2016 Recent Actions:

11/28/16
Texas became the second state in the continental United States to confirm a case of mosquito-borne Zika virus (ZIKV) infection on 11/28/16, when health officials announced that a resident of Cameron County had tested positive for the virus. The county is on the Gulf Coast close to the Mexican border.

11/18/16
AABB, the American Red Cross, and America's Blood Center presented a joint statement to the Food and Drug Administration's Blood Products Advisory Committee in response to the August 2016 Zika guidance document.

10/24/16
Food and Drug Administration representatives clarified, during the "Ask the FDA & CMS/CLIA" education session at the AABB Annual Meeting in Orlando, that blood collectors must update their Circular regarding testing for ZIKV using the language provided by their IND sponsor. In addition, since the language in the IND has been reviewed and approved by FDA, blood collectors can report this change to the Circular in the establishment's Annual report. The clarification was provided in response to the following question: "Following FDA's August 2016 ZIKV guidance, does FDA continue to require that establishments use language provided in their approved IND for Zika virus testing to update their Circular, or does FDA expect AABB's Circular of Information Task Force to develop language for the Circular?

9/28/16
AABB released Association Bulletin #16-07, Updated Recommendations for Zika, Dengue, and Chikungunya Viruses, pertaining to two FDA guidance documents. The first, Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components, published Aug. 26 classifies Zika virus (ZIKV) as a relevant transfusion-transmitted infection (RTTI). The second, Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus, published Feb. 16 and will remain in effect until blood establishments have implemented the recommendations contained in the August guidance. AB #16-07 supersedes both AB #16-04 and AB #16-06.

9/1/16
AABB posted an analysis of "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry" published by the Food and Drug Administration on August 26, superseding both the February 2016 Zika guidance and the March 2016 Zika guidance.

6/16/16
AABB published Association Bulletin #16-06, which supplements Association Bulletin #16-04 and provides additional information about Zika virus infection. Included in the bulletin are recommendations for 1) the availability and use of investigational blood donation screening tests for Zika virus, 2) the use of licensed or investigational pathogen reduction technologies for inactivating Zika virus, 3) actions following the recognition of local transmission as a result of voluntary investigational blood donation testing programs, and 4) posting of data to the AABB Zika Virus Biovigilance Network. The bulletin contains minimal information for HCT/Ps.

6/28/16
AABB posted the table, Tracking Zika Travel Notices, to assist with postdonation information, donor eligibility and inventory management decisions.

6/20/16
FDA approved the Procleix Zika virus blood donor screening assay on the Procleix Panther system under the agency's investigational new drug protocol. The test system is manufactured by Hologic and Grifols.

6/14/16
The Centers for Disease Control and Prevention has posted its Draft Interim Zika Response Plan on Tuesday. The document describes CDC's response plan for the first locally acquired cases of Zika virus infection in the continental U.S. and Hawaii.

6/10/16
AABB hosted a Zika Virus Symposium on June 10, 2016 in Washington D.C., that addressed the current knowledge of mosquito-borne Zika Virus (ZIKV) and risks facing the continental U.S. Sessions updated the public health and blood safety implications of ZIKV, including FDA recommendations on protecting blood and HCT/P safety and current research on ZIKV screening tests, pathogen inactivation technologies and other blood safety initiatives. Presentations from the symposium are available for purchase on the AABB Marketplace.

5/26/16
AABB, ABC and ARC submitted comments to FDA in response to the agency's February guidance, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus."

5/5/16
The CSTE posted a consensus proposal that State and local health departments can use to identify local vector-borne Zika virus transmissions. It includes steps for forwarding the information to the CDC so it can be used by blood establishments to activate blood safety interventions as described in the current FDA guidance.

5/2/16
AABB, America's Blood Centers and the American Red Cross expressed concern in a joint letter to Food and Drug Administration officials about the ability of blood establishments to comply with specific recommendations in the February 2016 FDA guidance on reducing the risk of transfusion transmission of Zika virus (ZIKV).

4/22/16
The Centers for Disease Control and Prevention and the Occupational Safety and Health Administration (OSHA) issued an interim guidance to help protect health care and laboratory professionals, outdoor and mosquito control workers, and business travelers from occupational exposure to Zika virus. The guidance contains steps employers can take to protect their workers and methods employees can take to protect themselves.

3/30/16
The FDA published an announcement on the availability of an investigational test, manufactured by Roche, to screen blood donations for Zika virus. Initially, the Roche Zika test, which is the first of its kind,

will be deployed to screen blood donations collected in Puerto Rico. The second stage will be to prepare for screening of blood donations collected by blood services in the southern US, which will most likely be impacted by any spread in the virus (Roche Media Release, March 30, 2016).

3/16/16
AABB posted an analysis of "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus" published by the Food and Drug Administration on February 16 for immediate implementation, and "Question and Answers Regarding Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus" published by the FDA on March 14 to answer common questions received since the publication of the first guidance.

3/1/16
AABB released Association Bulletin #16-04 "Zika, Dengue, and Chikungunya Viruses," superseding Association Bulletin #16-03 of the same name, following publication of the FDA final guidance, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus."

2/23/16
AABB Donor History Task Force posted Zika Additional Questions, compliant with the FDA guidance document, for use with screening blood donors.

2/17/16
AABB Zika Audioconference
Members of the AABB TTD Committee as well as representatives from the CDC and FDA provided an audioconference with updated information on Zika, the FDA recommendations for Zika as explained in the final guidance published the day before, and AABB Association Bulletin #16-03.

2/16/16
The FDA publishes an FDA final guidance, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus," with recommendations for blood collections in areas with active Zika virus transmission and areas without active Zika virus transmission. The recommendations can be implemented with ta combination of self-deferral and donor history questions.

2/1/16
AABB releases Association Bulletin #16-03 "Zika, Dengue, and Chikungunya Viruses" recommending self-deferral of blood donors for travel to Zika-affected areas, and use of postdonation information sheets for symptoms related Zika, dengue, and chikungunya following travel to identified tropical areas.