David Barrett – CEO, American Society of Gene & Cell Therapy



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David Barrett has led the American Society of Gene & Cell Therapy (ASGCT) since 2018, guiding its evolution into the leading professional body for scientists, clinicians, industry leaders and patient advocates in cell and gene therapy. Founded in 1996, ASGCT now sits at the centre of research, education and policy as the field enters a more commercially selective phase. In this interview, Barrett reflects on the maturation of cell and gene therapy (CGT), shifting investor dynamics, and the growing challenge of scientifically validated programmes being deprioritised for financial reasons. He also outlines ASGCT's efforts to support ultra-rare disease therapies through new partnerships and platforms, discusses regulatory developments shaping US competitiveness, and shares his perspective on what it will take to sustain momentum as the sector moves beyond the recent biotech downturn.

Give us an introduction to the American Society of Gene & Cell Therapy (ASGCT). What is your mission, the role you hold within the ecosystem of cell and gene therapies, your top priority areas?

ASGCT is the primary professional society representing scientists, physicians, industry executives and a growing number of patient advocates, all working towards the advancement of cell and gene therapies. Our mission is to advance knowledge, education and awareness, leading to the

discovery and clinical application of cell and gene therapies to alleviate human disease.

We have been in existence since 1996, and most people encounter us through our annual scientific conference. The ASGCT 2026 Annual Meeting will be in Boston from 11–15 May, bringing together between 7,000 and 8,000 attendees. A major feature is our invited programme, with around 150 speakers, alongside more than 2,000 abstracts showcasing the latest science across cell and gene therapy. We also host a trade show with approximately 300 exhibiting companies.

Beyond the annual meeting, we publish four peer-reviewed journals under the Molecular Therapy banner: *Molecular Therapy*, *Molecular Therapy Advances*, *Molecular Therapy Oncology* and *Molecular Therapy Nucleic Acids*. Collectively, these publish around 1,000 original manuscripts each year.

We also operate a very active policy and advocacy department, communicating regularly with members and representing their interests to policymakers, lawmakers, elected representatives, the FDA, the Centers for Medicare and Medicaid Services, and other government bodies.

In addition, we run programmes to recognise and support research in the field. This year, we expect to award around USD 1.5 million in funding for researchers and research projects. Altogether, ASGCT represents roughly 6,500 individual members, around 80 percent of whom are based in the US.

Following an initial wave of scientific breakthroughs and investment, some pharma companies are scaling back their CGT programs while others continue to double down. What phase do you see the field in right now?

What we are seeing is maturation. Some developers have exited the market, while others are definitively expanding their portfolios of cell and gene therapy products.

Between 2016 and 2021, there was an explosion of industry and investor interest, alongside rapid scientific progress. Over time, that science has continued to advance, with refinement of both development processes and eventual products. Looking back, not every programme launched during that period was going to reach the finish line. Some have progressed, others have not. In certain cases, products lacked sufficient efficacy. In others, programmes were paused or discontinued for financial reasons related to marketability and profitability.

Investment has continued, but in a different form. We no longer see the same diversity of biotech companies and investor types. ASGCT produces a quarterly landscape report tracking indicators such as startup financing. While the total number of programmes has remained relatively stable, overall investment dollars have declined. Our conclusion is that investors are now more selective and more precise in the types of programmes they advance, despite the continued growth in new science.

Another important signal is the volume of research coming into our annual meeting. Abstract submissions have increased significantly over recent years, and we have set another record in 2026, pointing to a sustained rise in scientific output.

As an organization dedicated to advancing knowledge, education and awareness in the CGT space, how does ASGCT support the continued development and clinical application of these programmes?

There is still space for programmes to advance that might not have enormous market-wide impact, such as cell modified gene therapies targeting certain cancers. However, a tremendous number of therapies have been developed for ultra-rare disorders, and this is where we have seen developers deprioritise or even abandon programmes.

This is problematic for the proliferation of cell and gene therapies. From a scientific and patient perspective, this trend of deprioritisation is troubling. When a programme shows scientific and medical promise, or even gains market approval, and is then deprioritised, some patient populations may never receive treatment. For those earlier in the clinical pipeline, individuals and families have invested time, money and effort in trials. Seeing those programmes stall can be heartbreaking and has broader implications for the field.

ASGCT is actively working to address this. One initiative is a task force focused on commercially pre-viable cell and gene therapies. These programmes may become commercially viable in the future, but are currently deprioritised despite scientific success. We convened a working group, hosted a workshop, and published a white paper outlining potential solutions, many of which are now being taken up by other organisations.

ASGCT has also partnered with the Orphan Therapeutics Accelerator (OTXL), a nonprofit biotech focused on identifying deprioritised therapies for ultra-rare conditions and advancing them through alternative funding models. By some estimates, there are well over 100 such therapies at risk of

stalling indefinitely.

Together with OTXL, we founded the Cell and Gene Therapy Exchange (CGTxchange), which is building a clearing house and marketplace to track these programmes and connect them with non-traditional investors. These may include academic institutions, patient advocacy organisations, family offices, charitable foundations and venture philanthropy groups, alongside some for-profit entities. Over time, this could also attract more traditional pharmaceutical and venture capital investors seeking proof of concept in new areas.

We have partnered with an artificial intelligence developer to review regulatory materials and product profiles within the exchange, providing concise risk assessments so investors can quickly understand programme viability.

Our goal is to find singular investors or tokenise these programmes such that they can be invested in by a conglomerate of investors quickly and easily to get them back into clinical development. We began demonstrating this approach in early March with a soft launch of the platform, with a public launch aligned with our annual meeting.

Given the complexity of manufacturing and delivery of CGTs, what challenges does this pose for infrastructure and scaling these therapies to reach patients?

From a delivery perspective, our focus is on accessibility. The manufacturing process is highly complex and specialised, and it is by its very nature a complicated and challenging set of drugs to manufacture and distribute at large scale. Despite these challenges, viral vector gene therapies continue to be refined over time, and investment and continued scientific focus will steadily improve.

Bigger changes are also occurring in relation to new delivery types, for example by using lipid nanoparticles as opposed to viral vector-based delivery, it is increasingly possible to manufacture at larger scale and design for broader delivery.

Another area we are seeing promising advances in is gene-modified cell therapy specifically being delivered in an outpatient setting as opposed to the inpatient setting. As more outpatient delivery becomes available, expertise in the medical environment is improved and expanded. We will see more gene-modified cell therapies being delivered this way, which will definitely be a factor leading to broader use and more efficient delivery.

With recent domestic policy changes and external competition, particularly from China, how do you see the opportunity of the US to position itself as a frontrunner in the CGT field today?

The US continues to be the global leader, despite other markets investing heavily in CGT, especially China. As an industry and a field, it is essential to monitor and understand how the global landscape is changing.

We are encouraged by developments emerging from the FDA, and as these changes come to fruition, it will further help to cement the US positioning as the global leader. For instance, we are optimistic that the FDA's new 'plausible mechanism' pathway will allow for more rapid approvals of cell and gene therapies that may treat very small patient populations.

There is also a promising commitment from the FDA to continue its stance towards increasing flexibility in Chemistry, Manufacturing and Controls (CMC) requirements for cell and gene therapies. As these initiatives take shape, they should further reinforce America's leadership in biotechnology and, specifically, cell and gene therapy.

What does the future of cell and gene therapy look like, and what will it take to sustain momentum?

The field is in a pivotal moment. We are seeing remarkable scientific progress, from personalised gene editing and in vivo delivery to an expanding pipeline addressing both common and rare disorders. Advances are occurring across multiple areas, including metabolic disease, solid tumours and many neurological applications.

At the same time there are still challenges in manufacturing. Whilst flexible, the rigorous regulatory pathways require significant investment in time and money to get cell and gene therapies across the finish line. Equitable access is another concern. We can continue to overcome each of these with sustained focus, scientific investment and expertise in the field, especially from ASGCT's membership.

Despite the challenges, the science being produced right now and the focus of lawmakers, regulators and the scientific and clinical experts in the space is moving CGT forward. We are starting to see a thawing of the so-called "biotech winter", which makes for an exciting year ahead.

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