

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
MEETING #150**

**November 7, 2017
FDA White Oak – Great Room B/C
Silver Spring, Maryland 20903**

MEMBERS

CHAIR

Edwards, Kathryn, M.D.
Expertise: Pediatric Infectious Diseases
Term: 02/01/2015-01/31/2019
Sarah H. Sell and Cornelius Vanderbilt
Chair in Pediatrics
Division of Pediatric Infectious Diseases
Vanderbilt University School of Medicine
Monroe Carell, Jr. Children's Hospital at
Vanderbilt
Nashville, TN 37232

Englund, Janet M.D.
Expertise: Pediatrics and Infectious Dis.
Term: 02/01/2014-01/31/2018
Professor
Department of Pediatrics
University of Washington
Director, Pediatric Transplant Infectious
Diseases
Seattle Children's Hospital
Seattle, WA 98105

El Sahly, Hana, M.D.
Expertise: Vaccines, Infectious Diseases
Term: 06/10/2016-01/31/2020
Associate Professor
Department of Molecular Virology and
Microbiology
Department of Medicine
Section of Infectious Diseases
Baylor College of Medicine
Houston, TX 77030

Greenberg, David, M.D.***
Expertise: Industry Representative
Term: 02/01/2016-01/31/2020
Associate Vice President
Regional Medical Head North America
Sanofi Pasteur
Swiftwater, PA 18370

Janes, Holly, Ph.D.+
Expertise: Biostatistics
Term: 06/10/2016-01/31/2020
Associate Member
Fred Hutchinson Cancer Research Center
Vaccine and Infectious Disease Division
Division of Public Health Sciences
Seattle, WA 98109

Toubman, Sheldon V., J.D.**
Expertise: Consumer Representative
Term: 08/16/2017 – 01/31/2021
Staff Attorney
New Haven Legal Assistance Association
New Haven, CT 06510

+ Not Attending
**Consumer Representative
***Industry Representative
++Acting Consumer Representative
^Acting Industry Representative

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MEMBERS (CONTINUED)

Kotloff, Karen, M.D.

Expertise: Pediatrics and Infectious Dis.

Term: 02/01/2014-01/31/2018

Professor of Pediatrics and Medicine
Head, Division of Infectious Disease and
Tropical Pediatrics
Associate Director for Clinical Research
Center for Vaccine Development
University of Maryland School of Medicine
Baltimore, MD 21201

Levy, Ofer, M.D., Ph.D.

Expertise: Infectious Diseases

Term: 02/01/2015-01/31/2019

Staff Physician, Division of Infectious
Diseases & Principal Investigator
Boston Children's Hospital
Faculty Member, Human Biology &
Translational Medicine and Associate
Professor, Harvard Medical School
Boston, MA 02115

Lynfield, Ruth, M.D.

Expertise: Epidemiology and Pediatrics

Term: 04/30/2014-01/31/2018

Medical Director
Minnesota Department of Health
St. Paul, MN 55164

Long, Sarah, M.D.

Expertise: Pediatrics and Infectious Dis.

Term: 02/01/2014-01/31/2018

Professor of Pediatrics
Drexel University College of Medicine
Chief, Section of Infectious Diseases
St. Christopher's Hospital for Children
Philadelphia, PA 19134

McInnes, Pamela, D.D.S., M.Sc. (Dent).

**Expertise: Translational and Clinical
Research**

Term: 05/13/2016–01/31/2019

Deputy Director
National Center for Advancing Translational
Sciences (NCATS)
National Institutes of Health (NIH)
Bethesda, MD 20892

Moore, Patrick, M.D. +

**Expertise: Epidemiology &
Microbiology**

Term: 02/01/2014-01/31/2018

American Cancer Society Professor
Distinguished Professor, Microbiology and
Molecular Genetics
University of Pittsburgh Cancer Institute
Hillman Cancer Research Pavilion
Pittsburgh, PA 15213

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MEMBERS (CONTINUED)

Monto, Arnold, M.D.

**Expertise: Epidemiology & Infectious
Diseases**

Term: 02/01/2016-1/31/2020

Thomas Francis Jr. Collegiate Professor of
Public Health

Professor of Epidemiology

University of Michigan

School of Public Health

Department of Epidemiology

Ann Arbor, MI 48109

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

**Expertise: Epidemiology, Vaccine Policy
and Safety Science**

Term: 05/13/2016–01/31/2020

Director, Immunization Services Division

National Center for Immunization and

Respiratory Diseases

Center for Disease Control and Prevention

Atlanta, GA 30333

Sawyer, Mark, M.D.⁺

Expertise: Pediatrics and Infectious Dis.

Term: 02/01/2014-01/31/2018

Professor of Clinical Pediatrics

University of California, San Diego

San Diego, CA 92123

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TEMPORARY Non-VOTING MEMBERS

Blackstone, Eugene, M.D.

Chair, Sydell and Arnold Miller
Family Heart and Vascular Institute
Cleveland Clinic
Cleveland, OH 44195

Bok, Karin, M.S., Ph.D.

Senior Vaccine Science Advisor
National Vaccine Program Office
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Svcs.
Washington, DC 20201

Follmann, Dean, Ph.D.

Assistant Director, Biostatistics
Chief, Biostatistics Research Branch
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Bethesda, MD 20892

Kirkpatrick, John S., M.D.

Chief, Orthopedic Surgery
Veterans Administration Medical Center
Orlando, FL 32837

Stephens, David, M.D.

Professor of Medicine
Division of Infectious Diseases
Department of Medicine
Emory University School of Medicine
Emory University
Atlanta, GA 30322

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SPONSOR SPEAKERS

Errico, Thomas, M.D.
Professor of Orthopedic Surgery
and Neurosurgery
NYU School of Medicine
Tuxedo Park, NY 10987

Gruber, Bill, M.D., F.A.A.P., F.I.D.S.A.
Senior Vice President
Vaccine Clinical Research &
Development
Pfizer Inc.
Pearl River, NY 10965

Parvizi, Javad, M.D., F.R.C.S.
James Edwards Professor of
Orthopedic Surgery
Sidney Kimmel School of Medicine
Rothman Institute at Thomas
Jefferson University
Philadelphia, PA 19107

FDA PARTICIPANTS/SPEAKERS

Gruber, Marion, Ph.D.
Director
Office of Vaccines Research
and Review
Center for Biologics Evaluation
and Research
Food and Drug Administration
Silver Spring, MD 20903

Mongeau, Tina, M.D., M.P.H.
Medical Officer
Division of Vaccines and
Related Product Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and
Research
Food and Drug Administration
Silver Spring, MD 20903

Roberts, Jeff, M.D.
Chief, Clinical Review Branch
Division of Vaccines and
Related Product Applications
Office of Vaccines Research and Review
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Food and Drug Administration
Silver Spring, MD 20903

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SPEAKER and GUEST SPEAKER

Otto, Michael, Ph.D.

Senior Investigator
Laboratory of Bacteriology
National Institute of Allergy and
Infectious Diseases (NIAID)
National Institutes of Health (NIH)
Bethesda, MD 20892

Proctor, Richard, M.D.

Professor Emeritus of Medical
Microbiology and Immunology
University of Wisconsin School of Medicine
and Public Health
Madison, WI 53705

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FDA ADMINISTRATIVE STAFF

DESIGNATED FEDERAL OFFICER

CAPT Hunter-Thomas, Serina

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COMMITTEE MANAGEMENT SPECIALIST

Harvey, Rosanna

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DIRECTOR

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