EMPLOYERS NAVIGATE NEW FRONTIERS IN CELL AND GENE THERAPY

Written By Laura Carabello

We live in an age of medical miracles now exemplified by the introduction of potentially life-saving cell and gene therapies (CGTs). This is just the beginning, as industry observers predict that succeeding generations are going to experience even more astounding cures that none of us could ever envision.

"This is truly amazing stuff -- really miraculous – and makes me think of Star Trek medical care," observes Shaun Peterson, vice president of Voya Financial and chair of SIIA's new Cell & Gene Task Force. In this latter capacity, he will provide the welcome remarks for the association's upcoming Cell + Gene Therapy Stakeholder Forum. "First and foremost, it's a given that the outcomes that could happen

from some of these treatments are extraordinary, and the improvement in life quality is most important."

Cell therapy is the transfer of live cells into a patient to lessen or cure a disease using cells from the patient or a donor.

Gene therapy is used to treat or cure a disease by replacing a missing or mutated gene in the targeted cell to "correct" the missing function.

From an actuarial perspective, Peterson acknowledges the financial burden of these million-dollar treatments, adding, "There's the price piece, but pricing doesn't have to be a stand-alone component of care. There is some management that needs to be done to ensure that the drugs are appropriately placed in the benefit structure, administered in the right setting and actually paid for in a reasonable way. There are a lot of levers and moving parts to this healthcare equation, with people scratching their heads and wondering how providers get paid and where people are making money."

Ashley Hume, chief commercial officer, Emerging Therapy Solutions and part of the Forum planning group, says that prior to the COVID-19 wave, it was actually hard to get people's attention on these therapies. "Then the furor subsided, and a number of therapies came to market, although everybody was primarily concerned about cost. Risk-bearing entities like self-insured employers, plan sponsors and their reinsurance brokers started to pay attention and support all of the work that needed to be done to manage members impacted by these rare diseases."

She says that as these therapies gained regulatory approval and members started accessing treatment -- albeit at a catastrophic price tag -- the challenge became to get members to the right centers for proper evaluation and then to ensure cost containment for the actual treatment.

These and other issues are the focus of the Forum as self-insured employers and their consultants weigh the pros and cons of covering the cost of these ultra-expensive medications and deciding how best to approach the delivery of care. SIIA stands as a source of truth to support this multi-faceted decision-making process.

ENSURING ACCESS TO BREAKTHROUGH THERAPIES

Since the long-term benefits and risks of these new treatments are largely unknown, financing these therapies is precarious for payers and the pharmaceutical companies developing them.

"Forum attendees are going to hear from all of the different stakeholder groups who will assess where we thought we would be since the time we met at last year's event," says Hume. "Really, a lot has happened. This year, we are including manufacturers that actually produce the therapies, along with representatives from different companies that are developing

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and introducing marketplace solutions that will help self-insured employers adapt to the evolving CGT realities. Everyone is coming together to talk about how the market is approaching CGT risk management."

Some of the leading CGT manufacturers will provide an overview of how their product launches have progressed since gaining regulatory approval last year. Attendees can also expect to learn about pricing implications, value-based payment arrangements, warranties, and patient access considerations. Rounding out the discussion will be an FDA spokesperson to talk about the approval process and why accelerated approval pathways impact medical policy and key coverage decision considerations.

PATIENT ADVOCATES SPEAK OUT, PROVIDERS WEIGH IN

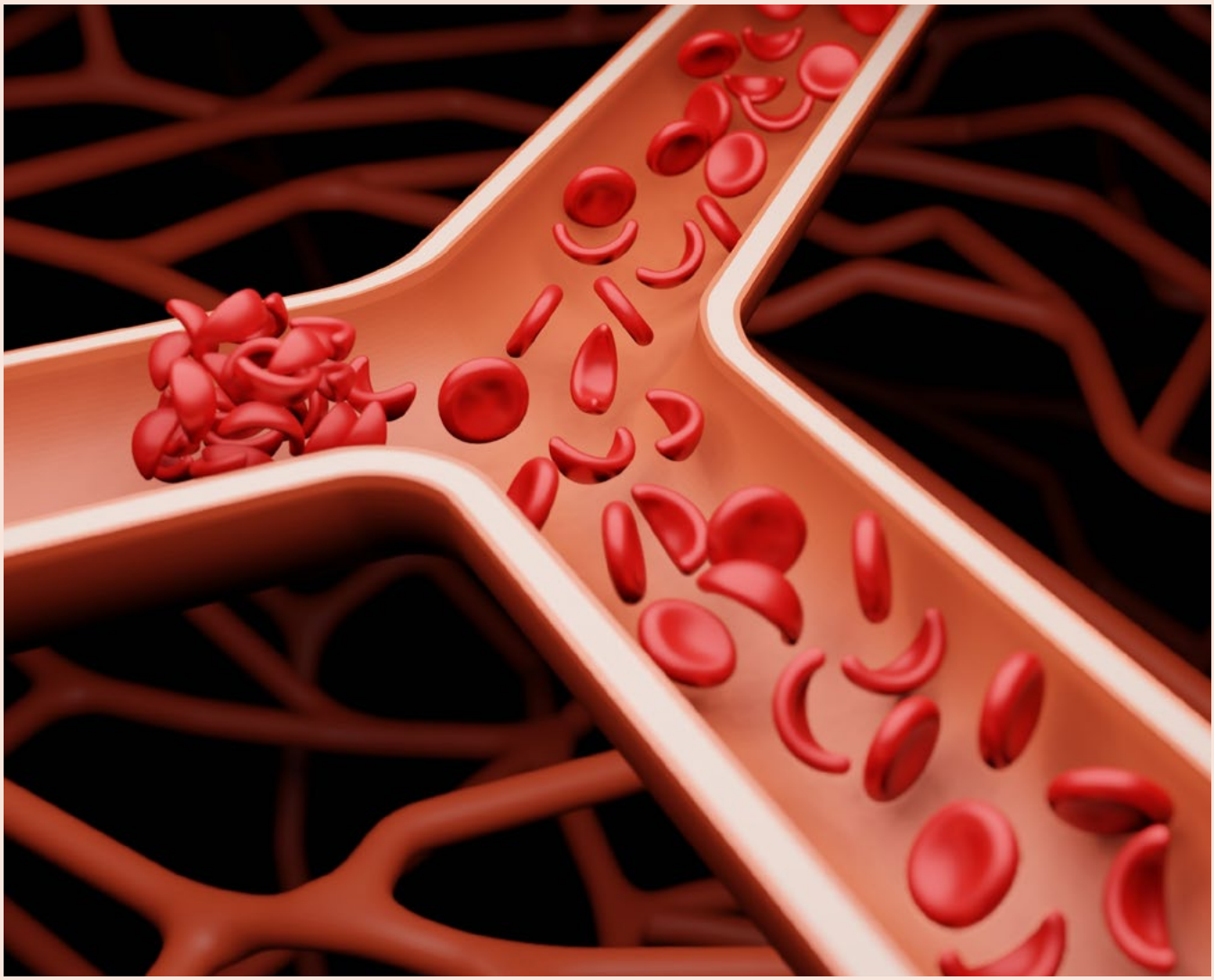
Patient voices will be heard during additional panels featuring patient advocacy organizations. Several patients who have received or are going to receive gene therapy for sickle cell anemia will relate stories about their personal treatment journeys with the new gene therapy that has drawn significant market attention.

WHO WILL PAY FOR SICKLE CELL GENE THERAPY?

The December 2023 FDA approval of the first two gene therapies to treat sickle cell disease (SCD) was an important step forward in managing the most common and clinically significant inherited blood disorder across the United States. As approved centers prepare to begin offering exagamglogene autotemcel (exa-cel; Casgevy, Vertex Pharmaceuticals) and lovotibeglogene autotemcel (lovo-cel; Lyfgenia, Bluebird Bio), many questions remain about cost, insurance coverage and access.

According to the American Academy of Family Physicians, the list price of Casgevy, the first and only CRISPR-based gene editing therapy for SCD and transfusion-dependent beta thalassemia (TDT), is approximately $2.2 million.

Source: Specialty Pharmacy Continuum, February 2024



Not to be overlooked, the provider community and medical facilities will describe the challenges they face and how these issues may affect patient access, including administrative policies from payers, payment policy issues and regulatory obstacles. While confronting these situations, physicians continue to reinforce their commitment to offering life-saving care while also addressing concerns about sustainability.

"The Fourm's provider panel will tackle some of their thorniest concerns for delivering patient-centered care without incurring substantial receivables or facing uncertainties regarding payment," says Hume. "We are truly honored to have the participation of Stephan A. Grupp, MD, PhD, the first physician to infuse a patient commercially with CAR-T therapy about ten years ago."

The NIH National Cancer Institute defines CAR T-cell therapy as a type of treatment in which a patient's T cells (a type of immune cell) are changed in the laboratory so they will bind to cancer cells and kill them.

Hume continues, "Dr. Grupp will discuss what's happened, how this market has evolved and what it's like as a provider to manage these complex therapies. He is highly qualified to lead this discussion as Section Chief of the Cellular Therapy and Transplant Section, Inaugural Director of the Susan S and Stephen P Kelly Center for Cancer Immunotherapy, and Medical Director of the Cell and Gene Therapy Laboratory and Children's Hospital of Philadelphia."

From the perspective of a medical center, the provider panel will also address what it's like to be looking at taking title of a $3 million drug and just hoping you're going to get paid.

NOT JUST ANOTHER BIG CLAIM – THEY'RE CATASTROPHIC

With a 25-year career spanning involvement in the stop-loss and reinsurance industries and managing various books of business across many different employers, Shaun Peterson shares this perspective, which serves as a preview of the Forum:

'My involvement in dealing with catastrophic claims leads me to say that a lot of these cell and gene therapies are really catastrophic claims. But people often ask me, 'As an actuary, why are you involved here, and why do you care?' In reality, the way the business works is I don't need to care. We could just continue perpetuating the same old, same old approach and be resigned that big claims happen."

He explains that actuaries look at their experience to set their rates. "If there are more large claims, we raise our rates and keep going forward. If there are more and more big claims, we will raise our rates again and continue to go forward – it's just wash, rinse, repeat."

He shares, "I don't have to care, but the economics of it aren't the incentive that drives my involvement. The reality is that I have to come home and look my kids in the face. If ten years from now, when I decide to retire, I want to look back and say, 'Yes! I feel like I made a difference, and I made an impact.'"

The issues around CGTs are where Peterson has chosen to lean in because "It is the beginning of a paradigm shift in medical treatments and the costs of those treatments."

He values his position because it provides a perspective that is broader than most of his clients, meaning that he can see across three, four or five million employees and see how these claims are emerging.

"Current treatments are for diseases that are still ultra rare, super-orphan conditions that affect an incredibly small percentage of the population," he explains. "Yet when these diseases occur, they incur a huge expense of two, three or four million dollars. While your average employer probably won't even see one of these claims, ten years from now, there will likely be more."

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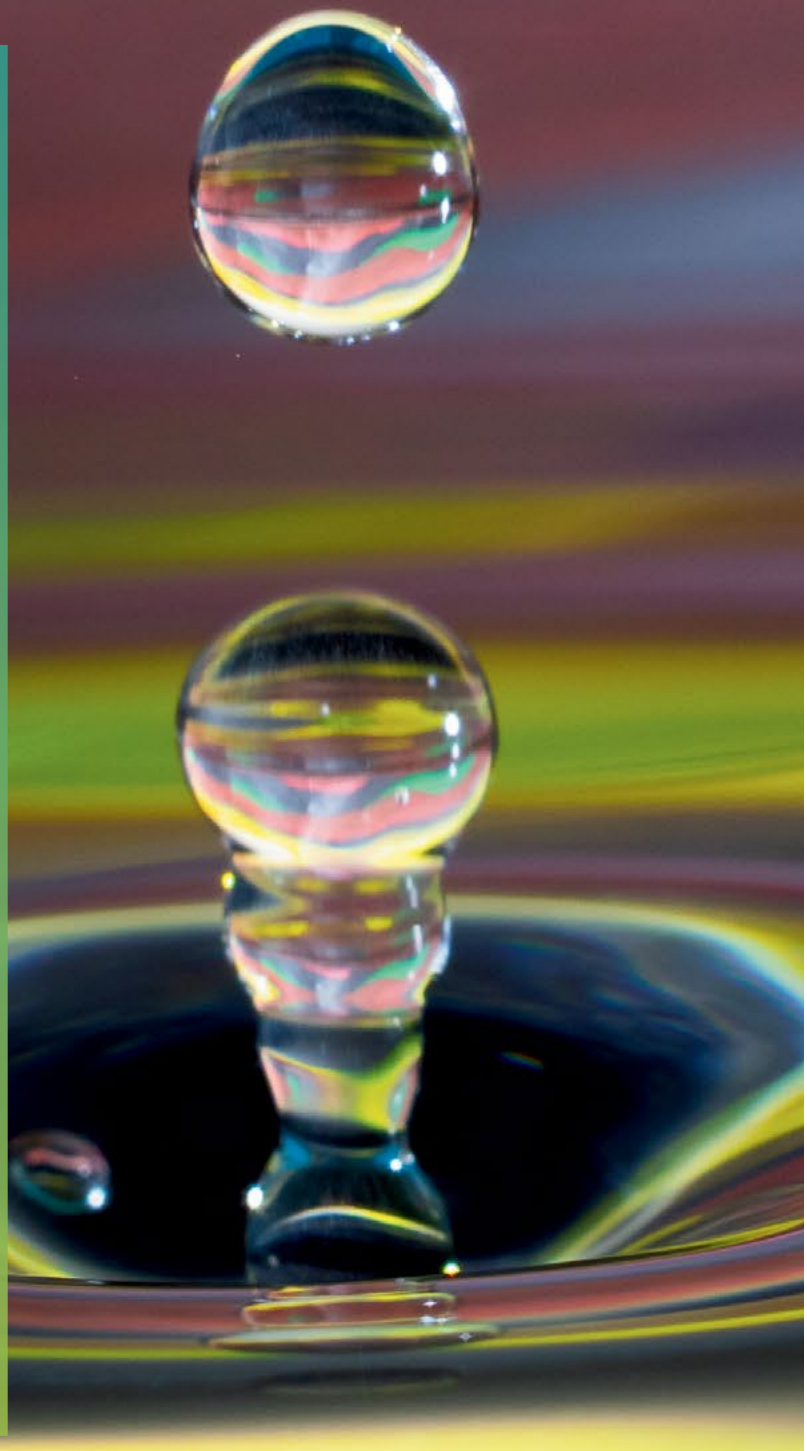

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For actuaries like Peterson, it's more an issue of aggregating costs across an enterprise -- +/-5 million employees -- and looking at the frequency of disease to assess the potential impact. While he emphasizes that the average employer is not going to see many of these rare diseases, there are some exceptions.

"There's now some gene therapies for multiple myeloma and others that are in the pipeline where there's going to be some more frequency," he points out. "These are going to be costly, but probably not nearly as costly as some of the super-orphan drugs we've seen. But I can actually see these trends so I can help other people understand them."

He says the question then arises about appropriate disease management and how we impact those claims. He anticipates that this topic is likely to be a good part of the upcoming discussion.

"While I don't have a clinical background and am not a treatment expert, I do know people within the industry and can get involved by bringing these people together to have a productive conversation," he offers. "Again, this is the reason these issues are important to me and why I lean in. I have a perspective that other people don't have, and I can bring people together who actually know what is involved and are in it day-to-day. The Forum is an ideal setting to have these conversations, try to make things better and figure out what better looks like."

WHAT'S TOP OF MIND FOR EMPLOYERS?

Hume reports that employers of all sizes have a lot of different concerns, noting her experience with one group representing multiple employers and the feedback from their recent CEO forum.

"CGTs and the surging costs of specialty drugs was the number one issue on their list, with GLP weight loss drugs trailing far behind," says Hume. "I mean, employers are getting hammered. What's critical for an employer is ensuring that they know what their coverage is, especially their stop-loss or reinsurance coverage. "

Employers want to have the right tools in place to ensure that their members are receiving care at the right facilities; as she advises, "You really don't want your members going to community hospital to receive a 3-million-dollar therapy. You do want to make sure that it's a hospital that's ready to address what could happen with those members."

Given the large price tags associated with many CGTs, there will be a panel dedicated to the introduction of various financial risk transfer strategies that enable employers to cover important new treatments. The session will provide perspectives on stop-loss coverage, MGU, reinsurance and captive insurance.

"We'll get some insights about what employers should be most concerned about – price or serving their workforce?" adds Hume.

Peterson counsels that there is a delicate balance between the upside or upfront cost of CGTs vs. the impact of this investment in terms of outcomes around people's ultimate health status.

"There is consensus on the value of health improvement, but the jury is still out as to whether the initial high cost is outweighed by the subsequent cost benefits," he explains. "There's the simple economics of it, the demand and capacity component. When you're talking about an ultra-rare disease, the individual costs can be quite high. When you're talking about something that's more common, such as CGTs for the more prevalent disease states like diabetes, the costs are going to be lower, and the treatments will likely be more accessible."

He points out that advisors and brokers are an important part of this decision-making process because the vast majority of the

employers in this country are not really equipped to address the business issues of delivering healthcare to their employees,

"Companies make bicycles, produce automobiles, grow fruit or operate retail sites, but they didn't decide to be in the business of delivering healthcare to their employees, nor should they necessarily be experts in that area," he comments. "They need the help of their consultants and advisors as well as the products and services that the self-insurance industry provides."

Peterson says there's a good reason the companies involved in SIIA exist – from stop-loss and medical management firms to bill review companies, captives, brokers and advisors.

"There's a healthy support structure in this market to guide individual employers, regardless of whether or not they're looking at CGTs from a pure financial standpoint or a paternal/fraternal perspective relative to how they're trying to really deliver value for their employees."

A LOOK AT THE CGT LANDSCAPE

Industry analysts point to 2023 as a breakthrough year for CGTs, with seven FDA approvals in the US and one in the European Union. Currently, more than 2,000 clinical trials are being conducted globally. With approximately 10% of them in Phase III, these thought leaders say it is likely that 75 therapies will be approved much sooner than 2030. Projections for 2024 are set at about 17 approvals between the US and EU.

Below is a brief introduction to CGTs currently approved by the FDA and available in the United States. For complete indications, safety, and packaging information, visit the manufacturer's website. List pricing is based on current known therapy cost from publicly available information and does not include administration or treatment costs. Thanks to Emerging Therapy Solutions for providing this research.

GENE THERAPIES

Adstiladrin®
(nadofaragenefiradenovec-vncg)
Condition: Bladder cancer
Company: Ferring Pharmaceuticals
Approved: December 2022
Current WAC*: $60,000 per instillation
More: ferring.com

Treats bladder cancer in adults
Adstiladrinis a novel adenovirus vector-based *in-vivo*gene therapy from Ferring Pharmaceuticals for the treatment of adult patients with high-risk Bacillus Calmette Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. This is the first gene therapy approved to treat bladder cancer.

Casgevy
(exagamglogene autotemcel)
Conditions: Sickle cell disease, Beta-thalassemia
Company: CRISPR Therapeutics and Vertex Pharmaceuticals
Approved: December 2023, January 2024
Current WAC: $2,200,000 (SCD), $2,200,000 (TDT)
More: vrtx.com

Treats sickle cell disease and transfusion-dependent beta-thalassemia in patients aged 12 years and older
Casgevy is an autologous genome-edited hematopoietic stem cell-based gene therapy indicated for the treatment of patients aged 12 years and older with sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or with transfusion-dependent beta-thalassemia (TDT) who need regular blood transfusions. It was the first-ever approved therapy using CRISPR/Cas9 gene-editing technology.

Elevidys®
(delandistrogenemoxeparvovec-rokl)
Condition: Duchenne muscular dystrophy
Company: Sarepta Therapeutics
Approved: June 2023
Current WAC: $3,200,000
More: sarepta.com

Treats Duchenne muscular dystrophy in ambulatory patients aged 4 to 5 years old
Elevidysis is an adeno-associated virus-based *in-vivo*gene therapy for the treatment of ambulatory DMD pediatric patients aged 4 through 5 years with a confirmed mutation in the *DMD*gene. This indication is approved under accelerated approval based on the expression of Elevidysmicro-dystrophin observed in patients treated with Elevidys, with continued approval contingent upon confirmatory trial(s). It is contraindicated in patients with any deletion in exon 8 and/or exon 9 in the *DMD*gene.

Hemgenix®
(etranacogenedezaparvovec-drlb)
Condition: Hemophilia B
Company: CSL Behring
Approved: November 2022
Current WAC: $3,500,000
More: cslbehring.com

Treats hemophilia B in adults
Hemgenix, an adeno-associated virus vector-based gene therapy for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy or have current or historical life-threatening hemorrhage or have repeated, serious spontaneous bleeding episodes is the first in-vivo gene therapy approved by the United States (US) Food and Drug Administration (FDA) for treating hemophilia B in adults and uses an Adeno-Associated Virus Type 5 (AAV5) vector.

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Lyfgenia
(lovotibeglogeneautotemcel)
Condition: Sickle cell disease
Company: bluebird bio, Inc.
Approved: December 2023
Current WAC: $3,100,000
More: bluebirdbio.com

Treats sickle cell disease in patients aged 12 years and older
Lyfgeniais a one-time ex-vivo lentiviral vector gene therapy approved for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events (VOEs). Lyfgeniaworks by adding a functional β-globin gene to patients' own hematopoietic (blood) stem cells (HSCs).

Cell Therapies

Abecma®
(idecabtagenevicleucel)
Condition: Multiple myeloma
Company: Bristol Myers Squibb
Approved: March 2021
Current WAC: $498,408
More: abecma.com

Treats adult patients with relapsed or refractory (r/r) multiple myeloma
Abecma is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T-cell therapy. Abecma is approved for adult patients with r/r multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

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Amtagvi
(lifileucel)
Condition: Metastatic melanoma
Company: Iovance Biotherapeutics
Approved: February 2024
Current WAC: $515,000*
More: amtagvi.com

Treats adult patients with unresectable or metastatic melanoma Amtagvi is a tumor-derived autologous T-cell therapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. Amtagviis a tumor-infiltrating lymphocyte (TIL) cell therapy and is the first and only one-time, individualized T-cell therapy approved for solid tumor cancer. This indication is approved under an accelerated approval based on overall response rate (ORR) and duration of response. Iovance is also conducting TILVANCE-301, a phase III clinical trial to confirm clinical benefit.

Breyanzi®
(lisocabtagenemaraleucel)
Condition: Large B-cell lymphoma & DLBCL, and follicular lymphoma
Company: Bristol Myers Squibb
Approved: February 2021, June 2022
Current WAC: $487,477
More: breyanzi.com

Treats adult patients with r/r large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) & r/r follicular lymphoma
Breyanzi, a CD19-directed CAR-T therapy indicated for adult patients with r/r LBCL, including DLBCL not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. Expanded indication is for those who have: refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. It is not indicated for the patients with primary central nervous system lymphoma.

Carvykti
(ciltacabtageneautoleucel)
Condition: Multiple myeloma
Company: Janssen Pharmaceutical/Legend Biotech
Approved: February 2022
Current WAC: $478,950
More: carvykti.com

Treats adult patients with r/r multiple myeloma
Carvykti is a B-cell maturation antigen (BCMA)-directed CAR T-cell therapy. Carvykti is approved for adult patients with r/r multiple myeloma after four or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.


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Kymriah®
(tisagenlecleucel)
Condition: Acute lymphoblastic leukemia, large B-cell lymphoma & DLBCL, and follicular lymphoma
Company: Novartis Pharmaceuticals
Approved: August 2017, May 2018, May 2022
Current WAC: $543,828 (ALL),
$427,048 (DLBCL, FL)
More: kymriah.com

Treats patients up to age 25 with r/r B-cell precursor acute lymphoblastic leukemia (ALL) and adult patients with r/r large B-cell lymphoma, including DLBCL and r/r follicular lymphoma
Kymriah is a CAR T-cell therapy approved for patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse. In 2018, Kymriah was approved for an expanded indication to include adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy. In May 2022, Kymriah was approved for another expanded indication for adult patients with r/r follicular lymphoma after two or more lines of systemic therapy. This expansion was approved under an accelerated approval; continued approval for this indication may be contingent upon clinical benefit in a confirmatory trial.

Lantidra®
(donislecel-jujn)
Condition: DiabetesType 1
Company: CellTransInc.
Approved: June 2023
Current WAC: N/A
More: celltransinc.com

Treats adults with Diabetes Type 1
Lantidra is approved for the treatment of adults with type 1 diabetes who are unable to approach target glycated hemoglobin (average blood glucose levels) because of current repeated episodes of severe hypoglycemia (low blood sugar) despite intensive diabetes management and education. It is the first allogeneic (donor) pancreatic islet cellular therapy made from deceased donor pancreatic cells for the treatment of type 1 diabetes.

Omisirge®
(omidubicel-onlv)
Condition: Umbilical cord-blood transplant for blood cancers
Company: GamidaCell
Approved: April 17, 2023
Current WAC: $338,000
More: gamida-cell.com

For patients requiring umbilical cord blood transplantation for blood cancer treatment
Omisirgeis a substantially modified allogeneic (donor) cord blood-based cell therapy intended for use in adults and pediatric patients 12 years and older to quicken the recovery of neutrophils (a subset of white blood cells) in the body and reduce the risk of infection for individuals with blood cancers planned for umbilical cord blood transplantation following a myeloablative conditioning regimen (treatment such as radiation or chemotherapy). Related conditions include acute lymphoblastic leukemia, acute myeloid leukemia, myelodysplastic syndromes, and others.

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Tecartus®
(brexucabtageneautoleucel)
Condition: Acute lymphoblastic leukemia
Company: Kite, a Gilead Company
Approved: July 2020 (MCL),
October 2021 (ALL)
Current WAC: $424,000
More: tecartus.com

Treats adult patients with r/r B-cell precursor acute lymphoblastic leukemia (ALL) and adult patients with r/r mantle cell lymphoma
Tecartus is a CAR-T therapy indicated for the treatment of adult patients with r/r B-cell precursor ALL.Tecartus is also indicated for the treatment of adult patients with r/r mantle cell lymphoma. This was approved under an accelerated approval; continued approval for this indication may be contingent upon clinical benefit in a confirmatory trial.

Yescarta®
(axicabtageneciloleucel)
Condition: Large B-cell lymphoma & DLBCL, and follicular lymphoma
Company: Kite, a Gilead Company
Approved: October 2017, April 2021, April 2022
Current WAC: $462,000
More: yescarta.com

Treats adult patients with r/r large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) and r/r follicular lymphoma
Yescarta is a CAR T-cell therapy that is indicated for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. In 2021, Yescarta was approved for an expanded indication to include adults with r/r follicular lymphoma after two or more lines of systemic therapy. In April 2022, Yescarta was approved for another expanded indication for adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma.

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IGNITING THE DISCUSSION

"At the end of this Forum, we really want participants to have a full picture of what is happening to all market sectors, open up discussions and conduct dialogue based upon what they heard," concludes Hume. "There's going to be an opportunity for attendees to express their thoughts and exchange ideas on where we go from here."

As CGTs move into the mainstream and take on higher prevalence conditions, both Hume and Peterson concur that there's just a lot we don't know.

"We don't know if higher prevalence will bring down the price point so there's a lot of questions around how far the manufacturer community will go with pricing," says Hume. "The main reason the price tags are so high for rare disease treatment is because manufacturers have to recover the cost of product development for small populations. But the pipeline is just full of activity for these higher prevalence conditions."

She believes that every employer is really on the fence right now, and there will be multiple questions that require answers regarding coverage.

"There's a lot of unknowns, and employers face a lot of challenges," she admits. "Denying coverage might result in bad press, especially if an employee has a child with spinal muscular atrophy and they can't access the gene therapy. That's going to make news, appear on social media and be announced on every single pulpit where a parent can bring attention for their child."

Peterson expresses his gratitude for all the scientific advancement that is bringing these opportunities to so many people.

"On Rare Disease Day, I attended an awareness event at the University of Minnesota where we discussed how much has changed," he shares. "We heard from patient advocates and families who have suffered losses. Now, these warrior champions are fighting against a rare disease and they're making such great progress, which is so wonderful for these families because access is a problem. There are a hundred different challenges to accessing a therapy

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even after it is approved. I encourage people to stay hopeful and keep fighting for access."

For employers and manufacturers, he says it's important to understand the other's perspective with a goal to hopefully see a path to a mutual conversation about how to manage CGTs.

"This Forum will foster mutual understanding of each other's perspectives and help facilitate that conversation in a better way," he observes. "I think the diversity of the people who are going to be attending and presenting is probably the biggest value of the event."

Peterson anticipates that this Forum will lead to a greater understanding of the right approaches, adding, "We look forward to examining how stakeholders can reach across the aisle in some areas to come up with a plan or actions that will ultimately facilitate the distribution of CGTs in a way that is providing the desired outcomes as efficiently as possible.'

He emphasizes that the goal is to get the right care in the right place and make sure the wrong care is not getting delivered in the wrong venue, noting, "Optimally, care should be financed or paid for, and that's the goal in bringing everyone together. Outcomes are the number one priority given that we don't have to just take the initial hypothesis that the price determines how or where treatment should be delivered."

He calls for expanded conversation about how we support those optimal outcomes and make sure that there's limited misuse, better efficiency in the delivery of care and enhanced value.

"Balancing the initial payment versus subsequent health improvements should be the focus -- it's not a math problem, it's an outcome problem," he stresses. "But there's math that needs to

be done behind the management to make sure that we're also optimizing the math on the other end."■

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SIIA RESPONDS TO HOUSE COMMITTEE REQUEST FOR INFORMATION ON HOW TO BUILD UPON AND STRENGTHEN ERISA

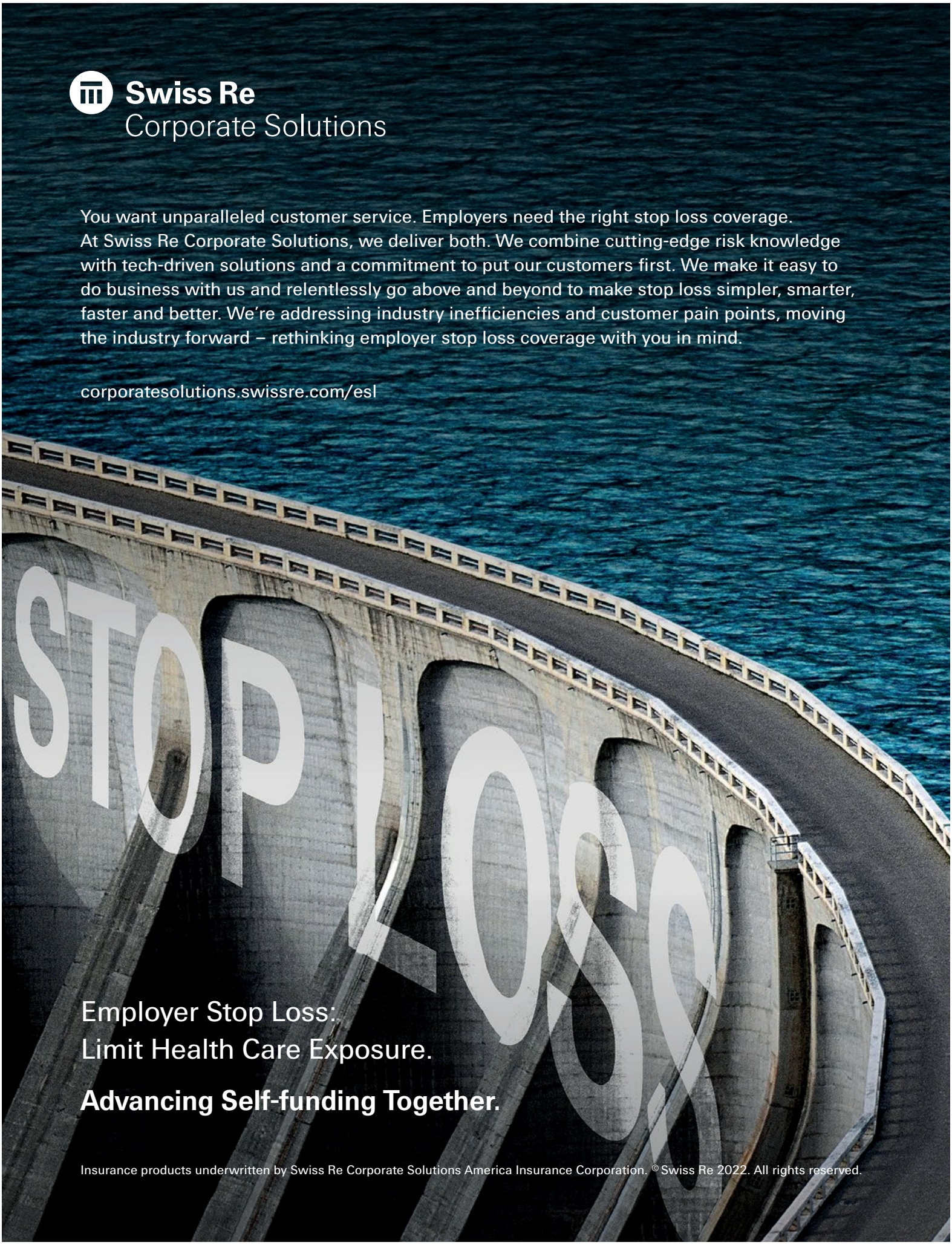
On January 22nd, the House Education and the Workforce Committee sent a Request for Information (RFI) to stakeholders in the employer-sponsored health plan community seeking feedback on ways the Committee can build upon and strengthen ERISA in specific areas, including ERISA preemption, ERISA's fiduciary requirements, and other areas such as Data-Sharing, Cybersecurity, and Direct and Indirect Broker/Consultant Compensation.

SIIA specifically provided feedback on ERISA preemption, highlighting the significance of ERISA's preemption powers and pointing out that the main reason for the enactment of ERISA itself was to ensure that, for example, health benefit plans are subject to a uniform Federal system of regulation, instead of a "patchwork" set of requirements established by each of our nation's 50 States. We also shared with

the Committee our White Paper on ERISA preemption that we developed last Fall. As we reported, our White Paper provides an overview of how ERISA is structured and enforced, an explanation of ERISA's requirements applicable to self-insured group health plans, and a detailed discussion of ERISA's preemption provision and how the Supreme Court determines whether and when a state law is preempted by ERISA.

SIIA also informed the Committee of the difficulties plan sponsors and their service providers are experiencing when it comes to accessing a complete and accurate set of pricing and health claims data. We highlighted that, in practice, owners of the provider networks continue to refuse to share pricing and claims information with plan sponsors by pointing to contractual restrictions set forth in "downstream" agreements with the plan sponsor and/or other plan service providers. We also explained that plan sponsors and their service providers believe that the presence of these contractual restrictions are prohibited "gag clauses" that prevent the plan sponsor from lawfully "attesting" that the plan is in compliance with the Gag Clause Prohibition. As a way to resolve these issues, we provided the Committee with detailed amendments to the Gag Clause Prohibition statute (set forth in ERISA section 724), which we hope the Committee will consider recommending that the full House and Senate pass into law.

Lastly, SIIA commented on fiduciary issues by discussing the recent Johnson & Johnson (J&J) employee-participant lawsuit filed against J&J (as plan sponsor) and the plan's fiduciaries (in their individual capacities), contending that J&J and the plan's fiduciaries breached their fiduciary duties by failing to prevent the plan from overpaying for covered benefits. We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specifically highlighted this lawsuit to explain that plan sponsors need access to a complete and accurate set of pricing and claims data so plan sponsors and the plan's fiduciaries can satisfy their fiduciary duties of acting prudently and adequately monitoring the plan's service providers. We encouraged the Committee to consider our recommended amendments to ERISA section 724 as a solution.

SIIA's RFI submission can be found here or you can request a copy from Anthony Murello at amurrello@siia.org.

SIIA will continue to keep members updated on any Congressional activity relating to ERISA. In the meantime, if you have any questions or if you would like to talk further about any ERISA-related issues, please contact Chris Condeluci(ccondeluci@siia.org) or Anthony Murrello (amurrello@siia.org). ■