



APR 25 2011

Howard K. Koh, M.D., M.P.H.
Assistant Secretary for Health
Office of the Secretary
U.S. Department of Health & Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Dr. Koh,

The Advisory Committee on Blood Safety and Availability (ACBSA) greatly appreciated the presentation on the Secretary's strategic initiatives given by Dr. Anand Parekh, Deputy Assistant Secretary for Health, during the November 4th and 5th 2010 meeting in Rockville, Maryland. It was an opportunity to hear the Department's perspective on the charge of our meeting – to discuss the Strategic Priority of HHS, including the Affordable Care Act.

The purpose of the meeting was to review and comment on, a) the current status of transfusion and transplantation safety, b) progress made in transfusion and transplantation safety, c) previous ACBSA recommendations towards elements of a strategic plan; and to recommend current priorities and how they align with the Secretary's strategic initiatives and key inter-Agency collaborations.

During the two day meeting, a number of experts in the field presented information that fostered a vigorous debate among Committee members and public members of the audience. After careful consideration of collective input, the Committee developed the following outline of key strategic priorities for blood, tissues, and organs safety, including cross-cutting priorities:

Blood Safety Priorities:

Patient Safety

- Promote and establish high value and effective evidence-based patient blood management

Product Safety

- Fund safety technology development and implementation (e.g., pathogen reduction technology and infectious disease/emerging infectious disease testing)
- Establish an evidence-based donor history questionnaire
- Fully reimburse costs of safety measures

Biovigilance

- Fully establish Biovigilance for blood donors and recipients to improve outcomes

Donor Wellness

- Promote and protect donor health

Risk Management

- Improve risk-based decision making and communication (e.g., informed consent)

Cell/Tissue Priorities:

Product Safety

- Determine the elements that contribute to product safety
- Assess the intrinsic quality of cell and tissue products
- Determine the optimal processing and testing of cells/tissues to mitigate disease transmission
- Establish an evidence-based donor history questionnaire

Patient Safety / Risk Management

- Improve risk-based decision making and communication for optimal tissue utilization (e.g., informed consent)

Biovigilance

- Establish Biovigilance for cell and tissue recipients to improve communication, traceability, and outcomes

Organs Priorities:

Product Safety

- Support the development of technologies for appropriate rapid screening of transmissible markers to quality organ availability
- Establish evidence-based donor history questionnaire

Patient Safety / Risk Management

- Improve risk-based decision making and communication for optimal patient management (e.g., informed consent)

Biovigilance

- Establish Biovigilance for organ recipients to improve communication, traceability, and outcomes

Cross-cutting Priorities:

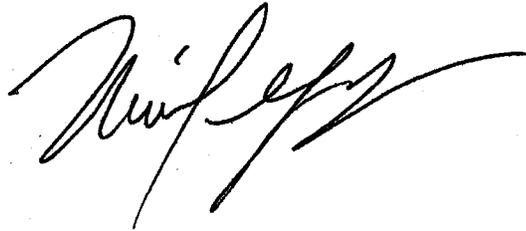
- Improve flexible funding mechanisms for emerging public health priorities

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- Increase public awareness of issues affecting the safety and availability of blood, cells, tissues, and organs
- Support International Collaborations that additionally leverage international experience

The Committee feels that adoption of its strategic outline for blood, organs, and tissues safety, including cross-cutting priorities, will place the Department on firm footing for strategic planning in the area of public policy for transfusion and transplantation safety. It is the Committee's genuine desire to continue working with the Department in guiding and recommending the best path forward in the development of its strategic plans and initiatives. Please accept my sincerest gratitude for the opportunity to present to you the Committee's strategic priorities on this, my inaugural meeting as Chair of the Advisory Committee on Blood Safety and Availability. The Committee looks forward to meeting with you in person in future meetings and continuing to provide advice on critical safety issues with regard to blood transfusion and cell, organ, and tissue transplantation.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael G. Ison". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Michael G. Ison, M.D., M.S.
Chair, ACBSA