FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
MEETING #146

May 17, 2017
FDA White Oak Campus, Building 31, Great Room (Room 1503)
10993 New Hampshire Avenue
Silver Spring, MD

MEMBERS

CHAIR
Edwards, Kathryn, M.D.
Expertise: Pediatric Infectious Diseases
Term: 02/01/2015-01/31/2019
Sarah H. Sell and Cornelius Vanderbilt
Professor of Pediatrics
Pediatric Infection Diseases
Vanderbilt University School of Medicine
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. +
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
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, Washington 98109

+ Not Attending
**Consumer Representative (Vacant position)
***Industry Representative
****(Acting Consumer Representative)
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., MSc. (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, Maryland 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
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, Michigan 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 Centers for Disease Control and Prevention  
Atlanta, Georgia 30333

Sawyer, Mark, M.D.  
Expertise: Pediatrics and Infectious Diseases  
Term: 02/01/2014-01/31/2018  
Professor of Clinical Pediatrics  
University of California, San Diego  
San Diego, CA 92123

TEMPORARY MEMBERS

Notarangelo, Luigi, M.D.  
Deputy Chief, Laboratory of Host Defense Chief, Immune Deficiency Genetics Sect. National Institutes of Health, National Institute of Allergy and Infectious Diseases  
Bethesda, MD

Tripp, Ralph, Ph.D.  
Professor, Department of Infectious Diseases  
0201 Animal Health Research Center University of Georgia  
Athens, GA 30602

Portnoy, Jay, M.D. ****  
Director, Division of allergy, Asthma & Immunology  
Children’s Mercy Hospital & Clinics  
Kansas City, MO 64108

**** (Acting Consumer Representative)
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
MEETING #146

May 17, 2017
FDA White Oak Campus, Building 31, Great Room (Room 1503)
10993 New Hampshire Avenue
Silver Spring, MD

SPEAKERS

Polack, Fernando, M.D.
Scientific Director
Fundación INFANT
CABA
Buenos Aires, Argentina

Dieussaert, Ilse
Director
Lead VDL, Maternal Immunization
GlaxoSmithKline

Gerber, Susan M.D.
Medical Epidemiologist
Centers for Disease Control and Prevention
Viral Division
Atlanta, GA  30329

Zahn, Roland, Ph.D.,
Senior Scientific Director, Nonclinical

Saville, Melanie, M.D.
Head of Late Development,
Clinical and Medical Affairs, Vaccines
Janssen Vaccines & Prevention B.V.
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
MEETING #146

May 17, 2017
FDA White Oak Campus, Building 31, Great Room (Room 1503)
10993 New Hampshire Avenue
Silver Spring, MD

FDA SPEAKERS/PARTICIPANTS

Browne, Sarah, M.D.
Medical Officer
Office of Vaccines Research and Review
DRVPA,
Center for Biologics Evaluation and
Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Krause, Philip, M.D.
Deputy Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and
Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Roberts, Jeffrey M.D.
Chief, Clinical Review Branch 1
Division of Vaccines and Related Product
Applications/OVRR/CBER/FDA
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
MEETING #146

May 17, 2017
FDA White Oak Campus, Building 31, Great Room (Room 1503)
10993 New Hampshire Avenue
Silver Spring, MD

FDA ADMINISTRATIVE STAFF

DESIGNATED FEDERAL OFFICER
CAPT Hunter-Thomas, Serina, R.N.
USPHS
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 20993
Phone: (240) 402-5771
Email: serina.hunter-thomas@fda.hhs.gov

DIRECTOR, DIVISION OF SCIENTIFIC ADVISORS AND CONSULTANTS
Atreya, Prabhakara, Ph.D.
Division of Scientific Advisory & Consultants
Center for Biologics Evaluation & Research Food & Drug Administration
10903 New Hampshire Avenue
Building 71
Silver Spring, MD 20993
Phone: (240) 402-8006
Email: prabhakara.atreya@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 20993
Phone: (240) 402-8072
Email: rosanna.harvey@fda.hhs.gov

COMMITTEE MANAGEMENT SPECIALIST
Royster, Denise
Division of Scientific Advisors & Consultants
Center for Biologics Evaluation & Research Food & Drug Administration
10903 New Hampshire Avenue
Building 71
Silver Spring, MD 20993
Phone: (240) 402-8158
Email: denise.royster@fda.hhs.gov