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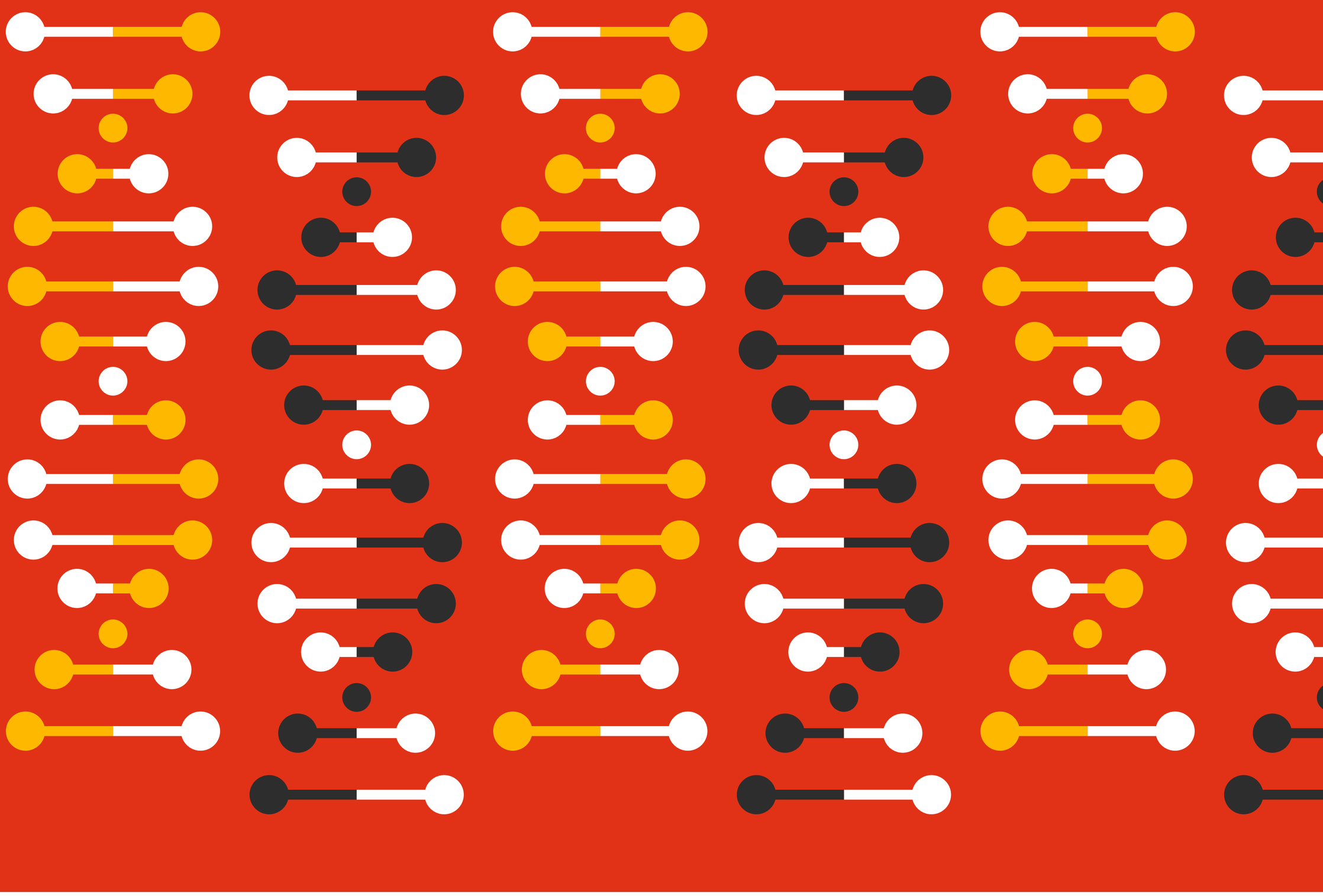
Beyond the hype:

Gene therapies require advanced capabilities to succeed after approval



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Heart of the matter

After the thrill of approval has worn off and press coverage has faded, producers of gene therapies will be left with the challenge of getting their products to patients and getting paid for it. They'll need to be able to modify cells and viruses with novel technologies and specialized staff. They will need to be able to distribute highly sensitive treatments while keeping patients informed about where they are in the process. They will need to be able to satisfy payers and providers with novel payment and support models to ensure these therapies are viewed as good science – and, critically, a good deal.

Driven by scientific advances, life sciences companies are rushing to develop and invest in gene therapies that can treat and even cure cancers and diseases.

The field is expected by industry experts to grow rapidly over the next decade. The FDA expects to receive more than 200 investigational new drug applications per year for gene and cell therapies starting in 2020. By 2025, the federal regulator expects to approve 10 and 20 cell and gene therapy products per year.[1] By 2030, 500,000 patients in the US are expected to have received treatment with gene and cell therapies, according to the Massachusetts Institute of Technology's New Drug Development Paradigms Initiative.[2]

Biotechnology companies are focused on obtaining regulatory approval for these therapies, but the post-approval period contains significant tests, too. That includes getting the therapies to patients and getting paid for them.

The manufacturing methods used to produce gene therapies may be very different from traditional batch manufacturing. Gene therapies are often made for a single patient. These personalized therapies require scaling out – ensuring patient-specific processes are established and can meet patient needs quickly – not scaling up.

Speed – for manufacturing, distribution and reimbursement – is of the essence. For patients waiting for cancer therapy, delays in treatment may mean the difference between life and death. Delays also may undermine outcomes-based contracts with insurers and government payers.

"If you have a sick child with not much time left, you're constantly going to be thinking: Where are his or her cells?" Vered Caplan, CEO of Orgenesis, a Maryland-headquartered global contract manufacturer and developer of cell and gene therapies, told PwC's Health Research Institute (HRI) in an interview.

Rapid production is difficult. In addition to the challenges of making the gene therapy products, biotechnology companies producing autologous gene therapy products will need to manage a complex supply chain to get a patient's cells from a hospital to a processing facility and back, vein-to-vein. A disruption at any point could ruin the product or harm a patient. Companies also should recognize that the lengthy process can induce patient anxiety, and work on ways to keep them actively informed.

Getting a product to patients is about more than delivery; it's also about making sure sites of care and methods of payment are available. In the US, as of July 2019, 13 states lacked facilities offering any approved gene therapies, according to HRI analysis. Just five ZIP codes in the country can boast health systems that offer all four gene therapies with FDA approval.

Payers, meanwhile, are experiencing sticker shock over the cost of approved treatments. “I think we are at the beginning of what’s going to be significant growth in the kinds of therapies that are available, and that could challenge insurers’ ability to absorb these costs over time as the applications of these therapies increase,” Patrick Fortune, vice president of market sectors at Partners HealthCare, a not-for-profit health care system, told HRI. Companies are adapting to these concerns by offering different payment models meant to spread costs out over time and guarantee outcomes.

Without addressing these barriers to market with new manufacturing, operational and commercial models, it will take longer for companies to realize the full sales potential of their therapies. Based on an HRI analysis of historical data and consensus forecasts for the sales of FDA-approved gene therapy products, these products can expect to realize less than half of their expected peak sales in the first two years, with some first-year products achieving less than 20 percent of peak expected sales.

Introduction to gene therapy

Gene therapies are medical products or treatments that modify the body to treat or cure disease. These therapies modify genes or cells to achieve a sustained or permanent outcome in a specific disease state or condition (see Figure 1). In comparison, most traditional chemical or biological drugs only temporarily modify a site of action within the body. Gene therapies can either be autologous, meaning they modify a patient's own cells, or allogeneic, meaning they do not use a patient's own cells.

Figure 1: What are gene therapies, and how do they work?
A general overview of what two examples of gene therapy look like in practice

Patient pretreatment	Preprocessing	Processing	Genetic editing	Finished product	Pretreatment	Treatment	Effect
Gene therapies							
Patient health status evaluated. Determined to be healthy enough or otherwise suitable for treatment.	Gene therapy company acquires starting materials needed to begin production	Virus modified in lab to use as a vector for gene transport.	Correct or missing gene inserted into modified virus for delivery.	Modified virus processed and placed into a finished form that can be administered to a patient.	Patient may receive treatment prior to administration with gene therapy.	Gene therapy transported to hospital and administered to patient.	Treatment produces desired effect in patient, such as by producing the correct protein or hormone.
Gene-modified cell therapies							
Patient cells extracted at hospital.	Patient cells transported to laboratory for processing.	Cells (such as T-cells) isolated and checked for quality.	Cells modified by introducing new gene using gene editing techniques.	Modified cells multiplied in lab.	Patient generally receives treatment prior to administration with gene therapy.	Genetically altered cells transported back to hospital and administered to patient.	New cells circulate withir the body and produce the desired effect (e.g. targeting a disease).

Source: PwC Health Research Institute analysis

The FDA recognizes a variety of approaches as gene therapy products, including human gene editing technology, patient-derived cellular gene therapy products, gene-edited bacterial and viral vectors, and plasmid DNA.[3] Since 2018, the FDA has approved four new gene therapies for rare diseases; the agency says it expects many more to receive approval in the years to come.

Because gene therapies are so different compared with traditional small- and large-molecule drugs, companies will need new capabilities in three different areas to be able to compete effectively: advanced manufacturing, responsive supply chains, and tailored commercialization and reimbursement models.

Capability 1:

Advanced manufacturing

Gene therapy products are more difficult to produce than small-molecule medicines or other biological medicines. The most striking difference: Traditional medical products are made for many patients to take, with differences in doses, release mechanisms or coatings allowing a regimen to be more personalized to the patients' needs. Manufacturers of these products have long relied on post-approval scale-up activities to quickly meet market demand by producing millions, and even billions, of doses of product per year.

Yet gene therapy products are generally made either for an individual using his or her own cells, blood or tissue, or in relatively small batches due to the phenomenal complexities of manufacturing (see Figure 2). Manufacturers of autologous therapies, for example, will find it more difficult to attain efficiencies in scale, since each product must be custom-made for each individual.

Figure 2: What's different about gene therapy?
The manufacturing and distribution process looks far different.

Batch manufacturing	Gene therapy processing (ex vivo, autologous)	Gene therapy processing (in vivo, viral vector)
Company obtains or makes active pharmaceutical ingredients (APIs) and excipients that will make up the final product.	Cells are collected from the patient and prepared to be shipped to a biopharmaceutical company's laboratory.	Company begins production of viral vectors to be used to transport the gene (adeno-associated virus, lentivirus, etc.) into the patient.
Company begins manufacture of finished dose form of product. Product made in batches.	Cells picked up by a specialized logistics company, which transports them to the laboratory.	Production generally occurs by infecting a cell line (such as mammalian or insect cells) or through a process known as transfection.
Company prepares to distribute pallets of finished product. Company may make thousands or millions of pills per week.	Cells received by the biopharmaceutical company, which begins processing the patient's cells for treatment.	Resulting batch of gene-modified viral vectors is filtered, tested, purified and put into a form (such as a solution) that can be injected into patients.
Logistics division or third-party logistics (3PL) company picks up pallets of drug product, distributes to wholesalers.	Company begins genetic engineering of cells and multiplying the cells. Process may take weeks.	Company produces a unit of the gene therapy product, customized to the needs of the patient population or a specific patient (e.g. weight, degree or type of illness).
Drug wholesaler distributes drug to retail or specialty pharmacy for use by any patient with a valid prescription. Patient prescribed product by doctor.	Completed cells are picked up by logistics company and transported back to the site where the specified patient will receive treatment.	Completed viral vector product is picked up by logistics company and transported to the site where the specified patient will receive treatment.
Patient with prescription orders or picks up the drug product. Patient takes the drug at home. (In some cases, the drug may be administered in a doctor's office or hospital.)	Genetically modified cells are delivered. Patient receives treatment at inpatient setting.	Gene therapy product is delivered. Patient receives treatment in an inpatient or outpatient setting.
Patient likely will follow up with their physician if there are any side effects or issues.	Patient can follow up with providers or the company if there are any concerns or side effects during the recovery period. Follow-up potentially required.	Patient can follow up with providers or the company if there are any concerns or side effects during the recovery period. Follow-up potentially required.

Source: PwC Health Research Institute analysis

To improve their ability to scale or manufacture more efficiently and effectively, some companies are seeking a manufacturing edge by acquiring gene therapy manufacturing technologies, capacity, expertise and intellectual property. For example, Thermo Fisher Scientific, Catalent and Danaher Corp. have acquired companies with expertise in gene therapy production, including Brammer Bio, Paragon Bioservices Inc. and GE Biopharma.[4] For companies whose products involve the administration of a viral vector directly to an individual that then passes along the correct gene, reliable production of viral vectors like adeno-associated viruses and lentiviruses remains a critical challenge, for example.[5]

Other companies are looking to new, decentralized manufacturing models in which genetically modified cellular therapies are produced on-site at the point of care and available to patients more quickly. Ziopharm Oncology Inc., for example, is developing a distributed manufacturing model that may decrease the time patients must wait from weeks to days by allowing the processing of cells at the site where the patient is being treated.[6]

Companies also must consider their ability to make a quality product. Manufacturers of traditional drug products can replace faulty batches with good ones. Producers of gene therapy products can't always do the same. A poor-quality autologous gene therapy product may require the whole process to start over. For patients waiting for cancer therapy, for example, time may be of the essence. Delays in treatment may mean the difference between life and death and could undermine outcomes-based contracts with insurers and government payers.

Product variability also is a challenge. Some gene therapies work via a specific type of cell, and the quality of those cells can differ depending on the patient and his or her condition.

"For autologous products, not only is there product-to-product variability, but there's patient-to-patient variability as well," Dr. Bruce Levine, president-elect of the International Society for Cell and Gene Therapy and the Barbara and Edward Netter Professor in Cancer Gene Therapy at the University of Pennsylvania, told HRI.

"For cancer patients, those who have had their disease for some time may have had the quality of their cells negatively impacted by their prior treatments or the disease," Levine said. "It's almost the base-level requirement for when you're developing these types of therapies that you need to have very good assays where you can positively identify particular cells and assess the quality of the cells that have been brought in. It's a combination of good laboratory practices and the right technologies."

In contrast to traditional manufacturing, clinicians and health systems are often an essential part of gene therapy production. For autologous therapies, they participate in the first step of the production process – collecting the cells

– and the last one – administering the altered gene therapy product. They are, in essence, extensions of the biopharmaceutical company.

Companies may need to expand their views of the “production facility” to include treatment centers, since improper collection, handling or administration during the process could put patient safety at risk and undermine quality. Already, some organizations like the Foundation for the Accreditation of Cellular Therapy are working to set standards for these organizations to ensure consistency of quality standards.[7]

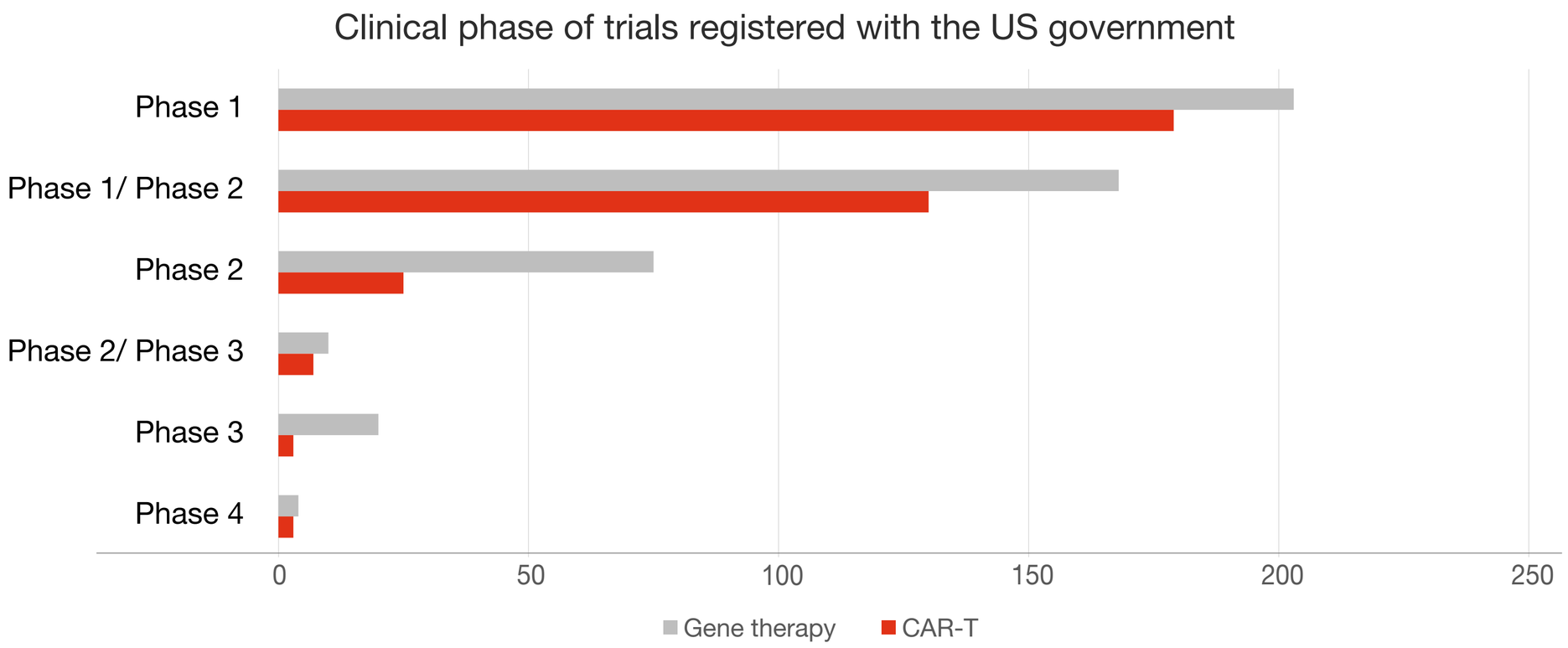
Implications for industry:

A war for manufacturing capacity will strain production capacity, making acquisitions or partnerships attractive options: As an increasing number of companies enter the gene therapy space, competition for contract manufacturing organization production capacity will increase, potentially raising costs or limiting its usefulness as an option.

The advanced therapies field is expected to grow rapidly over the next few years. The FDA has said it expects to receive more than 200 investigational new drug applications per year for gene and cell therapies starting in 2020, and by 2025 it expects to approve between 10 and 20 cell and gene therapy products per year.[8]

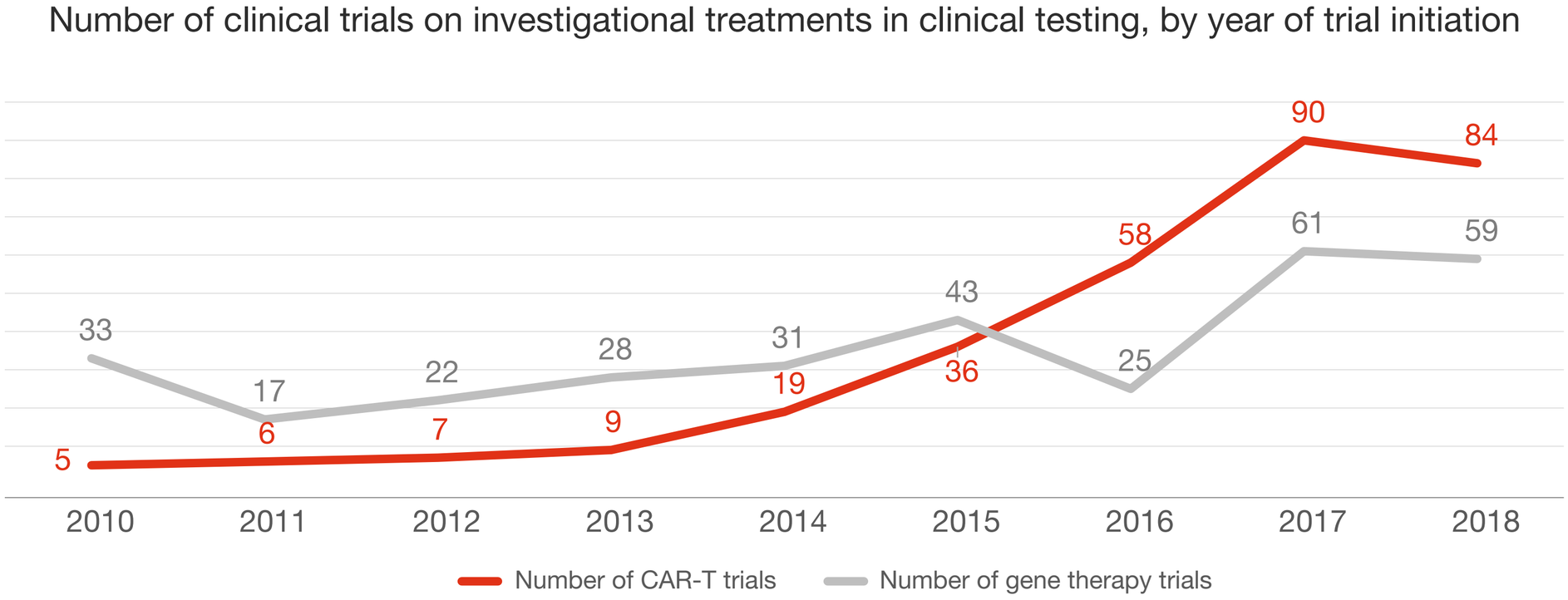
As of June 2019, there were 524 active, recruiting or enrolling clinical trials focused on gene therapy and Chimeric Antigen-receptor T-Cell (CAR-T) therapies, according to an HRI analysis of US government data (see Figure 3). CAR-T involves genetically modifying a patient’s T cells to produce a desired effect in the body, and approved CAR-T products are recognized by the FDA as gene therapies.

Figure 3: Most gene therapy trials remain in early-stage testing
But 30 products are in Phase 3 testing, which typically precedes a filing for FDA approval.



Source: HRI analysis of ClinicalTrials.gov data as of June 18, 2019

Figure 4: There is growing interest in gene therapies
A sustained increase in the number of clinical trials means competition for manufacturing and logistics partnerships will be fierce



Source: HRI analysis of ClinicalTrials.gov data as of June 18, 2019

Demand for these gene therapy manufacturing services is likely to increase due to the number of active or recruiting trials (see Figure 4). Greater competition for existing manufacturing capacity likely will result in higher costs or scarcer supplies for customers, and companies may need to make investments into manufacturing technologies – or purchases of companies for their manufacturing expertise – to ensure they are able to compete or gain an edge over other players.

For some traditional biopharmaceutical companies, investing in gene therapies is meant to ensure that a company is not missing out on the potential to cure a disease it now treats.

Train talent to avoid production bottlenecks: Staffing will be another key challenge for producers of gene therapies. Due to the novel techniques and technologies used in manufacturing gene therapy products – and the small number of approved gene therapy products – few prospective employees have ready-to-hire experience in gene therapy.[9]

Companies should prepare to train new employees or upskill existing ones. Competition for existing talent will be fierce, making upskilling of existing staff a potentially more feasible and cost-effective pathway to success. According to a 2018 PwC survey of US workers, 74 percent are willing to learn new skills or retrain to remain employable.[10]

Unlike other industries facing a shortage of specific expertise, life sciences companies already have an abundance of highly trained, highly educated scientific talent willing to learn and develop new capabilities and skills about new scientific disciplines. According to a 2017 survey by the National Science Foundation, there were 19,700 biochemists and biophysicists, 25,900 biological scientists and 40,250 medical scientists, all with PhDs, working in the US.[11]

“For some companies, there aren’t many internal resources familiar with gene therapy, or it’s expensive to go out and hire those resources. But most biotechnology companies have eager, hardworking, educated and smart people on staff,” Tim Largen, vice president of corporate quality at Caladrius Biosciences Inc., a New Jersey-based developer of autologous cell therapies, told HRI. “My preference has always been to develop those people and help them to grow.”

Training could pay dividends for an organization interested in keeping its newly trained talent. Thirty-four percent of consumers told HRI they were “very likely” to stay with an employer that offers them training that would help them prepare to meet future work demands.[12]

Focus on time-to-patient: For traditional drugs, Time-to-Patient (TTP) – the time between when a patient is prescribed a treatment and when they are able to receive it from a pharmacist – can be measured in hours. In the gene therapy space, TTP can be weeks after accounting for doctor’s visits, insurance approvals, manufacturing and the treatment’s time in transit. Decreasing this time will help increase patient and provider satisfaction, and potentially lead to better outcomes as well – a benefit for companies entering into outcomes-based contracts with insurers.

“For our customers, shortening that time to patient is a point of differentiation between different therapies, and a point of competitive advantage,” said Matthew Lakelin, vice president of scientific affairs at TrakCel Ltd., a UK-based provider of logistics software and services to gene and cell therapy companies.

Manufacturers can generate consistent TTP by developing standards for the burgeoning gene therapy industry. In the blood, tissue and organ donation industry, organizations such as the American Red Cross, America’s Blood Centers and the AABB work collaboratively on standards for the screening, collection, storage and processing of whole blood and blood components, which help drive consistency and confidence among providers.[13]

Reducing this time could require new models of distributed production, in which a product is produced in several sites across the US, or even at the site of care. As compared with scaling up, companies will need to consider how to "scale out."

However, companies also may need flexibility in their production capacity. Since some gene therapies are intended to cure conditions affecting relatively small populations of patients, they face the prospect of initially having a backlog of patients seeking treatment, followed by a modest number of new patients each year on an ongoing basis – a trend similar to the one seen in the hepatitis C space after the launch of new treatments in 2014 (see Figure 5).[14] Companies should consider how to scale in a manner that is consistent with long-term sustainability, such as through contract manufacturing agreements.

Figure 5: Big price, small patient populations

Approved gene therapies have so far targeted populations with few patients

Company/drug	Approved indication(s)	Type of therapy	Est. US patient population
Spark Therapeutics, Inc.: **Luxturna**	Inherited retinal disease due to mutations in both copies of the RPE65 gene.	Viral vector gene therapy	1,000-2,500 patients in total
Novartis International AG: **Kymriah**	Patients up to 25 years of age with B-cell precursor acute lymphoblasticleukemia (ALL) that is refractory or in second or later relapse.	CAR-T genetically modified cell therapy	600 patients per year
	Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy.		24,000 patients per year
Gilead Sciences, Inc.: **Yescarta**	Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy.	CAR-T genetically modified cell therapy	24,000 patients per year
Novartis International AG: **Zolgensma**	Pediatric patients less than 2 years of age with spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.	Viral vector gene therapy	300 - 450 patients per year
Amgen, Inc.: **Imlygic***	Local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery.	Genetically modified viral therapy	7,200 per year**

Source: PwC Health Research Institute analysis of FDA approval letters, company websites and insurance coverage decisions.
* The FDA does not consider Imlygic to be a gene therapy, stating that "its primary biologic activity is attributable to the oncolytic virus, not the genetic modification." The European Medicines Agency, however, does consider it to be a gene therapy.
** Based on estimate of total melanoma deaths in US on an annual basis

Capability 2:

Responsive supply chains

Gene therapy companies often must rely on a robust supply chain with advanced capabilities, from collection of the cells from a patient to administration of the treatment. Key among these capabilities is a “cold chain” ensuring products are stored at the right temperature and handled properly from manufacturer to patient or vein-to-vein. A single temperature failure in the supply chain could render the product useless, even dangerous.

“Patient-specific products require patient-specific supply chains,” TrakCel’s Lakelin told HRI. “Time constraints can be quite short, and the shipping conditions are quite specialized. And critically, many of these treatments are ones of last resort for a patient. They’re intended for desperate patients who are gravely ill. If a product gets lost, you may not have a second chance at treatment, so your supply chain has to have a lot of technical capabilities and safeguards that a traditional supply chain might not require.”

The logistical challenges are more pronounced when products are distributed to international markets. Networks may not be as developed, and delay times at ports of entry may be ruinous to products with limited shelf lives. Small-scale, hyper-specialized logistics networks may be beneficial like they are in transporting an organ to a specific patient within a donor network.

Companies also will need to comply with FDA serialization requirements, or “track and trace.” Under “track and trace,” each product is affixed with information to track its chain of custody. Companies also will want to ensure the packaging used to transport each product is tagged with technologies capable of tracking logistical information. This information may include the time each product spent in an entity’s custody, temperature of the product, whether the product packaging was opened and other information.

Data and logistics platforms such as Vineti, TrakCel and McKesson Corp. are working on these pain points. For companies looking to advance their operations to other countries, partnerships and contracts with contract manufacturing organizations and other logistics networks are likely to be essential. Planning around what happens to a product once it arrives at a hospital or provider facility will also be critical. Some companies, such as Amgen Inc., offer access to specialized freezers capable of storing products at specific, ultralow temperatures until they can be administered.[15]

A robust supply chain with real-time tracking and analytical capabilities will be important to another constituency as well: Patients. “If you have a sick child with not much time left, you’re constantly going to be thinking: Where are his or her cells?” Orgenesis’ Caplan told HRI. “You need to know: Are the cells doing well, where they are in the supply chain and when they’re due to arrive.”

Patients or their families wondering when their cells will come back may grow anxious, making frequent calls to doctors or the drug company for updates. This in turn can cause unnecessary consumption of time and resources for providers and manufacturers.

It’s also important to make sure patients aren’t overloaded with information, TrakCel’s Lakelin told HRI. “With the manufacturing cycle, small delays aren’t necessarily fundamentally important to the patient,” he said. “As a patient, you don’t necessarily want to find out on an app that your treatment has been delayed without hearing the context or what’s been done to solve the situation.”

Implications for industry:

Personalized medicine can learn from personalized pizza: Biotechnology companies can look to another sector for inspiration on how to keep all parties in the loop: Food delivery.

Apps made by companies such as Domino’s Pizza, Postmates, DoorDash and Uber Technologies Inc. create a seamless experience for the end user by integrating logistical details from different entities. That user, perhaps a hungry family awaiting a pizza, is able to see the status of their order, where it is in the production process and even where their driver is.

Gene therapy companies could borrow this approach, showing patients where their cells are, how far along they are in the production process, the status of delivery, when they need to prepare for treatment and more. Companies also could include educational, payment information and other support tools in these applications (see Figure 6).

Figure 6: Food delivery apps offer a roadmap for gene therapy producers, who will need to collect data, provide transparency and deliver a treatment

Food delivery

Order is placed by customer on Smart-phone.	Order received by a company; confirmation of order acceptance sent to customer.	Order prepared by employee; customer notified food is being prepared.	Order completed and ready for delivery.	Order picked up by logistics employee. Customer notified that food is on the way, and then again when it is very close to being delivered.	Order delivered to customer's door. Smart-phone application allows seamless contact between driver and customer.	Customer can follow up with the company if there are any issues with the order.

Gene therapy

Cells are collected from the patient, and prepared to be shipped to the biopharma-ceutical company.	Cells picked up by a specialized logistics company, which transports them to the company.	Cells received by the biopharma ceutical company, which begins processing the patient's cells for treatment.	Company begins genetic engineering of cells and multiplying the cells. Process may take weeks.	Completed cells are picked up by logistics company and transported back to the site where the patient will receive treatment.	Genetically modified cells are delivered.	Patient monitored for results of treatment.
Patient receives informati on on how to track progress of cells.	Patient notified that cells are being transported.	Patient notified that cells have been received.	Patient is kept updated throughout the process using con-textualized information.	Patient notified that cells are on their way.	Patient receives treatment at inpatient setting.	Patient can follow up with providers or the company if there are any concerns or side effects.

There is of course one critical difference: A late delivery or wrong order is often an inconvenience, while logistical challenges with the gene therapy supply chain can be fatal to patients.

These systems can be of significant help in driving efficiencies, patient and customer satisfaction, and regulatory compliance. Critical data to capture includes ordering (such as diagnostic or testing data), scheduling and clinical coordination, collection of cells (if needed), patient health status, the status of the production of the gene therapy, patient treatment and patient follow-up. This information will also be helpful to regulators, who require companies to track patients long after their treatment.[16]

Take into account the possibility of a returned product through good contracting: Another complexity may well be the stock return process, in which supply of a drug is returned from a distributor or provider to the manufacturer for a return of payment.

Because many gene therapies are customized for a patient or highly temperature dependent, the returned product is likely unable to be used or repurposed. A patient could die prior to treatment, resulting in the company incurring some or all of the costs of manufacturing the product. For more patients, their health status may deteriorate to a point where they may not be healthy enough to receive the treatment. For genetically modified viral therapies, it is also possible that a medical event at the time of administration could result in a therapy not being fully administered. It is also possible that providers might return a defective product, such as one with obvious contamination or a product sent in error to the wrong patient.

According to one study, the costs of manufacturing an autologous CAR-T gene therapy product is $95,780 per dose, and $4,460 for an allogeneic product – a steep price for any manufacturer to lose for any reason.[17] Many different factors may drive that cost higher or lower, however.[18]

Companies should consider what the “return” process would look like in practice and how they might structure contracts with payers to account for this possibility. Companies could, for example, require the payer to cover the manufacturing costs of the product under certain circumstances beyond the biopharmaceutical companies’ control.

Capability 3:

Tailored commercialization and reimbursement models

For gene therapies, commercial success may require novel reimbursement models that can assure payers – and patients – that the therapies are worth their often-high prices.

Already, companies are offering innovative pricing models to ease market access (see Figure 7). AveXis Inc., a subsidiary of Novartis Pharmaceuticals Corp., is offering payers a pay-over-time option for its new gene therapy treatment for spinal muscular atrophy in pediatric patients, a genetic disorder that causes muscles to atrophy. Under the plan, insurers would have up to five years to pay for the one-time therapy.[19]

Figure 7: A menu of contracting and price-assistance models could help gene therapy be more palatable for payers and providers

Model	Outcomes-based or financial risk-based contracts	Multiyear payments	Provider financing
Explanation	The producer of the therapy would agree to reimburse the payer if the gene therapy does not result in an agreed-upon health outcome in a patient, or if the overall costs of treatment for a patient exceed an agreed-upon level.	The producer of the gene therapy allows the insurer paying for the therapy to pay for the product over a period of time (i.e. years) rather than all at once.	The producer of a gene therapy offers financing available to healthcare providers that allows them to use a gene therapy with their patients and then seek reimbursement, rather than purchasing it prior to use.
Benefit to insurer or provider	The insurer has more certainty that permitting coverage for a gene therapy will result in expected primary and secondary costs, and will not be used unnecessarily.	Allows an insurer to minimize the cost of paying for a treatment on its enrollees, lessening the risk of a spike in premiums.	Providers no longer need to purchase the therapy and then seek reimbursement from a payer like Medicare.
Benefit to biotech company	The producer of the therapy is likely to obtain coverage for its patients more easily and is seen as standing behind its product.	The product is more palatable to insurers, increasing the chances of coverage and increasing product sales.	More healthcare providers are likely to offer gene therapy treatments for their patients, increasing product sales.

Source: PwC Health Research Institute analysis

Spark Therapeutics Inc. offers three payment models for its gene therapy treatment for a degenerative vision condition known as retinal dystrophy: An outcomes-based rebate arrangement, a multiyear payment model and a financing model meant to make it easier for providers to take possession of the gene therapies prior to obtaining reimbursement from a payer.[20]

Outcomes-based contracts may be especially important to insurers worried about paying six- or seven-figure prices for a therapy that might not work. This is especially true just after approval, when there is a relative lack of real-world use data.

“I understand why these therapies are approved with limited data, but it makes it difficult for insurers,” Dr. Michael Sherman, chief medical officer at Harvard Pilgrim Health Care Inc., a Massachusetts-based health services provider, told HRI. “The data is thin, and there are significant reimbursement challenges.”

Among the challenges, Sherman said, is that FDA-approved labels may sometimes be broader than the body of evidence supports, making outcomes-based reimbursements even more necessary. “We’re being very careful about the review process,” he said. “I think that robust outcomes-based agreements can help address the concern about approvals that go beyond data or evidence.”

Companies may also wish to discuss indication-specific pricing with insurers if the pricing of their products are set in accordance with their value. While uncommon, some CAR-T or gene therapies can be used for multiple indications, which may correspond with different value-based assessments.[21]

While value-based contracting will be critical, experience in this type of contracting remains somewhat limited. Just 57 percent of pharmaceutical executives surveyed by HRI reported using at least one value-based drug contract.[22] Just 14 percent of payer executive respondents to a 2017 HRI survey said they engaged in outcomes-based payments with biopharmaceutical companies.[23]

Another concern for insurers is the cumulative effect of paying for many gene therapies over time, Partners HealthCare‘s Fortune told HRI.

“As long as you’re talking about ultrarare disorders, the costs of providing these products to patients won’t bankrupt a health insurer,” Fortune said. “Even if it costs a million dollars for treatment, the probability of a health plan needing to treat more than two patients is extremely low. The concern we have is exemplified by what occurred with hepatitis C a few years ago, where there was a high price and a high incidence rate at the same time. Given that there is expected to be significant growth in gene therapies that are available, that could challenge insurers’ ability to absorb these costs over time as adoption of such applications grows.”

While payment for these products is unlikely to significantly affect larger insurers with millions of members and tens of billions in annual revenue, they could still have a significant impact on smaller or self-insured health plans where the per-enrollee cost could be significant.

This could change, however, if gene therapies for more prevalent diseases or conditions come to market, such as treatments for hemophilia or common cancers like breast cancer or leukemia. Already, some insurers are beginning to offer services to employers to help them to pay for the costs of gene therapy, acting as a stop-loss policy for a specific therapeutic category.[24]

Once payment and reimbursement are assured, companies have another novel barrier to contend with: Site certification. Companies will need to have the ability to train, certify, maintain the training of and monitor the performance of medical staff charged with the collection and administration of biological material used in the creation of gene therapies.

Here, companies may wish to look at the experience of manufacturers of complex medical devices. These companies are staffed with experts with experience understanding provider needs, medical staff training, oversight of logistics and product delivery, assisting with patient medical procedures and monitoring the performance of a product. More than just producers of products, gene therapy companies can become problem-solvers for their customers and patients.[25] They may also wish to partner with hospital networks in order to extend the reach of their certification efforts.

Gene therapy companies also likely will employ medical science liaisons who can answer complex questions for a clinician that are highly specific or beyond what a typical sales staff might know. Sales employees also may change due to the small patient population and limited number of treatment sites.

Traditionally, sales forces have targeted specific regions, but for gene therapy companies, workers likely will be more account-based, focusing on specific treatment centers and even individual patients and physicians.

Even once a site is certified, a provider may not necessarily stand to make money on all patients it administers gene therapy to. CMS has said it will only reimburse providers for CAR-T therapies used with Medicare patients up to a maximum of $242,450 for the 2020 fiscal year.[26] Most procedures will not be reimbursed at that full amount, however, and the amount falls short of the list price of approved CAR-T therapies. Some providers have claimed that the rate could lead to financial losses.[27]

Patient liaisons, too, will be essential. There are few treatment centers providing gene therapies within a close distance of most Americans, according to an analysis by HRI of company websites.

Even if a treatment is available, patients may have to travel far to obtain treatment, according to an analysis by HRI. There are just five ZIP codes in the US in which a patient would be able to receive all four approved gene therapy products. Only 126 ZIP codes offer patients any approved gene therapy. Idaho, Montana, North Dakota, Nevada, New Mexico, Louisiana, Maine, New Hampshire, Vermont, Rhode Island, Hawaii, Alaska and Mississippi have no gene therapy centers as of July 2019 (see Figure 8).

Figure 8: Gene therapy is not offered at treatment facilities in 13 states, and just 5 ZIP codes in the US offer access to all FDA-approved therapies

Source: PwC Health Research Institute analysis of company websites as of July 25, 2019.

Companies should consider how they can help patients get to appointments in distant places, secure and coordinate their initial treatment, infusion, follow-up treatments and then track those patients for follow-up and local care. An integrated solution, such as a patient portal that makes all of the information available in one location for patients and their providers, could give companies an edge in assuring stakeholder satisfaction.

Because most diseases being treated by gene therapies are so rare, companies should also be able to identify patients in the first place, investing in disease awareness campaigns, patient-finding analytics and patient advocacy.

Implications for industry:

Early, complex planning will be critical for ensuring a successful launch: Gene therapy companies should expect many hurdles to commercialization that are likely to slow down launches – insurance coverage, site certification, staff training, reimbursement and patient identification among them – and will need to begin identifying those hurdles and develop processes and systems with which to clear them.

For example, providers may require support to be able to prescribe gene therapies without assuming significant financial risk. Traditionally under Medicare Part B, providers would purchase a drug at cost and then obtain reimbursement for that product later once it had been administered (known as "buy and bill").[28]

While most entities administering gene therapies to date are large institutions, they may not want to incur the potential cost of purchasing a gene therapy and then waiting for CMS reimbursement, especially if – such as a premier academic medical center – they do a significant volume of these procedures.

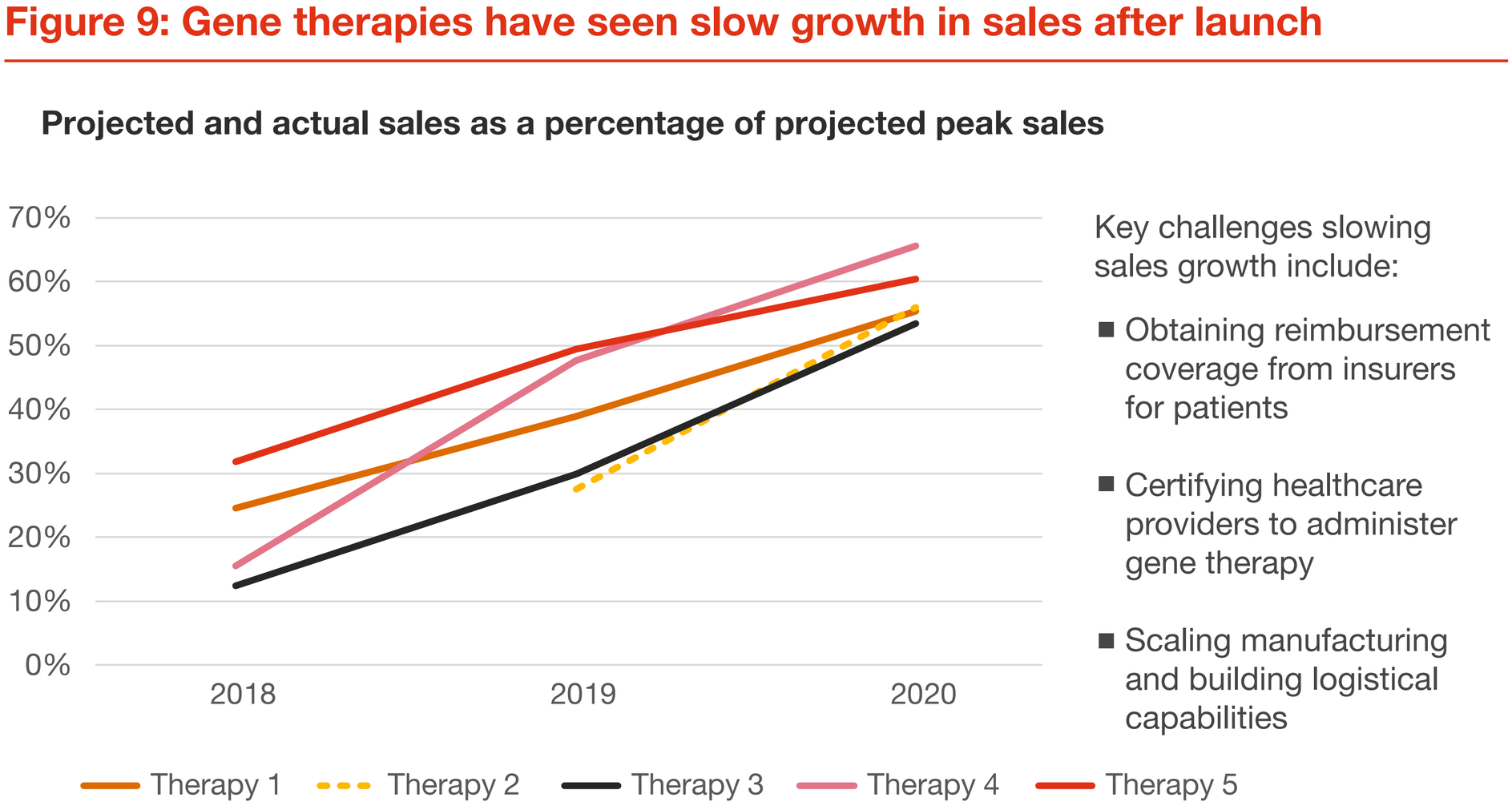
Gene therapy companies may wish to partner with a financial institution or pharmacy benefits manager to offer financing for their products on attractive terms to ensure providers are able to afford to prescribe them. However, the financial terms of those arrangements will need to be structured properly, since below-market rates might be construed as a kickback in some instances.

Even obtaining the appropriate reimbursement codes from payers may be a challenge, Erika Rogan, senior associate director of policy at the American Hospital Association, told HRI. "Often the coding system is playing catch-up with new service offerings like gene therapy," Rogan said in an interview.

Hospitals or providers may not be able to obtain sufficient reimbursement for a procedure. These issues may delay treatments, and therefore revenue for developers of gene therapies, and so companies should begin working to help develop the necessary reimbursement codes early on, since most gene therapies do not appropriately fall under existing codes.

Without these processes and systems in place, it will take longer for companies to realize the full sales potential of their therapies. Based on an HRI analysis of historical data and consensus forecasts for the sales of FDA-approved gene therapy products, these products can expect to realize less than half of their expected peak sales in the first two years, with some first-year products achieving less than 20 percent of peak expected sales (see Figure 9).

Figure 9: Gene therapies have seen slow growth in sales after launch



Source: PwC Health Research Institute analysis of Evaluate Pharma historical sales data and consensus sales estimates.
As of August 1, 2019.

Patient financial and logistical support will be crucial: Patients, too, likely will require support, even ones with favorable insurance coverage. Many consumers are enrolled in high-deductible health plans, with in-network deductibles ranging from $2,700 to $13,300 for a family in 2019.[29] For example, 37 percent of employers surveyed by PwC in 2018 reported a HDHP was their most-enrolled health plan, with a median in-network family deductible of $2,500.[30] These costs can escalate further when out-of-pocket costs are factored in, which max out at $15,800 for a family plan sold through the federal health insurance marketplace in 2019.[31]

Since most gene therapies are one-time, single treatments with list prices of hundreds of thousands of dollars, patients will likely have to pay their entire deductible and meet their out-of-pocket maximum at once.

Many patients may not be able to afford their share. Twenty-eight percent of consumers surveyed by HRI who have employer-sponsored insurance said they had $500 or less in emergency savings.[32] Among companies surveyed by PwC, the average family deductible was $2,690 for in-network coverage, and in-network out-of-pocket maximum was $7,379.[33]

For those patients enrolled in health plans with separate benefit designs for specialty pharmaceutical products, these costs could be significantly higher. According to the Kaiser Family Foundation's 2018 survey of employer health benefit plans, the average coinsurance for highest-tier specialty drugs was 26

percent, and 52 percent of large companies have a separate tier for specialty drugs. Twenty-one percent of plans surveyed did not have a maximum dollar amount tied to their coinsurance design for specialty drugs.[34]

The expense of a patient meeting their insurance deductible, paired with the costs of out-of-network providers, time off work for treatment, travel and lodging for treatment, and other lifestyle adjustments could make treatment unaffordable even for some insured patients. It will be important for companies to consider how to support their patients to be able to access needed treatments.

Biotechnology companies may face competition from hospitals: Over time, life sciences companies also may have to contend with competition from hospitals. Hospitals already form the bookends of the autologous gene therapy manufacturing and treatment process. Some academic medical centers also are involved with the discovery, development, processing and testing of therapies. In the future, such hospitals could compete with existing biotechnology companies.

“I think there is some interest and some hospitals are considering how they might play a role in this space in the future, but it’s currently too early to tell what a timeline for this might look like,” said the AHA’s Rogan.

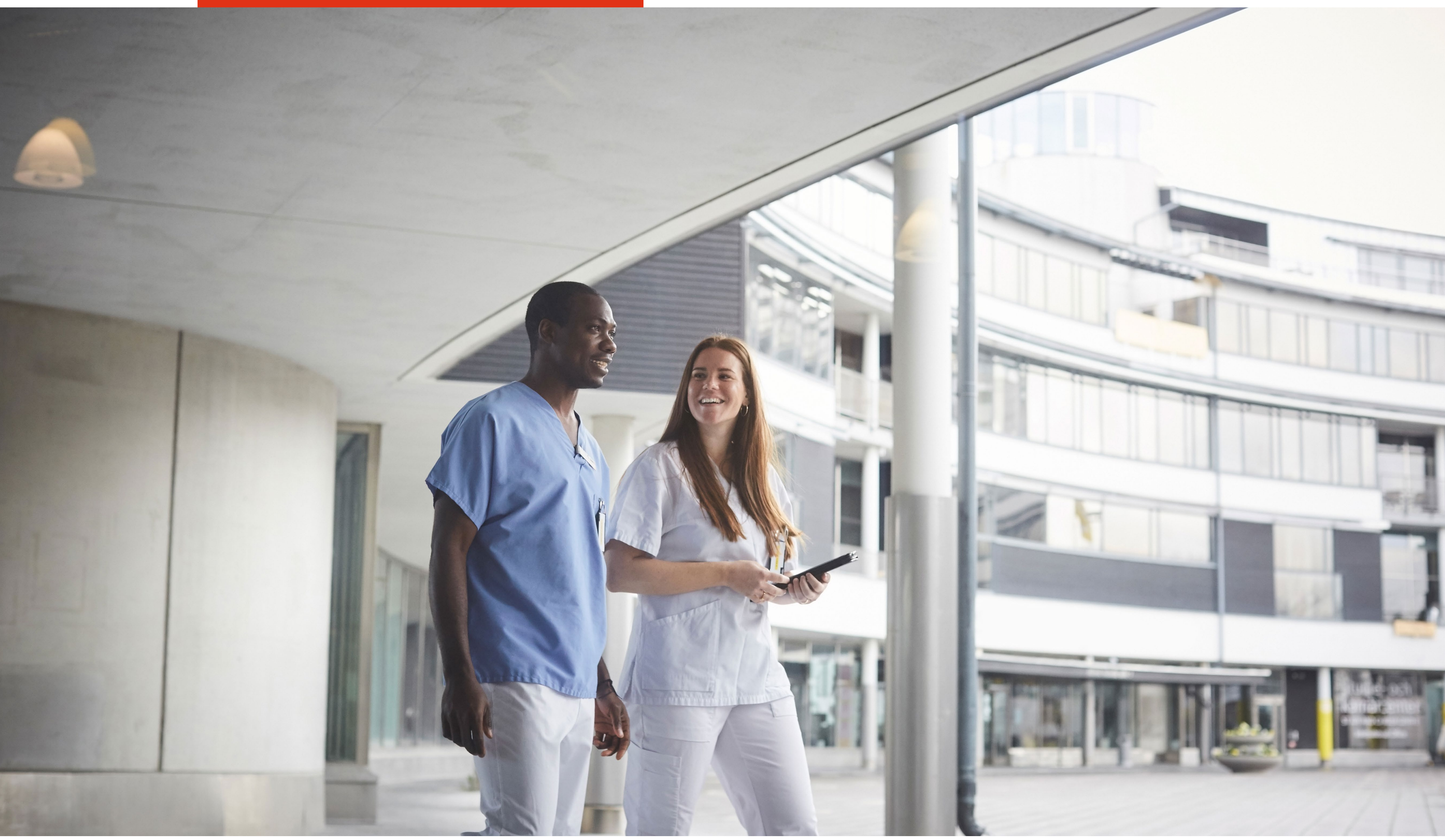
Already, some academic medical centers in Switzerland are teaming up to offer cell therapies at a reduced cost, which could be a harbinger of things to come in the US.[35] In the US, two medical schools have teamed up to establish a gene therapy production facility.[36]

Some academic medical centers are experiencing revenue crunches and are seeking new sources of revenue, which gene therapies could provide.[37] If hospitals are able to offer therapies at a more attractive price point, insurers could see them as a better means of controlling cost – a key concern for many insurers – and push their enrollees to those settings.

Some biotechnology companies could seek to counteract this by moving to a franchise-based model, in which the company handles regulatory submissions, trial data generation, product quality and product marketing and branding – all strengths inherent to the life sciences industry – while the hospitals handle the patient, on-site production and product administration. Companies could also choose to co-commercialize gene therapies with providers, sharing in the developmental risks – and commercial rewards – of bringing new gene therapies to market.

Technological advancements may also upend this potential for disruption, such as if biotechnology companies are able to develop gene therapies capable of being administered in outpatient clinical settings, thereby avoiding costly inpatient admission costs.

Final thoughts



While gene therapies likely will create opportunities for the life sciences sector, it may also produce new strains on existing business models and perhaps even society. Companies with product portfolios focused on managing disease could be upended by companies offering products that can cure or offer long-term relief from the symptoms of disease.

Government payers, private insurers and patients – already grappling with the pricing of drug products – will need to figure out how to pay for gene therapies with their high costs for an ever-growing patient pool. Low reimbursement levels may discourage investment given the high costs of production and small patient populations. High prices may put essential treatments out of reach for the patients who need them most.

As the life sciences industry enters this new, gene-focused world of development, it will need to think about their place in it, and how it plans to compete on behalf of patients and shareholders.

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About this research

PwC's Health Research Institute conducted interviews with industry executives working in the gene and cell therapy industry, including biotechnology companies developing gene therapies, researchers testing gene therapies, insurers paying for gene therapies, healthcare providers and logistics companies that transport gene therapies.

There are differences in how various regulators define gene therapies. For example, the European Medicines Agency considers a genetically modified virus administered to a patient to be a gene therapy, while the FDA does not.[38] For the purposes of this paper, HRI looked at FDA-approved products that include gene-modified components or methods, including gene therapy products, Chimeric Antigen Receptor T-cell (CAR-T) products (which the FDA considers to be cell-based gene therapies) and genetically modified vectors.

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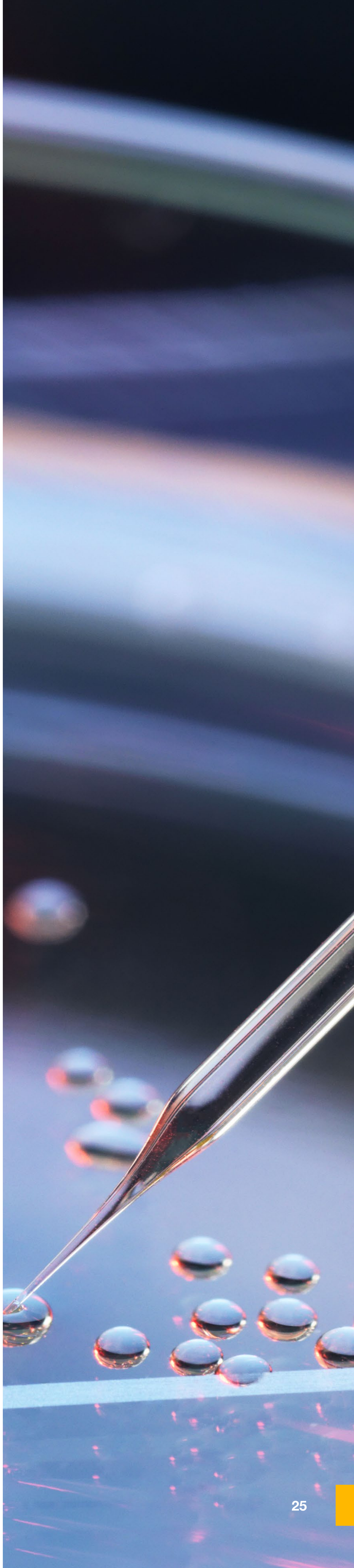

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