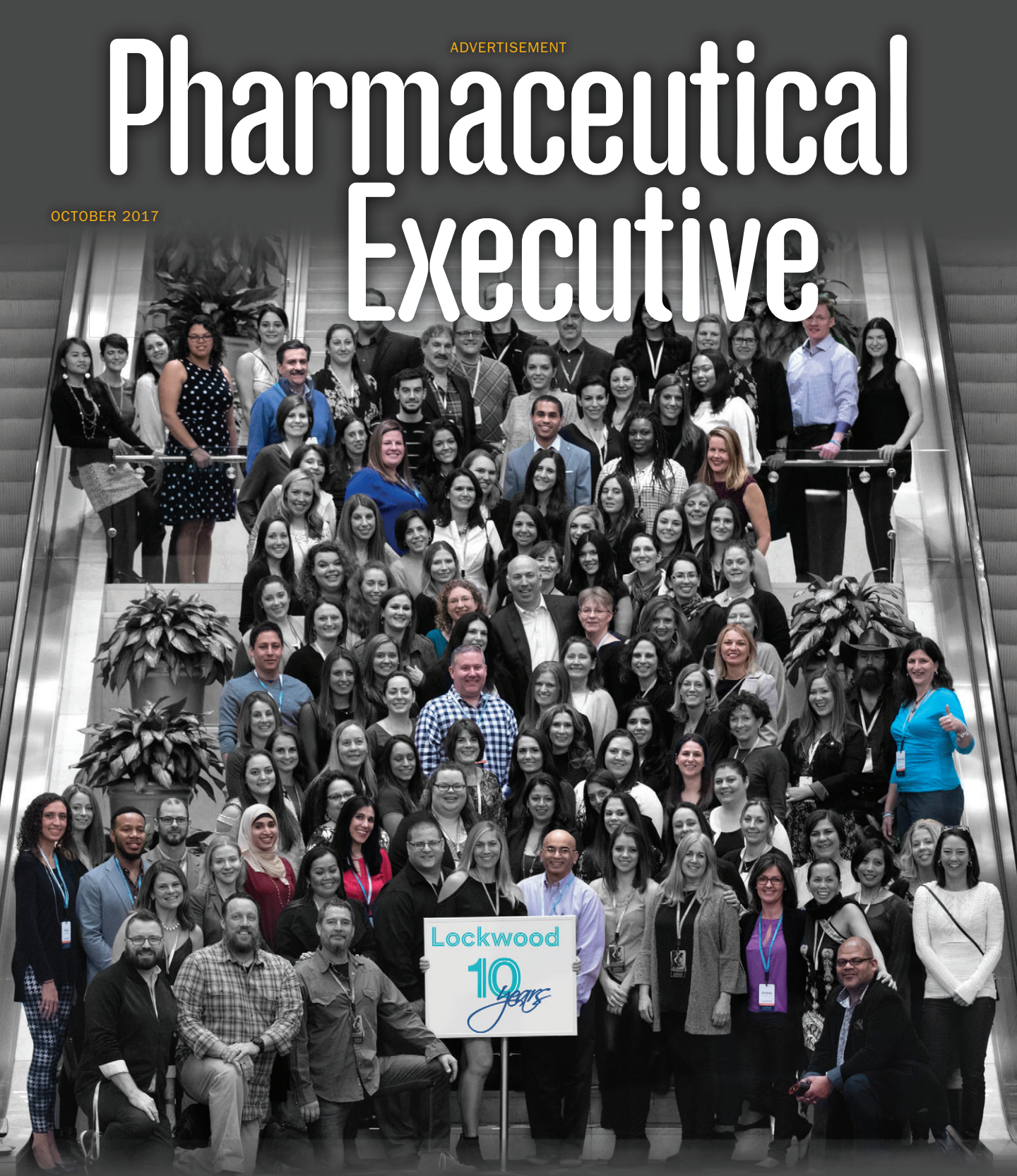
Pharmaceutical Executive

OCTOBER 2017



EXPLORE THEIR TRUE COLORS

Insights about the talent within today's hottest med comm agency

What is it that makes us today's hottest medical communications agency?

WE CARE ABOUT PEOPLE

Remarkable character that sets us apart from anyone you will ever work with again.

Explore our true colors yourself
www.thelockwoodgrp.com

Lockwood 10 years
Medical Communicators

EVIDENCE TRAIL
'REAL' DATA'S FUTURE

DE-RISKING R&D
DRUG PRICING LINK

COMPLIANCE
PHARMA'S FLAWED PARADIGM

WWW.PHARMEXEC.COM

Pharmaceutical Executive

OCTOBER 2017
COMMERCIAL INSIGHTS FOR THE C-SUITE
VOLUME 37, NUMBER 10

EMERGING ELEVEN

2017 EMERGING PHARMA LEADERS

PHARMACEUTICAL EXECUTIVE presents

CARSTEN BRUNN, HEATHER DEAN, MOHAMED HAMADA, TODD HORICH, ASHLEY KALINAUSKAS, MICHAEL K. LYONS, JOSHUA OFMAN, COREY PADOVANO, MARK RUS, RICHARD SCRANTON, and YARON WERBER

UBM

Inspiring People, Inspiring Teams

AFTER CONDUCTING INTERVIEWS and editing the stories for this month's Emerging Pharma Leaders section, I couldn't help but be inspired. Our Emerging Eleven for 2017 shine a positive light for the future of pharma. As I mention in the introduction on page 14, many of this year's alumni share commonalities, including a willingness to grow, the ability to listen, learn from their mentors, and an enthusiasm to lead their staff and share the load. The Emerging Eleven inspired me this month to feature the staff of *Pharmaceutical Executive* and highlight their unique skills and qualities that make this publication and website the very best it can be. They have great ideas and deserve recognition and a big thank you!

LISA HENDERSON
Editor-in-Chief
lisa.henderson@ubm.com
Follow Lisa on Twitter:
@trialsonline

Behind the scenes at *Pharmaceutical Executive*. Let's start with those who have been with the publication the longest. Julian Upton is our European and Online Editor, who has been with our organization in its previous and current ownership for 12 years. He was in charge of *Pharm Exec Europe* for several years, and is the institutional knowledge resident for the brand. Before *Pharm Exec*, he worked on trade/b2b mags focused on the defense industry, public-private finance, and healthcare.

Julian is a resident of Leicester, England, and is our go-to expert for anything related to the UK or all of Europe, for that matter. Julian tolerates and/or entertains all our questions about what people think overseas. He has also become the point person for reviewing contributed articles, and continues to interview and write on all aspects of commercial pharma for the magazine.

Mike Christel is our Senior Managing Editor, managing both *Pharm Exec* and *Applied Clinical Trials*. Mike has been on the brand for almost four years and is in charge of making sure everything in print goes out with all the i's dotted, t's crossed, photos in the right places, writing headlines and transitions, and dealing with the staff dragging out deadlines. In between managing all of that, he finds time to interview people and write articles, and help the newer staff members learn our systems and processes.

Mike started in journalism at local newspapers, first as a sports writer and eventually heading a newsroom. He then moved on to b2b, working for *R&D Directions*. With his experience, we all count on him for his clinical and commercial knowledge and sense of journalistic ideals.

Christen Harm is our Associate Editor, joining in March. Christen is becoming the go-to person for...everything. She writes, she interviews, she's learned our back-end systems quickly and is helping our migration to an updated web platform coming soon. Christen is our resident "millennial" (though she hates that term and swears she's not a typical millennial) and this is her second company in b2b publishing. She is very creative, funny, energetic, and willing to do whatever you ask and get it done with a smile and can-do attitude.

Michelle Maskaly is our Senior Editor who joined in April. The one word to describe Michelle is passionate. She truly believes in the pharmaceutical industry, and the innovation it brings to patients. I should also say, dogs. Michelle is an avid lover of dogs, and is interested in the intersection of veterinary and pediatric research in oncology (see http://bit.ly/2yM8KAj).

Michelle held numerous positions in journalism, and like Mike, also worked in the newsroom of a local newspaper, in addition to national cable news networks. She has experience with managing social media, as well as chief editor for b2b's in the pet industry and healthcare packaging. Michelle brings ideas, all day, every day, and along with Julian, works hard at crafting the articles that comprise our core features. Michelle's journalistic sense, combined with her passion is an inspiration to her colleagues.

Lisa Higgins joined in August as our Social Media Specialist. Having graduated college in May, making her a GenZ, she is quickly fitting into our company, and her dual role handling social media for both *Pharm Exec* and *Applied Clinical Trials*. Lisa is ramping up her knowledge in these industry areas, learning our back-end processes for editing and posting articles, as well as bringing new ideas for social media. Lisa, with Christen and Michelle's support, is the driver for our new Instagram and YouTube accounts and, thankfully, understands and manages that with finesse, bringing our content to a broader range of audiences.

While we focus on the content and excellent editorial, and I love leading this team, it takes a village to make a company or brand a success. We also have our sales team, marketing, audience development, digital team, special projects team, and executive management all excelling at their roles to make *Pharmaceutical Executive* the excellent resource it is. *Note: look for our team photo in the online version.*

Pharmaceutical Executive VOLUME 37, NUMBER 10

VP OF SALES & GROUP PUBLISHER	Michael Tessalone	TEL [732] 346.3016 michael.tessalone@ubm.com
EDITOR-IN-CHIEF	Lisa Henderson	TEL [732] 346.3080 lisa.henderson@ubm.com
MANAGING EDITOR	Michael Christel	TEL [732] 346.3022 michael.christel@ubm.com
EUROPEAN & ONLINE EDITOR	Julian Upton	TEL 011 44 [208] 956.2660 julian.upton@ubm.com
SENIOR EDITOR	Michelle Maskaly	TEL [732] 346.3025 michelle.maskaly@ubm.com
ASSOCIATE EDITOR	Christen Harm	TEL [732] 346.3079 christen.harm@ubm.com
COMMUNITY MANAGER	Lisa Higgins	TEL [732] 346.3014 lisa.higgins@ubm.com
ART DIRECTOR	Steph Johnson-Bentz	TEL [218] 740.6411 Sbentz@hcl.com
WASHINGTON CORRESPONDENT	Jill Wechsler	jillwechsler7@gmail.com
SENIOR DIRECTOR, DIGITAL MEDIA	Michael Kushner	TEL [732] 346.3028 michael.kushner@ubm.com
MANAGING EDITOR, SPECIAL PROJECTS	Kaylynn Chiarello-Ebner	TEL [732] 346.3033 kaylynn.chiarello.ebner@ubm.com
DIGITAL PRODUCTION MANAGER	Sabina Advani	TEL [732] 346.3081 sabina.advani@ubm.com
PROJECT MANAGER, DIGITAL MEDIA	Vania Oliveira	TEL [732] 346.3021 vania.oliveira@ubm.com
EDITORIAL OFFICES	485 Route 1 South, Building F, Suite 210 Iselin, NJ 08830	TEL [732] 596.0276 FAX [732] 647.1235 www.pharmexec.com
SALES MANAGER–MIDWEST, SOUTHWEST, WEST COAST	Bill Campbell	TEL [847] 283.0129 william.campbell@ubm.com
SENIOR PRODUCTION MANAGER	Karen Lenzen	TEL [218] 740.6371 karen.lenzen@ubm.com

AUDIENCE DEVELOPMENT MANAGER	Rochelle Ballou	TEL [218] 740.7005 rochelle.ballou@ubm.com
REPRINTS		877-652-5295 EXT. 121 bkolb@wrightsmedia.com Outside US, UK, direct dial: 281-419-5725. Ext. 121
C.A.S.T. DATA AND LIST INFORMATION	Melissa Stillwell	TEL [218] 740.6431 melissa.stillwell@ubm.com

2011 Neal Award
Winner for
"Best Commentary"

PharmaCord

Innovative Connections | Complete Care

YOUR SPECIALTY PRODUCT. OUR INDEPENDENT COMPANY.

Bypass the traditional limitations of gaining market access and increasing patient engagement. We are PharmaCord — your new lifeline between specialty biopharma manufacturers, physicians, payors and patients.

PharmaCord.com | For details, call David Hileman: 502.805.3420

PHARMACEUTICAL EMERGING EXECUTIVE PHARMA LEADERS

2017 Emerging Pharma Leaders

Pharm Exec's 10th annual list of rising leaders highlights a selection of pharma managers who are poised to help chart the industry's path forward. We profile 11 executives representing a range of critical functions, spanning areas such as science, business, patient care, marketing, policy, access, and customer strategy.

14

EPLs: Ones To Watch
32

Catching Up With Past Winners
33

Guingm/pokki77/shutterstock.com

Data Analytics

The Future of Real-World Studies

By Uttam Barick

Life sciences organizations today must increasingly provide evidence on real-world outcomes to differentiate and justify their products. But what is the true potential of real-world evidence studies and what are the right questions to ask in determining product performance in the marketplace?

34

NEWS & ANALYSIS

Washington Report

Global Report

STRATEGY & TACTICS

Information Technology

INSIGHTS

From the Editor

Back Page

Country Report: Colombia

Emerging as a bastion of peace, stability, and resilience in a region increasingly beset by political turbulence and economic stagnation, Colombia has been steadily reinventing itself as a Latin American pioneer and pacesetter, including in the world of healthcare.

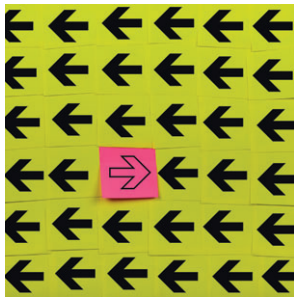
PHARMACEUTICAL EXECUTIVE VOLUME 37, NUMBER 10 (Print ISSN 0279-6570, Digital ISSN: 2150-735X) is published monthly by UBM LLC 131 W. First St., Duluth, MN 55802-2065. Subscription rates: $70 (1 year), $125 (2 years) in the United States and Possessions; $90 (1 year), $145 (2 years) in Canada and Mexico; $135 (1 year), $249 (2 years) in all other countries. Price includes air-expedited service. Single copies (prepaid only): $7 in the United States, $9 in all other countries. Back issues, if available, are $20 for the United States and Possessions, $25 for all other countries. Include $6.50 per order plus $2 per additional copy for US postage and handling. If shipping outside the United States, include an additional $10 per order plus $3 per additional copy. Periodicals postage paid at Duluth, MN 55806 and additional mailing offices. POSTMASTER: Please send address changes to PHARMACEUTICAL EXECUTIVE, PO Box 6180, Duluth, MN 55806-6180. Canadian G.S.T. Number: r-12421 3133rt001, Publications mail agreements NO. 40612608. Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, Canada. Printed in the USA.

Pharm Exec Connect

Join The Conversation!

@PharmExecutive http://linkd.in/PharmExecMag

Top Stories Online



2017 *Pharm Exec* 50
June issue online
Michael Christel
bit.ly/2sWPTSj

Status Update: Pharma and Social Media
August issue online
Peter Houston
bit.ly/2xqLasu

***Pharm Exec*'s Industry Audit**
September issue online
Bill Trombetta
bit.ly/2wmyCBg

New Value Framework for Orphan Drugs
Blog post
Leslie Isenegger
bit.ly/2k4SbfU

The Supply Chain and Patient Centricity
September issue online
Julian Upton
bit.ly/2wZquX4

Most-read stories online:
August 25, 2017, to September 24, 2017

Pharm Exec Webcasts

Accelerating Real-World Evidence for Faster Insights, Harmonization
bit.ly/2hAQZQu

The Quest to Align Drug Prices with Outcomes
bit.ly/2hAR2f8

On-Demand
Medical Affairs 2.0: New Data Strategies
bit.ly/2wmlY5b

RIM Strategies: Unifying Data and Processes
bit.ly/2vmcoml

Readers Weigh In

Twitter Talk

■ Need #medicines to suit #patient needs, not #bigpharma #pharma #biotech wants

hedley rees, @hedleyrees, 9/7/2017
"European Study Calls for a Patient-Centric Perspective on Value-Added Medicines"
bit.ly/2xAqG3e

■ Some good, some impracticals here. All CEOs must master this stuff, not just the techies. Simple HTA needed for India.

Subhanu, @subhanusaxena, 9/6/2017
"European Study Calls for a Patient-Centric Perspective on Value-Added Medicines"
bit.ly/2xAqG3e

■ The consistency of the companies' message is critical. Not just face-to-face but integrating with all of the touch points including digital.

Joe Doyle, @Rocket2010, 9/1/2017
"Executive Spotlight: A Conversation with Alex Azar"
wi.st/2w4FDrb

Keep in Touch!

Scan here with your smartphone to sign up for weekly newsletters

Coming soon to PharmExec.com

Annual Pipeline Report
In its 14th installment, *Pharm Exec* provides a comprehensive overview of the most promising drugs currently in development—and explores the overall hot disease targets in biopharma R&D today.

Shutterstock: KPG_Payless

Can Streamlined R&D Reduce Drug Prices?

FDA seeks to de-risk research and promote competition to achieve savings for patients and plans

The recent FDA approval of the first chimeric antigen receptor T cell (CAR-T) therapy to treat young patients with a serious form of leukemia reignited charges that high drug prices limit patient access to life-saving medicines. Novartis announced that it would charge $475,000 for treatment with Kymriah—less than most analysts anticipated, but a flash-point for advocates seeking to control pharmaceutical outlays.

FDA always emphasizes that it does not consider price directly in drug regulatory decisions. But agency officials do see potential savings from several regulatory initiatives and transparency proposals. Commissioner Scott Gottlieb recently announced actions to streamline research policies to reduce the risk of failure in costly development programs. This complements agency efforts to promote competition by speeding more generic drugs to market and to challenge branded firms that "game our rules." Payers and patients, says Gottlieb, thus should "capture those savings in the form of lower prices."

JILL WECHSLER is *Pharmaceutical Executive*'s Washington Correspondent. She can be reached at jillwechsler7@gmail.com

Research costly

The savings may be considerable, particularly for cutting-edge therapies that benefit from FDA accelerated and breakthrough regulatory policies. A recent study claims that it costs only $648 million on average to develop a new cancer treatment, challenging the generally accepted $2.7 billion cost for developing a new drug, including the cost of failures and of capital as calculated by the Tufts Center for the Study of Drug Development. Even if the new analysis (published in *JAMA Internal Medicine* last month) is skewed by limited data and sketchy assumptions, it undermines the conventional wisdom that high pharma prices are needed to finance important research.

In fact, it's now well-accepted that drug prices reflect "what the market will bear" based on current and prospective competition and have little correlation to R&D outlays. Even so, policymakers expect that less costly preclinical and clinical testing and speedier approval and regulatory processes, as described in FDA's "Medical Innovation Access Plan," should lead to savings and improve public access to medicines. The agency thus seeks to modernize clinical data collection and encourage more informative clinical testing methods that provide useful data faster and more efficiently. FDA encourages sponsors to utilize "seamless" clinical trials, master protocols, model-informed development, and study enrichment strategies that help predict which patients will respond to treatment and those likely to suffer adverse effects.

A high-profile initiative seeks greater use of real-world evidence to support decisions on product safety and efficacy. Both the 21st Century Cures Act and the newly authorized prescription drug user fee agreement expand FDA regulatory decision-making based on patient data from healthcare systems and observational studies, an approach that FDA and stakeholders are examining further in several public workshops. The aim is to use data from health plans and registries to answer questions about treatment effects and outcomes for broader patient populations than possible in a specialized research environment.

FDA proposals for accelerating clinical research are not new, but sponsors have been reluctant to rely on them without clear assurance that the regulators will accept the data. Agency reviewers also look to expand their use of advanced computing tools and statistical and computational methodologies to evaluate more efficiently the sophisticated data submitted in applications.

Calculating value

FDA acceptance of more real-world evidence on how well a drug treats a disease should bolster medical product value assessments that link drug prices and reimbursement to patient benefits, as Novartis has proposed for Kymriah. Under an innovative outcomes-based reimbursement arrangement,

the Centers for Medicare & Medicaid Services (CMS) will pay Novartis for the drug only if patients respond after a month of treatment.

The deal raises many questions about what constitutes "success," who measures it, and why a one-month period was selected for measuring patient response. But the plan also is stimulating greater interest in outcomes-based reimbursement policies. These adjust reimbursement to treatment success, with payment higher when individuals see improvement in health, and lower if patients fail to respond. There has been a trickle of such agreements between pharma companies and health plans, but progress has been hampered by limited consensus on how to measure health improvements and other outcomes, and payers have seen little or no savings so far.

FDA encourages sponsors to utilize "seamless" clinical trials, master protocols, model-informed development, and study enrichment strategies that help predict which patients will respond to treatment and those likely to suffer adverse effects

Analysts acknowledge that even six-digit price tags on gene therapies may be justified if the medicine cures deadly cancer or reverses blindness. And such equations may be bolstered by comparing drug costs and outcomes to the enormous outlays involved in treating a cancer patient with bone-marrow transplants and other procedures for years.

Long-term benefits, though, raise questions about who should pay the initial cost of drug treatment. Health plans with millions of enrollees can spread outlays for a very expensive therapy across broader populations, especially when treatment is highly targeted; the equation changes, though, when many individuals seek access to a new drug. One idea is that an insurer pay for initial coverage, followed by regular reimbursement if a drug continues to provide positive effects; another insurer would pick up the tab if the patient changes coverage.

Strategies for reducing uncertainty in the regulatory process, and drug pricing schemes that reflect value and effectiveness, should be more palatable to marketers than public formularies, price controls, liberal drug import policies, and curbs on patent and exclusivity protections. Greater transparency in practices and prices may be inevitable, though, as payers demand more details on rebates and costs and FDA champions greater disclosure of drug safety issues and regulatory decisions that deny or delay approval of a new drug. PE

Regaining public trust

For the most part, Americans acknowledge that private companies deserve to earn a profit on efforts to develop and sell products beneficial to customers. Biopharmaceuticals are highly valuable, in that they can improve health, reduce medical costs, and save lives. But high drug prices that limit patient access to needed treatment erode the perception that industry recognizes and supports an implicit "social contract." Medical product prices further should reflect the significant US investment in biomedical research and sizeable reimbursement for drug treatment by public health programs, which oblige industry to use resources wisely and fairly to promote the well-being of all.

A notable decline in "trustworthy" ratings for pharmaceutical companies, however, may reflect industry opposition to transparency in research and marketing practices. For years, sponsors failed to list clinical trials in public databases and were slow to conduct promised post-approval studies. Multiple patent listings extend monopolies well beyond intended time frames, a development that threatens to delay access to much-anticipated biosimilars. Marketers of opioid pain killers face charges from federal and state prosecutors for violative marketing of these dangerous drugs.

Yet, pharma companies have opportunities to turn things around. Recently, a collaboration sponsoring a new treatment for Chagas disease affecting children in the US announced it would use a "substantial" portion of proceeds from the sale of a valuable Tropical Disease Priority Review Voucher (PRV) to enhance access to this therapy and to treatments for other global infections. Despite rising criticism that PRVs provide huge windfalls for industry, this more socially responsible approach may help build support for such R&D incentives.

Preparing for the Future of Life Sciences with Expert Revenue Management Software

Examining the perspectives of Gartner and IDC Health Insights

AUTHORS: NATE TANINECZ, VP Life Sciences Product Marketing; VOYTECH SUDOL, Director Life Sciences Product Marketing; KATIE HAYES, Content Writer Life Sciences Product Marketing

With an industry on the cusp of rapid growth, innovation through IT seems to be the way every life sciences company looks to build a competitive advantage. To accomplish this, manufacturers are offered a myriad of supposed revenue management software options, which are often far from being a comprehensive solution. Recently, IDC Health Insights and Gartner each published their views on choosing the best revenue management software vendor. Each article emphasizes key points manufacturers should consider, though both articles lack the necessary context of industry expected growth combined with inadequate IT resources, which fully illuminate the value of having best-in-class revenue management software as an integral part of a comprehensive digital strategy.

In the short- to mid-term, both MedTech and Pharma companies are poised for explosive growth. Driven by the 3.5% growth of the global population, the expected surge of mergers and acquisitions (M&A), and justifiably higher prices of more complex products, the future of life sciences looks bright. In fact, the global life sciences industry is poised to reach 1.6 trillion dollars by 2020 through a record number of new product approvals accessible to more patients due to global wealth growth among a rapidly aging population requiring advanced medical care.

President Trump's expected tax holiday on overseas revenue will also give American manufacturers a break in paying the traditional 35% tax. Approximately 1.3 trillion dollars of extra cash will motivate M&A spending and further impact R&D productivity and innovation, according to industry analysts.[1] By combining the best science of the merged companies, the expected result is a rejuvenated approach to obtaining more drug and medical product approvals. Unsurprisingly, the fast-paced growth of the industry fueled by the extra cash on hand will result in additional manufacturer woes in the form of a burgeoning amount of critical data needed to be expertly processed and analyzed.

These internally generated data challenges will only be exacerbated by other upcoming externally induced data shifts, such as changes to the European Union's regulatory requirements for medical devices, the increasing use of companion diagnostics, and global as well as US price transparency. Each shift represents a substantial effort required to process complex data quickly and efficiently, a task that is already overwhelming to internal life sciences' IT infrastructures.

Clearly, taking advantage of appropriate experts and scalable technology is the only path to wrangle the necessary information. Naturally in preparation, many companies are focusing their efforts on moving their ERP and CRM software to the cloud. However, the familiarity and ubiquity of these systems seem to detract executives' focus from what is the key to market success of any life science product. After all, unlike ERP and CRM systems, Revenue Management systems process all types of information necessary for extensive market access. Why is it then that a solution meant to maximize revenue continues to be an afterthought and not an integral part of a comprehensive digital strategy?

Corporate Dissonance

Though 85% of industry CEOs believe that IT will be the foundation for innovative strategies—thereby reshaping the competition within the next five years—IT rarely has a place on the executive decision-making team. According to the IMS Report on IT Use, "The role [of CIO] has not been elevated to the C-suite, with less than one quarter of CIOs being part of the company's executive team, and only 14% at large companies."[2]

Instead of focusing on innovative digital solutions, IT is tasked with supporting the day-to-day functions of the company, addressing issues reactively rather than proactively. In a survey conducted by IMS Health, 22% felt that IT's role is limited in leadership and is primarily meant to "keep technology running," while 44% agreed that they "execute projects on behalf of the business."[2] New technological advancements in tandem with the rise of cloud-based approaches add further stress to hiring individuals who possess a specialized skillset.

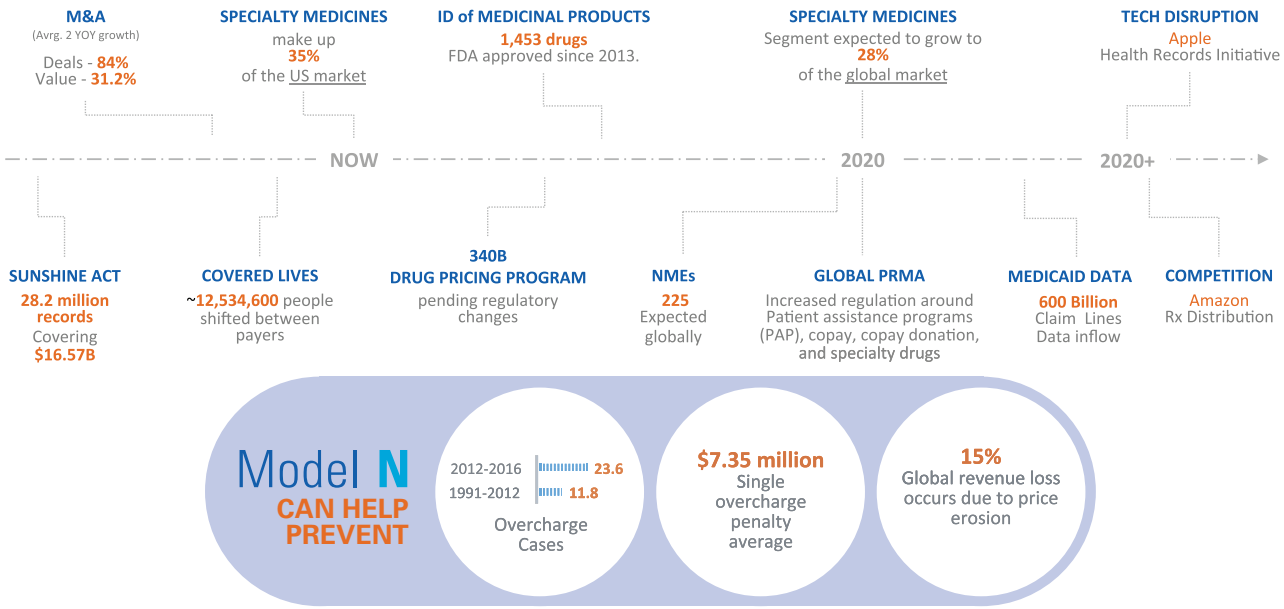
Interestingly, even the 31% of companies surveyed that utilize their IT department as a "partner in innovation with the business lines," revenue management cloud migration was not prioritized as part of their digital strategy. In fact, 38% of all current life sciences systems reside in the cloud but their function is primarily limited to CRM and ERP. Undoubtedly, companies focusing solely on CRM and ERP solutions will face revenue management challenges and a future devoid of comprehensive digital strategies. IDC Health Insights offered best practice advice to optimize revenue management in light of evolving ERP and CRM applications and explains, "as mission-critical enterprise applications such as ERP and CRM begin to take advantage of modern technologies such as cloud computing and analytics, wouldn't that strategy also make sense for revenue management and other applications that must interact with them?"

IDC Perspectives

As one of the most thorough and comprehensive research firms that emphasizes in forecasting key IT markets, IDC Health Insights offered their views on the necessity of using a cloud-based approach to maximize revenue in life sciences. "Eventually the efficiencies of SaaS, including revenue management, will become so compelling that every company will migrate to the cloud, so it's really a question of when, not if," said Michael Townsend, Research Manager for IDC Health Insights.[3] "Many IT and line-of-business decision makers are coming to view SaaS as a strategic advantage rather than a cost. Companies are also starting to realize that security is higher in cloud installations, including for proprietary data storage."

Townsend also advises companies to invest in a revenue management SaaS system that is user-friendly and is backed by "sufficient technical expertise and life sciences industry experience." While these are key components to running a successful system, relying on "sufficient experience" just isn't good enough because it no longer leads to maximized revenue. By having experts focused on continuous innovation with a system optimized to fit specific needs, manufacturers will experience maximized revenue.

Continuing on a leadership path, Model N recognized this and introduced Revenue Management as a Service (RMaaS) to close the expertise gap. Model N's global market expertise is substantial as it spans nearly 4,000 years of combined experience across 1,000 employees worldwide, focusing exclusively on revenue management.



Gartner Perspectives

Comparatively, Gartner's "Market Guide for Revenue Management in Pharma and Biotech" explores different vendors in the revenue management market and is a guideline catered to CIOs. In the analysis, author Stephen Davies, research director at Gartner, recommends migrating to a current revenue management solution "only if the return on investment and the increase in business capabilities driven by the upgrade justify the implementation effort and change disruption."[4]

While this approach may solve short-term issues—such as upfront migration costs—that solution is short-lived and will only lead to more complex and more expensive issues in the long-term. Drug patents span 20 years and market authorization times are becoming increasingly longer, so why would manufacturers focus their IT strategies to solve issues in the short-term? Faced with significant migration costs, it's a natural thought-process for many senior executives. However, with the RMaaS delivery model, such implementation efforts and change disruptions rest primarily on the expertise and time of Model N. Described by Gartner as simply an "as a service upgrade," RMaaS is so much more—more years of revenue management experience, more adaptability to meet market changes head-on, and more support to eliminate revenue leakage possibilities.

Gartner also describes revenue management as associated analytics management software that includes contract, chargeback and rebate processing, and is utilized to ensure accurate pricing practices. That said, revenue management systems cannot be fully actualized without an end-to-end process—at every step of the commercialization chain, including backend processing, and government reporting and compliance. On average, manufacturers have paid $7.35 million for a single overcharge penalty and the amount of overcharge cases have nearly doubled from 11.8 between 1991 and 2012, to 23.6 from 2012 and 2016.[5]

It's clear that data is continuing to be more complex and manufacturers increasingly find it difficult to process that data without experiencing costly errors. Simply implementing non-Model N "revenue management software" to maximize a specific revenue source will yield incomplete results. Model N is perfectly positioned to maximize revenue efficiently across all revenue sources, at a fraction of the speed, while significantly reducing the risk of government penalties.

The market analysis continues to focus on the costs associated with upgrading legacy software into the cloud, as "several Gartner clients have shared that the upgrade costs were significant and a deterrent to moving forward with a project. Movement to a cloud-based solution is becoming possible, but end-user organizations face high switching costs." While focusing on short term cost, Gartner fails to recognize the full value a manufacturer can derive from a vendor which combines years of industry expertise, market proven technology, and the ability to deliver all in the cloud. Additionally, it's important to consider the costs of not migrating to the cloud. Companies will be continuously affected by government pricing regulatory changes and in turn, run the risk of encountering immense penalties. In the ever-changing regulatory realm, is that a risk any manufacturers afford to take?

Value over Price

The necessity to consider long-term benefits when designing a comprehensive digital strategy is supported by other leading industry analysts. While the upgrade costs can be substantial when moving to the cloud, those costs are quickly offset by the value it delivers. For example, the cloud's infinite storage space allows companies to obtain vast amounts of data without dealing with a large infrastructure build. As a result of fully utilizing the cloud, innovative R&D practices are accelerated and companies experience reduced industry complexities through life science-specific applications. Companies can best achieve this by partnering with an expert revenue management vendor and in a recent survey, those using cloud-based technology for more than 25% of their software needs outperformed against the competition.[2]

For life sciences companies intent on meeting these growing business challenges head-on with a comprehensive digital strategy, outsourcing to an expert vendor may not be the least costly option upfront. Instead, the value of revenue management digital strategies stands out by maximizing revenue and significantly reducing vulnerability to massive fines and a negative brand reputation—making RMaaS a valuable option.

References

1. *A New Wave of Pharma Mergers Could Put Innovative Drugs in the Pipeline.* Stat News. 24 July 2017.
2. *New Strategic Information and Technology Roles in Life Sciences Companies.* IMS Institute for Healthcare Informatics. February 2016.
3. *Revenue Management in Life Sciences: The Benefits of a Cloud-Based Approach.* IDC Health Insights. May 2017.
4. *Market Guide for Revenue Management in Pharma and Biotech.* Gartner. 3 July 2017.
5. *Internal analysis of data courtesy of Statista and Public Citizen*

Rays of Hope for Pharma Innovation Support

European Commission talks drug industry investment, health issues during State of the Union

Obscured beneath bigger—and grimmer—news in a world overcrowded with events, an annual European Union policy event in mid-September might have seemed irrelevant to pharmaceutical executives. But the 2017 State of the Union address by the President of the European Commission contained more than a few nuggets that drug industry strategists are now starting to take seriously—aided by a few injections of real money too.

There was only one direct reference to health in Jean-Claude Juncker's 6,000-word speech. Just a paragraph on equality. But that was powerful enough to jar a few preconceptions about Juncker's attachment to health.

"In a Union of equals, there can be no second-class citizens," he said, denouncing as "unacceptable" that in 2017 there are still children dying of diseases that should long have been eradicated in Europe. "Children in Romania or Italy must have the same access to measles vaccines as other children right across Europe. No ifs, no buts," he said.

Juncker underlined that the Commission is working with all member states to support national vaccination efforts. "Avoidable deaths must not occur in Europe," he said. And he announced his intention to come forward with a joint action plan on national vaccination policies.

In itself, this determination provides an illuminating gloss to Juncker's thinking, since he has in the past tended to duck health issues, and has provoked concerns in Europe's healthcare community about neglect and even abandonment in future Commission planning.

Trade agenda

But the bulk of Juncker's remarks also offered some glimpses of an approach that could equally play to the interests of the drug industry. The emphasis that Juncker has frequently put on boosting Europe's ability to compete in the world market was even more evident in his outline of how he sees the future for the EU. Among the top priorities he spelled out were strengthening Europe's trade agenda, making its industry stronger, and deepening the single market so that it maximized support for innovation.

Trade, he said, "is about jobs, and creating new opportunities for Europe's businesses big and small," expressing satisfaction with the trade agreement with Canada that is now entering into force, with agreements reached with Japan, Singapore, and Vietnam on new economic partnerships, and with the prospect of doing the same with Mexico and South American countries by the end of the year and opening trade negotiations with Australia and New Zealand. The EU's trade ambitions have been strongly supported by most of Europe's pharma sector, as opening up market opportunities and enhancing, in some cases, intellectual property protection beyond Europe.

On strengthening industry and the internal market, there was still more music to the ears of pharma executives pursuing investment and innovation. Europe's global leadership in high value-added and sophisticated products and services has been built on a large single market with 500 million consumers, strong value chains, a skilled and talented workforce, and a world-class science base, Juncker acknowledged. But adjustments are needed or a new industrial age, he warned: the future of Europe's industry—and of its workforce of 32 million people—will depend on continuous adaption and innovation, "by investing in new technologies and embracing changes brought on by increased digitization."

Accompanying his speech, the Commission released a new industrial policy strategy, offering "a new boost for jobs, growth, and investment initiatives to be launched and/or completed by end 2018." This will respond to deficiencies that Juncker admits to in Europe's "enabling environment," and will "ensure that its risk-bearing disruptive innovations will create new markets and industrial leadership in Europe rather than outside." Action is also needed, he said, to accelerate and improve the uptake of technologies, particularly among smaller firms.

He also highlighted the need for flexibility in regulatory frameworks that will allow innovation to develop. "We must learn to consider the perspective of innovators," Juncker said, committing

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

the Commission to take into account the impact on research and innovation in developing regulation in all policy areas. Carried through into the current debates on adaptive pathways for new medicines authorizations, that sort of thinking may well help to counter resistance among regulators to evolution. And within the Horizon 2020 program, that already funds the Innovative Medicines Initiative, he is creating a $3 billion Innovation Pilot scheme "to more effectively support projects focused on market-creating innovation," with a focus on "highly promising but also potentially risky innovations."

Backed by action

Juncker's words coincided with some deeds that offer some tangible confirmation of intentions. The EU has just announced a series of investments in companies conducting innovative medical research, through its European Fund for Strategic Investments—the so-called "Juncker plan" introduced in 2015 to boost competitiveness in the European economy.

One of the agreements, a $90 million loan to Evotec of Germany, breaks new ground in risk-sharing finance. This unsecured loan facility is the first contingent investment guaranteed by the fund, meaning that the fund shares the risk of Evotec's research and development success. It is also the first large equity-type investment by the fund in any industry anywhere in Europe. The money is being provided as long-term financing "to finance drug discovery and the development of new treatments for serious illnesses and diseases," said the Commission at the signing ceremony for the deal. The demand for new therapies "requires innovation in drug discovery in a capital-efficient manner as well as through innovative financing models."

The Commission highlighted the potential of Evotec's drug discovery, such as its integrated patient-derived induced pluripotent stem cells platform, and innovative collaboration models such as its BRIDGE initiatives from Academia to Pharma. "Since 2010, Evotec has built a pipeline of over 80 partnered product opportunities through such partnerships, spin-offs, or equity investments," the Commission said.

Just days earlier, an agreement was finalized with German medical device company MagForce to develop new treatments for brain cancer. MagForce has developed NanoTherm therapy for local treatment of solid tumors by introducing magnetic nanoparticles and heating them in an alternating magnetic field. The financing, which permits the company to borrow up to $45 million over the coming three years subject to achieving a set of agreed performance criteria, will support NanoTherm's Europe-wide rollout for brain cancer treatment, and European and global approval for prostate cancer.

Austrian Apeiron Biologics is also to receive financing of $30 million to support its work in immuno-oncology, particularly in rare pediatric cancer treatments. Dinutuximab beta, its product for neuroblastoma, was recently granted marketing approval in the EU. The company is developing additional cancer immunotherapy projects based on targeted, tumor-specific approaches and on stimulation of the immune system via novel modes of action, such as unique checkpoint blockade mechanisms.

The Juncker speech does not resolve all of European pharma's problems. But it does hold out some hope of a more constructive attitude to innovation and investment

Measure of progress

In his speech, Juncker took credit for the plan, which has triggered $275 billion worth of investment so far across European industry, through loans to over 445,000 small firms and more than 270 infrastructure projects. And there is more to come. On the eve of his speech, the European Parliament and EU member states reached an agreement in principle on EFSI 2.0, extending and reinforcing the plan. The intention now is to win swift adoption of this expanded version, which will widen still further access to financing, particularly for smaller firms. EFSI's timeline is to be extended to 2020 and the target for triggering investment is increased from $400 billion to more than $600 trillion.

Of itself, the Juncker speech does not resolve all of European pharma's problems. But it does hold out some hope of a more constructive attitude to innovation and investment—and offers a welcome counterbalance to the pervasive atmosphere of gloom induced by a daily diet of North Korean threats, Russian meddling, and Brexit.

EMERGING ELEVEN

CARSTEN BRUNN HEAD OF PHARMACEUTICALS, AMERICAS REGION, BAYER
HEATHER DEAN HEAD, SPECIALTY SALES AND ACCOUNTS, TAKEDA PHARAMCEUTICALS
MOHAMED HAMADA COUNTRY PORTFOLIO LEAD, WOMEN'S HEALTH, EGYPT AND SUDAN, PFIZER
TODD HORICH VP OF MARKETING, SUPERNUS PHARMACEUTICALS
ASHLEY KALINAUSKAS CO-FOUNDER AND CEO, TORIGEN PHARMACEUTICALS
MICHAEL K. LYONS US CUSTOMER STRATEGY, IMMUNO-ONCOLOGY, ASTRAZENECA
JOSHUA OFMAN SENIOR VICE PRESIDENT, GLOBAL VALUE, ACCESS AND POLICY, AMGEN
COREY PADOVANO SENIOR DIRECTOR OF MARKETING OPERATIONS, GILEAD SCIENCES
MARK RUS GROUP VP - HEAD OF US NEUROSCIENCE, SHIRE
RICHARD SCRANTON CHIEF SCIENTIFIC OFFICER, PACIRA PHARMACEUTICALS
YARON WERBER CHIEF BUSINESS AND FINANCIAL OFFICER, SECRETARY, AND TREASURER, OVID THERAPEUTICS

Welcome to our annual feature of the Emerging Pharma Leaders! This was my first foray into this process, though the accolade has graced the pages of *Pharmaceutical Executive* since 2008. Apparently, we have no hard and fast rule of how many leaders we choose; they have ranged from 45 the first year, to an average of 15 the past five years. We received many submissions and narrowed them down based on the submission comments, internal review, and Editorial Advisory Board member input. We chose 11 to go along with our theme, a play on the movie *Ocean's Eleven*.

I encourage you, as you read their stories in the pages ahead, to think of individuals you would nominate for next year's group.

In these 11 individuals, you will find their experiences of how they got to be where they are; what challenges they face; as well as advice they can offer to others looking to rise the ranks in the pharmaceutical industry.

You will also find common themes of wanting to help patients; influencing others to grow; and a knowledge that their mentors greatly impacted their careers by believing in them.

It is an honor for us to showcase these individuals, the future leaders of pharma.

— *Lisa Henderson, Editor-in-Chief*

Big Brand Challenges?

You're carrying quite a load. Let us help.

Facing substantial sales expectations? Massive product launch? We'll shoulder the tasks. Since 1985, we've helped over 200 healthcare brands like yours succeed.

Looking for creative that's impossible to ignore? We'll help your brand get noticed. Our work has accumulated over 150 prestigious awards over the years.

Tired of being small peanuts to your large, blue-chip agency? As an independent agency, we challenge the idea of "bigger is better" by answering to clients, not shareholders.

Get rid of your heavy load.
Call Anshal at 312-935-5040 or email us at create@purohitnavigation.com

PUROHIT NAVIGATION™

CHARTING BRAND SUCCESS™

purohitnavigation.com

COOKING UP THE RIGHT FORMULA

Carsten Brunn, Head of Pharmaceuticals, Americas Region, Bayer

Carsten Brunn's entry into the pharmaceutical industry is somewhat unique—his PhD in chemistry from the University of Hamburg in Germany was funded by a scholarship from Eli Lilly. That connection gave him access to an industry lab at Lilly, but in the end, it wasn't the lab where Brunn would find his true passion.

"While I was interested in research from the beginning and was later offered a job in that area, I became very interested in the commercial side of the business," says Brunn, who is now head of pharmaceuticals for the Americas at Bayer. "So, I made that transition, and it was my time at Lilly 'carrying the bag' and then in a number of sales and marketing management positions in the US, when I really became passionate about meeting the needs of patients and customers. What I think I value most about my career path is the broad range of experiences I gained across different types and sizes of organizations and in different geographies."

In addition to big pharma, Brunn worked in a startup environment with Basilea Pharma and at Bausch & Lomb during a period when the company had been taken over by private equity firm Warburg Pincus. He's had the opportunity to work in the US, Europe, and the Asian markets of Singapore, China, and Japan—the latter two with Bayer. The experience has given Brunn an "incredibly helpful perspective" of working across different cultures and market dynamics. It's also given him an intimate view of how the industry has changed over the years.

"It's much more complex than when I came in," he says. "Back then, the model was a single brand approach; you'd develop a drug in-house, market it, or perhaps do a co-market, and then sell. Now, there are many more factors at play. R&D is much more expensive and developing drugs through partnerships is a norm. The markets are value-driven and market access is an essential and central part of the strategy. And we see smaller, more niche sales forces."

Arguably the most noticeable change has been that in the area of innovation—the discovery of the genome, development of biologics, immunotherapies, gene editing. Add to that, emerging dynamics like the increased involvement of patients in the development process, more data, etc., and you need a whole different set of skills than you did 20 years ago.

"All of these factors now require a different, more holistic view of the market," says Brunn. "Companies must adopt a more data-driven approach, using the technologies that are now available to do predictive analytics. This lets you be more flexible with strategic decisions, but it also requires different skill sets. The use of such data, though, can help with decision-making across the healthcare ecosystem and actually lower the cost of medicines while at the same time enhancing clinical outcomes. Thinking and working in this way is indicative of the fundamental changes that have taken place in our industry in recent years."

The ability to adapt and understand these new challenges facing the pharma industry is what helps shape a good leader, as does being authentic with the people you are working with.

"You have to encourage continued learning, risk-taking, and experimentation," says Brunn. "I have let the team in the US know that I am a firm believer in challenging yourself and the status quo and doing things differently, but also working hard and playing hard. It may be cliché, but it's true that our people are our greatest and most important asset. You need to be much more flexible and in touch in leading people in this complex environment."

Working and playing hard also comes with balance.

"I think it's important for people to really find an outlet that allows you to clear the mind, and to a degree feel relaxed," says Brunn, adding that for him, that outlet is cooking. "There's something to be said for cooking a great meal, from the prep work to the final product that can make you feel quite accomplished. I also work out often, and have been passionate about martial arts for many years. That's an important release."

Brunn led Bayer's pharma business in Japan for four years,

during which time the company went from 18th in the country to the top 10.

"That was the first time in many years the company had been ranked that high, and I'm proud of that," he says. "Also, we built a very diverse management team, including one of the first woman CEOs. We successfully launched several life-saving medicines and successfully set up one of the first open innovation centers in Japan, based in Osaka. As part of the center, we established a comprehensive research collaboration with the prestigious Kyoto University."

That collaboration played a key role in Bayer's joint venture with Versant Ventures to launch Blue Rock Therapeutics, a regenerative medicine company that plans to develop best-in-class induced pluripotent stem cell (iPSC) therapies in efforts to cure a range of diseases using an industry-leading platform. The basis for the overall approach is iPSC intellectual property invented by Nobel Prize winner Dr. Shinya Yamanaka of Kyoto University and licensed from iPS Academia Japan Inc., which manages iPSC IP. This foundational IP will allow the company to create iPSCs, which will be an important cell source.

Brunn has some simple, yet practical advice for future pharma leaders. "Don't be afraid to ask for help," he says. "Vulnerability is a strength. Things are a lot easier if you ask for help. Also, on the functional side, it used to be that everyone said you needed sales experience to advance on the commercial side. Now I think it's imperative to have market access experience."

— Michelle Maskaly

HITTING THE JACKPOT

Heather Dean, Head of Specialty Sales & Key Accounts, Takeda Pharmaceuticals

The pharmaceutical industry is full of bright, intelligent, successful individuals, but you rarely meet one that has known early on that they wanted to work in pharma. Most take a roundabout route that involves business or medicine, and then an opportunity to work in the industry comes up and turns out to be the winning ticket. And that's exactly what happened with Heather Dean's…babysitter.

Dean, head of specialty sales and key accounts for Takeda Pharmaceuticals, says when she was young, she looked up to her babysitter, a neighbor, who was smart, athletic, and very well-liked. She left their small town of 2,000 people in Illinois to become a brain surgeon. Later, in seventh grade, Dean's babysitter visited her hometown, not as a surgeon, but as a pharma representative.

"She talked to me about her job and she loved that she was working in business, but she was also helping patients and was speaking to doctors every day," remembers Dean. "I wanted to be a nurse, but I wasn't sure I could detach myself emotionally from patients. From that point on, I knew I wanted to be a pharmaceutical rep."

Dean wrote a paper about what she wanted to be when she grew up for English class, and hasn't wavered since.

Dean says she views her career to date in thirds. The first third was traditional, as a pharmaceutical sales rep; the next third, in a home office-based role in marketing, and the last third, which brought all her experiences together for an enterprise view in her current role. Dean joined Takeda in 2004 in that second-third, where she led the pre-launch, launch, and post-launch phases of the metabolic commercial program and eventually, GI Marketing, then onto area sales vice president, leading half of the General Medicine commercial sales organization before taking on the third-third, her current position, in October 2016.

She is most proud of embracing opportunities that have come her way, and points to two pivotal moments that influenced her 14-year career at Takeda.

The first, Dean explained that she had started in marketing at the lowest entry-level position and ultimately was one of the few people left on a brand team that had been built and dismantled a few times because of regulatory

Front & Center

Use Strategic Thinking to Excel

Executives across the biopharmaceutical industry deal with transformation on a daily basis, but few have learned to leverage the new norms in healthcare. Too many executives continue to apply the same strategies and rely on the same tactics that drove success five and 10 years ago. Strategic thinking brings the discipline that can generate new insights capable of building innovative strategies that lead to competitive advantage in today's ever-changing world.

Rich Horwath, CEO
Strategic Thinking Institute
StrategySkills.com

Strategic thinking is the ability to generate business insights on a regular basis to build competitive advantage. It's a popular concept that can yield profound benefits to a business, yet few executives master it. More than 40% of managers cannot articulate their company's strategy and fewer than 25% of U.S. executives demonstrate strong strategic-thinking abilities. Stronger strategic thinking can drive improvements in commercial and clinical results for almost any biopharmaceutical company. Yet, like any other skill such as putting in golf or playing the piano, strategic thinking needs to be practiced on a regular basis to yield results.

Pharmaceutical Executive spoke with Rich Horwath, CEO of the Strategic Thinking Institute (STI) and author of *Elevate: The Three Disciplines of Advanced Strategic Thinking*, to explore the potential of strategic thinking in the biopharmaceutical world. During the past two decades, he has engaged with more than 20 biopharmaceutical companies, including six of the top 10 in the world, facilitating strategy conversations among cross-functional executives to align strategies and helping leadership teams develop their strategic thinking and planning capabilities. As competitive pressures intensify and margins continue to compress, companies that master strategic thinking are more likely to survive and thrive than competitors continually stuck in the tactical weeds of the business. Mr. Horwath shared the following insights on how leaders can develop strategic thinking into an enterprise-wide capability.

Strategic Thinking Missing

According to studies with executive recruiters, strategic thinking is the most-valued skill among biopharmaceutical leaders. Companies and executives value strategic thinking for a very good reason: Strategic thinking generates results. Harvard Business School researchers compared financial results of companies over a 10-year period. Firms with coherent, well-articulated strategies outperformed their competitors in profits (by 304%), total sales (by 332%) and shareholder returns (833%).

A survey of 10,000 senior executives asked to identify leadership traits that are important to their organization's long-term success came up with "strategic" 97% of the time. Organizations respond positively to strategic thinking. Team members who believe their leader has a clear strategic direction are 40% more committed, but few ever get to demonstrate their commitment. American Productivity & Quality Center data show that not only is strategic thinking the single-most important executive skill, but it is also the number one skill deficiency among executives. Biopharmaceutical executives who master strategic thinking bring a significant advantage to their firms and to their personal careers.

A Strategic Thinking Framework

The process of strategic thinking can be captured in three phases.

1. Acumen. Acumen is insight into ways to bring new value to customers, patients and the company. Acumen has been in short supply. Product is at the heart of pharma firms, but managers are missing opportunities to provide differentiated value through other avenues such as service, support and education. Leaders who are unable to configure their resources—time, talent and budget—into a differentiated value chain of activities will find it difficult in the future to keep their heads above water.

Product-centric industries, including biopharma, are subject to competitive convergence. One successful new product begets a growing list of me-too products. Managers soon find themselves struggling to grow new and renewal prescriptions. The more follow-on products in the marketplace, the more difficult it becomes to define value except in terms of lower price, which sparks a race to the bottom in financial results, R&D support and shareholder returns. In an era of me-too products, generics, biosimilars and ever more narrowly defined patient populations, product alone no longer defines value to the different stakeholders that determine pharma success and failure. The key is for leaders to have the strategic ability to map out their product or therapeutic area ecosystems. Once these ecosystems are visually constructed with their spectrum of activities and connections, leaders can then determine where to apply their innovative resources.

Acumen generates the insight, the aha moment that sparks the recognition of that unique value a group can bring to

prescribers, patients, payers, regulators, pharmacy benefit managers, legislators, patient interest groups and other third parties that crowd the pharma ecosystem. Acumen prompts managers to recognize that a changing environment requires new strategies to continue success. Success today is not about being better than the competition—it's about being different from the competition in ways that customers, patients and other stakeholders value.

What constitutes value will likely change from company to company, but all successful pharma firms must identify ways in which they can provide value that sets them apart from the competition. Just as General Electric and other product-centric companies have evolved service and other non-product profit centers, successful pharma firms must develop new ways to deliver greater value to individual stakeholders and to the overall healthcare system.

2. Allocation. Allocation is the way managers choose to distribute resources, be it personnel, time, money or other assets, to turn those new insights into concrete activity. Not long ago, allocation was largely a matter of fielding an army of sales reps to support a new product, bringing the same product message in much the same way to every potential customer. Given changes in access to prescribers, the growing involvement of patients and others in product selection and the shifting landscape of purchasing decisions, flooding a market with sales reps may no longer be the answer.

Managers at all levels must have the urgency to reallocate their resources—their time, their people, their budgets—throughout the year from underperforming areas to ones with greater potential and performance. Unfortunately, most companies are still afraid to give their managers real resource allocation responsibility. As an example, regional and district sales managers rarely have the ability to move their sales and clinical specialists within their geographies to best meet the needs of customers. While "empowerment" is a nice word to toss out during a speech at the company's annual meeting, it's rarely realized in the field. If you want your people to move from tactical to strategic, you have to give them the knowledge and tools to effectively allocate all of their resources, including people.

3. Action. Action is the discipline to stay focused on a few key priorities. A to-do list of 15 tasks is not a priority action plan; it's a laundry list, and laundry lists do not set effective strategy.

Moving to action is focusing on the two or three key things that will drive business in a specific territory or region. That requires broad agreement within the company on both the insights and the resource allocation that is driving those priorities. Too often, strategy and the actions taken to implement strategy are unclear at the operational level. Top executives may think they have developed a clear strategy, but the real test comes at the regional and district levels. Do those lower level managers understand the strategy? Can they articulate it in their own terms? Can they translate it into concrete actions that will produce the expected positive results? For too many companies, the answer is no. Why? Because these managers have grown up with a sole focus on tactics, so they must now be equipped to think strategically.

Strategy Conversations Are Key

STI research found that only 35% of managers believe their local strategy is aligned with other functional units within the company. The familiar silo structure that built the biopharmaceutical industry is alive and well and throttling success in today's competitive environment. How often in your organization are the brand, field sales, account management and managed markets teams' strategies in alignment?

Communicating and aligning strategy throughout the organization is crucial. Meetings intended to communicate and foster strategic initiatives and execution are too often 80% presentation and 20% discussion. Successful companies flip that ratio to 20:80. In an era of specialized markets and non-product based value adds, the same old didactic dog and pony show that once supported product sales adds no new learnings, no new insights, and no new value to what the field force does or the results they produce. People are hungry to talk with one another face-to-face about their key business issues. Are you giving them the forum and framework to have those strategy conversations?

Strategy is traditionally set at the top, but the most successful companies understand that it is those who are closest to the customer are the ones who can best understand what constitutes value in the ever-changing marketplace. Companies that have developed ways to foster a free flow of insight in both directions, top down and bottom up, experience more profitable growth at faster rates because they are better able to deliver value that makes a difference to customers.

Creating an Insight Network to create, share and act on insights can seismically shift a company's culture from reactive and whiny to proactive and assertive. Companies that fail to share information throughout the organization increasingly find themselves unable to innovate, unable to identify or deliver new value and unable to thrive. Strategic thinking is no guarantee of success, but companies that think strategically on an enterprise-wide scale are far more likely to excel.

hurdles. When the brand director left to pursue another opportunity, Dean knew there were two paths for her, and one was brand director. "There was a big part of me that thought 'it would be really disappointing if I have to teach somebody everything I already know and not get the job,' and on the other hand, 'well, clearly they couldn't give me the job; I'm not ready for this.'" But her management said they had faith in her and that she was ready for it.

"I jumped in with both feet and loved every second of it," says Dean.

The next pivot ended her marketing tenure. "The leaders at Takeda said we think you need to move over and get sales leadership experience. I hadn't been a district manager or regional director but our culture here very much embraces diversity of thought and experience, and an enterprise leadership concept," says Dean. "Initially, I was concerned because I felt that marketing was so dynamic and difficult and interesting that I was worried it wouldn't be as challenging in sales. But I learned that I could take my experiences about how the home office worked and operated and share those insights with the field. We could align better on the strategy because I could give them that "why" of what the leadership wanted. I was also an earpiece for the field because I could tell the home office that some processes they did were not easy for those in the field, and if they made a few simple changes, it would make a world of difference."

Dean was selected to participate in Takeda's elite global development program for high potential leaders in 2013 and is now designated as a Global Enterprise Leader. Takeda has a clear chain for developing talent, and Dean says the company is focused on four principles: Enterprise thinking; focus; elevating capabilities; and inspiring others. These principles carry over into the culture of Takeda, of which she says values diversity, values communication, and allows all employees the opportunity to have their ideas heard.

For the next thirds of her career, Dean would like to continue expanding her scope of commercial leadership responsibilities either in Europe or the US. "In the long term, I would like to have a business unit leadership role," she says. "Again, I feel that enterprise leadership is so important and I think I have many good experiences over the years that will give me that big picture view, but I can also give that "why" to people in slightly larger settings such as in a business unit." Ramona Sequeira, president of Takeda US, is confident of Dean's skills and says, "I would love to see her in my role." Sequeira, in charge of the changes to Takeda's business unit structures, says, "Heather is a unique leader that can lead from the front and behind. People want to work with her, and she gets right in the trenches, connecting with people and their concerns."

As for Dean, she enjoys time with her husband and two young boys, family, friends, running, and mentoring activities. "I feel like I've hit the jackpot, with this industry and the roles I have had, and finding my home here at Takeda. It has been a pretty incredible opportunity."

— Lisa Henderson

LESSONS FROM THE PLAYING FIELD

Mohamed Hamada, Country Portfolio Lead, Women's Health, Pfizer

There are a lot of books that executives can read about leadership, how to succeed in business, and how to lead a corporate team through a tough time. But, for Mohamed Hamada, he gains his leadership style from a unique place—horses.

Hamada is the country portfolio lead for women's health, Egypt and Sudan, for Pfizer Essential Health, Egypt, but he is also a professional polo player who in addition to working in the pharmaceutical industry all over the world, has also competed in the sport of polo all over the world. His experience with horses has helped him learn to stay calm in high-pressure situations—a common occurrence in a volatile industry such as pharma.

When playing polo, a person has to juggle multiple competing interests at the same time—ride a horse at high speeds with competitors charging at you, while swinging a mallet to get

the ball in the goal. But, more importantly, as Hamada explained it, you have to control your emotions and stay even-tempered as to not upset the horse. Focus and fast decision-making is also very important as hesitation will cause you to be left behind during the game or, worse, you or your horse could get a serious injury.

Not easy skills to master, but definitely positive qualities that transfer to high-pressure business situations.

Another key element to success in polo, that is just as important in business, is strategic communication. "You have to use emotional intelligence in every situation that you are presented with," says Hamada. "Have a plan about what you are going to do, and communicate it with people regularly."

The pharma industry is changing at a fast pace, and being able to quickly adapt to those changes and welcome them with excitement is something Hamada believes makes a good leader in his field. "A good leader now in the industry is a transformative and a change agile leader," he says. "Being a transformative leader helps because you're agile enough to respond and deliver results, and teach others how to do that, too."

Being a good leader also means cultivating a positive team spirit and knowing how to work in a team environment, which may sound easier than it is.

"Like in polo, you have to have a good team spirit and have to learn the team dynamics if you want to win, and it's the same thing in business," says Hamada. "A winning team has a good team spirit. You have the best players and the best equipment. You each have clear roles and responsibilities, and a clear strategy of what you are expected to do."

While having all of these team elements is important, the team's execution is also critical; however, it doesn't always have to be perfect.

"You have to learn from mistakes," says Hamada. "You have to let them [your team] make mistakes, because they will learn from them. You cannot be afraid to make mistakes in business."

Hamada's career has allowed him to gain experience in different areas of the pharma industry. A pharmacist by schooling, he tried out a variety of different areas within the industry, but learned he liked the commercial marketing side best. He also has a strong academic background in business, holding a master's degree in pharmaceutical marketing from the European School of Business in Paris and an executive MBA from the Mediterranean School of Business in Tunis, majoring in mergers and acquisitions in the pharma industry.

Hamada has been with Pfizer for 11 years and explained that he enjoys the multitasking his job requires.

"You get to do a little bit of everything," he says. "Analysis, planning the execution of a marketing campaign, following up with sales, manufacturing, regulatory—you never get bored."

In his current role, Hamada is responsible for all aspects of the company's women's health marketing in Egypt. This includes planning the strategic and tactical marketing of the products and overseeing the execution.

Some products provide more challenges than others, and requires different strategies, which is why being able to adapt to various situations is extremely important in Hamada's point-of-view. For example, marketing a product that touches hundreds of thousands of patients is different than a personalized medicine that might touch 100 patients. Both have their pros and cons, and knowing how to tackle each one takes time and patience.

When asked about what he is most proud of during his career, Hamada quickly responds, "a lot of things, one of them is my experience in France. I studied and worked there for more than two years, it was a huge challenge for me—new language, new culture, tough curriculum in one of the top global business schools. I had to stretch my capabilities in different directions at the same time to succeed, which gave me a strong reserve of resilience that helps me a lot since."

Maybe what contributes most to Hamada's success is his answer to this question, "What keeps you up at night?"

"I don't ever let anything keep me up at night," he responds. "I believe everything will be solved in the morning."

That calm, level-headed approach to business shouldn't be underestimated. Hamada's determination is what has gotten him to where he is today. It's also something he encourages future pharma leaders to embrace.

His advice: "Read everything you can, be persistent, and don't be afraid to take a risk."

— Michelle Maskaly

BUILDING THE PLANE WHILE FLYING IT

Todd Horich, VP of Marketing, Supernus Pharmaceuticals

While beginning at the bench as a pharmacologist, earning a PhD in pharmaceutical sciences at the University of Maryland, Todd Horich always envisioned himself on the business side of the industry. Entrepreneurialism is in his genes, having come from a family of business builders and owners. This industriousness was evident during his days as a graduate student, where Horich completed his MBA in parallel with receiving his PhD.

Post-graduate, Horich worked for a time at the NIH's National Institute of Neurological Disorders and Stroke, before joining Novartis's neurology group as a market researcher, eventually mov-

ing onto the company's Trileptal brand team. Getting into pharma via market research "allowed me to use the skill set I developed as a scientist, while learning the business of pharmaceutical marketing," says Horich, noting it was "a perfect blend of science and business." Nearly every day, he still uses the tools he learned in market research.

As he progressed with Novartis, Horich kept an eye on his bigger goals. Following the advice of one of his mentors, Randi Roberts, he formed his own "mini board of directors, four or five people who I could bounce ideas off." Under their guidance, he made the leap from Novartis to a small startup of less than 40 employees (Vanda Pharmaceuticals) in 2006; it was a risky move, but, as his advisers told him, "you need to take the risk while you're young and can still recover from it." A few years later, this outlook led him to Supernus Pharmaceuticals, a young commercial startup company focused on treating CNS disorders. At the time (2010), he was Supernus's first commercial employee; by the end of 2013, Supernus had launched Trokendi XR® and Oxtellar XR®. "At first, neurologists couldn't even spell Supernus," says Horich, "but of the 10 anti-epileptic drugs launched in the last decade, Trokendi XR and Oxtellar XR have been among the most successful. And this is from a startup, building every department and process from zero, which had budgets (and still do) many magnitudes smaller than most other companies in the field."

As Supernus's vice president of marketing and new products marketing, Horich thrives on being involved in almost every function in the organization.

"From day one, I was at the table in clinical meetings, R&D meetings, and supply meetings, in addition to every commercial function," he says. "We make decisions very quickly as a unified team; there's not a lot of red tape." He highlights his "incredible partnership" of mutual respect with Taylor Raiford (VP of sales) in building the organization together, and notes that Supernus has "some very tenured folks—it's a misnomer about startups just having junior employees. The mentorship from veterans such as Jack Khattar, Victor Vaughn, and Stefan Antonsson has been invaluable to my continued professional growth."

Helping to build the commercial organization at Supernus "with no safety net" ("Building the plane as we were flying it!") was "incredibly scary, but also incredibly empowering," says Horich. "Employees and their families rely on you to help lead the organization to profitability." His background helped to ensconce him in the company culture. "Some startups transitioning to commercialization can look at the commercial people like they're from another planet," he laughs. "But with my skill set, I could speak the language of everyone here." Horich has since honed a leadership style focused not just on "getting people to do the things they need to do to be successful, but having them want to do the things they need to do." He adds: "We try to instill the feeling in all employees that this is their company, not just a company they work for. I have such a great team; never in my career have I seen such a small group accomplish such great things."

If Horich has any fear nowadays, it is one of an organization that grows extremely fast on its success, and staying focused on the fundamentals that got them there. The challenge for Supernus is maintaining its ethos as it grows larger. "Deloitte's 2015 Technology Fast 500 recognized us number one in biotechnology, and number three in 2016," he says. "We need to make sure we keep that up, but also protect our unique culture at all costs."

In a way, Horich's career has come full circle. He's back in his home state, Maryland, where he studied and began his career. But there's no danger of him sitting back. He is now looking to take Supernus "from a small- to mid-level organization to a larger organization with multiple business units."

With two psychiatry products in late-stage development, the company is "back to 2013, so to speak," says Horich. "Psychiatrists don't know us yet; we need to build up a new franchise. We're now looking to achieve in psychiatry what we're achieving in neurology."

— Julian Upton

CANCER MISSION IS PERSONAL

Ashley Kalinauskas, Co-Founder and CEO, Torigen Pharmaceuticals

If you asked people who have worked with Ashley Kalinauskas to describe her in one word, they would say, passionate.

The 27-year-old CEO of Torigen Pharmaceuticals Inc., the makers of VetiVax, a veterinary cancer treatment that uses the patient's own tumor cells to create a personalized immunotherapy, has made quite a name for herself in the biotech startup community.

It all started when the Connecticut native was home on fall break from the University of Notre Dame, where she was a graduate student, and a close friend died in a car accident. "Once I got back to campus, I needed something to take my mind off it and get back into the swing of work," she recalls. "I emailed my professor and said, 'I think we should create a business to launch this technology. He said, 'Ashley, if you want to do it, go for it. I will be with you every step of the way.'"

Kalinauskas decided to name the company Torigen after her friend and dove right in. The technology, which would become known as VetiVax, an experimental treatment regulated under USDA 9 CFR 103.3, was a therapy her graduate professor had been working on for a while.

Dr. Mark Suckow, former faculty member and associate vice president of research at Notre Dame, had spent his whole research career understanding ways to stimulate the immune system against cancer. Specifically, his research focused on tissue vaccines. Utilizing this approach, Suckow demonstrated that an effective anti-tumor response is associated with the enormous menu of antigens that are part of the tumor and surrounding stromal tissue.

In 2010, his family's Labrador retriever, Sadie, was diagnosed with squamous cell carcinoma and given less than a month to live. Suckow's daughters convinced their father to use the research he had been working on to develop a personalized cancer treatment to try and save their dog. Sadie survived for more than three years—cancer free—before dying of natural causes.

Inspired by that success, Kalinauskas, who always loved the intersection of business and science, formed a business plan, and entered a startup competition at Notre Dame. They came in second place.

"The day after, we had a line of investors waiting to meet with us," said Kalinauskas, who has a master's degree in engineering, science, and technology entrepreneurship. "We went from this really great idea and thesis project to a company."

Kalinauskas moved the company, which has experienced exponential growth over the past four years, back to her home state of Connecticut, specifically to a business incubator program at her undergraduate alma mater, the University of Connecticut, where she earned a bachelor's degree in veterinary pathology and pathobiology. When asked about her success, Kalinauskas credits having amazing mentors, including the former CEO and president of Cook Biotech, Mark Bleyer. Cook, an early investor in Torigen, offered Kalinauskas to work directly under Bleyer after graduation, to learn how the pharmaceutical industry worked and what it took to run a successful company.

"I had gone in and presented to their board and the CEO thought there was a lot of potential, but also understood one misstep with a startup company could lead to failure," says Kalinauskas. "He wanted to guide us and make sure we had everything in place, and were in a position to keep advancing."

As a young company just getting started, the chance for Kalinauskas to be mentored in a way that helped the organization set up a solid foundation was invaluable.

"Mark Bleyer and his whole team were really there for me," she says. "I had the resources, like clinical advisory teams and veterinary pathologists, available to me to ask them different questions every step of the way."

That experience helps Kalinauskas as she travels around the country meeting with veterinarians, investors, influencers, researchers, regulators, and others to spread the word about VetiVax, and bringing the company to the next level.

Kalinauskas never planned on being CEO of Torigen. In fact, they interviewed a number of candidates for the position, some who weren't the right fit and others who decided their talents would be a better fit in different role at the company. One day, Suckow and their new team members finally suggested Kalinauskas should just assume role; after all, it was her persistence and passion that led to the company's creation.

Kalinauskas's ability to straddle the human and animal worlds gives her a unique perspective on the pharma and veterinary industries. "Veterinary is not just a way for pharma to ease the costs of trying to launch a new drug," she says, before explaining what a difference therapies like this can make.

"I am most proud of how far we have come and looking back and seeing what a difference we have made," Kalinauskas says. "One of the first animals I treated after grad school was Lula Mae, in South Bend (Indiana). She had an oral tumor we had treated, and I stopped following up with her owners after a year and a half. I knew the dog was getting older and I didn't want to hear the dog had passed away. Recently, UConn had posted an article about us and under the post in the comments [Lula Mae's owner] wrote, 'because of VetiVax, my dog is alive four years later.' I just cried my eyes out. We changed this dog's life and their family's life."

— Michelle Maskaly

THE ACTIVE LISTENER

Michael K. Lyons, US Customer Strategy, Immuno-Oncology, AstraZeneca

Even before he started his pharma career in sales at Eli Lilly, Michael K. Lyons was well versed in the power of story. He had spent his high school and college years interning as a journalist at a New York City paper, "an exciting role," he says, that taught him at a formative age the importance of communication and information. Later as an intern at Young & Rubicam, he worked as a copywriter for brands such as Sony, Jell-O and Pepperidge Farms; he followed this with a stint in public relations for a boutique agency in Manhattan with equally large clients. Without being aware of it at the time, he says, "these early professional opportunities developed skills, such as learning how to capture a reader in a news report or urge a viewer to buy your product in a television commercial, that have helped me be a more effective communicator, marketer, and leader."

When Lyons joined Lilly in 2001, it was a time of great optimism and expansion in pharma, which enabled him to enter at a slightly senior level and work alongside executives who were 10–15 years older. Having always placed great faith in mentors, from his parents to his academic and professional supervisors, Lyons listened carefully to the advice he received from these counselors as he progressed through Lilly from neuroscience sales to global marketing of the company's oncology portfolio. His mentors encouraged him to take a pause and complete an MBA (at the Kellogg School of Management at Northwestern University); they then suggested "the best way to learn general management was to lead and deliver results in countries that do not have the same resources as the United States." So, Lyons headed to Thailand as a director for Lilly's affiliate, the first of three assignments in Asia that would see him handle increasing levels of responsibility.

Three years in Asia—first in Thailand, then as Lilly's oncology launch and innovation leader in Japan and latterly as chief marketing officer, ASEAN—made Lyons "a better leader and a better employee," he says. "Leading teams to drive results in those foreign cultures, fostering relations where locals want to deliver for you, and doing so without much of a budget was a huge undertaking. But with trusted advice, instinct, and a little bit of luck, we exceeded those challenges." He saw things he would never have seen in the US, such as the vastly different experiences of patients who were just a couple of hundred miles apart. That experience made him "very principled and pragmatic about how we build our business"—and the fundamental lesson he learned was that "it's not about us."

This lesson informed his approach when he returned to the US and was offered the chance to create and lead AstraZeneca's US customer strategy for its immuno-oncology (IO) portfolio. "I believe that it's about the patients and the healthcare professionals who serve them," he says. "That belief has allowed us to create a vision, design a strategy, and drive execution to help the IO team compete in a fierce market."

A colleague says that, among oncologists, Lyons is known as "a serial listener." For him, "it starts and ends with understanding that you must always meet the patient and oncologist on their terms."

In just over a year at AZ, Lyons and his team have developed an ongoing dialogue with the top US key opinion leaders (KOLs) across multiple tumor types to inform market strategies; created innovative community initiatives that feature influencers not traditionally leveraged by marketing; and strategically invested in the next generation of oncology KOLs. "The team now runs like a fine-tuned watch," he says. "People get along very well, the employees are selfless, they understand the goal and don't stray from it. With that, it is important to continuously instill the force of listening to our customers' needs and then strategically acting on those insights."

Lyons has now spent 13 consecutive years in oncology and in that time has seen personalized therapy change the landscape. "For example, in lung cancer, we have distinguished between histology of squamous and non-squamous, ALK, EGFR, PD1, PDL1, etc. These are tremendous leaps for science and create an exciting challenge to bring respective medicines to the patients who need them," he says. "And with those advances, the demand for excellence has increased. We need to be better listeners to the needs of our customers and use that information to be able to have the right conversations."

In an increasingly complex world with many therapeutic decisions, Lyons says that the craft of narration and navigation is vital. "It is important to help people understand 'the why' and not just 'the what' of a decision and action. The combination of story, execution excellence, and being close to the customer is a powerful one. It informs, unites, and drives better results."

— Julian Upton

FACING OUTWARD

Joshua Ofman, Senior Vice President, Global Value, Access & Policy, Amgen

When Joshua Ofman began his work in health policy and economics in the mid-1990s, it was a field still viewed with some uncertainty and skepticism by many in the pharma industry. At the time, Ofman was based in academia; completing his medical training at UCLA, he did post-doctorate work in gastroenterology and health services research, publishing widely in the disciplines of health economics and technology assessment, program evaluation, and health policy. On taking a faculty position at Cedars-Sinai, however, he could apply this research to a more practical setting. He was one of the initial physician leaders of a Cedars-Sinai spinoff company, Zynx Health, which provided evidence-based clinical decision support solutions for provider organizations, and consulting for life sciences companies.

During this time, Ofman transitioned from a research to a business focus. "I had a lot of corporate training while I was at Zynx Health," he says. "I was required to present to the board of Zynx and the Cedars-Sinai leadership, and I learned to build and lead an organization, with direct financial accountability. It was an incredible training ground, so by the time I arrived at Amgen (in 2003) I felt I had good management skills, and I understood how to operate in a complex corporation."

Joining Amgen provided Ofman with the opportunity "to move inside the industry and think about how we position biotechnology as a key solution to some of healthcare's problems." He was hired by Amgen's head of development in R&D to build the company's capabilities around access and health economics, but he had some way to go to convince some of the company leaders of the need to demonstrate the value of their products. "There were some parts of the organization that were just not built to do that," says Ofman. But the changing external environment, with increasing pressure on governments to focus healthcare spending on elements of high value, would soon bring more attention on Ofman's role. "We needed to do more dramatic things internally. Just adding new groups here and there was not sufficient; we had to dig down into the ways we worked and thought to get better at addressing those external issues."

Ofman's endeavors saw his organization become established as part of Amgen's whole commercialization process; his group "is now at the table at every level." As senior VP, global value access and policy, Ofman occupies a unique role at the intersection of policy and business, interfacing between R&D, policy, and commercial. "It's a very externally facing job," he says. "I'm interacting with governments and thought leaders and policy organizations. I sit on the majority of the company's large governance boards and I bring the perspective of the payer and pricing and access to all of those decisions."

Ofman remains highly motivated in leading Amgen's efforts as

the company moves toward a value-based healthcare system, where both long-term investment in health and patient access to innovative medicine is prioritized. His leadership success was recognized with his 2016 election to chairman of the board of directors for the National Pharmaceutical Council, and he sits on the boards of the California Life Sciences Association and the Biotechnology Innovation Organization. In defining his leadership approach, Ofman values having a strong technical base of knowledge and being able to paint a compelling picture of the future. "It's about looking around two corners, clearly articulating some likely future states, and describing what we need to do differently to be successful in this very dynamic healthcare environment," he says. "Once you can paint that picture, articulate it clearly, and create a compelling case for change, you can really get people to follow you."

It also helps that Ofman possesses a drive that is relentless until a vision has been realized. "Nothing makes me happier," he says, "than charging up a hill and having my team follow me, and seeing the organization respond effectively to change." Such relentlessness is vital in an era where the pace of change required to maintain a competitive leadership role in healthcare is more rapid than ever. "We're really at a revolutionary stage of biotechnology," Ofman says. "It's all much more dynamic now. We're trying to drive the company very hard around innovative approaches to value-based healthcare, innovative uses of technology, innovative contracting and pricing ideas. The challenge is to move fast enough to maintain our edge."

Ofman sees his task now as bringing to Amgen "a much more holistic and integrated view of how we address the external environment." To make the move from "a biotech company as a supplier of medicines to a company that is an integral part of the healthcare ecosystem," he is looking to pursue long-term investments in new partnerships and adopt a more external, customer-centric approach. He adds: "I'm really looking forward to driving this transition over the next decade."

— Julian Upton

TRANSFERABLE WILLINGNESS

Corey Padovano, Senior Director, Marketing Operations, Gilead Sciences

Corey Padovano is probably the only one of the *Pharmaceutical Executive* Emerging 11 that could perform an actual *Ocean's Eleven* role without a stunt double. In his spare time, when he's not engrossed in his role as senior director, marketing operations for Gilead Sciences or parenting his one-year-old daughter Grace with his wife Nikki, Padovano trains in Brazilian Jiu-Jitsu, a form of martial arts. "It's a great workout that helps keep me in shape and sharpens my mind in the process," explains Padovano. Jiu-Jitsu is also known for its style of ground-fighting, not dissimilar to wrestling, at which Padovano excelled in high school, earning him a scholarship to Drexel University in Philadelphia. "Many wrestling techniques are transferable to Jiu-Jitsu and there is definitely a strategic element to the sport, which makes it very challenging," he says.

The road Padovano has taken from college to his current position at Gilead involves many transferable skills, but also intuitiveness to know how to adapt those skills in different environments, and a healthy dose of willingness to stretch outside of his comfort zone.

Padovano also spent his college years as an Army ROTC cadet and, upon graduation, entered active duty as a second lieutenant leading a 30-soldier platoon responsible for millions of dollars' worth of military equipment. When he left the Army as a captain four years later, he had served in multiple capacities from an Air Defense Artillery platoon leader to an operations officer, and he even led a finance unit. While serving as a military officer, he had accumulated a combination of transferable skills—leadership, collaboration, teamwork, and strategic thinking—that the large pharma companies of his native Northeast US were interested in. Padovano began as a sales representative for Bayer and was soon promoted to district manager. Next, he was able to broaden his base of experience serving in a number of headquarters roles to include marketing, sales training, and operations. As a result of a series of mergers, Padovano eventually relocated to the West Coast to take a position as director of commercial operations responsible for hospital sales at Merck and Co. Padovano stretched his comfort zone with a move across the country and was responsible for a 10-state geography, which included multiple segments of business to include academic medical centers, integrated

delivery networks (IDNs), military accounts, VA institutions, and correctional facilities.

In 2013, Padovano became the director of US commercial learning and development for Gilead. In that role, his team was responsible for all therapeutic areas of training, leadership development, managed markets training, and marketer training. During his almost four-year tenure, he participated in eight product launches, which has been very "exciting as well as challenging." In fact, on his first day at Gilead, he was involved in training the newly established hepatitis C sales force, which was preparing to launch Sovaldi. "It's a great feeling when you are part of a product launch that can actually offer a cure for many patients."

With Padovano's desire to broaden his experience, stretch himself developmentally, and transfer his leadership skills, he moved to his current position five months ago. "I wanted to do something new and learn about different areas of the organization," he says. "I also wanted to put myself in a position where I could gain a deeper understanding of our business as a whole. One of my goals is continue to sharpen my leadership skills so I can be more effective in the future."

Padovano is now leading multiple functions, including: speaker program management, digital marketing operations, vendor management, Promotional Review Committee operations, and event planning. Another goal for Padovano is to identify operational synergies across these teams in order to optimally support stakeholders and drive consistent results. To achieve this, Padovano is examining processes for overall effectiveness. He says, "There will always be opportunities for us to improve. We have certain processes in place that might drive a favorable result, but how are we getting there? Are we working efficiently, are we working smart? I like the idea of exploring different processes in order to improve and streamline so that we can focus more on delivering sustainable results."

Working through the processes, he and his team have found some areas that could be improved or may be overly bureaucratic. "Driving change is difficult, there is always going to be a certain degree of pushback," says Padovano. "It is important to gain people's buy-in and support. You definitely need champions because you cannot expect to do everything on your own. Picking strategic partners who have skin in the game and want to drive meaningful change is critical. Staying focused on the end goal—beyond execution—to sustain change is important, but you need teamwork and accountability to keep change going for the long term."

Reflecting on how he began his career, Padovano clearly sees how the role of the pharma representative has changed since he entered the industry. The diminishing access to healthcare professionals (HCPs), along with the consolidation of practices into large IDNs, is top on that list. Challenges from a managed markets perspective have also added to the complexity in most therapeutic areas. "The reps in the field today have to be more sophisticated and better trained than ever before," says Padovano. "It's not enough to possess great selling skills. You also have to know your products and the competition inside and out, understand the shifting managed markets landscape and demonstrate a deep understanding of what is most important to customers and their patients."

Padovano believes that it is much harder to secure a role as a new rep in pharma today for a variety of reasons. Industry consolidation and increased competition from experienced sales professionals are two major reasons. However, he still believes people entering this industry should be willing to try different things and be flexible and open to new opportunities. "Developmentally, it is important to step out of your comfort zone and not be afraid to ask for help, support, or advice along the way," Padovano recommends.

For now, Padovano says he is still learning and enjoying being a part of the engine that is driving the overall US commercial team. But he says there are opportunities as Gilead continues to grow (the company has expanded from 4,000 people when he started to over 9,000 today) to leverage his transferable leadership skills into different functions and challenging roles in the future. "I want to continue to be an influencer into strategic decisions and provide opportunities for my team and others to develop and contribute to the organization."

— Lisa Henderson

GROOMED TO LEAD, INSPIRE

Mark Rus, Group Vice President – Head of US Neuroscience, Shire

Mark Rus has an impressive leadership track record and resume. Currently based at Shire's US HQ in Boston, this dual Canadian/EU citizen has an economics and international business master's degree from the London School of Economics, and a BA (Hons.) in Political Science & International Comparative Studies from Huron University. After graduation, and consulting experience on various pharma projects, he served in several roles in Canadian federal politics and policy. These ranged from the Privy Council Office (support staff to Canada's prime minister and cabinet), to election campaigns, to serving as speechwriter and policy advisor to Canada's Minister of State.

Now, group vice president – head of US neuroscience, Rus oversees more than 650 people, a growing multi-billion dollar P&L, new launches, and future strategy. He has spent the past 12 years holding a variety of positions at Shire in Europe, Canada, and the US, as well as joint venture co-chairmanship of Shire's Japanese partnership with Shionogi. As Shire has grown from less then 1,000 employees 15 years ago to over 25,000 today, Rus's journey has paralleled the company's growth.

Talk to him about his career, and how he has managed to be so flexible, and the main reason he gives is his family. His wife, 4-year-old daughter, and 17-month-old son have stood next to, supported, and moved with him through each career challenge and opportunity.

In fact, spending time with his family is his favorite thing to do outside the office. "Time with family is important," says Rus. "Traveling with them, helping them grow up, playing, or hiking with them. I love throwing one of them in a [kid-appropriate backpack carrier], and off we go!"

It's that solid, family-inspired foundation that may have contributed to Rus's authentic relatability and skill to quickly connect with almost anyone, whether it be a patient using one of Shire's therapies, a new sales or marketing executive he's coaching, a cross-cultural joint venture partner, or a government official.

His days of working in politics—running campaigns, meeting with constituents, developing policies, writing speeches, and being on the ground talking to people, seeing and watching government, politics, and business intersect—has also helped groom him to be a forward-thinking pharma leader. "I can't tell you how many times the lessons I learned from this non-traditional background have been useful/relevant to what I do today."

The big difference? "Instead of having several years between elections to get your objectives accomplished, our timelines are much shorter and the instant quarter-by-quarter results orientation significantly higher," Rus says. "You've got to be able to move fast as a team, make decisions with non-complete information, and still have everything connect up to a much broader, longer-term strategic vision that makes sense."

And instead of voters, it's now patients who hold him accountable. At Shire, those patients are a regular and constant voice in the company. Patients who have been touched in some way by a Shire medicine are regularly brought to meetings and events to share their stories, experiences, and unmet needs. "Every month, there is a story of someone coming in to talk to you about what our medicines or teammates in other therapeutic areas are doing and how it's impacted them," says Rus. "When you have multi-billion dollar blockbuster brands like Vyvanse that help literally millions of people, or our new launch brand Mydayis, this personal connection to individuals is critical to keep the team focused and grounded. You can't ignore it, and that's the whole point."

According to Rus, that type of corporate compassion flows straight from Shire's CEO Flemming Ornskov, into all aspects of the organization, creating an environment that promotes internal and externally sourced creativity and a desire to learn. Being curious about people in general, and about all industries outside of pharma in particular, is one quality every future pharma leader should practice, suggests Rus. "Soak up as much information as you can from people and industries around you and above you," he says. "It will help you think in new ways, toward new ends, and hopefully one day help us rebuild our industry's framework for it's future challenges and the long-term."

Good leaders should also not only build resilience in their teams, but learn to embrace the unknown.

"Not being afraid to step outside of your comfort zone is a well-worn but true cliché," says Rus. "Sometimes you don't have all the information, sometimes you feel uncomfortable. It's okay. If you can thrive in, shape, or improve in ambiguity, you can lead teams more effectively, help a lot of people, and accomplish a lot."

Rus knows a little about change. During his tenure at Shire, he has spent equal proportions of time in high level corporate strategy, global product strategy team leadership, country level or commercial business unit leadership in multiple therapeutic areas, and sales-force roles (as a representative and sales manager, attaining number one national ranks in both).

"At the end of the day, strong talent is strong talent, no matter where it comes from…and I've been very fortunate to have tremendous people and talented teams that have pushed me and I've learned so much from," says Rus. "But wherever possible in my hiring, I've tried to bring in people who were curious and resilient thinkers and didn't necessarily follow a classic path. For example, marketers with significant outside-of-pharma marketing experience."

The future of pharma in the US is exciting. There are clear reputational problems that need to be addressed. Rus believes pharma needs to change the conversation that is currently defining the industry if things are going to improve sustainably for the most important audience, patients, in the long-term.

The focus cannot just be on the cost of prescription medicines or other therapies. It cannot be just about the role of government policy in setting incentives (i.e., Orphan Drug Act/Medicaid negotiation mandates), or the role of pharmacy benefit manager rebates. It must be about what kind of society we wish to build, and innovation we seek to nurture, says Rus. He suggests more must be done to take a step back and encourage people to look at the big picture and drive bipartisan thinking and solutions to systemic challenges in the currently fragmented US healthcare landscape.

"We must of course work every day to serve patients and shareholders," he says. "Just like we all do as individual people, we must learn from our mistakes and build on our strengths. The industry

can and will enhance its reputation—it does too much good every day around the world not to. But part of the problem is that the overall system is so poorly understood, that simple solutions always seem the clearest when they are often not. The good news is that the tremendous quality of talent in our industry, combined with the scientific breakthroughs to come in CNS, and most other therapeutic areas soon, mean our best days are in front of us."

— Michelle Maskaly

A PROBLEM SOLVER AT HEART

Richard Scranton, Chief Scientific Officer, Pacira Pharmaceuticals

Despite a diverse leadership background, spanning influential roles in patient care, clinical research, and business, Richard Scranton is quick to call himself an epidemiologist before anything else. It's those roots—and the desire to find answers to complex puzzles that has guided much of his journey. It's what drove him to be the first in his family to go right to college. It's what convinced him to eschew the basic research path he was seemingly headed toward and search for solutions in the world of public health. It's a reason he joined the US Navy after getting his MD, where, as Lt. Commander Medical Corp, he established an anticoagulation clinic that still stands today. And it's that same passion that gave the New York native, who grew up in Johnson City, Tennessee, the courage to take the leap to industry, where, early on, "there were months when I only got half my paycheck." Joining a then-barebones startup, Scranton believed in the science behind a diabetes medicine derailed for a different indication 10 years earlier. His own investigative research would help the drug gain approval and launch.

"When I got out of college, I was pursuing more of a PhD route," says Scranton, who received a BA degree in biology from the University of Tennessee-Chattanooga and his MD at East Tennessee University's Quillen College of Medicine. "But when I spent about six to eight months with a hamster cheek pouch in very dark rooms, I realized I didn't want to do that for the rest of my life."

Today, Scranton is chief scientific officer for Pacira Pharmaceuticals, a specialty pharmaceutical company focused on developing and commercializing non-opioid products for postsurgical pain control. He joined the New Jersey-based firm in 2011 as executive medical director, and would ascend to vice president, scientific and clinical affairs, and then vice president, medical health sciences, before being named to his current role in June of this year. Scranton joined Pacira from VeroScience, where, as chief medical officer, he led the filing of Cycloset®, approved by the FDA in 2009 for type 2 diabetes. The drug, which represented a novel treatment approach, through boosting levels of dopamine, won approval largely due to the 3,000-patient trial Scranton designed assessing Cycloset's cardiovascular safety.

At Pacira, Scranton heads up a 90-person group responsible for medical affairs, health outcomes and value assessment, and market access. He also oversees clinical research and scientific communications. In another nod to his epidemiologist base, Scranton has helped build one of the largest health outcomes teams in a company Pacira's size. Amid today's focus on value-based medicine and innovations in patient engagement to help stem rising healthcare costs, Scranton is an advocate for closer collaboration with health networks and payers in areas such as health outcomes. His work behind the scenes helped Pacira strike a recent agreement with Trinity Health, a 93-center hospital system serving communities across 22 states. Trinity and Pacira will work together to develop an alternative approach to opioids for acute pain management and identify patient populations who would most benefit from opioid minimization strategies in hospitals.

The opioid-abuse epidemic in the US and beyond has been well documented—in the lives and families destroyed, and the economic toll. The societal cost of the crisis in the US is estimated at $78.5 billion a year, according to the CDC. Past studies have reportedly found that more than half of postsurgical patients prefer a non-opioid option.

"We've been at the forefront of getting the message out that the overuse of opioids in the surgical setting is harming patients, both acutely as well as the potential for chronic consequences," says Scranton, who, with data from Pacira's own analyses, has presented to the National Institute on Drug Abuse on this association, and has met with senators and members of Congress on Capitol Hill.

Scranton says the broader mission of advancing the conversation around ways, in the surgical community, to reduce exposure to opioids is bigger to Pacira than any one product it sells. Pacira's flagship product is EXPAREL® (bupivacaine liposome injectable suspension), a non-opioid local analgesic that is used in combination with the company's drug delivery technology DepoFoam®. The platform encapsulates drugs without altering their molecular structure, and releases them over a desired period of time up to 30 days. Pacira has six programs currently in clinical trials targeting pain from surgical procedures such as knee arthroplasty, shoulder surgery, spinal fusion surgery, laparoscopic colectomy, and elective c-section.

"If you think about how many people have surgery every year in the US, at least 25 million can benefit from a low-to-no-opioid treatment strategy," says Scranton. "And there are 20 million people in this country today that have a history of substance use disorder that need an opioid alternative. There's still a lot of work to do. We're trying to figure out if there are other scenarios and situations in which application of our drug could break the cycle of pain and provide an opportunity for a subset of patients to enjoy life without opioids."

Scranton is a longtime expert in health economics and outcomes research. Earlier in his career, as a consultant to several big pharma companies, he designed pharmacoepidemiology and burden of illness studies, and also consulted on clinical trial design with an emphasis on patient-reported outcomes. In the mid 2000s, Scranton served as VA Boston's co-director of Harvard's Clinical Effectiveness Program, where he trained physicians in the principles of clinical research. He started teaching there a year after he completed the fellowship program himself, becoming the youngest VA Clinical Effectiveness Program director at the time to do so, and earning a Masters of Public Health at Harvard. Scranton would go on to work in the Division of Aging at Brigham and Women's Hospital in Boston.

Scranton credits his time at Naval Medical Center Portsmouth in Virginia, from 1994-2000, for shaping much of his success as a leader, and the management style he employs today. First as chief of residents and then Lt. Commander, it's where Scranton's drive to problem-solve and "address difficult questions" were fostered. Case in point: his creation of the freestanding anticoagulation clinic. Recruiting the help of volunteer administrators, nurses, and pharmacists, Scranton set up a system to keep postoperative patients anticoagulated and then managed and followed in an out-patient setting, enabling the veterans to leave the hospital sooner. He was given two commendation medals for his work at the Naval center.

"The military taught me about diversity of teams and how the most important thing you need to understand is that the more diverse a team you can create, the better likelihood you're going to have the right outcome or the better outcome," says Scranton, a NJ resident and father of two sons in college, his eldest a Navy Reserve corpsman. "That's the central theme for me. I've always wanted to be on the cutting edge, looking at complex problems, and finding solutions."

— Michael Christel

MERGING SCIENCE AND STRATEGY

Yaron Werber, Chief Business and Financial Officer, Secretary, and Treasurer, Ovid Therapeutics

Yaron Werber never doubted that his entrepreneurial spirit, formed by the grit and self-reliance instilled in him by his parents, both Holocaust survivors, and his own deep-rooted love of biology and technology, would eventually carry him to his true calling. It just took a little longer to get there—as the saying goes, the path to professional and personal fulfillment is rarely a straight line.

Starting in 2000, Werber, fresh off earning a combined MD and MBA degree in healthcare administration from Tufts University School of Medicine (he collected his undergrad in biology at Tufts six years earlier), would spend the next decade and a half working in the topsy-turvy world of Wall Street. Eleven of those years were at Citigroup, where Werber served as managing director, heading up the healthcare and biotech equity research arms, and building a name for himself in the investment community as a leading biotech analyst, sizing up life sciences companies—public and pri-

vate—at all stages of development. "I became very fascinated by Wall Street," says Werber, 45, a native of Israel, who immigrated to the US (New Jersey) with his parents when he was 13. "You can have access to amazing people—entrepreneurs, management teams, scientists—and get involved in companies literally from when they are founded to when they get their first drug approved to when they are acquired. But that's not the reason I went to medical school. I always knew that the future for me was being an entrepreneur and helping to start a company that's going to be very patient-focused and do something innovative. … There was no question in my mind that I wanted to be a C-suite manager at some point."

That time would come in 2015, when Werber joined rare disease startup Ovid Therapeutics as a founding member. Today, he is Ovid's chief business and financial officer, secretary, and treasurer. The company focuses on developing drugs for rare, debilitating pediatric brain disorders, with few, if any, treatment options.

Despite a strong reputation in the banking arena—Werber was ranked among the top five biotech analysts in *The Wall Street Journal*'s "Best on the Street" survey—and an appreciation, himself, of the skills he would not have learned elsewhere, the physician at heart wanted a chance to directly impact patients from the inside. Werber began his career in academic research at the New England Medical Center—and also in his earlier days, was director of business development at NotifyMD, an e-health company that connects patients and healthcare providers, and spent time as a consultant to Pfizer. His switch to Wall Street began as a senior biotech analyst with Cowen and Company.

Werber credits his talks with a longtime mentor from his days on the Street, former CEO and co-founder of Celgene, Sol Barer, for ultimately giving him the conviction to make the jump to industry. Another mentor, Ovid CEO and Chairman Jeremy Levin, formerly the CEO of Teva, recruited Werber to the fledgling biotech, in need of more than just a financial wizard. Werber recounts, with a laugh, that on his first day at Ovid, his laptop crashed. When he asked the four others in the new company's then-crammed New York City office if there was someone he could call to fix it, they told him they figured he would handle IT duties. Still not a stretch two years later, Werber's core responsibilities today are leading Ovid's finance, business development, IR/PR (investor relations/public relations), IT, and operations.

Drawing from his experience and unique vantage point on the Street, Werber, as a first-time CFO, orchestrated Ovid's $75 million Series B round of financing in August 2015 and, more recently, the closing of the company's $75 million IPO in May. Now a public company with a staff of approximately 40, Ovid's long-term goal is to become an industry pacesetter in the niche area of orphan brain disorders in children. Trailing such a path in CNS, overall, a traditionally painstaking road for R&D, has "unique challenges," admits Werber, noting as well that investors have become increasingly interested in the field of rare neurological disease. For developers, any chance at success requires constant engagement with key opinion leaders, regulators, clinicians, patient foundations, and patients and their caregivers, Werber stresses. Ovid's pipeline includes two programs for its drug candidate OV101: one in Phase II trials targeting Angelman syndrome, a neurogenetic disorder that occurs in one in 15,000 live births and is characterized by seizures, motor deficiencies, and lack of speech; and the other in Phase I for Fragile X syndrome, a genetic disorder that causes mild-to-severe intellectual disability and behavioral and learning challenges.

Ovid is also collaborating with Takeda on OV935/TAK-935, currently in Phase Ib/IIa studies for pediatric epilepsies, including Dravet syndrome, Lennox-Gastaut syndrome, and tuberous sclerosis complex. The drug targets a novel pathway—the enzyme responsible for breaking down cholesterol in the brain. Werber led the negotiations that resulted in Ovid's collaboration with the Japanese drug giant, which was chosen as a finalist for the 2017 Scrip Awards for Best Partnership Alliance. The structure of the deal, announced in January, could usher in a new approach to partnering, where the molecule originates and is licensed out of the pharma company—in this case, Takeda—not the biotech. Ovid is leading the clinical development and will lead future commercialization of OV935 in the US and Europe. Expenses are shared 50/50, as would be the profits, if the drug is successful in treating rare epilepsies. OV935 was once Takeda's lead neurology asset, with eyes on developing it for broad neurological disorders such as Alzheimer's disease before the two companies jointly decided that it is better suited as a treatment for epilepsy.

In guiding his team at Ovid, Werber emphasizes the importance of being bold and what he calls "optimistically tenacious" in taking on largely uncharted waters in rare and pediatric disease, at least from a therapeutic perspective. He says a near-term mindset and making objective, dispassionate decisions, backed by rigorous scientific and clinical data, is critical for small innovator companies such as Ovid. The underlying cultural thread, however, is humor, he believes.

"It has to be fun," says Werber, a father of two young children, who, in his spare time, competes in Olympic-distance triathlons, and also half-marathons, including a recent one in support of the Angelman syndrome community. "But it's much more than that. You need to get to an environment where there's an egoless system and people feel empowered to voice their opinions. Culture and process don't just happen; it's something that you need to actively work on."

Much like the company's broader strategic planning, which it hopes will involve continued business development, hiring, and pipeline expansion, at the appropriate pace. Werber says he's excited about working together on new ways to execute Ovid's long-term strategy, and the job of motivating teams in the face of the tough decisions and calculated risks still to come.

"As an analyst, biotech executives would call me and want to know what's going on with their stock price," says Werber. "The answer would be don't worry about your stock price, you need to execute and the value will follow. The last thing you should be thinking of is your stock price."

— Michael Christel

Ones To Watch

Jennifer English, Insmed Inc.

With drug pricing, government contracts, and market access making headlines on a daily basis, the next generation of pharma leaders will be entering territory not seen by their predecessors. These issues have become a vital part of the healthcare industry. As a result, they will need people like Jennifer English in their corner.

English, who after being laid off from her paralegal job took a temporary job in the pharma industry, is now the director, market access – pricing, contracting, and government programs at New Jersey-based Insmed Inc. She eats, breaths, and sleeps pharmaceutical pricing. In 1996, English started out as a temporary assistant in the human resources department at Bristol-Myers Squibb. She was first to see the types of positions and the skills needed for them. It peaked her interest, and launched her career in a section of the pharma industry that until recently hasn't gotten much attention, despite it being such an important role.

It wasn't a total surprise to English that she found this type of work interesting—she holds an undergraduate degree in history/political science with a minor in American studies, as well as an MBA in marketing, both from Rutgers University.

"My path was one that I carved myself, because I was always open to learning new things," she says.

As a result, English has been involved in everything from marketing and business development to supporting a global team for the launch of a cholesterol-lowering drug. She's worked for large branded drug companies, mid-size generic manufacturers, and small startups. She's led commercial contracting and government pricing, among other positions.

She has no fear when it comes to a challenge. Like when English, who seven weeks prior had just given birth to her second daughter, took a job with a two-and-a-half-hour commute each way so she could help a company launch a new product in just three weeks. Or, like when English took on a role where she was leading her team remotely from New Jersey, and traveling to Alabama once a month to meet with them.

English has managed commercial and federal (TriCare, Part D, Medicaid) rebate and chargeback payments and processing, led all government pricing calculation policies and procedures including day-to-day operations, and monthly and quarterly price submissions, and served as lead negotiator of customer contract terms and conditions. She has organized and managed the pricing committee agenda at several companies, in addition to often being the key presenter of recommendations for pricing committee discussion and approval. Because of her unique line of sight to many of the categories impacting gross-to-net, English has been the lead forecaster of GTN for many of her small pharma roles. She admits her current role is not easy, and even some people inside industry have a difficult time keeping up to date on all the regulations and changing market dynamics.

"Pharmaceutical pricing is a hot button issue right now," she says. "The way the complexities of the pricing and reimbursement landscape have grown has created a lot of grey areas that need to be fully explored."

Karthikeyan Chidambaram, Genentech

There is heavy data utilization in the pharma industry, supporting strategic decision-making. But, as government requirements for serialization come to fruition, mobile health devices become more popular, and as people worry more about their personal information, data management takes a more significant role.

That's where Karthikeyan Chidambaram comes in.

As associate director of data strategy and acquisitions at Genentech, his job is to worry about all those things. Currently, he manages the acquisition of all the data assets for the commercial function and setting the strategy to manage, maintain, and govern the data assets, thereby unlocking the potential behind the data. Chidambaram has truly worked his way up the corporate ladder, and crafted a role that is unique to not just the company, but himself. He first spent two years in IT programming, followed by 10 years of pharma analytics consulting. He started as SAS administrator and built analytics teams that supported projects with 18 of the top 20 pharma companies. Then he built the SAS center of excellence from the ground up, from zero to 65 people, globally.

Chidambaram has been with Genentech for eight years, growing to lead analytics teams for two business units.

"Considering the advancements in machine learning and AI (artificial intelligence) and the data explosion in the industry, my team has the most crucial role on the data, analytics, and insights front," says Chidambaram. "Our team plays a crucial role in providing the pros and cons of the data assets, helping bring in the right data assets to support the business decision-making. We also play a key role in ensuring that the data assets are managed and maintained within IT systems, while balancing the regulations with the ease of use and access, with appropriate governance mechanisms."

Chidambaram strongly believes in mentorship and creating personal connections when it comes to business and advancement. "My mentors have provided me with some crucial advice and support that has helped me grow in the right direction," he says. " I am providing the same support that I received to my mentees, helping them develop in their career."

Chidambaram's volunteer position as president on the Pharmaceutical Management Science Association Board not only helps him network professionally, but keeps him in the loop on the latest developments in the field. Like everyone in pharma, Chidambaram is seeing it change.

"There is simultaneous data explosion as well in the industry with several entities attempting to commercialize their data [e.g., doctor networks, mid-level suppliers], creating a variety of data assets," he explains. "This has made my job more interesting and challenging at the same time. We are on a constant race to keep up with the new data assets and learning and evaluating them for our business needs.."

So what's next for Chidambaram? "I would like to continue help the industry to better unlock the potential behind the data assets, with linkage, supporting enhanced data collection, statistical techniques," he says. "I would like to serve as an official 'Commercial Data Officer' at some point in my career."

— Michelle Maskaly

An EPL Rewind

Now a decade old, *Pharm Exec*'s Emerging Pharma Leaders annual series is comprised of 205 alumni. As we celebrate this year's class, the Emerging Eleven, we catch up with two members of the 2008 induction—then called *Pharm Exec*'s 45 Under 45—to find out how being selected has impacted their careers in the pharma space almost 10 years later.

Mary Szela

Now: CEO, Novelion Therapeutics
Then: SVP, Global Strategic Marketing and Services, Abbott

PE: What has been your career trajectory since being selected as a *Pharm Exec* EPL?

When I took over the US pharmaceutical business at Abbott, the country went into an economic crisis, which affected healthcare in a way it never had before. That experience of navigating through an incredibly difficult year as well as addressing a personal health crisis, focused me on defining what I wanted to do next in my career. After careful thought and reflection, I focused on two major objectives as I contemplated my next role: 1) work alongside outstanding people; and 2) do something meaningful for patients.

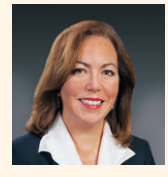
I left Abbott in 2012, then became CEO of Melinta Therapeutics, focusing on anti-infective development. My sister was recovering from a severe MRSA infection and the lack of antibiotics was staggering. I wanted to be part of a team to bring new antibiotic options to the market, particularly since there had not been a new antibiotic developed for severe infections in more than 10 years. I am so gratified to see the lead asset (Baxdela) from Melinta recently received FDA approval for complicated skin and skin structure infections. Patients and physicians now have another powerful option to address drug resistant/complicated infections.

In 2016, I was approached about Aegerion Pharmaceuticals, a company that had encountered numerous challenges, but had incredible opportunity to advance science on behalf of patients. Always loving a challenge, I became CEO of a company that is now part of the Novelion Therapeutics group, focused on serving rare disease patients with metabolic and endocrine diseases. At Novelion, we have the opportunity to profoundly impact metabolic rare disease patients through treatment, education, and awareness of the effects of leptin deficiency. Leptin was discovered in 1994 but was largely misunderstood until recently. We now understand the pleotropic effects of this essential hormone and its devastating effects when absent from the body.

PE: How did being selected as an EPL affect your career?

I love this industry and feel so privileged to be acknowledged as an Emerging Pharma Leader. I personally know many great pharma leaders, and I know our shared commitment to serve the needs of patients has never wavered, even as the environment for access and support has become more challenging. Yet, the way we are collaborating with our patients, regulators, physicians, and payers has improved greatly from what was done 10 years ago. All our stakeholders are seeking "value for money." Providing patients, payers, and physicians with robust, real-world clinical data is one of the most important ways we can ensure patients have access to therapy and are receiving optimal treatment.

Dagmar Rosa-Bjorkeson



Now: SVP, Portfolio Strategy, Mallinckrodt
Then: VP, Respiratory Franchise, Novartis

PE: Tell us about your career path since 2008?

Over the past 10 years, my career has been exciting and diverse. Most recently, I joined Mallinckrodt, just a few months ago, and I look to make an impact in this exciting organization. Mallinckrodt is a global business that develops, manufactures, markets, and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology, and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics and hemostasis products.

In 2007, I had returned from Sweden, having completed two years as a country head, and I took on a large US franchise leadership role, still at Novartis. My interest in specialty pharmaceuticals and rare diseases expanded. For the following six years, I led businesses that served patients across therapeutic areas such as asthma, cystic fibrosis, and multiple sclerosis, and also led the US business development and licensing organization at Novartis. My interest in continuing leadership development and seeking challenge brought me to the executive leadership at Baxalta, at that time an emerging spinoff biotech from Baxter. After two exciting years, the organization was acquired. I moved off to look for another leadership challenge in the mid-size pharma space, which I have come to enjoy and am finding my center in.

I've been able to work in areas that have engaged me completely. The experiences outside the U.S. as well as in the U.S. where I'm able to connect my work to furthering access to treatments that improve people's lives are very rewarding. Working with patients living with serious diseases is very impactful for me, and helping lead an organization toward realizing a strong patient value has become a personal mission.

PE: Do you have advice for upcoming aspiring leaders in the pharma industry?

The advice I give most emerging leaders is to take chances and choose challenging roles; those are typically the most rewarding and growth producing. We often focus too much on taking on roles where we are sure to succeed; this is a safe path, but usually not the one that results in most personal growth. I believe that the most personal and professional impact comes from working in the unclear, competitive areas and creating value there—those are the ones we later feel the most proud of.

— Christen Harm

From Emerging Leader to Novartis CEO

In 2016, *Pharm Exec* selected Dr. Vas Narasimhan as one of its Emerging Pharma Leaders. Last month—almost exactly a year later—he was appointed CEO of Novartis (effective February 2018).

Narasimhan joined Novartis in 2005 to work on pipeline development, and became global head of its meningitis franchise in 2007. By 2009, he was head of US vaccines for the company and leading its operation's pandemic H1N1 response. Narasimhan has spent the better part of a decade building Novartis' vaccine development pipeline. When he spoke with *Pharm Exec* last year, he was global head of drug development and chief medical officer at Novartis, leading a staff of more than 10,000 people across over 140 programs. The profile notes that in 2016, Narasimhan was included in *Fortune's* "40 Under 40" annual ranking of "the most influential young people in business."

"I've trained myself to really just focus on the day, the week, the month," he said.


shutterstock.com/ bluebay

Unraveling the Potential of Real-World Studies

Examining the importance of real-world evidence, the current issues involving randomized clinical trials, and what questions should be asked when trying to determine the performance of a marketed product

By Uttam Barick

In the pharmaceutical industry, there exist fundamental variations between clinical trials and the real-life utilization of medicines. Such variations create treatment and safety gaps that undermine the significant investments made by drug manufacturers.

When certain medicines are exposed to "real-world settings" and experience safety issues and reduced effectiveness, this seriously limits the success of the marketed medicine, especially when compared to the results projected at the clinical trial stage. On top of this, the gap between what is estimated during clinical trials and the reality of a given drug usually necessitates an increase in resources.

Why is real-world evidence increasingly important?

In this modern, competitive healthcare marketplace, pharmaceutical and medical device companies are increasingly required to provide evidence on real-world outcomes in order to differentiate, and justify, their products. In fact, in 2016, the FDA released a draft guidance document on how real-world data should be used when making both premarket and postmarket decisions for devices. This guidance has been created in order to develop a system that "would build on, and leverage, the vast amounts of data and information collected during the treatment and management of patients."

Data generated from real-world settings can help to provide significant insights into how a drug,

or class of drugs, performs or is used in a real-world setting. For this reason, it is important to continuously generate evidence-based information to attain optimum effectiveness and safety for the stakeholders involved.

RCTs versus real-world observational studies

Randomized controlled trials (RCTs), considered the "gold standard for clinical research," are not without disadvantages and drawbacks. They offer proof of efficacy only under very controlled conditions. Normally, Phase I, II, and III studies represent a niche pocket of the population with specific characteristics, and, therefore, underrepresent the greater patient populations. For this reason, RCTs might only be providing short-term outcomes.

It is for reasons such as these that some sources argue large-scale observational trials might reflect the "real clinical world" much better than an RCT performed in a specific, uniform subgroup of patients.

Late-phase and real-world evidence studies demonstrate and help drug and device companies to understand the real picture of patients through the entire patient journey. Since there are demands for ongoing investigations, it helps in generating and detecting the rarest safety signals by capturing data (structured and unstructured) from large populations and over prolonged periods of exposure.

Studies with a large number of patients from the real-world setting have an advantage over trials conducted under controlled environments. Real-world studies provide the flexibility to monitor a number of parameters in order to determine the performance of a marketed product. Some of these parameters are:

- Will the product provide an equal, or greater, benefit when compared to other marketed drugs?
- Will the product be more cost-effective than the existing options?
- Will the product's safety profile be equal to, or better than, the alternatives in a real-world setting?
- Does the product facilitate better compliance?
- Are there differences among individuals in terms of response rates?
- What are the differences in dosing and pharmacokinetic/pharmacodynamic modeling?
- How does the product react in combination therapies?
- What changes are needed in treatment patterns?
- Does genomics play a role?

Late phase and real-world evidence studies have varied styles and designs, and Phase IV clinical studies are designed to collect information from the real-world setting to assess the treatment effectiveness for specific patient subgroups, or enriched populations, under the controlled protocol.

Patient databases, chart audit/reviews, and registries expedite access to retrospective studies with sizable amounts of patients and data. These studies are ideal for the validation or generation of hypotheses for future studies, thereby feeding into research and development plans. The correct style and approach depend on the target, the required outcomes, and other limitations, like time and information.

In recent times, retrospective data has been a source to determine various patterns that are not visible in a controlled clinical study setting. The ability to determine the right patient populations for a particular drug in order to arrive at the best outcomes is an input that real-world data always provides to R&D teams. Through big data and predictive modeling, the existing real-world data determines:

Data Glance: Use in Key Settings

	Efficacy (Clinical Trail Data)	Effectiveness (Real-World Data)	Post-Marketing Surveillance (PMS)
Objective	Works under ideal circumstances	Works under usual circumstances	Works under customary condition of the drug use
Setting/Design	Controlled clinical trial	Real-world clinical practice	Controlled/spontaneous/ cohort/case control studies
Purpose	Regulatory approval (FDA)	Drug performance in real world	Monitoring the safety of the drug
Intervention or Treatment	Fixed regimen	Flexible regimen	Flexible regimen
Comparator	Placebo	Active comparator/usual care	Active
Subjects	Homogenous/highly selective (stringent inclusion/exclusion criteria)	Heterogeneous/any subjects	Heterogeneous/any subjects
Compliance	High	Low to high	Low to high

Patient personas for improved outcomes by determining:

- Patients who demonstrate better outcomes
- Patients who need support to be compliant
- Existing beneficial programs/interventions
- Comorbidities that change treatment outcomes
- Patients more likely to switch due to a lack of results
- Most practical frequency and methods to monitor in chronic diseases

Predictive analysis to determine:

- Future disease burdens
- Resource utilization
- Planning resources
- Funding requirements
- Benefits of population-based programs for screening

Given the importance of late-phase and real-world evidence studies, and the potential implications of the results, it is clear that these studies should be designed and conducted with the identical scientific rigor we afford to RCTs. Though there are multiple operational barriers, which can be overcome with structured approaches, scientific rigor can increase the credibility within the scientific forum and with the policymakers.

The timing of late-phase or real-world evidence studies are becoming increasingly important, as the market access landscape continues evolving and adapting to the variations occurring in the healthcare landscape. Pharma and device companies are facing challenges during the post-launch phase in order to get a product to the right audience to influence greater adoption. These companies are taking the help of post-launch market studies, which hold the capacity to spawn insights from a wealth of information available from different channels. This is in order to help pharma companies unveil trends and patterns about patient adherence, switching, adoption, physician sentiments, key opinion leaders, and sales force competency in a cost-effective way to create competitive advantage.

Life sciences firms must concentrate on these studies and appraise them from time to time to attain business goals. "The more you know, the better for the patients" is the motto that must drive companies in order to attain the ultimate goal of patient benefit.

Proving ground

Sensing the same, the pharma world is experiencing a transformation. But, there is still some ground to cover, which can be done with appropriate awareness by disseminating sensible information on these studies. The idea is to showcase the outcomes of these studies so that actual proof can encourage more companies to delve deeper and utilize the advantages of such studies.

Healthcare research and consulting firms have been striving to unearth the potential of real-world evidence studies, and some stake claims to have dug deeper than many on the impacts and implications of these studies.

Conducting observational studies, both prospective and retrospective, enables us to uncover hidden gems in the form of real-world data. Using these studies, the diverse concerns of stakeholders, such as the generalization of results, healthcare professional interests, the quality of data collected, and the level of accuracy involved in such studies, can be anticipated.

Studies with a sound scientific design, standard operating procedures (SOPs) specific to real-world studies, creating owners among clinicians in publishing results derived from these studies, leveraging technology for remote monitoring, reducing time between reports by ensuring e-capture of data on intuitive systems with smart checks, etc., are a few ways to ensure the robustness of data.

Real-world studies are here to stay, and their usefulness and full-potential are only just being unraveled. There are various facets that are yet to be uncovered and tapped. The involvement of artificial intelligence (AI) and machine learning in the drug development phase has put us on the threshold of faster drug discovery cycles, reducing the importance of expensive and drawn-out phase trials. However, monitoring these interventions in the real-world setting becomes more important as they need more intricate scrutiny.

Data unleashed

Real-world data has always been around, but its significance has not been realized to its full potential. However, the relatively easy access to it, technology interventions to capture quality data and make sensible decisions out of them, AI and machine learning to look at data in novel ways and decipher more meaning from them, big data capabilities to harness huge amounts of data over long durations of time and sift for quality information, and the economic sense of obtaining the desired results make this data source all the more interesting. PE

UTTAM BARICK is a Clinical Project Manager and Clinical Research Professional at phamax

e·pharmasolutions™

A WIRB-Copernicus Group Company

Simplify Your Safety Process with ePharmaONE™

What if you could distribute safety letters globally at a fraction of the cost and time?

What if you could:

- Automate your safety letter distribution workflow?
- Eliminate time, cost, and burden?
- Assure compliance with global regulations?

You can. Ask us how.

Learn more about our safety solutions: **www.epharmasolutions.com/oursolutions**
Or contact us: **info@wcgclinical.com**

How Pharmas, Payers, and Providers can Meet the 'Triple Aim'

Today's model requires a fourth partner—the systems integrator

In recent years, with the Affordable Care Act and consensus on the "triple aim" (better outcomes and patient experience at lower cost), payers and providers have been moving toward a value-based healthcare system. But the pace has been slow, and other than a few paradigm shifts, which have been positive (accountable care ogrganizations, medical homes, growing use of telehealth, and self-insurers), there has not been significant changes in care delivery.

Payers set pace

While some see the provider community as the primary player in meeting the triple aim, I believe the payer will lead the way, because it is the group that holds the purse strings. While providers want to meet the aim, fee-for-service financial incentives don't support their efforts. Ultimately, financial incentives will motivate providers to change practice patterns, and financial incentives are driven by decisions of payers (both public and private).

Payers are strongly indicating that value-based reimbursements are the future of healthcare, with the new Medicare financial incentives via the Medicare Access and CHIP Reauthorization Act (MACRA) legislation and a growing use of risk-based and capitated contracts in the private sector. Payers are also behind the increase in use of telehealth as a means of lowering costs and improving patient convenience.

So where does the pharmaceutical and clinical research community fit in this new paradigm?

As value-based payments for pharmaceuticals become more common, pharma companies will be engaging more directly with payers and providers. They will need to gather data to prove value and will need to engage with patients to improve adherence to treatments (and by extension, outcomes).

But beyond this financial necessity of greater involvement, there is an opportunity to accelerate value-based care through a stronger partnership between payer, provider, and pharmas. All three, along with patients, can benefit from this partnership, with pharmas offering two important opportunities to payers and providers, both involving data exchange.

For providers, pharmas offer the opportunity to gain value, in the form of insights to guide treatment decisions, from the enormous volume of electronic patient data they house. This data, of course, has to be appropriately anonymized to protect patient privacy, and pharmas will need to be specific about how and why the data will be used. R&D uses should be clearly separated from marketing and sales uses, and patient consent must be gained for using anything other than anonymous data.

Pharmas need the anonymous data to speed up drug research and development through better understanding of target patient populations, their most desired target outcomes, likely responders, non-responders or adverse responders, to a new drug or for repurposing existing approved therapies. Access, linkage, and analytics of this data in an integrated research platform can enable pharmas to test hypotheses before risking time and money in clinical trials. The data could also help predict which kinds of patients are good candidates for trials, and which are not, based on their clinical markers and patterns of adherence to treatment. Pharmas and contract research organizations (CROs) have the budget to support this spend on patient selection/recruitment, as it would significantly reduce their overall costs.

In addition to helping discover new treatments and lower the cost of research, providers and payers could benefit from the insights learned to help better match patients with existing treatments.

On the other side of the drug delivery process, lies an opportunity for payers to contract for reduced-cost pharmaceuticals in exchange for referrals from payers to their in-network provider communities, provided that the drug offers positive outcomes comparable to the results from published trials. To show evi-

ADAM NELSON is Chief Operating Officer, Life Sciences, at NTT DATA Services. He can be reached at Adam.Nelson@nttdata.com

dence of efficacy takes real-world data, and pharmas need to collect information on responders, semi-responders, and non-responders to the medication.

All of this information will be needed to retain or renegotiate contracts with the payer community, and will require significant exchange of information between providers and payers and pharmas. Pharmas will need to link clinical, claims, and pharmacy information to identify responders from non-responders, positive from negative outcomes, adverse reactions, and correlation of outcomes to medication adherence patterns.

Integration imperative

It is in this exchange that we should add a fourth partner to the community, and that partner will be a systems integrator. Payers have claims data, providers have electronic health record (EHR) systems, and pharmas have enterprise resource planning (ERP) and laboratory systems. Adding to the complexity, software designers tailor their products to narrow-use cases within a specific market, resulting in a vast array of disparate applications. Payers can have two systems for care management and customer service, with a third for mobile interactions. Providers can have outreach systems different from the EHR and also multiple, yet related, portals. And in the pharma community, the number of application systems is staggering and growing.

None of these systems are designed to interact easily with each other or share data with outside platforms, including those that are cloud-based and platform as a service (PaaS). To combine data from these systems requires massive systems integration. The interim step has been the sometimes-elusive, all-encompassing data lake to hold everything from every system, from structured to unstructured data, from which data can be drawn for all purposes. While this approach has benefits, positive use cases inside of a division or function, and should sit at the core of a corporation, sharing the information across the payer, provider, and pharma partnership brings numerous challenges in data and system integration, causing the continued use of calls, faxes, and flat files.

None of these systems are designed to interact easily with each other or share data with outside platforms, including those that are cloud-based and platform as a service

A supportive application to each organization's core data layer is a platform that can accept, organize, and analyze data from multiple sources and platforms, and within the patient-centric perspective, that would be the customer relationship management system (CRM). It's a platform that has been adopted by all three communities (mostly salesforce.com). Payers are starting to twist it toward care management, as it offers a way to organize, analyze, and use non-clinical data that is critical in population health management. A West Coast hospital system, for instance, has over 70 apps on the salesforce.com platform that sits on top of its EHR to ease the entry and view of information for individual roles, from the nurses to the staff to the patients themselves. Pharma has gone all in, with the top 200 globally adopting Veeva for sales and marketing activity (Veeva is built on the salesforce.com platform).

Data dreaming

Imagine the scenario of a pharma and CRO looking to accelerate enrollment in a trial and paying for provider clinical data to organize and analyze its search (providers earning new revenue streams) and during the trials identify those that actively adhere and those that don't. This data could be used to create a persona that can be shared with payers once they begin to correlate actual users of the drug and outcomes. Once a treatment is approved and prescribed, the provider can follow up with patients via salesforce.com apps and telehealth capabilities and allow pharmas and payers to use the community feature to mine the feedback, understand the experiences, and even get in front of any adverse effects or complaints.

Imagine if a patient has a complaint and shares it online, not in Twitter or Facebook, as most people do now, but in a secure, collaborative community forum. Users of the platform would be other people with the same condition and using the same drug, as well as stakeholders from the provider, health plan, and life science communities.

The answer is not in simply procuring a platform; it's all in the integration and the awareness of the real-world business of quality care across the payer, provider, and pharmaceutical ecosystem

Instead of venting frustration, as many patients do now, a collaborative platform offers the opportunity for the healthcare insurer's care manager to inquire as to how the patient is feeling and suggest follow-up with the doctor. Or the care manager could facilitate a conversation with the pharmaceutical manufacturer to understand if the patient is experiencing a known or new side effect. The care manager also could provide valuable interaction information based on other drugs the patient might be taking and provide a significantly higher level of information about the drug than the primary care physician.

Beyond the glitz

I don't know about you, but I'd like to live in a world where my health plan texts me, my prescription drug company (whose company name I probably don't even know) offers me a discount or to pay for a follow-up visit, and my doctor has more information about what is happening with users of the therapy and the real-world efficacy of its outcomes.

But the answer is not in simply procuring a platform; it's all in the integration and the awareness of the real-world business of quality care across the payer, provider, and pharmaceutical ecosystem. And that is where the fourth partner, the systems integrator, brings tremendous value. PE

STATEMENT OF OWNERSHIP, MANAGEMENT, AND CIRCULATION
(Requester Publications Only)
(Required by 39 USC 3685)

1. Publication Title: Pharmaceutical Executive
2. Publication Number: 0279-6570
3. Filing Date: 9/30/17
4. Issue Frequency: Monthly
5. Number of Issues Published Annually: 12
6. Annual Subscription Price (if any): $70.00
7. Complete Mailing Address of Known Office of Publication: 131 West First Street, Duluth, St. Louis County, Minnesota 55802-2065
   Contact Person: Rochelle Ballou
   Telephone: 218-740-7205
8. Complete Mailing Address of Headquarters or General Business Office of Publisher: 2 Penn Plaza, 15th Floor, New York, NY 10121
9. Full Names and Complete Mailing Addresses of
   Group Publisher: Mike Tessalone, 485 F Route 1 South, Suite 210, Iselin, NJ 08830-3009
   Editor-In-Chief: Lisa Henderson, 485 Route 1 South; Bldg F, 2nd Floor, Iselin, NJ 08830
   Managing Editor: Michael Christel, 485 F Route 1 South, Suite 210, Iselin, NJ 08830-3009
10. This publication is owned by: Advanstar Communications Inc., 2 Penn Plaza, 15th Floor, New York, NY 10121. The sole shareholder of Advanstar Communications Inc. is: Rocket Holdings, Inc., 1983 Marcus Ave., Suite 205, Lake Success, NY 11042.
11. Known Bondholders, Mortgages, and Other Security Holders Owning or Holding 1 Percent or More of Total Amounts of Bonds, Mortgages, or Other Securities. If none, check box. → ☑ None
12. Does Not Apply
13. Publication Title: Pharmaceutical Executive
14. Issue Date for Circulation Data Below: August 2017
15. Extent and Nature of Circulation

	Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
A. Total Number of Copies	14,692	14,081
B. Legitimate Paid and/or Requested Distribution		
1. Outside County Paid/Requested Mail Subscriptions Stated on PS Form 3541	9,950	8,644
2. In-County Paid/Requested Mail Subscriptions Stated on PS Form 3541	0	0
3. Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid or Requested Distribution Outside USPS	71	60
4. Requested Copies Distributed by Other Mail Classes Through the USPS	0	0
C. Total Paid and /or Requested Circulation (Sum of 15b (1), (2), (3), and (4))	10,021	8,704
D. Non-requested Distribution		
1. Outside County Non-requested Copies Stated on PS Form 3541	3,894	4,683
2. In-County Non-requested Copies Stated on PS Form 3541	0	0
3. Non-requested Copies Distributed Through the USPS by Other Classes of Mail	0	0
4. Non-requested Copies Distributed Outside the Mail	480	416
E. Total Non-requested Distribution (Sum of 15d (1), (2), (3) and (4))	4,374	5,099
F. Total Distribution (Sum of 15c and e)	14,395	13,803
G. Copies not Distributed	297	278
H. Total (Sum of 15f and g)	14,692	14,081
I. Percent Paid and/or Requested Circulation	69.61%	63.06%

16. Electronic Copy Circulation.
    *If you are not claiming electronic copies, skip to line 17
17. Publication of Statement of Ownership for a Requester Publication is required and will be printed in the October issue of this publication.

Name and Title of Editor, Publisher, Business Manager, or Owner:
Christine Shappell, Audience Development Director

Signature: Christine Shappell
Date: 9/30/17

I certify that the statements made by me above are correct and complete.

Tecnoquímicas, Totally Reliable

We are a leading company in the Colombian pharmaceutical industry, with one of the best reputation in the field.

For over 80 years we have manufactured pharmaceuticals with rigorous scientific criteria and the highest technological standards, which support their safety, quality and effectiveness. Millions of consumers and thousands of health professionals in different fields trust our products.

We sell our products in Colombia, Ecuador, El Salvador, Guatemala, Honduras, Panama, Nicaragua and Dominican Republic, where we contribute to the access to healthcare. We also export to other 12 countries in the Americas.

www.tqconfiable.com

TQ Confiable

COLOMBIA

Colombia: The New Place to Be!

Emerging as a bastion of peace, stability and resilience in a region increasingly beset by political turbulence and economic stagnation, Colombia has been steadily reinventing itself as a Latin American pioneer and pacesetter. Indeed, as Venezuela plunges into chaos and the traditional heavyweight markets of Brazil and Argentina continue to falter, Colombia looms proud, boasting GDP growth rates of around two percent for 2017, imminent membership of the OECD's "rich nations club" and a consistent sovereign credit rating of BBB. "15 years ago, we were on the brink of becoming a failed state and our economy was in reverse gear, but our turnaround has been spectacular and we have come to be seen as a flourishing, star economy and a highly prospective investment opportunity," enthuses President Juan Manuel Santos.

This sponsored supplement was produced by Focus Reports.
Project Director: Roxane Höck
Senior Editor: Louis Haynes
Project Coordinator: Anamarija Svedrec
Project Assistant: Anna-Luisa Vogt, Alan Le Roux
Project Publisher: Mariuca Georgescu
Editor: Patrick Burton
Graphic Assistance: Miriam León, Laura Breitfeld

For exclusive interviews and more info, please log onto www.pharmaboardroom.com or write to contact@focusreports.net

"There can be absolutely no doubt that Colombia has advanced in leaps and bounds, when you consider the old narrative of narco-terrorism, insurgency and rampant criminality," recalls Colombian Ambassador to the Unites States, Camilo Reyes. "Investor sentiment has been firming up considerably in the wake of a sturdy peace process and proper enforcement of the rule of law," he notes "and the chief commercial appeal, right now, derives from an attractively sized market of some 49 million people, a burgeoning middle class with a taste for new products and services, as well as a business-friendly, open market economy and stable operating environment."

These positive business winds are also being replicated across strategically significant economic sectors such as the pharmaceuticals and life sciences industries. According to the latest forecasts from La Asociación Nacional de Empresarios de Colombia (ANDI), thriving domestic consumption is set to propel the value of the local pharma market from USD 5 billion in 2015 to USD 7.1 billion by 2020, representing a compound annual growth rate of as much as 7.3 percent. "Globally, we can now be considered a pharmerging nation given that our industry is outpacing most traditional markets," explains Rodrigo Arcila Gómez, the association's executive director.

The same can be said for the Colombian medical device market. "The medtech segment is already reaching close to double digit growth and our figures are telling us that this USD 1.2 billion market will be valued at 1.8 billon by the end of the decade," reflects Kenneth García Márques, managing director of Smith & Nephew. "I reckon that investors will be hard pressed to find such an alluring scenario elsewhere: a highly underserved marketplace according to incidence and prevalence levels of many health indications, growing purchasing power, an ageing population along with the political will to increase coverage and access to quality healthcare."

Juan Manuel Santos, president of Colombia

Alejandro Gaviria, minister of health and social protection; Camilo Reyes, ambassador of Colombia to the United States

"Pharmaceuticals and medtech together certainly rank as one of those high-performance, growth sectors powering the prevailing economic boom," agrees Invest in Bogotá's executive director, Juan Gabriel Pérez. "Moreover they can be credited with contributing to the current rising economic prosperity of our capital city. A full 67 percent of pharmaceutical manufacturers and 50 percent of medical device players are concentrated in Bogotá, which also periodically plays host to prestigious Biopolis events that gather together some of the most significant actors in the biotech and life sciences fields."

THE NATIONAL HEALTHCARE SYSTEM: JEWEL IN THE CROWN

It is perhaps, however, in the healthcare arena where Colombia most distinguishes itself from its neighbors and has managed to cultivate a reputation for being a real outlier. "Colombian public healthcare incontestably rates as the best in Latin America with close to 97 percent coverage of the national population which is a rather impressive figure when you consider precisely where the country is along its development path trajectory," reflects Servier's general manager, Francois Léger. "In parallel to the free-at-the-point-of-delivery services, there's also a robust out-of-pocket system too, meaning widespread access to a whole plethora of therapies, though the institutional market is tending to grow at a faster tempo than the private," he adds.

Others very much concur. "Colombia is a key market for bioMérieux because of the quality of Colombian healthcare, the skills of its professionals and the many excellent hospitals. When it comes to innovation and health in the Latin American landscape, Colombia is at the avant-garde and being here helps us to take the pulse of Latin America," observes Rocío Méndez, general manager of the French in vitro diagnostics and industrial microbiology specialist, bioMérieux.

Making it into the Big League

Felipe Jaramillo, president, ProColombia

"Colombia is now an example of how a country can change the course of its history when the right decisions are made. Up until 15 years ago, this country was in a very bad shape… Nowadays, not only businessmen see the country with different eyes, but also people in general around the world are more and more interested in a country that had been blocked for international visitors for so many years," exclaims Felipe Jaramillo, president of ProColombia, the government agency charged with promoting inward investment.

Indeed, the country has now entered the closing stages of a process that will, if successful, render it the 36th member of the OECD club of developed nations and only the third ever Latin American economy to be granted admission. The Santos administration, expectant that membership will boost international confidence in the country's economic prospects and trigger a commensurate upswing in FDI inflows, has been pushing the nation's candidacy with gusto. "We're going to be pulling out all the stops to preserve our BBB rating and keep the national economy shipshape and internationally attractive to secure this," confidently confirms Finance Minister Mauricio Cárdenas.

SOLUTIONS
that help
preserve
the miracle of life

GRUPO AMAREY
NOVA MEDICAL

With more than 30 years of experience
in the healthcare segment,
Amarey Nova Medical Group
offers the highest standards in services
and logistics by representing
the leading hospital solutions
for Colombia and Central America

Customer Service: 01 8000 1800 66 • PBX: 571 744 73 00 • Bogotá - Colombia

Javier Humberto Guzmán, director general, INVIMA; Rodrigo Arcila Gómez, executive director, ANDI's pharmaceutical industry chamber

Juan Gabriel Pérez, executive director, Invest in Bogotá

International league tables certainly seem to support such perceptions of the country's prowess in the medical science and healthcare provision domains. Global Health Intelligence (GHI)'s Latin America Hospital Database, for instance, calculates that as many as half of the top 43 best-equipped hospitals in the region are to be found within Colombia, while the World Health Organization (WHO) ranks the nation's public health apparatus as 22nd out of the 191 countries they review, placing it ahead of both the United States and Canada.

Little wonder then, that Colombia represents such a popular choice as a destination for medical tourism. "Some ten percent of users of Colombian private health insurance actually live abroad. For them, it is comparatively economical and cheap to get on a plane and travel here for their treatment and they are, of course, attracted by the great reputation of our doctors and surgeons," notes Eduardo Franky, general manager of Italian pharma and chemical business, Zambon.

In certain specific therapeutic areas, such as heart surgery, the phenomenon is especially pronounced. "Colombia is currently blessed with some 59 medical schools and around 1,100 cardiovascular specialists, so it is hardly surprising that American and Caribbean patients suffering from heart conditions are coming over here in increasing volumes because they know they will benefit from a high-quality yet considerably more cost-effective service," reasons Enrique Melgarejo Rojas, president of the Colombian Society for Cardiology and Cardiovascular Surgery.

RAMPING UP THE LOCAL FOOTPRINT

With all these manifold attributes on offer, Colombia is fast becoming a destination of choice for multinationals, not only to set up shop in the sense of establishing a direct local affiliate, but also for opening regional headquarters and implanting managerial functions. "When you cast your eyes across the local landscape, it is clear that there has been a great deal of movement in recent months and years. Traditional big brand players like Bayer, Roche and Pfizer have been around a long time but, from around the year 2014 onwards, impressive growth figures have prompted the entrance of a multitude of global mid-cap players including Servier, Astellas, Shire, and Menarini, and, right at this moment, we are on the cusp of yet a further wave of investment: this time from rapidly emerging turbo economies such as India and countries from the Far East," perceives Invest in Bogotá's Pérez.

One of the most notable big-ticket investments underway is that of Johnson & Johnson (J&J) which will be spending some USD 20-30 million on the creation of a service center to be unveiled at the end of 2017 to serve as the working arm for the entire regional operations. "After extensive analysis, we ultimately selected Bogotá as the optimum host city primarily because of Colombia's macroeconomic stability, sound economic fundamentals, favorable geographic positioning as a gateway between north and south, and the ready availability of a scientifically skilled human resource base with multilingual capabilities," confides J&J Medical Devices' vice president for the Northern Region, Mircea Cubillos.

Yolanda Alagón, general manager, Janssen

Mircea Cubillos, vice president Northern Region, J&J Medical

"Colombia is the Latin American country that instills most confidence for the global organization right now and will become the seat of one of only five such service centers worldwide. When fully implemented, the hub will house some 200 employees, spanning support services from customer logistics and procurement to finance and human resources," elaborates Yolanda Alagón, general

manager of Janssen, the group's innovative pharmaceuticals subsidiary.

MSD, for its part, employs as many as 740 personnel in-country, having elected to base its pharmacovigilance operations and one of the company's six global data management centers out of Colombia. "The rationale behind setting up these strategic centers in Colombia is the relative stability in the country and an unmatched talent pool with high levels of education and good English knowledge," admits general manager, Guillermo Browne.

Kenneth García Márques, managing director, Smith & Nephew; David Leclercq, general manager, Mundipharma

Meanwhile smaller entities have been following a similar logic, identifying Colombia as suitably strategically placed to oversee the rest of the Andean area. "Colombia serves as a headquarter for Latin America, a focal point from where we can define marketing, commercial and medical strategies and deploy those to other markets. It simultaneously serves as a training base to our distributors' sales force," recounts Zambon's Eduardo Franky.

One important pull factor is the perceived sophistication of the local market. "Colombia stands out especially because of its manifold distribution channels, maturity and variety which enables you to fine-tune your strategies, before applying and replicating them elsewhere," deftly points out David Leclercq, general manager for the Andean Region at Mundipharma, yet another multinational choosing to lead out of Bogotá. "Ecuador, for example, is a full 10-12 years behind Colombia in terms of pharmaceutical development and the market is pretty one-dimensional, being heavily controlled to the point where only the institutional channels flourish. Peru, meanwhile, is marginally different in the fact that 70 percent of the market is institutionalized while Venezuela is barely functioning at all," he continues. As such, Colombia differentiates itself as being the naturally dominant market of the various Andean economies.

Prof. Enrique Melgarejo Rojas, president, Cardiology Society; Rocío Mendez, general manager, bioMérieux

The leadership of Japanese outfit, Astellas, who, as recently as 2016, turned to Colombia to establish only their second ever affiliate in South America, has reached a similar conclusion in their decision-making. "We are keen to earn our spurs


Alberto Bravo Borda, executive president, ASINFAR; Emilio Sardi, executive vice president, Tecnoquímicas

in one of the more regularized, mature markets and, to our mind, Colombia very much fits the bill with its extensive coverage, strong regulatory regime and overarching stability," details general manager, Sandra Cifuentes.

THE ENLIGHTENED STATE

Colombia's comparatively strong positioning for both pharma and healthcare has not come about purely by accident. On the contrary, it is very much the result of meticulous planning and careful cultivation on the part of the successive administrations of Alvaro Uribe and Juan Manuel Santos.

On the industry side, Colombia is conspicuous for not favoring domestic manufacturers in the tendering process or any other form of trade in the country's pharmaceutical sector, creating equal opportunities for any entity seeking to operate in the sector irrespective of whether they are indigenous or foreign. This is, of course, a far cry from the sort of protectionist

Jaime Calderón, president, IETS

'local content' criteria enforced in Brazil or the mandatory joint-venture ratios and import-substitution industrialization policies encountered in many of the neighboring Latin markets.

However, some Colombians bemoan the fact that their government has been so accommodating to foreign investors and complain that it has come about at the expense of nurturing homegrown drug development. "I personally feel we're lacking a well-defined national policy to guide and nourish a local manufacturing base," regrets Emilio Sardi, executive vice president of Tecnoquímicas, the largest national producer and manufacturer in the country. He is quick to point out that local production capacity only accounts for a mere 2.5 percent of the Colombia's GDP and that, though the manufacturing sector might hold some weight in volume, it remains disproportionately weak in value.

Alberto Bravo Borda, President of ASINFAR, the pharmaceutical association for Colombian companies, describes how "trade authorities have for years prioritized the interests of multinationals, disregarding the rights of patients and of society. This has become more noticeable since in the Superintendency of Industry and Commerce, which is the National Industrial Property Office, officials, who were previously working for multinationals, continue to prioritize MNC interests from their public offices." Borda continues, "Colombia has traditionally respected intellectual property rights, but in the last seven years the country has given an embarrassing amount of privileges to the monopolies."

MNCs, however, tend to be thrilled by the 'level playing field' on offer and the sheer openness of the market. Of the 400 free-trade zones in Latin America, 108 are located in Colombia; a major advantage in terms of importing and exporting products. One of these zones is even specifically dedicated to the pharmaceutical sector and counts household names such as Blue Pharma and Amgen among its participants. Then there is Colombia's steadfast and unwavering commitment to furthering regional economic integration via initiatives such as the 'Pacific Alliance', a kind of joint "nation-branding" exercise involving Chile, Mexico and Peru with a view to fostering free movement of merchandise, services, and people across the four member states.

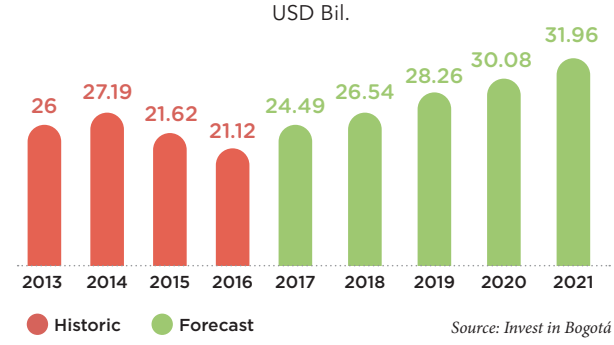
Meanwhile, on the healthcare side, considerable efforts have been made to fashion a forward-looking and modernistic public healthcare apparatus in line with international best practice. The national drugs regulator, INVIMA, for instance, is highly regarded across the region and has won plaudits for its time-efficient regulatory approval periods and streamlined approach. "I have been focusing my attention on four key priorities: institutional strengthening, efficiency enhancements, transparency and fostering the institution and country's competitiveness," confides Javier Humberto Guzmán, the agency's energetic and reformist director general. "The only way to attain these goals is to improve our risk based approach by making low risk

transactions automatic, to invest heavily in information technology and to collaborate closely with other regulatory agencies to avoid duplication and add value," he candidly acknowledges.

Francois Léger, general manager, Servier

These endeavors do seem to have been paying off. "It is a point of immense national pride that INVIMA is nowadays officially classified as Level Four regulator by the Pan American Health Organization (PAHO), which places it on an equal footing to 8 other best-in-class National Regulatory Authorities including COFEPRIS of Mexico, ANVISA of Brazil and the United States' FDA. Not only does this represent an international vote of confidence in the good manufacturing practices and high quality of drugs available in Colombia, but it also means an INVIMA-authorized product automatically gains recognition in certain other parts of the region such as Central America, which ultimately influences the commercial performance of the products," affirms Alberto Bravo, president of the Asociación de Industrias Farmaceuticas.

HEALTHCARE EXPENDITURE IN COLOMBIA (2013-2021)



Source: Invest in Bogotá

Then there is the admirable way in which the Colombian health authorities have been striving to embrace health technology assessment (HTA) methodologies and pharmacoeconomic approaches that deliver better outcomes to both patients and society at a large. To this effect, the Colombian Institute for Health Technology Assessment (IETS) has been created as an independent and impartial agency comprising a full-time core team of 30 health economists, epidemiologists and other healthcare professionals with a view to determining which treatments or health technologies should be considered exclusions from public financing and reimbursement. "Our mandate is to generate the best available evidence, taking into account state capacity, clinical and societal outcomes and even public opinion from which we draw up recommendations that can inform decision making. However, we play no direct role in the final reimbursement decisions," elaborates Jaime Calderón, the institute's president.

Sandra Cifuentes, general manager, Astellas; Carlos Estrada, general manager, Roche

GREAT EXPECTATIONS, UNSUSTAINABLE FUTURES

The OECD publicly commends Colombia for offering "a remarkable example of rapid progress toward universal health coverage that deserves to be better known internationally". Nevertheless, for all the heady ambitions about achieving close to 100 percent coverage and the enlightened thinking surrounding implementation of HTA, the brute reality is that Colombian healthcare is not yet on a financially sustainable footing and, at the end of the day, the entire system has been spending well beyond its means.


Gustavo Morales, executive director, AFIDRO; Jaime Arias, executive president, ACEMI

"Unfortunately, expanded drug coverage has placed a huge financial strain on the Colombian healthcare industry, which we calculate to have accumulated debts of more than USD four billion," warns Jaime Arias, executive president of the Asociación Colombiana de Empresas de Medicina Integral (ACEMI). Meanwhile the Ministry of Health has been bracing itself for what it says, in the worst-case scenario, could be year on year increases of some USD 700 million to the national annual pharmaceutical bill.

There are a number of underlying factors contributing to this unfortunate state of affairs. Firstly, there is the rather unorthodox public health structure in which Colombia operates a public healthcare system that is intermediated by private entities known as Empresas Promotoras de Salud (EPS), which function similarly to health insurance firms by collecting premiums from their members, and arranging the provision of services and treatments established and updated by the Ministry of Health.

According to Roche's general manager, Carlos Estrada, "It is paradoxical to have a privately managed system utilizing public funds and doing so can lead to a conflict of interests that would be impossible under a European-style single payer system in which public funds are managed and overseen by a public system." "The danger with these contradictions within the Colombian system," he says, "is that the system itself might opt for solutions that are financially beneficial in the short-term, but are clearly disadvantageous over the long-run." And indeed, many EPS firms now find themselves wallowing in debt and collectively owing the hospitals and clinics that provide treatments an estimated USD 2.9 billion according to Global Health Intelligence.


Eduardo Obraczka, general manager, Merck; Rafael Romero Pineros, member, Commission 7 at the Chamber of Representatives

Another factor relates to the epidemiological and demographic shifts taking place within the country. "Lifestyle diseases such as diabetes and cardiovascular ailments are growing exponentially in emerging markets and Colombia is no exception. Incidence of respiratory disease and cancers is also on the rise due to lifestyle habits such as smoking and exposure to pollution, and also in line with increased life expectancy, all of which is placing considerable strain on the system," asserts Boehringer Ingelheim's general manager, Javier Castro.

Most industry actors, however, attest that the root cause is more about the state's reluctance to allocate sufficient money towards health expenditure. "I think all stakeholders will agree, the government's health expenditure as a proportion of GDP is way too low. In Colombia, healthcare spending accounts for only 7.2 percent of GDP, whereas other Latin American countries have around nine percent. Reaching the OECD baseline on spending is of paramount importance if Colombia wants to reabsorb the financial and service strains linked to the lack of spending," declares Merck general manager, Eduardo Obraczka.

"Financial sourcing constitutes the principal challenge of our healthcare system today. The Ministry is going to be compelled to identify new channels of funding and the allocation of our resources is going to have to be optimized so that we can achieve more with less," bluntly concludes Congressman Rafael Romero Piñeros, a member of the House of Representatives' Commission Seven dedicated to public health and welfare.

Low Down On A Welter Of Reforms

The past 5 years have witnessed wholesale changes to Colombia's public health system. According to Minister Gaviria, "legal reforms are now done with, and implementation is the new name of the game."

2012

Creation of an Institute for Health Technology Assessment (IETS), modeled on Great Britain's NICE with a view to examining which drugs offer best value for money.

2013

Introduction of price controls requiring drug prices to fall into the 25th percentile based on international price referencing of a basket of seventeen comparable countries.

2014

Decree on Biologics creating an "abbreviated pathway" for well-known biosimilars with a view to speedily increasing competition and lowering prices.

2015

Statutory Health Law (LES) makes access to healthcare a fundamental right of all citizens.

2016

Government liquidation of two of the country's largest and most indebted healthcare intermediaries.

2017

Abolition of the Plan Obligatorio de Salud (POS) replacing the regular benefits package with a negative list of exclusions from reimbursement

Unveiling of a digital software system, Mipres, in which physicians enter the treatments they prescribe into an easily accessible database.

A RADICAL INSIDE THE MINISTRY

Faced with this harsh reality, the tremendously popular Health Minister, Alejandro Gaviria, an economist by background, has, since his nomination back in 2012, zealously been setting about implementing a tranche of measures aimed at reining in spending and catapulting Colombian public healthcare back into the black.

These have included subjecting drug price tags to international reference pricing (IRP), overhauling procurement, digitalizing medical records, and handing extra autonomy to physicians in their prescription decision-making. Much attention has also been given over to the redesign of entry requirement mechanisms and the introduction of an exclusion list of non-reimbursable items – namely treatments that do not have robust scientific evidence to back them up, and aesthetic procedures.

"In the future, we're going to be requesting laboratories to provide additional information on the comparative safety and efficacy of new products as we strive to inject efficiency and

Boom Time for Biosimilars

Colombia has raised eyebrows by introducing pioneering legislation for the approval of low-cost biosimilar medicines, putting in place an 'abbreviated,' fast track pathway for the award of market authorizations, whereby the products secure approval based on the studies of the mother drug that they are attempting to copy. The new regulation has been sternly criticized by local pharma watchdog AFIDRO, which fears that unsafe drugs could now end up on the market, but has been welcomed by local plays eager to participate in a biologics market that now makes up as much as 35 percent of Colombia's total pharma offering.

"We are betting on a bright future for the biotech industry; it is an increasingly significant niche worldwide with excellent growth projections. We really believe that biologics and biosimilars are what the future world of pharma is going to be about and as one of the leading companies in the Colombian market it's a phenomenon that we simply cannot afford to ignore and miss out on," affirms Emilio Sardi, executive vice president of Tecnoquímicas. "From my personal standpoint, biosimilars also represent a significant opportunity for a country having a universal healthcare system where it's difficult to sustain the service moving forward if the prices are set too high. We are therefore very much hoping that the new legislation achieves the desired impact in invigorating this particular sub-industry," he adds.

informed decision-making into the entire reimbursement process," affirms Héctor Castro, director of medicines and health technology at the Ministry. "The recent creation of a centralized purchasing unit within the Ministry of Health should also go a long way to increasing our price regulating power," he predicts.

Most controversial of all, however, has been the Minister's decision to subject Novartis' leukemia drug, Glivec, to a Declaration of Public Interest (DPI) and to threaten to issue a compulsory license that would have allowed the sale of generic versions of the drug in spite of the Swiss multinational's patent. Such a decision naturally sent shockwaves throughout the global pharma industry well beyond Colombia's own frontiers because it appeared to dispute the sanctity of intellectual property, one of the fundamental frameworks the biomedical research sector relies on for its existence. For El Tiempo's Carlos Francisco Rodríguez, what really made the issue so emotive was that "it appeared to confer legitimacy on the idea that social interests should be placed above economic benefits."

Whatever the initial intention, the upshot of the Glivec standoff (the agreed price of which has now been reduced by some 60 percent) has been to symbolically close a chapter on a period of Wild West, unregulated pricing structures when products such as Interferon beta-1b, used in the treatment of multiple sclerosis, would be listed in Colombia at prices some 30 times higher than in Western European markets. In the words of the Universidad de los Andes' Professor Tatiana Samay Andia "what used to be quite simply an orgy of profit for some of the big pharma MNCs locally implanted, has come to an abrupt end."

TOP 20 COMPANIES IN COLOMBIA (RETAIL)
MAY 2017

COMPANIES	MARKET SHARE (%)
1. Abbott Corp.	13.3
2. Sanofi Corp.	8.7
3. Tecnoquimicas Corp.	8.5
4. Bayer Corp.	5.8
5. Pfizer Corp.	5.0
6. GlaxoSmithKline	4.8
7. Procaps Corp.	3.4
8. La Sante Corp.	2.8
9. Novartis Corp.	2.2
10. Merck	2.0
11. J&J Corp.	1.6
12. Roemmers	1.6
13. Farma De Colombia	1.6
14. MSD	1.6
15. Genomma Lab	1.6
16. Tecnofarma	1.5
17. Sanfer Corp.	1.5
18. Grunenthal Corp.	1.5
19. Novamed	1.4
20. Siegfried	1.4

Source: QuintilesIMS

Héctor Castro, director of medicines and health technology, Ministry of Health & Social Protection; Carlos Francisco Rodríguez, medical advisor, El Tiempo

"It's tricky to find equilibrium between commercial interests, patient rights and financial sustainability, especially in a judicialized system with an empowered citizenry. Yet our blend of pharmaceutical policy, combining price controls, biosimilar competition, HTA, and centralized bargaining, strives to do just that. We are dedicated to crafting a system based on a coherent social contract that eliminates the regional and socioeconomic inequalities in outcomes, that bridges the gap between patient coverage and access, and that is appreciated by the public at large. Already we have the foundations in place and are making steady progress towards materializing this promise," confidently declares Gaviria.

RAGING AGAINST THE MACHINE

Predictably the industry has been vocal in its opposition to cost-cutting, albeit while simultaneously expressing sympathy with the public sector's woeful financial predicament. "We do accept the fact that there are price controls because this is a system that is, for the most part, paid for by the government. What matters most of all to our members, however, is that the regulation is applied in a systemic, predictable way so that it does not wreak havoc with company business plans. Unfortunately, we feel this has not always been the case," laments Gustavo Morales Cobo, executive director of the Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollos (AFIDRO). "In the areas of intellectual property and compulsory licenses, we think there has been a fundamentally misguided approach. Furthermore, we regret that the emphasis placed on prices has led the authorities to dismiss outstanding issues such as fraud, corruption inefficiency, and preventative care and resoundingly urge all stakeholders to work together in concert to address these pressing challenges," he declares.

Many industry commentators are quick to point out the adverse impacts of price-slashing and austerity. Claudio Ferrari, general manager of Scandinavia Pharma, laments that "Lately, the price of many drugs within the government tenders has been severely reduced. While we understand the necessity for such actions, the authorities need to realize that there is a risk that some products might disappear from the market entirely because their distribution is not rentable for the companies any longer, and that there is not always an alternative. In the end it is the patients themselves who lose out," he concedes. "High technology products that offer the greatest clinical advantages

should always be the priority in the reimbursement agenda, and yet this race to the bottom on price juxtaposed with an already highly competitive market sends out the wrong signal."

Others are appealing for a wholesale rethink. "While universal healthcare coverage is a seductive concept in theory, the basic facts on the ground tell us that the system cannot afford to realize this ideal. Despite a genuine willingness to provide access to the latest medical technology, there are insufficient public funds to achieve this goal. We therefore need to start thinking outside the box and constructively consider solutions that strike a better balance such as co-payments for specific treatments or performance related deals," advocates Boston Scientific's country director for the Andean region, Fernando Dussan. "We can start reconsidering the nature of healthcare as well, such as scoping in on contemporary, patient-centric formulas that simultaneously scale down costs by reducing medically unnecessary services such as some types of hospital stays."

Claudio Ferrari, general manager, Scandinavia Pharma

Rethinking Reagents

Emerson Lozano Garcia, general manager, Bioquigen

Even local, entrepreneurially minded SMEs active in the diagnostics field are seeking to step onto the bandwagon and come up with creative strategies to render healthcare processes more efficient and effective. Bioquigen Advanced Chemical is one such success story. "I founded Bioquigen back in 2005 essentially just as a distributor, but quickly spotted a niche opening up for the domestic development of diagnostic reagents. Soon we found ourselves transitioning into healthcare innovation when we realized that the standard waiting period for the analysis of a product on a patient was in the region of 20 to 30 minutes. I immediately thought, hang on a minute, we can come up with a system that does this much more speedily! Having gone back to the drawing board we were duly able to modify our reagents in such a way that the entire analysis could be completed in a mere 15 seconds." "What makes our ability to shorten the quality control process so vitally important is that you do not only save costs by ameliorating your operative capacity, but the risk of contamination of the biological samples is significantly lowered since there is considerably less time exposure," he laughs.

INTEGRATORS: WHITE KNIGHTS TO THE RESCUE

Of all the actors posing solutions to this conundrum, technology and medical device integrators spy an excellent opportunity to collaborate with the state and render public hospitals, clinics and surgeries more efficient and fit-for-purpose. Marisol Sánchez, executive president of ANDI's Medical Device Chamber, explains that "as Colombia hosts some of the best hospitals in Latin America, there is a high level of compatibility with the latest medical devices."

The big challenge in Colombia is the mismatch between needs and resources: the government has massive ambitions, but not always the commensurate financial firepower to materialize them. Therefore, companies like Philips are offering to implement efficient hospital management and assist the authorities in generating a bigger bang for every peso they spend.

Philips' pivot towards healthcare comes at a very opportune time for Colombia where there is excellent momentum behind putting in place radically new forms of healthcare


Marisol Sánchez, executive president, ANDI's Medical Device Chamber; Fernando Dussan, country director Andean region, Boston Scientific

provision. There seems to be great alignment between the structural changes within technology and equipment companies like Philips and Colombia's readiness to rethink its model of public healthcare provision.

In the past, medical device companies would bring innovative, best-in-class diagnostics to the market and others would perform the integration process. Nowadays these companies are the integrators as well. This means that the size of market is no longer necessarily a handicap. On the contrary, the Colombian market lends itself well to trialing out and experimenting with new kinds of solutions.

Indeed, right now, there is a stampede of big-brand technology firms offering integration services and turnkey solutions, all angling for a slice of the action. "We consider that it is time to change the relationship between the technology and the healthcare providers in Colombia so as to take costs out of the system," insists Siemens Healthineers' general manager, Guillermo Gómez. "A few years ago, we enjoyed great success collaborating with the Tumaco clinic on the construction of a new facility. Together with the architectural partner we rethought the design with a focus on reducing the number of movements for the patient within the clinic in order to impact the efficiency of the whole institution," he remembers. "We have other game-changing initiatives on the way and will be looking to harness the digital revolution to advance preventative healthcare."

Baxter RTS, the renal service segment of Baxter in Colombia, another heavyweight multinational, has been mobilizing its 82 partnerships with hospitals around the country to establish an innovative integrated care model for patients requiring dialysis, cardiovascular and diabetes treatments.

A Market in Profound Transition: Then and Now

Some of Colombia's longstanding heads of industry reflect on the emerging trends afoot.

Javier Castro, general manager, Boehringer Ingelheim

"I left Colombia 7 years ago for Peru and returned only in January. The healthcare market has undergone massive upheaval. Intermediaries between drug developers, logistical operators and the EPSs now possess considerably more purchasing and bargaining power. Also, the regulatory regime has become noticeably more stringent." **– Javier Castro, general manager at Boehringer Ingelheim**

Diego Forero, general manager, Pfizer

"There is much to be positive about. The progress in expanding healthcare coverage to over 97 percent of the population in such a short space of time has been a truly incredible achievement. This has developed hand in hand with a shift in market dynamics from trade to institutional. Subsidized regime benefits are on the rise and Colombians' out of pocket spending on healthcare have decreased."**– Diego Forero, general manager at Pfizer**

Victor Cardona, founder, Knovel

"Standards have shot up and the local market had become much more aligned with international norms. There has also been quite a shakeout in the contract manufacturing segment with some players not able to keep up with the regulations and losing their licences. Nowadays for some specialist fabrication services we have to look abroad." **– Victor Cardona, founder of Knovel**

"Colombia is actually very open to embracing new concepts of provision such as home care: 40 percent of hemodialysis functions are now performed within the patients' own home, compared to the sort of figure we would normally expect for this type of country which would be around 10 percent," points out the American entity's general manager, Juan Moncada. "We are now going to be operating across the entire healthcare continuum leveraging real-time data so that doctors can track how effectively their patients are following the treatment course and so they can make the necessary adjustments to ensure optimum results," he discloses.

Guillermo Gómez, managing director Andean zone, Siemens Healthineers; Juan Moncada, general manager, Colombia & South Latin markets, Baxter

Grupo Amarey Nova Medical, meanwhile, has been focusing its energies on smoothing out delays in drug delivery, misclassification and storage failure, having identified that up to 30 percent of hospital overcharges result directly from bad logistics practices. "Hospital logistics tends to be an inefficient and impoverished activity, not only in Colombia, but across the world. Many public health providers are decades behind private sector benchmarks on best practice in supply chain management, so we are confident that this is an area where we can deliver big impacts… right now we are deploying a state-of-the-art logistics model that is able to supply any pharmaceutical or medical device product in less than two hours to public facilities within the Colombian national territory," proudly claims general manager Esteban Lizarazo.

Esteban Lizarazo, general manager, Grupo Amarey Nova Medical

Already, Grupo Amarey has been making waves in associated areas of health provision optimization. Conscious that having latest generation medical devices is useless without the requisite expertise in how to operate them, the group has established a high-end simulation center, inspired by the Harvard University model, dedicated to training up medical professionals in orthopedic, laparoscopic and robotic operations. Equally the firm has raised eyebrows for its introduction into Colombia of Da Vinci Robotic Surgical Systems that facilitate complex surgery using a minimally invasive approach that is controlled by a surgeon from a console.

Going All Out For Volume

Eduardo Franky, general manager, Zambon

Despite Colombia boasting one of the best healthcare systems in Latin America in terms of both quality and coverage; in a country with a minimum wage of only USD 1.18 an hour (USD 246 a month), there are inherent difficulties in providing medicines to the entire nation.

One international pharma company that has successfully adapted its Colombian strategy to this economic reality is the family-owned Italian outfit, Zambon. Now established as Colombian market leaders in mucolytics with its Fluimicil drug, as well as holding second place in the urinary tract infection (UTI) market, Zambon is also expanding into the pain-related and Parkinson's Disease markets.

Eduardo Franky, general manager of Zambon Colombia, highlights the company's success in the country, pointing out that "We achieved 12 percent growth in units last year and 20 percent growth in value. We are now the third best performing multinational company both in terms of volume and value."

This success has been achieved by, in Franky's words, "offering innovative medicines at affordable prices… Zambon has been very careful on increasing prices. Moreover, our business strategy to drive growth is oriented towards increasing volume rather than price - which finally results in us being able to put more affordable medicines on the market."

THE QUEST FOR SOLUTIONS

Innovative drug developers are also increasingly looking beyond their traditional roles as purveyors of pills as they too scramble to identify win-win solutions to the funding squeeze. "Our recently launched immuno-oncology drug is tied with a biomarker, meaning that the patients go through a test, and if the test is conclusive, the doctor will prescribe the product assuring that the treatment will be personalized. This action increases the likelihood of success in the treatment and reassures the payer and the government that the product will be effective," attests MSD's Guillermo Browne.

GSK has also been trialing out a fresh approach. "We have been integrating a strong pricing strategy into our business model, focused on reducing the prices of our products as this has actually become part of our corporate DNA at our Colombian affiliate," narrates general manager, Adriana Forero. "A good example of the progress that we have made is the Expanded Program of Immunization in Colombia that operates under the Ministry of Health and Social Protection with the goal of making vaccines available and accessible countrywide. In view of the significant volumes of vaccines that the Colombian market requires and associated onerous cost-burden, we have been working up and down the entire value chain to identify savings that are consistent with our pricing policy, access commitment and reputation for upmost quality. I am proud to be able to announce that the price of our pneumococcal vaccine has subsequently dropped by some 20 percent in the space of five years."


Adriana Forero, general manager Colombia & Venezuela, GSK; Guillermo Browne, general manager, MSD

At the same time, Janssen, having long championed the concept of 'patient centricity' is looking forward to the challenge of outcome-based assessment being conducted locally with the onset of bodies such as the IETS. "The regulatory framework seems to be gradually moving in the direction of appreciating the comparative value that the drugs bring to the marketplace. We believe that we are well positioned to deliver up precisely the sort of transformational innovation that compete on these terms," remarks Yolanda Alagón, recalling the July launch of a sophisticated new product for multiple myeloma which will not only prolong the lifespan of patients but will also significantly enhance their quality of life thus enabling them to live more productively.

HEALTHCARE INVESTMENT IN LATIN AMERICA (2015)
(USD Bil.) *Source: Invest in Bogota*

1. Brazil	149.4
2. Mexico	71.4
3. Argentina	27.7
4. Colombia	21.6
5. Chile	19.4

COPING STRATEGIES

For other firms, and especially the locals, responding to the authorities' cost-containment drive actually entails modifying their business strategies. Biopas, which has had a stratospheric rise from 60th position in the Colombian pharma market to its current top 20 ranking, has diversified its product offering to become the distributor of Sativex, the first marijuana-based drug in Latin America, used by patients with multiple sclerosis to treat muscle pain. Executive vice president Pierre Faraldo explains that "Bringing to the market the first cannabinoid based drug in the whole of Latin America perfectly matches our company's values and mission to remain one of the most innovative companies in the market targeting unmet needs, while bringing new therapies in CNS, one of our core areas of focus."


Harold Karam, general manager, Farma de Colombia; Pierre Faraldo, executive vice president, Laboratoires Biopas

Biopas's accumulated knowledge of the Colombian market, especially in terms of market access, has helped it establish a reputation as a leading expert in the field and an ideal partner for international companies. Faraldo points out that "Biopas's customers have had to cope with market access difficulties and in this context, Biopas has undoubtedly been positioned as an expert in the field, having registered a significant number of products in a relatively short time-span. In the last 12 months, we registered 114 products in the markets we are in, while we are currently presenting more than 100 products in the registration process."

Farma de Colombia has meanwhile been experimenting with different techniques to ensure success. "We decided to make certain amendments to shore up our positioning. First, we have been increasing our market share, simultaneously in the primary care and OTC markets as a way of spreading or risk exposure and hedging our bets. The intention is to achieve 50-50 split between private and institutional clients so as to insulate our cash flow, but we continue to believe big in the future of the institutional segment in view of the relentless expansion of public healthcare coverage," explains general manager, Harold Karam.

PharmExec.com

THE LATEST

- News
- Analysis
- Webcasts
- Whitepapers
- e-books
- And more

www.PharmExec.com features easy-to-use navigation with content available by targeted category, keyword search, or by issue. Fresh content supplied by *Pharmaceutical Executive's* expert staff as well as external sources make **PharmExec.com** the source for comprehensive information and essential insight.

Pharmaceutical Executive

Challenging the Current Compliance Paradigm

Pharma needs a reeducation on what it means to be compliant

The compliance paradigm in pharma is flawed. My evidence, I confess, is largely anecdotal but as in medicine, a weight of anecdotal evidence does warrant further investigation and these are not simply my own observations. If you provide an opportunity to express frustration with "compliance," you can hear the problems for yourself. In no particular order and without any claim to being exhaustive, here is a list of some of the things I heard from a mixed medical and commercial group to whom I gave the opportunity to vent.

Among other things, compliance was described as:

- Boring
- Inadequately explained
- Arbitrary and unmemorable
- A legal exercise to apportion blame when things go wrong
- Tribal

From a business perspective, one could perhaps reasonably say "so what?" to most of this. So what if compliance is made boring? Lots of jobs are boring. So what if it appears arbitrary and a legal exercise? The company has to cover its responsibilities in law. So what if it is tribal? Medical and commercial functions have differing roles and objectives. By themselves, perhaps these aren't problems, but they do reflect a compliance paradigm that has negative consequences for our business and society. It is a paradigm in which the central flaw is the belief that rules are the sole protection against immoral behavior and individuals cannot be trusted to reach good decisions.

Consider for a moment how commercial ideas are developed and progressed. An idea is created by a brand team (a sales aid, a meetings program, or a website) and it is flung with its details at a compliance sieve; what takes place is whatever gets out the other side. Too often that is very little or nothing. The compliance sieve is getting finer and finer as more and more mesh is added, not by regulators, but voluntarily by companies. This is in the mistaken belief that more rules make things clearer and less risky: doing nothing is compliant—surely the fewer things we can do, the more compliant we must be.

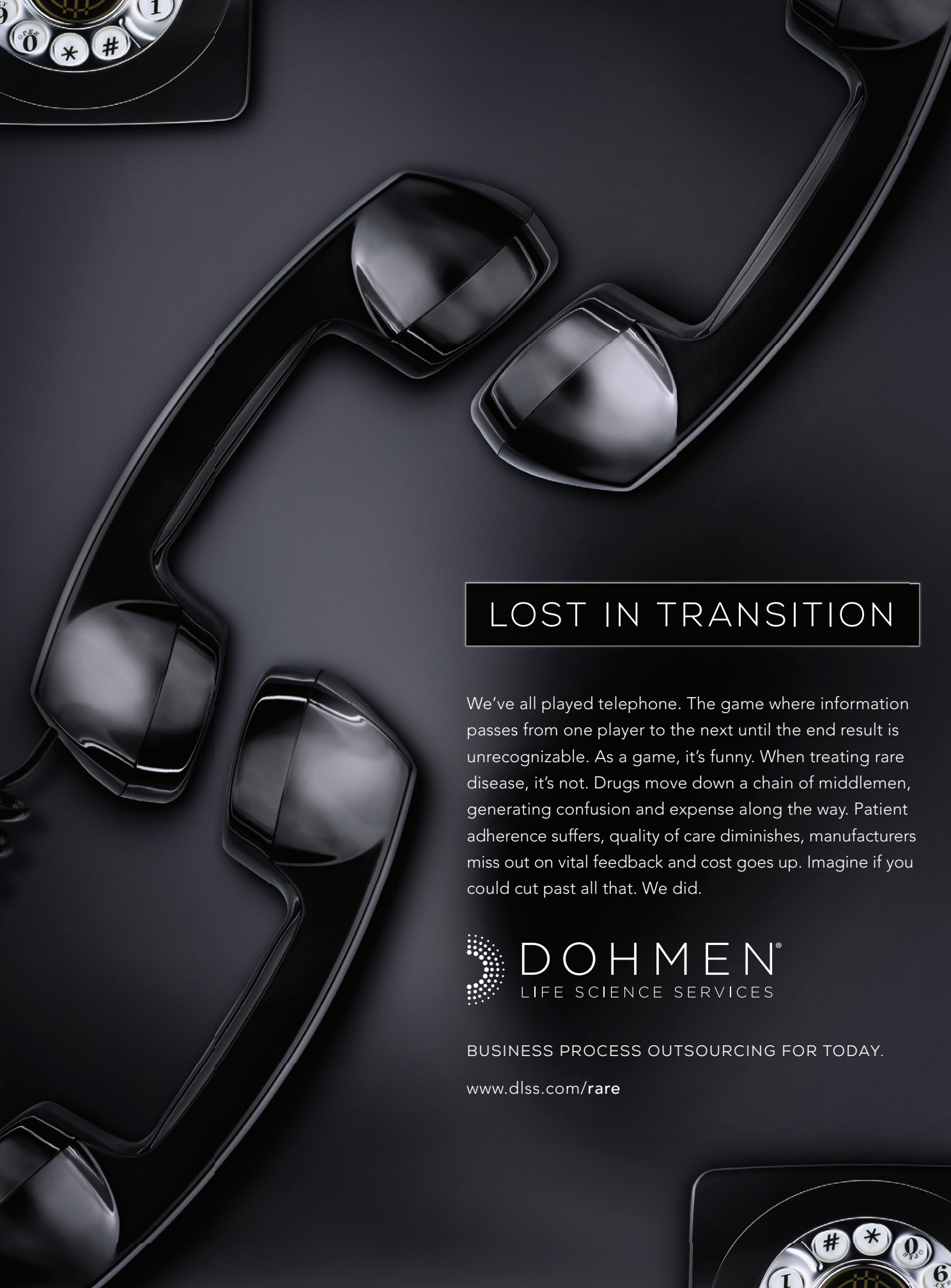
This "do-nothing default" may achieve compliance but it is ethically deficient; if a program of education and communication in a neglected disease area is abandoned because of a small imagined risk, compliance is achieved, but no one is helped and the ethical equation is in the negative. Worse perhaps is that doing nothing is more usually not even a conscious decision; it is simply a consequence of uncertainty about what is allowed and fear of repercussions that leads to inertia and projects ending up in the long grass that has grown around them.

The obsession with adding internal company compliance rules not only engenders inertia, it also undermines the very thing that most protects the pharma industry: the ethical good sense of the people within it. Every time a new compliance SOP is issued, dictating the actions an individual must take in a particular arena of activity, it restricts further the need for that individual to decide for themselves. That may be the aim, but simultaneously it removes from the individual their accountability to do the right thing. They must comply with a course of action—not decide a course of action. They must learn a rule—not understand how to make a decision.

None of this is to say compliance regulations within companies is unnecessary; it is only to say it is not a panacea to address the ethical problems the industry gets itself into. We cannot write a rule for every scenario and we should stop trying to. Lay out basic expectations and critical processes to get things done, but let's stop trying to dictate every action, or identify every possible wrong.

Just as internal company compliance regulations need to change, so too does compliance education. We need the good people in pharma to think and we must empower them to do so. The pharma industry employs people with well-above-average intellect who in their day-to-day lives have formed views about some of the most complex moral issues humanity has faced, from euthanasia to stem cell research to capital punishment and beyond. These are people we should trust. Compliance education should utilize those natural ethical abilities, making the links between morality and compliance strong and intuitive such that being compliant is not seen as a company hurdle but a personal moral obligation. PE

NICK BROUGHTON is a consultant and trainer in pharmaceutical ethics and compliance with Makara Health


LOST IN TRANSITION
We've all played telephone. The game where information passes from one player to the next until the end result is unrecognizable. As a game, it's funny. When treating rare disease, it's not. Drugs move down a chain of middlemen, generating confusion and expense along the way. Patient adherence suffers, quality of care diminishes, manufacturers miss out on vital feedback and cost goes up. Imagine if you could cut past all that. We did.
DOHMEN®
LIFE SCIENCE SERVICES
BUSINESS PROCESS OUTSOURCING FOR TODAY.
www.dlss.com/rare

Are you ready for the real-world revolution?

At UBC, we're dedicated to real-world evidence solutions that support the full product lifecycle.

PRODUCT SAFETY

- Late Stage & Postapproval Research
- Risk Management & Pharmacovigilance

BRAND LOYALTY

- Nursing & Adherence
- Reimbursement Services

PATIENT ACCESS

- Patient Support & Engagement
- Healthcare Analytics & Technology

You're in the middle of a Real-World Evidence Revolution. We understand. Demands from payers, patients, prescribers & regulators for definitive data have never been greater. At UBC, we've built our reputation on supporting pharma companies of all sizes in developing and commercializing medical products in the real-world setting. For our team of experts, this revolution isn't new – it's the real world and right where we belong.

To learn more, visit **www.ubc.com**

UBC®
AN EXPRESS SCRIPTS COMPANY