

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE  
MEETING #148**

**September 13, 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  
1161 21st Avenue South  
D-7227 MCN  
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  
4800 Sand Point Way, N.E., #MA7.234  
Seattle, WA 98105

**El Sahly, Hana, M.D.**  
**Term: 06/10/2016-01/31/2020**  
**Expertise: Vaccines, Infectious Diseases**  
Associate Professor  
Department of Molecular Virology and  
Microbiology  
Department of Medicine  
Section of Infectious Diseases  
Baylor College of Medicine  
One Baylor Plaza Rm 225D, BCM-MS280  
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  
One Discovery Drive  
Swiftwater, PA 18370

**Janes, Holly, Ph.D.**  
**Term: 06/10/2016-01/31/2020**  
**Expertise: Biostatistics**  
Associate Member  
Fred Hutchinson Cancer Research Center  
Vaccine and Infectious Disease Division  
Division of Public Health Sciences  
1100 Fairview Avenue North, M2-C200  
P.O. Box 19024  
Seattle, WA 98109

+ Not Attending  
\*\*Consumer Representative (Vacant position)  
\*\*\*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  
685 W. Baltimore Street  
HSF 1, Rm 480  
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  
300 Longwood Avenue  
Boston, MA 02115

**Lynfield, Ruth, M.D.**

**Expertise: Epidemiology and Pediatrics**

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

Medical Director  
Minnesota Department of Health  
625 Robert Street North  
PO Box 64975  
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  
Erie Avenue at Front Street  
Philadelphia, PA 19134

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

**Expertise: Translational and Clinical Resea**

**Term: 05/13/2016-01/31/2019**

Deputy Director  
National Center for Advancing Translational  
Sciences (NCATS)  
National Institutes of Health (NIH)  
6701 Democracy Blvd., Suite 904  
Bethesda, MD 20892

**Moore, Patrick, M.D. +**

**Expertise: Epidemiology & Micro.**

**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,  
Suite 1.8  
5117 Centre Avenue  
Pittsburgh, PA 15213

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**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  
Room M5146, SPH II  
1415 Washington Heights  
Ann Arbor, MI 48109-2029

**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  
1600 Clifton Road NE, Mailstop A19  
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  
3020 Children's Way  
San Diego, CA 92123

**TEMPORARY VOTING MEMBERS**

**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.  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Toubman, Sheldon V., J.D.++**

Staff Attorney  
New Haven Legal Assistance Association  
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New Haven, CT 06510

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**SPONSOR SPEAKERS PRESENTATION**

**Poffenberger, Kimber, Ph.D**

Vice President and Head  
North American Regulatory Affairs  
GSK Vaccines

**Yawn, Barbara, M.D., M.Sc., F.A.A.F.P.**

Adjunct Professor  
Department of Family and Community Health  
University of Minnesota, School of Medicine

**Didierlaurent, Arnaud, Ph.D.**

Director and Head of Adjuvant Platform  
Belgium R&D, GSK Vaccines

**Miller, Jacqueline M. M.D., F.A.A.P.**

Vice President and Head  
U.S. Clinical R&D, GSK Vaccines

**Stegmann, Jens-Ulrich, R.N, M.D.**

Vice President and Head  
Clinical Safety and Pharmacovigilance  
GSK Vaccines

**FDA SPEAKERS/PARTICIPANTS**

**Gruber, Marion, Ph.D.**

Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and  
Research  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

**Sun, Wellington, M.D.**

Director, Division of Vaccines and  
Related Product Applications  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and  
Research  
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10903 New Hampshire Avenue  
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**FDA SPEAKERS/PARTICIPANTS Cont'd.**

**Collazo-Custodio, Carmen Ph.D.**

Microbiologist  
Division of Vaccines and Related Product  
Applications  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and  
Research  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

**Agger, Paula, 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  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

**Cohen, Jeffrey, M.D.**

Chief, Laboratory of Infectious Diseases  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

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**FDA ADMINISTRATIVE STAFF**

**DESIGNATED FEDERAL OFFICER**

**CAPT Hunter-Thomas, Serina**

Vaccines and Related Biological Products  
Advisory Committee  
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**COMMITTEE MANAGEMENT SPECIALIST**

**Harvey, Rosanna**

Vaccines and Related Biological Products  
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