

**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.

Vitreo-Retinal 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

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

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

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SPONSOR PRESENTATION SPEAKERS

High, Katherine, M.D.

President and Chief Scientific Officer
Spark Therapeutics
Philadelphia, PA

Kelly, Deborah, M.D.

Head of Pharmacovigilance
Spark Therapeutics
Philadelphia, PA

Maguire, Albert, M.D.

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

Pennesi, Mark, MD, Ph.D.

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

Reape, Kathleen, M.D.

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