

FOOD AND DRUG ADMINISTRATION  
Center for Biologics Evaluation and Research  
Summary Minutes  
*123<sup>rd</sup> Meeting of the Blood Products Advisory Committee*  
December 8, 2022

OPEN Session

**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  
Nahed El Kassar, M.D., MSc-Ph.D.+  
Brenda J. Grossman MD, MPH  
Frank Maldarelli, 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) +  
Richard Scanlan, M.D.  
Amy Shapiro, M.D.+  
Kenneth Sherman, M.D., Ph.D.  
Abdus Wahed, Ph.D.

**Chair**

Zbigniew “Ziggy” Szczepiorkowski,  
M.D., PhD, F.C.A.P.

**Consumer Representative**

Susan U. Lattimore, RN, M.P.H.\*

**Industry Representative**

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

**FDA Participants**

Chintamani (C.D.) Atreya, Ph.D. (Speaker)  
Anne Eder, M.D., Ph.D.  
Indira Hewlett (Speaker)  
Peyton (John) Hobson, Ph.D.  
Sanjai Kumar, Ph.D. (Speaker)  
Peter Marks, M.D., Ph.D.  
Hira Nakhasi, Ph.D. (Speaker)  
Nicole Verdun, M.D.  
Monica (Burts)Young, Ph.D. (Speaker)

**Designated Federal Official**

Christina Vert, M.S.  
Sussan Paydar, Ph.D.

**Division Director**

Prabhakara Atreya, Ph.D.

**Committee Management Officer**

LaShawn Marks  
Joanne Lipkind

**Committee Management Specialist**

Tonica Burke

+ Not in attendance

< Industry representative

\* Consumer Representative

These summary minutes for the December 8, 2022 meeting of the Blood Products Advisory Committee were approved on December 16, 2022.

I certify that I participated in the December 8, 2022 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

\_\_\_\_\_/S/\_\_\_\_\_  
Christina Vert, M.S.  
Designated Federal Official

\_\_\_\_\_/S/\_\_\_\_\_  
Zbigniew Szczepiorkowski, M.D., PhD, FCAP  
Chair

On December 8, 2022 at 9:30 a.m. Eastern Time (ET), Zbigniew “Ziggy” Szczepiorkowski, M.D. PhD, FCAP (Chair) called to order the 123<sup>rd</sup> meeting of the Blood Products Advisory Committee. The partially closed meeting was held virtually by Zoom web conference platform. The Designated Federal Official (DFO), Christina Vert, made administrative remarks, conducted roll call, 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 Non-Particular Matters, no COI screening was needed or conducted for this meeting. It was stated that no COI waivers were issued under 18 U.S. Code 208 in connection with the meeting.

The topic of the meeting was “ Overview of the Research Programs of the Laboratory of Emerging Pathogens (LEP) and the Laboratory of Molecular Virology (LMV), Division of Emerging and 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 Monica Young, Ph.D., Senior Advisor to the Associate Director for Science, OD, CBER
- Overview of OBRR and Research Programs, by Chintamani Atreya, Ph.D., Associate Director for Research, OBRR, CBER
- Overview of Research and Regulatory Program of DETTD, by Hira Nakhasi, Ph.D., Director, DETTD, OBRR, CBER
- Summary of Viral Diseases Research Programs of LEP, by Sanjai Kumar, Ph.D., Chief, LEP, DETTD, OBRR, CBER
- Overview of LMV Research Programs, by Indira Hewlett, Ph.D., Chief, LMV, DETTD, OBRR, CBER

After the FDA presentations, the Committee then proceeded with the Open Public Hearing (OPH). There were two pre-registered open public hearing speakers. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the

website.

The open session adjourned at 11:55 a.m. ET. Following the open session, the Committee met in closed session to discuss and vote on the Site Visit report. Dr. Zbigniew Szczepiorkowski then handed the meeting to the DFO, who adjourned the meeting December 8, 2022 at 12:38 p.m. ET.

Additional information may be obtained from the transcript and the webcast recording of the meeting, available at:

<https://www.fda.gov/advisory-committees/advisory-committee-calendar/blood-products-advisory-committee-december-8-2022-meeting-announcement-12082022>

Direct Link to Recording of the Open Session:

[https://youtu.be/AQhF3AM\\_ssg](https://youtu.be/AQhF3AM_ssg)