Overcoming Barriers to Accessing Cell-based Gene Therapy: A Workshop

Committee

Patrick Hanley

Co-Chair

Patrick Hanley, PhD, is Chief and Director of the Cellular Therapy Program at Children's National Hospital and Associate Professor of Pediatrics at the George Washington University. He oversees stem cell transplantation processing and the development, manufacturing, quality, and testing of novel cell and gene therapies. Hanley's research and clinical work focus on translating cell and gene therapies into clinical practice. Over the past 20 years, he has helped advance more than 650 cellular therapy products across more than 25 clinical protocols, including mesenchymal stromal cells, virus-specific T cells, tumor-associated antigen-specific T cells, and chimeric antigen receptor (CAR) T-cell therapies. Hanley previously served as Vice President–North America and on the Board of Directors of the International Society for Cell and Gene Therapy, where he co-founded and served as inaugural co-chair of the Early Stage Professionals Committee and is Managing Editor of Cytotherapy. He also serves on the Board of Directors of the Foundation for the Accreditation of Cellular Therapy and represents the organization at the Cell Therapy Liaison Meeting with the U.S. Food and Drug Administration. He received the International Society for Cell and Gene Therapy's inaugural Mid Career Award in 2026. Hanley earned a BA in Biology and Chemistry from Hartwick College and a PhD in Immunology from Baylor College of Medicine.

Kathleen Zackowski

Co-Chair

Kathleen Zackowski, PhD, OTR/L, is Associate Vice President for Research at the National Multiple Sclerosis Society, where she oversees the Society's research portfolio focused on clinical and rehabilitation care, the Wellness Initiative, and the Community Review of Multiple Sclerosis Research Committee. She also serves on the scientific leadership team of the International Progressive MS Alliance. Zackowski's research focuses on clinical rehabilitation and the mechanisms underlying sensorimotor impairments and disability associated with central nervous system disorders, particularly multiple sclerosis. Prior to joining the National Multiple Sclerosis Society, she was a faculty member in the Departments of Physical Medicine & Rehabilitation and Neurology at the Johns Hopkins School of Medicine and the Kennedy Krieger Institute, where she directed a research laboratory for 15 years. She remains an Adjunct Associate Professor at both institutions and has more than 25 years of clinical experience as an occupational therapist, including more than 15 years caring for individuals with multiple sclerosis at the Johns Hopkins MS Center. Zackowski earned a PhD in Movement Science from Washington University in St. Louis and completed postdoctoral training in neuroscience and neurology at the Johns Hopkins School of Medicine.

Kapil Bharti

Member

Kapil Bharti, PhD, is Scientific Director of the National Eye Institute at the National Institutes of Health. Bharti's research focuses on stem cell-based therapies, regenerative medicine, gene therapy, and disease models for inherited and age-related eye diseases. His laboratory developed an autologous induced pluripotent stem cell-derived retinal pigment epithelium patch that advanced to a Phase I/IIa clinical trial for age-related macular degeneration. He has also pioneered new approach methodologies in ophthalmology, including three-dimensional bioprinted eye tissue, and is developing cell and gene therapies for rare and common eye diseases. He has authored more than 100 peer-reviewed publications. Bharti has received numerous honors for his contributions to stem cell and vision research, including the International Society for Stem Cell Research Public Service Award (twice), the NIH Director's Award (twice), and the National Eye Institute Director's Dr. Karl Kupfer Visionary Award. He earned a bachelor's degree in biophysics from Panjab University, a master's degree in biotechnology from Maharaja Sayajirao University, and a PhD in molecular cell biology from Johann Wolfgang Goethe University. He completed postdoctoral training at the National Institute of Neurological Disorders and Stroke.

Maria Bonneville

Member

Maria Bonneville is Vice Chair of the Independent Citizens' Oversight Committee at the California Institute for Regenerative Medicine (CIRM). She also chairs CIRM's Accessibility and Affordability Working Group, which develops recommendations to improve the accessibility and affordability of CIRM-funded therapies and clinical trials. Since joining CIRM in 2011, she has held several leadership positions, including Vice President of Board Governance and Public Outreach and Vice President of Administration, and leads the agency's government relations efforts. Bonneville's work focuses on regenerative medicine policy, public engagement, government relations, and strategies to improve access to innovative therapies. She collaborates with California legislators and other stakeholders to advance policies that support accessibility and affordability for patients and participates in CIRM board committees and working groups. Bonneville earned a Bachelor of Arts in Political Science from the University of California, Berkeley.

Tammy R.L. Collins

Member

Tammy Collins, PhD, is Program Officer at the Burroughs Wellcome Fund, where she directs the Career Awards at the Scientific Interface and the Innovations in Regulatory Science Awards programs. Previously, she served as Training Director at the National Institute of Environmental Health Sciences, National Institutes of Health, where she was also Chair-elect of the NIH-wide Training Directors' Committee. Collins' work focuses on research training, scientific workforce development, and career outcomes for biomedical scientists. She has published on postdoctoral scholar career outcomes and led a national effort through the Graduate Career Consortium to evaluate career outcome classification and visualization methodologies in North America. She also helped develop the National Institute of Environmental Health Sciences Scientific Director's Traineeship for Inclusion, Diversity, and Equity (STrIDE) program and served on the Trainee Subcommittee of the NIH UNITE initiative. Collins received an NIH Director's Award for her contributions to scientific workforce initiatives. She earned a bachelor's degree in chemistry from Appalachian State University, where she was the university's first Goldwater Scholar, and a PhD in biochemistry from Duke University. She completed postdoctoral training at Duke University and the National Institute of Environmental Health Sciences.

Lee A. Fleisher

Member

Lee A. Fleisher, MD, ML, is Founding Principal and Chief Executive Officer of Rubrum Advising and Emeritus Professor of Anesthesiology and Critical Care. Previously, he served as Chief Medical Officer and Director of the Center for Clinical Standards and Quality at the Centers for Medicare & Medicaid Services from 2020 to 2023. From 2004 to 2020, he was the Robert D. Dripps Professor and Chair of Anesthesiology and Critical Care and Professor of Medicine at the University of Pennsylvania. Fleisher is an anesthesiologist and health policy leader whose work focuses on health care quality, patient safety, clinical standards, and health system improvement. At CMS, he was responsible for national clinical, quality, and safety standards for health care facilities and providers, as well as Medicare coverage determinations for items and services that improve health outcomes. Fleisher is an elected member of the National Academy of Medicine and has served on multiple National Academies committees, including the former Board on Health Care Services. He also serves as Senior Advisor to the Bipartisan Policy Center and FasterCures at the Milken Institute, Visiting Fellow at the Duke-Margolis Center for Health Policy, and as a member of the Health IT Advisory Committee of the Office of the National Coordinator for Health Information Technology and the American Hospital Association Patient Safety Initiative. Fleisher serves on the board of directors of CoRegen, a cancer therapy company developing an immune cell-based adoptive cell therapy, and he is also the CEO of Rubrum Advising, a regulatory and market access consulting firm. He received the SUNY Distinguished Alumni Award and the Lindback Award for Distinguished Teaching at the University of Pennsylvania. He earned a bachelor's degree in molecular biology from the University of Pennsylvania, an MD from the State University of New York at Stony Brook, and a Master of Law from the University of Pennsylvania Carey School of Law.

Tim Hunt

Member

Tim Hunt, JD, is Chief Executive Officer of the Alliance for Regenerative Medicine (ARM). He brings more than 25 years of biotechnology industry experience, including executive leadership roles at Editas Medicine, Cubist Pharmaceuticals, and Biogen, where he oversaw global policy and government affairs, early commercial planning, bioethics, communications, and human resources. Hunt's expertise spans biotechnology policy, regenerative medicine, gene and cell therapy, and bioethics. His work has focused on advancing the development and commercialization of innovative therapies through policy, regulatory engagement, and industry collaboration. Hunt has chaired the Ethics Committee and the Government Affairs Committee of the American Society of Gene and Cell Therapy. He previously served as a member of the Duke-Margolis Center for Health Policy advisory group on value-based payments for medical products, ARM's Gene Editing Task Force, and the Biotechnology Innovation Organization's Gene Editing Working Group. He earned a bachelor's degree in history and philosophy from Boston College and a Juris Doctor from the Columbus School of Law at The Catholic University of America.

Derek Robertson

Member

Derek Robertson, JD, MBA, is co-founder and President of the Maryland Sickle Cell Disease Association, where he oversees the organization's strategic direction and advocacy efforts. Professionally, he is a Managing Director at Apogenics, Inc., where he advises health care organizations on federal drug pricing, health care compliance, Medicare and Medicaid reimbursement, and grants management. Previously, he served as Executive Director and General Counsel of the Hemophilia Alliance and as General Counsel of the Hemophilia Alliance Group Purchasing Organization. Robertson's work spans patient advocacy, health policy, and health care law, with expertise in newborn screening, sickle cell disease, federal drug pricing, and regulatory compliance. He has served on numerous federal advisory bodies, including the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, the Maternal and Child Health Bureau's Newborn Screening Expert Panel, and the National Heart, Lung, and Blood Institute's Sickle Cell Disease Advisory Committee. Robertson earned an MBA from Baruch College, City University of New York, and a Juris Doctor from the University of Houston Law Center. He is licensed to practice law in Texas and the District of Columbia and is certified in health care compliance.

Rachel Salzman

Member

Rachel Salzman, DVM, is Chief Executive Officer of Armatus Bio, a privately held preclinical biotechnology company developing precision therapies for genetic neuromuscular disorders. Previously, she served as Executive Vice President of Portfolio, External Affairs & Development at Alcyone Therapeutics, co-founded SwanBio Therapeutics and served as its Chief Executive Officer, and was Chief Science Officer of The Stop ALD Foundation. Salzman's work focuses on the development of therapies for rare genetic diseases, with expertise spanning gene therapy, precision medicine, and drug development. For more than 20 years, she has led scientific and strategic efforts to advance therapies for rare diseases where complex biological, clinical, and business challenges intersect with significant unmet medical need. She also founded UltraSquared Bio, a nonprofit organization dedicated to advancing gene therapies for ultra-rare diseases. Salzman is a Termeer Foundation Fellow and has served in numerous leadership roles within the American Society of Gene and Cell Therapy, including on its Board of Directors. She currently represents the American Society of Gene and Cell Therapy on the National Academies Forum on Regenerative Medicine. She earned a Doctor of Veterinary Medicine from Oklahoma State University and a bachelor's degree in animal science from Rutgers University.

Eric Sid

Member

Eric Sid, MD, MHA, is Program Director in the Division of Rare Diseases Research Innovation at the National Center for Advancing Translational Sciences, National Institutes of Health, where he leads research efforts addressing the health information needs of individuals with rare diseases. He also leads programs that support patient-focused therapy development, rare disease registries, and access to health information for individuals with rare genetic diseases. Sid's work focuses on data science, health informatics, and community-engaged research to improve access to and use of rare disease research data. He leads programs that promote FAIR data practices, data harmonization, knowledge base development, and the use of artificial intelligence to advance rare disease research. His research emphasizes scalable approaches that can benefit multiple rare diseases, including broader sharing of AI-ready datasets and predictive models to accelerate therapeutic development. Sid earned his MD and Master of Health Administration from the University of Washington.

Katherine Tsokas

Member

Katherine Tsokas, JD, is Senior Vice President of Regulatory Affairs at BlueRock Therapeutics. Previously, she served as Vice President of Regulatory, Quality, Risk Management and Drug Safety for Canada at Johnson & Johnson Innovative Medicine, where she also held global leadership roles as Head of Regenerative Medicine & Advanced Therapy, Head of Data Science, and Head of Research and Early Development. Tsokas has more than 30 years of global experience in regulatory affairs, quality, pharmacovigilance, and regenerative medicine. Her work has focused on the development and commercialization of small molecules, biologics, and regenerative medicine advanced therapy (RMAT) products across all stages of development. She has worked extensively with industry, academic, and government partners to advance the development and commercialization of regenerative medicine therapies. Tsokas serves as co-chair of the National Academies Forum on Regenerative Medicine, where she promotes collaboration among stakeholders to advance regenerative medicine. She earned a Bachelor of Science in Biology from Temple University and a Juris Doctor from Widener University Law School. She is admitted to the practice of law in Pennsylvania and New Jersey.