

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
70th Meeting of the Cellular Tissue and Gene Therapies Advisory Committee
September 2-3, 2021 Meeting Roster
Web-Conference

MEMBERS

<p><u>CHAIR</u> Lisa Butterfield, Ph.D. Expertise: Tumor Immunology Term: 11/28/2016-03/31/2023 Vice President, PICI Research Center University of California, San Francisco San Francisco, CA 94129</p>	<p>Eric Crombez, M.D.< Expertise: Alternate Industry Representative Term: 12/26/2019-03/31/2024 Chief Medical Officer Ultragenyx Gene Therapies Cambridge, MA 02139</p>
<p>Tabassum (Taby) Ahsan, Ph.D. Expertise: Biomedical Engineering Term: 05/17/2021-03/31/2024 Head, Analytical Development and Characterization Therapeutic Discovery at MD Anderson Cancer Center Houston, TX 77030</p>	<p>Bernard Fox, 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</p>
<p>Kenneth Berns, 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</p>	<p>Randy Hawkins, M.D.** Consumer Representative Expertise: Pulmonary and Critical Care Medicine Term: 04/01/20021-03/31/2022 Private Practice Inglewood, CA 90301</p>
<p>Christopher K. Breuer, 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</p>	<p>Jeannette Yen Lee, Ph.D. Expertise: Biostatistics Term: 05/30/2019-03/31/2023 Professor if Biostatistics University of Arkansas for Medical Sciences Little Rock, AR 72205</p>

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MEMBERS (Cont'd)

<p>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</p>	<p>Joseph Wu, 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</p>
<p>Martin G. Nichol, 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</p>	<p>John A. Zaia, 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</p>
<p>Mark C. Walters, 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</p>	

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TEMPORARY VOTING MEMBERS

<p>Frederic Bushman, Ph.D. Professor and Chair Department of Microbiology Co-Director Center for Research on Coronaviruses and Other Emerging Pathogens Perelman School of Medicine University of Pennsylvania Philadelphia, PA 19104</p>	<p>Peggy DiCapua> Executive Assistant/Transaction Coordinator Advanced Real Estate, LLC Crown Point, IN 46307</p>
<p>Barry J. Byrne, M.D., Ph.D. Professor and Associate Chair of Pediatrics, Molecular Genetics & Microbiology Director, Powell Center, School of Medicine University of Florida Gainesville, FL 32610</p>	<p>Theo Heller, M.D. Section Chief, Translational Hepatology Section, Liver Diseases Branch National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institutes of Health Bethesda, MD 20892</p>
<p>LaTasha Crawford, V.M.D., Ph.D., D.A.C.V.P. Assistant Professor Department of Pathological Sciences University of Wisconsin-Madison School of Veterinary Medicine Madison, WI 53706</p>	<p>Roland W. Herzog, Ph.D. Professor of Pediatrics Director, Gene and Cell Therapy Program Herman B. Wells Center for Pediatric Research Indiana University School of Medicine Indianapolis, IN 46202</p>
<p>James DeFilippi, M.B.A., P.M.P.> BR+A Consulting Engineer Private Practice DeFilippi Consulting, LLC Arlington, VA 22201</p>	<p>Raymond Roos, M.D. Marjorie and Robert E. Straus Professor in Neurological Science Department of Neurology University of Chicago Chicago, IL 60637</p>

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<p>Carlos Sanchez, M.D. Pediatric Neurosurgeon Principal Investigator, Center for Cancer and Immunology Research Children's National Hospital Washington, DC 20010</p>	<p>Charles Vite, B.S., D.V.M., Ph.D. Diplomate, ACVIM (Neurology) Professor of Neurology Department of Clinical Sciences and Advanced Medicine School of Veterinary Medicine University of Pennsylvania Philadelphia, PA 19104</p>
<p>Charles P. Venditti, M.D., Ph.D. Head, Organic Acid Research Section Senior Investigator, National Human Genome Research Institute (NHGRI) National Institute of Health (NIH) Bethesda, MD 20892</p>	<p>Caroline Zeiss, D.A.C.V.P., D.A.C.L.A.M., Ph.D. Professor, Comparative Medicine Chief of Pathology Professor of Ophthalmology and Visual Science Yale University School of Medicine New Haven, CT 06520</p>

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INVITED GUEST SPEAKERS

<p>Deepa Chand, M.D. (Session 3) Executive Medical Director Global Patient Safety & Pediatric Nephrologist Novartis Gene Therapies Bannockburn, IL 60015</p>	<p>Mark S. Sands, Ph.D. (Session 1) Professor, Department of Medicine Oncology Division, Stem Cell Biology Department of Genetics Washington University School of Medicine St. Louis, MO 63110</p>
<p>Roland Crystal, M.D. (Session 5) Chair/Professor Department of Genetic Medicine Weill Cornell Medicine New York, NY 10065</p>	<p>Denise E. Sabatino, Ph.D. (Session 1) Research Associate Professor of Pediatrics Vice Chair of the Gene Therapy and Vaccine Graduate Program Perelman School of Medicine University of Pennsylvania The Children’s Hospital of Philadelphia Philadelphia, PA 19104</p>
<p>Lindsey A. George, M.D. (Session 2) Assistant Professor Department of Pediatrics Perelman School of Medicine University of Pennsylvania The Children’s Hospital of Philadelphia Philadelphia, PA 19104</p>	<p>James (Jim) Wilson, M.D., Ph.D. (Session 2 & 3) Rose H. Weiss Orphan Disease Center Director, Gene Therapy Program Department of Medicine Perelman School of Medicine University of Pennsylvania Philadelphia, PA 19104</p>

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FDA PARTICIPANTS/SPEAKERS

<p>Peter Marks, M.D., Ph.D. Director Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	<p>Celia Witten, Ph.D., M.D. Deputy Director Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>
<p>Wilson Bryan, M.D. Director Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	<p>Rachael F. Anatol, Ph.D. Deputy Director Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>
<p>Leila Hann Associate Director for Policy (Acting) Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	<p>Tejashri Purohit-Sheth, M.D. Director Division of Clinical Evaluation and Pharmacology/Toxicology Office of Tissues and Advanced Therapies Center for Biological Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>
<p>Raj Puri, M.D., Ph.D. Director Division of Cellular Tissue and Gene Therapies Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	<p>Andrew Byrnes, Ph.D. Branch Chief Gene Transfer and Immunogenicity Branch Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>
<p>Denise Gavin, Ph.D. Branch Chief Gene Therapies Branch Office of Tissue and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	

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<p>Mercedes Serbian, M.S. Supervisory Toxicologist Pharmacology/Toxicology Branch 1 Division of Clinical Evaluation and Pharmacology/Toxicology Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	<p>Zenobia F. Taraporewala, Ph.D. Team Lead Gene Therapies Branch Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>
<p>Rosa Sherafat-Kazemzadeh, M.D. Medical Director Division of Clinical Evaluation and Pharmacology/Toxicology Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	<p>Gaya Hettiarachchi, Ph.D. Pharmacology-Toxicology Reviewer Pharmacology and Toxicology Branch 2 Division of Clinical Evaluation and Pharmacology/Toxicology Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>
<p>Vijay Kumar, M.D. Physician Division of Clinical Evaluation and Pharmacology/Toxicology Office of Tissues and Advanced Therapies Center for Biologics Evaluation and Research Food and Drug Administration Silver Spring, MD 20993</p>	

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FDA ADMINISTRATIVE STAFF

<p><u>DESIGNATED FEDERAL OFFICER</u> Jarrod Collier, M.S. Division of Scientific Advisors & Consultants Center for Biologics Evaluation & Research Food and Drug Administration Silver Spring, MD 20993 Phone: (202) 906-0043 E-mail: CTGTAC@fda.hhs.gov</p>	<p><u>COMMITTEE MANAGEMENT SPECIALIST</u> Joanne Lipkind, M.S. Division of Scientific Advisors & Consultants Center for Biologics Evaluation & Research Food and Drug Administration Silver Spring, MD 20993 Phone: (240) 402-8106 E-mail: CTGTAC@fda.hhs.gov</p>
<p><u>BACKUP DESIGNATED FEDERAL OFFICER</u> Christina Vert, M.S. Division of Scientific Advisors & Consultants Center for Biologics Evaluation & Research Food and Drug Administration Silver Spring, MD 20993 Phone: (240) 402-8106 E-mail: CTGTAC@fda.hhs.gov</p>	<p><u>DIRECTOR</u> Prabhakara Atreya, Ph.D. Division of Scientific Advisors & Consultants Center for Biologics Evaluation & Research Food and Drug Administration Silver Spring, MD 20993 Phone: (240) 402-8006 E-mail: CTGTAC@fda.hhs.gov</p>

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