FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
Summary Minutes
122nd Meeting of the Blood Products Advisory Committee
November 4, 2021

Committee Members

Adaora Adimora, M.D., M.P.H. +
Marc Ballow, M.D.
Sridhar Basavaraju, M.D., FACEP, (CDR-USPHS)
Evan Bloch, M.D., M.S.
Melissa A. Cumming, M.S., CIC
Brenda J. Grossman MD, MPH
Andrei Kindzelski, M.D., Ph.D.+
Marissa B. Marques, M.D.
Elena Perez, M.D., Ph.D., F.A.A.A.A. I
Jeremy G. Perkins, MD FACP, COL, US Army (ret)
Martin Schreiber, M.D., +
Amy Shapiro, M.D.
Abdus Wahed, Ph.D.

Chair

Richard M. Kaufman, M.D.

Temporary Voting Members

Alfred DeMaria, Jr., M.D.
Jack Stapleton, M.D.

Consumer Representative

Judith Baker, DrPH, MHSA*

Industry Representative

Susan N. Rossmann, M.D., Ph.D. <

Designated Federal Official

Christina Vert, M.S.
Kathleen Hayes, M.P.H.

FDA Participants

Rachael Anatol, Ph.D.
Chintamani (C.D.) Atreya, Ph.D.
Wilson Bryan, M.D.
Anne Eder, M.D., Ph.D.
Karen Elkins, Ph.D. (Speaker)
Suzanne Epstein, Ph.D.
Mahmood Farshid, Ph.D.
Basil Golding, M.D. (Speaker-Topic I)
Leila Hann, Ph.D.
Peyton (John) Hobson, Ph.D.
Orieji Illoh, M.D. (Speaker-Topic II)
Chava Kimchi-Sarfaty, Ph.D.
Sanjai Kumar, Ph.D. (Speaker-Topic III)
Peter Marks, M.D., Ph.D.
Hira Nakhasi, Ph.D. Speaker-Topic III)
Wendy Paul, M.D.
Jennifer Scharpf, M.P.H
Dorothy Scott, M.D. (Speaker-Topic I)
Nicole Verdun, M.D.
Jaroslav Vostal, M.D., Ph.D. (Speaker-Topic II)
Celia Witten, Ph.D., M.D.

Division Director

Prabhakara Atreya, Ph.D.

Committee Management Specialists

Joanne Lipkind, M.S.

+ Not in attendance
< Industry representative
* Alternate Consumer Representative

These summary minutes for the November 4, 2021 meeting of the Blood Products Advisory Committee were approved on January 6, 2022.

I certify that I participated in the November 4, 2021 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/S/_____
Christina Vert, M.S.
Designated Federal Official

_____/S/_____
Richard Kaufman, M.D.
Chair

On November 4, 2021 at 9:30 a.m. Eastern Standard Time (EST), Richard Kaufman, M.D. (Chair) called to order the 122nd Meeting of the Blood Products Advisory Committee. The partially closed meeting was held virtually by an Adobe Connect web conferencing platform. The Designated Federal Official (DFO), Christina Vert, made administrative remarks, conducted roll call, and invited members to introduce themselves, and read into the official record the conflicts of interest (COI) statement. Given that the topics of this meeting were determined to be a Non-Particular Matters, no COI screening was needed or conducted for this meeting. It was stated that no conflicts of interest waivers were issued under 18 U.S. Code 208 in connection with the meeting.

The topics of the meeting included:

Topic I: Overview of the Research Programs of the Plasma Derivatives Branch (PDB), Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER)

Topic II: Overview of the Research Programs of the Laboratory of Cellular Hematology (LCH), Division of Blood Components and Devices (DBCD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER)

Topic III: Overview of the Research Programs of the Laboratory of Emerging Pathogens (LEP), Division of Emerging & Transfusion Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER)

In open session, the Committee heard presentations on the following:

- Overview of CBER research programs
  by Dr. Karen Elkins, Associate Director for Science, CBER.
- Overview of OTAT and DPPT Research Programs
  by Basil Golding, M.D., Director, DPPT, OTAT, CBER
- Overview of PDB Research Programs

by Dorothy Scott, M.D., Chief, PDB, DPPT, OTAT, CBER

- Overview of OBRR and DBCD Research Programs
  by Orieji Illoh, M.D., Director, DBCD, OBRR, CBER
- Laboratory of Cellular Hematology Overview of Site Visit Presentations
  by Jaroslav Vostal, M.D., Ph.D., Chief, LCH, DBCD, OBRR, CBER
- Overview of Research and Regulatory Program of DETTD
  by Hira Nakhasi, Ph.D., Director, DETTD, OBRR, CBER
- Biomarkers of Malaria and Babesia Detection, Immunity and Pathogenesis, Scientific Site Visit Report Summary
  by Sanjai Kumar, Ph.D., Chief, LEP, DETTD, OBRR, CBER

After each of the topic FDA speaker presentations, the Committee then proceeded with the Open Public Hearings. There were no open public hearing speakers for any of the topics. The open session adjourned at 11:10 a.m. EST for Topic I, 1:30 pm EST for Topic II, and 3:30 p.m. EST for Topic III. Following each of the Open sessions, the Committee met in separate closed sessions for each Topic to proceed with Site Visit report discussions followed by a vote. Dr. Richard Kaufman handed the meeting over to the DFO who adjourned the meeting November 4, 2021, at 4:20 p.m. EST.

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-november-4-2021-meeting-announcement-11042021-11042021#event-materials

Direct Link to Recording of the Open Session:
https://youtu.be/2Xz4YzkwNDs