

**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