Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C

ROSTER

MEMBERS

CHAIR

Kathryn Edwards, M.D. +

Expertise: Pediatrics

Term: 02/01/2015 - 01/31/2019

Sarah H. Sell and Cornelius Vanderbilt Chair in Pediatrics

Director, Vaccine Research Program

Vanderbilt University School of Medicine

Monroe Carell, Jr. Children's Hospital at Vanderbilt

1161 21st Avenue South

Nashville, TN 02115

Ruth Lynfield, M.D. †

Acting Chair

Expertise: Epidemiology and Pediatrics

Term: 04/30/2014 - 01/31/2017

Medical Director

Minnesota Department of Health

625 Robert Street North

PO Box 64975

St. Paul, MN 55164

Janet Englund, M.D. +

Expertise: Infectious Diseases

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, NE, M7.234

Seattle, WA 98105

Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

David Greenberg, M.D. *

Expertise: Industry Representative Term: 02/01/2016 – 01/31/2020

Vice President, Scientific and Medical Affairs

Chief Medical Officer Sanofi Pasteur US One Discovery Place Swiftwater, PA 18370

Karen Kotloff, M.D.

Expertise: Pediatrics and Infectious Diseases

Term: 02/01/2014 – 01/31/2018 Professor of Pediatrics and Medicine

Head, Division of Infectious Diseases and Tropical Pediatrics,

Associate Director for Clinical Research

Center for Vaccine Development

University of Maryland School of Medicine

686 W. Baltimore Street, HSF 1, Rm 480

Baltimore, MD 21201

Ofer Levy, 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 & Medicine and Associate Professor, Harvard Medicine School

300 Longwood Avenue

Boston, MA 02115

Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Sarah Long, M.D.

Expertise: Pediatrics and Infectious Diseases

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

Arnold Monto, M.D.

Expertise: Epidemiology

Term: 02/01/2016 - 01/31/2020

Thomas Francis, Jr. Collegiate Professor of Public Health

Professor of Epidemiology University of Michigan

1415 Washington Heights, Rm M5146

Ann Arbor, MI 48109

Patrick Moore, M.D.

Expertise: Epidemiology & Microbiology

Term: 02/02/2014 – 01/31/2018 American Cancer Society Professor

Distinguished Professor, Microbiology and Molecular Genetics

University of Pittsburgh Cancer Institute

Hillman Cancer Research Pavilion

5117 Centre Avenue Pittsburgh, PA 15213

Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Mark Sawyer, 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 92121

TEMPORARY VOTING AND NON-VOTING MEMBERS, TEMPORARY INDUSTRY REPRESENTATIVE

Gillian Air, Ph.D.

Vice-chair, Department of Biochemistry & Molecular Biology University of Oklahoma Health Sciences Center Department of Biochemistry and Molecular Biology BMSB 840 PO Box 26901 Oklahoma City, OK 73190

Ellen Andrews, Ph.D. **

Executive Director Connecticut Health Policy Project 760 Chapel Street New Haven, CT 06510

Jack Bennink, Ph.D.

Chief, Viral Immunology Section
Laboratory of Viral Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
MSC 3209, 33 North Drive
Bethesda, MD 20892

Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Filip Dubovsky, M.D., M.P.H., F.A.A.P ∫

Vice President, Clinical Biologics
Therapeutic Area Head Infectious Disease and Vaccines
AstraZeneca/MedImmune, LLC
One MedImmune Way
Gaithersburg, MD 20878

Bruce Gellin, M.D., M.P.H.

Director

National Vaccine Program Office Health and Human Services 200 Independence Avenue, SW, Rm 715H Washington, DC 20201

Judith Goldberg, Sc.D. ***

Professor of Biostatistics
Department of Population Health and Environmental Medicine
New York University School of Medicine
650 First Avenue, 534
New York, NY 10016

Jacqueline Katz, Ph.D.

Deputy Director (Acting) Influenza Division Director, WHO Collaborating Center for Surveillance Epidemiology and Control of Influenza Centers for Disease Control and Prevention 1600 Clifton Rd., Bldg. 24, MS A-20 Atlanta, GA 30320

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

Deputy Director

The National Center for Advancing Translational Sciences, National Institutes of Health 6701 Democracy Blvd., Room 900, MS 4878 Bethesda, MS 20892

Center for Biologics Evaluation and Research

 $142^{\rm nd}$ Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Scott Stanek, D.O., M.P.H.

Colonel, US Army of Medical Countermeasures Directorate Office of the Assistant Secretary of Defense for Health Affairs 7700 Arlington Blvd.

Falls Church, VA 22042

Melinda Wharton, M.D., M.P.H..

Deputy Director National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention 1600 Clifton Road, MS A27 Atlanta, GA 30333

SPEAKERS/PARTICIPANTS

Anissa Cheung, M.Sc.

Regulatory Coordinator
Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993

Michael Cooper, Ph.D.

CAPT, USPHS
Leader, Respiratory Pillar Activities
Division of Global Emerging Infection Surveillance
Armed Forces Health Surveillance Center (AFHSC)
11800 Tech Road, Suite 220
Silver Spring, MD 20910

Center for Biologics Evaluation and Research

$142^{\rm nd}$ Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Matthew Downham, Ph.D.

Associate Director
Biopharmaceutical Development
AstraZeneca/MedImmune
Renaissance Way
Boulevard Industry Park
Liverpool L24 9JW UK

Lisa Grohskopf, M.D., M.P.H. ***

CAPT, USPHS

Associate Chief for Policy and Liaison Activities, Epidemiology and Prevention Branch, Influenza Division Center for Disease Control and Prevention Atlanta, GA 30333

Marion Gruber, Ph.D.

Director, Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993

Manju Joshi, Ph.D.

Lead Biologist
Division of Biological Standards & Quality Control
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Jerry Weir, Ph.D.

Director, Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Zhiping Ye, M.D., Ph.D.

Senior Investigator, Division of Viral Products Office of Vaccines Research and Review Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993

FDA ADMINISTRATIVE STAFF

Designated Federal Officer

Sujata Vijh, Ph.D.
Division of Scientific Advisors and Consultants
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Tel: 240-402-7107 Fax: 301-595-1307

sujata.vijh@fda.hhs.gov

Center for Biologics Evaluation and Research

142nd Vaccines and Related Biological Products Advisory Committee Meeting

March 4, 2016

White Oak Building 31, Great Room, Salon B/C ROSTER

Committee Management Specialist

Denise Royster
Division of Scientific Advisors and Consultants
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Tel: 240-402-8158 Fax: 301-595-1307

denise.royster@fda.hhs.gov

∫ Temporary Industry Representative

- + Not in attendance
- † Acting Chair
- * Industry Representative
- ** Temporary Consumer Representative Consumer Representative Position is vacant
- *** Via Teleconference
- # Non-voting Temporary Member & Speaker