

**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.

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
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.

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
1100 Fairview Avenue North, M2-C200
P.O. Box 19024
Seattle, WA 98109

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

Expertise: Attorney

Term: 08/16/2017 – 01/31/2021

Staff Attorney
New Haven Legal Assistance Association
426 State Street
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
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
Research**

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 &
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,
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
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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
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San Diego, CA 92123

TEMPORARY VOTING MEMBER(S)

Bok, Karin, M.S., Ph.D.
Senior Vaccine Science Advisor
National Vaccine Program Office
Office of the Assistant Secretary for Health
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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
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Agger, Paula, M.D., M.P.H

Medical Officer
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FDA SPEAKERS/PARTICIPANTS Cont'd.

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Microbiologist
Division of Vaccines and Related Product
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Medical Officer
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Cohen, Jeffrey, M.D.

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

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FDA ADMINISTRATIVE STAFF

DESIGNATED FEDERAL OFFICER

CAPT Hunter-Thomas, Serina

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COMMITTEE MANAGEMENT SPECIALIST

Harvey, Rosanna

Vaccines and Related Biological Products
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