FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
116th Meeting of the Blood Products Advisory Committee
White Oak Conference Center
Great Room, Building 31
10903 New Hampshire Avenue
Silver Spring, MD 20993

December 1, 2017

Committee Members
Meera B. Chitlur, M.D. #
Michael DeVan, M.D., F.C.A.P.
Alfred DeMaria, M.D.
Miguel Escobar, M.D.
John B. Holcomb, M.D, F.A.C.S. #
Susan F. Leitman, M.D.
Norma B. Lerner, M.D, M.P.H.
Roger Lewis, M.D., Ph.D, FACEP
Thomas Ortel, M.D, Ph.D.
Robert J. Rees, MHA, MT(ASCP)
Sonja Sandberg, SB, Ph.D.
Christopher Stowell, M.D, Ph.D. (Acting Chair)
Kathleen Sullivan, M.D, Ph.D. +
Jack Stapleton., M.D.

FDA Participants
Anne Eder, M.D., Ph.D.
David Leiby, Ph.D.
Alan Williams, Ph.D.

Temporary Voting Members
Mathew Arduino., MS, DrPH, PSHEA
Sridhar V. Basavaraju, M.D, FACEP
Karen Carrol, M.D.
Patricia Kopko, M.D.
Karen Quillen, M.D, MPH
David Stroncek, M.D.
Cliff Sullivan, M.D.

Consumer Representative
Judith Baker, DrPH., MHSA

Industry Representative
Susan Stramer, Ph.D.

Designated Federal Official
LCDR Bryan Emery B.S.N. USPHS

Committee Management Specialists
Joanne Lipkind
Rosanna Harvey

Did not attend
+ Attended by phone

These summary minutes for the December 1, 2017 meeting of the Blood Products Advisory Committee were approved on _Dec 19, 2018__.

I certify that I participated in the December 1, 2017 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

__Signed XXXXXX___
Bryan Emery, LCDR
Designated Federal Official

___Signed XXXXXXX_____
Christopher P, Stowell, M.D., Ph.D.
Acting Chair

The Acting Chair, Dr. Christopher Stowell, called the meeting of the Blood Products Advisory Committee to order at 8:00 a.m. EST on December 1, 2017. The meeting was held in an open session. The DFO, LCDR Bryan Emery read into the official record the conflicts of interest statement pertaining to the meeting participants. There were no waivers issued for conflicts of interest for this meeting.

QUICK SUMMARY

Topic III: Strategies to Reduce the Risk of Transfusion -Transmitted Zika Virus

An introduction and overview of the topic was presented by Dr. Anne Eder from the Division of Emerging Transfusion Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). Dr. Carolyn Gould of the Centers for Disease Control and Prevention (CDC) presented an update on the epidemiology of Zika virus. This was followed by presentations on Zika virus nucleic acid testing in blood donors by Mr. Anthony Hardiman of Roche Molecular Systems, Inc. and Dr. Jeffery Linnen of Grifols Diagnostic Solutions Inc. Finally, Dr. Anne Eder presented on FDA's current consideration for reducing the risk of transfusion-transmitted Zika virus.

After questions of the speakers and a short break, the committee reconvened for the Open Public Hearing (OPH) session. Dr. Stowell the Acting Chair read the statement at the beginning of the OPH. The first presenter was Dr. Mike Busch from Blood Systems Inc. The second presenter was Dr. Steven Kleinman, who presented a joint statement from AABB, America's Blood Centers, and the American Red Cross.

After the Open Public Hearing, the Committee began the Open Committee Discussion and the Questions for the Committee.

The final questions addressed by the Committee are as follows:

1. At this time, do the available scientific data on the course of the ZIKV epidemic justify the elimination of all blood safeguards for ZIKV pending another significant outbreak in the United States or its territories (Option 5)?

   The committee voted unanimously as follows: 10 no votes, 0 yes votes, 0 abstain

2. Do the available scientific data on the course of the ZIKV epidemic identify a risk to the blood supply that justifies continuing universal ID NAT testing (Option 1)?

   The committee voted unanimously as follows: 10 no votes, 0 yes votes, 0 abstain

3. A. Do the available scientific data on the risk of transfusion-transmitted ZIKV support the regional use of ID NAT in at-risk states and territories combined with the use of MP NAT in all other states (Option 2)?

   The committee voted as follows: 8 no votes, 3 yes votes, 0 abstain

   B. Do the available scientific data on the risk of transfusion-transmitted ZIKV support the use of MP NAT in all states and territories with a trigger for ID NAT to be defined?

   The committee voted as follows: 9 yes votes, 1 no vote, 1 abstain

   C. Do the available scientific data on the risk of TT ZIKV support the discontinuation of all testing in some states and territories?

   The committee voted as follows: 5 yes votes, 4 no votes, 2 abstain

4. If the answer to Q3 is "Yes," please comment on the following criteria to switch from MP NAT to ID NAT within a defined geographic area or a state:

   - A defined number of presumptive viremic donors in a 7-day rolling period based on results of MP NAT in a defined geographic collection area

   - A defined number of cases based on 1) presumptive viremic donors in a 7-day rolling period and 2) a defined threshold of symptomatic clinical cases reported by national surveillance in a defined geographic collection area

   The general consensus of the Committee was that the criteria need to take into account whether ZIKV was acquired through travel or local, mosquito-borne transmission, and that ID NAT should start when local transmission is suspected in a geographic area. Committee members commented that one presumptive viremic donor should trigger ID NAT testing in a state in which local transmission is suspected or possible. In addition, members commented that the

trigger should take into account clinical (symptomatic) cases reported to local health departments and CDC as well as presumptive viremic donors. Other committee members commented that other surveillance tools, such as Zika positive mosquitos, should be considered.

5. Would selective ID NAT performed based on the donors' responses to questions about 1) travel to ZIKV endemic or epidemic countries; 2) sexual contact with partners diagnosed with ZIKV; and/or 3) sexual contact with partners having travel risk for ZIKV provide an adequate and appropriate safeguard against transfusion transmission of ZIKV (Option 3)?

   The committee voted unanimously as follows: 11 no votes, 0 yes votes, 0 abstain

6. Would the option to provide ID NAT-negative blood components to selected patients based on clinical indications (e.g., pregnant women, intrauterine transfusion, neonates) and ZIKV-untested blood components for all other transfusion recipients provide an adequate and appropriate safeguard against transfusion transmission of ZIKV (Option 4)?

   The committee voted as follows: 9 no votes, 2 yes votes and 0 abstain

7. Please provide any additional comments on considerations for selective testing of blood donations using ID NAT or MP NAT for ZIKV.

   - One member of the asked whether an increase in the mosquito population itself is enough trigger to ID NAT.
   - Several comments were made about when to detrigger IDNAT and to return MP testing.

Topic IV: Informational Session on the Transfusion Transmissible Infections Monitoring System

In open session, the committee listened to an informational session on the Transfusion Transmissible Infections Monitoring System (TTIMS). Dr. Alan Williams of the Office of Biostatistics and Epidemiology (OBE), CBER FDA introduced the session and gave an overview of TTIMS. Next Dr. Whitney Steele of the American Red Cross presented an update on the activities of TTIMS Donation Database Coordinating Center. Dr. Brian Custer of Blood Systems Research Institute presented an update on the Laboratory and Risk Factor Coordinating Center and provided data on the proportion of HIV seropositive donors with recently-acquired infection in the United States. Next, Dr. Alan Williams provided concluding remarks.

Committee Update:

Dr. David Leiby of DETTD, CBER, FDA, provided an update presentation to the Committee on the April 2017 FDA public workshop on tick-borne diseases and blood safety.

An Open Public Hearing was announced after the presentation. Dr. Stowell, the Acting Chair, read the Open Public Hearing statement. One presentation was made by Dr. Steven Kleinman on the Transfusion Transmissible Infections Monitoring System.

After the Open Public Hearing was completed, the Acting Chair, Dr. Christopher Stowell,

Additional information may be obtained from the transcript and the recording of the webcast of the meeting. The transcript and webcast are available at the following link:

https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm554807.htm