy implications related to emerging research developments involving blood and tissue products available for use during public health emergencies, and to provide recommendations to the Department about this topic.

The Committee was charged to consider:

1. Should the Advisory Committee provide policy recommendations to advance research and development of innovations in blood and tissue products supporting emergency preparedness?
2. Does an opportunity exist to further develop critical supply-chain infrastructure of blood and tissue products to support emergency preparedness?
3. Should the Department consider providing further resources for research and development of blood and tissue products and their supply-chain infrastructure in order to positively impact emergency preparedness? If yes, what is the best way to accomplish this?

Over the two day meeting, a panel of experts presented information in the following areas:

- Considerations for blood products emergency plans and use
- System experiences/scenario based considerations
- Platelet consideration and blood product storage
- Red blood cells and plasma innovations
- Pathogen reduction, reagents, and Department of Defense considerations
- Tissue product emergency use considerations

After careful consideration and collective input, the Committee developed the following recommendations:

### 2012-1

Whereas blood systems have been capable of providing adequate supplies in historic disaster and mass casualty situations, modeling efforts have indicated the likelihood of larger scale disruptions that could easily overwhelm the current response and recovery capacities; and recognizing that the principal role of the AABB Interorganizational Task Force for Domestic Disasters and acts of Terrorism to respond to disruptions of the blood system has been established under ESF #8 (National Response Framework); the committee believes that preparedness for such disasters could be enhanced by advancements in the following areas:

- 1) Stable government funding to support the functions of the AABB Interorganizational Task Force for Domestic Disasters and Acts of Terrorism;
- 2) Infrastructures, including reserves of end products and manufacturing consumables; logistic support for transportation, information technology systems, and communication; connectivity with other disaster response systems (especially including hospitals and state and local governments); designation of committed blood and plasma donors and essential blood center staff as healthcare responders;
- 3) New Products
  - a. Extended storage blood products and products not requiring cold storage including modified plasma, platelets, and Red Blood Cells; and oxygen carrying solutions;
  - b. Rapid, low technology screening tests for transfusion transmitted infectious diseases;
  - c. Pathogen reduced blood components;
  - d. Stem Cell based products and growth factors;
- 4) Regulatory flexibility

To address these issues, the committee recommends that HHS provide support for gap analyses in these areas to

- a) Identify unmet needs including funding;
- b) Characterize and address barriers;
- c) Establish evidence to project the likely risks and benefits of candidate interventions

Subject to HHS support, the committee will establish subcommittees to pursue these objectives in cooperation with other parties inside and outside of government.

2012-2

Whereas at the current time there is no nationally coordinated system to manage tissue supplies and distribution during a disaster; the committee recommends that HHS support a gap analysis to address similar issues regarding maintaining safety and availability of tissue products in large scale disasters. Subject to HHS support, the committee will establish a subcommittee to pursue these objectives in cooperation with other parties inside and outside of government.

The Committee feels that adoption of the recommendations identified will assist the Department in developing strategies related to innovations in blood and tissue products and emergency response. We thank the Department for considering our recommendations and for the opportunity to enhance blood and tissue safety and availability.

Sincerely,

Jay E. Menitove, M.D.  
President/CEO and Medical Director  
Chair, ACBTSA