Leading Gene and Cell Therapy Organizations Call for a 10-year Moratorium on Heritable Human Genome Editing

Washington, DC – May 27, 2025

Three leading organizations that represent the scientists, academic centers, biotechnology organizations, patients, and service providers closest to the cell and gene therapy field today called for a ten-year global moratorium on heritable human genome editing (HHGE). Warning that HHGE remains far too risky and ethically fraught for clinical use, the Alliance for Regenerative Medicine (ARM), the International Society for Cell and Gene Therapy (ISCT) and the American Society for Gene and Cell Therapy (ASGCT) issued their statement following a conference held in Washington, DC, on March 26, 2025, that convened leading scientists, bioethicists, religious leaders, biotechnology executives, patients, and policy experts.

HHGE is a technology that raises deeply controversial and unresolved issues. Specifically, HHGE involves editing the germline—embryos, eggs, or sperm—and passing changes down to future generations. In theory, this could be used for medical applications, but also to 'program' traits deemed desirable and eradicate undesired ones (eugenics), potentially altering the course of evolution. The signatories state that current scientific capabilities are insufficient to ensure the safety of HHGE. They also caution that the world lacks the necessary regulatory infrastructure and ethical consensus to move forward responsibly. While HHGE is presently banned in the United States, across Europe, and much of the world, the first gene-edited children were revealed in 2018, and select scientists continue to call for it to be permitted.

In contrast to HHGE, gene therapies targeting somatic cells, including somatic cell gene editing (SCGE), have provided remarkable advances in treating genetic diseases within an ethical and regulatory framework. SCGE involves modifying a patient's DNA within the body's non-reproductive cells to treat or potentially cure diseases, including those caused by genetic mutations. SCGE holds vast potential for treating a range of genetic and non-genetic conditions. The results of somatic cell editing cannot be passed on to future generations.

"Germline editing has very serious safety concerns that could have irreversible consequences," said Dr. Bruce Levine, the Barbara and Edward Netter Professor in Cancer Gene Therapy at the University of Pennsylvania and past President of the International Society for Cell and Gene Therapy (ISCT). *"We simply lack the tools to make it safe now and for at least the next 10 years."*

"There is no compelling medical need to use HHGE," added David Barrett, chief executive officer of ASGCT. *"We should not pursue this problematic technology when we have effective, proven tools, including gene therapy and gene editing techniques, that can transform the treatment of serious diseases."*

HHGE represents a profound shift because it introduces long-term risks with unknown consequences. The ARM-ISCT-ASGCT declaration underscores that progress in genetic medicine depends on public trust, transparency, and shared ethical commitments. It cautions that moving ahead with HHGE prematurely could jeopardize not only patient safety but also the credibility and integrity of the broader field of genomic medicine.

"We convened a broad and diverse group of stakeholders recognizing that the question of whether we should use HHGE is not just for scientists, but also for patients, religious leaders, bioethicists, biotechnology leaders, and policymakers – all of us," said Tim Hunt, chief executive officer of ARM. *"This is one of the most important bioethical questions of our time — and a 10-year global moratorium will help ensure it will not be rushed."*

In addition to the recommendation for a moratorium, the declaration outlines guardrails to prevent premature adoption of HHGE. These include strengthening international and national legal prohibitions on clinical use of HHGE, denying academic or financial incentives to researchers who pursue unsanctioned HHGE work, and restricting access to equipment, materials, and regulatory pathways necessary for implementation.

"Global regulatory bodies have an important role to play in preventing immature science like germline editing from reaching patients before significant safety and ethical questions have been resolved," said Bambi Grilley, Professor of Pediatrics and the Director of Clinical Research and Early Product Development for the Center of Cell and Gene Therapy at Baylor College of Medicine, and the Chief Regulatory Officer at ISCT.

The declaration signatories also stressed the importance of ongoing global, inclusive dialogue in the years to come so that ethical considerations, medical necessity, and governance frameworks are appropriately considered alongside scientific advancement.

About the Alliance for Regenerative Medicine (ARM)
The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and modernize healthcare systems so that patients benefit from durable, potentially curative treatments.

As the global voice of the sector, we represent more than 400 members across 25 countries, including emerging and established biotechnology companies, academic and medical research institutions, and patient organizations.

About the American Society of Gene and Cell Therapy (ASGCT)
The American Society of Gene & Cell Therapy is the primary professional membership organization for gene and cell therapy. The Society's members are scientists, physicians, patient advocates, and other professionals.
The mission of ASGCT is to advance knowledge, awareness, and education leading to the discovery and clinical application of genetic and cellular therapies to alleviate human disease.

About the International Society for Cell & Gene Therapy (ISCT)
Established in 1992, the International Society for Cell & Gene Therapy (ISCT) is a global society of clinicians, regulators, researchers, technologists, and industry partners with a shared vision to translate cell and gene therapy into safe and effective therapies to improve patients' lives worldwide.

ISCT is the global leader focused on pre-clinical and translational aspects of developing cell and gene-based therapeutics, thereby advancing scientific research into innovative treatments for patients. ISCT offers a unique collaborative environment that addresses three key areas of translation: Academia, Regulatory, and Commercialization. Through strong relationships with global regulatory agencies, academic institutions, and industry partners, ISCT drives the advancement of research into a standard of care.

Comprising over 4,000 cell and gene therapy experts across five geographic regions and representation from over 60 countries, ISCT members are part of a global community of peers, thought leaders, and organizations invested in cell and gene therapy translation. For more information about the society, key initiatives, and upcoming meetings, please visit isctglobal.org, @ISCTglobal.