

FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
Summary Minutes
124th Meeting of the Blood Products Advisory Committee
April 26, 2023

OPEN Session

Committee Members

Adaora Adimora, M.D., M.P.H. +
Mark 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.
Marisa 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

Mark Becker <

FDA Participants

Karen Elkins, Ph.D. (Presenter)
Basil Golding, M.D. (Presenter)
Chava Kimchi-Sarfaty, Ph.D. (Presenter)

Peter Marks, M.D., Ph.D.

Designated Federal Official

Christina Vert, M.S.
Marie DeGregorio, B.A.

Division Director

Prabhakara Atreya, Ph.D.

Committee Management Officer

Joanne Lipkind

Committee Management Specialist

Tonica Burke

+ Not in attendance

< Alternate Industry representative

* Consumer Representative

These summary minutes for the April 26, 2023 meeting of the Blood Products Advisory Committee were approved on June 5, 2023.

I certify that I participated in the April 26, 2023 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 April 26, 2023 at 9:30 a.m. Eastern Time (ET), Zbigniew “Ziggy” Szczepiorkowski, M.D. PhD, FCAP (Chair) called to order the 124th 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, 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 topic of the meeting included:

Topic: Overview of the Research Programs in the Division of Hemostasis, Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls, Office of Therapeutic Products (OTP), Center for Biologics Evaluation and Research (CBER)

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

- **Overview of CBER Research Programs**
by Karen Elkins, Ph.D., Associate Director for Science, OD, CBER.
- **Overview of OTP and Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls Research Programs**
By Basil Golding. M.D., Acting Director, Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls, OTP, CBER
- **Overview of Division of Hemostasis Research Programs**
By Chava Kimchi-Sarfaty, Ph.D., Acting Associate Director for Research, OTP, CBER

After each of the topic FDA speaker presentations, the Committee then proceeded with the Open Public Hearing. There were no pre-registered open public hearing speakers. The open session adjourned at 11:07 a.m. ET. Following the Open sessions, the Committee met in closed session to proceed with the Site Visit report discussion followed by a vote. Dr. Zbigniew Szczepiorkowski, handed the meeting over to the DFO who adjourned the meeting April 26, 2023 at 12:30 p.m. ET.

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-april-26-2023-meeting-announcement-04262023>

Direct Link to Recording of the Open Session:

<https://www.youtube.com/watch?v=avlyUZDDfCQ>