March 4, 2020 FDA White Oak Campus – Great Room – Salon B & C Silver Spring, Maryland 20903

MEMBERS

<u>Chair</u>

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

Tammy Beckham, D.V.M., Ph.D.

Expertise: Infectious Diseases

Term: 02/01/2020 – 01/31/2024 Deputy Assistant Secretary

Vaccines and Infectious Diseases Director

Office of the Assistant Secretary for Health

Department of Health and Human Services

Washington, DC 20201

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

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

Professor and Chair

Department of Pediatrics

University of South Dakota

Sioux Falls, SD 57105

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

+ Not Attending

**Consumer Representative

***Industry Representative

< Alternate Industry Representative

^ Via Teleconference

March 4, 2020 FDA White Oak Campus – Great Room – Salon B & C Silver Spring, Maryland 20903

MEMBERS (Cont'd)

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

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

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

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

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

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

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

March 4, 2020 FDA White Oak Campus – Great Room – Salon B & C Silver Spring, Maryland 20903

MEMBERS (Cont'd)

Paul Spearman, M.D.

Cincinnati, OH 45229

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

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

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

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

March 4, 2020 FDA White Oak Campus – Great Room – Salon B & C Silver Spring, Maryland 20903

TEMPORARY VOTING MEMBERS

Jack Bennink, Ph.D.

(Topic I) Senior Investigator and Chief Viral Immunology Section National Institute of Allergy and Infectious Diseases National Institutes of Health Bethesda, MD 20892

COL Andrew Wiesen, M.D., M.P.H.

(Topic I)
Director
Preventive Medicine
Office of the Assistant Secretary of
Defense (Health Affairs)
Falls Church, VA 22042

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

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

TEMPORARY NON-VOTING MEMBERS

David Wentworth, Ph.D.

(Speaker, Topic I) Chief Virology Surveillance and Diagnosis Branch Influenza Division Centers for Disease Control and Prevention Roybal Campus Atlanta, GA 30329-4027

March 4, 2020 FDA White Oak Campus – Great Room – Salon B & C Silver Spring, Maryland 20903

SPEAKER(S) AND GUEST SPEAKER(S)

CAPT Lisa Grohskopf, M.D., M.P.H. ^

(Topic I)
Medical Officer
Influenza Division
Centers for Disease Control and Prevention

Atlanta, GA 30329

Penny Post, Ph.D.

(Topic I) Head of Regulatory Affairs, Flublok Protein Sciences, A Sanofi Company Meriden, CT 06450

CDR Mark Scheckelhoff, Ph.D., M.P.H.

(Topic I)

Respiratory Pillar Chief

Global Emerging Infections Surveillance

Section

Armed Forces Health Surveillance Branch

Silver Spring, MD 20904

FDA PARTICIPANTS/SPEAKERS

Carolyn Wilson, Ph.D.

(Speaker, Topic II)
Associate Director for Research
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Philip Krause, M.D.

(Topic I)
Deputy 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.

(Topic I)
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

Marion Gruber, Ph.D.

(Topic I) Director

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

Konstantin Chumakov, Ph.D.

(Topic I)

Associate Director for Research

Office of Vaccines Research and Review

Center for Biologics Evaluation and Research

Food and Drug Administration Silver Spring, MD 20993

March 4, 2020 FDA White Oak Campus – Great Room – Salon B & C Silver Spring, Maryland 20903

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

(Topic I) 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

Manju Joshi, Ph.D.

Silver Spring, MD 20993

(Speaker, Topic I) Lead Biologist Division of Biological Standards & Quality Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

Jay Slater, M.D.

(Speaker, Topic II) Director Division of Bacterial, Parasitic, and Allergenic Products Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

Michael Schmitt, Ph.D.

(Speaker, Topic II) Chief Laboratory of Respiratory and Special Pathogens Division of Bacterial, Parasitic, and Allergenic Products Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

Zhiping Ye, M.D., Ph.D.

(Topic I) Branch Chief, Division of Viral Products Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

Anissa Cheung, M.Sc.

(Speaker, Topic I) **Regulatory Coordinator Division of Viral Products** Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

Drusilla Burns, Ph.D.

(Topic II) **Deputy Director** Division of Bacterial, Parasitic, and Allergenic Products Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

March 4, 2020 FDA White Oak Campus - Great Room - Salon B & C Silver Spring, Maryland 20903

FDA ADMINISTRATIVE STAFF

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

DIRECTOR

Prabhakara Atreya, Ph.D. Division of Scientific Advisors & Consultants Center for Biologics Evaluation & 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 & Consultants Center for Biologics Evaluation & Research

Food and Drug Administration Silver Spring, MD 20993 Phone: (301) 796-4620

E-mail: Monique.Hill@fda.hhs.gov