

**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

**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 (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

**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**

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
426 State Street
New Haven, CT 06510

**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**

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
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

**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**

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

**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**

FDA ADMINISTRATIVE STAFF

DESIGNATED FEDERAL OFFICER

CAPT Hunter-Thomas, Serina

Vaccines and Related Biological Products
Advisory Committee
Division of Scientific Advisors & Consultants
Center for Biologics Evaluation & Research
Food & Drug Administration
10903 New Hampshire Avenue
Building 71
Silver Spring, MD 20903
Phone: (240) 402-5771
Email: serina.hunterthomas@fda.hhs.gov

COMMITTEE MANAGEMENT SPECIALIST

Harvey, Rosanna

Vaccines and Related Biological Products
Advisory Committee
Division of Scientific Advisors & Consultants
Center for Biologics Evaluation & Research
Food & Drug Administration
10903 New Hampshire Avenue
Building 71
Silver Spring, MD 20903
Phone: (240) 402-8072
Email: rosanna.harvey@fda.hhs.gov