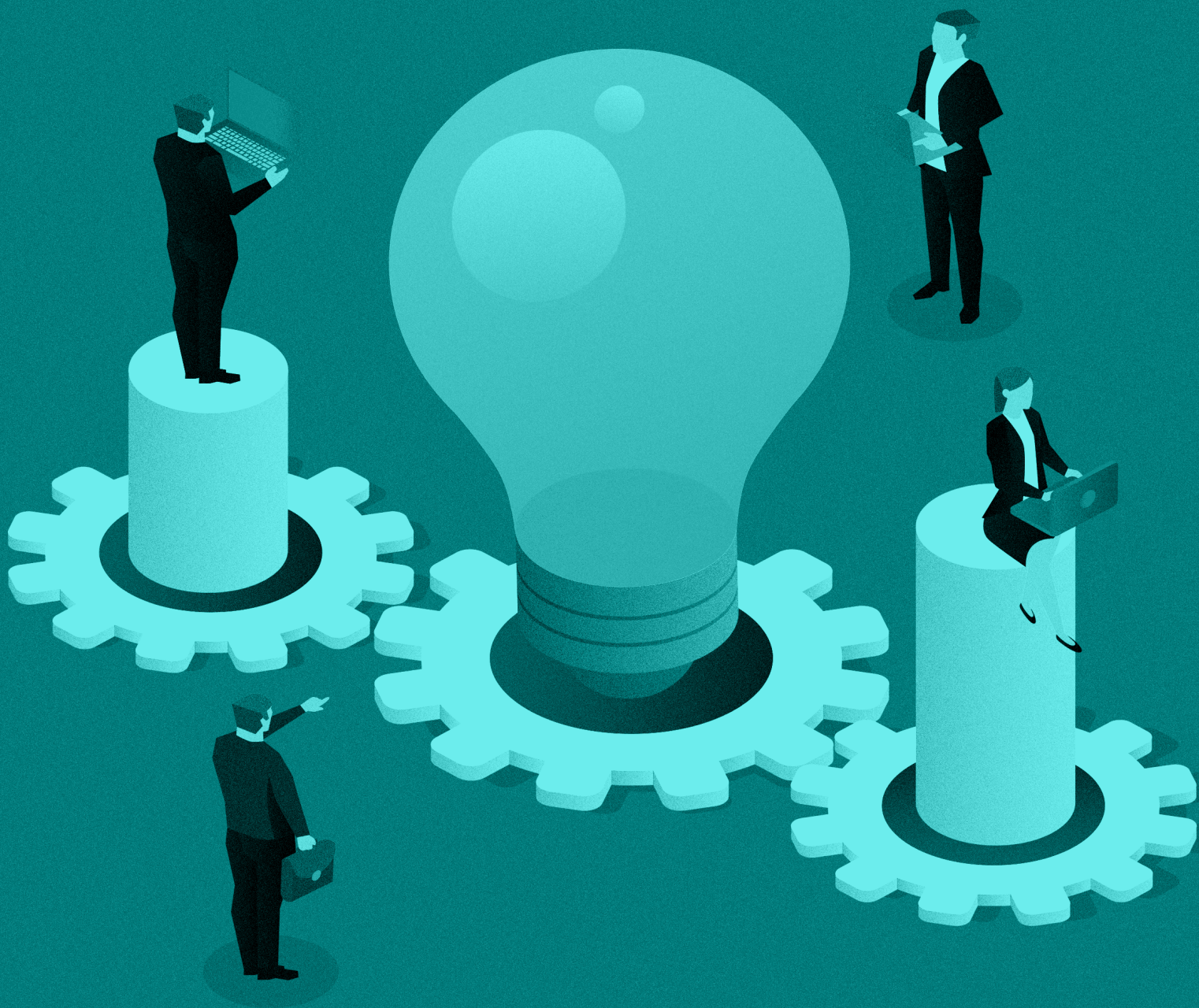


3RD ANNUAL

LEADERS IN LIFE SCIENCES

Key Takeaways



FALL 2020



**BOSTON
HEALTHCARE**
ASSOCIATES

Buchanan
Ingersoll · Rooney

levlane
who loves ya?

A

MODERATORS | SPONSORS



Mr. Edward John Allera
Shareholder, Co-chair, Life Sciences
Buchanan Ingersoll & Rooney PC



Mr. Timmy Garde
Chief Innovation Leader
LevLane Advertising



Dr. Thomas Goss
Senior Vice President
Boston Healthcare Associates

PANELISTS



Mr. Al Altomari
Chairman & Chief Executive Officer
Agile Therapeutics



Mr. Randy Burkholder
Vice President of Policy & Research
PhRMA



Ms. Natalie Cummins
Senior Vice President & Chief Commercial Officer
BioReference Laboratories, Inc.,
an OPKO Health Company



Dr. Paul Katz
President
University of the Sciences



Dr. Stephen Klasko
President & Chief Executive Officer
Thomas Jefferson University and
Jefferson Health



Mr. Alexander Mironov
Chief Business Officer
Covis Pharma



Dr. Jennifer Simpson
President & Chief Executive Officer
Sun Biopharma, Inc.



Mr. Todd N. Smith
President & Chief Executive Officer
Assertio Therapeutics, Inc.

INTRODUCTION

Former General and President Dwight D. Eisenhower observed that “leadership is the ability to decide what has to be done and get people to want to do it.” We are in the midst of a global pandemic that is exposing major issues in the commercial environment in which healthcare companies must operate, with changes that will completely alter the landscape long term. Leading in this environment is more difficult than ever. With these concepts in mind, our **3rd Annual Leaders in Life Sciences Roundtable**, the first one held virtually, discussed these changes, their impacts, our observations and best practices learned and applied on the fly in an attempt to share the only thing we can during this period of isolation: information. With our key takeaways outlined below, we hope that these learnings will help create a sense of consistency and comradery within the Life Sciences industry.

KEY TAKEAWAY 1

COVID-19 accelerated and accentuated the structural weaknesses in the healthcare delivery system.

The leaders represent every element on the healthcare continuum and were able to provide a broad perspective. Dr. Stephen Klasko, the President and CEO of Thomas Jefferson University and Jefferson Health, was able to put much of this issue in perspective because of the scope of Jefferson Health’s role in the Philadelphia area.

He reminded everyone that the Affordable Care Act was designed as a first step in the reform process to make quality healthcare accessible to more people. Dr. Klasko has focused much of his efforts thinking long term about how to provide affordable access to people throughout the Philadelphia metro area. Even

during the crisis, Dr. Klasko has had Jefferson Health focusing on providing healthcare to as many people as possible. People are the coin of the realm. The systems that can attract the most people will be able to introduce them to all ranges of services provided by the system, especially with the advances in all types of technology. In this era of branding and virtual living, his goal is to create a healthcare brand that people can turn to for everything for healthier living. This includes food delivered in food deserts, to home monitoring, to local outpatient care with the goal of being more efficient, higher quality and easier to access.

As **Ms. Natalie Cummins, SVP and Chief Commercial Officer of BioReference Laboratories, Inc., an OPKO Health Company**, noted, healthcare dollars are not rationally distributed. Therefore, changes in the distribution of services are necessary and will be ongoing. The ability to test and respond rapidly showed that the system can respond, but that it has limits. Consideration must be given to improved integration of testing, delivery of results and communication of the public health procedures that should be followed. Transparency and integrity of the information and the process are essential.

Mr. Randy Burkholder, VP of Policy & Research, PhRMA, provided a sobering fact from a recent study of the pharmaceutical distribution process: nearly 50% of the money spent on pharmaceuticals is absorbed by entities in the middle that neither provide a product or a healthcare service, but they add complexity and cost. Significant revenue exists in the healthcare system that is going to middlemen who neither sell nor deliver products or services nor provide real healthcare value. This concern was reiterated by **Mr. Todd Smith, President & CEO of Assertio Therapeutics, Inc., Mr. Al Altomari, Chairman and CEO of Agile Therapeutics, and Mr. Alex Mironov, Chief Business Officer of Covis Pharma.**

Dr. Jennifer Simpson, President & CEO of Sun Biopharma, Inc., noted the difficulties biosimilars face in getting into the distribution system because they provide less profit to the middlemen. Dr. Klasko cited a revealing statistic: Operating revenue of US healthcare system providers declined \$600 billion in the first 6 months of the pandemic, while insurers' profits increased 3 times. The money is not going into the healthcare system.

With or without Congressional action, realignment will occur. Healthcare and business leaders are taking the initiative to address their issues, which the pandemic has magnified. As Dr. Klasko noted, people respond to direct financial incentives if they have access to healthcare facilities. People also respond to pronouncements of political officials. Ms. Cummins noted that her company was initially able to provide testing responses within 48 hours nationally. When testing for nursing homes was dictated with no advance warning, the nursing homes created a tidal wave of demand. Supply chain issues became magnified. Unprecedented shortages in routine medical supplies such as testing swabs created an increase in cost by a large order of magnitude. Pipettes became back ordered. As will be discussed below, a vast increase in her on-site work force was necessary to address unprecedented demand.

Consumers are becoming more politically active and advocating for their interests in nearly every industry. Healthcare will be next.

KEY TAKEAWAY 2

Telehealth and other technologies focused on people and their overall health will be at the forefront of the revolution. Every leader emphasized the role that telehealth and other technologies have played in assisting us in getting through the current crisis. They view the

new technologies as increasing their roles and disruptive effects in healthcare, just as technological advances have disrupted all other elements of commerce in the US over the past decade. They view healthcare as an industry that will be similarly disrupted as others have been as information becomes more widely available and consumers become more demanding. The use of telehealth visits by healthcare systems have increased by a great magnitude in the last 6 months due to need. This example illustrates the future.

We have a population that will need more healthcare over the next decades. In healthcare parlance, to an insurer, a healthy insured employee is an asset, where a "patient" is a liability, giving both insurers and employer purchasers of insurance aligned incentives toward improving population health by doing innovative things that don't fall under the rubric of traditional healthcare service delivery, such as improving access to healthy, nutritious foods.

Further, people prefer to be treated near home. Therefore, getting people into the system and treated as close as possible to home will be even more important in the future. Dr. Klasko has focused Jefferson Health on investing in new technologies that can accomplish these tasks. But his experience has led him to be a more selective, creative, and practical investor. He is no longer swayed by young pitchmen hawking a technology without delivering a fully integrated solution. He is looking for people who can help translate his healthcare system into the next Target, not Amazon. The technology must fit into the broad health of the public, rather than just delivering existing services. Others, such as United Health and Optima, have done the same, and the results can be transformative.

Complete systemic care will become more important. Keeping people healthy, and getting them into a

system while healthy will be key to long-term growth for healthcare systems. For example, can healthcare systems drones deliver healthy food into food deserts to preserve health?

The pandemic has shown that technology for managing patients has been invaluable and sets the stage for continued disruption. With these changes occurring, Dr. Klasko believes that hospital admissions may decrease 30% in the next decade, and the specialty pricing hospitals may become outmoded.

As Ms. Cummins noted, we should examine which technologies are valuable. Laboratory tests have been the most important tool in dealing with the pandemic, but they are historically undervalued. However, lab tests have been shown to be invaluable. Ms. Cummins also noted that the imprecision of many diagnostic tests has created confusion for the public, especially given the vast number of tests being performed.

Dr. Simpson noted that the technology can assist the delivery of lower cost biogenerics to reduce healthcare costs. Mr. Smith, Mr. Altomari, and Mr. Mironov echoed the concerns of Dr. Klasko that the payers are now trying to claw back the special pandemic payments that the government authorized for telehealth visits. They have all faced increased demands by payors (middlemen) in the pandemic to squeeze more money from the product providers, which does not pass through to the providers.

KEY TAKEAWAY 3

The impact of the social determinants of health has been exposed and highlighted.

Site-of-patient versus site-of-testing and access have been revealed as major weaknesses in the healthcare delivery system, and has required major scrambling to address unanticipated issues. Ms. Cummins emphasized the need to adjust rapidly on

the fly with no in-person contact. This element of business has been difficult.

In this environment, people respond to statements of political leaders, and it is important for leaders to recognize the need to coordinate and alert people who provide the services in advance, if possible. Perhaps nothing illustrated the problem more than the response of people to the positions articulated by political leaders, whether scientifically based or politically based. People with the highest risk factors and lowest economic status have been shown to be the most vulnerable. More importantly, when provided with the opportunity to receive healthcare, they have responded actively. This response shows the possible market for new technology to improve their health. Providing these people with access to healthcare opens new channels of opportunity, as noted by Mr. Smith, Dr. Simpson, and Dr. Klasko.

Variation in the supply chain created unexpected but huge problems. Glove prices increased with limited quantities available. Pipettes and other necessary equipment not readily available. The difficult logistics of performing the tests, getting the samples to labs, and returning the results as soon as possible illustrated an underlying issue that transcends the entire healthcare delivery system. The military adage that tactics are for amateurs and that logistics are for professionals has particular resonance here.

Providing healthcare information to the people at greatest risk is vital. That information guidance is critical not only for pandemic risks, but also for dealing with the normal healthcare problems that continue. As Drs. Katz and Klasko noted, Philadelphia hospitals saw a huge decrease in stroke and MI patients at hospitals.

This decrease contrasted with 70% increase in DOAs at emergency rooms in medically underserved areas. Everyone expects improved telehealth and technology to make education easier and access to healthcare better. We need to shift the money paid to middlemen for the delivery of product to people delivering healthcare information and services. Dr. Katz expressed concern about developing healthcare professionals to provide these services due to the high costs of higher education.

KEY TAKEAWAY 4

An opportunity exists to adapt or change your brand to be more technical and consumer-oriented.

If you are expanding, launching new products, or taking advantage of new classes of customers, you have the opportunity to examine your brand and footprint. Mr. Altomari is the poster child for this point and led the discussion. He received FDA approval of a new drug in February 2020. Because everyone is virtual and using technology to communicate, he was able to more easily create and disseminate his story to his new markets. Creating this new vision/version in-person would have been much more difficult. As Mironov noted, his sales staff is stuck at home and cannot visit physicians and healthcare providers in person. Although there is no substitute for face-to-face interaction, we must deal realistically with the situation we have. Waiting for a return to pre-Covid behavior will be fatal for business.

We found Mr. Altomari's observation that restructuring in this time of crisis faced less internal inertia fascinating. Smith directed a publicly-traded merger with Assertio smoothly while dealing with most of the principals virtually. Of course, he still had to travel and meet with some of the most prominent shareholders, which was an arduous undertaking.

New classes of customers are unencumbered by your past model. Ms. Cummins noted that the pandemic has opened new channels of customers, such as the NFL, the NBA, and others, who view the value you provide completely differently than many of your historic customers.

The economic crisis caused by the pandemic has forced companies to quickly identify previously unfamiliar problems and decisively demand change within their organizations to survive. Leaders who have been successful have been able to fight inertia, make changes, monitor and adjust quickly in an adaptive cycle. Many of these changes have been made through rapid and successful deployment of technology, which, absent the crisis, may have taken years to accomplish (if ever), and in some cases significantly changed the business model due to the technological advantage gained through rapid deployment.

For this reason, introduce yourself as a highly technical company and more easily change your presence from a brick-and-mortar enterprise. The change from an "old line undervalued services company" to a "new, cutting-edge company" gains the benefit of new industry multiples in the eyes of investors. Companies can spend years and millions in trying to acquire market share to increase the value of their enterprise. Building the high-tech story of your company in the pandemic can more quickly and efficiently transform your company. You are now Cinderella, not the scullery maid.

KEY TAKEAWAY 5

Capital is extremely important. The ability to adapt to the changing environment is in part related to access to capital. Keep investors you know in close and frequent contact.

From investing in new healthcare delivery facilities like Jefferson Heath's new specialty care pavilion to developing new biosimilars, Capital is King. As Smith and Mironov noted, the capital markets always fluctuate. It is important to account for the fluctuation and make sure your financing is secure.

Currently, Life Sciences is a hot sector of the market, while other sectors are up in the air. However, this favored status of Life Sciences could change rapidly. Mr. Mironov stated that generalists and debt investors are getting into the healthcare space. Nevertheless, raising money is always a tough job. Miraculously, Dr. Simpson was able to raise significant financing for her development efforts at her previous company and shortly after arriving at her new company, Sun Biopharma, in late July 2020. For her first close, she had started early in the year and was able to close in the midst of the pandemic because she had an established a track record and was known to all of the principal investors. Even with Life Sciences being a hot market, investors are reluctant to write checks to people they have only met virtually. Even if they know you, you must listen, assure, and clarify, witnessed by Smith flying to a number of cities to meet with known, satisfied investors to provide them with assurance and confidence through frequent contact.

The ability to expand hiring in this crisis also requires capital. Excessive leverage can be a problem. But as Dr. Klasko noted, multiple structures are available for investment from small investments to joint ventures to new entities to hiring in-house. Distressed asset opportunities will exist. If you have capital, now is good time to shop, because many assets need funding.

KEY TAKEAWAY 6

Take the time to analyze the industry and competitors from your business perspective to truly gauge competition, inefficiencies, middlemen and more to make sure you are getting the largest slice of the revenue stream possible.

Smith stated the issue concisely: "Who really is our competition?" He asks his team to step back and at critical points to examine every element/segment of their market. Each leader at the roundtable had the same goal of getting patients access to affordable healthcare, from patient monitoring to patient testing to providing valuable products and services through refined delivery systems. Amazon, Google, Facebook, and drones have disrupted conventional commercial distribution of products and information. People in the healthcare system who are able to create disruptive models will be the most successful. Everyone on your team must ask questions such as: "Where are the redundancies?" "What people, trends and subsets of the industry can be replaced or eliminated?" Mr. Smith has been an innovator in creating closed-loop distribution systems to provide affordable products to patients. As Mr. Altomari launches his company's new product, a combined hormonal contraceptive patch, television and other video vehicles show a new distribution channel for women's contraception by mail--a concept that was unheard of even 5 years ago. Changes in the state practice of medicine laws plus improvements in technology have made this breakthrough possible.

Because roughly 50% of the revenue stream attributed to pharmaceuticals goes to people who have little to do with the actual Life Sciences/healthcare industry, as Randy Burkholder from PhRMA and others noted, financial opportunities in

the billions of dollars exist by cutting excessive redundant costs from the middle where little value is gained. Producers and providers are starting to view the external 50% of the revenue stream as a series of inefficiencies, and they are trying to eliminate as much of it as possible.

For example, there are no pharmaceutical companies in the Fortune 50, but insurers and intermediaries make up 25% of that list. This statistic begets action, which we discuss in more detail in our ninth "Key Takeaway."

Dr. Klasko sees it in the fight for patients. Mr. Altomari, Smith and Mironov see it as the costs of formulary access are increasing and the costs for distribution by small- and medium-size specialty pharmaceutical companies are routinely increased. Dr. Simpson sees the fight against her novel cancer therapeutics as well.

Technology is key to reducing the need for middlemen, increasing competition and creating disruption in the industry. Further, technology provides newer ways of branding that can help you build a more comprehensive vertical network. Access to patients and increasing their accessibility to product have been the driver for the internet of things. The same can be true in healthcare and Life Sciences. Decreasing hassle and increasing access is key.

Cracking the code on reaching patients in rural and other underserved areas where representatives are not able to market in person is going to be an important issue as we move forward.

KEY TAKEAWAY 7

Virtual management has been difficult and created inefficiencies. It takes longer to uncover problems and implement solutions.

Six months into the pandemic, there is no sign of an imminent return to a pre-COVID world. The Stockdale paradox has become evident. Admiral Stockdale was the highest ranking POW during the Vietnam War. Like everyone, he was exposed to horrendous indignities. When asked who survived, he noted that optimists, who believed that they would be home by Christmas or Easter, died of broken hearts. People who were pragmatic about surviving at any cost with a positive attitude, survived. We face a similar situation today. Before the crisis, every one of our participants was a leader and manager. Some, like Dr. Klasko, managed vast institutions that already had extensive planning procedures, teams, and infrastructures. Dr. Katz, at an academic institution, had similar support. The others were building enterprises. Their plans existed, but they have had to change. The launch plans for Mr. Altomari will now be different. Mr. Mironov's existing system will have to change. The post-merger plan of Mr. Smith will be different than the pre-Covid plan. Dr. Simpson will be revising her clinical development plan. Ms. Cummins' company has doubled in size. Any prior plan will require change.

Virtual planning can be done well, but requires real communication, action, accountability, decisiveness and adaptability.

All were concerned about maintaining the "stickiness" of their team. Although people in many service industries have stated that they are getting the same productivity from their employees at home, it is not clear how long that productivity can be maintained, and most of the productivity is based on

implementation of existing plans combined with an increased level of flexibility.

The longer the virtual environment lasts, the more it may expose cracks in your ability to maintain cohesion and a positive environment.

Accomplishing this long-term cohesion virtually will be harder and harder as times goes on. As Mr. Altomari noted, the inefficiencies are large, especially for a growing company. Mr. Smith was concerned about making midcourse corrections. Both run virtual companies that are geographically dispersed. Extra effort to build that cohesion is necessary. Hiring and having the right people on your team is always essential, but in the current environment, the management team is even more important. Dr. Simpson is facing similar concerns, further exacerbated by the challenges of enrolling, treating and monitoring patients in clinical trials disrupted by the pandemic. Ms. Cummins faces a slight variation on this theme as her company has doubled in size, and almost all are essential workers working on site in the laboratory environment. You must convey your revised vision and plan for the entity to everyone in the entity. Communicating and reinforcing it to your management/leadership team can be harder when isolated, and their ability to translate and transmit the change is more difficult. Selling the change to a multitude of new hires is even more difficult. Increased effort is required.

KEY TAKEAWAY 8

Employees with children, especially working mothers, have taken on additional responsibility when it comes to providing primary care and educational support, pushing their obligations to the maximum level between work and family life. It is important to allow for work boundaries in this virtual environment so that employees do not

burn out. It is equally important to allow for personal lives to bleed into the working environment at a reasonable level to show flexibility and understanding employee needs.

In a sense, this takeaway is self-evident. Ms Cummins raised this issue initially because many of her staff are women with school-age children. Although this issue has been on the radar since March, the start of the school year, with many schools continuing to be virtual, brought it back to the forefront. Everyone recognized its significance. Dealing with this challenge is more complex. Companies and institutions pride themselves on touting their family friendliness. But implementing that ethos in the pandemic is more difficult. When people are working virtually, the adage of providing a flexible working environment becomes clichéd. Understanding the employees' needs virtually is difficult. The lack of face-to-face interaction by people throughout the workforce makes detecting undercurrents of concern even more difficult than normal. Healthcare and Life Sciences have historically been havens for female professionals and others who seek flexible working hours.

Today, everyone is facing more demands with less time. Additionally, in today's complex work environment, one parent can be working on site, another virtually, and the children may be attending school virtually. Or they may be in different schools with different attendance policies. If anyone gets sick, chaos ensues. Our leaders need to consider using technology to address the issues for our employees. If we wait until a crisis, the economic disruption will be greater and more difficult to repair. Hopefully, addressing the issues now will increase the cohesiveness among employees that is so valuable in the long term. When we are building our teams, addressing these issues with new hires is invaluable in identifying, hiring, and retaining the right employees.

KEY TAKEAWAY 9

Life Sciences leaders must become more politically active with Washington and the States to remain competitive and in tune with insurer political activity.

As Dr. Klasko noted at the beginning, the ACA was designed to be the first step in healthcare reform, but the next steps were never legislatively implemented. Its goal was to decrease the uninsured and provide more affordable access to insurance to the people who qualified as working poor and younger people who were employed in the new economy. Benefits were also provided that were basic to a healthier lifestyle that could reduce overall healthcare costs. Improved women's healthcare was one particular benefit. A bitter partisan fight has emerged over healthcare, but Congress has nevertheless passed several pieces of legislation that have otherwise directly affected healthcare. The 21st Century Cures Act and legislation that provides user fees for FDA operations have been passed every 5 years. The current authorization expires in September 2022, and FDA has already begun discussions over the terms of the next user fee bill with stakeholders. In addition, the pandemic has led to multiple pieces of legislation that have impacted the healthcare system.

The Administration has also spoken ardently about reducing the price of pharmaceuticals, and it has attempted to act unilaterally through Executive Order. Bipartisan support for reducing the costs exists. Differences exist about the terms, however. The terms vary widely from the federal government negotiating prices for Medicare and Medicaid to importation of drugs from Canada or the use of an international price index. Reducing out-of-pocket costs to Medicare and Medicaid recipients is an issue that has bipartisan support as does the concept of returning manufacturing of drugs, especially generics, to the United States.

Because the federal government, through Medicare and support for state Medicaid programs provides approximately 44% of the funds for pharmaceuticals, it has a vested interest in reducing its spending. The Centers for Medicare and Medicaid Services has initiated several administrative actions this year to reduce spending on pharmaceuticals. But the actions have been directed at small and mid-size specialty pharma companies as opposed to "Big" Pharma. Big Pharma has been organized and discreet in its dealings with the Administration. This will continue beyond the election.

In fact, these issues will become more acute as many states and municipalities are facing budget shortages caused by the pandemic. Thirty-eight states have balance budget requirements. When shortfalls occurred during the Great Recession in 2008, healthcare, first responders (police, firefighters, and EMTs), and education bore the brunt of the cuts. Nobel Laureate Paul Krugman began raising concerns about a repeat of this issue early in the pandemic. Complicating this issue is that a new set of legislators will be seated in January, and dialogue on these issues will begin after the election. As Mr. Altomari implored everyone, if you are not at the discussion table regarding new legislation, you will get the bill. He has been making repeated trips to Washington to plead his case for the maintenance of the women's healthcare provisions in the ACA. Big Pharma, BIO and the big generics manufacturers are organized and active.

The insurers and PBMS are even more focused. Because of the breadth of insurance and distribution, they are able to plead to legislators that they are local entities and provide local, high-paying jobs, which is always appealing to them. In the pandemic, it may be even more so.

As Mr. Smith noted, people on Medicare and Medicaid are trapped because they cannot, by law, benefit from copay support. They are the guinea pigs for one-off pilot projects, and they have few options for improved care. Payors are using them for profit.

The legislative process is lengthy, time-consuming and subject to compromise. Many business leaders lack the patience for its ethereal nature or do not believe that they can affect the process to their advantage. But your competition does. In a sense, they are counting on the short-term focus and lack of long-term commitment to prevail.

The issues are comparable at the state level. Life Sciences and healthcare are a high stakes three-dimensional chess game. The participants must be alert. Just as you must take a step back to assess who your competition is, you must monitor what they are doing on the federal and state legislative level.

KEY TAKEAWAY 10

Academia is facing a crisis with decreased enrollment as people are less willing to pay a premium for a virtual learning experience.

A recent article in the *New York Times* simplified that issue. Since the turn of the 21st century, state legislatures have recognized that they can reduce their expenditures for state university spending, and the universities can make up the shortfall by admitting out-of-state students and often foreign students who have been happy to pay the higher tuition rates. That model is becoming as outmoded as gas guzzling autos of the last half of the 20th Century. Dr. Katz noted that the pool of 18 year olds is decreasing. The pandemic follows on the heels of the Great Recession, which caused many middle- and lower-class families to question the value of higher education.

Dr. Klasko questioned the longer term viability of the tuition-based model for higher education, especially for healthcare students.

Starting post collegiate/academic life with low, six-figure debt, even at the current low interest rates, is an enormous burden that many can never shake. That burden dictates life choices to the most economically rewarding, especially in healthcare.

That burden creates an inertia to resist the changes in healthcare that must occur to provide reasonable access at a lower cost to all. At least a dozen smaller liberal arts colleges have been forced to close or merge in the past year. The prospects of many more are equally depressing. As the pandemic shifts more of the learning to virtual, even more questions about long-term viability exist.

Will these likely changes in education affect the available talent pool for Life Sciences companies in the future? Will the mutually beneficial partnerships between academic and healthcare institutions survive?

.....