

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
#67 CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE
MEETING**

**October 12, 2017
FDA White Oak – Great Room B/C
Silver Spring, Maryland 20903**

MEMBERS

CHAIR (Acting)

Byrne, Barry J., M.D., Ph.D.****
**Expertise: Molecular Genetics/
Pediatrics/Microbiology**
Term: 04/01/2014 – 03/31/2018
Professor
Pediatric and Molecular Genetics
And Microbiology
Powell Gene Therapy Center
University of Florida College of Medicine
Gainesville, FL

Ando, Dale, M.D.*

Expertise: Industry Representative
Term: 04/01/2015 - 03/31/2019
President
Gene Editing and Gene Therapy Consulting
Richmond, CA

Bartlett, David, M.D.+

Expertise: Allergy/Immunology
Term: 10/21/2014 – 03/31/2018
Director, Surgical Services for UPCI
Department of Surgery
University of Pittsburgh
Pittsburgh, PA

Bollard, Catherine, M.D., MBChB+

**Expertise: Pediatric Oncology,
Blood Marrow Transplants**
Term: 09/30/2015 – 03/31/2019
Director, Program for Cell Enhancement
And Technologies for Immunotherapy
Children's National Medical Center
Washington, DC

Butterfield, Lisa, Ph.D.

Expertise: Surgery and Immunology
Term: 01/04/2017 – 03/31/2020
Professor of Medicine
Surgery and Immunology
University of Pittsburgh
Pittsburg, PA

Hawkins, Randy, M.D. **

Expertise: Consumer Representative
Term: 04/01/2017 – 03/31/2021
Private Practice
Inglewood, CA

Longo, Daniel, M.D.+

Expertise: Hematology
Term: 04/01/2017 – 03/31/2021
Professor of Medicine
Senior Physician
Brigham and Women's Hospital
Boston, MA

Pluhar, Grace E., DVM, Ph.D.

Diplomate. ACVS
Expertise: Veterinary Medicine
Term: 04/01/2014 – 03/31/2018
Associate Professor
College of Veterinary Medicine
University of Minnesota
St. Paul, MN

*** Industry Representative**

**** Consumer Representative**

***** Alternate Industry Representative**

****** Chairperson – Acting**

+ Not Attending

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MEMBERS (Cont'd)

Roos, Raymond, M.D.+

Expertise: Neurology

Term: 04/01/2017 – 03/31/2020

Marjorie and Robert E. Straus Professor in
Neurological Science
Department of Neurology
University of Chicago
Chicago, IL

Stegemann, Jan, Ph.D.+

Expertise: Biomedical Engineer

Term: 06/06/2016-03/31/2020

Professor
Department of Biomedical Engineering
University of Michigan
Ann Arbor, MI

Wu, Joseph, M.D., Ph.D.

Expertise: Cardiology and Radiology

Term: 12/12/2016 – 03/31/2020

Director, Stanford Cardiovascular
Institute and Professor of Medicine and
Radiology
Stanford University
Stanford, CA

Zovein, Ann C., M.D.

Expertise: Stem Cell/Developmental

Biology/Regenerative Medicine

Term: 04/01/2014 - 03/31/2018

Assistant Professor
Cardiovascular Research Institute
Division of Neonatology
University of California, San Francisco
San Francisco, CA

Willenbucher, Robert, M.D., M.B.A. +***

Expertise: Alternate Industry Rep.

Term: 04/01/2015 – 03/31/2019

Head of Janssen Incubator
Johnson & Johnson, New Brunswick, NJ
Janssen Research & Development, LLC,

Wittes, Janet, Ph.D.+

**Expertise: Biostatistics and
Mathematical Sciences**

Term: 11/18/2015 - 03/31/2019

President
Statistical Collaborative, Inc.
Washington, DC

*** Industry Representative**

**** Consumer Representative**

***** Alternate Industry Representative**

****** Chairperson – Acting**

+ Not Attending

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TEMPORARY VOTING MEMBERS

Brooks, Brian, M.D., Ph.D.
Senior Investigator and Clinical
Director
Pediatric, Developmental and Genetic
Ophthalmology Unit
National Eye Institute
National Institutes of Health
Bethesda, MD

Carney, Marcia, M.D.
Ophthalmologist
Veterans Administration (VA)
Hospital
Fayetteville, NC

Chiorini, John (Jay), Ph.D.
Senior Investigator and Deputy Chief
Adeno-Associated Virus Biology Section
National Institute of Dental and
Craniofacial Research
National Institute of Health
Bethesda, MD

Emerson, Geoffrey, M.D., Ph.D.
Chief of Staff
Phillips Eye Institute
Assistant Adjunct Professor
University of Minnesota
Vice-President, Retina Center of
Minnesota
Minneapolis, MN

Flotte, Terence, M.D.
Celia and Issac Haidak Professor
Dean, Provost and Executive Deputy
Chancellor
Chief Research Officer
University of Massachusetts Medical School
Worcester, MA

Hunsberger, Sally, Ph.D.
Mathematical Statistician
Biostatistics Research Branch
National Institute of Allergy and
Immunology
National Institutes of Health
6700B Rockledge Drive
Bethesda, MD

Lai, Michael, M.D., Ph.D.
Vitreoretinal Surgeon
Retina Group of Washington
Chief of Pediatric Retina and Clinical
Instructor
Department of Ophthalmology
Children's National Medical Center
111 Michigan Avenue NW
Washington DC,

Lee, Brendan, M.D., Ph.D.
Professor, Department of Molecular and
Human Genetics
Baylor College of Medicine
Investigator, Howard Hughes Medical
Institute
One Baylor Plaza
Houston, TX

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TEMPORARY VOTING MEMBERS (Cont'd)

Massof, Robert W., M.D.
Professor of Ophthalmology
Founding Director, Lions Vision research
and Rehabilitation Center
Wilmer Eye Institute
The Johns Hopkins University School of
Medicine
Baltimore, MD

West, Constance, M.D.
Pediatric Ophthalmologist
Private Practice
Belmont, MA

Raasch, Thomas W., M.D.
Professor
College of Optometry
The Ohio State University
Columbus, OH

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SPONSOR PRESENTATION SPEAKERS

High, Katherine, M.D.

President and Chief Scientific Officer
Spark Therapeutics
Philadelphia, PA

Pennesi, Mark, MD, Ph.D.

Associate Professor in Ophthalmic Genetics
Oregon Health and Science University (OHSU)
Portland, Oregon

Kelly, Deborah, M.D.

Head of Pharmacovigilance
Spark Therapeutics
Philadelphia, PA

Reape, Kathleen, M.D.

Head of Clinical Research and Development (R&D)
Spark Therapeutics
Philadelphia, PA

Maguire, Albert, M.D.

Clinical Associate in Division of Pediatric
Ophthalmology Children's Hospital of
Philadelphia (CHOP)
Philadelphia, PA

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FDA SPEAKERS/PARTICIPANTS

Bryan, Wilson, M.D.

Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD

Chambers, Wiley A., M.D.

Supervisory Medical Officer, Ophthalmology
Center for Drug Evaluation and Research
Food and Drug Administration
Silver Spring, MD

Zhu, Yao-Yao, M.D., Ph.D.

Medical Officer
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD

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FDA ADMINISTRATIVE STAFF

DESIGNATED FEDERAL OFFICER

Atreya, Prabhakara, Ph.D.

Cellular, Tissue and Gene Therapies Advisory
Committee (Acting)

Director

Division of Scientific Advisors & Consultants

Center for Biologics Evaluation & Research

Food & Drug Administration

Silver Spring, MD

COMMITTEE MANAGEMENT SPECIALIST

Lipkind, Joanne, M.S.

Cellular, Tissue and gene Therapies Advisory
Committee

Division of Scientific Advisors & Consultants

Center for Biologics Evaluation & Research

Food & Drug Administration

Silver Spring, MD