FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
119th Meeting of the Blood Products Advisory Committee
White Oak Conference Center
Great Room, Building 31
10903 New Hampshire Avenue
Silver Spring, MD 20993

July 18, 2018

Committee Members
Meera B. Chitlur, M.D.#
Michael DeVan, M.D., F.C.A.P.
Alfred DeMaria, M.D.
Miguel Escobar, M.D.
Robert Kaufman, M.D.
Andrei Kindzelski, M.D., Ph.D.#
Susan F. Leitman, M.D.
Roger Lewis., M.D, Ph.D., FACEP
Thomas Ortel, M.D., Ph.D. #
Robert J. Rees, MHA, MT(ASCP)
Sonja Sandberg, SB, Ph.D. #
Martin Schreiber, M.D., Ph.D.
Amy Shapiro, M.D. #
Jack Stapleton, M.D. #

Acting Chair
James Allen, M.D., MPH

Temporary Voting Members
Barbara Alving, M.D., MACP
Angela Caliendo, MS., Ph.D., FIDSA
Lizzie Harrell, Ph.D.
Jefferson Jones, M.D., MPH ##

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

FDA Participants
Emily Storch, M.D.
Nicole Verdun, M.D.

Guest Speakers
Mary Beth Anheuser, B.S.
Richard Benjamin, M.D., Ph.D.
Evan Bloch, M.D., MS
Steven Field, MBChB, MA, MMed
Michael Jacobs, M.D., Ph.D.
Carl McDonald, Ph.D., MSc, BSc
Ralph Vassallo, M.D., FACP

Consumer Representative
Judith Baker, DrPH, MHSA

Industry Representative
Susan Stramer, Ph.D.

Committee Management Specialists
Joanne Lipkind, M.S.

Did not attend
Attended by phone

These summary minutes for the July 18, 2018 meeting of the Blood Products Advisory Committee were approved on _Oct 24, 2019__.

I certify that I participated in the July 18, 2018, meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

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Prabhakara Atreya, Ph.D. Director Div. Sci. Advisors and Consultants	James Allen, M.D, Ph.D. Acting Chair

For Bryan Emery, MA, BSN, LCDR
Designated Federal Official

The Acting Chair, Dr. James Allen, called the meeting of the Blood Products Advisory Committee to order at 8:00 a.m. EST on July 18, 2018. The Chair invited the members, temporary members, and other participants seated at the table to introduce themselves. The Designated Federal Official (DFO), LCDR Bryan Emery, 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, presentations began.

QUICK SUMMARY

Topic I: Strategies to Control the Risk of Bacterial Contamination in Platelets for Transfusion

The meeting topic was introduced by Dr. Emily Storch from the Division of Blood Components and Devices (DBCD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). Next, Ms. Mary Beth Anheuser from bioMerieux presented on bacterial culture testing of platelets. This was followed by a presentation by Dr. Evan Bloch of Johns Hopkins University School of Medicine on the use of primary culture testing followed by secondary culture on day 3 of storage. Next, Dr. Steven Field of the Irish Blood Transfusion Service presented data on primary culture testing following by secondary culture testing on day 4 of storage. Dr. Ralph R. Vassallo of Blood Systems, Inc. then presented on the minimal proportional sampling volume testing strategy. Then, Dr. Carl McDonald of the United Kingdom, National Health Service Blood and Transplant presented on the large volume and delayed sampling testing strategy used in the UK. Next, Dr. Michael Jacobs of Case Western Reserve University presented on rapid testing as a strategy to control bacterial risk on behalf of Verax and Immunetics. Finally, Dr. Richard Benjamin of Cerus Corporation presented on pathogen reduction technology.

The committee adjourned for lunch after the presentations.

After lunch, the committee reconvened for the Open Public Hearing session and Dr. James Allen, the Acting Chair, read the Open Public Hearing statement.

Eleven oral presentations were made during the Open Public Hearing.
The following individuals made comments:

- Dr. Ed Snyder, Yale University and Yale-New Haven Hospital
- Dr. Susanne Marschner, Terumo BCT
- Dr. Nancy Dunbar, Dartmouth College
- Dr. Peyton Metzel,
- Dr. Mark Brecher, Professor Emeritus, University of North Carolina
- Dr. Louis Katz of America's Blood Centers, on behalf of AABB, America's Blood Centers and the American Red Cross
- Dr. Heather Pidcoke, representing Cellfire and Dr. Andre Capp of the U.S. Army
- Dr. Steve Wagner, American Red Cross.
- Dr. Laurence Corash, Cerus Corporation and University of California in San Francisco.
- Dr. Ralph Vassallo, Blood Systems Inc.
- Dr. Carl McDonald, National Health Service Blood and Transplant, United Kingdom

The following topics were among those discussed by various speakers at the Open Public Hearing:

- Implementation of pathogen reduction technology and secondary rapid testing
- Importance of operational considerations, including the difficulty of maintaining a dual inventory
- Advantages and disadvantages of anaerobic bottles
- Questions regarding safety and efficacy of older platelets
- Limitations of passive safety surveillance
  There is no defined threshold of safety

Following the Open Public Hearing, Dr. Nicole Verdun, OBRR, presented the following question for the committee:

"Please comment on the advantages and disadvantages of each of the various strategies to control the risk of bacterial contamination in platelets, including the scientific evidence and the operational considerations involved."

The committee discussed various strategies to control the risk of bacterial contamination of platelets with 5-day and 7-day storage. A broad range of considerations were discussed. The following is a summary of the Committee's discussion:

- Multiple strategies appear to improve the safety of platelets.
- Sparse data creates challenges in strategy evaluation and comparison.
- There is a continued need for hemovigilance and future research.

- Operational considerations are important and different strategies may serve different regions or populations.
- Multiple options are necessary to ensure platelet availability.
- The existing data incomplete; however, this should not preclude timely action.
- FDA guidance recommending enhanced safety measures is needed.

After the discussion was completed, the Acting Chair, Dr. James Allen, adjourned the meeting at approximately 4:30 p.m.

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

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