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

January 11, 2010

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
Washington, DC 20201

Dear Secretary Sebelius

The Advisory Committee on Blood Safety and Availability (ACBSA) met on November 19 and 20, 2009 The Assistant Secretary for Health, Dr Koh, provided to the committee the PHS Working Group's white paper *"Biovigilance in the United States Efforts to Bridge a Critical Gap in Patient Safety and Donor Health "* We appreciate the time and consideration that the Department spent in responding to this ACBSA recommendation of 2006

The Committee reviewed and approved the findings in PHS Working Group white paper, *"Biovigilance in the United States Efforts to Bridge a Critical Gap in Patient Safety and Donor Health "* The Committee recommends the Secretary address the gaps and recommendations listed therein

A quorum of voting members was present to discuss and respond to the following questions

1 Please comment on mechanisms to identify and address information gaps related to infectious disease risks of organs and tissues
2 Please comment on types of tools of policy analysis that may be used to enhance the current decision making process, such as risk assessment and cost effectiveness/cost utility modeling and how they might be integrated into the current system.
3 What next steps, does the Committee recommend to enhance the quality and transparency of federal decision making for organ and tissue safety policy?

The Committee responded as follows

General: Biovigilance initiatives should be included in an integrated national system to identify preventable adverse outcomes

The Committee recommends that the Secretary develop a dashboard for monitoring adverse event reporting for blood, organs, and tissues to be reviewed regularly by the

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Organs: It was recognized that there are significant gaps in identifying the risk of disease transmission

Donor Risk Assessment

There is currently no standardized approach to collecting the medical and social history This is critical to assess as it directly impacts classification of donors as increased risk vs standard risk of latent infection with a blood-borne pathogen, currently this drives additional testing of donors, which may lead to increased use or loss due to false positive testing, and additional consenting

The Committee recommends the Secretary support development and validation of a uniform donor health history screening questionnaire

Access to medical and laboratory testing of donors

Currently, there are no standard approaches to allowing procurement organizations to access and review the comprehensive amount of data available on each donor

The Committee recommends the Secretary investigate mechanisms to allow Organ Procurement Organizations easier and complete access to appropriate records

Informed Consent

Currently, the OPTN policy requires specific informed consent of recipients of "high risk" donors There is significant variability in how information is provided to potential recipients and research is needed to understand gaps in clinician and patient knowledge related to high risk donors in particular and all organ donors in general Further research is also needed to understand the impact of the consent process on how organs are used

The Committee recommends the Secretary direct funding to understand the knowledge gaps and impact of the organ transplantation consent process.

Testing

There are currently limitations related to donor laboratory screening

The Committee recommends that the Secretary explore more effective use of screening and confirmatory laboratory donor testing of potential donors and explore options to enhance accessibility and innovation

The Committee recommends that standards be developed for donor and recipient sample retention

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Risk Assessment

Significant underreporting of donor derived disease transmission is suspected. The Committee recommends the Secretary

1 To fund a prospective study to outline the risk of disease transmission through organ transplantation – similar to the Spanish Resitra Cohort or the U.S. REDS I study

2. Provide resources for national implementation of the Transplantation Sentinel Network (TSN)

Tissues There is concern regarding inadequate bidirectional traceability of tissues, impairing adverse events surveillance and timely public health intervention There are no accurate data on the number of recipients in whom tissues are implanted and thus rates on adverse events cannot be calculated

The committee recommends

1. Development of a system employing bidirectional traceability from donor to recipient which would use a unique Identifier linking a single donor to all recovered organs and tissues

2. All adverse events possibly related to tissue grafts should be promptly reported and investigated.

3 Assess the adequacy of the current language and process of informed consent for tissue implantation

4. Assess the adequacy of current oversight mechanisms to ensure patient safety in tissue recipients

5 Develop uniform questionnaire for donor screening to optimize patient safety

On behalf of the Committee, I want to thank you in advance for the attention to these recommendations The recommendations both on the white paper and related to organs and tissues will help improve the safety of the transfusion and transplantation

Sincerely,

Arthur W Bracey, M.D.