

Exclusive Coverage of the

2023 ASEMBIA SPECIALTY PHARMACY SUMMIT

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Specialty Pharmacies Should Leverage AI Tracking to Increase Drug Delivery Efficiency

SKYLAR JEREMIAS

During a presentation at the 2023 Asembia Specialty Pharmacy Summit on leveraging technology in health care, speakers outlined how specialty pharmacies could use artificial intelligence (AI) tools to increase drug delivery efficiency and reduce operational costs.

The session, “Leveraging Technology to Improve Medication Delivery Performance,” featured data from a case study of how a specialty pharmacy reduced annual medication resend and product loss by more than \$2 million.

Kirk Nilson, CEO of ParcelShield, began by outlining some of the main business challenges that specialty pharmacies face, including increased expenses for package

(Continued on page 3)

Why Is Collaboration So Important in VBAs? Panelists Explain at Asembia 2023

HAYDEN E. KLEIN

In the rapidly evolving landscape of health care, the concept of value-based care has gained significant momentum in recent years. This shift toward focusing on the value delivered by providers rather than just the volume of services rendered has led to the development of various value-based agreements.

At Asembia 2023, a panel led by Erin Hulbert, MS, director of value-based contracting at Optum Life Sciences, discussed the importance of collaboration in creating successful value-based agreements (VBAs). Hulbert was joined by Mark Gimbert, vice president of specialty pharmacy and channel management at Takeda, and Alex Hindman, vice president of rebate strategy and account management at OptumRx.

(Continued on page 4)

ALSO IN THIS ISSUE

Removing the Taboo: Talking About Women’s Health Is the First Step to Improving Health Equity **5**

Q&A: Asembia Presenters Highlight the Role Payers, Providers Can Play in Growing Specialty Pharmacy Pipeline **6**

Julie Reed: The Status Quo for Biosimilars Needs to Change to Maintain the Industry **8**

IQVIA’s Luke Greenwalt on Increasing Payer Pressures: We Can Change the Path We’re on **9**

Q&A: Elizabeth Johnson Shares Why Empathy Is Missing From Patient-Centered Care **10**

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AI Tracking (Continued from page 1)

shipping, medication delays, and lost or missing packages. Additionally, a lack of proper proof-of-delivery documentation for every medication that gets dispensed can make it difficult to track how much is being spent on these issues and how often they happen. Overall, up to 25% of the packages that are delivered do not arrive on time. Nilson explained that carriers of drug packages need help and specialty pharmacies need protection.

“The [parcel] carriers over the last couple of years have experienced record poor performance and challenges, as we think about what they went through during the COVID-19 [pandemic] to how volumes have increased overall, like with all types of e-commerce, mail order, and brick-and-mortar stores.... As we think about the future, there are many things that the carriers will continue to face, whether it’s structural changes in their own organization or continuing to increase volume without the capacity to handle it,” Nilson explained.

Specialty pharmacies also struggle with knowing what geographic zones will be affected by weather events and being understaffed. Nilson noted that it’s more expensive to scale up a workforce than to leverage technology.

Pharmacies should have access to data on the number of total packages shipped, packages with issues, late packages, carriers with challenges, and carrier services’ level of inconsistency on a daily, weekly, and monthly basis. Parcel tracking technology that uses predictive analytics can help with real-time package delivery monitoring and ensure on-time delivery. Specialty pharmacies should also look into tools that can increase communication about drug delivery between providers and patients.

“One of the biggest calls that most customer service pharmacies get is the ‘Where’s my order?’ call. And so effective communication along the way can ultimately decrease the amount of these calls and keep your patients better informed

along the way. And then...having this insight to be able to take action, either prior to shipping or return shipping, will ultimately help the delivery performance as well. Because at the end of the day, the most important piece is that the patient is at the center of it all, and ensuring that the medication arrives on time is the price of admission of a specialty pharmacy,” Nilson commented.

AI and predictive analytics tools can aid pharmacies by:

- Identifying weather threats
- Accessing historical and real-time parcel carrier performance data
- Assessing pharmacy logistics
- Providing demographic data
- Understanding which states and zip codes are associated with consistent delivery levels
- Preventing reships/resends of medications and reducing product losses

Jessica Cooley, chief growth and customer officer at ParcelShield, outlined results of the case study, which found that when a specialty pharmacy leveraged drug delivery enhancement technology, it was able to increase overall profitability by avoiding \$2.4 million in product loss, improve shipping efficacy by improving planning across multiple origin sites, and improve patient satisfaction (measured via net promoter score).

In addition to AI, machine learning tools, and parcel distress forecast technology, Cooley recommended that specialty pharmacies look into the following strategies:

- Real-time scheduling decision support to provide shipping recommendations based on service deliverability and patient need-by date
- Intuitive scheduling dashboards
- Minimum workforce investment so as not to affect call center handle times and avoid the need for classroom training ●

Hulbert and Hindman started the conversation by explaining the partnership between Optum Life Sciences and OptumRx in creating successful VBAs. Serving as the point of contact for the pharmaceutical industry, OptumRx's industry relations team works to understand client pain points and identify VBA opportunities. This team then collaborates with Optum Life Sciences' team to negotiate and develop these agreements, utilizing their data methodology and ability to compile data from both pharmacy and medical benefits to create a more comprehensive understanding of both the patient and client. Through this partnership, they have been able to create what they called "some of the best compliance VBAs" in the industry.

“ The example illustrates how VBAs can benefit both patients and providers by focusing on outcomes that matter most to patients and by aligning the goals of all stakeholders who are involved. ”

Gimbert went on to speak about Takeda's approach to VBAs. He stressed that Takeda is patient focused and has a strong value system rooted in integrity, honesty, perseverance, and trust. To ensure that these values are at the forefront of decision-making, Takeda follows a governance model based on PTRB: patient, trust, reputation, and business.

“The order of that really matters because we follow that order in a sequential manner from left to right,” Gimbert said.

Takeda also believes in simplifying the VBA process to make it more applicable to the real world. By focusing on meaningful clinical outcomes and designing with a purpose, the company ensures that that it can start and finish the process while achieving the desired outcomes. Transparency is also a critical component of its VBA philosophy, and Takeda aims to share its modeling and predictions with partners to avoid any surprises.

“We want to have no surprises throughout the process, and I think that ladders over to trust,” Gimbert said. “We look at value-based agreements as long-term commitments with each other, and they're partnerships, not just transactions.”

By approaching VBAs with its core values and governance model in mind, Takeda has found success in making these agreements mutually beneficial for all parties involved.

Over at OptumRx, the goal is to align these agreements with expected or actual outcomes and maintain sustainability while

helping members and clients afford their medications. To achieve this goal, OptumRx formed a team that focuses on everything outside of the traditional agreement method.

“In the spirit of keeping the definition simple, our approach has been that each one of these agreements are often very highly unique,” Hindman said. “You can't come up with one deeper definition.”

When thinking about VBA criteria, OptumRx considers its clients' pain points, including high-cost or ultra-high-cost drugs, ensuring that clients pay a reasonable amount for the product when it works and receive a discount when it doesn't work. They also consider new products that come to market relative to what would have been the gold standard at the time, and they address gaps in products with highly variable dosing to create predictability for their clients.

So how do organizations align these philosophies when partnering with other organizations? Takeda does this by focusing on the main goal of patient centricity, considering what each organization can expect from each other and aiming to find alignment around their values.

In addition to values, practicality is essential in creating successful VBAs. Gimbert explained that part of their approach is focused on data, making sure to ask questions about whether the data are available and if they have the collective ability and resources to tap into them. In cases in which the necessary resources are absent, partnerships can leverage the expertise of other teams. By aligning their values and focusing on practicality, organizations like Takeda and their partners can identify problems early in the process and find solutions quicker, leading to increased opportunities for successful VBAs. Ultimately, this approach helps them to better serve patients and achieve their goals in providing affordable and accessible medications.

As an example, Gimbert and Hindman used hemophilia as an important disease that can be better served by VBAs.

Hemophilia A can lead to a range of complications, which can be more or less severe depending on the patient. One of the most common issues is breakthrough bleeds, which occur 4 times a year on average. However, in more severe cases, the frequency can be 3 to 4 times greater.

Focusing on this, Takeda and OptumRx partnered to create a VBA focused on the clinical costs associated with the drug and hospitalization costs for patients who need to undergo treatment for breakthrough bleeds. Gimbert said this partnership allowed Takeda to gain greater insight into OptumRx's population of patients with hemophilia A and demonstrate the value that the company's products bring.

The example illustrates how VBAs can benefit both patients and providers by focusing on outcomes that matter most to patients and by aligning the goals of all stakeholders who are

involved. By combining the perspectives and expertise of Takeda and Optum, the partnership was able to develop a practical solution that improved patient outcomes and reduced costs.

Hindman also highlighted that OptumRx's clients have members with hemophilia within their plans and that many of them are interested in understanding the relationship among hemophilia, medical costs, and treatment. Specifically, the focus of the partnership with Takeda is on the unexpected or unexplained bleeding events that occur despite a patient receiving appropriate hemophilia treatment, leading to increased medical costs and spending.

These unexpected bleeding events result in lost value for the client and the member, prompting the need to generate

meaningful information and data to understand the space better and put members and clients in a better position. This is why the team homed in on this issue to first understand the relationship, generate valuable data, and then develop a VBA that addresses the issue.

Now when a member experiences a bleeding event despite receiving appropriate treatment, OptumRx has partnered with Takeda to exchange value for clients, allowing them to better manage the costs associated with these unexpected events. The development of VBAs for hemophilia has the potential to improve the lives of those affected by this rare genetic condition and reduce the financial burden on both patients and health care systems, the panelists concurred. ●

Removing the Taboo: Talking About Women's Health Is the First Step to Improving Health Equity

SKYLAR JEREMIAS

Panelists at the 2023 Asembia Specialty Pharmacy Summit discussed the myriad of challenges that women face when they encounter the health care system and how these issues can be addressed to provide female patients more agency.

The panel, titled "Women's Health Inequity—Candid Conversations on Why Women & Health Should Be a Strategic Imperative," featured speakers from various areas of the health care sector who talked about how stakeholders can join forces to improve health equity for women.

Joanne Armstrong, MD, vice president and chief medical officer of women's health and genomics at CVS/Aetna, began by championing digital tools, saying that women are the dominant users of digital solutions but only 5% are targeted toward them. She also emphasized the role that gender biases play in health disparities, especially for women of color, and why topics predominantly experienced by women, such as menstruation, should not be considered taboo.

"It's just astonishing to me that the major life events for half of the population are so stigmatized that we cannot even say the word [menstruation].... If you can't say it, it represents stigma that gets carried into medical settings, educational settings, workplace settings. Clinically, if you can't say it, you don't present to say what your problem is. And there are tons of data that look at the delay and the medical costs associated with that," Armstrong said.

Additionally, discussion around women's health should extend beyond talking about menstruation and pregnancy to include all aspects of health, including mental health and

conditions that predominantly affect women, such as lupus and multiple sclerosis.

Stephanie Sassman, portfolio leader of women's health at Genentech, noted that researchers were not required to include women in clinical trials until 1993 and because women may have different gene expressions compared with men across major organs, the science community has a lot of catching up to do to understand how the body functions and the effects of treatments.

"If we're out looking at those effects and we're not really trying to understand that, we're not understanding women's health, but we're also not fully understanding men's health either. And so there's a business imperative, but there's also a health imperative. If we truly want to bring forward personalized health care, we cannot leave 50% of the population aside," Sassman explained.

She recommended that clinics and government agencies need to establish more partnerships to address major gaps in care for women and normalize discussions around women's health equity.

Diana Zuskov, associate vice president of health care strategy, LexisNexis Risk Solutions, noted that more than half of pregnancies in the United States are covered by Medicaid and most women with commercial plans get access through their male partners, which represents a huge differential in access to care for women. She also spoke about the social expectations placed on women to forgo medical care to take on family responsibilities and juggle multiple tasks, placing an extra burden on women to be the spokespeople for their own health.

“Where the solutioning really starts is [that health care organizations should be] taking the data and the evidence that have been built to proactively say, ‘You know what, we should be pushing our co-pay programs to women with these indicators of economic instability, and let’s just push that out and make that known to them in a proportionate way so that we don’t have to put the burden on the patient to be accessing these amazing solutions,’” Zuskov continued.

Regarding women who are a part of the transgender community, the speakers noted that more data are needed to understand how gender health gaps affect transgender individuals and get a better picture of which impacts on health and health disparities

are gender based vs sex based. They expressed hope that more research is being conducted.

The speakers expressed sympathy for women in states such as Texas and Iowa, where strict abortion bans have been signed into law and reproductive specialists are leaving their practices, and they advocated for people to vote during every election and reconsider whether to engage with businesses that are either ambivalent about or in favor of restricting access to abortion care.

“When we talk about abortion care, it is health care, it is medical care, that women need to be able to have access to,” Sassman said. ●

Q&A: Asembly Presenters Highlight the Role Payers, Providers Can Play in Growing Specialty Pharmacy Pipeline

INTERVIEWS BY SKYLAR JEREMIAS AND ASHLEY GALLAGHER

At Asembly 2023, *The American Journal of Managed Care* (AJMC®) spoke to 2 presenters about the ever-changing specialty pharmacy space. Between 2015 and 2021, the number of specialty pharmacies increased by 315%, with hospital- or health system-owned specialty pharmacies accounting for about a third of the total growth. Additionally, the specialty drug pipeline is expected to grow about 8% annually through 2025.

Ray Tancredi, RPh, MBA, CSP, divisional vice president at Walgreens, presented on the current specialty pharmacy pipeline and provided insight into how payers can make a difference in the space. Naveen Mansukhani, RPh, the director of operations and account management for retail pharmacy services at Cardinal Health, discussed some of the strategies (ie, value-based pricing tactics and leveraging data analytics) health systems are using to address the rising costs of specialty therapies.

AJMC: Which specialty drug approvals do you expect to have the largest impact in managed care in 2023, and what are these impacts?

TANCREDI: That’s a great question. I think the unmet need is NASH [nonalcoholic steatohepatitis]. So there are 2 products, [obeticholic acid] Ocaliva, currently approved for primary biliary cholangitis, and there’s also a product from Madrigal Pharmaceuticals called resmetirom. Ocaliva could be approved for NASH in June, so I’m looking forward to that, and then Madrigal’s product could be approved in September. So I know from a managed care perspective, 5% to 6% of the US population could actually have NASH. It’s a significant patient

population—12% of those could progress to cirrhosis. So these drugs are very important.

From a managed care perspective, pharmacy directors and medical directors have been awaiting these products. I don’t think it’s a surprise. I’m sure they’ve factored it into their per-member per-month costs, but nevertheless, very exciting from a patient perspective. It gives physicians the ability to treat this subset of the patient population and have some successful therapies so patients don’t progress to cirrhosis of the liver.

Additionally, we could see a couple of gene and cell therapies approved this year. And as you know, gene and cell therapies can cost in the millions of dollars. I think there are 2 drugs that are really important to follow that we could see approved. The first one is SRP-9001 for Duchenne muscular dystrophy. When you look at Duchenne, 1 in every 3500 to 5000 male births has Duchenne muscular dystrophy. So this really has an unmet need. Second, there’s a product called valoctocogene roxaparvovec [Roctavian], which is for severe hemophilia A, so it’s a subset of patients with hemophilia A. The product would be very expensive, but would really fill an unmet need in hemophilia. I think those 4 products, for the remainder of this year, I know that managed care will have their eye on.

AJMC: What are some other drugs and biologics in development? Do you anticipate any specific outcomes for these regarding their approval/use?

TANCREDI: A lot of the products that I named are in development. I think, though, if you look at the pipeline, there are a

significant number of drugs in general. Last year, there were 37 drugs approved and I think 20 of them were first in class. So if you're a managed care organization, I think that's something to keep an eye on.

There are drugs like [mavacamten] Camzyos, [deucravacitinib] Sotyktu for plaque psoriasis, and [nivolumab/relatlimab] Opdivalag for metastatic melanoma that were all significant improvements, first-in-class products. And again, I think that even this year, we'll see that again. Twenty of 37, or 54%, were first-in-class products and I know the pharmacy directors will keep their eyes on those drugs.

AJMC: Do you see any overarching trends or stark differences in the pipeline each year?

TANCREDI: It's remarkably consistent, the pipeline. However, cell and gene products are really beginning to take it over. In fact, when I did my presentation at Asembia, I broke it out into 5 sections. The first section was rare and orphan diseases. We know there are 7000 rare and orphan diseases, and only 5% of those actually have an FDA-approved drug. I think I covered [more than] 20 drugs in rare and orphan diseases that'll make an impact. Second, you have traditional specialty pharmacy drugs—still significant. I covered another 20 drugs in that area.

Oncology remains a large part of the business and in oncology, we had [approximately] 25 drugs that we were able to cover. And then, cell and gene therapies were an additional section.

And ultimately, I covered some approvals. There were some blockbusters last year in specialty pharmacy, maybe drugs like [efgartigimod alfa] Vyvgart for generalized myasthenia gravis, [mavacamten] from BMS [Bristol Myers Squibb], and even [deucravacitinib] from BMS that are really meeting unmet needs and could help patients on a large scale.

So far in 2023, we've had about 15 drugs approved. Of those, 12 are considered specialty pharmacy products.... And [over] the rest of the year, there could be 39 more drug approvals from the FDA, of which 28 could be specialty. So the pipeline is certainly robust. Even in oncology, we've only had 2 drugs approved so far this year, but over the last 10 years, we've seen about 13 drugs per year approved in oncology. When this year is over, I think we'll be very close to that number again.

AJMC: What roles do payers play in specialty pharmacy?

TANCREDI: Payers play a big role. When you think about what a payer will do for the specialty pharmacy industry, I look at a couple of things. They'll create a specialty pharmacy network that has the ability to dispense drugs to their plan sponsors and insurers. I think that's so important. They evaluate, they vet the pharmacies, they ensure that they can dispense the drugs that are required, and meet all the needs of that payer.

Second, they have the ability to adjudicate the claims for accuracy and the appropriateness of therapy, which is so important to the physicians, to the patients, and even to the pharmacists to ensure that the claims that they're submitting are paid in an accurate manner. So payers continue to be an important part of that specialty continuum.

AJMC: What strategies are health systems employing to combat the increasing costs of specialty drugs within their specialty pharmacy programs?

MANSUKHANI: It's really about employing a collaborative approach. It's not just a pharmacy problem of controlling costs. It's also patient navigators, the pharmacy department, the billing department, ensuring that things are getting billed properly before it's administered to a patient, where it ends up being a cost to the hospital.

AJMC: How are health systems leveraging data and analytics to identify cost-saving opportunities and make informed decisions regarding specialty drug pricing and procurement?

MANSUKHANI: This is where the importance of a specialty GPO [group purchasing organization] comes into play. Specialty GPOs can help with these data analytics and ensure that the hospitals are buying the best possible drug at the lowest possible cost.

AJMC: Are there any best practices or success stories of health system specialty pharmacy strategies that have effectively tackled the challenge of escalating specialty drug costs?

MANSUKHANI: Yes, many hospitals have employed strategies that [can help with], from a retail perspective, getting specialty drugs into the community, so—from the hospital into the community—ordering these drugs, and now, they become a revenue to the hospital vs just simply a cost. And that's where a specialty pharmacy strategy really makes sense and where hospitals are finding success. It also helps with the patient end-to-end approach where the hospital is able to work with patients on the outside when they become outpatients. It improves compliance, it improves outcomes, and it controls overall health care costs.

AJMC: What considerations should health systems keep in mind when implementing strategies to address rising specialty drug prices, such as patient access, quality of care, and patient outcomes?

MANSUKHANI: All of these [things I mentioned before] are part of that collaborative approach. It's a collaborative approach of the patient navigator on the floor down to the

person who's billing the claim down to the specialty pharmacy to ensure that the patient has the drug when they need it. And collaboration with a manufacturer or a co-pay savings card can ensure that the patient is getting [their medication] at the lowest possible price.

AJMC: How can health systems balance the need for cost containment with the imperative of ensuring patient access to lifesaving specialty drugs?

MANSUKHANI: Yes, so again, this collaborative approach and usage of the specialty GPO is very important for hospitals to collaborate to ensure that they're giving the patient the right

drug with the best cost containment strategy and also employing a biosimilar approach when those drugs are covered.

AJMC: What impact do emerging trends in specialty pharmacy, such as biosimilars and value-based pricing, have on health system strategies for combating rising drug prices?

MANSUKHANI: Biosimilars are very important. They will play an important role in the future in controlling costs. But payers also determine what drugs will be covered on a patient's health plan. Hospitals are really employing these specialty retail pharmacies to get the patient the right drug at the right time at the right price. ●

Julie Reed: The Status Quo for Biosimilars Needs to Change to Maintain the Industry

SKYLAR JEREMIAS

Amid anticipation that more adalimumab biosimilars will launch, market dynamics and pricing structures could make or break these products, Juliana (Julie) Reed, MS, executive director of the Biosimilars Forum, argued during "A Review of the Current Biosimilars Landscape: Updates & Opportunities Ahead," presented at the 2023 Asembia Specialty Pharmacy Summit.

“Payer coverage issues, rebate walls that incentivize prescribing the originator, and patent thickets continue to prevent biosimilar adoption and savings.”

In 2023, at least 9 biosimilars referencing Humira (adalimumab) are expected to enter the market after years of patent litigation cases that postponed launches. In January, Amgen's Amjevita became the first adalimumab biosimilar to enter the US market.

Reed started her presentation by emphasizing the role biosimilars can play in addressing health equity, saying that women, seniors, and low-income patients will benefit the most from biosimilar competition. Education efforts that target these patient populations are needed to increase access and adoption of biosimilars.

She went on to explain that although market competition has been useful in lowering drug prices, competition works

only where there is market access. In other words, having a lot of products on the market isn't always enough. Payer coverage issues, rebate walls that incentivize prescribing the originator, and patent thickets that keep products from entering the market despite FDA approval continue to prevent biosimilar adoption and savings. Of the 40 FDA-approved biosimilars, only 27 have entered the market.

Additionally, although adoption has grown significantly in well-established areas of the US biosimilars industry, such as the oncology space, growth stagnated in 2021 and 2022. Reed warned that without biosimilar adoption and subsequent savings, companies may reconsider whether biosimilars are worth the investment.

“What we're experiencing, why we as an industry are scratching our heads, is that we're not getting the cost savings or the market access and the uptake that we expected when we started this journey.... And if there's not a market to launch and to be successful in, it's a very high-cost proposition that companies are going to reconsider,” Reed said.

Reed noted how the pricing structure taken with Amjevita may influence pricing structures for all biosimilars to come. When Amgen launched the product, it used a dual pricing structure (one list price 5% lower than Humira and the other 55% lower, depending on the purchaser) for the purposes of gaining access to formularies and rebates while still offering employers cost savings. Reed predicted that more companies will take a similar approach and stressed that pharmacy benefit manager interference in formulary decisions is forcing this strategy.

Furthermore, the few payers that have publicized that they will cover adalimumab biosimilars have all said they will cover

only a few and put them on the same preference tier as the originator, limiting market competition and access for most adalimumab biosimilars.

Reed explained the ethical issue of step edits that require patients to “fail first” using the originator before being prescribed a biosimilar, saying that officials at the FDA with whom she has spoken agree with her.

“If a patient clinically failed on the reference product and the biosimilar is FDA approved to be the same safety, quality, and [efficacy], why would the physician ever give the same product to the patient?” Reed asked.

Reed concluded her talk by saying that things need to change at the industry and policy levels in a way that prioritizes patients

over profits and back-end rebates. She especially noted the Biologics Price Competition and Innovation Act (BPCIA), which was passed as part of the Affordable Care Act and established the biosimilar regulatory framework.

“The status quo for biosimilars cannot continue if there is to be a biosimilars industry. What’s really important about [the BPCIA] is the first authorization by Congress giving and authorizing the FDA to create competition through regulation of a new competitive market. If this one fails, what one is ever going to [work]? And you’re seeing wonderful new innovations, but if you continue to have no competition, the cost for the access to any of these new innovations is going away,” Reed declared. ●

IQVIA’s Luke Greenwalt on Increasing Payer Pressures: We Can Change the Path We’re on

HAYDEN E. KLEIN

In his day 1 session at Asembia 2023, “State of the Payer: Payers, Patients, Policy, and Pressure in 2023,” Luke Greenwalt, MBA, vice president of market access at IQVIA, guided the crowd through trends affecting demand and margin and led the discussion on the path toward success over the next decade.

“As we look over the next decade, the climb is going to be steep, it’s going to be challenging, but success is still possible,” Greenwalt said.

He first highlighted the significant margin compression that has occurred in the industry over the past 10 years, including a striking trend in which the collective discounts paid by the top 15 pharmaceutical manufacturers increased by 265% between 2012 and 2021. This growth rate of discounts is 7 times faster than gross sales, which grew by 36%, and 13 times faster than the rate of inflation, which grew by 21%.

In terms of percentages of gross sales during this time period, discounts increased 114%, while selling, general, and administrative expenses dropped by 29% and operating profit dropped by 30%. Investment in research and development remained fairly consistent, dipping by only 1% over the decade. This investment is crucial for the development of innovative therapies, which Greenwalt expects to enter the market in greater numbers than ever before over the next decade. According to him, this is reason for optimism in an industry facing significant pressures.

He also noted that the 340B program, which is used to offer discounted products to covered entities and hospitals, is growing rapidly, with \$105 billion moving through the 340B channels in

2022—more than the entirety of the Medicaid drug outpatient program. Starting at \$57.6 billion in 2018, 340B total dollars increased between 9.9% and 14.6% annually, growing more year after year. In the next 5 years alone, Greenwalt anticipates this number could hit \$200 billion, creating even more pressure.

Greenwalt then discussed trends in compound annual growth rate and how they affect the industry. There has been major growth in the industry over the past decade, with top-line drug spending increasing from \$418 billion in 2013 to \$858 billion in 2022. However, margin pressures are also increasing, with a projected 44% margin in 2027. This decline in net sales is happening for several reasons, including increased rebate pressures and increased co-pay card offset costs.

Additionally, high-cost product launches have doubled in the last 4 years. Recent launch brands are also 5 times as likely to fail to hit \$10 million in the first year of sales, with only 1 in 4 patients new to the brand who attempted to fill the brand being successful, largely because of payer controls. Also, as many as 70% of newly launched brands are supported by manufacturer assistance, and co-pay cards are becoming increasingly important to the success of a launch. The launch window is now between 18 and 36 months, and capitalization and investment are required to find success.

There is also a rising trend of launch products priced greater than \$200,000 per year per cost of treatment, with a total of 53 products launched in the past 3 years alone at this price point.

“The question that this begs isn’t whether or not one of these products is worth it,” Greenwalt said. “Often, these are lifesaving

products where there are no other alternatives for a patient to turn to for treatment. The question becomes how does the system pay for all of this? That's where we see the rising controls happening not just on these products, but broadly, as the system struggles to get in front of these rising trends."

He also stressed that payer control of new launch products continues to increase over time, making it harder for brands to turn patient demand into volume and making patient access to medications more and more challenging. According to Greenwalt, it is "becoming much more difficult to have a successful batting average today than it has been at any other point that we've ever measured."

Market data show that it is now twice as difficult to achieve the same patient demand as it was in 2015. Manufacturers are consequently turning more frequently to patient support programs, with some giving away up to half of the market value of their launch products. According to Greenwalt, payer controls are a major factor, with 85% of patients facing them in the commercial market on United Caremark Express Scripts. There is also evidence of pervasive controls in classes such as HIV immunology, oral oncology, multiple sclerosis, and hepatitis.

Formulary exclusions leave 90% of patients unable to access the medications they require, and patients now are 22% less likely to fill a prescription after 30 days compared with only a few years ago.

Greenwalt advised a shift in focus from patient centricity to patient forward, recognizing that patients face a series of hurdles and that their journeys must be better understood and segmented in order for providers to intervene effectively.

The health care industry invested a record-breaking \$19 billion in co-pay programs in 2020 to help patients manage affordability challenges. A third of this investment, nearly \$6 billion, came

from accumulator adjusters and co-pay maximizers. Without these programs, the co-pay costs would have been significantly lower, at approximately \$1.5 billion. The industry's investment in these programs has resulted in increased utilization of free goods, which cost more than \$2 billion in full-cost items in 2020. A recent report examined these programs through a health equity lens and found that patients who are least able to afford their co-pay programs are the most exposed to accumulator adjusters and co-pay maximizers. Notably, non-White patients were found to have a 30% higher probability of being exposed to these programs compared with White patients.

"This is a health equity claim that everyone in the industry needs to be aware of," Greenwalt emphasized.

Data suggest that patients who use co-pay accumulator adjusters and maximizers experience negative impacts on their health and that understanding patients' journeys is essential to identify barriers to treatment adherence. In 1 data set, financial hurdles were found to be the primary obstacle for one-third of patients from the start of their treatment. Intervening early in a patient's journey has a significant impact on their ability to adhere to prescription treatment.

Policy changes, such as the Inflation Reduction Act, have a significant impact on the health care industry, as brands may move toward price discounting because of net negative pricing and Medicaid, high margin pressure in commercial channels, and the potential to be selected for negotiation of maximum fair price from CMS. The impact of these policy changes can be seen in the market, and it is essential to keep an eye on these trends.

"We need to challenge ourselves and challenge the vendors that we work with to bring together some of these new innovative ideas on how to address some of these changes," Greenwalt said. "We can change the trajectory and the path of where we're going." ●

Q&A: Elizabeth Johnson Shares Why Empathy Is Missing From Patient-Centered Care

INTERVIEW BY SKYLAR JEREMIAS AND ASHLEY GALLAGHER

Elizabeth Johnson, LPN, PACS, BPCA, the CEO of MedicoCX and co-CEO of Healthcare Advocate Summit, presented at Asembia 2023 about how patient trust in the health care system is in jeopardy and how more patient-centered and empathetic approaches can improve quality of care and provide better insight into the patient experience. *AJMC* interviewed her at the conference.

AJMC: How can empathy play a role in drug development, marketing, and delivery, and why is it considered the missing link in health care?

JOHNSON: I think understanding empathy vs sympathy is a really big deal. Empathy is what we want to strive for; we want to make people feel comfortable. But I think we need to hire and bring in the right people to deliver that.

I was talking about this earlier with someone: When you see an ad for mental health, it's always somebody with a hoodie pulled up over their head looking really sad. And sure, that catches your attention, but that's not always what depression looks like. I think to really home in on empathy, we need to be empathetic to these disease states and what's going on and appeal to the masses in a way that's appropriate for all. I personally don't

like the [imagery of] patients with cancer singing and dancing, walking down the beach with their hair blowing in the wind. That's not really what they're going through. We need to portray it from both sides, right? Both the positive and the negative.

AJMC: What are the potential consequences of a lack of empathy in drug development, marketing, and delivery? How can it affect patient outcomes and trust in the health care system?

JOHNSON: With patients having access to social media—you've got TikTok, Instagram, and all of that—there's so much information out there and there's so much that a patient can digest quickly. But the empathetic part, the part that matters, is really where the dollars will come in, because when a patient is prescribed a new medication, the first thing they do is hit Google or social media looking for that. And that can lead to prescription abandonment if they're scared by what they find or what they see. So, making sure that they have something that is sensitive to all walks of life, while still being relevant and appropriate, is really what needs to happen.

AJMC: How can patient-centered approaches and empathetic communication positively influence patient engagement, adherence, and satisfaction in the context of health care?

JOHNSON: First, we have to take true patient-centric approaches and really let the patients speak and put them first. Right now, that's really hard to find. When you watch a commercial, it'll say "actual patient" or "not actual patient," so we're not appropriately displaying the patient's perspective. By having that and by supporting that, good or bad, if a medication didn't work for a patient, that's OK because what that then shows is the patient went back to their provider, communicated that something didn't work, and then went on to something else.

So, I think highlighting both the positive "Hey, this worked for me, I'm better," but also, "I communicated with my provider," that shows a real patient-centric health care focus from both the manufacturer standpoint and the provider standpoint.

AJMC: What are some practical approaches that can be employed to ensure that patient preferences, values, and perspectives are considered in drug development and delivery, and how can empathy be integrated into these processes?

JOHNSON: The No. 1 thing is bring the patient in. Have the patient involved from the very beginning. In research and development, that's tough, but start asking the patient: "If our outcomes are this, what does that look like to you? How does that make you feel?" And continue that through the journey. Advisory boards are a great way to bring patients in at multiple steps throughout

the process and get their thoughts and opinions on what is being developed. I think with that empathy component, patients will feel attached to the product or to the brand. And then, word of mouth spreads from there. If 1 patient feels comfortable, another patient will go to them, and then lots of patients [will]—it trickles down. So yes, bring them in early.

AJMC: What are some real-world examples of successful integration of empathy-building strategies in drug development, marketing, and delivery? What lessons can be learned from these experiences?

JOHNSON: My favorite is YouTube and social media. For years I followed this patient [with spinal muscular atrophy], Squirmy [Shane Burcaw]—that's what he goes by—Squirmy and Grubs. He and his wife [Hannah Aylward] have partnered [with Genentech] for one of [the company's] products. They do a phenomenal job highlighting the challenges of the disease state but also the support of the manufacturer and what that does for them.

“ I think we need to go beyond the patient-is-first mentality and actually put the patient first and then show relationships beyond the patient. Maybe it's the patient and their financial navigator, the patient and their biologics coordinator, or nurse, or pharmacist. ”

They make it relatable. There are daily "what's going on," "getting ready with us," and "what challenges we face traveling" videos. I think that's probably my best example of where research-and-development partnerships between patients and a manufacturer have been shown. I like being able to see real people doing real things, and a manufacturer backing that up because that's where their best outcomes lie.

AJMC: What are the ethical considerations related to empathy in health care, including issues such as cultural sensitivity, diversity, and inclusion? How can they be addressed in drug development, marketing, and delivery?

JOHNSON: Right now, we as a health care organization just in general look at equity and diversity as almost checkboxes. Do you have someone from this ethnic background? Do you

have someone from this socioeconomic category? Really, the top problem with all of this is people are afraid to have the conversation. If I have a patient of a different race ask me a question, I may not know the answer, but I can't be too squeamish or shy to say, "I know of an organization that can do that." Right? "I may not be of the same race, but I know someone who is. Let me connect you."

So instead of it being weird or awkward, we really need to embrace that diversity and we need to make better connections out there. So when a patient comes to me and has a question—[an example is that] in the African American population, asthma affects more individuals—and I can't relate, but I know an organization that can, I have no problem saying, "You can get your information from them because they're more qualified than I am." I have no problem saying that to support that patient. And so I think we need to stop making it awkward. We need to stop making it a buzzword, because yes, equity, diversity, we know all this—let's just actually make real relationships out of it.

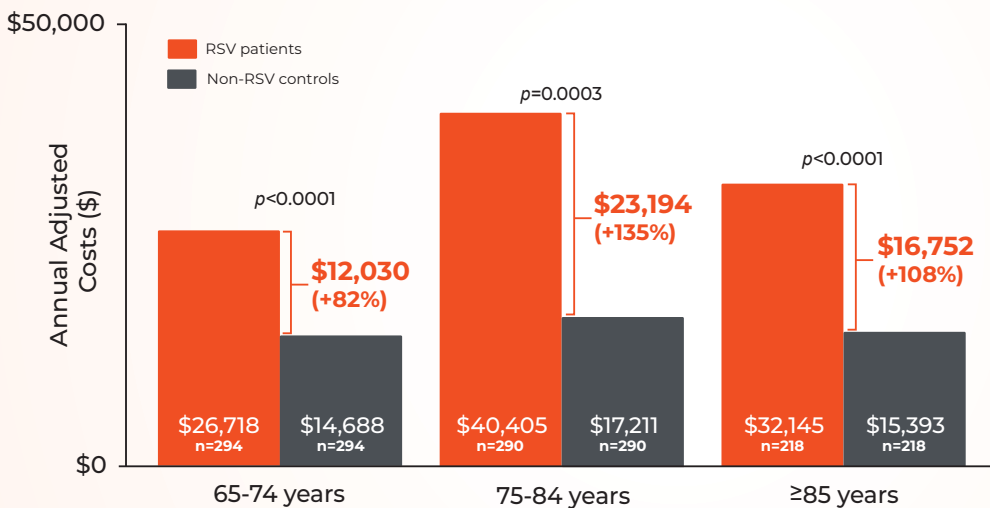
AJMC: How can collaborative efforts among patients, health care providers, industry representatives, policymakers, and other stakeholders be fostered to create a health care ecosystem that values trust and empathy in drug development and delivery?

JOHNSON: I think we need to go beyond the patient-is-first mentality and actually put the patient first and then show relationships beyond the patient. Maybe it's the patient and their financial navigator, the patient and their biologics coordinator, or nurse, or pharmacist, or whatever else you want to put between the provider and the patient. All of those roles are so essential in showing this relationship. It's almost like a pyramid. We put the patient first, the support staff second, then we've got our providers, and then we've got our manufacturers and pharmaceutical companies, and we show that without one, you don't have the other. We connect them all together to really show what that collaboration looks like. ●

DON'T LET **RSV** RAISE THE STAKES FOR YOUR OLDER ADULT MEMBERS AND YOUR PLAN

Each year in the US, approximately 177,000 adults 65 years and older are hospitalized due to respiratory syncytial virus (RSV) infection¹

Adjusted Annual Healthcare Costs Among Patients With RSV and Matched Controls^{2,*}



Adults 65 years and older with RSV may have

\$12,030
to
\$23,194

in additional healthcare resources annually compared with those without RSV

*A retrospective case-control study (N=11,432 in each group) used patient data from Truven Health MarketScan[®] Commercial Claims and Encounters, and Medicare Supplemental and Coordination of Benefits databases to identify patients aged >1 year with an RSV diagnosis between August 31, 2012 and August 1, 2013. Patients with RSV were matched 1:1 with controls based on age, sex, region, health plan, and index date. Adjusted annual healthcare costs among patients with RSV and matched controls were measured during the follow-up period, with costs adjusted to 2014 US dollars. Associated costs were computed for each resource category and included inpatient, ED, ambulatory, outpatient, and prescription medications.

RSV is a common and contagious virus that typically produces mild, cold-like symptoms but can put older adults at risk for severe outcomes.^{3,4}



To learn more about the risks of RSV in older adults, visit [RSVinAdults.com](https://www.rsvinadults.com)

ED=emergency department.

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