December 19, 2014

Karen B. DeSalvo, MD, MPH, MSc
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
HHH Building
Washington, DC 20201

RE: Forty-Fifth Meeting of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), November 13-14, 2014

Dear Dr. DeSalvo,

I am writing on behalf of the Advisory Committee on Blood and Tissue Safety and Availability, which met on November 13-14, 2014. The purpose of this meeting was to continue discussions from previous meetings about the MSM blood donor deferral policy. Additionally, the Committee discussed and made recommendations on testing blood donors for Hemoglobin S, the variant which causes sickle cell. The Committee also heard an update from the Informed Consent Subcommittee and a presentation on Babesia, an emerging infectious parasite.

Regarding the MSM discussion, the Committee was charged to consider:

1. Do the completed HHS MSM Blood Donor Deferral Studies, along with other additional studies and data, provide the ACBTSA with sufficient information to support a change from the current MSM deferral policy (deferral for MSM, even once, since 1977) to an alternative policy that would permit blood donations by some MSM?
2. After hearing the MSM study results, if the committee determines that a policy change is supported by the evidence, what deferral time frame does the committee recommend for a change to the MSM Blood Donor Deferral Policy recommendations?
3. Based on the Donor History Questionnaire (DHQ) study performed by CDC's NCHS, and the data from the REDS Blood DROPS study, what approaches does the ACBTSA recommend for exploration of potential enhancements to the DHQ format and associated public health education and outreach to blood donors and public stakeholders?

Regarding the Hemoglobin S Testing Issue, the Committee was charged to consider:

On Donor consent:

1. Should blood centers inform blood donors that testing for Hb-S will be performed? If so, specify what elements of information should be provided.
2. Please discuss whether your recommendations would apply differently to scenarios where all donors are "routinely" screened for Hb-S (as may occur when a molecular screening assay is used that includes testing for Hb-S) in contrast to scenarios where donors or donations are "selectively" screened for Hb-S (e.g. following leukocyte reduction failure or for transfusion to a specific patient).

On Donor management:

1. What are the obligations, if any, of blood centers to notify blood donors of positive screening tests for Hb-S?
2. Can a blood donor "opt out" of being notified of their Hb-S test results?
3. Should blood centers perform confirmatory testing (for example, hemoglobin electrophoresis) on Hb-S screen positive donors?

4. What are the obligations of blood centers to provide medical counseling and follow-up? Alternatively, should blood centers refer donors to a health care professional for counseling and follow-up?
5. What are the obligations of a hospital transfusion service to inform the blood center of a positive Hb-S screen obtained on a RBC unit for transfusion?

Over the two day meeting, the Committee heard from subject matter experts on:

- Current Epidemiology of HIV in the US
- Studies related to the current MSM Policy
    - Retrovirus Epidemiology Donor Study-II TTI Marker Prevalence and Risk Factor Study
    - Retrovirus Epidemiology Donor Study-III Blood Donation Rules Opinion Study
    - Cognitive Interviewing Evaluating of the UDHQ
- Australia's MSM Blood Donor Deferral Experience
- Background of Hemoglobin S Testing in Blood Donors Ethics of Hemoglobin S Testing in Blood Donors
- Experiences in Hemoglobin S Testing in Blood Donors
- Babesia Epidemiology
- Ethics of selective Infectious Disease Testing

After the careful consideration and thoughtful discussion, the Committee made the following recommendations:

<u>Recommendation 2014-1</u>

The Committee voted (16 in favor, 2 against) to change the current MSM blood donor policy to an alternative policy. The Committee voted (16 in favor, 2 against) to change the lifetime deferral of MSM to a one-year deferral.

<u>Recommendation 2014-2</u>

The Committee developed the following recommendations, with a unanimous vote:

- Implementation of the recommendations made during the December 2013 ACBTSA meeting, especially those regarding surveillance of transmissible diseases
- Develop and implement a coordinated communication plan regarding a change in MSM deferral policy focused on all relevant stakeholders
- In addition, the ACBTSA recommends for all donations that the Secretary:
    - Undertake studies to evaluate the effectiveness of the administration of the DHQ
    - Take steps to improve transparent communication to recipients of the relative risks and benefits of blood, organs, cells and tissues
    - Evaluate and revise the donor education material in order to improve its uptake, comprehension, and utility to promote accurate disclosures of risk
    - Improve the sensitivity and specificity of the donor selection criteria to identify donors at increased risk of transmissible diseases

<u>Recommendation 2014-3</u>

Whereas the Committee finds that:

- There are limited, although well documented donor health implications for sickle cell trait
- Knowledge of sickle cell trait status has significant psychological and social implications e.g. reproductive choice
- Withholding of medically and socially sensitive information could undermine trust in the blood system

- Donor notification and medical referral are the responsibility of the blood collection establishment, counseling in regard to the medical significance of sickle trait lies with the donor's health care provider
- While there may be potential adverse consequences of notification of test results, the overall benefits outweigh the risks

Therefore, the Committee recommends, with a unanimous vote, the Secretary take steps to assure that:

- Donors are informed within the framework of routine consent for donation that their donations may be tested for hemoglobin S and that they will be notified of positive results
    - Implicitly, donors who do not wish to be tested or notified may decline to donate
    - Donors who test positive for hemoglobin S or present with known history of sickle cell trait may be encouraged to donate plasma or apheresis platelets
- Opportunity is provided for donors to become informed about the significance of sickle trait
- In order to facilitate donor notification, transfusion services will inform the blood collection establishment in instances where a product is found to be positive for hemoglobin S
- Given the possibility of false positive tests for hemoglobin S with certain technologies and in certain donor groups, collection centers should be encouraged to provide information on the specificity of test results (e.g. through confirmatory testing) though this is not a primary responsibility of the blood establishments
- Additional research and dissemination of findings of the impact of sickle trait to clinicians and the public be performed

The Committee feels these recommendations 2014-1 through 2014-3 will assist the Department in achieving several of its goals around blood safety and availability. We thank the Department for considering our recommendations and for the opportunity to contribute to blood and tissue safety and availability.

Sincerely,

Jay E. Menitove, M.D.
Chair, ACBTSA

CC: Mr. James Berger, Designated Federal Official (DFO), ACBTSA