FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
120th Meeting of the Blood Products Advisory Committee
White Oak Conference Center
Great Room, Building 31
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 20-21, 2019

Committee Members	**FDA Participants**
Sridhar Basavaraju, M.D., FACEP	Caren Chancey, Ph.D. (Topic I)
Evan Bloch, M.D.M.S.	David Leiby, Ph.D. (Topic I)
Barbara Bryant, M.D.	Abdu Alayash, Ph.D. (Topic II)
Meera B. Chitlur, M.D.##	CD Atreya, Ph.D. (Topic II)
Michael DeVan, M.D., F.C.A.P.	Orieji Illoh, M.D. (Topic II)
Alfred DeMaria, M.D.	Monica Young, Ph.D. (Topic II)
Miguel Escobar, M.D.#	Anne Eder, M.D. Ph.D. (Topic III)
Andrei Kindzelski, M.D., Ph.D.	Alan Williams, Ph.D. (Topic III)
Thomas Ortel, M.D.,Ph.D.	Barbee Whitaker, Ph.D. (Topic III)
Robert J. Rees, MHA, MT (ASCP) ##	Carlos Villa, M.D., Ph.D. (Topic III)
Amy Shapiro, M.D.	**Guest Speakers**
Jack Stapleton, M.D.	Jim AuBuchon, M.D., FCAP, FRCP (Topic III)
	John Brooks, M.D. (Topic III)
Chair	Marc Fischer, M.D. (Topic I)
Richard M. Kaufman, M.D.	Mindy Goldman, M.D. (Topic III)
	Srijana Rajbhandary, M.PH. (Topic I)
Temporary Voting Members	
F. Blaine Hollinger, M.D.	**Consumer Representative**
	Judith Baker, DrPH, MHSA
Patient Representative	
Christopher Templin (Topic III)	**Industry Representative**
	Susan Stramer, Ph.D.
Designated Federal Official	
Prabhakara Atreya, Ph.D.	**Committee Management Specialists**
	Joanne Lipkind, M.S.
# Did not attend	Natalie Mitchell-Funderburk, M.H.A.
## Attended by phone	Angelica Jones, M.P.H.

These summary minutes for the March 20-21, 2019 meeting of the Blood Products Advisory Committee were approved on _____.

I certify that I participated in the March 20-21, 2019 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

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_____	_____
Prabhakara Atreya, Ph.D.	Richard Kaufman, M.D.
Designated Federal Official	Chair

The Chair, Dr. Richard Kaufman, called the Meeting of the Blood Products Advisory Committee to order at 8:30 a.m. EST on March 20, 2019. The Chair invited the members, temporary members, and other participants seated at the table to introduce themselves. The Designated Federal Official (DFO), Prabhakara Atreya, made administrative remarks and read into the official record the conflicts of interest statement pertaining to the meeting participants. The meeting was held in an open session. There were no waivers issued for conflicts of interest for this meeting. After the conflicts of interest statement was read for the public record by the DFO, the presentations began.

QUICK SUMMARY

March 20, 2019

Topic I: Evaluation of Strategies to Reduce the Risk of Zika Virus (ZIKV) Transmission by Blood and Blood Components

The meeting topic was introduced by Dr. Caren Chancey from the Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) after which, Dr. Marc Fischer presented an update on the status of the ZIKV epidemic. This was followed by a presentation on the AABB ZIKV Biovigilance Network by Srijana Rajbhandary of AABB. This was followed by a presentation by Dr. David Leiby from OBRR on current consideration for reducing the risk of transfusion transmitted ZIKV. Following questions to the speakers, an Open Public Hearing (OPH) was held for 30 minutes between 11:10 a.m. to 11:40 a.m. Dr. Richard Kaufman, Chair, read the OPH statement.

The following individuals made oral presentations during the OPH:

1. Tony Hardiman from Roche Diagnostics
2. Jerry Holmberg from Grifols Diagnostics Solutions and
3. Michael Busch from Vitalent Research Institute

Following the OPH, the Committee began the Open Committee Discussion on the questions before the committee.

Dr. David Leiby of OBRR presented with the following three questions for the committee.

Question 1: At this time, do the available data support continuing universal testing for ZIKV using MP or ID NAT, as recommended in the July 2018 Final Guidance (no policy change as this time) (Option 1)?

The committee members voted as follows: 11 voted Yes, 4 voted No and 0 Abstained

Question 2: Do the available data support a regional testing option strategy for ZIKV using MP or ID NAT in at-risk U.S. states and territories (Option 2)?

Discussion of Regional Options

a. **Florida, Texas and Puerto Rico, U.S. Virgin Islands** where documented local, mosquito-borne ZIKV transmission has occurred

and

a. **California and New York** where the mosquito vectors are present, and the states previously accounted for a significant proportion of the ZIKV-reactive donations from travelers returning from ZIKV-affected countries

and

a. **Hawaii, U.S. territories** where the mosquito vectors are present and documented transmissions of other *Aedes*-borne arboviruses (DEN, CHIK) have occurred

The committee members voted as follows: 6 voted Yes, 9 voted No and 0 Abstained

Question 3: Do the available data support the elimination of all testing for ZIKV without re-introduction of donor screening for risk factors (e.g., travel) in areas with no risk of ZIKV infection, pending another outbreak in the United States (Option 3)?

The committee members voted as follows: 1 voted Yes, 14 voted NO and 0 Abstained

The committee the adjourned for lunch.

Topic II: Review of the Research Programs in the Laboratory of Biochemistry and Vascular Biology, Division of Blood Components and Devices, OBRR, CBER

Dr. Monica Young presented an overview of the CBER research programs and was followed by Dr. CD Atreya who presented an overview of OBRR research programs. Then Dr. Orieji Illoh presented an overview of the research programs in the Division of Blood Components and Devices. Finally, Dr. Abdu Alayash presented on the research programs conducted in the Laboratory of Biochemistry and Vascular Biology, for which

he is Chief. These presentations were followed by clarifying questions from the committee to the speakers. Then a short Open Public Hearing was held but no one registered to make comments. Therefore, after a short break, a closed session was held to permit committee discussions where disclosures would constitute a clearly unwarranted invasion of personal privacy according to 5 U.S.C. 552 b (6).

Following the closed session, the meeting was adjourned at 4:45 p.m.

Additional information and details may be obtained from the transcript and the recordings of the webcast of the meeting that may be viewed at:

https://www.fda.gov/advisory-committees/advisory-committee-calendar/blood-products-advisory-committee-march-20-21-2019-meeting-announcement-03202019-03212019#event-materials

March 21, 2019

The Chair, Dr. Richard Kaufman, called the meeting of the Blood Products Advisory Committee to order at 8:30 a.m. EST on March 21, 2019. The Chair invited the members, temporary members, and other participants seated at the table to introduce themselves. The Designated Federal Official (DFO), Prabhakara Atreya, made administrative remarks and read into the official record the conflicts of interest statement pertaining to the meeting participants. The meeting was held in an open session. There were no waivers issued for conflicts of interest for this meeting. After the conflicts of interest statement was read for the public record by the DFO, speaker presentations began.

Topic III: Blood Donation Policies Regarding Men who have Sex with Men (MSM) and Topic IIIA: Update on Donor Deferral Policies and MSM Questionnaire Study

The meeting topic was introduced by Dr. Anne Eder of OBRR followed by a presentation by Dr. Mindy Goldman of Canadian Blood Services on the review of global developments in MSM deferral policies. This was followed by a presentation by Dr. John Brooks from CDC on the epidemiology of HIV in the United States. Subsequently, Dr. Alan Williams of the Office of Biostatistics and Epidemiology (OBE), CBER presented data from the Transfusion-Transmitted Infections Monitoring System (TTIMS). After a short break, Dr. Barbee Whitaker of OBE made a presentation on the HIV Risk Questionnaire study. A brief question and answer period followed. An Open Public Hearing (OPH) was held for 30 minutes between 11:25 a.m. to 11:55 a.m. and Dr. Richard Kaufman, Chair, read the OPH statement.

One oral presentation was made by Dr. Daniel Brunner from Whitman-Walker Clinic in Washington D.C. during the OPH.

After the OPH ended, the Committee began the Open Committee Discussion on the two questions before the committee as presented by Dr. Anne Eder of OBRR.

Committee Discussion Question 1:

- Comment on what has been learned from implementing other MSM policies internationally (such as risk-based deferral methods or quarantine and retest for plasma) and how this information can inform the current U.S. MSM deferral policy.

The Committee members commented on the question as follows:

- One member commented that the individual risk assessment approaches in Spain and Italy appeared to be implemented without much data. Retrospective data in Spain shows that the HIV rate in the general population appears the same as in first time blood donors, whereas the rate in US first time donors is much lower than in the general population. Another member comments that the individual questioning approach is very labor intensive.

- One member commented that the plasma quarantine and retest issue does not necessarily address the underlying issue of blood equality, while another member commented that economic and logistical considerations needed to be considered with this strategy.

- Several members commented that not enough is known about the use of PrEP in the donor population and its effect on the window period and seroconversion.

- Others commented on the strong epidemiological evidence of HIV risk in certain populations.

- Other members commented that there is actually a declining demand for blood and changes to deferral policies are not intended to address a blood availability issue.

- Members agreed that any policy change should not diminish blood safety, but perhaps there are approaches where current levels of safety could be maintained.

- Several members agreed that data from countries that recently changed their time-based deferral to 3 months, such as UK, Canada and Japan, would be informative.

- One member commented on the importance of having a program like TTIMS that can measure the effect of a policy change moving forward.

Committee Discussion Question 2:

- Comment on the questions proposed for study in the HIV Risk Questionnaire and whether there are any additions or modifications to this study in order to best

identify behavioral risk questions to predict risk of HIV transmission in the MSM population.

The Committee members commented as follows:

- One member commented that sampling in only high-risk areas may not yield data applicable to other regions of the country.

- Another member noted that the primary and secondary endpoints of the study are not clearly defined.

- Several members expressed concern about the value of the study if only a few infections are identified in the study. One member asked what FDA would do with the information if zero infections are found.

- Members discussed the statistical analysis challenges with the study.

- One member commented that the question about number of sexual partners needed to be clarified to include only male sexual partners.

- One member expressed concern that the study did not have sufficient endpoints to draw a conclusion.

- One member stressed the importance of sharing the TTIMS outcome data on the safety of the blood supply to a broader public audience.

Topic III B: Variance Request for Pathogen reduction of Platelet Donations from MSM

The afternoon session followed the lunch break. The topic for discussion was introduced by Dr. Carlos Villa from OBRR. This was followed by a presentation by Dr. Jim AuBuchon from Bloodworks Northwest on a proposal for pathogen reduction of platelet donations from MSM.
After questions for the speakers and a brief break, an Open Public Hearing (OPH) was held and Dr. Richard Kaufman read the OPH statement.

Oral presentations were made by the following individuals during the OPH:

- Dr. Richard Benjamin from Cerus Corporation
- Dr. Janet Hershman from BioLife Plasma, part of Takeda, on behalf of PPTA

After the OPH presentations, the committee held open committee discussion and commented on the two issues presented to the committee. The following two issues were presented to the committee for their comments:

- Discuss the use of pathogen reduction of apheresis platelets as an alternative to the current MSM deferral policy
- Discuss any associated risks and possible mitigations

The Committee members discussed the following issues:

- One committee member commented that much of the risk reduction in blood safety is because of the donor deferral process and the question is whether pathogen reduction technology (PRT) is more or less reliable than donor questioning.

- Several members questioned why the benefit of bacterial control of platelets was highlighted in the proposal.

- Several members commented that PRT is more a more robust strategy than behavioral deferrals, and PRT helps address the limitations of other approaches such as donor compliance with risk questions.

- Some members also commented that following NAT testing for HIV and PRT, the risk of the platelets is near zero. Other members, however, expressed a preference to retain donor questioning while implementing PRT.

- Some members commented on the potential value of increasing the population that donates platelets.

- Members asked whether recipients would be notified or if labeling would identify the units as unique. Some members suggested conversations with the end users of platelets.

- Some members commented on potential challenges with logistics, computer systems and implementation of the device itself.

- Overall, some members supported the Bloodworks proposal as safe, while other members preferred to retain donor risk questions after implementation of PRT.

The meeting was adjourned at 4:45 p.m.

Additional information and details may be obtained from the transcript and the recordings of the webcast of the meeting that may be viewed at:

https://www.fda.gov/advisory-committees/advisory-committee-calendar/blood-products-advisory-committee-march-20-21-2019-meeting-announcement-03202019-03212019#event-materials