

Expert perspective: JAMES REILLY

Commercializing cell and gene therapies: Four keys to success.

As the CGT field matures, new challenges are emerging on the path, from FDA approval to broad patient access. While exciting scientific breakthroughs continue to expand the pipeline, manufacturers seeking commercial success must navigate a complex landscape shaped by

Build a Strong Value Proposition

Foundational to a successful CGT launch is a clear and concise value proposition that describes how the new therapy is different from the current standard of care (SOC). Manufacturers must be able to clearly explain how their therapy improves on existing options and present data that speaks to each stakeholder.

A well-defined value proposition is especially important in areas where outcomes with SOC are already strong. In these cases, being able to demonstrate significant improvement, such as extended benefit, improved quality of life, or fewer side effects, may be needed to convince providers and payers to make a change.

“Communication strategy and execution is critical. Where I’ve seen manufacturers be more effective, they really have a clear value proposition that they can convey and they’re doing it consistently. So, you don’t have your commercial teams communicating one thing and your medical affairs and/or corporate communications teams communicating something else. Alignment is critical,” Reilly said.

Back Up Claims with Robust Durability Data

Long-term benefit is a priority for payers and providers. Evidence of a durable response is often required by payers to secure and retain reimbursement, especially for high-cost, one-time therapies. As part of the commercial planning process, biopharma manufacturers should consider what clinical trials and real-world evidence may be needed to support product uptake and drive favorable reimbursement, and they need to be ready to invest in gathering the necessary data.



Communication strategy and execution is critical. Where I’ve seen manufacturers be more effective, they really have a clear value proposition that they can convey and they’re doing it consistently too.



— James Reilly

Co-Founder and Managing Partner
of A3Access Advisors



payer expectations, provider skepticism, and heightened scrutiny on value.

James Reilly, Co-Founder and Managing Partner of A3Access Advisors and a veteran of market access strategy, said therapies that are scientifically sound and medically effective can still struggle commercially if the right prep work isn’t completed well in advance of approval. Reilly has deep experience in this space, both as a consultant and an in-house leader. He spent 25 years at Genentech during a time when the biotech giant launched a string of blockbuster medicines for cancer and other challenging diseases—including Rituxan, Herceptin, Avastin, and Perjeta—that would help define standards of care.

Based on his expertise and experience, Reilly offers four lessons for manufacturers striving to deliver on the promise of CGT.

Further, given that it can take time to establish long term durability in CGT, pre-launch engagement with payers is critical to align on what surrogate measures will be sufficient (e.g., disease progression, reduction in acute events, absence of retreatment) and tracked, and if outcome-based agreements will be needed. By partnering with payers in launch communications and planning, manufacturers can develop solutions that address payers' durability questions and enable patient access.

"Will you have the data that's going to show or help establish durability of response over time? That can be really powerful," Reilly said. "If you don't have that, it is important to proactively build your value rationale using interim clinical and natural history data to tell a compelling story."

Engage Early with Payers, Providers and Patient Advocates

Early, sustained engagement with payers, providers, and patient advocacy organizations builds credibility and helps identify barriers ahead of launch. Reilly said involving these groups in advance supports faster adoption by prescribers and often leads to stronger payer support when it comes time to negotiate coverage.

"Those manufacturers that have done this well have gone out and they've been willing to stand behind the value of their products. They also had strong provider and KOL support along with patient advocacy. Early engagement with those stakeholders is critical," he said.

Supporting patients with education, training, and administrative workflows is another way drugmakers help with uptake. Offering financial support, patient payment assistance where appropriate, and other logistical aid for travel will go a long way in ensuring a successful patient experience. Navigating coverage and reimbursement can be complex in the CGT world, so manufacturers need to ensure that patients have the necessary support.

"Making sure that there's good investment in the support services is really going to matter," he said.

Drugmakers also need to think through strategies for addressing potential logistical concerns that health systems and patients will face before approval so that the rollout isn't hampered by these challenges.

"The last thing you want to have happen is the patient shows up there and then there's a disruption and they can't get the therapy that they need," he said. "The distribution and treatment logistics, particularly for cell therapies, are complex and require a rigorous focus on quality, training, and execution."

Understand the Financial Landscape

In disease areas with high unmet need, CGTs have delivered broader and faster adoption, especially when positioned and priced to reflect the needs and expectations of the treatment ecosystem. However, in disease areas where patients have available therapies that are delivering satisfactory outcomes, the calculations change.

Gene therapies for hemophilia, for example, faced significant pushback when high prices and uncertainty about long-term results met a population already well-served by reliable, lower-cost treatments.¹

Reilly also noted that successful commercialization depends on understanding the full range of financial levers at play beyond the list price, such as the impact of competitors contracting with providers and/or payers. Negotiations can determine whether a new therapy secures favorable coverage or is relegated to a higher-cost tier, regardless of its scientific merits.

Reilly emphasized that manufacturers should engage early with payers and providers while conducting market research to understand these dynamics and, where necessary, structure agreements that align incentives across the ecosystem.

"That can play a big role in some therapeutic areas," he said. "Understanding this early and having a thoughtful mitigation strategy is critical."

Strategic Alignment Drives Commercial Success

The CGT market is growing more complex. Broad adoption requires more than scientific progress—it calls for strong data, early engagement, and pricing strategies that reflect the realities of payers and providers. The most successful manufacturers listen to stakeholders, respond to feedback, and provide clear, credible evidence of value.

Unlike the early years where each new cell and gene therapy was a scientific breakthrough, a regulatory first, and often the only treatment for certain diseases, the market has become much more competitive. Success now hinges on strategic execution.

"Where I've seen challenges is when a manufacturer waits too long to figure out the strategy and what's needed to support the therapy, and then it's scrambling to try to address these needs by launch," Reilly said. "It takes time, discipline, and expertise to understand the potential access issues along with the best near/long term mitigation strategies. Moving from strategy to precise execution when you have your pivotal data is critical—that's a real inflection point where there is significant opportunity." ●

Reference

James Reilly: Commercializing cell and gene therapies: Four keys to success

1. Liu A. Pfizer discontinues hemophilia treatment BEQVEZ, emptying its gene therapy portfolio. *FiercePharma*. Published February 21, 2025. Accessed September 23, 2025. <https://www.fiercepharma.com/pharma/pfizer-empties-gene-therapy-portfolio-discontinues-hemophilia-treatment-beqvez>



Want to learn more?

Connect with InspiroGene by McKesson at [InspiroGene.com/contact](https://www.inspirogene.com/contact)

Visit us online

Learn more about our solutions and services at [InspiroGene.com](https://www.inspirogene.com)

About InspiroGene by McKesson

InspiroGene by McKesson (“InspiroGene”) is a dedicated business unit focused solely on supporting the commercialization of cell and gene therapies (CGTs). At InspiroGene, we turn CGT innovation into a reality. We offer flexible, sustainable solutions to help you navigate CGT commercialization to achieve long-term success. As your ally, we’re dedicated to transforming patient care and driving better health outcomes. Learn more about the InspiroGene advantage at [InspiroGene.com](https://www.inspirogene.com).

About McKesson

McKesson Corporation is a diversified healthcare services leader dedicated to advancing health outcomes for patients everywhere. Our teams partner with biopharma companies, care providers, pharmacies, manufacturers, governments, and others to deliver insights, products, and services to help make quality care more accessible and affordable. Learn more about how McKesson is impacting virtually every aspect of healthcare at [McKesson.com](https://www.mckesson.com) and read Our Stories.

MCKESSON

© 2026 McKesson Corporation. All rights reserved. MCKESSON and the MCKESSON logo are registered trademarks of McKesson Corporation in the U.S. and other countries. All other trademarks shown are the property of their respective owners. You may not copy, reproduce, transmit, distribute, download, or transfer in any form or by any means any part of this presentation without the prior written permission of McKesson Corporation.

InspiroGene™
By McKesson

Download the Full Report at [inspirogene.com/cgt-report/](https://www.inspirogene.com/cgt-report/)