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Dear Dr. Koh,

The Advisory Committee on Blood Safety and Availability (ACBSA) greatly appreciated meeting Dr. Galson, Acting Assistant Secretary for Health during the April 30-May 1, 2009 meeting in Gaithersburg, Maryland. It was an opportunity to hear the Department's perspective on the topic of our meeting—to evaluate strategies for decision making in matters pertaining to transfusion safety. We welcome you to your new position as Assistant Secretary for Health and look forward to the direction and guidance that you have for the Committee.

During the two day meeting, a number of noted experts in the field presented information that fostered a vigorous debate among Committee members and public members of the audience. After careful consideration of the collective input, the Committee developed the following statements and recommendations for the Secretary's consideration:

Decisions regarding transfusion and transplantation safety are often complex and require consideration of multiple features including scientific, medical, economic, social and political aspects of the issue in question. Medical and scientific considerations should be paramount in guiding blood policy decisions on transfusion and transplantation safety; however, the state of knowledge is often incomplete or imperfect. Ultimately safety, and not economic considerations, should be the primary feature considered; however, decisions should not be made in an economic void. Safety decisions should be made in an ethical, transparent manner with adequate input from all involved stakeholders including end users, the public and expert resources from diverse backgrounds relevant to the question at hand.

In the area of transfusion and transplantation safety the advisory committee identified certain areas where enhancements are needed.

To foster the highest degree of decision making a well-designed decision making process should be employed. Elements important should include:

Stabilization of the role of HHS in the decisional process

The infrastructure and funding support for the transfusion safety function of HHS (OPHS) has been unstable.

1. Recognizing the importance of stability in staff and funding for transfusion safety within HHS, the committee recommends establishment of a line-item in the Secretary's budget for support of these activities.

Access to critical public health information

High quality decision making requires access to accurate information that would permit meaningful risk assessment and projection of the impact of decisions.

Recognizing that a robust and sustained Biovigilance reporting network for monitoring transfusion and transplantation safety is essential, the committee recommends that:

2. Department of Health and Human Services identify and provide short term bridge funding to continue the necessary pilot and recruitment phases of the National Biovigilance Network with consideration of mandatory requirements in participation and reporting.
3. Convene a group of stakeholders to define the optimal long term funding model for a national Biovigilance (including blood, tissues and organs) program whose implementation the Secretary will insure.

Prioritization of issues

Whereas optimizing the safety of transfusion and transplantation is a universally shared priority, policy making without overt consideration of reimbursement and other systemic implications may have adverse impacts on the allocation of limited health resources and on patient health.

To address this issue:

4. The committee recommends ongoing assessment of transfusion risk and prioritization of threats and opportunities.

Alignment of funding

The implementation of blood safety initiatives requires funding that currently is not linked with policy decisions. This disparity creates distortions to decision making, adverse tradeoffs and possible delays of implementation of safety measures within the blood system.

The committee recommends:

5. When policy decisions are reached, there must be linkage of funding to ensure system-wide implementation of desired safety enhancements.

Transparency

Blood safety decisions require inclusion of all stakeholders to insure quality as well as to promote public trust and confidence.

The committee recommends:

6. The rationale for blood safety enhancements must be communicated to all stakeholders including end users, the public and treating physicians. Where needed, adequate support should be provided to meet educational needs of these stakeholders.
7. Convening a workshop, including requisite legal, ethical, economic, and consumer representation to explore public understanding and tolerance of transfusion related risk and its relationship to mechanisms of compensation for harm.

The Committee feels that adoption of its recommendations will place the Department on firm footing for decision making in the area of public policy for blood safety. While my tenure with the Committee is at an end, the Committee and Executive Secretary are ready to continue at full speed in addressing its charges. We hope that the Department will take on these recommendations.

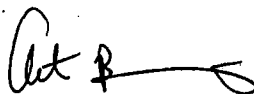
During the meeting, I was asked to bring two other important topics to your attention. As you may know, the blood industry is considered a vital component of the healthcare industry in pandemic preparation and response. During our review of the 2009 H1N1 epidemic, our plasma industry representative indicated that this sector of the blood industry had not yet been incorporated as a member of the vital healthcare infrastructure. Given the key role that plasma-based products can play in managing influenza pandemics, the Committee asked that I bring this matter to your attention. There was no

doubt among the Committee regarding the importance of including the plasma industry among key providers whose operations should be sustained during an influenza pandemic.

On another matter, there was concern that the Committee needed to pay greater attention to its expanded charter and increase its attention to matters related to the safety of organ and tissue transplantation. Specifically, the potential loss of some infectious disease testing, issues related to informed consent regarding high risk donors and the state of transplantation biovigilance were considered as worthy topics in need of discussion by the Committee. It was also suggested that the balance of members and invited experts engaging on that discussion be carefully considered.

On a final and personal note, it has been my distinct honor to serve the Department over the last several years. It is clear to me that the spirit of partnership between all engaged in the field of blood therapy (patients, industry, government, etc.) thrives in the HHS Blood Safety and Availability Advisory Committee. Our past and present recommendations, in my view, follow the intent of those who made this activity possible.

Sincerely,

A handwritten signature in black ink, appearing to read 'Art B', with a long horizontal flourish extending to the right.

Arthur W. Bracey, M.D.  
Chairman, ACBSA