

**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  
^Participating by Phone

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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.<sup>+</sup>**

**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  
Chief, Division of Spine Surgery  
NYU School of Medicine  
NYU Langone Orthopedic Hospital  
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

**EDA 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  
Center for Biologics Evaluation and  
Research  
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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Center for Biologics Evaluation & Research  
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**COMMITTEE MANAGEMENT SPECIALIST**

**Harvey, Rosanna**

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Food & Drug Administration  
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Silver Spring, MD 20903  
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**DIRECTOR**

**Atreya, Prabhakara, Ph.D.**

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