The Honorable Susan Collins Chair, Senate Appropriations Committee 413 Dirksen Senate Office Building Washington, DC 20510

The Honorable Tom Cole Chair, House Appropriations Committee 2207 Rayburn House Office Building Washington, DC 20510 The Honorable Patty Murray
Vice Chair, Senate Appropriations Committee
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Rosa DeLauro
Ranking Member, House Appropriations Committee
2413 Rayburn House Office Building
Washington, DC 20510

Dear Chair Collins, Vice Chair Murray, Chair Cole, and Ranking Member DeLauro,

On behalf of the undersigned organizations, we ask you to ensure robust appropriations for NIH in the remainder of fiscal year (FY) 2025 and for FY 2026. We further urge Congress to reaffirm the current statutory arrangement for Facilities & Administrative (F&A or "indirect") cost reimbursements.¹ NIH funding is an integral part of the United States research enterprise, which leads the world in innovative research and development for transformative medicines and rare disease treatments. Our organizations believe cuts to the overall NIH budget or caps on F&A would significantly slow scientific advancement and ultimately cause harm to patients.

NIH funding has supported an untold number of breakthroughs for patients, providing hope for those facing both rare and common diseases. These biomedical advances can offer improved quality of life or, in some cases, an effective cure for devastating illnesses. Cell and gene therapies (CGTs) have revolutionized treatment options for a wide range of diseases. CGTs have changed the treatment paradigm for certain blood cancers for pediatric and adult patients, can cure genetic diseases such as sickle cell anemia and spinal muscular atrophy, and are forging pathways for new therapies to treat, and potentially cure, patients with serious diseases such as lupus and Huntington's Disease, among hundreds more.

While there is a strong therapeutic pipeline,<sup>2</sup> continued investments in basic, translational, and early clinical research are needed to build on deep scientific underpinnings. A critical component of NIH funding is F&A reimbursements to support research. These are funds provided to an institution when a scientist receives a grant. They are neither supplemental nor insignificant. Rather, they are integral to CGT research and support critical functions including:

## Manufacturing and Materials

Institutions establish complex patient cells and vector production facilities that can be
utilized across multiple research groups. While some project-specific machinery may be
paid for with grant funding, costs of other shared equipment such as bioreactors or
incubators, centrifuges, chromatography systems, and cryopreservation storage are
shouldered by the institutions and supported through F&A. F&A funds also support the

<sup>&</sup>lt;sup>1</sup> U.S. Congress (2024). Further Consolidated Appropriations Act [H.R.2882]. https://www.congress.gov/118/plaws/publ47/PLAW-118publ47.pdf

<sup>&</sup>lt;sup>2</sup> ASGCT and Citeline (2024). Gene, Cell, & RNA Therapy Landscape: Q4 2024 Quarterly Data report. https://www.asgct.org/global/documents/asgct-citeline-q4-2024-report.aspx

- biomedical engineering staff who install, calibrate, maintain, and repair those apparatuses.
- Specialized disposal services are required for biological, chemical, or radioactive waste products created in the course of research.

## Research Outputs

- Research design and compliance programs oversee informed consent and monitor
  patient safety in clinical trials. Principal Investigators (PIs) may run multiple clinical trials
  simultaneously; therefore, they rely on specialized teams at their institutions to help
  streamline processes. This allows PIs to maximize the clinical trials performed and the
  number of patients who can safely enroll in any given trial.
- Staff experts help ensure promising research can advance beyond the lab to patients' bedside.
- Access to advanced data systems which play a keystone role in CGT research, including cloud-based data management, high performance on-site computing resources, and specialized image rendering software.

This short list represents a sample of the ways in which F&A funds support research. If F&A cuts are enacted, institutional efficiency and the speed of scientific advancement will be severely curtailed.

The undersigned organizations represent the scientists, physicians, patient advocates, and other professionals developing, and committed to the advancement of, CGTs across the United States. US institutions perform critical work to advance the underlying research that has led to today's robust pipeline of transformative therapies. From the bench to the bedside, this work has improved the lives of patients – but ongoing, stable investment is necessary to continue that positive trajectory.

For these reasons, we again urge Congress to protect robust NIH appropriations in FY 2025 and FY 2026 and prevent sudden and significant changes to Facilities & Administrative costs. Thank you for your leadership to ensure continued investment in this research to save and improve lives.

If you have questions, please do not hesitate to contact Margarita Valdez Martínez, Chief Advocacy Officer at the American Society of Gene & Cell Therapy (ASGCT) at mvaldez@asgct.org.

## Sincerely,

American Society of Gene & Cell Therapy

A Foundation Building Strength for Nemaline Myopathy

Alexander Graham Bell Association for the Deaf and Hard of Hearing

Alliance for Aging Research

American College of Medical Genetics and Genomics

American Society for Transplantation and Cellular Therapy

Amyloidosis Support Groups Inc.

Angelman Syndrome Foundation

Association for the Advancement of Blood and Biotherapies (AABB)

Association of Departments of Family Medicine

**Barrow Neurological Institute** 

**BDSRA** Foundation

Better Future 4 U

CACNA1A Foundation

Canavan Foundation

**Cancer Support Community** 

**CHAMP1** Research Foundation

Children's Cardiomyopathy Foundation

Children's Hospital of Philadelphia

The Children's Medical Research Foundation, Inc.

Child's Cure Genetic Research

**CMT Research Foundation** 

Coalition to Cure Calpain 3

CTNNB1 Connect and Cure

Cure CMD

Cure GM1 Foundation

Cystic Fibrosis Foundation

**Danon Disease Foundation** 

**Dravet Syndrome Foundation** 

**Duke University School of Medicine** 

The Emily Whitehead Foundation

Friedreich's Ataxia Research Alliance (FARA)

**HD-CARE** 

HealthTree Foundation

Help 4 HD International

Hypertrophic Cardiomyopathy Association

Innovative Genomics Institute

International Fibrodysplasia Ossificans Progressiva (FOP) Association

International Society for Stem Cell Research

The LCC Foundation

Lymphoma Research Foundation

Malan Syndrome Foundation

Mass General Brigham

Mila's Miracle Foundation

Mississippi Metabolics Foundation

Moonshots for Unicorns

**NAPCRG** 

National Bleeding Disorders Foundation

National Fabry Disease Foundation

National Organization for Rare Disorders

National Tay-Sachs & Allied Diseases Association Noah's Hope - Hope4Bridget Foundation

Oklahoma Outreach

Pathways for Rare and Orphan Solutions

Phelan-McDermid Syndrome Foundation

Project 8p Foundation

**Project Alive** 

Research!America

Rett Syndrome Research Trust

Sickle Cell Warriors Foundation

Society for Immunotherapy of Cancer

Society of Teachers of Family Medicine

The Abigail Wexner Research Institute at Nationwide Children's Hospital

Tulane University School of Medicine

The UCLA AIDS Institute

**UMass Chan Medical School** 

**United MSD Foundation** 

University of Pennsylvania

Usher 1F Collaborative

**Usher Syndrome Coalition** 

**Usher Syndrome Society**