

EHconnect



KENT STATE
UNIVERSITY

discovery and success

Member Spotlight KENT STATE UNIVERSITY

The Value
of a Healthy
Workforce

WHAT PLAN
SPONSORS NEED TO
KNOW

Our Q&A with Kimberly Hauge
Director of Employee Wellness

→ 20

OptumRx: Helping you harness the power of pharmacy

Employers' biggest concerns



SPECIALTY DRUG COSTS

Average annual industry trend in specialty costs **exceeds 21%** over the last three years¹



CONSUMER ENGAGEMENT

78% of employers cite **lack of engagement** as a top obstacle to a successful health and wellbeing program³



FRAGMENTED CARE

Poor health care coordination nearly **doubles the cost** of patient care²



OVERALL COST INCREASES

Total health care costs have **increased 82%** over the last ten years⁴

Beyond traditional pharmacy benefit management

At OptumRx®, we take a fresh approach to pharmacy benefits. One that uses our data, technology and leadership across the entire health care system to promote better care and deliver value. We help our clients manage not just pharmacy spend but clinical outcomes and medical spend, too. The result: smarter health care, easier system navigation and healthier outcomes.

PHARMACY BENEFIT MANAGEMENT

- Formulary and drug cost management
- Specialty pharmacy
- Clinical and utilization programs
- Network management
- Member services and adherence
- Home delivery



PHARMACY CARE SERVICES



smarter



easier



healthier

Delivering value where others can't

Together with Optum®, we bring the scale, resources, knowledge and perspective to transform pharmacy benefit management.



1.2
billion

prescriptions
processed



80
billion

total pharmacy
spend



65
million

pharmacy
members served



20
thousand

physicians
and nurses



180
million

lives of
claims data

To learn how OptumRx can help you use pharmacy care services to drive better outcomes and lower costs, please email Jason Quillin, area vice president, sales, at jason.quillin@optum.com or visit optum.com/optumrx.



1. Holcomb, Katie and Harris, Justin. Milliman Research Report – Commercial Specialty Medication Research: 2016 Benchmark Projections – December 28, 2015. | 2. Brigham R. Frandsen, PhD; Karen E. Joynt, MD, MPH; James B. Rebitzer, PhD; and Ashish K. Jha, MD, MPH, Care Fragmentation, Quality, and Costs Among Chronically Ill Patients; American Journal Managed Care, May 2015. | 3. Improving workforce health and productivity – U.S. Report, Willis Towers Watson, 2016. | 4. The Future of Health Calling All Employers: Be Agents of Change - Highlighting results from the 2015 Aon Hewitt Health Care Survey.

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2017 Meetings & Events

Stay ahead with Employers Health and save these dates!

You can always find our events calendar at www.employershealthco.com/events

**Employer Members only*

OCTOBER 10

STRATEGIES TO IMPROVE MENTAL HEALTH IN THE WORKPLACE – OHIO

EMPLOYERS HEALTH
CANTON MEETING CENTER
8:30 - 11 AM

OCTOBER 25

STRATEGIES TO IMPROVE MENTAL HEALTH IN THE WORKPLACE – MICHIGAN

RADISSON PLAZA HOTEL AND
SUITES, KALAMAZOO, MICHIGAN
8:30 - 11 AM

NOV 30

EMPLOYERS HEALTH ANNUAL MEMBERSHIP MEETING

OPIOID EPIDEMIC AND THE OPTUMRX STRATEGY
DAVID CALABRESE, CHIEF PHARMACY OFFICER
AND SENIOR VICE PRESIDENT AT OPTUMRX

THE CONFERENCE CENTER
KENT STATE UNIVERSITY AT STARK
8-10 AM

DECEMBER

HOLIDAY MEMBER LUNCHEONS*

DECEMBER 6

J Liu Restaurant
Worthington, OH
12 - 1:30 p.m.

DECEMBER 7

Glenmoor Country Club
Canton, OH
12 - 1:30 p.m.

DECEMBER 8

Ken Stewart's Grille
Akron, OH
12 - 1:30 p.m.

DECEMBER 12

The Crush House
at Gervasi
Canton, OH
12 - 1:30 p.m.

DECEMBER 13

Bravo
Cincinnati, OH
12 - 1:30 p.m.

DECEMBER 14

Brookside Country Club
Canton, OH
12 - 1:30 p.m.

DECEMBER 18

Delmonicos
Independence, OH
12 - 1:30 p.m.

CINCINNATI
OHIO PBM
CONFERENCE

SAVE THE DATE

MAR 29

CINCINNATI, OH

CANTON
ANNUAL
BENEFITS
CONFERENCE

SAVE THE DATE

MAY 16

CANTON, OH
KENT STATE UNIVERSITY AT STARK

**Employer Members Only*



Message from Chris

With just a few months left in 2017, it is exciting to reflect on the year so far. This year has brought significant changes to the organization that continue to benefit our membership.

We started the year with 29 new members and more than \$1 billion in pharmacy spend. At the time of this publication, we have added 25 new member organizations, enabling our organization and its members to benefit from the collaborative group spend of more than 400 organizations with 3 million lives in all 50 states.

Also this year, we launched Benefits Accelerator, opened our new Canton headquarters and added three team members to serve our growing membership. As our organization continues to grow, we uphold our commitment to provide resources, tools and advice to help plan sponsors provide access to high-quality health care benefits at a sustainable cost.

The 2016 Employers Health Annual Report focused on the theme of growing stronger, together. As the team at Employers Health grows, we continue to provide additional access and expertise for navigating the complex relationship between an employer and its Pharmacy Benefit Manager (PBM). With the added value of an account management representative overseeing your specific plan, programs and initiatives, we are able to enhance the experience of both the plan and its participants.

Our two newest account managers come to us with specific education in health care and pharmacy to assist you in navigating the relationship with your PBM and other ancillary vendors. Taylor Nervo joins us with prior health care experience working as a clinical trial manager. She obtained her bachelor's degree in biology and most recently, her masters in health care administration and management from Colorado State University. Eric Chen is a recent graduate of Ohio Northern University, where he majored in pharmaceutical and health care business.

Rounding out our new hires so far in 2017 is Michael Ell, covering business development in the western and northwest portions of the United States. His health care industry experience includes serving as an audit

associate for an accounting firm serving non-profit health care entities and as treasurer and finance chair for the New Mexico Healthcare Executives. He is also board certified in health care management as a Fellow of the American College of Health Care Executives.

The addition of these three professionals to an already exceptional team helps us to achieve our mission to provide resources, tools and advice to help plan sponsors provide access to high-quality health care benefits at a sustainable cost.

Finally, we work to keep you and your organization informed on the latest developments in the benefits industry. In this issue of EH Connect, you can learn the business value of a healthy workforce from Consulting Medical Director Bruce Sherman, MD; what employers need to know about biosimilars and why from Associate Counsel Garrett Brown, JD; the latest developments in gene therapy from Director of Pharmacy Matt Harman, PharmD, MPH; and an insightful look into the Employers Health book of business from Chief Marketing Officer Mike Stull.

As always, we thank you for your confidence in our team as we help you navigate the complex industry of employee benefits.

Christopher V. Goff
CEO & GENERAL COUNSEL

Welcome to our newest members!

Archdiocese of Atlanta	Institute of Electrical and Electronic Engineers
Buyers Products	JFK Health
CBIZ	Knoll, Inc
CentraState Healthcare System Inc	Loyola University of Chicago
City of St. Charles School District	Matrix Medical Network
City of Surprise, Arizona	Ohio Health Choice
DHS Group	OneAmerica Financial Partners, Inc.
Elkhart Community Schools	Pohanka Automotive Group
Emergency Medicine Associates	Robertson Heating Supply Co.
Express, Inc.	Sandusky City Schools
Garrett County Employees Health Care Plan (GCEHCP)	Shipco Transport Inc.
GGPLP REIT Services, LLC	Winnebago County, IL
Hanover County, VA	

A BIOSIMILAR PRIMER AND REGULATORY UPDATE: What Plan Sponsors Need to **KNOW**

WRITTEN BY: **GARRETT BROWN, JD** // Associate Counsel

In late June 2017, the Supreme Court issued a 9-0 opinion in *Sandoz v. Amgen*, an opinion that can be seen as a win for biosimilar drug manufacturers. This decision presents an excellent opportunity to provide a refresher on what a biosimilar drug is and why plans need to keep abreast of any developments in this industry.

A rudimentary way to describe a biosimilar is that it is a generic specialty drug. An understanding of how generic and biosimilar medications come to market is important. While similarities exist, the unique nature of biologics and the relatively recent regulatory scheme for their entry into the market resulted in *Sandoz v. Amgen*. This article will provide a summary of what a biosimilar drug is, a biosimilar drug's path to market, an overview of *Sandoz v. Amgen* and how plans should respond.

What is a biosimilar?

Biological products include a wide range of products, such as vaccines, blood components, allergenics, gene therapy and recombinant therapeutic proteins. In contrast to small-molecule non-biologic drugs that are chemically synthesized and their structure is known, most biologics are large-molecule drugs created by complex mixtures and processes that are not easily identified or characterized. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other

cutting-edge technologies. The development of a large molecule drug is a risky and costly process for a manufacturer. Figures vary, but the cost to develop these products may exceed a billion dollars and may take more than 10 years to complete.

PLAN SPONSORS HAVE BEEN
IMPACTED BY SOME OF THESE
HIGH-COST PRODUCTS AS PART
OF THEIR SPECIALTY SPEND.

While a concrete definition of a specialty drug is a moving target, most biologics are deemed specialty drugs, but not all specialty drugs are biologics.

A biosimilar product is a biological product that is approved based on showing that it is highly similar to a Food and Drug Administration (FDA)-approved biological product, known as a reference product. It has no clinically meaningful differences in terms of safety and efficacy from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

A biosimilar's path to market

For small-molecule drugs, the Hatch Waxman Act (HWA) of 1984 governs the FDA approval process for generic medications and creates a pathway that allows generic drugs to be approved based on their bioequivalence. The HWA expedited process allows a generic manufacturer to forgo clinical trials to demonstrate safety and efficacy of its bioequivalent products. As discussed below, the biosimilar approval process may appear similar to the approval process for a generic small-molecule drug, but while a biosimilar drug needs only to be highly similar, a generic small-molecule drug must demonstrate that its active ingredients, strength and dosage form are identical.

In the face of significant growth in the biologic space and an understanding that a biosimilar medication is not identical to its reference product, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) as part of the Affordable Care Act (ACA). The BPCIA creates a regulatory framework designed to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. While the FDA-licensed reference product is provided with market exclusivity for 12 years and an additional six months if the product is approved for pediatric use, the BPCIA's abbreviated process allows the applicant to piggyback on the showing made by the manufacturer of a previously licensed biologic.

As the reference product nears the end of this exclusivity period, manufacturers seeking to introduce a biosimilar product begin an application process under the BPCIA's abbreviated pathway. The applicant must provide notice to the reference product manufacturer within 20 days of the date the applicant is notified by the FDA that its application has been accepted for review. Following this notice, the applicant and reference product manufacturer exchange information so that the reference product manufacturer can identify if any intellectual property has been inappropriately copied by the applicant. Despite the lapse of the exclusivity period, the reference product manufacturer may hold multiple patents covering the biologic, including the processes used to manufacture it. These patents may constrain an applicant's ability to market its biosimilar

even after the expiration of the exclusivity period. This nuance represents the need for an alternative pathway.

In anticipation of the need to address these intellectual property issues, the BPCIA then channels the parties into two phases of patent litigation. In the first phase, the parties collaborate to identify patents for immediate litigation. Upon the applicant's notice to begin marketing the biosimilar commercially, the second phase is initiated and involves any patents not litigated in the first phase. The applicant's notice of commercial marketing is required to be provided to the reference drug manufacturer not later than 180 days before the date of the first commercial marketing of the biological product. Failure to comply with the regulatory construct allows the reference drug manufacturer to bring immediate litigation for declaratory action and litigate any patent infringement issues that would otherwise be off the table under the BPCIA construct.

Sandoz v. Amgen

A reference drug manufacturer reading the BPCIA, prior to *Sandoz v. Amgen*, may assume that it would have an additional six-month window from the time a biosimilar product is licensed until the biosimilar product is commercially marketed. This timing was challenged in *Sandoz v. Amgen* and ultimately argued before the Supreme Court earlier this year. In this court case, Sandoz, a generic pharmaceutical company, sought a license from the FDA to market Zarxio, which is a drug used to help the body make white blood cells after receiving cancer medications. Zarxio is a biosimilar of Amgen's drug, Neupogen. However, Amgen contested what it believed to be Sandoz's failure to comply with the BPCIA process because Sandoz (1) did not provide application and manufacturing information to the reference manufacturer and (2) provided its notice to market concurrently with the application and prior to obtaining a license from the FDA to manufacture its biosimilar product. Regarding the first issue the court held only that a federal court could not grant an injunction to Amgen, the reference product manufacturer, that would require Sandoz's information be turned over to Amgen. It deemed this disclosure to not be mandatory following application if the applicant did not wish to utilize the BPCIA process. In the second issue, the court held that an applicant may provide notice before obtaining approval.

Certainly, one can see the desire of Sandoz to not share its application and manufacturing information with the reference manufacturer, especially if its product and manufacturing processes may be the subject of litigation outside of the BPCIA's framework. Moreover, one can recognize its desire to commercially market its product as soon as possible. Conversely, one can appreciate when a reference product manufacturer seeks to vigorously protect its intellectual property and delay the entry of a competitor into the market. In the face of a pipeline full of biosimilar drugs, these dynamics will likely give rise to more legislation in the future.



Despite the lapse of the exclusivity period, the reference product manufacturer may hold multiple patents covering the biologic, including the processes used to manufacture it. These patents may constrain an applicant's ability to market its biosimilar even after the expiration of the exclusivity period.



What does all of this mean for plan sponsors?

This ruling signals that some biosimilar drugs may be coming to market prior to what some may otherwise have anticipated, especially in situations where there is no patent infringement and the FDA approval process takes more than 180 days. As with the small-molecule generic drugs, savings from a single biosimilar entrant may be initially limited, but this entry is only the beginning of downward cost pressure as additional entrants enter the market. In the face of accelerating specialty drugs, any downward cost pressure will be welcome relief for plan sponsors.

From a medical management perspective, it is important to understand if a plan sponsor's medical plan administrator is engaging with physicians to educate and ensure that any value from biosimilar drugs can be realized by the plan and its participants. As physician payment arrangements are generally based on a percentage of average sales price, physicians are faced with little incentive to evaluate and administer biosimilar medications over their reference product counterparts. For example, in 2016, the FDA approved biosimilar, Inflectra, which is approximately 10 to 15 percent cheaper than its reference product, Remicade. It is important to understand how the medical vendor is addressing the entry of biosimilar drugs and promoting the use thereof.

From a prescription benefit management perspective, this ruling is another example of the complexity that exists in the prescription drug marketplace. The complex supply chain that supports this market must carry on and proceed in the face of such uncertainty. This compounds the need to understand the bigger picture and how the prescription drug market operates. While this complexity is nothing new, it emphasizes the need to approach this market in a very different manner than other health and welfare benefits. The ability to quickly respond to these market changes will be important to capture the value that biosimilars offer. This response must take the form of plan sponsors ensuring that their plan designs and contracts are able to respond to such entries. From a plan design perspective, this necessitates the need to have an actionable plan to incentivize the use of these medications. From a contracting perspective, this reinforces the value of a market check provision that allows a prescription drug services contract to be renegotiated and adjusted based on market conditions. Ultimately, having the correct partner is the key to managing this complex and shifting landscape.

References:

1. <https://www.americanbar.org/> | 2. <https://www.fda.gov/> | 3. <http://www.npr.org/>

HOURS OF CONTINUING EDUCATION

9 HOURS OF CE CREDIT OFFERED THROUGH THE OHIO DEPARTMENT OF INSURANCE

6 HOURS OF CLE CREDIT OFFERED THROUGH THE SUPREME COURT OF OHIO

10 HOURS OF CREDITS FROM HRCI



24

EVENTS

18 | 6
IN PERSON | VIRTUAL

47

EVENT SPEAKERS



2017

EVENTS RECAP

As members of Employers Health, organizations and their benefits professionals gain valuable knowledge at our numerous learning and networking opportunities offered throughout the year. Here are just some of the highlights of member events so far this year:



"Employers Health went above and beyond as always and put together a truly top-notch event. This was the best conference so far. I enjoyed each speaker and found the full day to be of value."

600+

EVENT ATTENDEES

22

SPONSORS





COMING SOON:
MILLION DOLLAR DRUGS –

How can employers prepare for gene therapies?

WRITTEN BY: **MATTHEW HARMAN, PHARM.D, MPH** // Director of Pharmacy

A new age of medicine is upon us, and it comes in the form of personalized gene therapy. Recent developments have pushed the single-dose, potentially curative treatments with high projected price tags closer to launch. Thus, the benefit design and coverage for engineered genes to treat, prevent and cure diseases are a rapidly growing concern for plan sponsors preparing for the pharmaceutical pipeline.

At the start of 2017, more than 500 gene therapies were in active development with roughly 95 percent yet to reach Phase III trials. Still, it appears by mid-January of 2018, the FDA may approve two types of groundbreaking genetic therapies. Both are made and administered in vastly different ways, but they share alarming projections of near-term budget implications for employers using our current payment models. *The long-term potential savings from curing conditions, such as cancer, blindness, hemophilia and more, has many in the medical community anxiously awaiting approval.*

It is important to appreciate the basics of genes and therapies targeting them to understand why high prices are expected and why new payment options should be considered.

What is gene therapy?

Comprised of DNA, genes give the instructions to make the proteins necessary for cells to function properly. When a gene mutation occurs, the proteins may be made faulty or not at all, which could lead to genetic disorders. The goal of gene therapy is to use normal gene copies as drugs to compensate for the malfunctioning or missing protein(s), which can be performed in two different approaches: in vivo or ex vivo.

In vivo gene therapy involves transferring correctly functioning genes to specific cells inside the body through delivery vehicles called vectors. This is the approach Spark Therapeutics is using for its gene therapy, Luxturna™ (voretigene neparvovec), which treats a rare form of inherited blindness (Leber's congenital amaurosis with RPE65 mutation) that impacts about 1,750 Americans. The one-time injection appears to be a cure for more than 90 percent of patients in Phase III trials, with a low side effect profile. With the FDA giving Luxturna a priority review date of January 12, 2018, plan sponsors are awaiting the proposed pricing scenarios and should be seeing if their medical carriers can determine if any participants have the specific blindness diagnosis (a small subset of ICD-10 code: H47.22).

Other uses of in vivo gene therapy in development have broader patient populations with expensive chronic pharmacy and medical costs, such as cystic fibrosis, hemophilia and cancer. Introducing "anticancer" genes to create tumor suppression proteins are still in the early stages of clinical trials, but an ex vivo cancer gene therapy was approved for a form of leukemia on August 30, 2017, which comes in the form of chimeric antigen receptor T-cell, or CAR-T, therapy.

CAR-T therapy is considered ex vivo (Figure 1) since a patient's cells are sent to a manufacturer and modified for implantation back into the patient with the goal of curing the disease. During the FDA Oncologic Drugs Advisory Committee meeting, the first CAR-T therapy, known currently as Kymriah™, was called "probably the most exciting thing I've seen in my lifetime" by Timothy Cripe, chief of hematology and oncology at Nationwide Children's Hospital in Columbus, Ohio. That is because Kymriah™ sent 83 percent of children and young adults into remission with B-cell acute lymphoblastic leukemia (ALL) who had exhausted all other treatment options, which impacts about 600 Americans annually. ALL is just the beginning when it comes to future uses of CAR-T therapy. Other blood cancers are being treated in trials with CAR-T as well as solid tumors in the breasts, lungs and brain, which may require multiple injections.

It is imperative to note that these genetic cancer treatments are intended for patients with refractory or recurring cancers. This is not only due to costs, but also to the significant safety concerns associated with gene therapy, especially CAR-T that has shown collateral damage by creating a super-charged immune system. In general, patients will need to remain hospitalized for at least one week to monitor for toxicity to therapy. High fever and flu-like symptoms, sometimes severe enough to require ICU admission, due to cytokine release syndrome, actually indicates a positive response to therapy but can require administration of specialty medications, such as Actemra®, to control.

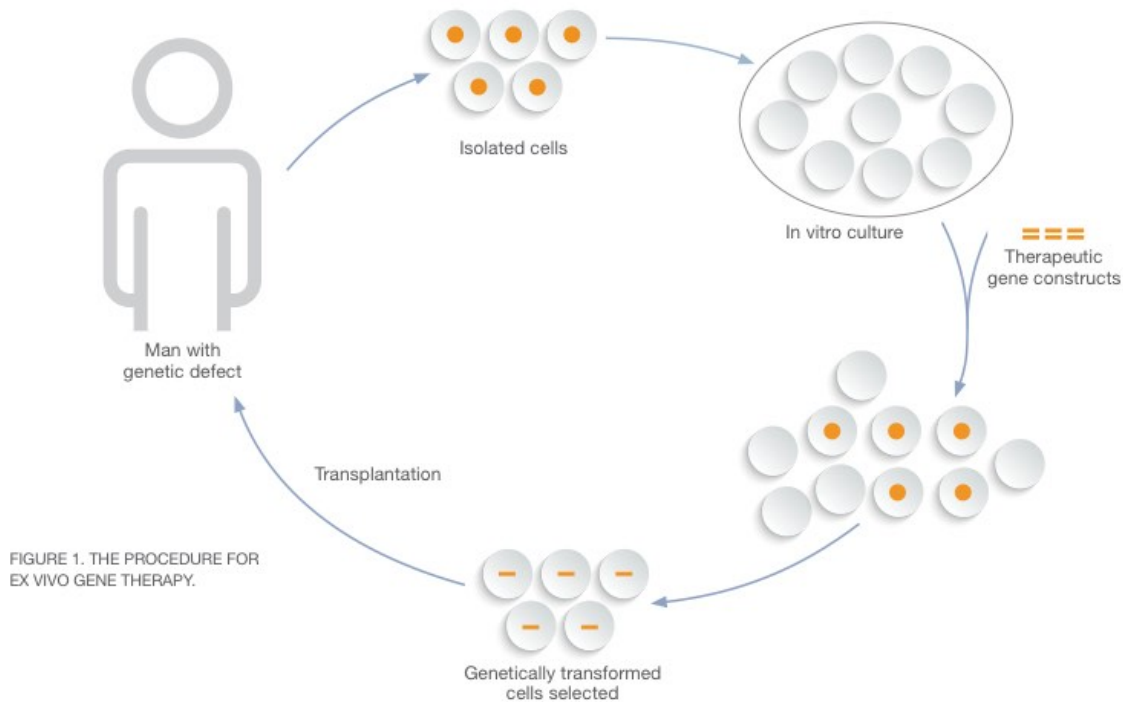


FIGURE 1. THE PROCEDURE FOR EX VIVO GENE THERAPY.

The costliest expected side effect could be B-cell aplasia, which are low or absent B-cell levels needed to protect against infections, caused by CAR-T cells wiping out both cancerous and normal B-cells. Every patient in the Kymriah™ trials acquired B-cell aplasia, and it appears to be permanent, which must be treated monthly with intravenous immunoglobulin that can cost payers tens-to-hundreds of thousands of dollars annually. The permanence of developing the chronic, costly condition seems to be avoided by the other CAR-T products in development, such as KTE-019 for non-Hodgkin's lymphoma that could be approved in late November 2017.

How can employers manage gene therapy?

Over the next decade, it appears gene therapies will begin to take a foothold in the treatment of rare, genetic conditions with the potential to expand to more common conditions, such as diabetes or Alzheimer's disease. The excitement surrounding these therapies is understandable, but so is the trepidation of payers who will be footing the bill for treatments that may cost over \$1 million for each eligible patient. To reduce those fears, below are vendor strategies available today, as well as potential payment models that may apply if vetted properly.

Current Vendor Strategies

>> **FIRST**, start discussions with your medical carriers about how they plan to handle the complexity of gene therapies and ensure cost-effective usage. For example, the ex vivo therapies take weeks to develop for a specific patient and encompass different procedures at multiple locations. The billing and procedural codes should be optimized to represent the full cost of care as well as to best facilitate alternate payment methods. Perhaps more importantly, usage for unapproved diagnoses should not be billed back to the payer. Ask your medical vendor how they plan to protect your plan from this situation (e.g. prior authorization, limits based on severity).

>> **ONCE** a new gene therapy is approved, self-insured employers with carved-out pharmacy benefits may see communications from their PBM to block these drugs from processing under the pharmacy benefit in order to ensure medical benefit administration. If you do not receive these types of emails currently for drugs with complex administration (e.g. Spinraza™), discuss this with your PBM and/or consultant to guarantee the plan is protected from suboptimal dispensing of costly therapies best suited for the medical benefit.

>> **REVIEW** your stop loss policy to see if gene therapy coverage has limitations or is excluded altogether. Theoretically, stop loss carriers may try to laser patients for conditions with pending gene therapy diagnoses as well.

Payment Options

THE STATUS QUO – Depending on the size of the plan, an approval of one gene therapy at a single-dose may be sustainable with the current payment system. However, manufacturers must demonstrate the economic value of avoided medical and drug costs by treating patients with each gene therapy to minimize the rationing and barriers to access similar to what happened with hepatitis C medications. Drug makers should also consider the downstream impact of potential side effects due to treatment (e.g. B-cell aplasia) when determining costs and value to payers.

OUTCOMES-BASED CONTRACTING – Also known as pay-for-performance or value-based contracting, this philosophy has gained momentum with the rise of expensive specialty medications that can be thought of as a warranty between the manufacturer and the payer. A refund, typically in the form of rebates, or payment by the drug maker for additional rounds of treatment could be made if the initial gene therapy fails. Implementing this type of contracting has been a challenge, especially for employers, due to the extensive operational requirements as well as the desire to contract for chronic medications, which leads to less reliable monitoring of outcomes. The gene therapies that cure a condition with one administration may make this more feasible for employers with competent medical carriers.

PAYMENT INSTALLMENTS – Spreading out the costs of gene therapies in the form of annuities either by months or years may be best for budgeting purposes and easier to implement than outcomes-based contracting. Ideally, the two strategies could be combined, so that all stakeholders come out ahead. One concern is that a manufacturer would launch at a higher price tag to increase its rate of return. Determining what happens when a treated patient leaves the plan would also need to be addressed.

As the field of gene therapy evolves, so will the strategies and payment models. No matter the payment system, the fragmentation of our health care system will still pose its challenges. As seen with hepatitis C, payers may not realize the full financial benefit from paying for cures, especially for those employers with high employee turnover rates. However, some conditions, such as hemophilia and cystic fibrosis, with gene therapies in the pipeline could benefit immediately based on their current medical and pharmacy treatment costs. The question is: Will the therapies be priced appropriately with the patients and payers in mind over profits? Plan sponsors should take the steps to protect themselves now in the chances they might not like the answer.

For reference information or to discuss further, please contact Matt Harman at mharman@employershealthco.com.

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IN-FOCUS: A SNAPSHOT OF THE PHARMACY BENEFIT INDUSTRY INCLUDING EMPLOYERS HEALTH'S BOOK OF BUSINESS MID-YEAR TREND

WRITTEN BY: MIKE STULL, MBA // Chief Marketing Officer

The pharmacy benefit marketplace has been at the center of attention lately due to a combination of factors, including the growing list price of brand medications and the impact their prices have on the participant, particularly those enrolled in high deductible health plans. The outrage over Mylan's price inflation of its EpiPen® product fostered an array of news articles, television interviews, congressional hearings, campaign promises and finger-pointing among pharmacy supply chain stakeholders.

The pharmaceutical supply chain is complex both by necessity and design. Distributing medications, including temperature-controlled biologics, from the manufacturer to the patient necessitates a mechanism that provides adequate patient access and uncompromised quality and safety. Given the unique distribution channel and the imperfect market, stakeholders have also designed a system that maximizes revenues and profit at the expense of patients and plan sponsors. While the stakeholders in the supply chain point fingers, plan sponsors should recognize that nearly all members of the system benefit when prices increase.

However, price inflation is nothing new. In a *Health Affairs*¹ article penned by former United States Senator David Pryor from 1990, it was noted that prescription drug prices, as measured by government price index data, soared 88 percent between 1981 and 1988, a rate three times faster than the rate of general inflation. The article also cited a study at the time that price increases explained 97 percent of the increase in overall national prescription drug expenditures from 1980–1987. Since then, prices have continued to rise, fueled by a broad number of factors.

The point?

The anecdotes provided by most pundits who write or speak on pharmacy benefits and the pharmacy marketplace may be contributors to the problem, but no single action by any single player can be characterized as the overall cause. The system we have today is the result of decades of action and inaction, and everyone shares some of the blame.

What's the fix?

There clearly isn't a simple fix, but employers and other plan sponsors can start by identifying and acting on those things that they can control. For example, plan sponsors can't control what list price a pharmaceutical manufacturer assigns a product. It can control, however, how it contracts for those products, including the negotiated discount off list price and manufacturer rebates. Plan sponsors can also adopt more limited formularies and implement more restrictive clinical criteria for drugs that offer little clinical value at high list prices, even when they come with large rebates. Pharmacy cost trends are a result of changes in both price and utilization, and there are numerous strategies plan sponsors can take that are within their control. The key is to execute on fundamental contracting and plan design strategies before trying to tackle the entire delivery system.

2017 MID-YEAR TREND

Evaluating trend can be tricky business. Like any prudent analysis, an important aspect of evaluating pharmacy trend is to put the data within context. One way to do this is by looking at all data using a common denominator, such as per member per month (PMPM). First half gross trend for the Employers Health book of business (BOB), before application of rebates, increased by \$1 PMPM, which equates to about 1.2 percent. The gross PMPM for the BOB tends to have a higher PMPM than the general marketplace given the mix of active employees versus retirees within the population, along with a higher incidence of chronic diseases such as diabetes.

34.5% of the population in the Employers Health program used the benefit in the first half of the year, versus a market average of around 32 percent.



TRADITIONAL
product brand price
inflation up
▲ **9.3%**

SPECIALTY
product brand price
inflation up
▲ **9.8%**

GENERIC
product price
inflation was nearly
FLAT

ANTI-DIABETICS
\$15.70
IN PMPM COSTS

ANTI-INFLAMMATORY
\$14.44
IN PMPM COSTS

Both classes saw double-digit price inflation during the first half of the year.

**TRADITIONAL
BRANDS COST**
\$48
PMPM

**SPECIALTY
DRUG COST**
\$40
PMPM

**TRADITIONAL
GENERIC COST**
\$24
PMPM

The Generic
Dispensing Rate (GDR)
CLIMBED TO
86.4%

References:
1. D Pryor A prescription for high drug prices Health Affairs 9, no.3 (1990) 101-109 doi: 10.1377/hlthaff.9.3.101



Connecting the Dots: What's the business value of a healthy workforce?

WRITTEN BY:
BRUCE SHERMAN, MD, FCCP, FACEOM //
Consulting Medical Director

Human resources (HR) departments, and more specifically the benefits function, have traditionally been viewed as organizational cost centers, responsible for managing benefits costs. But this is now changing. There is increasing recognition of the fact that strategic investments in the health of the workforce can have a meaningful impact on not only health care costs, but also workforce performance and the business bottom line.

Until the last decade, the organizational perception of the business impact of a healthy workforce was effectively limited to the potential for lower health care costs. Within the past 10 years, health-related absence and presenteeism – being at work but not fully productive – are now recognized as additional sources of business impact, though not typically incorporated into value considerations. This is likely due to the fact that absence data is frequently siloed and unavailable for integration with health-related data. Additionally, with more widespread use of paid time off, it can be difficult to differentiate health concerns from other reasons for absence. Within the past few years, there has been a growing interest in the business value of health. It's relatively easy to make an intuitive argument that a healthier workforce is more productive. If one accepts that assumption, it is then easy to appreciate that improved workforce productivity has the potential to lead to greater business profitability.

Let us take a step back and address the concept of well-being. This is a broad term that encompasses several dimensions, including physical well-being, emotional well-being and financial well-being. Impairments in any of these dimensions can lead to poor on-the-job performance. For example, if someone is in great health but has



major financial concerns, they'll likely be preoccupied with their financial issues and less attentive to work. In fact, research tells us that these individuals may lose 20 percent or more of their work capability – a day a week – due to distractions by financial issues. So, high levels of well-being can be considered as a desired attribute for employees; free from preoccupations of health, financial or other concerns, they're able to fully engage and perform their work.

In fact, this association has been convincingly demonstrated by Healthways, a company on the Employers Health credentialed list of health and wellness vendors. Figure 1, below, depicts the relationship between individual well-being scores and manager assessment of individual performance. As shown, higher well-being scores are associated with a higher manager performance ranking.

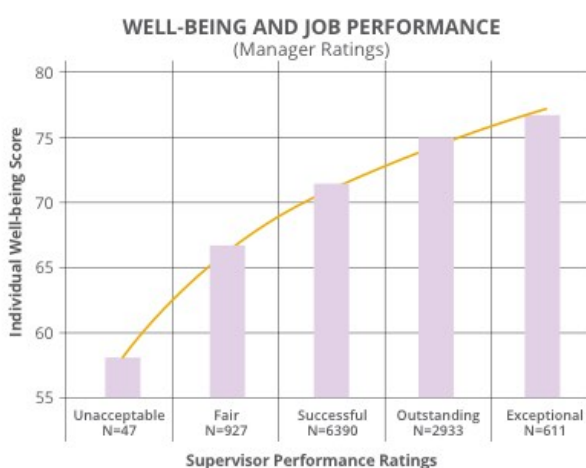


FIGURE 1. ASSOCIATION OF WELL-BEING AND MANAGER RATING OF JOB PERFORMANCE. Source: Healthways, Inc. Used with permission.

So, if individual well-being is associated with individual performance, then it seems reasonable to assume that aggregate or workforce-level well-being is then associated with workforce performance – and therefore, business performance. And while this may be a rather simplistic view, published reports show a compelling link between company investments in health and shareholder return, as shown in Figure 2.



FIGURE 2. IMPROVEMENT IN PORTFOLIO VALUE OF COMPANIES WITH A CULTURE OF HEALTH COMPARED WITH S&P 500 PORTFOLIO VALUE. Source: Faltus RJ et al. *Journal of Occup. Environ. Medicine*, 2013.

Getting back to the title of this article, human resources personnel can change the dialog with the C-suite by showing how the organization's expenditures on workforce health and well-being can effectively be translated into improved business performance.

But this may not be easy. A 2012 survey of 240 CEOs performed by The Economist found that managing benefits costs is one of the primary responsibilities that CEOs expect of their human resources departments. In order for CEOs and the rest of the C-suite to appreciate HR as a strategic business partner, objective data that links individual health and well-being to business performance will be necessary.

What is interesting is that the necessary data elements are already available for most employers to demonstrate this relationship. Most human resources personnel have some level of quantitative performance evaluation for their workforce, and many also have either health risk assessment scores or risk scores from medical claims data. These datasets can be merged – with the appropriate HIPAA considerations – to evaluate the link between individual health/well-being risk and manager performance evaluation.

An additional step that employers can take is to link the above reports to business performance data. Every organization collects some type of performance data, whether revenue, quality metrics, market share, customer satisfaction or other variables. Human resources personnel can identify which of these are perceived as important by the C-suite, and generate reports to link health/well-being risk with these business measures. The results are likely to cast a new light on the business value of health. Figure 3 shows the relationship between work quality and employee health care costs at many large (>2,000 employees) manufacturing facilities. Note that increases in health care costs are associated with greater impairments in work quality.

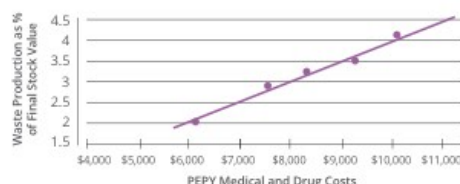
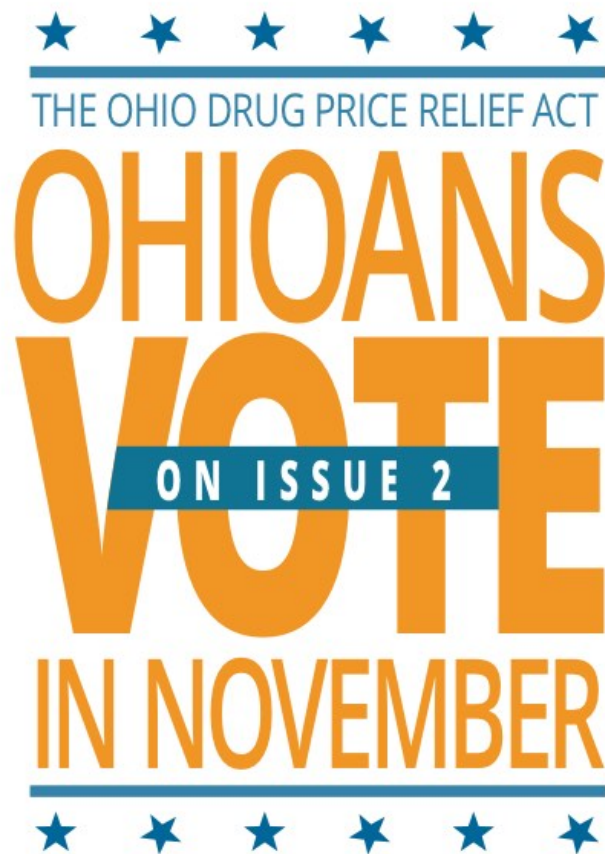


FIGURE 3. ASSOCIATION OF MEAN ANNUAL EMPLOYEE HEALTH CARE COSTS WITH WORK QUALITY. Source: Sherman BW, et al. *American Journal of Managed Care*, 2014.

Understanding the relationship between worker health and business performance is not simply an academic exercise. With this approach, employers can better understand the business impact of workforce health concerns, and transform their thinking to make investments in workforce health and well-being that can lead to improved business performance. Simply put, instead of viewing health benefits as a line-item expense, employers can make their benefits strategy an important contributor to the business bottom line. For human resources personnel reading this commentary, consider sharing this article with your leadership team, and explore considerations for next steps.



THE OHIO DRUG PRICE RELIEF ACT

OHIOANS VOTE ON ISSUE 2 IN NOVEMBER

WRITTEN BY: **CHRISTOPHER GOFF** // CEO & General Counsel

This November, Ohioans will be asked to vote on Issue 2, a statewide ballot initiative.

This initiative is referred to as "The Ohio Drug Price Relief Act." The title of the proposed legislation and the campaign advocating for its success make claims that the legislation will protect Ohio taxpayers from the corporate greed associated with pharmaceutical companies. While most Ohioans will agree that the costs of prescription medications are too high and pharmaceutical companies seem to be making more money, Issue 2 is not the solution that Ohioans so desperately want.

Voters may be shocked to hear that the proponents of this act are actually a small, special interest group based in California with little stake in the outcome of this vote.

Despite its clever name, Issue 2 will not provide any of the relief it claims for most Ohioans. We encourage you to educate yourself on the impact that this legislation will have on the access and cost of prescription drug care for Ohioans and vote "No" on Issue 2.

If Issue 2 is passed, public entities and public programs will be required to purchase medications from the pharmaceutical companies at or below the price paid by the U.S. Department of Veterans Affairs.

Federal law generally requires pharmaceutical companies to provide their medications to the U.S. Department of Veterans Affairs (VA) at a price that is 24 percent below the average manufacturer price paid by wholesalers.

Proponents of the legislation argue that everyone ought to be able to purchase prescription medications at the same cost as the VA.

However, the VA's steep discount on prescription medication is based on several unique factors, including its ability to purchase medications directly from pharmaceutical companies. The initiative fails to address a key issue; the initiative mandates what prices the public health insurance programs can pay for the prescription medications, but pharmaceutical companies would be under no obligation to sell their products at prices set by this initiative. This could result in Ohioans being unable to obtain necessary medications under their state funded prescription plan.

Despite its clever name, Issue 2 will not provide any of the relief it claims for most Ohioans.

Private and public entities often work in collaboration to combine their purchasing power to leverage pharmaceutical prices.

If passed, Issue 2 will limit the role that public entities can play in this collective and directly impact the bargaining power of both public entities and private companies in negotiating pharmaceutical prices. Representatives from Veterans Affairs have voiced their own concerns that this initiative could end up costing the VA an extra \$3.8 billion because of the necessity of manufacturers to increase what will become a benchmark price.

Public insurance programs include government-funded health care and employment-based insurance offered to state and local government employees and make up approximately 35 percent of all coverage in the state.

If pharmaceutical companies are forced to sell their products at drastically reduced prices to 35 percent of their consumers, they will make up for their losses by increasing the prices they charge to the other 65 percent of Ohioans who have private health insurance. In shifting this burden, individuals with private insurance will see an increase in their insurance premiums and co-pays, essentially causing private companies to indirectly subsidize state funded prescription plans.

Moreover, any litigation subsequent to Issue 2 passing, must be funded by Ohio taxpayers.



— EXCELLENCE IN — **BENEFITS** — AWARD —

presented annually by Employers Health,
seeks to recognize an individual who has
made a meaningful impact in the field and/or
delivery of employee benefits.

Nominations will open November 13, 2017, and close on January 31, 2018.
The 2018 award winner will be announced at the Employers Health
Annual Benefits Conference in May.

AWARD OBJECTIVES

- > Recognize contributions of an outstanding individual in the field of employee benefits.

EVALUATION PROCESS

The evaluation process will be as follows:

1. All submissions will be anonymous (e.g., submitter and company information redacted) and sent to an evaluation panel for review.
2. All submissions will be reviewed and scored. The panel will rank submissions based on their contribution to the delivery of employee benefits.
3. The highest ranking submissions will be evaluated by the Employers Health Evaluation Committee to determine the winner.

HOW TO SUBMIT

Only Employers Health Members are eligible to be nominated. The following information should be included in each submission:

- > **General Information** – For both nominator and nominee, please provide name, title, company, phone number, email address and affiliation.
- > **About the Nominee** – Describe why the nominee should be recognized and the impact he/she has made in the field/delivery of employee benefits (500 words or less).
- > **Achieved Outcomes** – (e.g., improved health outcomes, realized savings, innovative ideas) Please be specific about the level of cost savings, process improvement, etc. Outline the achieved outcomes in 500 words or less.
- > **Industry & Civic Contributions** – Please provide details on any contributions the nominee has made to advance the profession of employee benefits and/or the betterment of the overall workplace.
- > **Supporting Documentation (optional)** – Feel free to provide any additional information or documentation that will be helpful to the review panel regarding nominee.


**Deadline is
January 31, 2018**

If you have any questions about
this award or the process, please email
mmiles@employershealthco.com.

**We look forward to receiving
your submissions!**

**Submit nominations and learn more
at benefitsaward.com.**



Member Spotlight

Kimberly Hauge

DIRECTOR, EMPLOYEE WELLNESS,
KENT STATE UNIVERSITY



With a challenge from its president to be the healthiest university in the nation, Kim Hauge, director of employee wellness at Kent State University in Kent, Ohio, has worked to develop and implement a strategic plan for employee well-being for a university of more than 6,000 employees and 40,000 students. Working toward that goal, the university was recently named One of the Most Active Employers in the Nation by the Wellness Council of America (WELCOA).

How long have you been in HR and where did you get your start?

I have worked in human resources at Kent State for 17 years total. Prior to coming to Kent State, I worked with two major insurance carriers and another institution of higher education. That prior insurance and leadership experience proved valuable in landing and leading in various positions at Kent State, which include benefits, talent acquisition, project management and communications and employee wellness.

What is your current role with the university and how/why did you get involved in the employee benefits industry?

As director for employee wellness, I am part of the Benefits and Wellness Department within Human Resources at the university. As I indicated previously, I came to Kent State with several years of experience in the insurance industry, particularly in property and casualty, health, life and disability claims management. After relocating to Ohio from New York, I discovered a benefits opening at Kent State and applied. That prior insurance experience proved beneficial in stepping right into the benefits position at Kent State. From there, I continued to grow my understanding of other aspects of human resources, led several special projects and really became acutely interested and passionate about workplace wellness, and how a comprehensive strategy could “bend the trend” in the cost of providing health benefits to the workforce.

Over the years, I’ve seen the changes and challenges that employers face in trying to provide value-added benefits to employees without breaking the bank. Employers have tried MCO, HMO, PPO and High-Deductible options to help control costs. We’ve also seen more and more cost-sharing on behalf of employees. What made more sense to me than anything, is focusing on prevention and well-being. Let’s face it, if you are not incurring the expense your cost share will go down! Prevention is the best medicine and that’s where focusing on workplace well-being, as part of the benefits strategy, can help. Not to mention the recruitment, retention and productivity benefits that can also benefit the employee and the organization.

How does your organization approach health benefits and overall well-being for your employees?

Kent State has been steadfast in their commitment to preserve employee health benefits while seeking other ways to provide health care benefits more efficiently and cost-effectively. This is an area that Employers Health has been key in assisting us with through its pharmacy benefits management with CVS. The savings we gain from the group purchasing arrangement with CVS allows us to offer a richer benefit level for our employees without adding cost. In fact, that savings, goes right back into benefits and wellness programs for our employees and is one of the reasons we can offer such a robust wellness program to our faculty and staff.

Another aspect that allows us to stand out from the rest is looking at employee health and well-being on a very holistic level. We are looking to provide programs, partnerships and resources that treat the whole person. We put a strong emphasis on preventive care, self-care resources and programs, and addressing mental health.

We also work hard to sustain health benefits and employee well-being by being great collaborators, both internally and externally. As employee wellness director, I am able to reach out to my peers in our Student Recreation and Wellness Center for great opportunities to develop yoga and other group exercise programs, call on other administrators or faculty to take us for a “walk and talk” or “Flashfleet” bike ride, or call up dining services to design nutritional lunch and learns. This is how we will become one of the healthiest campuses in the nation, and we are well on our way!

Our employees and others tell us we are moving in the right direction. Kent State was recently recognized for its commitment to providing a strong value for its employees by the Chronicle of Higher Education by receiving the “Great College to Work For” award, for the eighth time. This recognition has come as a specific result in how the employees of Kent State University have rated the university for its benefits and compensation. Kent State was the only Ohio higher education institution in the State of Ohio to be recognized for this prestigious award.

When it comes to human resources, benefits, and wellness, how does your organization define success?

Put as simply as possible, we measure our success through our ability to attract and retain employees. We work to ensure we are offering a highly-valued total rewards package to our employees and their covered dependents. From a wellness perspective, we track engagement and value through employee participation numbers and satisfaction surveys. Our annual culture survey enables us to see, hear and compare employee perceptions around wellness year-over-year. We also seek recognition for employing best practices and have received multiple awards from the American Heart Association for a Healthy Workplace (gold and silver) as well as an Innovators Award, that we are exceedingly proud of!

From your perspective, how have wellness offerings changed and evolved?

Wellness is becoming more holistic in nature. Previously, the emphasis was mainly on weight control and physical activity. Wellness is really evolving to incorporate the whole person, including mental, physical, spiritual, social and financial well-being. At Kent State, we approach wellness from the employee's vantage point, letting them pick their path. We call it "Wellness Your Way," allowing employees to choose programs and self-care options they would like to work toward.

We are also seeing more and more employees start to have the conversation around mental health in the workplace, a long overdue conversation. As human resource professionals and leaders, we need to recognize that if one's mental health is suffering, so will their physical and work life. We have embraced the Right Direction educational initiative brought to our attention by Employers Health, and its relationship with the Partnership for Workplace Mental Health, a program of the American Psychiatric Foundation.

Right Direction equipped us with the platform and tools to talk about mental health freely within the workplace, thereby decreasing the stigma and secrecy around talking about mental health. It's really been an impressive cultural shift amongst our employees and they love the tools and the bear that has become associated with the initiative. We can't dare show up at a benefits or wellness event without Right Direction! In addition, we have been able to track the engagement in mental health resources through our Employee Assistance Program and our health and pharmaceutical costs, and the results demonstrate that we have employees reaching out for help sooner, practicing better self-care and having better health outcomes. We love Right Direction and the door it has opened for our employees and leaders!

How has Kent State been innovative in delivering health care benefits?

Kent State consistently evaluates our benefits for value added and sustainability. As I referenced previously, the goal is to try to maintain benefits, minimize costs and seek innovative ways to do so. One of those innovations includes working with Employers Health and reaping the benefits of group purchasing for pharmaceutical coverage. Employers Health holds the PBM to a high standard, while allowing us to implement our own plan design and strategies for pharma coverage. Through this type of partnering, we are able to take those savings dollars and turn them directly back into the benefits and wellness budget.

Rebates are like that holiday bonus check we didn't know was coming. We take these funds and look at how we can benefit the largest number of employees and align that with our strategic approach to wellness.

What are your thoughts on the future of employee benefits, particularly as they pertain to wellness?

I think you will continue to see insurance companies and other vendors incorporate more wellness into their benefits design as employers and purchasing groups hold them accountable for supporting wellness versus managing illness. In addition, it is my hope that employers will recognize that benefits design and wellness design are not separate silos. Employee benefits design should be "part of" a benefits, wellness and productivity management strategy. And, if leadership wants to see a cultural shift toward well-being, they need to be present and engaged in that process. They cannot simply delegate culture. They must demonstrate it.

"Wellness is really evolving to incorporate the whole person, including mental, physical, spiritual, social and financial well-being."

What advice would you give an organization interested in developing a wellness program?

Workplace wellness is hard work. You cannot simply impose healthy living onto someone. What you CAN do is help to create an environment where someone may WANT to engage in healthy living. Know it is sometimes very lonely and counteract that by finding other champions within and outside the organization. Know and study best practices in workplace well-being and stick with best practices. It's important to not allow the noise in the background to derail you. You'll often be a department of one, so you need to be focused, and make sure you have good partners like the National Wellness Institute, WELCOA and Employers Health, who will help to support and refuel you. And, at the end of the day, you are seeking to build an environment where employees can thrive. If you are sincere and they see and feel that in you, they will come. If you are not, they will know.

How long have you been engaged with Employers Health?
We joined Employers Health in 2002.

What value do you derive/perceive by being part of an organization like Employers Health?

We value our relationship on many levels. First, we can sustain better benefits through the purchasing power of Employers Health. We appreciate the opportunity to stay up on the latest news and best practices in addressing our benefits challenges and learning how other employers overcome these challenges. In the world of human resources and benefits, the advice and mutual understanding of where we're trying to go is invaluable. Employers Health's mission aligns easily with what we are trying to do – which is to create highly valued benefits and resources, establish sustainability and minimize challenges and barriers.

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For more information about Transform Diabetes Care, contact your CVS Health Account Team.

¹ Source: CDC.gov

*Our program employs several cost containment and clinical strategies to help produce additional savings. While the guarantee will vary by client according to plan population demographics and other programs implemented by the client, an employer client's current spending on these diabetes drugs, and other factors, we have developed the program to help clients reduce trends for diabetes drugs to single-digit.

**Based on a model 100,000 life commercial client population and CVS Health analysis. Actual savings will vary based upon factors such as demographic changes, plan design changes, and law/regulation changes). Source: CVS Health Analysis, Gilmer et al., Diabetes Care, (2005), CDC Prevalence Data.

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Listen to our new podcast to learn about *trends, developments, changes* and other topics of interest in the employee benefits world from Employers Health's Senior Director of Marketing, Marcas Miles. Submit your questions and topics of interest for a chance to have them addressed in future editions.

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Northeast Ohio Office
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Canton, OH 44718
330.305.6565

Central Ohio Office
5775 Perimeter Drive, Suite 100
Dublin, OH 43017
614.336.2883

Southwest Ohio Office
9032 Union Centre Blvd, Suite 202
West Chester, OH 45069
513.889.3952

Dallas Office
1777 North Record St.
Dallas, TX 75202

Denver Office
PO Box 13885
Denver, CO 80201
303.586.7315