# Food and Drug Administration Center for Biologics Evaluation and Research Office of Tissues and Advanced Therapies

71st Meeting of the Cellular Tissue and Gene Therapies Advisory Committee March 10, 2022

> Meeting Roster Web-Conference

### **MEMBERS**

### **CHAIR**

## Butterfield, Lisa, Ph.D.

Expertise: Tumor Immunology
Term: 11/28/2016-03/31/2023
Adjunct Professor, Microbiology and
Immunology, UCSF
Vice-President
PICI Research & Development
Parker Institute for Cancer Immunotherapy
San Francisco, CA 94129

### Ahsan, Tabassum (Taby), Ph.D.

Expertise: Biomedical Engineering Term: 05/17/2021-03/31/2024 Vice President of Cell Therapy City of Hope Duarte, CA 91010

#### Berns, Kenneth, M.D., Ph.D.

Expertise: Molecular Genetics, Microbiology Virology, Viral Vectors and Gene Therapies Term: 09/27/2018-08/31/2022 Distinguished Professor Emeritus, Molecular Genetics and Microbiology University of Florida Gainesville, FL 32610

## Breuer, Christopher K., M.D.

Expertise: General Surgery and Pediatric

Surgery

Term: 06/07/2018-03/31/2022

Director of Tissue Engineering Program and

Surgical Research

Director, Center for Regenerative Medicine

Nationwide Children's Hospital

Columbus, OH 43215

### Crombez, Eric, M.D.<+

Expertise: Alternate Industry Representative Term: 12/26/2019-03/31/2024 Chief Medical Officer Ultragenyx Gene Therapies Cambridge, MA 02139

### Fox, Bernard, Jr., Ph.D.

Expertise: Tumor Immunology/Cancer

Therapies

Term: 01/27/2020-03/31/2023

Chief, Laboratory of Molecular and Tumor

**Immunology** 

Providence Portland Medical Center

Portland, OR 97213

### Hawkins, Randy, M.D.\*\*

Consumer Representative

Expertise: Pulmonary and Critical Care

Medicine

Term: 04/01/20021-03/31/2022

Private Practice Inglewood, CA 90301

## Lee, Jeannette Yen, Ph.D.

**Expertise: Biostatistics** 

Term: 05/30/2019-03/31/2023 Professor of Biostatistics

University of Arkansas for Medical Sciences

Little Rock, AR 72205

+ Not Attending

\*\* Consumer Representative

\*\*\*Industry Representative

<Alternate Industry Representative

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## MEMBERS (Cont'd)

#### Morrison, Sean, Ph.D.+

Expertise: Stem Cell Biology Term: 06/07/2018-03/31/2022

Director, Children's Medical Center Research

Institute

University of Texas Southwestern Medical

Center

Dallas, TX 75390

### Nichol, Geoffrey M., M.D., M.B.A.\*\*\*

Expertise: Industry Representative Term: 12/26/2019-03/31/2024 Senior Vice President, Global Clinical Research and Chief Medical Officer BioMarin Pharmaceutical Novato, CA 94949

#### Shah, Nirali N., M.D., MHSc

Expertise: Pediatric Oncology
Lasker Clinical Research Scholar
National Cancer Institute
NIH Distinguished Scholar
National Institutes of Health
Assistant Professor in Pediatric Oncology
Part-Time, Johns Hopkins University
Bethesda, MD 20892

## Walters, Mark C., M.D. +

Expertise: Hematology and Oncology,

Blood and Bone Marrow Transplantation, and

Stem Cell Biology

Term: 04/01/2018-03/31/2022

Jordan Family Director Blood and Marrow

Transplantation

USCF Benioff Children's Hospital Oakland

Oakland, CA 94609

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

Expertise: Cardiology and Radiology

Term: 11/28/2016-03/31/2023

Director, Stanford Cardiovascular Institute

Professor of Medicine and Radiology

Stanford University Stanford, CA 94305

### Zaia, John A., M.D.

Expertise: Virology and Infectious Disease

Term: 06/07/2018-03/31/2022 Director, Center for Gene Therapy, Hematologic Malignancies and Stem Cell

Transfer

Department of Hematology, Aaron D. Miller and Edith Miller Chair in Gene Therapy Beckman Research Institute of City of Hope Duarte, CA 91010

### Wolfe, Gil, M.D., F.A.A.N.

**Expertise:** Neurology

Term: 12/22/2021 - 03/31/2026

Department of Neurology

Jacobs School of Medicine and Biomedical

Sciences, University at Buffalo/SUNY

Buffalo, NY 14202-1102

+ Not Attending

\*\* Consumer Representative

\*\*\*Industry Representative

<Alternate Industry Representative

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## FDA PARTICIPANTS/SPEAKERS

### Marks, Peter W., M.D., Ph.D.

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### Kimchi-Sarfaty, Chava, Ph.D.

Deputy Associate Director for Research Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993

## Byrnes, Andrew, Ph.D.

Branch Chief
Gene Transfer and Immunogenicity Branch
Division of Cellular and Gene Therapies
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#### Elkins, Karen, Ph.D.

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## Anatol, Rachael, Ph.D.

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#### Oh, Steven, Ph.D.

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## **FDA ADMINISTRATIVE STAFF**

### **DESIGNATED FEDERAL OFFICER**

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#### **DIRECTOR**

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# **COMMITTEE MANAGEMENT SPECIALIST**

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