July XX, 2026

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

The Honorable Patty Murray
Vice Chair, Senate Appropriations Committee
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Tom Cole
Chair, House Appropriations Committee
2207 Rayburn House 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,

The undersigned organizations are writing to express our significant concern about the impact of Office of Management and Budget's (OMB) proposed update to the Uniform Guidance, published on May 29, 2026.[1] OMB's proposed revisions to the Uniform Guidance, the framework governing federal grants and financial assistance programs, would apply across all 42 federal grantmaking agencies. That includes major supporters of biomedical research such as the National Institutes of Health (NIH), Advanced Research Projects Agency for Health (ARPA-H), and National Science Foundation (NSF). If implemented, the changes would formally restructure federal grant administration, changing how research proposals from basic science through clinical trials are reviewed, funded, and managed after being awarded. These changes would disrupt the federal research ecosystem, including the development of innovative, potentially curative cell and gene therapies (CGTs) and other emerging biomedical technologies.

CGT breakthroughs require a stable, predictable research funding environment that enables scientific discoveries to advance from the laboratory to patients. The world's first individualized CRISPR therapy,[2] multiple gene therapies for sickle cell disease,[3] and CAR T-cell therapies that have changed the course of treatment for refractory blood cancers[4] were developed here in the United States, with initial discovery work made possible by federal research dollars. Often the foundational work leading to therapies which eventually transform lives arises from basic research that, at the time, does not have an obvious link to specific disease priorities. For instance, the CRISPR system was developed from learnings about how bacteria resist infection by phage.[5] The biology of GLP-1s emerged from studying Gila monster saliva.[6]

[1] Office of Management and Budget (2026). *Regulation for Federal Financial Assistance (91 Fed. Reg. 32198)* [Proposed Rule]. https://www.federalregister.gov/documents/2026/05/29/2026-10817/regulation-for-federal-financial-assistance#print
[2] Children's Hospital of Philadelphia (2025). *World's First Patient Treated with Personalized CRISPR Gene Editing Therapy at Children's Hospital of Philadelphia* [News Release]. https://www.chop.edu/news/worlds-first-patient-treated-personalized-crispr-gene-editing-therapy-childrens-hospital
[3] US Food and Drug Administration (2023). *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease* [News Release]. https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease
[4] Cappel, K., Kochenderfer, J. (2023). Long-term Outcomes Following CAR T Cell Therapy: What We Know So Far. *Nat Rev Clin Oncol*. 20(6), 359-371. https://pmc.ncbi.nlm.nih.gov/articles/PMC10100620/
[5] Ishino, Y., Krupovic, M., Forterre, P. (2018). History of CRISPR-Cas from Encounter with a Mysterious Repeated Sequence to Genome Editing Technology. *J Bacteriol.* 200(7). https://journals.asm.org/doi/10.1128/jb.00580-17
[6] Friedman, J. (2024). The Discovery and Development of GLP-1 Based Drugs That Have Revolutionized the Treatment of Obesity. *Proc Natl Acad Sci*. 121(39). https://www.pnas.org/doi/10.1073/pnas.2415550121

A recent report by the bipartisan National Security Commission on Emerging Biotechnology (NSCEB) highlighted: "*For the United States, achieving global biotechnology superiority is an imperative. If America secures its position as the greatest biotechnology power in the world, we will see major gains in… defense, supply chains, agriculture, healthcare, and computing."*[7] By injecting uncertainty in the federal grantmaking process, this proposed Unified Guidance update threatens our successful innovation ecosystem that has made the United States the global leader in biomedical research.

Proposed changes that would pose the greatest challenge to CGT research include:

- **Move to Binding Regulation:** The Uniform Guidance is currently organized as a non-binding advisory document for federal agencies, which then implement their own rulemaking processes. With this update, the Uniform Guidance would have the same effect as binding federal regulation. Under the proposed system, future amendments issued by OMB could apply government-wide without separate agency-by-agency regulatory action. That change removes the flexibility agencies have long had to implement the Unified Guidance in the way that is most suitable for their grantees.
- **Diminished Role for Scientific Peer Review:** Senior political appointees would be required to review and approve proposals before an award is issued. Scientific peer review would be explicitly designated as advisory only, and subordinate to agency discretion. Expert review is essential for all scientific research, especially specialized fields like CGTs, in order to assess rigor, feasibility, innovation, safety, and potential patient impacts. The proposed changes would cement the unpredictable nature of funding outcomes experienced over the last year, particularly for early-stage, high-risk, or exploratory research programs that are common in CGT development.
- **Expanded Authority to Terminate or Suspend Awards**: Agencies could terminate any discretionary grant when they determine it is no longer in the "national interest" - a broad and subjective standard. In addition, a new suspension authority would allow agencies to halt award activity without formally ending an award. This could be devastating to CGT programs, which depend on long-term continuity to support preclinical-to-clinical translation, manufacturing process development, patient safety during clinical trials, and long-term patient follow-up. Codified discretion to terminate or suspend awards midstream would introduce additional uncertainty into long-horizon research planning and infrastructure investments.
- **Restrictions on International Collaboration**: A government-wide prohibition would bar the use of federal funds for collaborations with countries or entities designated as foreign adversaries or subject to national security sanctions, covering research, travel, and indirect costs. However, the proposal does not clearly define how agencies will operationalize eligibility determinations, leaving significant uncertainty about how international participation is evaluated. While the United States is the world leader in biomedical research, we do not stand alone - CGT research is often global, including multinational clinical trials, cross-border manufacturing partnerships, and international academic collaborations. This is especially true for rare diseases with small, globally-distributed patient populations. These provisions may introduce complications for institutions evaluating existing or prospective partnerships.
- **Limits on Conferences, Publications, and Professional Society Participation:** The proposal would place added restrictions on participation in scientific conferences, publications, and professional memberships. For the biomedical research community,

[7] National Security Commission on Emerging Biotechnology (2025). *Charting the Future of Biotechnology: An action plan for American security and prosperity* [Introduction]. https://www.biotech.senate.gov/final-report/chapters/

conferences, publications, and professional societies are core mechanisms for disseminating new findings, fostering collaboration, and accelerating scientific progress. Restrictions on knowledge sharing mechanisms would only limit transparency and reproducibility in the scientific community and further exacerbate inequities between researchers at small or rural institutions and those at large urban centers.

Taken together, these proposed changes would increase uncertainty surrounding research funding and award management. Over time, disruptions to these capabilities could slow scientific innovation, weaken workforce development, and delay patient access to future therapies.

The undersigned organizations represent the scientists, physicians, patient advocates, and other professionals developing CGTs across the United States. We urge you to protect the United States' role as a leader in biomedical research and innovation – as the NSCEB report urged, *"We must lean into our inherent strengths… We are home to many of the world's leading public and private research institutions, with more biotechnology patents, companies, and Nobel Prize winners than any other country. Modern biotechnology is an American innovation."* [8]

We thank you for your leadership to ensure that the federal funding system remains strong and dependable for patients today and into the future and urge you to consider language in the FY2027 funding bills that would suspend implementation of these policies.

Sincerely,

American Society of Gene & Cell Therapy
[additional signatories]

[8] National Security Commission on Emerging Biotechnology (2025). *Charting the Future of Biotechnology: An action plan for American security and prosperity* [Executive Summary]. https://www.biotech.senate.gov/final-report/chapters/