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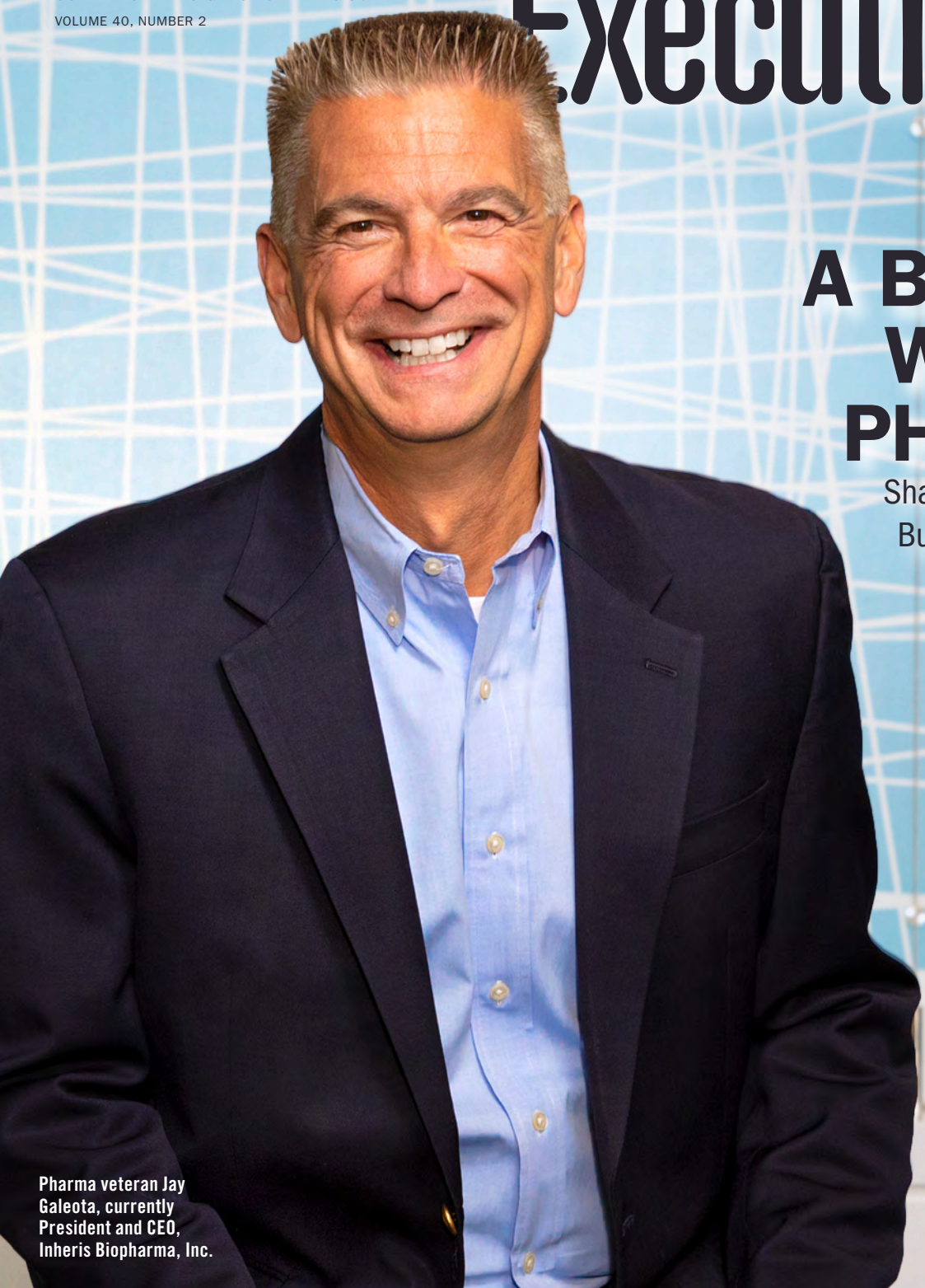

A BETTER WAY TO PHARMA

Shaking Up Industry's Business Risk Model

Pharma veteran Jay Galeota, currently President and CEO, Inheris Biopharma, Inc.

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Becoming a Pharma Industry Leader

AT THE END OF THIS MONTH, FEBRUARY 28, we will close the nomination process for the 11th *Pharmaceutical Executive* Emerging Pharma Leaders (EPL) recognition. As you won't be reading this until mid-February online, I encourage you now to nominate the person you know who is headed for the C-Suite. Or you can nominate yourself! Go to our judging platform at https://emergingpharmaleaders.awardsplatform.com/.

LISA HENDERSON
Editor-in-Chief
lhenderson@mmhgroup.com
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It's not a coincidence that James (Jay) J. Galeota, Jr., president and CEO of Inheris Biopharma, is our featured February Executive Profile. Jay is a *Pharmaceutical Executive* Editorial Advisory Board Member and was recognized as an Emerging Pharma Leader in our first class of 2008. At that time, Jay was SVP, general manager, diabetes and obesity at Merck. Since then, Galeota led Merck's pharma and vaccine integration of Schering-Plough; served as SVP, global human health, strategy & BD; was president, hospital & specialty care; and was chief strategy & BD officer, president, emerging business, all at Merck. He then moved on to become president of G&W Laboratories, before taking the position as CEO of Inheris Biopharma.

When I reached out to Jay to participate in the executive profile, the timing seemed perfect. We were opening the EPL nominations, he is a former selection, a well-accomplished executive, and Inheris Biopharma was nearing FDA review action on NKTR-181, the potential first new molecular entity opioid in over 30 years with a target profile of less unwanted side effects while delivering effective pain relief. Potentially timely indeed for the tens of millions of people suffering from chronic pain in the midst of the current opioid crisis.

But, like many best laid plans, Galeota is now facing what many CEOs and executives in the life sciences have faced, reflecting the inherent and extraordinary risk in our industry—a situation that requires a new plan.

How Galeota navigates through to the next step will build on the skills, qualities, experiences, and vision that has guided his career through to this point. His profile starts on page 12.

And Galeota's story also connects with what we ask of your nomination for the next class of Emerging Pharma Leaders. Like Galeota, do they have what it takes to make the tough decisions that will continue to face manufacturers in the coming years? Can they navigate the commercial, financial, scientific, R&D, marketing, sales, and/or market access landscapes with leadership and inspiration? Do they have what it takes to get to the next level?

The 2020 EPL winners will be announced at eyeforpharma Philadelphia in mid-April, showcased on the cover and inside of *Pharm Exec*'s May issue, and featured on episodes of the *Pharm Exec* podcast.

Galeota is now facing what many CEOs and executives in the life sciences have faced, reflecting the inherent and extraordinary risk in our industry—a situation that requires a new plan

As Galeota emphasized in his interview, there is tremendous opportunity to take advantage of the current convergence of technology, biology, and engineering to change the trajectory of the more conservative paradigms that currently exist in the pharmaceutical industry. "The opportunity to innovate has never been greater, and innovation now moves beyond the discovery at the bench to how that brilliance is applied in practice in ways that maximize the potential benefit conveyed to people who are suffering," he says.

Where ultimately the future of pharma goes depends on leaders, emerging and otherwise.

We look forward to featuring the future of pharma leadership. PE

Pharmaceutical Executive VOLUME 40, NUMBER 2

Pharmaceutical Executive's 2020 Editorial Advisory Board is a distinguished group of thought leaders with expertise in various facets of pharmaceutical research, business, strategy, and marketing. EAB members suggest feature subjects relevant to the industry, review article manuscripts, participate in and help sponsor events, and answer questions from staff as they arise.

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Jay Galeota: A Better Way to Pharma

Lisa Henderson, Editor-in-Chief

Pharm Exec speaks with veteran industry leader Jay Galeota, currently president and CEO of Inheris Biopharma, Inc., who shares perspectives from a diverse, off-the-beaten-path journey—one driven today by his mission to align pharma's risk-taking approach across the entire drug life cycle.

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Cover Photo/John Halpern

Reaching the Physician in 2020

Engaging the New HCP

Lisa Henderson, Editor-in-Chief

Amid the growth but still-cautious embrace of social media and other digital marketing channels, appealing to the younger physician requires a nuanced approach—mixing proven expertise with fresh ideas.

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The Link from Lab to Physician

Elaine Quilici, Senior Editor

How current barriers along the roadway between biomarker testing and drug prescribing can affect decision-making for precision medicines.

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Julian Upton, European and Online Editor

Exploring the advent of data analytics and pharma marketing automation in generating insights and guidance for targeted messaging and brand engagement.

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Country Report: Hungary

Hungary is fast staking a reputation for itself as one of Central and Eastern Europe's most dynamic economies. A major factor has been pharmaceuticals, where Hungary's history of research and production is reflected today in an attractive pharma investment landscape and the presence of home-grown success stories.

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Pharm Exec Podcasts

Episode 48: Top Pharma Trends
Pharm Exec editors discuss the themes highlighted in our annual pharma industry outlook, which tapped experts from several areas to uncover the top new-decade trends to watch—from finance and policy to talent and technology, and more.
http://bit.ly/2TN11Pr

Episode 47: Identifying Adherence Issues
Heather Monte, director of operations for DirectRx, speaks with *Pharm Exec* about specialty pharma's new Patient Scorecard, which aims to identify and improve medicine adherence by reporting patients' prescription patterns to doctors.
https://bit.ly/2S047Nq

Episode 46: Persistence Pays Off
Julia Owens, co-founder and CEO of Millendo Therapeutics, talks about how to keep a company on the path to success, even when there are bumps in the road. She discusses the value of focusing on strengths and how that is currently working for Millendo in the endocrine space.
http://bit.ly/38TPTWf

Episode 45: The Limited Population Pathway
William Lewis, chairman and CEO of Insmed, discusses the company's rare disease treatment, Arikayce, the first drug to be approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs.
https://bit.ly/2GGf1CK

Episode 44: Inside the Pipeline Report
Pharm Exec editors discuss the articles and special features they focused on related to our latest Annual Pipeline Report.
http://bit.ly/2KJ1CfQ

Episode 43: Wrestling with Reputation
Sven Klingemann, research director at Reputation Institute, talks with *Pharm Exec* about the industry's negative public perception and what steps it can take to improve it.
http://bit.ly/2JZDjtx

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Reader Feedback

■ Instead of trying to incentivize companies to invest in products that are nearing patent expiry, it would be more productive for society to ensure adequate funding for other organizations (mostly NIH) to perform these studies. They already do some of this work, and they do not require a profit.

Anonymous
"The Bad Rap on Pharma: In Defense of Patents"
bit.ly/2RNYvHz

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Multi-Channel Marketing
In today's new world of multi-channel marketing, where a combination of data, micro-campaigns, and insights all come to bear, *Pharm Exec* examines the core strategies critical to targeting the customer at the right time.

Minimizing Negative Impact of Sales Rep Vacancies

The impact of vacant sales territories on overall brand performance is often underestimated within pharma and biotech companies. There are varying causes of vacancies, including rep promotions and transfers, resignations, terminations, FMLA leaves, and organizational restructuring. These vacancies have significant impact on pharma and biotech brands. The most obvious impact is a decline in sales and market share as competitors take advantage of no personal selling SOV for affected brands. This can result in a 25-50% decline from baseline market share. In addition, there are significant declines in service-based items such as samples, copay cards, etc., which are critical to driving new patient starts. Business declines for brands begin very quickly following a vacancy occurrence and even once the vacancy is filled, new reps require training and a ramp-up period while they get familiar with the territory and its customers.

One of our major customers requested a comprehensive marketing solution to address the negative impact of territory vacancies on their key brand. They had two major objectives for the plan—protect as much market share as possible during vacancy periods and provide valued services to their key HCP customers for items such as copay cards and samples. They also asked us to coordinate our non-personal promotion plans with their tele-detailing and alternative sampling partners.

The first step was to integrate with our customer's human resource team to develop a process for becoming immediately aware of when territories became vacant and were subsequently filled. We then coordinated our plan with the sales management team to ensure that we factored into the plan any temporary sales rep coverage within the vacant territories. We then integrated with their sales force automation system to identify relevant called-on HCP targets within vacant territories who would participate in this plan.

Our customer made the decision to include all called-on HCPs in the Vacancy Management Plan, as well as HCP targets who were not previously in the call plan, as the cost for this six-month initiative was extremely low, approximately 10% of the cost for a single HCP sales call. To achieve organizational alignment within our customer's various involved departments, we developed a comprehensive communication plan that included training and development for the various stakeholder groups.

A core element of the Vacancy Management Plan was our brand messaging campaign with personalized journeys delivered to HCP targets through our internal marketing automation platform. These brand messages were delivered through multiple channels, including email, direct mail, and banner ads. In addition, our comprehensive plan coordinated tele-detailing and delivery of service items to HCP targets such as samples and co-pay cards through their designated partners.

Our client's primary objective in minimizing business loss by the brand was to maintain the same market share trend in vacant territories that existed prior to the vacancy occurring. This objective was met. It was measured by evaluating the market share trend during the 12 months preceding the vacancy and comparing it with the first six months of the vacancy. Results showed that for the overall HCP target group, there was no significant change in brand prescription trend during the six-month vacancy period when the Vacancy Management Plan was in effect. In addition, HCPs who received minimal calls pre-vacancy or were not previously in the call plan, showed a positive upswing in brand prescription trend during the vacancy period. It was also noted there was significant usage by the HCP targets of both tele-detailing and the sampling program. Our client was extremely pleased with the results of this Vacancy Management Plan and requested it for additional brands.

Vacant territories are a significant challenge for pharma and biotech companies, resulting in loss of business, as well as additional negative impact on company and brand image with HCP targets; these negative factors can linger for a significant period of time after the territory is filled. Through successful implementation of our Vacancy Management Plan, we maintained the overall business trend for the brand during the six-month timeframe and actually showed increases in business with some target HCP subgroups. PE

STEVE CARICKHOFF
Brand Insights Contributor, President, BioPharm Communications

Brand Insights - Thought Leadership from Marketers I Paid Program

The Risks and Rewards of Expedited Review

Weighing new strategies to accelerate biomedical product development

With more new drugs and biologics gaining FDA approval based on accelerated research and review strategies, concerns have emerged about whether such innovations raise added risk for long-term product safety and efficacy. FDA officials maintain that they are not compromising the agency's traditional "gold standard" for testing new medical products, and that it should utilize opportunities to efficiently address unmet medical needs of very ill patients.

An added benefit of FDA flexibility in clinical trial design and speedy reviews may be to reduce the cost of drug development, which could translate into less expensive treatments for patients. So far, though, many critical new drugs have set high launch prices despite expedited FDA vetting, clouding the sense of gain from these regulatory innovations and maintaining support for drug price control legislation.

In a report on Innovation in Drug Approvals of 2019, the Center for Drug Evaluation and Research (CDER) outlines an impressive record for expediting development and oversight of important new drugs last year. The report cites the use of expedited programs to advance access to 60% of 48 novel drugs approved last year, many to treat rare diseases and deadly cancers (see https://bit.ly/30wpfz0). While last year's approval numbers for new molecular entities (NMEs) fall below FDA's record 59 approvals in 2018, the latest list includes numerous first-in-class therapies and advances in care across a range of conditions, from heart disease, macular degeneration, osteoporosis, and migraine, to sickle cell disease, Parkinson's, multiple sclerosis, and blood disorders. The report also cites multiple approvals of indications for expanded uses and additional patient populations, as well as new dosage forms for already marketed medicines.

These gains reflect a more efficient and predictable review process at CDER, as demonstrated by its success in meeting all user fee goals for timely assessments, reviewing 90% of applications in the first review cycle, and approving nearly 70% of new drugs in advance of other countries.

The report points out that initiatives by sponsors in developing more targeted therapies for vulnerable patient populations, often based on genetic characteristics, benefit from the agency's increased use of innovative and accelerated review procedures in recent years.

But while highlighting such gains in expedited drug development and review, CDER Director Janet Woodcock emphasizes that the agency's "high standards for safety and efficacy have remained unchanged." This responds to some fears that speedy approvals based on limited clinical studies raise risks related to long-term safety and efficacy. Woodcock states that the agency is maintaining approval policies while also utilizing innovative methods and new regulatory tools to bring "a wide range of new drugs to patients in need." (see https://bit.ly/2svwo5T)

More flexibility?

Accelerated strategies for biomedical product development have advanced through new guidances on a range of methods and policies for streamlining clinical studies and updating FDA policies. These include increased reliance on real-world data gleaned from electronic medical records, particularly for documenting additional indications of a medicine, for developing natural history studies, and for advancing gene therapies. A final guidance on Adaptive Design Clinical Trials for Drugs and Biologics, issued in November, sets out key principles for designing, conducting, and reporting results of investigations utilizing Bayesian adaptive studies and other methods (see https://bit.ly/2FWrrq4).

A particularly notable move is FDA's recent decision to revisit the controversial issue of when and how only one clinical trial may provide sufficient evidence to support approval of a new drug. The topic has been hotly debated for more than 20 years and now headed for further examination, as outlined in a December draft guidance on "Demonstrating Substantial Evidence of Effectiveness for Human

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Drugs and Biologics." (see https://bit.ly/30pdPgk)

Federal law indicates that sponsors should conduct at least two randomized, blinded, placebo-controlled clinical trials to document drug efficacy, and that's still FDA's basic approach. But "there are circumstances where evidence generated using a variety of clinical trial designs, endpoints, and statistical methodology can support effectiveness," commented FDA Principal Deputy Commissioner Amy Abernethy in announcing this new policy review (see https://bit.ly/2FY1O8g).

Agency officials explain that studies with concurrent, active, and historical controls may be appropriate in certain situations, such as testing treatments for rare conditions—in addition to utilizing the gold standard randomized controlled trial (RCT).

The report cites the use of expedited programs to advance access to 60% of 48 novel drugs approved last year, many to treat rare diseases and deadly cancers

At the same time it is advancing accelerated research policies, FDA is taking steps to better monitor the safety and performance of both investigational therapies and approved drugs on the market. One initiative has established a new system for sponsors to report electronically adverse events involving study participants to more effectively track safety signals that occur during clinical trials. Recent legislation, moreover, authorizes the agency to request post-marketing studies to address questions about a new drug's long-term effectiveness, in addition to safety issues. This added oversight may help reassure the research community that FDA has the tools to detect problems with expedited treatments, while also speeding new therapies to market based on fairly limited clinical experience. PE

Biotech executives pledge 'reasonable' price increases

Can a commitment to limit prices to ensure patient access to important new medicines regain public trust and confidence in the biopharmaceutical industry? That's the hope of a large cadre of biotech company executives who recognize that recent scientific advances that promise to cure critical diseases must be linked to high integrity and corporate responsibility or face price controls and other policies that could undermine support for continued discovery of new medicines.

In a "New Biotechnology & Pharmaceutical Industry Commitment to Patients and the Public," penned by six CEOs, more than 200 leaders from some 150 small and medium-sized companies and research organizations acknowledge that out-of-pocket costs for individuals must be limited to sustain support for fiscal and patent policies key to advancing innovation (view the letter here: https://bit.ly/3agdHnU).

The group, led by executives from Amicus, Nkarta, Ovid, Global Blood, GlycoMimetics, and Alnylam Pharmaceuticals, back collaboration with healthcare entities, including payers, hospitals, and distributors, in efforts to eliminate copays and deductibles for all patients.

Those signing the commitment letter also pledged to support ethical business practices and to invest "only in novel therapies that address unmet patient needs." And they oppose companies and stakeholders who "abuse this commitment to patients and who abuse policies aimed at fairly rewarding innovation." At the same time, the group supports the marketing of biosimilars and generic drugs after "legitimate patents and regulatory protections expire."

Big pharma stays out

By itself, the public letter offers few specifics for effective change in current industry practice. Even so, the list of supporters is notable for the absence of big pharma and biotech firms who did not sign on, ostensibly due to legal concerns about joining any industry initiative that could be construed as involving multi-company price-setting agreements.

The Biotechnology Innovation Organization (BIO) voiced support for the principles expressed here by many of its members, but did not officially endorse the statement. And while manufacturers can face stiff penalties for actions even hinting at price-setting agreements, these commitments to ethical practices should avoid such consequences by emphasizing responsible actions by individual companies.

Unlocking the Black Box of Pharma Pricing in Europe

New OECD study doesn't shed much light on the effectiveness of managed entry agreements for drug access

While the agencies that pay for medicines continue to struggle with the inadequacies of external reference pricing (ERP) systems that many of them rely on, parallel attempts to pry open the black box of managed entry agreements (MEAs) seem even more unproductive. A panel of experts working with the richest countries in the world has just been obliged to admit failure in its search for an easy key to unlock the secrets held by deals on payment for results or population-level coverage.

"It is difficult to assess to what extent performance-based MEAs have so far been successful," conclude the authors of a study for the Organization for Economic Cooperation and Development (OECD), because "little information is currently shared," particularly on the products for which MEAs are in place, on the design of MEAs, or on their results, and there is a consequent "lack of evidence." (See the report here: https://bit.ly/30OeqIN)

Advocates of tougher pricing controls on medicines will find little comfort in the findings of the OECD study, because it confirms what European discussions of ERP during 2019 already made clear: that as long as confidentiality remains the norm in pricing negotiations between drug firms and national payers, information and evidence is always going to be in short supply. The ambitions of European national payers to leverage a shift in focus from list prices to net prices are evident in the burgeoning regional groupings now emerging along the lines of the Beneluxa model, and were at the heart of last year's ERP discussions in their Euripid grouping too (which this column covered in May 2019, see https://bit.ly/2uh4dbB). So far, the ambitions remain a long way from fulfilment.

Reform record

That is not to say that the concept of MEAs is called seriously into question in the study. These agreements between firms and healthcare payers can, in principle, allow for coverage of new medicines while managing uncertainty around their financial impact or performance, it concedes. And at least two-thirds of OECD countries and EU member states have made use of financial agreements designed to reduce prices and/or budgetary impact of medicines in OECD countries and EU member states without linking them to product performance.

Many of them have also used performance-based agreements that link to payments or rebates, it says. The most common designs for agreements are patient-level payment-by-result (PbR), paying firms only for treatments to which patients respond, and population-level coverage with evidence development (CED), which aim to reduce uncertainty around comparative effectiveness or cost effectiveness.

The problem is that it is hard to say whether these agreements do what they are intended to do. Few countries have formally evaluated their experience. And the confidentiality that surrounds these agreements is a permanent barrier to independent evaluation.

There is little evidence in the public domain, admit the authors of the study—and such information as is available, including from expert interviews they have conducted—indicates that CED agreements have so far had a poor track record of reducing uncertainty around the performance of medicines, and PbR agreements "do not always generate evidence on product performance because data used for triggering payments are not always aggregated and analyzed."

As a result, some countries have recently reformed CED schemes, and some are discontinuing CED agreements altogether in favor of alternatives, notably with restricted or conditional coverage without an MEA, and with coverage initially restricted to certain indications or patient groups and only broadened if and when additional evidence becomes available.

Pushing transparency

Where the advocates of tougher pricing controls may find more comfort—and pharmaceutical executives may entertain more reservations—is in the study's suggestions that the situation is

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

not without some hope of remedy. One of the avenues that the report recommends for exploration is "ensuring a minimum level of transparency of content, limiting confidentiality to those parts of MEAs that may be commercially sensitive (e.g., prices)." It also urges sharing information on results of MEAs, and how performance of products is measured within them.

According to the study, this would benefit payers. It says it would reduce duplication of effort between countries; it would allow payers to learn from experience elsewhere to inform their negotiations with firms; and it could reduce uncertainty over results from small patient samples in the case of rare diseases. Greater transparency over the performance of products would also "be useful for other stakeholders with legitimate interests and the general public," it says.

Ethical factors

The study also raises a hitherto less remarked issue. It suggests that reticence over the outcome of MEAs could have a dimension beyond the strictly technical. "The potential non-disclosure of results of clinical studies conducted under performance-based MEAs raises ethical concerns, as available information on the effectiveness of medicines could be withheld from the public."

The ways forward that the study recommends amount to a radical change in current practice. If MEAs are to be more useful, "payers would need to change their policies in negotiations with pharmaceutical firms to ensure that information on future MEAs is not confidential," it says—somewhat glibly, since abandoning confidentiality is not entirely within the exclusive gift of payers; companies would have to agree to it too.

"There is significant interest in sharing of information on the existence of MEAs, on how product performance is measured, and in decisions made as a result of MEAs," it continues.

As long as confidentiality remains the norm in pricing negotiations between drug companies and national payers, information and evidence is always going to be in short supply

"Payers could agree on which information to share, in which form, and through which mechanism.

Various mechanisms of information exchange are possible, including publishing information on existing websites, establishing new central repositories, and using existing initiatives for sharing of information on medicines and health technologies."

In what sounds like a belated—and even then possibly inadequate—acknowledgement that it does indeed take two to tango, the study does recognize that "further assessments might be necessary to determine which information is commercially sensitive and ought therefore to be protected."

Legislation letdown?

But its optimistic attitude still seems to rather miss the point: "Changes to legislation might not be necessary in most countries to achieve greater transparency." Legislation is unlikely to deliver the transparency aspired to. As this column has observed in the past, industry—and many national authorities who benefit from confidential agreements—are resistant to the extensive transparency that more radical commentators are mulling. And drug firms are on the record as saying that if they are forced to disclose net prices, they will stop making agreements that involve discounts, and provide their products only at list prices.

Similarly, pricing authorities who currently obtain discounts in return for confidentiality agreements say they will not be able to afford the acquisition of expensive medical treatments if they are available only at list prices. It is hard to see the legislation that—in Europe at any rate—could compel either side to enter into agreements that they were strongly opposed to.

More to surface

So despite the meticulous engagement of the OECD's researchers, the black box of MEAs remains almost as hermetic and opaque as ever. Something more than an academic review may be needed to advance meaningful discussion on revealing its innermost secrets. PE

Jay Galeota, President and CEO, Inheris Biopharma, Inc.
Photo/John Halpern

A Better Way to Pharma

Veteran pharma leader Jay Galeota shares learnings and perspectives from an off-the-beaten-path career rise—one driven today by a mission to align the industry's risk-taking approach across the entire drug life cycle

By Lisa Henderson

When Jay Galeota entered the pharma industry through the doors of Merck & Co. in 1988, he questioned whether he belonged with this group of smart, over-achieving co-workers at then the world's Most Admired Company, which was changing the practice of medicine globally and improving people's lives. But Galeota felt blessed to be a part of Merck and surrounded by intellectual, quality individuals trying to do the right thing. This formed the basis for his career path and foundation for how he viewed what pharmaceutical companies and their leaders should aspire to be.

Galeota wasn't so far out of his element, though he might have felt that way at the time. Clearly, Merck saw something in Galeota beyond his biology degree and four-year Air Force ROTC training, which in a world of best-laid plans, would have landed him a pilot seat in an F-16. An eyesight issue instead led Galeota down the road into a seat in the C-suite.

Galeota had heard it was harder to get into Merck than Harvard Business School, and he felt fortunate to come into the pharmaceutical industry when it was in its prime. Galeota describes a hallway at Merck's research laboratory headquarters in Rahway, NJ, where the molecular structures of many of the world's greatest medicines that came out of Merck's lab through the 1940s, '50's, '60's, to today, hang above the hall.

He says, "I had the opportunity frequently to walk down that hallway and each time I did I was struck, really awestruck, by the magnitude of these medicines that had such dramatic impact on the health and wellness of humankind worldwide, and grateful that I had the good fortune of helping to

bring many of these life-changing medicines to people in need."

And for 28-odd years, Galeota worked his way up at Merck, not in a step-wise fashion, but in roles that allowed him to step out of his comfort zone. "I'm most effective when I'm learning," he says. "I find that when I'm comfortable, I'm not learning as much as when I'm uncomfortable. I was fortunate to take some off-the-beaten-path assignments that, traditionally, people would have viewed as risky, but in my mind, they were opportunities to trailblaze and try new things."

With each role—from entry-level sales representative to President of G&W Laboratories and, today, President and CEO of Inheris Biopharma, Inc.—a new perspective, an insight, an intriguing observation came to shape Galeota's vision for what constitutes the best-of-the-best of pharma and its teams.

The following are some highlights of Galeota's roles and perspectives, sampled from his full professional pedigree.

■ A sales rep at Merck, where "carrying the bag" gave Galeota an understanding of how healthcare is delivered, which is locally, in geographic communities. This has been and remains the case, not just in the US, but globally. How the pieces fit together and where the goals and objectives of the involved stakeholders are aligned, as well as conflicted, is an experience Galeota applied to his broader roles at Merck. He says that made him more effective at recognizing opportunities to positively influence care delivery and more mindful of how medicines were brought into various healthcare paradigms.

■ In his multiple roles in primary care, including Executive Director, Atherosclerosis Franchise, and Senior Vice President and General Manager, Diabetes and Obesity Franchise, Global Human Health, Galeota learned about many different primary care therapeutic areas, and, again, how they affect the way medicine is practiced on the ground, and how Merck could impact patients' lives on a large scale.

■ As Integration Leader, Global Human Health, Galeota led the integration of the pharmaceutical and vaccine businesses when Merck and Schering-Plough merged in 2009. This was another assignment where Galeota went out of his comfort zone, and learned a lot in the process. Leaving the highly successful diabetes group, Galeota thought he lacked experience to lead an integration of this scale, but the results proved he had the instincts and requirements to be successful.

■ Senior Vice President, Strategy and Business Development, Global Human Health, tasked Galeota with building two new functions and new capabilities within the commercial part of the now much larger post-merger Merck. He again became a student, learning the disciplines of business development and strategy in the process of creating the new organization.

> "I find that when I'm comfortable, I'm not learning as much as when I'm uncomfortable."

■ As Merck President, Hospital and Specialty Care, Global Human Health, a large business line that comprised 27 different products in seven therapeutic areas, which were all new to Galeota, the role gave him another significant opportunity to learn and work through improving the business through hard decisions.

■ Chief Strategy and Business Development Officer and President, Emerging Businesses, was Galeota's last role at Merck, and brought corporate-wide responsibility for strategy and business development, along with leadership of multiple new business and Merck's corporate venture fund. This positioned Galeota for his next move to President of G&W Laboratories, a 100-year-old, family-owned specialty generics company.

After 28 years at Merck, Galeota thought he knew a lot about the pharma industry. But, again, he found himself with a tremendous learning oppor-

FAST FOCUS

» Jay Galeota is a 32-year industry veteran; he spent 28 of those years serving at Merck & Co. in many diverse positions across commercial operations, business development, strategy, and innovation, both globally and in the US.

» The executive was instrumental in bringing Merck into diabetes and led the team that developed and launched the company's top grossing products, Januvia and Janumet.

» Galeota holds a B.S. in Biology from Villanova University and is a graduate of Harvard Business School's Advanced Management Program. He is the co-author of several publications in *Harvard Business Review* and *Chief Executive*.

» He currently serves as the Honorary Commander of the US Air Force 113th Wing, DCANG, Joint Base Andrews and has been a guest lecturer at the Wharton School of the University of Pennsylvania.

tunity. "The majority of the pharma industry in the US is not innovative pharma, it's generics; that is a very different business model," he says. "It's a complex and really difficult one. The chance to lead at G&W was a great opportunity from which I gained a lot of insights to carry forward and inspired a commitment to ensuring affordable access to medicines for those who need them."

Gifts of science

Galeota's business decisions and professional trajectory were never far removed from his foundational view of science, and the hallway of innovation at Merck. "I feel passionate about the value of the pharmaceutical industry to humankind," he says. "I feel like every discovery that these brilliant scientists have gifted us with are really gifts to humanity that must be guided in ways that ensure their full potential to improve human health is realized."

"The role of a responsible, innovative pharmaceutical company is to be the guardian of these jewels, these gifts, not act as the owners of them."

Achieving this, Galeota believes, is the industry's obligation. "The role of a responsible, innovative pharmaceutical company is to do just that—to be the guardian of these jewels, these gifts, not act as the owners of them," he says. "And that is an important distinction because there are, rightfully, many stakeholders with legitimate, relevant interests in how these special innovations are applied to society."

To carry that philosophy then into the role of the C-suite executive, believes Galeota, is to ensure that when those meaningful opportunities to improve human life appear, the executive does everything possible to bring them to patients. And do so in ways that ultimately convey the maximum benefit to humankind, while reflecting the true value of the therapy.

Galeota acknowledges that he came into the pharma industry in its golden age, shaped by a time when its new medicines and vaccines were quite literally changing the way medicine was practiced and impacting millions of lives in positive ways. He believes that pharma is on the cusp of another wave of meaningful advance and that, with the right kind of leadership, the industry can experience a resurgence in image that more accurately reflects the positive impact it has on humankind. However, Galeota observes, "In many ways, I think some companies lost their way, and some of that belief in the purpose of our industry and the value it brings to the world got clouded by other considerations."

If executives stick to a compass that comes from doing the right thing for patients and stakeholders—and keeps that focus front and center to the business—then the profits will come, Galeota contends. "And the profits will come in abundance if it's done the right way," he says. "It's a formula that is often taken for granted or even shortcutted in our industry, and it's a disservice to the industry when that happens."

Risky business

One could view Galeota as a risk-taker. Who else would knowingly get into a 49.3' x 16.7' fighter plane, with speeds capable of 1,500 mph, fly a straight vertical up 18,000 feet in the air, roll upside down, and then skim the surface of South Jersey at 600 mph, 500 feet above the ground? Sounds like a risk-taker; Galeota, however, says no. "I think of myself as somebody that imagines the possibility of things, but I am also very thoughtful about analytics and assessment and trying to understand the plausibility and probability of things."

The willingness to think originally and experiment in new environments does not necessarily equate with risk in Galeota's mind.

"Investing heavily in intelligence, and I don't mean the kind that's between your ears, provides one with unique insights that frequently lead to unfair advantage when a new trail is being blazed," he says. "The ability to accurately sense and assess probabilities helps minimize the riskiness of being out of one's traditional comfort zone. Using the fighter plane metaphor, accurate radar, sensors, and intelligence are as important as creative agility in the art of surprise and outmaneuver in combat. The three Ps—possibility, plausibility, and probability—are components of balance that I try to always bring to bear on decisions."

That balance in Galeota's own approach to risk is not one he sees operating at innovative pharma companies.

"At the industry level—and this has always intrigued me—is the existing dichotomy in pharma where we take enormous risk and make extraordi-

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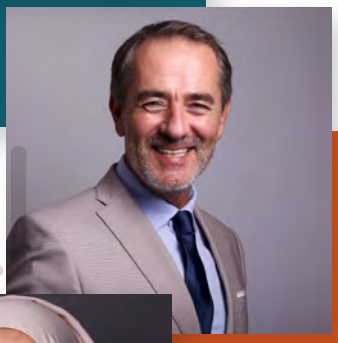

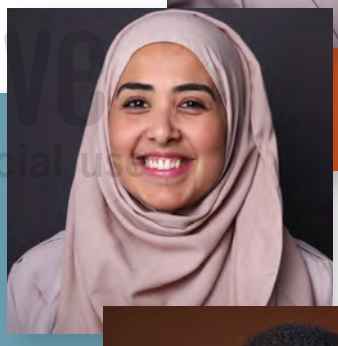

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nary investments over multiple years, on sometimes very little data, and organizations, within this industry, we are comfortable accepting this risk," he says. "Yet, when it comes to things like business models, go-to-market strategies, pricing approaches, supply and distribution, and policy issues, we are traditionally very conservative, unwilling to experiment and unwilling to take chances, by and large. I think that's why we are in the same paradigm that we have been in for decades with respect to those functions of the business."

"When it comes to things like business models, go-to-market strategies, pricing approaches, supply and distribution, and policy issues, we are traditionally very conservative, unwilling to experiment and unwilling to take chances."

To take that unbalance, the extraordinary appetite for risk on the research, discovery, and development side, and apply the same desire for innovation in commercial, manufacturing, and go-to market models to more effectively get medicines to the people who need them, is something Galeota would like to change. It's one ideal that he and his team at Inheris Biopharma were heavily committed to when the company was formed.

Team chemistry

The composition of a pharma company is its people, and they are, ideally, as Galeota first noted in the 90s, smart, achieving, professional, concerned, and ethical. In those early days at Merck, Galeota never feared that others had ulterior motives; he trusted his co-workers to have his back. Again, a moment in time that shaped Galeota's views early on for the types of people he preferred to work with, and as he moved up the ranks, the people he preferred to manage and develop and choose for his teams.

"I look for people who start a sentence with 'what if…,' are positive and resilient, tell it like it is, have diversity of perspective and experience, but an absolute commonality around ethics and ethos, and who also enjoy the journey," explains Galeota.

Being very careful around fit is an important attribute that executives and team leaders need to be cognizant of, he adds. "I heard years ago, and it's stuck with me, that in the end, leaders are remembered for three things: who they hire, who they fire, and who they promote," says Galeota. "It might be a trite statement, but there's a lot of truth in it because it is what leads to extraordinarily high-performing teams. They are rare, but when we see them, they all tend to have similar characteristics, and it's always around not only the skills, but also the chemistry of the people involved. Superior skills are expected, it's the price of admission, but the chemistry—how individuals work together—is the spark that differentiates extraordinary from simply above average."

There is also the secret sauce from "super teams," and Galeota says he has been fortunate to have been on a number of them. The team Galeota led that brought Januvia and Janumet to market, and ushered Merck into the diabetes space, he attributes to the experience of people with different expertise—clinical, regulatory, early development, marketing, legal, and manufacturing—that came together and aligned on a common purpose and succeeded beyond expectations. "That's the measure of a super team," says Galeota. "When you've exceeded what others or even you thought was possible for yourself as an individual and the team as a group, that's magic."

This dynamic also played out in the integration of Merck and Schering, according to Galeota. "It was the result of this super team—the chemistry, the magic that excited us all about what we were doing, and the prospects of the unique opportunity that we had," he says. Galeota adds that good leaders should look for that chemistry when gathering a team around a table. Is the dynamic just mechanistic, or is there a spark or reaction among members that could result in something that is greater than the sum of the parts?

Another super team Galeota was involved in was Merck's Hospital and Specialty Care leadership team. When first formed, it needed to understand which of those seven businesses the company could win in, which they could improve upon, and which they may have lost competitive advantage in. "We had to fundamentally reshape the business in a way that enhanced growth, but it meant exiting some businesses that were led by members of our leadership team," says Galeota.

But in doing so, those leaders stuck to what was right for the team and the enterprise. Galeota says

each one, ultimately, ended up in better positions afterwards because they were focused on doing the right thing for the business and doing it the right way—and other leaders wanted people like that on their teams.

"For leaders, there is a fine line between belief in a path to success that others don't see and ... folly. There can be a pet project, a view, an opinion that someone just won't let go of," says Galeota. "And the leader has to make the call to address that. Frequently, that is something a lot of leaders shy away from and, as a result, teams get stuck in mediocrity for too long."

Mediocrity of individuals or teams can also lurk in another fine line between constructive vs. destructive discourse, says Galeota. While he's a big believer that diversity of experience and the ability to voice an alternative opinion is a positive, with the best leaders instinctively seeking this out among their teams, sometimes discourse can drift to the negative.

"In those circumstances, you have to identify it and then work with the individual or individuals who are bringing the team down," says Galeota. "And if they aren't able to be coached into a contributory role, then in my experience, you have to make some changes."

He adds of those decisions: "A lot of times it should happen sooner than it does. Many times teams linger at suboptimal composition because leaders are hesitant to make the change, and, frequently, I've seen once the change is made, the level of the team's performance is remarkably impacted almost always to the positive."

Reinforcing again the importance of balance, it is Galeota's belief that the people who maintain that approach make the strongest leaders, and having balance in life and drawing on diverse experiences outside of work helps bring broader thinking to their business. For example, volunteering frequently brings fresh perspectives to individuals, as well as benefit to society. Just as appropriate work and life balance usually enables people to make more natural, creative, and considerate choices. While a 70-plus hour work week, for instance, is often equated with the road to professional success, Galeota disagrees.

"We all work hard, but balanced, thoughtful, diverse thinking is what separates the good from the great, and that's frequently enhanced by balance in life, not how much time you spend in the office," he says.

Galeota believes this balance—time for volunteering, time with family, time for activities that provide personal fulfillment—must be modeled from the top, or it just becomes rhetoric. The employees won't trust that it is a principled and desired behavior, unless their leaders walk the talk themselves, and model the way.

> "The chemistry—how individuals work together—is the spark that differentiates extraordinary from simply above average."

Culminating visions

Honoring science. Believing pharma can operate both dutifully and profitably. Leading super teams and shaping employees. Innovation in all aspects of the business, not only the labs. Trust and balance. These are many of Galeota's beliefs that have come together over decades of varied experiences. He saw a chance to build a new company reflective of these beliefs when Inheris was formed as a CNS-focused spin-out from Nektar Therapeutics last year.

"What swayed me the most to take this on was the quality of the people I met at Nektar," says Galeota. "I was impressed with their leadership and science focus from the start, along with their clear desire to do things the right way. It seemed like an ideal fit."

Galeota is optimistic about the future of pharma and the role that principled leadership will play in its continued impact on the world. But the challenge is great. The industry's reputation has never been worse, he contends, which is disheartening for those who are dedicated to improving the quality of human life. Something is fundamentally wrong when an industry exists for the good of others, yet is viewed so poorly.

"The opportunity to innovate has never been greater, and innovation now moves beyond the discovery at the bench to how that brilliance is applied in practice in ways that maximize the potential benefit conveyed to people who are suffering," says Galeota. "The creativity we each bring, and enable in others, matched with thoughtful assessment and analysis, will undoubtedly enable a new golden age of pharma if we focus on doing the right things the right way." PE

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Engaging the New HCP in the Digital World

Amid the growth but still-cautious embrace of social media and other digital marketing channels, appealing to the younger physician requires a nuanced approach—mixing proven expertise with fresh ideas

By Lisa Henderson

While pharmaceutical marketers are well aware of the changes in engaging with younger physicians and healthcare professionals (HCPs), the saying "don't throw the baby out with the bathwater"—probably a generationally relevant idiomatic expression—applies. While a brand team's methods to reach HCPs should incorporate the tried and true, it should be experimenting with new ideas to engage with a younger audience.

Market research firm InCrowd recently conducted a microsurvey to gain deeper insight into physicians' online habits by age. According to Philip Moyer, InCrowd vice president of crowd operations, the study data, which is to be regarded as directional only (total n=123), is based on responses from:

- Primary care physicians (PCPs) and specialists in practice for fewer than 10 years, n=62
- PCPs and specialists in practice for more than 20 years, n=61

For social media channels used for professional purposes, Doximity (63%), Facebook (49%), and LinkedIn (49%) are the top choices for all physicians surveyed. However, though both generations of respondents still use Doximity as a first choice, older physicians preferred LinkedIn over Facebook. Moyer noted that younger physicians use social media to crowdsource clinical questions, seek informal advice from peers, and learn from cases.

And while social media is used for professional connections in these examples, the personal connections are ones that physicians are justly wary of.

Moyer noted that HCPs prefer to communicate with patients in a limited capacity, and using social media or texting is very limited. "Examples of doctors doing that are few and far between. They have to be careful what they say online and they don't want to be cast in a negative light," says Moyer. "Though younger physicians may be online more, many don't want to go beyond communicating directly through their CRM (customer relationship management). Part of this is about privacy and comfort. But it's also about protecting their own time and limiting the way they are connected to work outside of office hours."

However, InCrowd did find that younger physicians generally embrace the use of new technology to communicate with patients more than their older counterparts do. For instance, younger HCPs are more comfortable pulling up an app or searching for information while in the room with a patient.

In addition, older physicians are more likely to reach out to patients by phone, whereas younger doctors have higher comfort levels in using electronic medical records (EMRs) to communicate with patients and share articles or other resources.

While the InCrowd survey did find that there was "a level of consciousness about not posting controversial opinions online," there are anecdotal observations around social media that some are taking to those platforms to raise concerns.

For example, Murray Aitken, executive director of IQVIA Institute, who reported the Institute's findings on the oncology landscape to the *Pharm Exec* Editorial Advisory Board, said, "Oncologists are becoming more aware and more vocal as to whether all of these new drugs are really breakthrough even when the FDA tags them as breakthrough drugs. And if you follow Twitter, there is a very active debate among leading oncologists around the quality of the evidence, and that's not something we saw too much of five years ago. So I think that scrutiny is worth watching." While this is not controversial nor personal (except in that it is a person sharing their opinion), it is an area of social media use that may change in the future.

> "Pharma wants trustworthy sources, and to be able to guide the conversation, which is difficult with social media."

But as for the use of social media outside of the personal purview, most believe pharma is hesitant, though many pharma companies do maintain corporate social media accounts, and on Twitter some promote progress on public health initiatives, innovation, and patient stories.

The IQVIA Commercial Compliance division plans, on average, 130,000 HCP meetings and engagements per year. According to Frank Spender, its senior director, compliance services, and Staci Hutchinson, director, global client services, the use of social media for pharma to engage or communicate to physicians is still in its very early stages for a variety of reasons, mostly related to trust and the wariness factor.

"Pharma wants trustworthy sources, and to be able to guide the conversation, which is difficult with social media," says Spender.

However, that concern doesn't limit what the IQVIA team is experimenting with in other technologies to engage with the younger HCP. "We see a shift away from email and phone and a shift toward things that are quicker, as well as text," says Hutchinson. "That is playing out in the type of events people are interested in. We see virtual and e-learning more popular with the younger HCPs, so high-tech solutions to be able to participate in e-learning is grabbing the attention of pharma." For example, Hutchinson says holograms, which might seem far out there, is something drugmakers are exploring.

Use of video is also transforming the younger HCP engagement. Hutchinson notes that events can shift from entirely live interactions, to possibly a blend of live studio broadcast with members available via video conferencing and viewed on a panel wall, or speaker trainings that are virtual with a video component.

In a nutshell, Spender and Hutchinson agree that all the technologies that the public is exposed to in general life—exemplified by how far smartphone capabilities and video/audio conferencing has come in a very short time—are reflected when engaging the younger HCP. "We see that technology changes with engagement will be signifi-

cantly different in the next two years," says Hutchinson.

Trusted sources and access

As noted, there is a level of skepticism and trust among all parties involved with new technologies—be they digital or social media. Eli Phillips, Jr., vice president of insights and engagement, Cardinal Health, says that newer HCPs are still looking for guidance and mentorship in their practice and seek the expertise of those who have been around the block.

"We think about how we put channels together for these new practitioners," says Phillips. "And what that looks like is a mix of podcasts, webcasts, and on-demand recordings with KOLs (key opinion leaders) that the younger HCPs can easily access and use as a trusted source." Phillips notes that KOLs have adapted to the use of digital technology and social media because they recognize that is where the world is going and continue to take leadership roles in these mediums as well.

The InCrowd survey did find, however, that both older and younger physicians see KOLs as having diluted clout in the current environment of readily available information, and shared these sentiments on reasons why KOL impact seems diminished:

- Access to information has changed the "authority" of KOLs.
- It's easier today than ever to get a broad range of information.
- It's harder for any single voice to break through the noise.
- It's more difficult to tell today who are the actual KOLs.
- Some feel that KOLs are less experts and more pharmaceutical spokespeople than they used to be—perhaps related to wider societal distrust of institutions.

Moyer did say that the role of the KOL will always be important, because their interpretations can help filter out the noise and best translate data. Another factor is that most information online still comes from KOLs and leaders at academic institutions—it just doesn't feel so closely attached to a KOL when the HCP is reading the source online rather than hearing that person speak from the lectern at a conference.

Another generational finding from the InCrowd survey was that older physicians pride themselves on still reading physical books and physical journals. If they see an interesting summary or comment on an article online, they are more likely to read the primary literature rather than be "spoon-fed" high-level summaries. In that regard, they felt that residents and students know their way around online apps, but they also can tend to latch onto the first answer that catches their eye rather than spending time developing a broader perspective.

Phillips believes that more novice practitioners do have a propensity to not want to read journals or articles at that stage of their careers.

"New practitioners have just spent all their time on education and learning, and now they want to focus on patient care," explains Phillips. "So it's not engaging for them to go back to print and read a journal article. They want easy online access… maybe clinical decision tools, algorithms…and they really want to be with patients." PE

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Improving the Link from Lab to Physician

How current barriers can affect prescriptions in precision medicine

By Elaine Quilici

The value of precision medicine, which relies on identifying biomarkers to treat particular conditions, is clear. And its prevalence to treat disease—especially cancer—is only expected to grow. According to an October 2019 report by The Insight Partners, the global cancer biomarkers market could reach $31.2 million in 2027.

Yet despite such a strong current, the biopharmaceutical industry faces a number of barriers along the pathway between biomarker testing and drug prescribing. These include how physicians order diagnostics, how samples are transported to the lab, how results are returned to healthcare professionals (HCPs), how doctors interpret reports, and regulatory and reimbursement issues surrounding the entire process.

In these areas, something seems to be getting lost in the flow between laboratory professionals and physicians, and pharma would benefit from stepping in to offer support before the issues grow exponentially along with the field.

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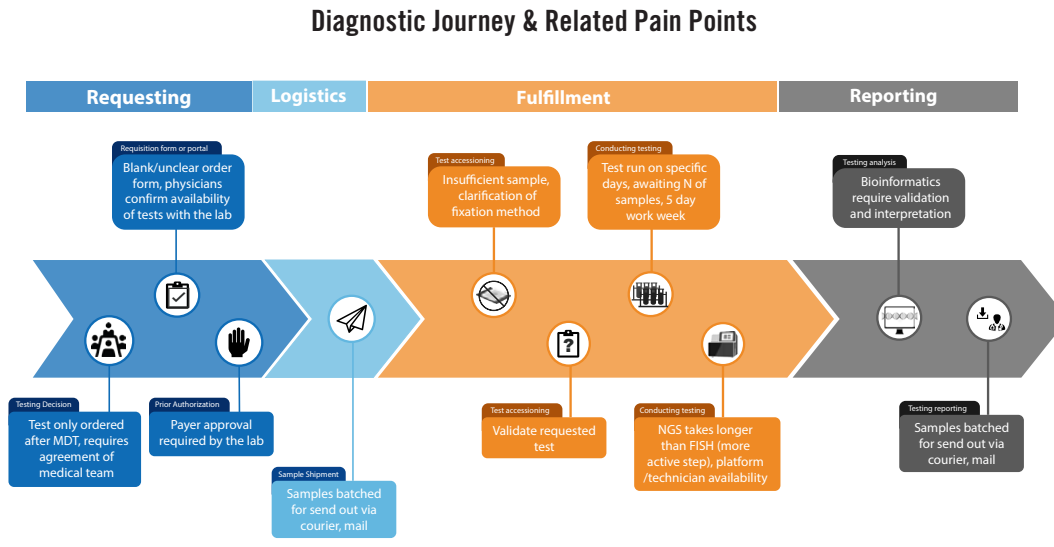

Source: Diaceutics

Developing diagnostics

Many precision drugs require tests called companion diagnostics. These differ from complementary diagnostics, which may not be required per the label but may be ordered by physicians at their discretion to use in therapeutic decision-making.

When developing a drug that requires a companion diagnostic, development of the diagnostic should ideally be run in parallel, and the drug and test should be available at the same time. However, as many precision drugs are fast-tracked by regulators, these medicines are leaving diagnostics in their trail. When a test does not progress at the same pace, FDA has been approving the drug with post-marketing commitment, so as to not limit access to a life-changing drug.

"I think we have to look at those situations and understand what is the risk-benefit of putting the drug out there and having it available to these patients," says Jordan Clark, chief technical officer, Diaceutics, a diagnostics data analytics and implementation services provider for global pharmaceutical companies. "[Bayer cancer drug]Vitrakvi has a 91% response rate in pediatric cases. That's a wonder drug. And delaying that by a year or two just because the test isn't available, in my view, it's probably not ethically right."

Multiple-choice tests

To ensure there was a diagnostic available for Vitrakvi, Loxo Oncology and Bayer supported using laboratory-developed tests (LDTs) and worked with big institutes and independent labs to make sure testing was available without an approved companion diagnostic.

According to Diaceutics, almost 75% of oncology testing in the US is provided using such LDTs. These tests take the place of commercially developed, FDA-approved tests and, says Clark, are "perfectly fine" in the US under the Clinical Laboratory Improvement Amendments (CLIA) regulation framework.

But physicians often don't realize substitutions are being made. When ordering a test where there is no approved diagnostic, it is the lab that generally decides which LDT to use. And a lack of education often leads clinicians to leave choices up to the labs.

"What we find is the physicians just order a biomarker—so they'll say, I want an EGFR test, or I want a PD-L1 test—they don't specify a methodology or an FDA-approved test," says Clark. "This can be confusing for physicians, particularly if you look at a Quest, LabCorp, or NeoGenomics test menu. They may have two or three different tests that cover the same biomarker. Physicians are not aware of the differences, and the advantages and the disadvantages between those. In many cases, the lab is not giving that information for them to make an informed decision. I wouldn't purely put it at the physician's feet; labs could be better there as well."

Without a requirement for FDA clearance, labs are free to develop their own tests, either alone or in partnership with pharma, which is creating mar-

ket competition. "Now you're a physician hearing from 10 different laboratories as to why you should use their assay over others," says Jeff Ellis, cofounder and managing director of Crosstree Capital Partners. "I can't imagine how challenging it is for physicians to keep up with the latest and greatest, because there's constantly three new things coming out, which are the latest and greatest, arguably, so it's a challenging landscape for physicians."

To address this confusion, pharma companies could reach out to physicians to keep them informed of current research that might prove insightful. They could also improve engagement through providing online diagnostic tools to assist in HCP decision-making.

But it goes beyond educating the physician. As new biomarkers come to light, the importance of multidisciplinary teams should play a bigger role. "It's fairly hard for one treating physician to keep up to date with all of the latest advances," says Clark. "We really should be thinking about this as a team effort and having particular specialties [such as the oncologist, radiographer, and pathologist] involved in order to ensure those patients are tested in the most appropriate manner. There's a really key role there for pathologists to educate."


Jordan Clark

Input and output

Logistics can be another hurdle. Many of these specialized tests aren't available locally, meaning samples oftentimes need to be transported.

"As we look at some of our newer tests in precision medicine, particularly around liquid biopsy testing and gene therapy testing, those logistics can become more complicated," says Clark. "We may have to get samples to a lab within four hours, or we may have to use specific tubes, or we may have to use ultra-cold temperature (dry ice) logistics. Those things make it more complicated than perhaps a routine tissue sample and EGFR-type of mutation testing."

Turnaround time of lab results is another area that could be improved. A delay in reading results could prolong a physician's treatment decisions.

"One of the biggest areas of patient leakage is the interpretation of the results and making sure that result is given to the physician at the right time," says Clark. "Here, the clarity of reporting is very important—actionable reports that allow physicians to understand and interpret the result into a clinical and/or therapeutic decision. Making sure that they're getting that at the right time is key."

For example, Clark points out that most acute myeloid leukemia patients will be treated within three days of their diagnosis. Glioblastoma patients however, who just had open brain surgery to remove a tumor, don't need those biomarker test results for multiple weeks, until they recover before going on any systemic therapy. "So understanding the disease and the urgency is really important as well," he says.

Much of the sample input and data output falls on the laboratory, but there can be other gaps that cause problems, such as basic technology.

> "You can educate the laboratory around tests and around eligibility for therapy, which then can be used as an information channel."

"An important KPI for laboratories is the time between when the sample or order comes in—receiving—and when they report the result out—lab turnaround time," says Clark. "But there is time on either side of that, that is not within the laboratory's control, which is not measured very well. [For example,] in Europe, we actually see that fax machines are still being used for reporting, and that adds a day or two to when that result is available to when the physician actually sees it in front of them. If you don't use a well-integrated [electronic medical record] system, then sometimes there can be delays in that reporting aspect of it."

Pharma should look to the laboratory as a valued communication conduit to physicians. "You can educate the laboratory around tests and around eligibility for therapy, which then can be used as an information channel from that laboratory to physicians," says Clark. "We often talk about the physician-lab interface as an untapped com-

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munication channel, whereas if we educate the laboratory, they can disseminate that information at the right time when a physician is needing to make treatment decisions."

Interpreting results

Pharma also could benefit from investing in education and training of physicians when it comes to understanding lab reports. Explaining how to interpret genetic information and then how to communicate its meaning to patients along with any treatment implications could improve the process.

Though oftentimes genetic counselors are used for this role, the better informed HCPs are, the better they can work with patients to make life-changing decisions.

"Last year, [a study by] Flatiron and Foundation Medicine said even when patients received the right test and they had the report in front of them, the physician still didn't put them on a targeted therapy," says Clark. "That was in lung cancer, and it ranged from around 60% to 70% in EGFR/ALK, but down at 33% for NCCN [National Comprehensive Cancer Network] biomarkers and therapies with lower prevalence. So even if you get everything right in that testing journey, your physician may still not give you a targeted therapy even though the guidelines support that. I think that talks a lot to the education needs of those oncologists."

Regulatory and reimbursement

Ellis believes that one of FDA's biggest challenges is trying to regulate the diagnostics market. "It's a huge task for the FDA," he says. "I think we'll continue to see more progress toward definition for reasonable ways for diagnostic tests to get approval and benefit patients in the end, but I think we still have a good ways to go before there's a structure in place that everyone feels comfortable with."

> "The more lockstep pharma and diagnostics are, the clearer the message will be to physicians in their decision-making."

Ellis does think regulators have made significant strides in trying to adapt to the changing landscape. "Look at Foundation Medicine—owned by Roche—and their comprehensive genomic panel diagnostic test," he says. "They worked with the FDA to expedite. The FDA set up a program wherein a company like that, if they make the requisite investment and develop a diagnostic test, they can have a pretty unique market position in the end. So the FDA are taking the right steps, but the landscape is changing so fast, and patient needs and innovation are advancing so quickly that it is hard for the FDA to keep up."

Jeff Ellis

Issues around treatment reimbursement also exist. For example, some healthcare insurance plans may require a patient to undergo conventional chemotherapy before they can access a targeted therapy, even though the guidelines state that those patients should go on targeted therapies beforehand.

"Sometimes, it's not just the physician, but it's the reimbursement systems around them and their practice within their institute or their managed care, where they have local guidelines to reduce costs, which actually might be inhibiting precision medicine," says Clark.

Missed opportunities

A recent study by Diaceutics revealed a loss of 77,856 patients per year to therapy and a revenue loss of $8.3 million per year to pharma in the US. These losses amounted to an estimated 30% of the oncology patient market and more than $16 billion per year in the US alone.

"Some pharmaceutical companies [still] have not fully embraced diagnostics," contends Clark. "They still think of it as a barrier, which they really shouldn't do, because it's that important for the success of their drug. Diaceutics has shown that every dollar spent in your diagnostics strategy has a return of investment of around 30 times. It really is that gatekeeper to those patients, and it is as simple as if you have a targeted therapy and don't get the test, you don't get the therapy."

As precision medicine continues to explode, Ellis echoes the importance of further cohesion and alignment between pharma and diagnostics and medical laboratories. "The more lockstep pharma and diagnostics are there, the clearer the message will be to physicians in their decision-making and the hope it will benefit patients in the end," he says. PE

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Surfacing Insights: AI and the Physician

The advent of data analytics in pharma marketing automation

By Julian Upton

In marketing to physicians, the days of "spray and pray" are, if not totally behind us, then definitely numbered. The spray and pray approach saw marketers complete their market research, create the message they wanted to send, and then fire out an email to everyone on their list, with no attempt to personalize the messages. The uptake of artificial intelligence (AI), however, in targeting and personalizing messages has been changing this practice. Now, when marketers send out an email, says Pratap Khedkar, managing principal, ZS Associates, "they can actually tell who opened it, when they opened it, whether they clicked through to the second page or click on any of the links." Accordingly, the ability to use these data and insights to understand what customers need, what kinds of information they want, and how they want to consume is driving a marked improvement in the way pharma engages with physicians.

For James Anderson, chief customer officer at Aktana, a company providing AI-enabled decision support for the global life sciences industry, "the growth in this area has been insane." Aktana's biggest challenge, he says, "is keeping up with the increase in customers we have." While the use of AI in marketing is not a new concept, what has changed over the last couple of years, explains Paul Shawah, senior VP of commercial strategy at Veeva, is the ability "to bring data together from multiple different sources and in a way that's ready for AI to generate insights and guidance on messaging for specific customers." Anderson agrees: "Ten years or so ago, pharma companies were starting to get their data warehouses together. Now the large companies, especially, have a lot of data that is ready to use. Combine that with the advances in AI, analytics, our ability to compute things quickly, and that leads to the big rush we're seeing now."

For Khedkar, harmonizing the way the marketing channels are managed has become a crucial factor. "The job of sending these things out channel by channel used to be outsourced. You had an email vendor—all the emails got sent to them along with the target list and they managed it." But with another party dealing with, say, iPhone alerts and another dealing with the reps, there were two or three other channels being managed independently.


Pratap Khedkar

"Companies have realized that you have to harmonize, which means one entity has to be in control of all these different channels to the same doctor," says Khedkar. This is where AI is beginning to help, he adds. "The technology has given pharma back the control of how it can actually modulate when different channels get used, and in what order they get used with the same doctor. You cannot harmonize manually, because you don't know what type of cadence, what type of timing, what type of sequences actually work with this particular HCP—that's all data driven."

With healthcare practitioners increasingly composed of millennials—for whom digital technology has long been not just a tool of work but, in many respects, a way of life—it should perhaps follow that the new developments in messaging are met with more active engagement by the younger generation than the baby boomers of old.

Khedkar has found, however, that "it's much more about how many years the physician has been in practice, rather than the physician's age." Anderson adds, "I know physicians who are older and more tech savvy than me; I know younger physicians who aren't as tech savvy. It all comes back to the individual preference. And we're getting to the point where you don't have to use proxies like age to figure those things out."

A more digitally savvy audience is by no means an "easier" one, however. According to Krishna Kadiyala, vice president, head of commercial operations and innovation at therapeutic antibody company MorphoSys, "customers have raised expectations in terms of how they consume and how they disseminate knowledge." The explosion of digital and social media channels, he says, is forcing companies to redefine their engagement strategies and shaping how they can be better partners to their customers.

Khedkar has observed variances in specialty more than in the ages of healthcare professionals (HCPs). "For example, rheumatologists and dermatologists remain very accessible to sales reps," he says. "On the flip side, oncologists are much less accessible. They are much more likely to open emails and much less inclined to talk to sales reps." Khedkar notes that dermatologists are still "very open to talking to sales reps, but their email open rate is only around 4.9%." He adds: "AI and data has to be able to exploit all this information."


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The evolving rep (and MSL)

Sales reps may be relieved to hear that certain specialty physicians still very much value their physical presence. Indeed, in the face of increasingly sophisticated automated marketing, reports of the sales rep's death have been greatly exaggerated. Large pharma is getting more comfortable with the idea that this technology is helping to make the rep more effective, says Khedkar.

While sales rep numbers have dropped compared with a decade ago, he doesn't see any further major disruption to the numbers. "The access situation has stabilized, and the number of reps now is about 70,000," explains Khedkar. "The peak used to be about 103,000, so it has come down a lot. I don't think the numbers will continue to drop—the 60,000–70,000 is here to stay." But with AI's mark on the sales and medical field teams proving to be an indelible one, the rep role will have to evolve. "Not by leaps and bounds," Khedkar goes on. "Maybe 20% to 30% of the reps will not be able to do their job all that well. But I think the majority of them will have to adopt this technology so they can use it as an additional arrow in their quiver."

Indeed, at the heart of the pharma–physician relationship, the rep's role will remain vital. Khedkar points to a statistic about emails sent to doctors. If the email is forwarded to a doctor by a rep—with the rep's email address and signature—instead of a third party, the doctor is six times more likely to open it.

For Shawah, AI is having two big, positive effects on the sales role. One is the "reinforcing of good behaviors." He explains, "The AI initiatives that have sprung up over the last four to five years have generally coincided with field teams having access to more digital ways of engaging with their customers, like remote meetings. Before that, most field personnel did not engage with their customers digitally. AI has reinforced the use of these new channels and when to use them, how to use them, and how they become part of their customer engagement process."

The second impact is where AI surfaces insights that the customer account team "would never have known," says Shawah. As an example, "a key account manager may not be aware of something that has happened with their customer, or even the patient; perhaps they get an alert that patients associated with a particular specialty pharmacy are delayed receiving their medications because of a reimbursement issue. Using AI to surface those insights, the account manager can then intervene and becomes more of a trusted advisor."

Salvatore Paolozza, director of sales operations at Antares Pharma, agrees. "Basically, the intelligence that we're giving to our reps is a lot further advanced than it was before," he says. Antares is an adopter of Andi, Veeva's AI application for customer relationship management. "What the application brings," Paolozza explains, "is greater flexibility and greater interoperability between sources. It completes the picture, if you like." Crucial here is AI's ability to learn, he says. "We're moving out of a coding environment to more of a learning environment. These applications can learn with time what they should and shouldn't surface up."

What to adopt next?

To stay in tune with the advances and possibilities of new applications and algorithms, pharma is

keeping a close eye on the activities of the big tech companies.

No one can attend a conference on using technology to communicate with HCPs without hearing about Netflix, Amazon, Apple, Google, or, to a lesser extent, Facebook. Pharma is some way behind these digitally native companies, of course; says Khedkar, "that's partly why the industry is looking to them. The question is, what else can it adopt?"

"Pharma needs to be a little bit more courageous in using AI on the data it has, because AI will compensate for the holes."

Some of the algorithms coming into pharma marketing and medical communications are indeed being adopted from Netflix and the like. Khedkar points to an algorithm called collaborative filtering, which is the way Netflix figures out what movie to recommend to individual viewers. "We took that algorithm, which is in the public domain, and modified it to work for pharma to identify specifically what type of content to send to a particular physician," he says. "As well as figuring out which channel you like, it's crucial to figure out what content to send. Should you send an efficacy message? An affordability message? A safety message?"

The problem with adopting such an approach, however, is that pharma "has gotten spoiled with sales data; they think that if they don't have 90% of the data right, then nothing can be done," says Khedkar. This is a mindset that needs to change, the executive believes. "What data do you think Netflix has?" he says. "When Netflix looks at the ratings from people who watched a certain movie, they have 2% of the data. What they're doing is extrapolating the 98% they don't know from the 2% they do know."

Pharma has to get more comfortable working with "poorer or incomplete data," says Khedkar, and let AI do its work. "The AI team is important because the data is not going to be perfect. Pharma needs to be a little bit more courageous in using AI on the data it has, because AI will compensate for the holes in the data."

Of course, pharma marketers are dealing with a considerably smaller audience than Netflix, maybe a pool of 10,000 physicians rather than millions of viewers. But for Khedkar, the "spray and pray" approach that turns physicians off is a much bigger risk in the smaller pool. "Both extremes are bad—hesitating and not doing anything because it's a limited pool or opting for spray and pray," he says. "You have to avoid both extremes and find the happy medium, which is where AI and data comes in."

While attempting to emulate some of the Netflix or Amazon methods is ambitious, pharma can look to other, more regulated industries for a more cautious approach. Says Shawah, "We often look to financial services because they are one of the best industries at identifying really valuable, high-net-worth customers and then managing them through the relationship life cycle."

He adds that in the telecom industry, the wireless service providers, for example, have a wealth of information about a customer before that customer walks into a physical store. "They know everything the customer's been doing on their phone; they may know if the customer is at risk of moving to a different carrier, or whether the customer is over or under his or her data limits," says Shawah. "They're able to use that information to have very targeted conversations."

Some industries are not always relevant, adds Shawah, "but it's important to look outside of life sciences as much as we like to look inside of the life sciences," he points out. "There's no monopoly on good ideas and where they come from."


Paul Shawah

All the advancing algorithms and technologies notwithstanding, the pharma industry must remain mindful of "the human being in the middle." In engaging HCPs, drugmakers are not dealing with a machine-to-machine interface; it is machine to human. "Because of this linkage, the data, the interactions, and the nuances will never be perfectly captured," contends Khedkar. AI provides "just a different model."

There will always be an element of complexity and imperfection, he adds. "It's about balancing the personal and the non-personal."

The key to success in using AI to engage physicians is making that marriage more fruitful. PE

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Using Service to Drive Commercial Value

One 'team' model's advantages in brand outreach and awareness

By Mike Stout

Accessing and impacting healthcare professionals (HCPs) is a complicated process, yet at its core it is still a critical driver of healthcare delivery. To optimize these efforts, the industry is using sophisticated sales analytics and planning to drive physician promotion through multiple channels and models. All the while it is striving to develop the flexibility and responsiveness needed to target and adapt the promotional mix in response to these tracking analytics. A commercial field service model, developed in partnership with major pharmaceutical companies, has morphed and developed to be a significant commercial program in delivering compelling value and return on investment (ROI) in support of key brands across their life cycle.

Why a service team—and why now?

The Commercial Service Team (CST) field model was developed to address commercial challenges in three key areas: loss of exclusivity (LOE) brands, brand launch support, and amplifying growth brands. With LOE brands, the challenge is to slow down the sales bell curve drop-off as these brands lose exclusivity and awareness, since they still tend to represent significant revenue potential, be beneficial to patient wellness, and be better known to prescribers than their generic counterparts.

Field sales teams representing launch or growth brands are often not able to get their brand messaging to resonate with target accounts as cost effectively as desired, so amplification of this promotional effort through the service channel is an ideal solution. Only reaching the prescribing HCP and retail pharmacy with a traditional field sales rep to harvest the LOE brand potential or reinforce launch and growth brand messaging is not always practical.

Not wishing to leave these end-of-life brands to sell by inertia along the diminishing-returns bell curve, or lose the upside potential in launch and growth brands, the industry has looked to other promotional methods. Some companies chose to use non-personal multichannel outreach exclusively for these products. Others sought to incorporate a field solution that would maintain brand awareness at a more effective cost point.

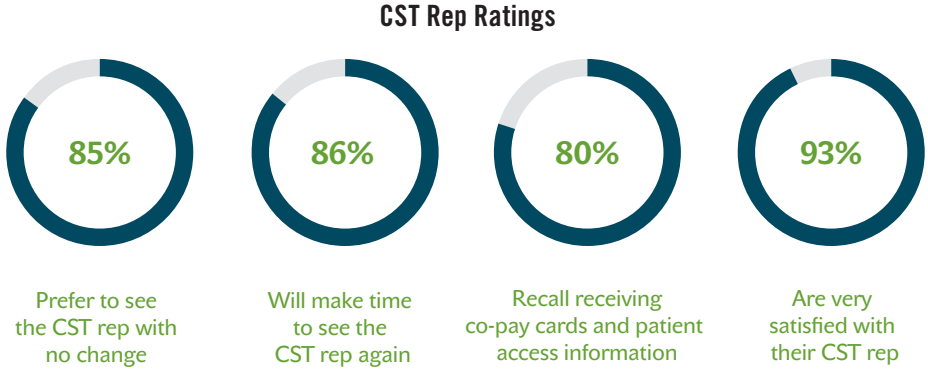
The CST model can be considered a solution to these challenges. This non-clinical model maintains face-to-face contact and promotional messaging on brands that could otherwise go unrepresented. It deploys a full-office engagement team that complements existing commercial channels by connecting brands to patients and their HCPs.

These teams provide savings cards, samples, patient starter kits, payer access information, product training, and other support materials. In so doing, the model offers brand engagement at 50% to 75% less cost than a traditional field sales representative, and maintains the face-to-face contact that cuts outside the digital noise accompanying many multichannel campaigns.

How it works

The CST model can be tailored to meet a variety of promotional needs focused on providing non-clinical product support and pull-through. CST reps are fully trained within compliance standards to service physician offices with samples, literature, reimbursement and access information, and copay cards. Many teams are also tasked with demonstrating to the staff the correct administration of the brand's delivery mechanism, as well as providing information on the patient support programs available in order to improve adherence. To maximize customer coverage with optimal frequency, the typical service territory covers a 50 to 75 mile radius, and the model is most effective when these territories cover metropolitan statistical areas.

Commercial service reps come from many different backgrounds. They are college educated, but do not need previous pharma sales experience or a scientific degree. Rather, individuals are hired based on their service mindset (i.e., hospitality, retail expertise) and ability to build rapport and create opportunities for discussion, and to do so repeatedly and consistently to achieve daily target goals. Inherently, they have a different motivational driver than field sales reps, as they are expected to reach daily target goals of office calls and distribution of samples



Source: Ashfield Healthcare

HCP and staff impressions of the commercial service team (CST) rep.

and/or non-sample resources, as well as being knowledgeable in managed care to support patients and their use of the brand.

Each deployment is based upon the needs of the client's particular brand promotion, with flexibility of implementation the key. Some teams cover LOE brands. Some will supplement field coverage of launch or growing brands to heighten awareness by providing samples or managed care information while the sales rep concentrates on clinical messaging. Some handle vacancy management or whitespace promotion. The ultimate goal is to optimize face-to-face interactions with prescribers and key influencers in order to make a difference to the patient and thereby maintain or increase script writing.

Since this is a model based on core activities, customers are targeted based on where they can be optimally reached (group practice prioritized over solo practitioner). Commercial service reps can support upwards of 20 or more brands across multiple portfolios in their bag, but will only address the designated brands targeted for that specific account. In some cases, the CST rep supports brands from more than one manufacturer in the same call, based on the targeting and allocations for that account. One to six brands are the average representations in a call, although as many as 10 brands can be represented. Average account calls per day range from 15 to 20 over 220 days in the field, versus 190 days in the field for traditional sales reps.

On paper, the CST is a very attractive model to pursue—in practice, even more so when one considers the impact these service visits to the office can have in terms of brand awareness at a significantly lower cost than traditional sales visits.

Why it works

The CST model is effective because it offers patient support service to the physician and staff in a quick face-to-face visit (average of two minutes). While the field sales team works to deliver messaging and create brand awareness, it may be necessary for them to see a prescriber 12 times before the brand is remembered. In the case of LOE brands typically having a strong clinical voice already, or in other brands where samples are needed, the CST rep is offering information to help better serve patients. The HCP tends to be more receptive to this type of rep interaction.

Although HCPs find the service provided to them and their staff by the CST rep inherently appealing, the CST model requires laser-focused back office analytics and an innate flexibility to reach program goals. All reps are tied into the CRM system, which draws upon leading-edge targeting technology based on the criteria of high prescribers, total prescriptions (TRx), brand loyalty, and other segmentations. The rep records activity at each account, which, in turn, drives weekly or monthly analytical reports to measure progress and keep the program effective at all times. Initial call activity is built in tandem with an analytics team and the pharmaceutical company, based on prior experience, goals, and industry-specific data. The technology platform allows for program parameters to be changed in real time to optimize the rep's call plan.

Creating commercial value

Since its inception, the CST model has delivered strong impact on TRxs. One nationwide program representing an LOE brand showed TRx increases ranging from 46% to 74%, delivering a marketing ROI of 75%. In a launch brand program, where the CST was tasked with elevating perception of the brand, the team delivered a +2.1 TRx impact among high-value customers. When surveyed, 93% of the customers reached were extremely satisfied with the CRT rep. Eighty percent recalled receiving copay and/or access information and 86% said they would see the CRT rep in the future (see chart). Other multi-year programs have shown ROI results ranging from 3:1 to 5:1. PE

MIKE STOUT is President, Ashfield Commercial, US, part of UDG Healthcare plc

Knowledge is Power

Keeping oncologists current through online continuing medical education

According to the Centers for Disease Control and Prevention (CDC), lung cancer is the leading cause of cancer death in both men and women in the US, with about 228,150 new cases diagnosed in 2019 and approximately 143,000 deaths reported annually.[1] Treatment for lung cancer varies widely depending upon the type of cancer targeted (small cell or non-small cell), the stage of the cancer, as well as other factors, with innovative therapeutic strategies emerging every year.

Online CME as a change agent

As these new cancer treatment approaches evolve, it is more important than ever for oncologists to stay up to date with the latest information on how to achieve the best outcomes for their patients. Online continuing medical education (CME) is a demonstrably effective option[2] for preparing oncologists to integrate therapeutic discoveries into clinical practice—offering high-value education rooted in science in formats that match oncologists' learning preferences.

Online CME personalizes learning by identifying gaps in knowledge and skill through pre-activity assessment of participants, and subsequently delivering independent, accurate, unbiased, and scientifically rigorous educational content via formats that are clinically relevant and interactive in nature.

"As treatment options for lung cancer increase at a staggering speed, educating the practicing oncologists and care teams in real time is critical to ensure that patients are benefiting from the scientific advances," says Suresh Ramalingam, MD, FACP, FASCO, Professor of Hematology and Medical Oncology at Emory University School of Medicine. "Independent CME programs, such as the ones offered by Medscape Oncology, play a major role in ensuring rapid dissemination of new knowledge to ensure quick adoption of new standards of care in the academic and community settings."

Medscape Oncology has an unparalleled and unique relationship with its community of oncologists as an independent resource to them throughout their daily workflow. Across Medscape's diverse pillars—News & Perspective, Drugs & Diseases, Education, Business of Medicine, Journals, and Medscape Consult—clinicians find value throughout their careers.

Medscape is the leading provider of online CME to physicians[3] and offers blended learning solutions covering the many types of lung cancers and the treatment options available; moreover, they are committed to delivering precision education when and where clinicians want to learn.

A team of experts in lung cancer—including a Steering Committee of world-class oncologists, together with Medscape Oncology's Medical Education Directors, Clinical Strategists, and Program Managers—guide each program throughout its life cycle to deliver high-quality education.

"We learned from an analysis of cancer immunotherapy activities that timely continuous education designed to meet the learners' needs is impactful, resulting in an average 33% relative improvement from pre- to post-education from 2014 and 2018," says Katie Lucero, PhD, Medscape's Director of Outcomes Research. "However, on average, about a third of participants still need more education in the topics covered."

"As treatment options for lung cancer increase at a staggering speed, educating the practicing oncologists and care teams in real time is critical to ensure that patients are benefiting from the scientific advances."

As treatments for lung cancer continue to evolve, likewise will physician education and CME continue to be of the highest importance in helping oncologists learn what they need to know to improve patient outcomes. PE

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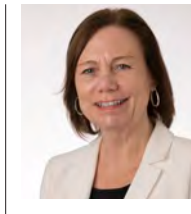

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A Q&A

Navigating Global Signing and Compliance with Signature Standards

Michael Yatsko
Senior Director of Compliance
DocuSign

The adoption of the EU General Data Protection Regulation (GDPR) put life-science companies on notice that even in the digital era, not all information is free. But GDPR was hardly the first or only regulation intended to manage and protect critical information, including life-science research and data. Complying with multiple international regulations can tax even sophisticated companies, so it helps to know the ins and outs of compliance, as well as best practices for thriving within these systems. Here, Michael Yatsko, senior director of compliance at DocuSign, explains how companies can navigate data-security regulations, at home and abroad.

Pharmaceutical Executive: How does DocuSign maintain compliance with 21 *CFR* Part 11 internationally?

Yatsko: In countries worldwide, health and life-science companies are regulated for the products they sell. Each country has its own version of the US Food and Drug Administration's (FDA) 21 CFR Part 11 regulation for electronic records and electronic signatures. For instance, the European Medicines Agency has Annex 11, while the Japanese Pharmaceutical Medical Device Agency follows the Pharmaceutical Affairs Law.

Fortunately, regulators expect the electronic records and signature regulations to be incorporated with the industry-standard Good Practices (GxP) already performed by health and life-science companies. GxP refers to quality standards such as Good Clinical Practices (GCP). Health and life-science companies need to validate electronic records and signatures as part of their quality assurance efforts.

We have customers in the US, EU, and Japan that use the 21 CFR Part 11 functionality in DocuSign's Life Science module to meet their electronic records and signature requirements in those countries.

Pharmaceutical Executive: How should data be stored and accessed to be compliant with GDPR and binding corporate rules (BCRs)?

Yatsko: GDPR, a new regulation that came out in May 2019, codifies the EU Citizen Privacy Rights and the defined roles and responsibilities of data processors and sub-processors on how to handle EU citizens' privacy data. While GDPR outlines the requirements, it doesn't indicate exactly how companies should meet those requirements. Companies may propose any solution to meet the requirements.

One popular way of doing that is through BCRs, which lay out how companies meet every requirement within the GDPR regulation. DocuSign has outlined its BCRs and got them approved by the Irish Data Protection Commission. As part of that, our customers are "data processors" because they own the data being requested and managed on behalf of EU citizens.

When a document is put in the DocuSign e-signature cloud, EU citizens are asked to fill out personally identifiable information. Then, data processors manage that data.

At DocuSign, we store that data within EU data centers. Only the sender or the signer have access to the data. Once there's no longer a business need for that data, DocuSign has tools to help the data processors redact or delete data upon request from an EU citizen.

Pharmaceutical Executive: When companies adhere to GDPR, are they compliant with other data privacy and protection laws in other countries?

Yatsko: Many countries passed privacy laws

before GDPR. Argentina, South Africa and Japan all had data-privacy laws, some dating back to the early 2000s. GDPR also outlined a roadmap for other countries to follow. Countries following their lead include Australia, Singapore, and South Korea. In January 2020, California will enact a California Consumer Privacy Act (CCPA), which follows what the GDPR outlined. Each country has the right and ability to set up different requirements. As a software-as-a-service (SaaS) company, DocuSign is responsible for ensuring we comply with the regulations in the countries in which we do business.

Pharmaceutical Executive: Cybersecurity is a concern for pharmaceutical compliance officers. What are some strategies for ensuring that documents are safe?

Yatsko: The challenge for compliance officers is securing the document throughout its lifecycle. All activities must follow the core security tenets of confidentiality, integrity and availability.

Confidentiality means only authorized users can access that document, so we must know the identity of those users and have strong authentication of them using something like two-factor authentication and implementing protocols like data encryption in transit and at rest.

Integrity means that the document and data added to it haven't been modified. We do that through checksums to verify file integrity and through audit trails.

Availability is the ability to access documents on demand, and for that, we need data-center redundancy and backups of the files and databases to ensure that if data corruption occurs, we have a last-known good copy to fall back on.

For SaaS-based services, compliance officers must ensure vendors have ISO 27001 certification or a service organization control (SOC) 2 report. An ISO 27001 certification is an information-security industry standard that many companies adhere to across the globe; SOC 2 tends to be focused on US-based companies, but it goes into excruciating detail on confidentiality, integrity and availability controls widely recognized within the US.

For on-premise software such as SharePoint, compliance officers must ensure that the corporate IT team follows the information-security requirements and standard operating procedures to deploy and secure the software to their specifications.

Pharmaceutical Executive: How does single sign-on comply with electronic signature regulations?

Yatsko: Single sign-on binds the user's identity with acceptable credentials based on the company's information-security policies and access-control standards.

Credentials can fall into one of three categories: something you know (e.g., username and password), something you have (e.g., a one-time passcode) or something you are (e.g., fingerprint). This is how single sign-on companies can centralize that credential into one place rather than having it dispersed amongst multiple systems.

With SaaS-based services, documents are stored in one place rather than being dispersed through multiple systems. We can secure the connection and leverage transport layer security connections to ensure that data to encrypt it in transit. We can also put in audit-trail capabilities to go back and record all the events in the lifecycle of that transaction.

Pharmaceutical Executive: How does DocuSign conform to FDA's guidance on the use of e-signatures?

Yatsko: DocuSign pioneered electronic signatures in the cloud. The Uniform Electronic Transactions Act and E-SIGN acts within the US make electronic signatures legally admissible in a court of law. With that, we created audit trails and certificates of completion to explain how a transaction works, so that if judges looked at it, they'd understand what happened in the actual transaction with the document. We can also provide information to FDA or other regulators, such as the Office of Civil Rights (OCR).

In 2014, we launched a specific Life Science module designed to meet 21 CFR Part 11 requirements. From a transparency standpoint, DocuSign maintains numerous information-security certifications. For example, we have an ISO 27001 certificate, produce SOC 2 reports annually, and maintain PCI compliance.

We've also achieved several government certifications. In the US, we have US FedRAMP authorization at a moderate level for US federal agencies. We're currently pursuing Department of Defense IO4 certification for military agencies. In the EU, we have Trust Service Provider certification for electronic signatures, and in Australia, we have IRAP certification to sell into federal agencies.

Pharmaceutical Executive: Can you talk about advances in paperless clinical trials? How can pharma and CROs move away from "wet" signatures?

Yatsko: It depends on how the company is set up. For paper-based companies, DocuSign provides the ability to upload required documents and create templates that define the order and signers in the workflow. Companies can create transactions based on these templates and process those transactions through internal or external signers, all through DocuSign. Once the transaction is complete, the signed documents can be retained either within DocuSign or exported into another solution.

For companies that already implemented an electronic solution, DocuSign has application programming interfaces to integrate with that electronic clinical-trial software or service. In these cases, companies can fill out some or all of their documents within the clinical trial solution. Then, the integration pushes these documents into DocuSign and kicks off the workflow to get internal and external signers to add data and sign the documents. When we get the complete documents, the signed documentation can be returned to the clinical trial solution, retained within DocuSign or exported to an on-premise solution or other type of cloud-based solution.

Pharma Outsourcing: Keys to Productivity in 2020s

Eight lessons to drive better outsourcing decisions

Outsourcing in the pharmaceutical industry has become increasingly prevalent in the last 10 years. Grand View Research estimates the global market for business process outsourcing (BPO) was valued at $195.2 billion in 2017 and is expected to exhibit a CAGR of 7.4%. By 2025, this market could well reach over $340 billion.

According to the new TMR report, the global life sciences BPO market will register robust growth driven by a CAGR of 8.9% during 2015-2023. The market was valued at $127.4 billion in 2014. It is expected to touch $286.3 billion by 2023. Focus on core business, relentless pressures on cost, and the growing competency of R&D outsource providers will drive further growth, though this will surely tail off at some point as the outsourced market peaks.

Until the mid-2020s, we expect outsourcing to provide a critical contribution in a sector where only the biggest players can invest in the diverse range of discovery, development, and commercial platforms necessary to shepherd a molecule from laboratory bench to commercial success. We can't claim to have thought of everything, though organizations adopting the following eight experience-based lessons can increase the chances of business success rather than a frustrating deal that doesn't deliver value.

MARK BOUCH is managing director, Leading Change

1. Prioritize opportunities to increase quality over cost

Experience from other sectors suggests a desperate need to reduce the cost base, although it doesn't always take account of the true costs of outsourcing, which can impact customer experience. Low rates for service often correlate with poor quality. Don't compromise on customer experience to save a few dollars.

2. Failure to understand/mitigate business risk

It's generally accepted that first-generation outsourcing carries risks to supplier and customer. In an immature market, it's easy to under-quantify risk to supply chains and service functions. But experience shows it's also possible to do so in subsequent generations of outsourcing. Operational rehearsal and/or pilot programs to test proofs of concept and continuity plans are essential to understand operational risk and minimize reputational fallout.

3. Build on strengths, rather than compensate for weakness

In addition to cost reduction, "we can't do it/we don't want to do it" may provide valid reason to outsource, but there is little point in outsourcing in response to failure to manage internal capability. Outsource service vendors are established to manage consistent, repeatable processes at optimal costs, not compensate for management deficit in the outsourcer's business. Another trap outsourcers fall into is to use contract research organizations (CROs) to supplement scarce in-house resources, but unwittingly duplicate in-house activity (and increase costs). Pharmaceutical companies must still provide clear direction, influence internal opinions, overcome internal resistance, and make key decisions. They will need to retain and reward experienced staff with the knowledge and skills necessary to manage their own business and outsource partners.

4. Build genuine engagement

It's a fatal error to establish adversarial relationships based on a tyranny of key performance indicators, which can have unintended consequences. Common hallmarks of "challenging" partnerships include a tendency for intrusive micro-management of outsourcing partners—perhaps unsurprising if this also represents prevailing culture in the pharmaceutical partner. Let's not be in denial about this—organizations pre-disposed toward control are all too common, but they're not well suited to the more agile, boundaryless ecosystems that will prevail in the future.

Successful partnerships involve outsourced vendors in building a shared strategic intent—this means co-creation of a rich picture of success, why it's important, and how the relationship will be developed. We facilitated an example with practical benefits where a clinical trials vendor was regularly invited to key leadership team offsites to discuss strategic priorities, align objectives, integrate activity, and build relationships. As a result, they readily engaged in collaborative problem-solving outside the transactional

framework. If techniques work well to engage your own staff, think about how you can apply them to external vendors.

5. Aim for a good cultural match

Most outsource deals take full account of scientific and operational capabilities during the sourcing process. More need to take account of subjective factors like cultural fit, ways of working, and the potential for strong complementary relationships. Understanding the cultural fit between your business and the outsource vendor is critical. Outsourcers often expect the vendor to adopt their business culture, but you need to recognize they have their own culture too. It's a two-way street. Both parties need to value, embrace, and adapt to each other's culture, investing time to build effective relationships.

6. Start with a collaborative mindset

Companies sometimes outsource business processes with an unhelpful mindset. It's tempting to regard outsourced (often offshored) partners as employees, which they are not, or as a fully expendable resource to be stretched or eliminated at will. When selecting outsource partners, a good match of values and an emphasis on building open, productive, and collaborative relationships will help lead to success.

Successful partnerships need close acquaintance with respective company cultures and ways of working. In our experience, this doesn't happen by chance. Active intervention is necessary to build trust and respect—without effort, a more adversarial mindset can result (them and us). Early engagement is always best to co-develop vision and goals, build positive relationships, clarity about accountabilities, and how success will be measured and delivered. It's self-evident this is easier when long-term strategic partnerships are in place.

we've seen outsourcing deals where the company attempts to outsource the risk without taking adequate account of the service provider's capability or inherent project challenges; this approach is based on denial. We like to see

Organizations pre-disposed toward control are all too common, but they're not well suited to the more agile, boundaryless ecosystems that will prevail in the future

7. Build on effective communication and oversight

Improving communication and oversight is commonly cited as a challenge in our organizational development work. Time zones, language, and culture play a role, and do not always help. It's tough enough with organizational boundaries and geographically dispersed in-house teams, but when you throw in a different company, there is plenty of potential for misunderstanding and error. Getting work done with outsourced vendors is a team sport. It requires frequent exchange of concepts and ideas and appropriate, though not over intrusive, governance. Social interaction, building trust, and a willingness to engage in productive conflict is essential to developing cohesive teams.

Put the best people on it. Too often, managers used for oversight of in-house teams are reassigned to manage outsourcing relationships, but they lack experience in doing so and this can weaken relationships due to overlap or duplication in roles and responsibilities.

A risk-sharing approach is preferable in many cases, but greater emphasis on realistic, jointly developed, performance targets and incentivization for exceeding them.

8. Lack of commitment

Many business process outsourcing deals tend to be of five-years duration, providing opportunities to reassess and change vendors. In the case of outsourced pharmaceutical R&D activities, changing course mid-contract will inevitably be a painful process with implications for delivery milestones. Hence, you need to ensure organizational commitment, a supportive executive coalition, and thorough stakeholder engagement before the deal is agreed and maintain a healthy relationship throughout the project or deal lifecycle. This will include robust processes for performance review and planned service improvement.

While cost-efficiency remains a vital driver of outsourcing decisions, building scalable capacity, improving service delivery, and freeing up resources to focus on high-value activities provides significant untapped potential to make organizations more effective and agile. PE

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HEALTHCARE & LIFE SCIENCES REVIEW

Raising the Bar

HUNGARY

Hungary is fast staking a reputation for itself as one of Central and Eastern Europe (CEE)'s most dynamic economies. Thanks to increased European Union (EU) funding, higher EU demand for its exports, and a rebound in domestic household consumption, the country achieved year-on-year GDP growth of 4.8 percent in 2019. GDP per capita stands at USD 16,500 today, significantly above the pre-global financial crisis high of USD 14,000.

A major factor behind this economic growth is pharmaceuticals, which account for 7.5 percent of Hungary's GDP and have long been a national flagship industry. As Dr György Bagdy, professor and former vice rector at Semmelweis University, notes, "after the Second World War the eastern bloc countries were given special commitments by the Soviet Union, and Hungary was bestowed drug research and discovery responsibility." This history of pharmacological research and production is reflected today in an attractive pharma investment landscape and the presence of home-grown success stories such as Gedeon Richter and Egis on the international scene.

Around 60 companies are licensed to manufacture human medicinal products in Hungary, making it one of Eastern Europe's leading pharmaceutical manufacturers, and medical and pharmaceutical goods account for a full 4.9 percent of the nation's total exports, the highest percentage in the CEE region.

Industry insiders are keen to play up Hungary's investment potential. "There are several incentives such as tax benefits and grants from the Hungarian government to stimulate industry R&D and manufacturing investments," exclaims Dr Istvan Hodász, CEO of Egis, Hungary's largest generic manufacturer. "Moreover, due to Hungary's strong tradition in pharma, the skill and availability of the workforce has been a significant factor in attracting several pharmaceutical companies to establish their R&D and manufacturing capabilities in the country," he continues.

However, despite the overall attractiveness of the Hungarian pharma investment landscape, several challenges exist, most notably in terms of market access for innovative treatments. Medical device and pharmaceutical importers often face a number of hurdles when attempting to obtain approval to be placed on the national health insurance reimbursement lists.

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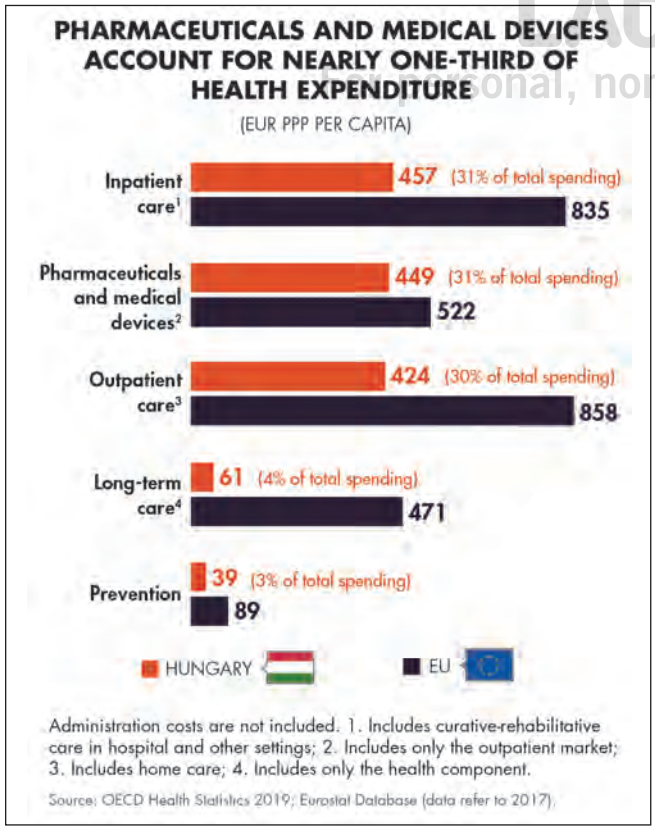
ENTERING A NEW AGE OF ACCESS

In 2016, Hungary transitioned from a second-tier member to a full member of the EU. As Judit Bidló, deputy director general of pricing and reimbursement for Hungary's National Institute of Health Insurance Fund Management (NEAK), explains, this has already had a significant impact on patient access to innovative new products. "As soon as there is a new product registered in the EU, within days, patients who are eligible for this treatment are made aware of it," she outlines. "This has improved transparency within the healthcare ecosystem, and inadvalertently, increased the velocity and scale of reimbursement appeals as well."

Access to innovation remains the most pressing matter for Hungary's pharmaceutical ecosystem, and Bidló acknowledges that the "NEAK needs to find solutions to reconcile the number of new products registered with a reimbursement system that can adapt to this new influx of registration." The current regulatory framework for reimbursement is a bone of contention for innovative industry players who operate in the country.

"Hungary has one of the most bureaucratically clad and complicated systems in Europe and it takes up to two years before a new drug is approved for reimbursement. The process requires political decision, as the healthcare budget is not under the state secretary for health, but under the minister of finance; some decisions even require approval from the prime minister's office,"





Ildikó Horváth, minister of state for health; Mátyás Szentiványi, director general, OGYÉI; Judit Bidló, deputy director general for pricing and reimbursement, NEAK

proclaims Peter Holchacker, director general of the AIPM, Hungary's association of innovative pharmaceutical manufacturers.

Despite being a highly strategic market within CEE, Hungary lags behind its neighbors in terms of market access. "As I manage Bulgaria, Romania, and even Slovenia, I have a benchmark reference for what access conditions are like in these other markets. In these countries, the reimbursement process is faster and more transparent," laments Dr Attila Lukács, general manager and head of commercial operations EEU for CSL Behring in Hungary, Romania, and Bulgaria.

IBSA's Anna Wienner concurs, pointing out that "only one-third of products which are submitted into the reimbursement scheme are accepted by NEAK, which is unacceptable." For example, since 2016, 71 and 69 medicinal products have become available for patients in Bulgaria and Slovakia respectively, yet this number is only 48 in Hungary.

Furthermore, the country's pricing system adds additional complexity to solving the market access equation. CSL Behring's Lukács points out that "Hungary has one of the strictest price-referencing systems in the EU, which then plays into how products are analyzed for cost-effectiveness in the country."

Lukács insists that this evaluation system is not effective because "some innovative products cannot be benchmarked to the existing standards of care which have extremely low costs, such as steroids or antibiotics. This limits growth opportunities not only for CSL Behring, but for the entire pharma industry. Because of this, certain brands and products will never be launched in Hungary."

The AIPM's Holchacker goes on to clarify that from a legislative perspective, the Hungarian decision-making procedure is quite in line with the European requirements and transparency directives, but adds, "however, the political influence in the decision-making process makes it hard to support improvement efforts." So the question remains: How can a fast, effective, and sustainable reimbursement system be created?

While bureaucracy has hindered the upper levels of Hungary's regulatory infrastructure, the 2018 appointment of a new director general for the National Institute of Pharmacy and Nutrition (OGYÉI) – the administrative authority for medical product evaluation – offers the possibility of new dynamism in the country's market access scheme.



Peter Holchacker, director general, AIPM; György Bagdy, head, department of pharmacodynamics, Semmelweis University; Attila Lukács, general manager Hungary, Romania, Bulgaria & Commercial Operations EEU, CSL Behring

Having had a longstanding career in the pharmaceutical industry, Dr Mátyás Szentiványi, OGYÉI's newest leader, aims to bring a fresh and collaborative mindset to the organization. "It has been my goal to streamline regulatory processes in areas where we have sufficient expertise and establish more successful deadlines. Furthermore, I aspire to create a clear regulatory framework for activities such as drug promotion, which are often interpreted differently by government, industry, doctors, etc," promises Dr Szentiványi.

The industry has made its need for transparency known, and having a regulator with a pharma background who can see both sides of the coin and hopefully deliver win-win solutions is a promising step in the right direction. Looking towards the future, Irma Veberič, general manager of the Hungarian affiliate of Roche, expresses that the pharma companies "hope to see reimbursement publications without limitations and with a higher frequency."

VALUE-BASED HEALTHCARE: EXPLORING POSSIBILITES

Among the efforts of Hungarian stakeholders to determine more efficient pricing and reimbursement structures, there is a common ambition to explore what is considered by many to be the next epoch of healthcare; a value-based system.

Understanding the universal issue being faced by healthcare systems around the world, Roche's Veberič insists that "the cost of healthcare in Hungary is increasing at least twice as fast as GDP growth. The clear solution is moving from paying for each individual box of pharmaceuticals to a value-based healthcare system."

Bidló of NEAK agrees that creating such a system is "not a possibility, but a necessity." However, the lingering doubts of how such a transformation can be accomplished are not to be overlooked. "The EU published recommendations on how to implement this, which is a great step forward, but no one

Success in Serialization

Having become a bona fide member state of the EU, Hungary must ensure compliance with all EU regulatory initiatives, including the Falsified Medicines Directive 2011/62/EU that came into effect in February 2019.

Anna Wienner, general manager IBSA; Antal Feller, CEO, Hungaropharma

"When the regulation was first introduced, there was heavy resistance from the industry in Hungary and across Europe," admits Dr Mátyás Szentiványi of the National Institute of Pharmacy and Nutrition (OGYÉI). Understanding that resisting such changes almost always leads to delays in adoption, Szentiványi adds that "we made sure that we were prepared in Hungary before February and established our own Hungarian Pharmaceutical Identification Non-profit Limited Liability Company (HUMVO) to facilitate the process."

Dr Antal Feller, CEO of Hungaropharma and Anna Wienner, general manager of IBSA, both board members of HUMVO, agree. "The fact that wholesalers, manufacturers, and pharmacists represented themselves within HUMVO has helped to speed up the process; allowing concerns to be addressed instantaneously," states Feller.

Although counterfeit drugs were not historically an issue in the Hungarian market, the regulation had a significant impact on Hungary's entire pharmaceutical supply chain. "The biggest challenge was to connect this system with the end-users – the pharmacists. For context, Hungary has more than 2300 pharmacies," explains Wienner.

Despite this initial hurdle, the market has recovered, and pharmaceutical players have implemented the unique identifiers. "Hungary is now the fourth most compliant European country regarding the serialization guidelines," assures Feller.

Hungary also has the most successful pharmaceutical transactions per capita in the EU. "Hungary is ranked the sixth lowest for alert-rate in the EU," adds Wienner. "We are now in the stabilization phase of embracing this regulation and we are hoping to conclude this transition quite soon without jeopardizing the supply chain of medicines for patients," she concludes.

knows how to manage it perfectly. The biggest challenge with such a healthcare system is defining and quantifying value. It is important to determine whether incremental innovation can be considered as value or whether only a significant improvement in survival chances can be considered as such. This requires investing more in improving the analysis of real-world evidence for medication but also hospital treatments: define the areas of improvement and understand what is effective with more accuracy," she adds.

Despite details which remain unresolved, there are high hopes that the healthcare system will move in this direction. The question is, how quickly can such a transformation be achieved? Ildikó Horváth, minister of state for health explains that "in Hungary only incremental changes happen as it requires the involvement

of several authorities and ministries when making decisions."

Nevertheless, among the regulatory authorities, there is an acknowledgement that a unified effort across stakeholders is the key to successfully creating a tangible framework and achieving such a system. "It is important to identify the areas of unmet needs, which are the basis of defining value," says Bidló. "In collaboration with the industry and companies, defining value will not only help to create a value-based healthcare system, but the insurance and reimbursement systems will be better understood and implemented."

According to Horváth, "fair and affordable" is the guiding mantra that the government is striving towards as they look to establish a closer network of cooperation with the industry to resolve the challenges in reaching this next era of healthcare. "I believe the more discussion there is between the industry and the health authorities, the higher the possibility of success for this transition," agrees Veberič.

REDEFINING HEALTHCARE PRIORITIES

The prospect of a truly innovative Hungarian healthcare system is still some way in the future and there are several pressing concerns in terms of the country's health today. Hungarians live five years less than the EU average with female life expectancy standing at just over 80 years and men at 70.

However, life expectancy figures in Hungary are increasing faster than the EU average and improved by nearly four years between 2000 and 2015 to 75.7. Nevertheless, there is a long way to go and Horváth insists that "the top priority of the administration is to close the gap with other European countries."

The vast majority of stakeholders agree that Hungary's healthcare system remains severely underfinanced, even when stacked up against some of its more underdeveloped neighbors. Healthcare expenditure as a percentage of GDP has been relatively stagnant over the last ten years. In 2017, healthcare spending was 7.1 percent of GDP compared to the EU average of 9.9 percent. Roche's Veberič affirms that "the system as it is currently is unsustainable. It would be good to have a stronger government policy to address this."

Veronika Ferencz, general manager of Exeltis, adds that "health is a very pressing issue in Hungary and the current conditions are difficult. Generally speaking, the vast majority of the population is not satisfied with the quality of care, and some may say healthcare in the country is worse than ever."

Out-of-pocket payments account for 29 percent of all health spending in Hungary – nearly twice as high as the EU average of 15 percent – about half of which are used to pay for pharmaceuticals. Additionally, growing public hospital debt remains one of the biggest problems in the country's healthcare system, resulting in the postponement of surgeries and other treatments. This trend has caused an increasing number of patients to turn to the private hospital sector, further driving out-of-pocket expenditures.

Dr András Szabó, CEO of Szinapszis, a Hungarian market research and consulting agency specialized in the health industry, confirms the advancement of the private healthcare sector. "All countries have limited resources to pay for healthcare solutions and, in Hungary, high levels of innovative and quick treatments have always been available through the private sector... So far, the out-of-pocket private market size stands at HUF 300 billion (USD 1 billion)."

"This has a negative impact on the industry because patients are spending more money to visit private institutions and will find it more difficult to access quality products, ultimately resulting in long-term health issues and therefore even more trips to the doctor. In Hungary, we have now reached the level where it will be very difficult to make changes to the healthcare ecosystem, let alone the rapid reforms which are desperately necessary," says Ferencz.

Egis, The Most Successful Biosimilar Distributor In The Region

Egis Group (headquartered in Hungary) is one of the leading generic pharmaceutical companies in Central Eastern Europe. The vertically integrated company's activities incorporate all areas of the pharmaceutical value chain.

Egis' active ingredients and branded generics are available in 71 countries in total through a network of subsidiaries and partners. "Focusing on high-quality, value-added branded generic products, Egis devotes approximately EUR 50 million yearly to R&D," highlights CEO, Dr Istvan Hodász.

István Hodász, CEO, Egis

Dr Hodász goes on to explain that "based on new strategic decisions, Egis has acquired new IP, registration, and business development expertise to obtain the licenses of several biosimilar products and developed new special capabilities." A new biological quality control laboratory was created to perform analytical testing for the pre-marketing quality control of biological products. A new, cold chain logistics system was also established for in-house packaging, labeling, transportation and storage of biosimilar products.

"Strengthening its presence on the biosimilar market is one of the key strategic initiatives for Egis," reveals the CEO. In 2013, the company launched its first biosimilar monoclonal antibody (mAb) medicine, infliximab, which was also the first mAb in the European Union. Since then, Egis launched three additional biosimilar drugs.

"Egis biologicals distribution performance on the field of biosimilar mAbs became exceptional in the region, overperforming competitors. We achieved market shares are not only the highest among other biosimilars but reached best position in related INN, beating originator–eg infliximab–in a short period of time. This outstanding result is owed to the highly educated and engaged colleagues who managed to tailor market access and commercial activities to the biosimilar's specific challenges, via strong key account management and promotion. In collaboration with Medicines for Europe and local pharma associations Egis take active role in the fight for better patient access to biologicals," Dr Hodász proudly describes.



Irma Veberič, general manager Roche; Veronika Ferencz, general manager, Exeltis; András Szabó, CEO, Szinapszis

Dr Szentiványi admits that the Hungarian health authorities, "must find more strategic ways to combine and manage the public health expenditure of the government with the out-of-pocket expenditure of citizens. Hungary has a good health infrastructure and skilled professionals, so our goal is to continue improving to create an even stronger healthcare environment."

IMPROVING LIFE EXPECTANCY: A CENTRALIZED EFFORT

While many industry players are calling for a shift in priorities, general manager of Novo Nordisk Hungary, Calin Galaseanu, offers a reminder that the big picture should be considered in these discussions. "It is important to look at healthcare as an ecosystem because expenditure cannot be judged singularly. While the economy has strong prospects, the government has to distribute its budget where the need is greatest," he prompts.

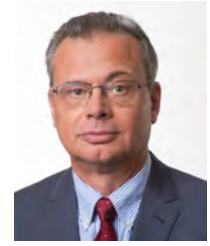
"There is no such thing as a perfect healthcare environment. Looking at investment in health as a percentage of GDP in Hungary compared to the EU gives us hope that there is room for improvement here. However, we must be careful not to treat healthcare expenditure as a percentage of GDP as the only KPI of a healthcare system," Galaseanu continues.

Healthcare needs are changing, and the government must be adaptive to these trends. "As a collective administration, a balance needs to be struck between flexibility and sustainability, while being accountable for the long-term quality of the results. More attention needs to be given to patients' response as their feedback is invaluable. Through transparency and receptiveness of their input, it will allow us to identify and target areas that need improvement," insists Horvath.

One of the key contributors to the country's poor life expectancy statistic is preventable deaths, which are twice as high as the European average. This is related to lifestyle; an amalgamation of bad habits such as excessive smoking, drinking, and unhealthy eating. These factors play a major role in the incidence

of cardiovascular and oncological diseases: the two leading causes of deaths in Hungary.

More than 80,000 new cancer patients are registered in Hungary each year and, once a patient is diagnosed, the prospects are grim. As highlighted by Veberič, "the cancer-related mortality rate in Hungary is the highest in Europe according to OECD statistics. We have 38 percent more deaths due to these diseases than the country with the lowest death rate – Switzerland."



György Bodoky, founder & honorary president, MKOT

The biggest challenge being faced in oncology is that patients enter the physician room to receive treatment at a very late stage. In lung cancer, 49 percent of patients in Hungary are in stage four, and combined with stage three, this figure increases to more than 70 percent of patients.

Dr György Bodoky, founder & honorary president of the Hungarian Society of Clinical Oncology (MKOT), emphasizes that "there needs to be more push for screening programs and diagnosis in oncology. Hungary was one of the first countries to introduce mammography and gynecology screenings, but there is still room for improvement in attendance." In 2018, a national colorectal screening program was introduced by the Hungarian government in hopes of better reaching the at-risk population.

In a similar vein of motivating patients to be proactively involved in their own health, improving health literacy is another priority for healthcare stakeholders. "Patient adherence is very low in Hungary which is a major issue if medicines and treatment regimens are not followed as they should be. These factors together [with poor health habits] create an added burden for the healthcare system by increasing medical needs and reducing efficiencies," says Szabó.

"While good access to treatment is essential, adherence is also important in the management of the disease. When patients do not follow their treatment regimens properly for whatever reason this leads to major complications down the line," states Galaseanu, who understands the magnitude of this issue firsthand as the leader of the country's top diabetes player.

INCH BY INCH, CATCHING UP TO THE EU

With ambitions to resolve the country's healthcare issues and improve patients' access to innovation, the pharma industry in Hun-

Mid-Cap Strategy: Gedeon Richter

Gedeon Richter stands alone as the only one of Hungary's four historical pharmaceutical manufacturers to have resisted international acquisition. However, the company does not exist in a vacuum and, like many globally active mid-cap pharma players, establishing partnerships across the entire value chain has been made a fundamental pillar of its operational strategy.

Gabor Orbán, CEO, Gedeon Richter

Ranging from manufacturing to R&D and licensing agreements, the firm has built a wide network of collaborators across the globe. These partners include not only small and medium sized peers, but also Big Pharma players with strong marketing capabilities. One of its most significant collaborations has been with Allergan to market the potential blockbuster biosimilar cariprazine (VRAYLAR in the US). While Allergan covers the marketing of the drug in the Americas, Gedeon Richter has also inked agreements with leading Italian mid-cap Recordati to market the drug in Western Europe and Algeria, Tunisia, and Turkey.

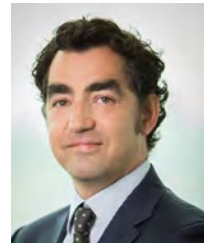
As CEO Gábor Orbán notes, "we have secured several licensing agreements with trusted partners around the world to ensure access to [cariprazine] to patients globally. In particular, VRAYLAR has seen tremendous success and it continues to be the fastest-growing antipsychotic drug in the market. We are also continuing to add new indications to the label to broaden its commercial potential very significantly."

Orbán outlines, "Our approach to partnership is a necessary part of our operations because we cannot cover the entire value chain for every product category. CNS is an example where we start with the initial research and develop up until proof of concept, where we then need a partner to help bring the product to certain key markets like the US." He adds, "We also work with other midcaps around the world to sell specialty pharma products in markets where Richter does not have a strong presence such as MENA."

As well as Big Pharma partnerships, Richter also offers CDMO and in-licensing opportunities to companies looking to access the Central and CEE region, especially in women's health. In October 2019, the firm signed a series of agreements with US-based biotech Mycovia for the co-development, manufacture, and commercialization of a novel oral antifungal product.

Through these partnerships, Richter and its partners can utilize their individual strengths to reduce risk and increase the chance of mutual success. "Partnerships are absolutely an essential strategy for mid-size players like Richter," concludes Orbán.





Calin Galaseanu, general manager, Novo Nordisk; Jānis Meikšāns, general manager, TEVA; Francesco Banchi, managing director, Boehringer Ingelheim

gary must consider how it will continue its growth trajectory into the coming years. Meanwhile, Hungarian authorities must determine how the country can elevate its healthcare infrastructure to meet European benchmarks while maintaining competitiveness as a pharma investment center within the region. "Like most markets in CEE, we also see the same risks in sustainability to the system as expenses increase at a much faster pace than GDP growth," explains Jānis Meiksans, general manager of TEVA.

While new approaches are necessary to resolve these challenges, there is a mutual understanding that drastic changes are unrealistic in Hungary. Therefore, joining forces is the best opportunity for advancing on the issues at hand. Dr Szabó emphasizes that being a partner not only to patients and doctors, but health authorities as well, is an necessary shift within today's healthcare environment. "Pharmaceutical companies should not only be drug sellers but service providers…Establishing initiatives such as risk-sharing agreements with the government or programs to improve patient education and adherence are all tangible ways for the industry to embrace this trend and secure their margins," he asserts.

Better communication will be of key importance moving forward. As Francesco Banchi, managing director for the local affiliate of Boehringer Ingelheim, concludes, "Having an open conversation with the authorities is the most important trick; putting ourselves in their shoes and trying to understand how they manage their role." Hungary has a unique and delicate balance between the political sphere, national manufacturers, and multinational companies who are all interdependent of each other. Though the direction of progress has been set by Hungary's stakeholders, a long journey lays ahead which will reveal just how the country's longstanding pharma tradition will be translated in the future within the context of an evolving European healthcare landscape.

The Roots and Rise of Cell and Gene Therapy

Continued investment will mean new cures in a new decade

As a new decade begins, promising research and treatments using cell and gene therapies are significantly improving or saving the lives of patients suffering from rare diseases. These new treatments and even cures are where science is now headed, but it will take continued investment to ensure the future.

The Greater Philadelphia region is a hotbed of cell and gene therapy and connected health and we have had a front-row seat acting as catalysts for continued success. The early chapters of cell and gene therapy's history were written in laboratories in Philadelphia. In the 1990s, scientists at the University of Pennsylvania began to study how to manipulate the body's immune system to recognize and destroy specific types of cancer cells. Using gene therapy methods, they also developed successful approaches to replace missing or mutated genes as a way to cure or treat debilitating—or even fatal—diseases.

Several doctors working at Children's Hospital of Philadelphia and Penn discovered that mutations of the *RPE65* gene, present in patients with leber congenital amaurosis (LCA) or retinitis pigmentosa (RP), could be treatable through a one-time gene therapy injection. Mutations in the *RPE65* gene are rare. In LCA, for example, which is present in two to three out of every 100,000 newborns, mutations in the *RPE65* gene occur in only 8% to 16% of patients. The aim of the gene replacement therapy is to transport a copy of a functional gene into the patient's retina. In late 2017, FDA approved the therapy, called Luxturna, as the first gene therapy for a genetic disease in the US.

In the cancer field, another research team discovered that the body's own immune system could be engineered to treat certain blood cancers by removing patients' own immune cells and reprogramming them to seek and destroy their tumor cells. In record time, these discoveries were translated into the first FDA-approved personalized cellular therapy for cancer in May 2018, now known as Kymriah. One year later, in May 2019, FDA approved another transformative gene therapy to treat the rare disease spinal muscular atrophy (SMA), which claims the lives of small children.

While these recent success stories are phenomenal discoveries in their own right, there are many more researchers and companies that are striving toward cures and treatments for other widespread and rare diseases. Studies are underway to apply these same techniques—harnessing the power of the body's very own cells—to fight more common forms of cancer, like prostate cancer, as well as autoimmune diseases. In fact, former FDA Commissioner Scott Gottlieb projected at the 2018 BIO International Convention that FDA will approve 40 gene therapies alone by 2022.

It is the investment of government, industry, and academia in breakthrough research that will ensure a clear future for this work. The first approved therapies relied on visionary private philanthropists and institutions. Those early investments paid off and captured international headlines. Researchers quickly began reporting unprecedented success treating patients who had run out of options and were destined to die of their diseases. These investments are down payments on the future and pave the way for lower, long-term healthcare costs by reducing the need for long-term chronic disease treatments for rare disease patients.

As biopharmaceutical companies of all sizes know, scientific progress and clinical breakthroughs require years of innovation, hard work, and rigorous study. While we have seen the pace of innovation quicken, we must also realize that patience and a shared vision will be critical for even greater success.

Cell and gene therapy is where medical science is headed, and we can all take great pride in each new treatment for a rare disease while continuing our search for future cures. PE

Editor's note: The Chamber of Commerce for Greater Philadelphia, through its CEO Council for Growth and Select Greater Philadelphia Council, has launched the Cell & Gene Therapy and Connected Health Initiative—a collaboration between companies, institutions, and universities in Southeastern Pennsylvania, Southern New Jersey, and Northern Delaware to build awareness for the region's leadership role in cell and gene therapy, gene editing, and connected health research, commercialization, and treatment.

CLAIRE MARRAZZO GREENWOOD is Executive Director, CEO Council for Growth

MATT CABREY is Executive Director, Select Greater Philadelphia Council

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DEFINING THE COURSE & NAVIGATING THE FINISH LINE

Why Life Sciences Companies Need Medical Affairs in Today's Highly Competitive Pharmaceutical Landscape

Despite the significant education and experience of Medical Affairs Professionals, their value is often questioned — likely because the business objective of a Medical Affairs team is unclear. Their colleagues in Regulatory, R&D, and even Commercial have specific and defined goals, making it easier to track outcomes and measure their contribution toward business objectives. The Medical Affairs goal is less defined and outcomes are described in terms of tactical wins — the number of engagements, publications, or insights collected — it's a struggle to communicate their deep connection to an overall strategic goal and how each member of the medical team contributes. This challenge impacts the effectiveness of the team and their ability to stand as a strategic partner within the company.

Imagine a rowing team in which each crew member understands their position and the role they play, but they don't know how to navigate the course or when — or if — they cross the finish line. Although individual focus, motivation, and energy may be there, would the value of this team ever be known? How would they synchronize actions and navigate to the finish? That's the conundrum Medical Affairs teams face when their goal is undefined. Would the situation change if we define the goal and clarify the finish line?

Medical Affairs is responsible for ensuring patient access to the company's approved medicines by enabling informed decisions by Providers, Payors, and Patients.

Defining the role of Medical Affairs as focused on patient access may seem controversial. Within Pharma, "access" is often associated with commercial roles dedicated to price and reimbursement. But the landscape is changing — medicine is more complex and barriers to access are expanding. Clinical guidelines, reimbursement pathways, and growing consumerism all influence access to medicine. There is a greater demand for data and transparency to help Providers, Payors, and Patients make informed decisions so that everyone wins.

Just as a coxswain provides information, motivation, and encouragement to their crew, Medical Affairs generates evidence, develops a clear, concise narrative, and delivers the information directly to the key decision makers who can remove those barriers to access. Advocating for their crew in the midst of a moving landscape, helping them to navigate and constantly communicate in order to keep the team safe, Medical Affairs is the force that propels movement in the right direction for patients.

The preceding excerpt is taken from *"Defining the Course & Navigating the Finish Line,"* written by Peg Crowley-Nowick, PhD, MBA, President of Zipher Medical Affairs Co., LLC. The white paper explains the importance of Medical Affairs in helping teams to recognize, analyze, and utilize information to support patients and business goals. When defined and planned strategically, Medical Affairs can support critical insights from both internal and field teams allowing for strengthened engagements with thought leaders and generating data for an evidence-based practice.