Supply Chain Debt is Coming Due in Advanced Therapies

Why supply-chain fragmentation becomes harder to fix the longer programs scale around it

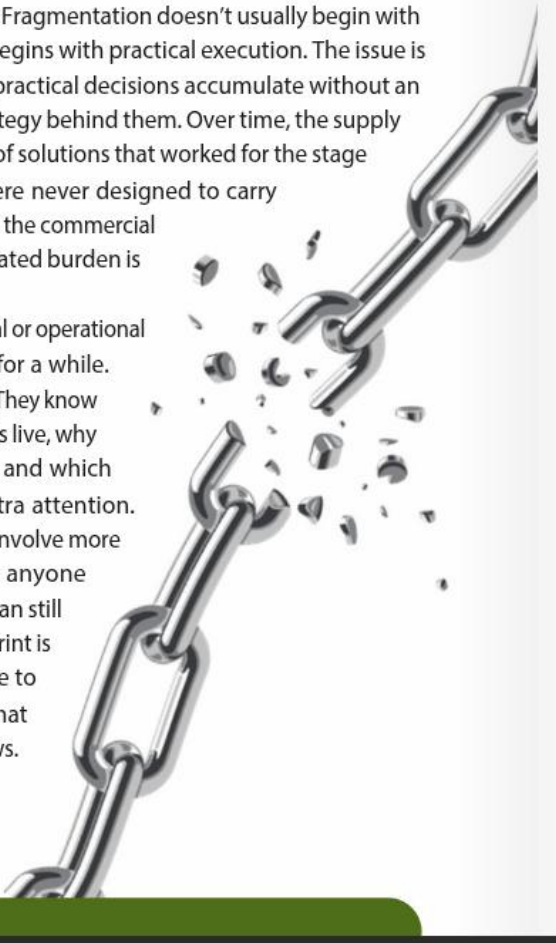
Mark Sawicki, Ph.D.
CEO
Cryoport Systems

Advanced therapy supply chains rarely become fragmented all at once. They're usually built through a series of reasonable decisions made at moments when the program needs to keep moving.

When a storage solution is needed before the next milestone, a provider is selected. If a new site or geography creates a lane challenge, a new logistics partner is brought in. If a secondary packaging or labeling need surfaces quickly, the team solves it with the partner who can act the fastest. Cryopreservation, biostorage, clinical sample management, regulatory support, and temperature-controlled logistics may each be added as the program evolves, often under legitimate pressure and with sound rationale at the time.

That's the important part. Fragmentation doesn't usually begin with a poor decision. Instead, it begins with practical execution. The issue is what happens when those practical decisions accumulate without an integrated supply chain strategy behind them. Over time, the supply chain becomes a collection of solutions that worked for the stage the program was in, but were never designed to carry the program through toward the commercial launch ahead. That accumulated burden is the supply chain debt.

Like other forms of technical or operational debt, it can remain hidden for a while. Early teams know the details. They know who to call, where the records live, why a workaround was created, and which exception needs a little extra attention. Operational workflows may involve more manual coordination than anyone would prefer, but the team can still manage it because the footprint is still small enough for people to hold the system together. That changes as the program grows.



Mark Sawicki, Ph.D., has more than 20 years of experience in commercial leadership for the pharmaceutical and biotechnology sectors. He holds bachelor's and doctoral degrees in biochemistry from the State University of New York at Buffalo, and is CEO of Cryoport Systems, an integrated temperature-controlled supply chain provider serving the life sciences and advanced therapies across logistics, cryopreservation, biostorage, and advisory support.

The Debt Builds Before Anyone Names It

Supply chain debt is the cost of yesterday's necessary workaround becoming tomorrow's operating constraint. It rarely arrives as a single, standalone event, showing up instead as friction that feels manageable... at least until the volume or regulatory expectations increase.

If a documentation update moves more quickly through one provider and more slowly through another, or a deviation investigation takes longer than expected because the relevant data sits across multiple platforms, this creates supply chain debt. Issues can be resolved, at least in the moment, but over time, that resolution increasingly depends on the sponsor's ability to coordinate across a fragmented network that was never built to work as one system.

This is where the debt becomes easy to underestimate. The team responds with solutions, maybe adding another review call or internal owner, maybe creating an additional escalation pathway. The extra effort keeps the program moving, but it also shifts more of the operating burden back onto the sponsor. What started as vendor management becomes system integration by force of necessity.

The Real Opportunity Cost is Lost Continuity

The deepest cost of fragmentation isn't the number of vendors involved. It's the loss of continuity that occurs when program knowledge, process ownership, documentation, and decision logic are scattered across too many places.

Every provider may perform its own role well, but still only holds a partial view of the program. That may sound manageable until the program changes, which advanced therapy programs always do. In a fragmented model, each change (for example, a protocol update that changes the kit, or a new geography that changes the documentation, etc.) has to be translated across separate systems, quality processes, and teams. The risk isn't always that the change itself fails. Often, the risk is that it moves unevenly or without the original context. An example of this might be a situation where a packaging change causes the environmental transport packaging to no longer be suitable, causing validation of an alternate transport packaging to become necessary, at the cost of time and significant resource.

This is how fragmentation becomes more expensive with time. The longer a program scales around disconnected workflows, the more institutional knowledge becomes embedded in people, workarounds, and vendor-specific interpretations rather than in a durable operating model. A supply chain built through disconnected decision becomes heavier as it grows. Growth should create momentum, but in a fragmented model, it can create drag.

And this is when supply chain debt starts to come due.

An End-to-End Platform Reduces the Debt Before It Compounds

The practical answer to supply chain debt is not simply to use fewer vendors. A shorter vendor list may reduce administrative burden, but it does not automatically create continuity. The more important question is whether the supply chain is designed to maintain a scalable operating structure as the therapy advances.

For advanced therapy developers, this is where an end-to-end platform becomes materially different from a conventional outsourced model. Cryopreservation, biostorage, clinical sample management, kitting, secondary packaging and labeling, regulatory support, and temperature-controlled logistics are deeply connected activities. When they are managed separately, the sponsor often becomes responsible for translating decisions across disconnected systems. When they are connected through a unified platform, the process has a better chance of staying aligned as the program moves from early development into clinical expansion, commercialization, and global reach.

> Over time, the supply chain becomes a collection of solutions that worked for the stage the program was in, but were never designed to carry the program through toward the commercial launch ahead.

Cryoport Systems' end-to-end supply chain platform is designed around that need for continuity. Rather than asking developers to assemble and manage a network of standalone providers, Cryoport Systems brings critical supply chain capabilities together within a single quality-driven ecosystem built specifically for the realities of advanced therapies. That structure reduces handoffs, supports consistent documentation, and helps preserve continuity across the program's lifecycle.

The Cost of Waiting

Supply chain debt is easiest to address before it becomes embedded. The longer the debt remains in the system, the more expensive it becomes to correct.

This is why defragmentation is a scalability decision. Advanced therapy programs need flexibility, but flexibility loses its value when built from disconnected parts. The goal is to preserve adaptability while creating enough continuity for the program to move forward without reinterpreting itself at every stage.

As more therapies advance toward larger trials, commercialization, and global patient access, the supply chain will increasingly determine how reliably scientific progress can translate into patient impact. Supply chain debt rarely comes due all at once. It builds through small decisions that were reasonable in the moment, until the program reaches the point where consistency and speed matter most.

The programs that recognize this early will be better positioned to scale without carrying the weight of a supply chain built on urgent, one-at-a-time decisions.