## FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

## Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland May 8, 2019

#### **MEETING ROSTER**

#### **DESIGNATED FEDERAL OFFICER (Non-Voting)**

# Cindy Chee, PharmD

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

## PULMONARY-ALLERGY DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

#### David H. Au, MD, MS

(Chairperson) Professor of Medicine University of Washington Director, Health Services Research and Development Center of Innovation VA Puget Sound Health Care System, Seattle Division

#### John M. Kelso, MD

Staff Physician Division of Allergy, Asthma, and Immunology Scripps Clinic San Diego, California

#### David J. Lederer, MD, MS

Seattle, Washington

Associate Professor of Medicine and Epidemiology Division of Pulmonary, Allergy and Critical Care Medicine Columbia University Medical Center New York, New York

#### Gailen D. Marshall Jr., MD, PhD, FACP

The R. Faser Triplett Sr MD Chair of Allergy and **Immunology** Medical Director, UMMC Clinical Research Support Program/Clinical Research and Trials Units Professor of Medicine, Pediatrics and Pathology Vice Chair for Research, Department of Medicine Director, Division of Clinical Immunology and Allergy Chief, Laboratory of Behavioral Immunology Research

The University of Mississippi Medical Center Jackson, Mississippi

#### Loretta G. Que, MD

Professor of Medicine Department of Internal Medicine Division of Pulmonary, Allergy and Critical Care Medicine Duke University Health System Durham, North Carolina

# Carrie A. Redlich, MD, MPH

Professor of Medicine, Pulmonary Section & Occupational and Environmental Medicine Director, Yale Occupational and Environmental Medicine Program Yale University School of Medicine New Haven, Connecticut

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## **MEETING ROSTER (cont.)**

## PULMONARY-ALLERGY DRUGS ADVISORY COMMITTEE MEMBER (Voting) (cont.)

#### Richard W. Weber, MD

Professor Emeritus Department of Medicine National Jewish Health Denver, Colorado

#### PULMONARY-ALLERGY DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

## Stuart Green, MD

(Industry Representative)
Vice President
Respiratory and Immunology
Merck Research Laboratories
Rahway, New Jersey

#### **TEMPORARY MEMBERS (Voting)**

## Kathryn Blake, PharmD, BCPS, FCCP, CIP

Director, Center for Pharmacogenomics and Translational Research Principal Research Scientist Associate Professor of Pharmacy, Mayo Clinic College of Medicine and Science Nemours Children's Specialty Care Jacksonville, Florida

## Mary Cataletto, MD, MMM

Professor of Clinical Pediatrics Stony Brook University School of Medicine Stony Brook, New York

#### Daniel L. Gillen, PhD

Professor and Chair Department of Statistics University of California, Irvine Irvine, California

## Erica Brittain, PhD

Mathematical Statistician
Deputy Branch Chief
Biostatistics Research Branch
National Institute of Allergy and Infectious
Diseases (NIAID)
National Institutes of Health (NIH)
Bethesda, Maryland

## Scott S. Emerson, MD, PhD

Professor Emeritus of Biostatistics Department of Biostatistics University of Washington Seattle, Washington

#### Erin Moore, BS

(Patient Representative) Hummelstown, Pennsylvania

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## **MEETING ROSTER (cont.)**

## Richard B. Parad, MD, MPH

Associate Professor of Pediatrics Harvard Medical School Department of Pediatric Newborn Medicine Brigham and Women's Hospital Connor's Center for Women Boston, Massachusetts

#### James M. Tracy, DO

Managing Partner Allergy, Asthma and Immunology Associates, PC Associate Clinical Professor of Pediatrics University of Nebraska College of Medicine Omaha, Nebraska

# Karen S. Schell, DHSc, RRT-NPS, RRT-SDS, RPFT, RPSGT, AE-C, CTTS

(Acting Consumer Representative)
Clinical Assistant Professor
University of Kansas Medical Center
School of Health Professions
Respiratory Care Education
Kansas City, Kansas

## FDA PARTICIPANTS (Non-Voting)

#### Sally Seymour, MD

Acting Director
Division of Pulmonary, Allergy, and Rheumatology
Products (DPARP)
Office of Drug Evaluation II (ODE II)
Office of New Drugs (OND), CDER, FDA

# Yongman Kim, PhD

Biostatistics Team Leader Division of Biometrics II (DB II) Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA

#### Cesar Torres, PhD

Statistical Reviewer DB II, OB, OTS, CDER, FDA

## Robert H. Lim, MD

Clinical Team Leader DPARP, ODE II, OND, CDER, FDA

#### Khalid Puthawala, MD

Clinical Reviewer DPARP, ODE II, OND, CDER, FDA