

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

MEMBERS

Chair

Hana El Sahly, M.D. +

Expertise: Vaccines, Infectious Diseases
Term: 06/21/2019 – 01/31/2022
Associate Professor
Department of Molecular Virology and
Microbiology
Department of Medicine
Section of Infectious Diseases
Baylor College of Medicine
Houston, TX 77030

Paula Annunziato, M.D. *+**

Expertise: Industry Representative
Term: 2/01/2020 – 01/31/2024
Vice President and Therapeutic Area Head
Vaccines Clinical Research
Merck
North Wales, PA 19454

Archana Chatterjee, M.D., Ph.D.

Expertise: Pediatrics, Infectious Diseases
Term: 06/21/2019 – 01/31/2023
Dean Chicago Medical School
Vice President for Medical Affairs
Rosalind Franklin University
North Chicago, IL 60064

CAPT Amanda Cohn, M.D.

Expertise: Pediatrics, Vaccines
Term: 02/01/2020 – 01/31/2024
Chief Medical Officer
National Center for Immunizations and
Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA 30333

Acting Chair

Arnold Monto, M.D.

Thomas Francis Jr. Collegiate Professor
of Public Health
Professor of Epidemiology
Department of Epidemiology
University of Michigan
School of Public Health
Ann Arbor, MI 48109

Hayley Gans, M.D.

Expertise: Pediatrics, Infectious Diseases
Term: 06/21/2019 – 01/31/2023
Professor of Pediatrics
Department of Pediatrics
Stanford University Medical Center
Stanford, CA 94305

Holly Janes, Ph.D. +

Expertise: Biostatistics
Term: 02/01/2020 – 01/31/2023
Associate Member
Fred Hutchinson Cancer Research Center
Vaccine and Infectious Disease Division
Division of Public Health Sciences
Seattle, WA 98109

+ Not Attending

**Consumer Representative

***Industry Representative

< Alternate Industry Representative

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

MEMBERS (Cont'd)

Michael Kurilla, M.D., Ph.D.

Expertise: Infectious Diseases, Pathology
Term: 08/6/2018 – 01/31/2021
Director, Division of Clinical Innovation
National Center for Advancing Translation
Sciences
National Institutes of Health
Bethesda, MD 20852

Myron Levine, M.D., D.T.P.H., F.A.A.P +

Expertise: Infectious Diseases
Term: 05/9/2018 – 01/31/2022
Simon & Bessie Grollman Distinguished
Professor
Associate Dean for Global Health,
Vaccinology & Infectious Diseases
University of Maryland School of Medicine
Baltimore, MD 21201

H. Cody Meissner, M.D.

Expertise: Infectious Diseases
Term: 08/6/2018 – 1/31/2022
Professor of Pediatrics
Tufts University School of Medicine
Director, Pediatric Infectious Disease
Tufts Medical Center
Boston, MA 02111

Paul Offit, M.D.

Expertise: Infectious Diseases
Term: 02/01/2018 – 01/31/2022
Professor of Pediatrics
Division of Infectious Diseases
Abramson Research Building
The Children's Hospital of Philadelphia
Philadelphia, PA 19104

Steven Pergam, M.D., M.P.H.

Expertise: Infectious Diseases
Term: 02/01/2020 – 01/31/2024
Medical Director
Infection Prevention
Seattle Cancer Care Alliance
Seattle, WA 98109

Andrea Shane, M.D., M.P.H., M.Sc. +

Expertise: Pediatric & Infectious Diseases
Term: 02/01/2018 – 01/31/2022
Chief, Division of Pediatric Infectious
Diseases
Marcus Professor of Hospital Epidemiology
and Infection Control
Emory University School of Medicine &
Children's Healthcare of Atlanta
Atlanta, GA 30322

Paul Spearman, M.D. +

Expertise: Pediatric & Infectious Diseases
Term: 05/9/2018 – 01/31/2022
Director, Division of Infectious Diseases
Albert B. Sabin Chair in Pediatric
Infectious Diseases
Cincinnati Children's Hospital
Medical Center
Professor, Department of Pediatrics
University of Cincinnati School
of Medicine
Cincinnati, OH 45229

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

MEMBERS (Cont'd)

Geeta K. Swamy, M.D. +

Expertise: Infectious Diseases
Term: 08/6/2018 – 01/31/2022
Senior Associate Dean
Vice Chair for Research & Faculty
Development
Associate Professor
Department of Obstetrics & Gynecology
Division of Maternal-Fetal Medicine
Duke University
Durham, NC 27710

Sheldon Toubman, J.D. **

Expertise: Law/Consumer Representative
Term: 08/22/2017 – 01/31/2021
Staff Attorney
New Haven Legal Assistance Association
New Haven, CT 06510

Gregg Sylvester, M.D., M.P.H. <

Expertise: Alternate Industry Representative
Term: 2/01/2020 – 01/31/2024
Vice President
Medical Affairs
Seqirus Inc.
Summit, NJ 07901

TEMPORARY VOTING MEMBERS

A. Ovetta Fuller, Ph.D.

African Studies Center
International Institute
Associate Professor of Microbiology
and Immunology, Medical School
University of Michigan
Ann Arbor, MI 48109

James Hildreth, Sr., Ph.D., M.D.

Professor
Department of Internal Medicine
School of Medicine
President and Chief Executive Officer
Meharry Medical College
Nashville, TN 37205

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

TEMPORARY VOTING MEMBERS (Cont'd)

David Kim, M.D., MA

CAPT, U.S. Public Health Services
Director, Division of Vaccines
Office of Infectious Disease and
HIV/AIDS Policy
Office of Assistant Secretary for Health
U.S. Department of Health and
Human Services
Washington, DC 20024

Jeannette Lee, Ph.D.

Professor
Department of Biostatistics
University of Arkansas for Medical Sciences
Little Rock, AR 72701

Pamela McInnes, DDS, MSc.

Retired, Deputy Director
National Center for Advancing
Translational Sciences
National Institutes of Health
Bethesda, MD 20892

Patrick Moore, M.D., M.P.H.

Distinguished and American Cancer
Society Professor
Pittsburgh Foundation Chair
in Innovative Cancer Research
University of Pittsburgh Cancer Institute
Pittsburgh, PA 15213

James Neaton, Ph.D.

Professor, Division of Biostatistics
Adjunct Professor of Medicine
Division of Infectious Diseases and
International Medicine
School of Public Health
University of Minnesota
Minneapolis, MN 55414

Stanley Perlman, M.D., Ph.D.

Professor
Departments of Microbiology and
Immunology
Professor of Pediatrics
Mark Stinksi Chair in Virology
University of Iowa
Iowa City, IA 52242

Eric Rubin, M.D., Ph.D.

Editor-in-Chief
New England Journal of Medicine
Adjunct Professor
Department of Immunology and
Infectious Diseases
Harvard TH Chan School of Public Health
Associate Physician
Brigham and Women's Hospital
Boston, MA 02115

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

TEMPORARY VOTING MEMBERS (Cont'd)

Mark Sawyer, M.D., F.A.A.P.

Professor of Clinical Pediatrics
Division of Infectious Diseases
Vice Chair for Education
Department of Pediatrics
University of California San Diego
School of Medicine
Director, UC San Diego Pediatrics
Residency Program
Rady Children's Hospital San Diego
La Jolla, CA 92093

Robert Schooley, M.D.

Distinguished Professor of Medicine
Division of Infectious Diseases and
Global Public Health
Co-Director, Center for Innovative Phage
Applications and Therapeutics
Senior Director, International Initiatives
Interim Faculty Director, Global Education
University of California, San Diego
San Diego, CA 92093

Melinda Wharton, M.D., M.P.H.

Director, Immunization Services Division
National Center for Immunization and
Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA 30333

GUEST SPEAKER

Steven Goodman, M.D., Ph.D.

Professor of Medicine
Associate Dean for Clinical and
Translational Research
Professor of Epidemiology and Population
Health, and Medicine
Stanford University
Stanford, CA 94305

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

FDA PARTICIPANTS/SPEAKERS

Doran Fink, M.D., Ph.D. (Speaker)

Deputy Director-Clinical
Division of Vaccines and Related
Products Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Marion Gruber, Ph.D.

Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Philip Krause, M.D.

Deputy Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

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

Director
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

CDR Valerie Marshall, M.P.H., P.M.P.

Senior Public Health Advisor
Division of Viral Products
Immediate Office of the Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Jerry Weir, Ph.D.

Director, Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Celia M. Witten, Ph.D. M.D.

Deputy Director
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Rachel Zang, M.D. (Speaker)

Medical Officer
Division of Vaccines and Related
Products Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Food and Drug Administration
Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee
163rd Meeting

December 17, 2020
Web-Conference
Silver Spring, Maryland 20993

FDA ADMINISTRATIVE STAFF

**DESIGNATED FEDERAL OFFICER
DIRECTOR**

Prabhakara Atreya, Ph.D.
Division of Scientific Advisors and
Consultants
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993
Phone: (240) 402-8006
E-mail: Prabhakara.Atreya@fda.hhs.gov

COMMITTEE MANAGEMENT SPECIALIST

Monique Hill, M.H.A.
Division of Scientific Advisors and Consultants
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993
Phone: (301) 796-4620
E-mail: Monique.Hill@fda.hhs.gov

DESIGNATED FEDERAL OFFICER

Kathleen Hayes, M.P.H.
Division of Scientific Advisors & Consultants
Center for Biologics Evaluation & Research
Food and Drug Administration
Silver Spring, MD 20993
Phone: (301) 796-7864
E-mail: Kathleen.Hayes@fda.hhs.gov