Pharmaceutical Executive

AUGUST 2014

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EFPIA'S BATTLE PLAN

M&A CHECKLIST
DOING DUE DILIGENCE

Pharmaceutical Executive

AUGUST 2014
WHERE BUSINESS MEETS POLICY
VOLUME 34, NUMBER 8
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2014 Emerging Pharma Leaders

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Leader Speak

William Looney
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wlooney@advanstar.com
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***PHARM EXEC*'S 2014 ROSTER OF EMERGING LEADERS**—our eighth, comprising an honor class of nearly 200 recipients to date—is more than just a way to recognize young executives who've made a difference in their organizations. Each list also serves as a window on work in an industry that, perhaps more than any other, relies on human capital as the coinage of success. Because our nominees are selected on the basis of a track record in directing teams, we can identify current trend lines around leadership behaviors: in a distracted world, fixing clear goals, with messages that motivate; keeping people on point and accountable for results; taking on reasonable risks while accommodating failure; and avoiding those process regimens that plague large institutions through a commitment to diversity—in culture, ideas, and talent.

The following is a capsule summary of insights about our changing industry gleaned from the 15 emerging leader profiles compiled by the *Pharm Exec* editorial staff:

New competitors in the pharma space. This year's list features two young CEOs from Russia and Portugal whose companies are venturing beyond their protected domestic base to test big-time opportunities in the US, Europe, and Japan. Antonio Portela, CEO of Portugal's Bial, capped years of effort in securing an FDA marketing license in November 2013 for the epileptic drug *Aptiom*—the first new medicine developed in Portugal for sale in the US. R-Pharm CEO Aleksey Repik is transforming Russia's second-largest domestic drug company into a global player linked to a network of partnerships with the cream of big Pharma, all while making his company top of the league within Russia as the sole local producer able to meet global standards for GMP. Both companies are family owned, a familiar model for successful businesses in the emerging market countries, and one that insulates them from the short-term investor pressures associated with being publicly held. Interestingly, many of today's big Pharma players started out the same way—give or take a century.

Globalization of the talent pipeline. Job assignments and career growth are tracking to a much more global trajectory, with many of our leaders remarking how they have benefited from postings outside their cultural comfort zones. Europeans are obtaining high-profile assignments managing US businesses, while one of our American leaders became a change agent in transforming his company's approach to market analytics in Japan. Overall, the immigrant experience continues to enrich the managerial talent pool in the US. Legislators in Washington, take note.

Supply chain manufacturing—from pumpkin to the gilded coach. As three of our leaders can attest, operations management is no longer a technical backwater but a front line strategic capability that has the undivided attention of the "c-suite." There will be no profits from tomorrow's individually targeted biologics if process technologies fail to keep pace with the complexities of reproducing them in a scalable, cost-efficient manner, for safe use by patients worldwide.

Numbers don't tell the full story. While big data has been touted as the solution to the industry's evidentiary challenges, there is a growing awareness that numbers alone do not create the interpretive knowledge required to guide decisions. A prized asset for managers these days is the ability to draw insights, establish context, and simplify the complex, which means that data is best applied as a tool toward that larger end, where the necessary judgments must be made by people relying on learned experience and—yes—intuition. It follows that none of our leaders wish to be known as "quants," but emphasize those softer people skills that allow managers to adapt and stay ahead of the curve imposed by today's unruly markets. As one leader says, "always start with the end in mind." And data can only take you part of the way.

Science is shaping career choices. As the recording of the human genome allows more precise targeting of drugs to address specific conditions, all diseases are becoming rare diseases, with dozens of specialty biologics to treat them now emerging from industry labs. For our leaders in commercial development, the best therapeutic opportunities are now found in this space. This is despite the fact they all cut their management teeth on traditional small-molecule products for chronic, big population conditions applied in primary care settings with a high level of generic penetration. The transition to specialty drugs imposes a significant learning curve on all marketers, and this generation of leaders is first to experience it.

Silo thinking—the albatross that still wanders. Organizational structure, office politics, culture barriers, and the inbreeding created by functionalized expertise remains the key obstacle to turning strategy into results. The will to change has to be matched with real incentives, says our group.

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VP OF SALES & GROUP PUBLISHER — TEL [732] 346.3018
Russ Pratt — rpratt@advanstar.com

EDITOR-IN-CHIEF — TEL [212] 951.6735
William Looney — wlooney@advanstar.com

MANAGING EDITOR — TEL [732] 346.3022
Michael Christel — mchristel@advanstar.com

SENIOR EDITOR — TEL [212] 951.6738
Benjamin Comer — bcomer@advanstar.com

EUROPEAN & ONLINE EDITOR — TEL 011 44 [208] 956.2660
Julian Upton — jupton@advanstar.com

SPECIAL PROJECTS EDITOR — TEL [212] 951.6742
Marylyn Donahue — mdonahue@advanstar.com

COMMUNITY MANAGER — TEL [732] 346.3009
Hannah Becker — hbecker@advanstar.com

ART DIRECTOR — TEL [218] 740.6411
Steph Johnson-Bentz — steph.johnson@media.advanstar.com

WASHINGTON CORRESPONDENT — TEL [301] 656.4634
Jill Wechsler — jwechsler@advanstar.com

EDITORIAL OFFICES — TEL [212] 951.6600
641 Lexington Avenue, 8th floor — FAX [212] 951.6604
New York, NY 10022 — www.pharmexec.com

SALES MANAGER-EAST COAST — TEL [732] 346.3054
Mike Moore — mmoore@advanstar.com

SALES MANAGER–MIDWEST, SOUTHWEST, WEST COAST — TEL [847] 283.0129
Bill Campbell — wcampbell@advanstar.com

SENIOR PRODUCTION MANAGER — TEL [218] 740.6371
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2014 Emerging Pharma Leaders

This year's class of 15 leaders is engaged in work that is very much of the moment, with capabilities that range from deep therapeutic know-how to management and operational excellence—all bound by an underlying commitment to the patient perspective that brought them to this industry in the first place. Our choices are a reflection of a simple truth: pharma remains at heart a people business.

Healthcare Reform

A Mission to Transform

William Looney, Editor-in-Chief

Mid-career students at Brown University's new Executive Masters in Healthcare Leadership program are challenging the status quo with workplace projects focused on one thing: removing the organizational silos that slow innovations in the delivery and financing of heathcare.

NEWS & ANALYSIS

STRATEGY & TACTICS

INSIGHTS

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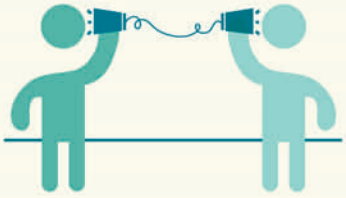

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2014 Pharm Exec 50

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bit.ly/1qkZbyr

Vaccines: Fire in the Cold Chain

July issue online
Kevin Fitzpatrick, Nitin Mohan
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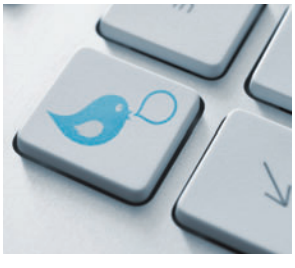

Abrams Talks Social Media at DIA

Blog post
Ben Comer
bit.ly/1rC6YuE

Social Media Questions Pharma Should Be Asking

Blog post
bit.ly/1icXNh3

Most-read stories online: June 25 to Julu 24, 2014

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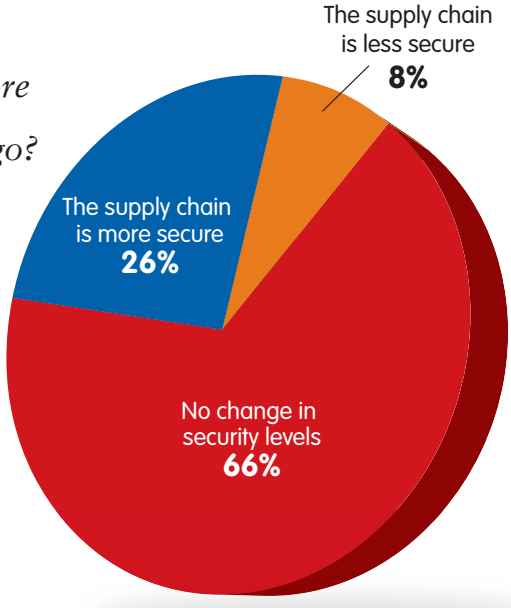
Data Point

Poll data courtesy of online *Pharm Exec* readers between June 3 and July 15, 2014

Q: Is the pharma supply chain more secure than five years ago?



Readers Weigh In

Amazing that GSK is so motivated to treat an entirely preventable disease. If they were really about health instead of profits, their sales force would be out selling smoking cessation products and advocating for clean air legislation. Oh well, I guess if getting an extra 5% improvement on your FEV1 (statistically significant, clinically not-so-much) is worth breaking the healthcare bank account, then party on GSK reps, party on!

TMACK, 7/8/14
"Deep Breadth: GSK Doubles Down on COPD and Asthma"
bit.ly/1chKB4V

When you say "monitor," you mean monitor what they themselves, and those acting on their behalf, are posting, right? If you mean monitoring for independent user-generated content (to correct misinformation, maybe?), I can't find reference to that.

Laurie Meehan, 7/10/14
"Making the Most of Social Media (Within FDA's New Guidelines)"
bit.ly/1jbDO2H

I see a history-making alliance in the works. The pharma industry should partner with women's health advocates to form the "Freedom to Fornicate Foundation."

Skip Mendler, 7/3/14
"Will the Supreme Court Spur OTC Contraceptive Development?"
bit.ly/Uj2x9F

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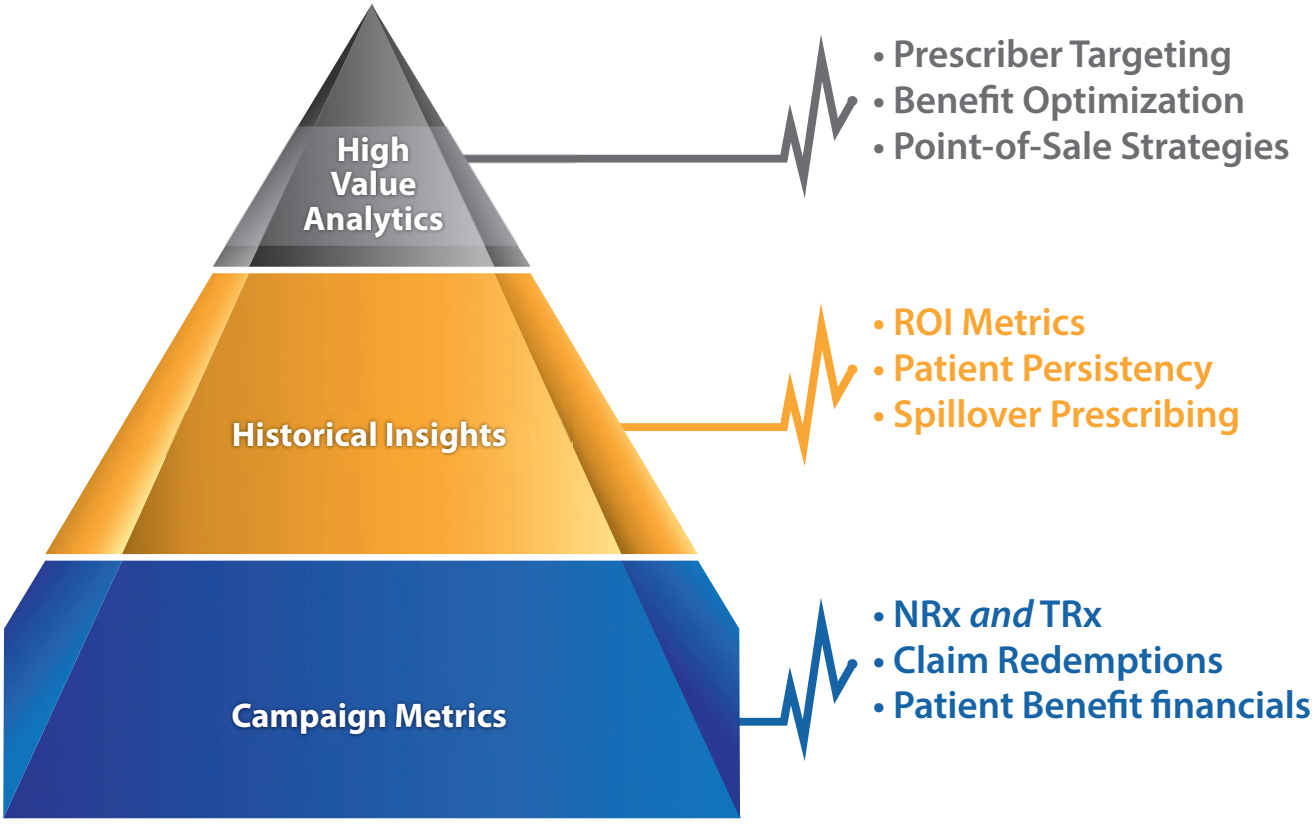

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Struggle Over Social Media Continues

Tweeting limited, corrections okay, says FDA, as industry, regulators wrestle with the digital world.

The Internet and interactive social media provide an efficient, low-cost way to send messages fast to millions of people—and to targeted patient populations. But pharma companies have been slow to take advantage of these methods, largely because of FDA rules that control what manufacturers can state about their products. FDA has been rolling out new guidelines for using interactive media in recent months. The new guidances clarify some murky areas, but may not make online communications any easier.

FDA's Office of Prescription Drug Promotion (OPDP) provides some useful advice in its new advisories, which were discussed further in an OPDP webinar July 10 (slides available at www.fda.gov). Overall, the agency sticks to its rules requiring ads and promotional messages to be accurate, not misleading, balanced, and limited to approved uses. Because it's very hard to get full risk information into a 140-character tweet or search engine listing, such communiqués may not fit FDA's regulatory scheme for drugs and medical products, according to a draft guidance on using the Internet and social media platforms with character space limitations (published June 16, 2014 at www.fda.gov). There's no leeway to use icons to indicate that all drugs are risky, as proposed by industry; without equal presentation of risks and benefits in a character-limited message, OPDP advises marketers to "reconsider using that platform," especially for products with complex indications or serious risks.

A second draft guidance gives marketers some leeway to correct misinformation on drugs and medical devices posted on the Internet by independent third-parties. Corrections of "user-generated content" (UGC) have to be truthful and not misleading, apply only to messages outside company control, and should not be used as "a springboard to engage in promotional messaging," explained attorney Jeffrey Wasserstein on the FDA Law Blog (www.fdalawblog.net, June 17, 2014). Marketers should address only the specific misinformation cited, but are not expected to continually monitor the site and track further comments.

Marketers don't have to inform FDA of every corrective posting, but should keep a record of such communications. That advice builds on another FDA guidance published in January 2014 that aimed to simplify how marketers should inform OPDP of Internet postings. FDA acknowledges that presubmission is not practical for continued participation in social networks and online forums; after initially submitting information on a website, OPDP permits companies to send in a monthly list of its postings, while keeping records of postings on file.

The irony of the social media marketing debate is that patients increasingly turn to the Internet to search for health information, identify possible treatments, and confirm diagnoses. FDA, itself, is a heavy user of social media.

But in trying to define which communications are a marketer's responsibility and thus should be submitted, this earlier guidance raised a lot of objections from industry. Marketers complained that the guidance makes them responsible for too broad a range of Internet postings and question whether tweets and "likes" constitute advertising or labeling—or really fall under "free speech" that lies outside FDA rules.

A final guidance is slated to address FDA's concerns about using links to other Internet sites that discuss drug risks and benefits. FDA has warned against connecting to off-label information, and that a "one-click" process

Jill Wechsler is *Pharm Exec's Washington* correspondent. She can be reached at jwechsler@advanstar.com.

for linking to full risk and benefit information does not satisfy its requirements for fair balance and full disclosure.

FDA also includes on its list of social media guidances a document published in December 2011 on how industry can respond to "unsolicited requests" for off-label information—both online and in public meetings. OPDP advised marketers to provide answers to such questions privately and off-line, an approach that remains in effect despite loud objections that it's impractical and confusing.

Nothing new

These social media guidances reflect FDA's continuing struggle to reconcile drug advertising regulation with changing information technology. The agency held a hearing on FDA & the Internet back in October 1996 to explore appropriate pharma use of websites and chat rooms. The discussion addressed strategies for correcting erroneous product information posted on the Internet, manufacturer use of links to other websites, and impact of rules set by the Federal Trade Commission and international agencies—all issues that were not resolved and remain controversial today.

Meanwhile, FDA ramped up citations for noncompliant Internet messages, culminating in 14 violation notices in 2009 to companies sponsoring search engine ads that lacked full risk information. Other letters held companies accountable for statements from third-party websites and blogs. Marketer objections prompted another FDA public hearing in November 2009, where dozens of industry representatives and IT vendors demanded changes in FDA rules to better fit the digital age. The agency's response was to propose new research on how consumers respond to risk information presented on various websites. So Congress added a provision to the FDA Safety & Innovation Act of 2012 (FDASIA) requiring the agency to address social media communications by July 2014.

Even with the new advisories, pharma companies may continue to lag far behind other industries in utilizing the Internet to communicate important information to the public. Drugmakers have been using social media primarily for corporate operations—announcing financial reports, hiring employees, recruiting clinical trial investigators and participants, and disease awareness. There is disagreement over how effective the Internet is for detecting adverse drug events. And it's not clear how pharma can utilize opportunities to implement "multi-channel" marketing to support new product launches and to reach targeted patient populations.

The irony of the social media marketing debate is that patients increasingly turn to the Internet to search for health information, identify possible treatments, and confirm diagnoses. FDA, itself, is a heavy user of social media to announce new approvals, broadcast safety warnings, and raise policy issues.

FDA's insistence that marketers convey only truthful and balanced information on products also ignores developments that permit outside parties on all sides to weigh in on company claims and present alternative positions. Increased transparency in research results and treatment recommendations, readily available through Internet websites and social media, speaks to the need for new regulatory approaches by FDA and much greater enforcement "discretion." PE

Sunshine gets murkier

Pharma marketers received an unpleasant surprise from the Obama administration just as everyone was leaving Washington for the July 4th holiday. As part of an extensive update to rules governing Medicare payments to physicians for 2015 is a proposal to kill an important provision in the Open Payments program that exempts reporting for payments to providers of certified continuing medical education (CME) programs. That policy recognized that marketers don't know which physicians attend a CME session or what the program costs per attendee.

The Centers for Medicare and Medicaid Services (CMS) justified the change as creating a "more consistent reporting requirement," without explaining how marketers should calculate the value of educational programs for physicians and teaching hospitals. The about-face evidently reflects pressure from patient advocates who consider industry-supported CME a backdoor way to influence prescribing and feared the reporting exemption would encourage more pharma funding of such programs. The change "will be a blow to doctor education and good patient care," says John Kamp of the Coalition for Healthcare Communication. It also dims prospects for marketers to gain any leeway from CMS on reporting the value of textbooks and journal reprints provided physicians.

EFPIA's 'Integrated Strategy': Out of the Frying Pan, Into the Fire?

Industry's grand vision for reshaping the life sciences in Europe may ultimately prove to be a lost cause.

It's difficult to open an email or an envelope in Brussels these days without yet another agenda falling out of it, carrying the promise of a new start. With a new European Parliament installed, a new European Commission president appointed and a new Commission on the way, and guarded optimism that the worst of the recession is over, this outpouring of recommendations and recipes is hardly surprising. Hope springs eternal in the human breast.

The trend is reflected in the medicines sector, with a plethora of manifestos and strategy proposals from industry, regulators, and campaigning organizations. One of the most grandiose is the self-styled "groundbreaking vision towards a life sciences strategy for Europe," launched in high summer by the European Federation of Pharmaceutical Industries and Associations.

This "landmark paper" claims to provide steps towards "an integrated strategy" for the sector in Europe. "With Europe now emerging from the crisis, there is an opportunity to improve health prospects of citizens, while promoting economic growth. As new European leaders and policymakers across the political spectrum begin work to improve Europe's future, EFPIA calls for greater political collaboration," the industry association specifies.

Into the fire

It is reasonable to expect that new European leaders and policymakers will begin work to improve Europe's future. But given the notorious absence of political collaboration in European health affairs, it is imprudent to assume that all that work will improve the situation for the drug industry. Given the fundamental nature of the challenges that Europe is facing, what emerges may actually be worse than the current imperfect context for medicines. EFPIA and other industry advocates of radical change run the risk of jumping out of the frying pan only to find themselves in the fire.

Given the fundamental nature of the challenges that Europe is facing, what emerges may actually be worse than the current imperfect context for medicines.

The essence of the EFPIA call to arms is a plea for "a new generation of partnerships and collaborative solutions to address the EU's growing health and competitiveness challenges." It urges changes in perception, more "thinking outside the box," better understanding of future demands and of the value of investment, and the "need to address the system as a whole" in order to create sustainable systems. Of course the central refrain of the vision is "ensuring that the pharmaceutical and life sciences industries—jewels in Europe's economy—continue to thrive." Consequently, much of the content is devoted to the need for the industry to be "highly competitive" and for "innovation-led growth." The merits of the industry—in terms of those familiar claims relating to products, jobs, exports, or research commitment—occupy much of this manifesto.

So, too, does the catalogue of the economic problems the industry faces. EFPIA warns against "making it difficult to obtain innovative medicines, increasing user charges, or delisting services from the benefits catalogue." It complains about the distortion that international reference pricing creates in the European market for medicines—going so far as to call for an urgent review of "the practical operation of the free movement of goods principle in medicines." It blames "the

Reflector is *Pharmaceutical Executive*'s correspondent in Brussels.

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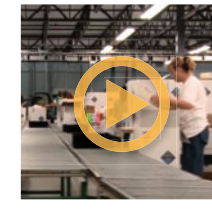

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current patchwork of valuation and assessment criteria across Europe" for being "arbitrary and politicized," and "leading to wasteful and costly duplication of effort." And it cautions that "arbitrary financial policies" are inhibiting investment in research.

Other voices clamoring

All this is fair enough. It is the role of a powerful sector association to extol the merits of the sector it represents, and argue the case for it to receive favorable treatment. But there are other voices clamoring to be heard, and other tendencies shaking the ground. The presumption that in all the prospective changes, "medicines have a key role to play," is one that the industry will naturally make. It is not, however, universally shared—and some of the alternative thinking comes from sources which are also powerful.

Not least among those voices is the European Union itself. Its years of ruminations about how to make health systems sustainable have still to lead to definite conclusions, but the trend is evident in the interim decisions it is now reaching. In early July, the EU Council gave legal force to a long series of recommendations that include telling Austria "to reinforce preventive healthcare, for which public spending is below EU average," Croatia that control over public expenditure on healthcare "is not achieved," and France that pharmaceutical spending is one area where "efficiency could be further improved." By contrast, Finland's "stronger focus on prevention" is "credible and relevant."

At a summit in April to discuss chronic disease, Tonio Borg, European commissioner for health, was unambiguous in urging greater emphasis on prevention rather than treatment: "Only a tiny fraction is spent on prevention," he said, asking "Does this proportion make sense, when many of the most prevalent chronic diseases are largely preventable?" And the EU health council in June championed health promotion and disease prevention as "key factors for better health," and recognized "the importance of investing in health promotion and disease prevention in improving the health of the population."

Selective myopia

There is a form of selective myopia in the vision of the EFPIA strategy. Its president, Christopher Viehbacher, who is also CEO of Sanofi, said as he outlined the strategy: "Only a significant improvement in health outcomes, supported by increased innovation, can keep healthcare expenditure under control." This is not strictly speaking true. It presupposes that the long-hallowed approach to healthcare expenditure remains intact: that is, seeking better and better medicines to treat more and more illnesses.

That presumption is at the very least questionable, and at worst, may be rendered invalid by a seismic shift in European health strategy that could profoundly modify the resource-allocation between treatment and prevention. If the allocation of resources was inverted (it is customarily estimated that less than 5% of current healthcare spending is devoted to prevention, with the rest devoted to treatment), it might also be possible to keep healthcare expenditure under control and improve health outcomes without the contribution from increased innovation that Viehbacher and EFPIA appear to be counting on. EFPIA quotes European Commission estimates that, without new approaches, average healthcare spending could rise from 7% to 9% of GDP by 2060, placing a strain on national finances. The conclusion EFPIA draws, that "halting and reversing the progression of chronic diseases is the best investment that health systems can make," may be correct—but it may also be true that the objective might be achieved by prevention rather than by treatment.

Against this background, EFPIA may not win the backing it expects for its priorities of "removal of inequalities to better patient benefits," support for "systems to speed access to medicines," or "the building of a thriving innovative life sciences sector." If the outcome of all this radical re-thinking and new partnerships is that much greater priority is given to prevention, EFPIA's ambitions for a "new European life sciences strategy that will benefit patients and society as a whole" may prove to be of no benefit whatever to the drug industry.

On the contrary, budgets for treatment might be subject to cuts much sharper than those that industry currently complains of, and the trends in spending might move resources irreversibly from treatment to prevention. Industry optimists would do well to remember the somber conclusion of that famous couplet about hope springing eternal in the human breast. It concludes tartly: "Man never is, but always to be, blest." PE

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Iya Khalil, PhD
Executive
Vice President
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For questions, contact Sara Barschdorf at sbarschdorf@advanstar.com

2014 Emerging Pharma Leaders

This year's class of 15 young executives is deeply of the moment, with assignments that include advancing therapies against hepatitis C, building new cell-based platforms in regenerative medicine, creating new businesses beyond a protected home base, restructuring the supply chain to accommodate a new generation of complex biologics, and transforming raw data into "news I can use" analytics. The emotional viscera that binds all is a commitment to the patient. Despite those legions of lawyers, accountants, bankers, and regulators—none of whom made the list this year—pharma remains at heart a people business.

And the Leaders Are…

(In alphabetical order)

Joerg Ahlgrimm, VP of Operations, Baxter BioScience

Jenise Doutsas, Global Strategic Lead, Fertility, Ferring Pharmaceuticals

Brian Goff, Global Franchise Head, Hemophilia, Baxter Healthcare

Ian Harris, Senior Director and Platform Leader, Cell Therapy, Janssen Research & Development

Susanne Heinzinger, Executive Director of Product Strategy and Alliance Management, Achillion Pharmaceuticals

Michael Injaychock, Director, Marketing Innovation, Research and Commercial Analytics, Eli Lilly & Co.

Sachin Jain, Chief Medical Information and Innovation Officer, Merck & Co.

Arnaud Lesegretain, Vice President, Global Brand Development , Eli Lilly & Co.

Tom McDonnell, Vice President, Product Strategy Lead–Neuroscience, Shire Pharmaceuticals

Jamey Millar, VP Oncology Business Unit Head, GlaxoSmithKline

António Portela, CEO, Bial

Alexsey Repik, Founder and Chairman of the Board, R-Pharm

Monica Tellado, VP, US commercial operations. Gilead Sciences

Hayden Thomas, VP, formulation development, Vertex Pharmaceuticals

Jocelyn Trokenheim, Head of Global Business Development Office and Strategy, Takeda Pharmaceuticals

Man on the Mark

Joerg Ahlgrimm, VP of Operations, Baxter BioScience

By the middle of 2015, global healthcare giant Baxter International Inc. is expected to officially split off its BioScience business, establishing the unit as an independent, innovation-focused biotechnology company. The new organization, which will maintain its industry-leading role in developing and manufacturing plasma-based proteins to treat hemophilia and other rare bleeding disorders, plans to support as many as 20 product launches in the next few years. Helming the operational component of these pursuits will be Joerg Ahlgrimm, the division's current vice president of operations and global supply chain. Ahlgrimm was appointed to the post in late 2013, when the BioScience unit combined its global operations structure and network under one leader. As the defining stage in the division's evolution nears, Ahlgrimm is developing an aggressive strategy to ensure that operations and supply chain management is optimized to support BioScience's future growth.

Amid Baxter's business transformation and the completion of final steps in separating its BioScience and Medical Products businesses, one could certainly assume Ahlgrimm's focus is on the big picture these days. After all, as head of operations, his organization supports more than $5.5 billion in sales and more than $2 billion in value of production. Ahlgrimm's belief is that operations, which he calls the "backbone" of a premiere biotech company, will be an important enabler for the new BioScience company in the years ahead. It seems clear that Ahlgrimm—who has held a number of leadership positions at Baxter since 2001—is intent on viewing the looming spinoff and all the accompanying expectations as his opportunity to apply the day-to-day management skills that have gotten him this far—on the precipice of leading the operations of a new global biopharmaceutical company. Ahlgrimm's forward-minded and collaborative leadership style has served as a driving force of change at Baxter, his colleagues contend.

Liquid advice

"Don't preach water and drink wine," says Ahlgrimm, whose operations arm encompasses more than 10,000 employees across facilities in the US, Europe, and in Singapore. "You have to demonstrate the expectations you have from the organization through your own behaviors."

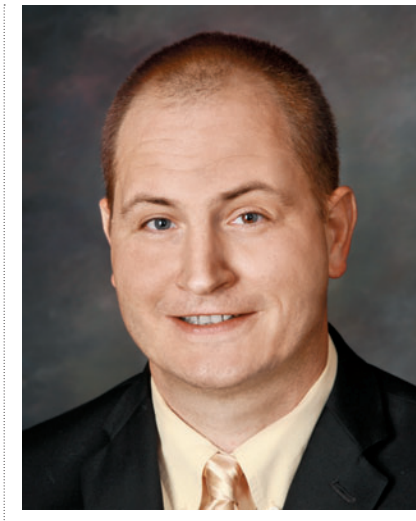
For Ahlgrimm, that philosophy adheres to the mantra: "never become complacent. Something can always be made better." He is quick to acknowledge that he had to learn that mindset himself early in his career. Ahlgrimm's first experience in the pharmaceutical industry was through an internship while enrolled at Ernst-Abbe-Fachhochschule Jena, an applied sciences university in Jena, Germany. He eventually joined Baxter in 2001 as supervisor of packaging scheduling in Vienna, Austria. Three years later, Ahlgrimm was promoted to director of supply chain for Baxter BioScience before being named vice president of global supply chain in 2008.

"At the beginning of my career, I was convinced that to play to my strengths was much more important than to consider my weaknesses," says Ahlgrimm, 41. "I received good constructive feedback in some of our talent review processes around my personal behaviors. This taught me to be much more open to feedback."

Ahlgrimm credits those experiences for adjusting his leadership style for the better. Ahlgrimm became a better listener and instead of focusing more on all the things he already did well, he took a hard look at opportunities for improvement.

"One big learning over time was this whole notion of building networks, establishing mentoring relationships, gaining feedback, and continuously working on becoming a better you," says Ahlgrimm.

Following that process has translated to tangible success for Ahlgrimm. During his career at Baxter, he has helped identify ways in which the company can expand its global supply chain to accommodate new products and growing global demand, while allowing enough flexibility to be a leader in local markets. In today's cost-constrained market, Ahlgrimm has been integral in finding ways to gain consistency and efficiency across Baxter's manufacturing facilities. In 2012, his team successfully negotiated and implemented a manufacturing services partnership with Sanquin Blood Supply Foundation, which provides Baxter up to 1.6 million liters of incremental plasma fractionation capacity annually to support global growth of plasma-derived treatments. The agreement not only helped meet a supply need for Baxter in a relatively short timeframe, but it also prevented the need to build another facility in the short-term.



Ahlgrimm's hope is that such efforts will help raise the bar in developing effective therapies for some of the most complex conditions in the world. Along with targeting hemophilia and other chronic bleeding disorders, Baxter produces plasma-based therapies to treat immune deficiencies, alpha 1-antitrypsin deficiency, and burns and shock. The company is also developing programs in new priority focus areas, including niche areas of oncology and biosimilars.

"The products we produce support patients who rely on them every day to manage very challenging, chronic, and often rare conditions," says Ahlgrimm. "For every patient who needs them today, we have an obligation to make sure they

have uninterrupted access to our quality products. My day-to-day job is also one of my biggest challenges—just making sure that our patient community gets a reliable supply. And in the long term, we are challenged to find ways for more people to get these valuable treatments. There are so many people in the world with rare diseases who don't receive any treatment, or who are not even diagnosed, even though a treatment or help for their condition is available. Our goal is to make sure that those people are being helped, too."

Ahlgrimm believes the limited treatment reach for patients with rare disorders is a combination of lack of awareness and funding or health economic issues in certain regions. Baxter's goal of 20 product launches in the next few years, the company hopes, will make a difference for patients around the world—provided respective clinical trial programs are successful.

"From the operations point of view, we're getting involved very early in these projects," says Ahlgrimm. "The commercial success of these launches, especially in a biopharmaceutical company, is very much dependent on how strong operations is able to keep up with demand, set up the large-scale manufacturing process to execute those launches from a day-to-day management point of view, and then successfully deliver these new treatments to patients."

Though certainly ambitious, Baxter feels the 20-product goal is an achievable plan, Ahlgrimm says. He believes, from an operations standpoint, that the recent restructuring of the BioScience business has helped establish the organizational foundation to enable successful product launches over the next few years. In fostering internal alignment around these efforts, Ahlgrimm is inspiring BioScience colleagues about the importance of the operations strategy through global internal town hall meetings, recorded video messages, and presentations. He notes that industry trends continue to reflect a shift from drugmakers being very much internally focused to now tapping more heavily into external networks to support the many diverse aspects of their business. This has resulted in increased activity around industry consolidation, asset transfers, and spinoffs, Ahlgrimm acknowledges. He points to the importance of companies "sharpening their profile" by removing silos in supply chain manufacturing, purchasing, R&D, and other specialty areas—and integrating them into a more end-to-end-focused organization.

"When you look at the microeconomic environment, the ability of an organization to change faster than the market conditions and the competition will determine success going forward," says Ahlgrimm. "Demonstrating change, being a change agent yourself, and then helping your organization to go through change and accept change as a normal part of how you run your business is, in my eyes, critical for our future success."

— Michael Christel

Thriving Through Change

Jenise Doutsas, Global Strategic Lead, Fertility, Ferring Pharmaceuticals

In the late 1990s, Jenise Doutsas, a psychology major with a master's degree in occupational therapy, was working at a hospital in Detroit when she found she was about to be laid off, a result of institutional changes at the hospital stemming from the Clinton Administration's tranche of healthcare reforms. So she set about thinking about what she else could do that was "both healthcare-related and fulfilling." At the hospital she would see pharmaceutical reps coming and going and thought, "I could do that."

She applied to Organon Pharmaceuticals for a sales job. Organon noted her lack of a traditional sales background but Doutsas convinced them she had been "selling" every day: selling to patients the importance of doing their exercises, selling to physicians the need for an occupational therapy consult before a patient was discharged. She got the job.

From there her upward trajectory has been steady and swift. Organon promoted her to district manager and she moved from Detroit to Virginia, where, aligned by territory rather than therapeutic area, she was given responsibility for managing the reps for women's health, pain, and anesthesiology. She then headed for Chicago, managing the fertility business for 12 states "at a much bigger scale, geography, and dollar volume." But as she took on this role, Organon announced they were going public; "literally two days later," says Doutsas, "they were acquired by Schering-Plough."

But her rise continued apace; at Schering she became an executive district sales manager for the company's fertility products. Two years later, another merger meant another paymaster, Merck & Co., where she moved up to associate director of global marketing, working with the *Januvia* team.

Doutsas is proud of how she not only survived but thrived during those major company upheavals. "I think what they taught me is that there really isn't anything constant," she says. "You wonder if you're going to like working for a new organization, but you have to be agile. If you believe in yourself and what you're working toward, you can make it through the transitions."

It helped, she says, that she had outstanding colleagues. "Organon had a family feel and at Merck I was surrounded by really talented people, such as Arpa Garay (executive director and US market leader, diabetes, at Merck), who is by far the best leader I've worked with. She taught me that strategy is really about picking one or two things you want to do and doing them big. She challenged me to think differently and push myself into areas where I might initially be uncomfortable."

Doutsas also had very clear ideas about her goals and aspirations and has not been afraid to communicate them—"If you're not your own biggest advocate, you might find yourself stuck where you don't want to be," she explains. But perhaps her biggest strength has been her flexibility, her willingness to face up to hard choices and those major upheavals. "I've taken risks and made big moves," says Doutsas. "To do that demonstrates commitment and the ability to adapt to new environments."

She is currently demonstrating that ability again. As *Pharm Exec* went to press, Doutsas was in the midst of embarking on the biggest change of her life and career so far, leaving Merck —and the United States—to move to Europe to become global strategic lead for fertility at Ferring Pharmaceuticals, a Swiss-based, mid-size biopharmaceutical company.

Fertility is a therapeutic area she already knows well, of course, but, as she explains, "with a big move like this you have to do something you can leverage, something you can contribute straight away." For Doutsas, the key draw is the opportunity to experience a global marketing position outside the US.

Heading abroad is a natural step for someone so well versed in relocating from state to state. And this is just the start of a new phase in her nomadic career. After Europe, she says, "there's China, Brazil, all those amazing places. I see myself being engaged with the emerging markets at some point."

— Julian Upton

The Healing Mission

Brian Goff, Global Franchise Head, Hemophilia, Baxter Healthcare

For Brian Goff, a successful career can be measured by a single metric—the steady, uninterrupted cycle of progress in human health. With more than 20 years in the industry under his belt, Goff can cite numerous examples of how new medicines have transformed adversity into advantage, reducing the burden of disease for patients. The 45-year-old therapeutic franchise leader at Baxter likes to show audiences a video short of two boys at play and then ask if they recognize one of them has hemophilia. "My point is you cannot tell the difference. In a stunning reversal from the disability and premature death that plagued victims in previous generations, that young boy with hemophilia can now be treated with medicines that allow him the right to a normal life."

Goff was exposed to the industry early on, through a family neighbor who happened to be a sales rep. "Typically, he talked a lot about his work in educating physicians and from that I learned about the direct relationship between medicines and controlling disease." Immediately after earning an undergraduate degree from Skidmore College, Goff was recruited by J&J, where he was offered an internal audit position. "I wanted a more outward facing role that exposed me to the broader business, which led me to sales and marketing." Goff spent 14 years at J&J in a series of brand building assignments, then in 2005 joined Novartis at its Basel HQ as a global marketing director. After his first year he moved to the cardiovascular franchise to lead global marketing in the antihypertensive space. Success here led to his appointment in 2010 as VP in charge of Novartis US Primary Care Business Unit, where Goff led work on new patient care models to drive the company's therapies for hypertension, Alzheimer's disease, and osteoporosis.

In 2012, Goff was approached by Baxter's BioScience division for a new opportunity as head of the global hemophilia franchise, a big selling, high-profile segment where the company had a strong market advantage due to its breakthrough work on the biology of blood disease. "The position attracted me because it covered an area I was less familiar with—difficult, hard to treat, and often rare diseases with a high level of unmet medical need. Another thing I liked was Baxter's connection to patients." As a pioneer with 60 years of innovations in this area, Baxter had extensive patient knowledge to draw on as it advanced the state of care for hemophilia, from the early blood transfusions to the safer and more patient-friendly clotting protections provided through recombinant therapy.

Looking back, Goff tells *Pharm Exec* that culture counts. Each of the three pharma majors he has worked for provided valuable insights that broadened his career horizon. "At J&J, I was tutored in the credo that ethical behavior toward the

patient is central to being a leader. Novartis was strong on operational discipline, including the expectation that performance could be measured. Here at Baxter, I see a hybrid of these two, with a more entrepreneurial focus as well as the desire to align to the patient through targeted, personalized medicine. So I am glad my career has unfolded the way it has."

Goff decided the first thing he needed was a vision statement to help drive and execute the group's strategy. A key support for this work was Dr. Bruce Ewenstein, a Harvard Medical School hematologist and also Baxter's VP for clinical strategy on hemophilia. Ewenstein had long advocated a research agenda he chose to summarize in the succinct declarative "bleed free, one patient at a time." Goff decided to make this concept the core of the vision, but to render it in a bit larger type: as "a bleed free world."

Live, not scripted

Every key function in the company was enlisted to help draft the vision, the centerpiece of which is a commitment by Baxter to raise the standard of care for all patients with a blood disorder. "By standard of care, we mean enhancing all aspects of patient care—with a particular focus on efficacy —to help every patient strive to be bleed free. To the patient, every single bleed matters, so it must matter to us as well." Goff also wanted to make this pledge work globally, from two dimensions: geographically, making no distinction between Baxter's commitments to patients in emerging and developing countries as well as the mature markets; and by disease area, including not just hemophilia but a host of much rarer human blood disorders like Von Willebrand's disease, all marked by the absence of essential protein factors that promote normal clotting. "The vision declares that Baxter intends to be active in the rare disease space, customizing treatments and services at the level of personalized medicine."

The vision is a living document, integrated with the group's annual operating plan and used as a key performance benchmarking tool. "It's a calling, not a statement. It aligns with all the decision points taken around the business," Goff says. In fact, the vision contributed to success with the project that Goff is particularly proud of: a partnership Baxter negotiated with Hemobras, a Brazilian parastatal enterprise supervised by the Ministry of Health, to provide Baxter's advanced recombinant protein blood clotting therapy for the more than 10,000 hemophilia A patients in Brazil who lack it. The pact, signed in November 2012, grants Baxter exclusive rights to supply the drug to Hemobras for use

by Brazilian patients over a 10-year period, after which Baxter will transfer the production technology required to manufacture this complex biologic to Hemobras, in return for royalty payments that will continue for another decade.

"The arrangement is a win for everyone involved. It amounts to a new business model, in which Brazil eventually becomes self-sufficient in an essential medicine; Baxter benefits from a stable market, with a guaranteed revenue stream; and patients get assured access to the product." According to Hemobras, 30% of eligible patients have been converted to Baxter therapy in the first year alone, a stark contrast to the decades it took to provide treatment cover for this high-cost, high maintenance population in the US. "Our key learning from this project is how difficult it can be to get all three main parts—infrastructure, education, and access—to fit together, in a way that conforms to local practice patterns that can be very different than we have here."

On a more basic level, Goff believes the most important aspect of being a leader is developing new talent. That requires, today, a strong commitment to diversity, evidenced by Goff's work to advance women at Baxter and his recognition by the Healthcare Businesswomen's Association as recipient of its 2014 Honorable Mentor award. "The industry is changing so fast. What keeps me up at night is worrying that our talent bench might be lagging or too thin—I actually believe that, from a long-term investment point of view, the people pipeline outweighs the product pipeline." For the next generation of managers, Goff offers a single insight, drawn from experience: take bets on yourself; expose your inventory of skills and assets to risk; and don't let the learning curve go flat. "If there is an assignment that scares you more than others, take that one. And if you are a people manager, give the best of your people new assignments before they are ready."

—William Looney

Road to Ex-cell-ence

Ian Harris, Senior Director and Platform Leader, Cell Therapy, Janssen Research & Development

When he left school, Ian Harris wanted a career in brewing. He enrolled on a biochemistry degree with the intention of going on to study a master's in brewing at Heriot-Watt University in Edinburgh, UK. But after spending, as part of his first degree, a year in the pharmaceutical industry developing *in vitro* disease models for dermatology and oncology at the old GlaxoSmithKline site in Greenford, brewing fell off his agenda. Harris now wanted a career translating science into therapies.

Following a PhD in Biochemistry and Molecular Biology at the University of Leeds, UK, and a postdoctoral fellowship at the University of California, Harris became a group leader at Beiersdorf Skin Research Center in Hamburg, Germany. He joined Johnson & Johnson in 2000, becoming principal research scientist for its subsidiary, Janssen, in 2005. Today, as senior director and platform Leader for Janssen Cell Therapy, Harris leads a group responsible for manufacturing clinical supplies of cell products and determining mechanism of action.

Harris's work at Janssen on the cell-based therapy *CNTO 2476* has gained international renown. *CNTO 2476* has the potential to be the first marketed allogeneic product to improve vision loss in individuals with dry age-related macular degeneration (AMD) with geographic atrophy, a condition for which there is currently no treatment. As one of the key inventors of the platform used for the development of the therapy, Harris was responsible for the preclinical pharmacology, mechanism of action studies, cell manufacturing process development, and product characterization.

Such work, of course, can't be done alone. "You can achieve more through colleagues than you can on your own," says Harris. He's striven to create meaningful ways to engage his team in the work surrounding *CNTO 2476*, drawn from Janssen's "start-up culture driven to create value according to milestones." He entrusts ownership of projects to each of his team members, mentoring them on the tools needed to meet their goals. He has passed on the advice he has taken to heart during his career: "Start with the end in mind. Be efficient. Question everything. Do what you believe in. And if things are not working, it is up to you to fix it." The result has been to unite his group with a shared vision: to

embrace change and be open to inventive technologies and platforms.

Bringing a novel therapeutic platform into a mature company like J&J, which can be predisposed to standardized protocol and resources, can have its challenges. But Harris's command of open, effective communication helped him secure the necessary investment and support from leadership. He helped to devise and execute a two-day summit for 130 J&J attendees, including the company's chief biotechnology officer, chief medical officer, and worldwide chairman of

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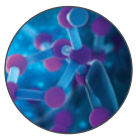

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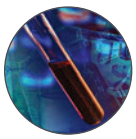

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pharmaceuticals, to foster team building while informing on all aspects of the product development, supply chain and marketing of *CNTO 2476*. The feedback from the event was overwhelmingly positive. His influence on the J&J manufacturing supply chain saw him win the Worldwide Supply Chain Collaboration Excellence Award in 2008.

Harris's reach extends far beyond J&J. As an active member of the Alliance for Regenerative Medicine (ARM) Technology Committee and the Commercialization Committee of the International Society for Cellular Therapy (ISCT), Harris has an influence on the regulatory environment for cell-based therapeutics and regenerative medicine, participating in conversations with global health authorities about how products like *CNTO 2476* can be evaluated and brought to market. His recent conference and meeting presentations have looked at approaches to the regulation of the importation of tissues and cells; as keynote speaker at the International Alliance for Biologics Standardization joint workshop he discussed viewpoints from the US industry regarding first-in-human and marketing authorization. In essence, says a colleague, "he's assisting in the identification and establishment of a whole new class of therapies."

Having proved himself capable of the career goal he set when he caught the pharma bug at university—that is, translating innovative science into meaningful therapies for patients—Harris is now aiming to broaden his skills and experiences "to enable a general manager role." His Janssen colleague, Rob Willenbucher, has no doubt that Harris will gain further strength and recognition as a leader and pioneer in regenerative medicine. "Over the next decade I expect his efforts to lead to the further development, approval, and success of treatments like *CNTO 2476*," he says. "He will truly have a hand in shaping the future of this industry."

Brewing's loss, it seems, has very much been cell therapy's gain.

— Julian Upton

A 'Rare' Find

Susanne Heinzinger, Executive Director of Product Strategy and Alliance Management, Achillion Pharmaceuticals

To say that Susanne Heinzinger's career trajectory has taken her from one spectrum of the healthcare arena to another may be an understatement. Before entering the pharmaceutical industry as a sales person, Heinzinger, who earned a Bachelor of Business Administration degree in accounting, worked as an auditor; she picked the job of auditing hospitals and home healthcare companies, mainly because she had always had an interest in the healthcare industry.

"But after I was exposed to the sales representatives coming in and seeing how they interacted with the providers and the value that they provided the doctors and how the doctors really listened to what they had to say, I thought maybe I should have a career change," says Heinzinger.

A reference from a friend in the industry helped Heinzinger land a job as a pharma sales rep, and the career transition was underway; and not just any transition, but a launching point to the influential and all-encompassing roles that she now seemed destined for. Through the years, Heinzinger has led marketing strategies at a big pharma subsidiary and, more recently, with two specialty biotech companies, including directing the successful marketing launch of the C1 esterase inhibitor, *Cinryze*, approved in 2008 for hereditary angioedema (HAE), a rare blood disorder. Today, Heinzinger is executive director of product strategy and alliance management at Achillion Pharmaceuticals, where she leads the company's global product positioning and launch efforts for its hepatitis C virus pipeline built around developing commercially competitive regimens that address many patient types while offering high cure rates and favorable safety profiles. A career focus on rare disease and new ways to fight infections with still-significant unmet medical need is indeed a long way from the days of audit trails and financial cross-checks.

"It's funny, because a lot of people thought I was crazy at the time," says Heinzinger. "People that I knew in accounting kind of questioned, 'What are you doing? Are you sure you're making the right move?' I have to say it's one of the best career choices I've made, getting into the pharmaceutical industry."

A choice, according to Heinzinger, that has deliberately attracted her to smaller, startup companies in the life sciences space. Such motivation, she says, stemmed from a desire to view and contribute from the inside to many different facets of the biopharmaceutical business. And that versatility, combined with the perspective of working at R&D companies, where risk and failure are natural occurrences, has proven invaluable in not just helping Heinzinger cement a diverse

industry background, but preparing her for the changing healthcare environment. From 2002 to 2005, Heinzinger was a senior regional manager at OraPharma Inc., a former subsidiary of Johnson & Johnson, which was acquired by Valeant Pharmaceuticals International in 2012. While at OraPharma, Heinzinger was promoted to a newly created position of director, reimbursement. There, she helped spearhead a new approach to reimbursement and directed its implementation by the sales team. The effort was a key driver of product growth at OraPharma, an oral care company, and its eventual acquisition. Heinzinger joined Lev Pharmaceuticals, the developer of *Cinryze*, in 2006 as director of marketing (Lev was acquired by ViroPharma in 2008). She led the marketing efforts around *Cinryze* from Phase II through year-one launch. Today, Cinryze is the only FDA-approved C1 esterase inhibitor for routine prevention of HAE. HAE, which is triggered by deficiencies in C1 inhibitor proteins, is characterized by unpredictable and recurrent attacks of inflammation affecting the hands, feet, face, abdomen, urogenital tract, and larynx. With the tendency of throat attacks, suffocation resulting from HAE is a real concern.

In early 2010, Heinzinger was hired at Achillion, where she directs efforts around commercial strategy and planning, market assessments, reimbursement, patient access, valuations and forecasting, and pricing and business development support. Her alliance management role involves overseeing drug licenses Achillion has with companies in China and elsewhere. It is in the areas of patient access and engagement, however, where Heinzinger has distinguished herself from other young executives in the industry. Her extensive relationships with patient advocacy groups—making sure the patient perspective is represented in product development and commercialization plans—has been integral to *Cinryze* and the current HCV portfolio at Achillion. For example, when other drug developers targeting HAE were pursuing acute indications, Heinzinger, through her close interaction with the patient advocacy community, uncovered that patients were really interested in a prophylaxis indication. This enabled the focus of the commercial plan to be directed towards this specific patient need. *Cinryze* currently owns more than an 80% share of the HAE-treatment market.

"I interacted with the patient advocacy groups before the drug was available and I really understood the burden of hereditary angioedema on the patient and on many of the family members and friends," says Heinzinger. "I also interacted with them after *Cinryze* was launched."

Patient portfolio

Heinzinger notes that with HAE, a genetic disorder that only affects about 1 in 10,000 to 1 in 50,000 people worldwide, it was easier to get to know those afflicted more intimately through advocacy groups and setting up advisory boards. "I remember talking to a mother who said, 'My son has HAE and I know exactly how long it takes me to get from my house to the school to pick him up and take him to the hospital if he has an attack," says Heinzinger. "That was the unpredictable nature of it. There were patients that said they were afraid to fly on airplanes because what if they had an attack on an airplane? Once *Cinryze* was available, patients would tell me that they can live a more normal life."

Though the market for HCV is considerably larger (the virus infects 170 million to 200 million people globally), Heinzinger was drawn to Achillion with a similar motivation: to work in a disease area with significant unmet need. While newer and more responsive treatments for HCV have emerged in recent years, many are still used in combination with interferon, the traditional standard of care known for its severe side effects. Achillion is currently developing multiple direct-acting antiviral agents for HCV, with the hopes of a once-daily oral regimen with shorter treatment durations.

"Going from a small, rare disease to a large disease state, it was definitely different; but there's still a lot of similarities in the two markets," says Heinzinger.

Working for a company involved in the suddenly burgeoning HCV treatment space has given Heinzinger a unique perspective on the changing healthcare delivery landscape. She recalls how when she started in the industry, it was healthcare providers and physicians that wielded the biggest influence in therapeutic prescribing decisions. That has shifted to the payer community today, she says, noting, as evidence, the extensive market research her team conducts on what drives prescribing behavior.

Heinzinger believes that the shifting influence of stakeholders in the healthcare process, combined with advancing R&D paradigms in a number of disease settings, reinforces the importance of leadership groups in pharma that foster adaptability. Particularly in the world of startups and specialty biotechs, nimble workflow and quick thinking is a strategic imperative for R&D and brand teams alike; they could be focused on one strategy one day and a very different one the next.

"Things change very quickly at our company, especially in hepatitis C," says Heinzinger. "The development landscape is moving at such a fast pace. Almost every time we go to a medical conference, there's new data that comes out and we adjust our strategy accordingly. Tracking the competitive landscape and adapting your commercial focus to adjust for the changing environment is essential to launch and commercial planning."

— Michael Christel

The Culture Connection

Michael Injaychock, Director, Marketing Innovation, Research and Commercial Analytics, Eli Lilly & Co.

Michael Injaychock owes his unusual surname to the butchered efforts of a US immigration official to interpret the handwritten scrip on the landing card of his great grandfather from Poland. It's a small but ironic footnote to the blazing path the 36-year-old marketing executive at Lilly has made in delivering purposeful multichannel market experiences, removing much of the mystery from market research through high-tech data analytics that accurately define and decode successful customer engagements. Even more intriguing: the focus for his efforts is in Japan, a country whose approach to business has always been more relationship-driven than analytical.

Injaychock joined Eli Lilly in 2007 after five years in a Washington-based financial services consulting role and a subsequent MBA from the University of North Carolina. Course work there as well as a stiff self-evaluation of his former job led Injaychock to conclude his future lay in a post that carried a larger purpose. "I captured my ideal position in three words: marketing that matters."

That desire was reinforced by an early personal experience in the power of modern medicine. "Just after I finished my undergraduate course at the College of William and Mary, my grandfather suffered a severe stroke. The right drug administered at the right time saved his life. My grandfather lived another ten quality years, long enough for me to name my daughter after my grandmother. That real-life testimonial about the value of medicines is better than any marketing message, which is what attracted me to a career in pharmaceuticals."

Injaychock interviewed with a number of drugmakers but chose Lilly due to the company's emphasis on the long-term opportunities for leadership. "I liked that my discussions with Lilly

focused on personal and professional growth, not just the job." He quickly advanced to a brand leader role in the diabetes franchise at HQ in Indianapolis, where he helped rejuvenate the aging genetically engineered insulin product, *Humulin*. While few saw opportunities in the business, he set out to re-launch the franchise, using a tailored pricing strategy and reserving his limited marketing investments around targeted niche segments to improve share of voice in areas where the product still made a difference for endocrinologists and patients.

His work caught the eye of Lilly's chief marketing officer, who was looking for a candidate to more deeply understand relationships with customers in Japan, the company's second largest market outside the US, through modern, insights-based market research. Among other things, Lilly had an active portfolio of relatively new products in Japan but little was known about how the changing role of the traditionally all-important physician was affecting the product life cycle—were Lilly's messages about its medicines actually getting through? Could new technology platforms make a difference as the local customer base evolved? A stronger hand on the market research function would go far in helping affiliate management answer these basic questions.

Venturing east

Injaychock thought for a while before taking the job, largely because he had no experience working outside HQ and he and his wife had a six-month old child at home. He acted because of the opportunity it provided to mobilize an entire function across all the disease areas Lilly serves and test new ideas in a local business that was ripe for change. "The best work in market research involves thinking ahead, not just reinforcing decisions of the brand teams. We wanted to unlock the complementary power of qualitative and quantitative customer insights. By understanding customer motivations and unlocking the vast amounts of data that was being released through advances in IT, we could tap into a truly innovative approach to marketing—one that informs our messaging and service packages to help differentiate against the competition and ensure our medicines reach the right patient every time they are needed."

After arriving in Japan, Injaychock quickly realized his mandate necessitated a transformation of market research from a support function to a strategic driver of change. To do that, he set a goal to make market research the "go-to source" for innovation within the organization. "I felt that a mission focused on finding innovative ways to track and shape the customer experience, with metrics that allow the commercial organization to benchmark progress against sales targets, would make market research a full partner to the brand teams. I wanted my group to be recognized as an amazing service leader, starting from the premise if you can measure it, you can improve the experience of the customer: to plan, do, check and act."

Concepts like leading and partnering demanded a sea change in attitudes within the Japanese organization to-

ward market research. To address that, Injaychock introduced a new vision concept, the Shield of Market Research, which repositioned the function as in-house champion of the customer, relying on hard data analytics to inform product teams when they are not delivering what the customer needs —and to demand a corrective change in course, when required. "It fostered a cultural change in how we worked, from introspection around decisions already made, to outward, forward-looking engagement."

Changing minds through innovation

After witnessing the successful transformation of the Market Research function, Injaychock was offered an extension on his assignment along with expanded responsibilities, with a new mission to leverage his 20 member-team to deliver innovative experiences across key customer touch points, including the Web and "peer to peer" detailing. He also got the nod to create a new Commercial Analytics team. In the Web space, by combining consistently market research evaluations and analytics, his team was able to quantify that interactive product content was more productive: physicians needed to view this content at times most convenient to their own schedules, and that these online engagements actually enhanced, rather than limited, the effectiveness of later live contacts with Lilly sales representatives.

In addition, Injaychock negotiated to extend and enhance an e-channel alliance with a local network producer, M3 Global, which gives Lilly Japan the opportunity to leverage the network's local digital technology expertise to test different ways to reach out to various segments of the healthcare community. This proved a benefit to both companies. Also, under Injaychock's lead, Lilly has championed expanded group detailing programming that keep Lilly in front of the medical profession as the door closes on traditional means of engagement through the deployment of legions of individual sales staff. Such initiatives enable Lilly Japan to make more highly differentiated channel investments through the insights derived from advanced customer analytics. These have led to a significant improvement in consistency and satisfaction indicators based on the metrics of customer feedback and market performance.

Injaychock's efforts earned him the Lilly Marketer of the Year award at the end of his first year at the affiliate HQ in Kobe. The award highlighted his skill in "turning the complex into simple, understandable solutions."

"I regard my three years in Japan as my biggest accomplishment because it made me appreciate diversity and the importance of a connected, global mindset," Injaychock told *Pharm Exec*. "I also gained an appreciation for diversity in both opinion and background. I arrived in Kobe as a minority, an experience I did not have back home. I am a contrarian by nature, which can sometimes make people uncomfortable. But being in Japan, where I had such little cultural understanding, it made me aware that when I am the only one in the room with a different opinion, I need to do a self-check and consider I might be wrong—and actually there might be a good reason for being wrong. In other words, success in Japan meant I had to work harder and to be more selective in bringing people along with me, making sure my influence could be felt when it really mattered. It's a trait I learned here that I expect that will carry residual benefits further along in my career."

Three points to ponder

Injaychock anticipates returning to Indianapolis later this year in a senior marketing role, perhaps with the assignment to build a better customer experience around Lilly products. Projecting his own experience to others, what skills or talents does Injaychock think are important for future success in the biopharmaceutical space? He points to three. First is what Injaychock describes as "learning agility," which involves discerning what is key and strategic about any situation despite having limited information. Being able to "see around the corners" of those information gaps is critical. Second is flexibility in decision-making, because today there are few hard and fast rules that will guide a particular course of action. Third is a determination to execute—getting it done. "This is an industry riddled with disruptions, from new technologies to the endless restructurings among the stakeholders that drive our business. So there are always going to be barriers to realizing your plan; don't turn this reality into an excuse to not get to the goal."

— *William Looney*

Information Innovator

Sachin Jain, Chief Medical Information and Innovation Officer, Merck & Co.

For Sachin H. Jain, health is a family vocation, with roots that extend back to his grandfather's philanthropic work to provide basic medical services to India's rural poor. Jain's father is an academic physician who for many years specialized in pain management at New York's Memorial Sloan-Kettering Cancer Center and who has devoted much of his time raising awareness of this critical patient care issue among health practitioners in India and other countries. With dual degrees from the Harvard Medical and Business schools, Jain, at age 33, has chosen his own distinctive career path by focusing on that larger policy world beyond the clinic, where advanced data analytics and systems management can be leveraged to improve the quality of the patient experience in confronting disease. "Healing is an art, but today the

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real creativity lies in the hard evidence behind it," Jain says.

Jain's commitment to digital innovation as a driver of health improvement dates back to an undergraduate class at Harvard taught by quality expert Don Berwick. "I joined the class by accident," relates Jain, "but I quickly realized data-driven quality measurement was becoming a driver in healthcare operations as well as the centerpiece of efforts to reform the US system. That's precisely where I wanted to be." Jain developed a close relationship with Berwick, who he considers a mentor along with Commonwealth Fund President David Blumenthal, who served as the Obama Administration's first National Health Information Technology Coordinator (NHITC), and Harvard Business School Professor Michael Porter.

Half-way through Jain's medical residency at Boston's Brigham and Women's Hospital, Blumenthal offered him a position as his Special Assistant to help support the phase-in of the $19 billion Electronic Health Record (EHR) meaningful use incentive program covering physician practices and hospitals. After a stint with Blumenthal, Jain was approached by Berwick, who by then had been appointed by Obama as Administrator of the Center for Medicare and Medicaid Services (CMS) at the Department of Health of Human Services. "Berwick was aware of my interest in new payment models for health, so he offered me the chance to help launch the new CMS Center for Medicare and Medicaid Innovation (CMMI), established through the Affordable Care Act (ACT) to initiate pilot projects testing alternatives to traditional fee for service."

Jain spent a year with Berwick, serving as a Senior Advisor and, briefly, as CMMI's Acting Deputy Director for Policy and Programs, where he helped to draft the unit's strategic plan and recruited staff for hands-on operational roles in approving and executing new value-based payment models, including accountable care organizations (ACOs)

and bundled payments; these also gave Jain exposure to the politics and policy around healthcare at the state level, since many of the proposals came from there. Jain tells *Pharm Exec* that helping to build this critically important unit from scratch stands as one of his most important career accomplishments, noting that the CMMI is responsible for stretching the boundaries of the ACA beyond what was feasible politically. "I am most proud of the talented team we hired because these people are the best guarantor that the reform law will be applied in ways that make a difference in patients' lives."

Move across healthcare

Jain left Washington to finish his medical residency at the Brigham and Women's Hospital and to co-found the Elsevier journal, *Health Care: The Journal of Delivery Science and Innovation*, of which he is co-editor-in-chief. Jain's work in government required extensive outreach to stakeholders in the private sector, including, most importantly, the patient. Jain still sees patients regularly at the VA hospital in Boston and is a member of the teaching faculty at Harvard Medical School. These exposures led to conversations on digital health with Merck's Chief Medical Officer, Michael Rosenblatt, M.D. Rosenblatt believed that mastery of the digital information space is an essential part of doing business for any pharmaceutical company seeking to broaden its offerings beyond the pill to a more integrated, service-oriented model shaped by hard evidence around outcomes. "What he did was offer me the opportunity to create new strategies within Merck, putting in practice the ideas that came out of my government service and patient care training and experience," Jain told *Pharm Exec*.

Soon after, Jain accepted the new position as Chief Medical Information and Innovation Officer, responsible for leading and executing on new strategies to leverage digital information to draw new insights about human health, and apply them to future innovations. Sachin began by recruiting additional talent from diverse areas like health information technology, logistics, clinical medicine, health services research, market access, and investment banking. His strategy has been two-pronged: building information-based collaborations with leading global payers, provider organizations, and delivery systems to derive relevant insights into human health; and working with health information technology organizations to co-develop innovative solutions that will improve patient outcomes. Specific areas of focus include appropriate use of medicines, improving adherence rates, promoting health literacy, avoiding medical errors, and advancing clinical decision supports to produce better health outcomes.

Bridging the digital divide

The team has launched more than a dozen innovative projects involving collaborations with outside companies whose strengths and data resources complement Merck's own. Highlights include projects to empower patients to achieve better outcomes from their medical care and their adherence to their medicines. One is with Walgreens and researchers at Northwestern University and the Alliance of Chicago to develop and digitize a patient-friendly and accessible standard for the writing of prescriptions that conforms to drug label requirements. Another is a first-of-its-kind collaboration with a major ACO, Heritage Provider Network, to support high-tech solutions to engage patients and improve their adherence to care plans for chronic diseases.

Other projects leverage well-established real-world databases to better understand diseases, patient perceptions and behaviors, use of medicines, and medical outcomes. These include collaborations with the Regenstrief Institute, a major health information exchange with 13 million unique patient histories, as well as Maccabi Healthcare Services, a major health system in Israel.

What binds these initiatives is the desire to demonstrate how digital information can be applied productively to solve practical challenges facing the health system. Says Jain, "It's an opportunity to work this theme across all the silo platforms in health. In doing so, we are making the larger point that efficiency in healthcare depends on a stronger societal commitment to the interoperability of standards on electronic health information, a commitment that in many quarters is lacking at present."

Looking ahead, Jain is optimistic that the promise of a digitized health world will be realized. "I see a real convergence of thinking in healthcare. Everyone is now talking the same language, about the importance of decisions that improve outcomes; the issue is how best to get to that destination together."

— William Looney

Launch Leader

Arnaud Lesegretain, VP and Global Brand Development Leader, Lilly

Arnaud Lesegretain is a chart-busting marketer who works on the cutting edge of some very novel science. As a VP for global product brand development at Eli Lilly and Co., Lesegretain is pioneering the transition to a new generation of innovative cancer therapies. In little more than a year, the 44-year-old brand leader and his 30-member cross-functional commercial launch team worked with numerous medical, regulatory, and manufacturing colleagues to overcome hurdles to secure the recent approval and launch of one of Lilly's most promising new biologic drugs—*Cyramza (ramucirumab)*. In April, *Cyramza* was approved by the FDA for use in certain patients with advanced recurrent stomach cancer.

The fast timing required real focus, an attribute Lesegretain retains from his introduction to the industry in 1994, when, after a brief six months as a consultant for Arthur Andersen, he joined the diagnostics firm bioMerieux, serving six years in a variety of finance roles in his native France as well as in the US and the UK. "After spending some time in finance, I wanted to try something more customer-facing, so I left bioMerieux to obtain an MBA at Harvard. There, I decided I wanted to be a leader in global pharmaceuticals and set my sights on joining a leading company that was dedicated to not only discovering life-changing medicines but also developing its people."

Lesegretain says this is what led him to Lilly, whose recruiters emphasized long-term career development rather than filling the day's job titles. "Lilly was looking for people interested in spending the time necessary to grow in a job and eventually serve as a leader. It was a mission that matched my motto, so I accepted a position in the French affiliate and started as a sales representative. That was 12 years ago; I've taken on more responsibility over time in different roles and increased my scope from local to global."

True to Lilly's word, Lesegretain's work has exposed him to major brand areas of opportunity, leading teams spanning three key therapeutic areas. The first was in neuroscience, where he accelerated sales in France for *Zyprexa* and prepped for the *Cymbalta* launch, followed by a stint in a global payer role based in Indianapolis, then three years in Germany leading a diabetes team of 280. That led to his current U.S.-based global assignment in the highly competitive oncology segment, where Lilly researchers are seeking to break new ground in the complex science of monoclonal antibodies and angiogenesis inhibitors, among others.

Lesegretain notes how each assignment bolstered his functional skills. "France was 'marketing 101' for me, learning how all key functions interplayed at an affiliate level. In my global payer role, I really built more in-depth understanding of the payer needs in major markets. In Germany, I tested my general management skills by leading a large organization in a key strategic market for Lilly and role modeling putting the customer and patient at the center of everything we do. In my current role, in oncology, I oversee key brand activities for the *Cyramza* program, including brand strategy, market research, launch preparation, market access, lifecycle management, and public relations. The big challenge in oncology is keeping pace with the science, which is very complex and fast moving. Cancer is not one disease but rather more than 200 diseases, all of which have different causes and treatments. Even within one tumor type, such as lung cancer, there are subtypes of cancer being identified and further understood."

Lesegretain's most significant win to date is his global brand stewardship of *Cyramza*. Getting it through registration and launch depended on executing from a unique and challenging road map. "This innovative molecule is being in-

vestigated in a variety of cancers. In only 24 months, my team had to prepare for data readouts from six Phase-III trials, spanning five tumor types. Our timeline was compressed. Yet, in each of the five cases we were required to develop cross-functional launch plans across multiple countries." With launch of *Cyramza* for stomach cancer in the US well underway, the global team is prepping for potential approvals in multiple European markets and Japan.

Lesegretain cites three lessons from his *Cyramza* journey thus far. The first is pursuing your target with clarity and confidence. "When you face this kind of complexity, with so many moving parts, you have to strive for simplicity and flexibility. Boil it down to the essence and challenge your group to stay focused on the big picture. Lilly was on uncharted turf when it came to gastric cancer; it was not an indication where we had much experience. So we worked closely with the professional community, listening for insights around a central question: where can this new product make a difference to patients?"

Second, the team made sure its activities were aligned to the markets. "Our remit was global but what we did not do is wait until we were finished to 'hand off' launch strategy to the U.S. The U.S. team worked with us from the start, which saved considerable time once it was decided that *Cyramza* would debut here." Globally, stomach cancer is the third-leading cause of cancer death worldwide. Through market research, we discovered that is not just more prevalent but also treated very differently in Asia than in Western countries. It is actually a rare disease in the US but common in Asia, with Japan having the largest incidence. Therefore, the Japan team was also integrated in the virtual launch team that shaped the global strategy for the molecule.

Lastly, constant dialogue between the global launch team and medical and regulatory submission teams is crucial. "Particularly as the development program for *Cyramza* spans many potential indications and geographic regions, it has been critical that we continuously update each other and fine tune our overall plans across the board—clinical development, submissions and approvals—to ensure our success and continued progress."

Lesegretain expects to keep applying these learnings as Lilly seeks registration for a second indication on *Cyramza*. "Despite its importance, people tend to take group collaboration for granted. In fact, its merits are elusive in large organizations because you cannot expect people from different functions spread in various places of the world to see everything the same way. Leaders have to keep emphasizing the value of each skill set in the group activity and how it contributes to the larger objective."

Above all, it's essential to assemble the right team. Attracting and developing talent must always be a priority. "Great teams make great things happen, and your role as a leader is to enable that."

— *William Looney*

Pushing Boundaries

Tom McDonnell, Vice President, Product Strategy Lead—Neuroscience, Shire Pharmaceuticals

For Tom McDonnell, the accomplishments were flowing in fast and furious. Still in his 30s, the then-Shire Pharmaceuticals product and marketing director had already led the successful launches of the company's key ADHD drugs, *Vyvanse* and *Intuniv,* in the late 2000's; *Vyvanse*, today, is the eighth-most prescribed therapy in the US. But it was actually a few years later, when acting on the advice and encouragement of a mentor at Shire, that McDonnell took on perhaps his most fulfilling challenge, accepting a position with the drugmaker in Switzerland, and uprooting his life across the Atlantic.

"It was the greatest personal and professional experience of my life," says McDonnell, who relocated his wife and three young children to Nyon, Switzerland, where, as senior director and GM, he helmed the global brand responsibilities for *Equasym XL*, Shire's first introduction of an ADHD treatment outside North America. "It's always a tough decision when you move your family to another country. But it really broadened my perspective of the world. It enhanced my creativity, my problem solving—even down to becoming a better listener because of the language differences. Coming back then to the U.S., those skills have really enhanced my ability to lead."

McDonnell and family spent 18 months in Switzerland, returning to the states, close to Shire's Wayne, Pa., headquarters, in 2012. Since then, McDonnell, known for his energetic and enthusiastic leadership style, has directed the global effort for Shire's adult psychiatry brand team, orchestrating the commercial and clinical development project teams for the potential use of *Vyvanse* in binge eating disorder (BED); and currently serves as VP and product strategy lead for Shire's U.S. neuroscience business unit, where he oversees a group of 35 people supporting *Vyvanse* and *Intuniv* for the treat-

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ment of ADHD and the development program for Vyvanse in BED.

McDonnell, 42, originally helped shepherd *Vyvanse* onto the market scene in 2008. *Vyvanse*, the first long-acting prodrug indicated for the treatment of ADHD, is approved for treating the disorder in patients six and above and for maintenance of ADHD in patients six and above. The drug, upon its original launch, achieved greater than 10% market share in 18 months, a result that proved to be a testimony of sorts to McDonnell and his team's passion for helping patients in with ADHD.

"For me, it was when I was a product manager and sitting in market research behind the glass watching mothers of children with ADHD talk about their struggles and how it affected their children and their family," says McDonnell. "To be able to be a small part helping that patient and that family is what gets me up in the morning."

The US cost burden attributed to ADHD, according to the most recent estimates, is between $36 billion and $52 billion. McDonnell, as commercial and product strategy lead, was also instrumental in the 2009 US launch of *Intuniv*, which represented a new class of ADHD drugs. *Intuniv* is approved as an adjunctive therapy for children and adolescents with ADHD who are having a suboptimal response to their current stimulant therapy. The drug, which is not a controlled substance, is a once-daily treatment that, as a nonscheduled medicine, provides flexibility in managing the symptoms of ADHD. McDonnell's team helped *Intuniv* achieve $200 million in gross sales in the drug's first full year.

In a forward-driven business, however, McDonnell does not rest on the laurels of past success. Responding to what he believes is a changing and much more global biopharmaceutical marketplace, McDonnell continues to explore new ways to promote medicines in the neurosciences, particularly in specialty markets such as ADHD and BED. To that end, he is directing the pursuit of innovative physician education channels, patient education methods, and targeted partnerships with the major players in the healthcare ecosystem to achieve consistent branding and increase clinical development interest for hopeful new indications.

"As your marketplace changes, if you don't change, you won't be in that marketplace for very long," says McDonnell. "You need to take a much more holistic approach now than in the past, and understand the role that each of the individual stakeholders play and be able to address their needs in order to have better patient outcomes."

McDonnell believes the role of the patient or caregiver in this scenario is much more powerful than it has ever been, citing a "tenfold" increase from a decade ago in consumer access to health information and education amid the explosion of digital media. Mindful of this evolution, McDonnell's approach is to inspire colleagues at Shire to share a collective vision—by understanding what motivates each of his team members and framing their goals in the context of the patient. To help that cause, McDonnell brings customers into Shire on a regular basis and also fosters close collaborations between vendors and product teams to better enhance brand engagement with the consumers and professional audiences.

"When you keep the patient in the center of everything that you do, it makes it easy to understand and address what the needs are in the marketplace," says McDonnell. "Your approach to the different stakeholders may be different. It may be new, it may not feel as comfortable, but it's important to challenge yourselves and challenge your team to see the larger picture."

When it comes to launching products, McDonnell—who began in the industry as a sales representative for Knoll Pharmaceuticals in 1997 and then worked his way up at Abbott Laboratories, which acquired Knoll in 2000—believes organizational alignment and commitment is the most critical factor for success. That may seem obvious, but McDonnell points to struggles the industry still has at times in clearly articulating a product's benefits to the consumer. Remembering that the fundamentals in areas such as people management and sales and marketing have not changed—despite added industry complexities in recent years—will be key to steering product strategies and positioning in the future, he says.

"We still need to have the right target market, we still need to have correct and compelling messages, and we still need to track our success and how those messages and information are being received," says McDonnell.

In delivering on these core beliefs at Shire while also adapting to change, McDonnell says the most critical skill he draws upon as a leader is his ability to listen— specifically around defining a simple and strategic framework for the brand: "Where we play, how we're going to win, what capabilities we need, and how do we measure success." McDonnell also stresses the importance of a leader in the product strategy space who can build a collaborative culture throughout the organization and be a bold decision-maker. It is these people, McDonnell says, that are the ones usually able to take a long view of what the future market for a brand and its life cycle looks like or should look like before others catch on. The true test for success, however, may come down to simply the ability to keep things simple.

"We work in a very complex industry with lots of regulations and lots of data and information," says McDonnell. "It's very important that we simplify for people our programs and our tactics in order to cut through the clutter."

— Michael Christel

Corporate Raconteur

Jamey Millar, VP Oncology Business Unit Head, GlaxoSmithKline

Storytelling, since time immemorial, has served an important role in conveying information, expectations, and obligations. Stories can function as orientation guides, uniting readers or listeners around a common set of assumptions. The best stories also contain an element of surprise, a reminder of the unexpected possibilities, and chance occurrences that bind our lives together.

After completing a liberal arts undergraduate degree in English Literature at Hamilton College, in upstate New York, Jamey Millar, GSK's vice president, oncology business unit head, took the logical next step: he got a job with Procter & Gamble Pharmaceuticals.

"I don't think that's necessarily the direct path into the pharmaceutical business, but as it turned out, Hamilton College had a career channel pipeline to Procter & Gamble," says Millar, who has worked in the pharmaceutical industry for 24 years. "I interviewed with P&G and evaluated options between consumer packaged goods and pharmaceuticals, and chose healthcare without hesitation and haven't looked back."

At the end of his 11-year tenure at P&G, Millar served as a country manager in the UK, Netherlands, and Ireland. Working for an American company in England, he decided to join a British company and work in America. Thirteen years later, Millar has held a variety of leadership posts at GSK in general pharmaceuticals, pricing, contracting, and payer marketing, and the health system/hospital businesses. In addition to heading up the company's oncology unit, Millar also sits on GSK's commercial leadership team, which reports up to North American president Deirdre Connelly.

Colleagues at GSK say Millar is a good listener, but also a good storyteller. Does the ability to spin a tight yarn come in handy in the corporate setting? "I think, increasingly, storytelling in the workplace is a way to frame and contextualize strategic intent, explain rationale

behind decisions, set direction, and to motivate and inspire—all of this is so important," says Millar. "I think we're often overwhelmed by businesspeak that has gotten increasingly harder to relate to in a meaningful way. To personalize it and tell a story can be effective, but it has to relate to the message that's being communicated. It can't be storytelling for storytelling's sake."

Millar says he worked on the company's diversity and inclusion initiative, for example. "There are two approaches: you can share the background statistics, the demographics and make the business case for diversity and inclusion, which is irrefutable. Or, you can tell a story about how diversity and inclusion have impacted your view of things. That's what I chose to do, and I think that resonates with people because it's more personal and memorable than quoting the rational side of a particular subject."

One story pharma likes to tell is about the shift from cost to value, from quantity to quality. GSK was the first company to de-couple sales rep compensation from the amount of product sold. But despite significant strides being made on the payer and provider side, instigated in large part by the Affordable Care Act, prescription drugs are still paid for by the pill, not by the outcome they provide to patients. For that to happen, a sophisticated, real-time patient assessment is needed, which requires "a move from siloed fragmentation in delivery of care to truly more integrated care that is connected to information systems," says Millar. "EMRs and other health information technology must converge so that people can see the whole as opposed to the component parts. All stakeholders need to be looking at the same holistic picture, as opposed to the skewed version seen from their parochial points of view."

On the subject of failure as a prerequisite for success, Millar says he worked in a global product strategy role at P&G, working closely with a cardiovascular research and development team. "I spent four years on medicines that, in the end, never made it out of late stage development," says Millar. "But those four years taught me more about drug development as a process, the nature of interactions with regulators, the challenges with clinical trial design, recruitment, and completion, functions critical to our industry."

Millar lives in Chapel Hill, NC, where his wife, Anna, is a senior associate at the University of North Carolina's Kenan-Flagler business school. Millar boastfully says that his wife graduated in the top 10% of her class at Harvard Business School, which is "why I bring a lot of work home." Millar has four children, including 14-year-old twins. Outside of the office he stays busy with travel ice hockey, travel soccer, chorus, musicals and a nine-year-old son who plays three different sports. Millar himself plays in a 40+ fast pitch baseball league, and coaches his son's baseball team, too.

On the question of younger generations entering the workforce, and what if any challenges they present to leadership, Millar says the difference today is that the older generation looked for a company that could offer a long-term career, while the newer generation, fresh out of school, is "looking basically for work that subsidizes what they want to

do in terms of their lifestyle and work-life balance…two very different things."

Asked to tell a story about the next phase of his career, Millar says he'll hold the narrative he's used since the beginning of his career, "which is not to seek specific roles but to continue to be stretched, to continue to learn, and to continue to look for opportunities to lead teams that make a difference for patients."

— Ben Comer

Taking the Plunge

António Portela, CEO, Bial

Portugal's Bial is a mid-sized, family-owned company that has just celebrated its 90th birthday. Its pre-history goes back to 1908, when the resourceful 14-year-old Álvaro Portela began working at the Padrão Pharmacy in Porto. By 1924, the pharmacy had grown into a laboratory, thanks considerably to the efforts of a young Alvaro, who was now in charge, at age 30.

Álvaro inaugurated a new company, Bial, and began marketing the hugely successful Benzo-Diacol in Portugal from 1929. He ran Bial for nearly 40 years, his son António Emílio taking over in 1962. When António Emilio died suddenly in 1979, his 21-year-old son Luís was readied for the role, becoming president of the company at 27.

Luís was initially reluctant to enter the business—he wanted to pursue a career as a medical doctor—but came on board out of respect for his father and grandfather's work. He proved to be as adept a businessman as Álvaro had been. During Luís's tenure, Bial began its own R&D activities (in 1993), expanded internationally (first to Spain, South America, and Africa), and in 2009 received EMA approval for its epilepsy drug *Aptiom* (known as *Zebinix* in Europe), which became the first 100% Portuguese drug to be distributed to the world market.

When Luís handed control to his son António, Bial entered the fourth Portela era. But like Luís, António had not been immediately sure he'd wanted a career in the family firm. He studied economics, not science, graduating from the University of Porto with an economics degree. He'd been Portuguese swimming champion in his youth. But blood is thicker than water. Still, he decided to "test" himself first, away from Bial, going to the UK to work as a medical rep for Roche, carrying the bag for a year and a half before moving to business analysis and later marketing.

After four years at Roche, Portela was convinced this was the right industry for him. Being a medical rep, particularly, gave him a vital perspective, seeing how the drugs impacted people's lives. He came back to Portugal in 2004 and joined Bial. Working his way up over seven years from deputy marketing director to heading the company's international operations, he became CEO in January 2011 at the age of 36.

Again, like his father, Portela is proving to be more than up to the job. While he champions Luís's 1993 decision to embark on an innovation strategy as the source of Bial's major expansion, António has been at the helm as the company started chalking up successes at a dizzying rate. He took the reins of a firm that had not only weathered the financial crisis that had hit Portugal harder than most, but was thriving where other indigenous companies were going to the wall. If this was a swimming relay, he was given the baton at the climactic last lap of *Aptiom*'s race to market and trusted to finish the job. November 2013 saw FDA approval of the drug, making it the first Portuguese drug to be approved in the US. Under a license agreement with Sunovion Pharmaceuticals, it hit US pharmacy shelves in April this year.

Maintaining family control of the company in an era of rampant consolidation is also no small achievement. "Bial's R&D investments—more than EUR40 million annually—are huge for a company of its size," he says. "It's not common for a company based in a Latin country to have a clear, long-term strategy. But our long-term view of where the company needs to be is only possible through a family-controlled business model."

Portela's commitment to the Bial "family" is as sentimental as it is strategic. "My father ran Bial for over 30 years and he probably knew everyone in the company by name," he says. "Today, with employees spread all over the world, that's not really possible, but I can say that I know most people by name. I have a lot of respect for the work that the previous generations have done."

But he is also well aware that securing Bial's long-term focus is as important as maintaining its traditions. Portela is looking out to the open water. "We want to make sure the R&D wheel is properly oiled," he says. "It was difficult to go through the innovation process the first time, so it's key that we stabilize our R&D efforts as we close this first cycle of innovation and move on to new countries."

In 2012 Bial's revenue exceeded "the 200-million-euro barrier" for the first time; its products are now available in 53 countries. With another

promising Bial-developed drug (*Opicapone*, for Parkinson's disease) now in Phase III trials (and recently licensed for commercialization in Japan by Ono Pharmaceutical) and the establishment of a new, EUR12 million research unit in Bilbao, Spain, the 90-year-old company's future looks pretty solid.

— *Julian Upton*

The Sole Proprietor

Alexsey Repik, Founder and Chairman of the Board, R-Pharm

Alexsey Repik is a practicing contrarian, whose credo for success rests on renunciation of the stereotypes associated with the typical emerging market business: hierarchical, risk-averse, and inward-looking, with little interest in opportunities beyond what public patronage offers in the form of predictable returns and protection against foreign competition. With an initial investment of only $40,000, Repik followed his own singular instincts in building what is today Russia's second-largest domestically-based pharmaceutical company, with $2 billion in sales last year. Those instincts rely on commitments often rejected by others in his position, such as refusing to define progress as meeting only what is standard for Russia. Repik believes the benchmark for future growth is competing at the level of the global market, and R-Pharm is determined to get there first.

Repik's current high profile is rooted in some early career disappointments. "I was an inquisitive young man with a strong interest in the arts, especially history, where under the Soviet system I was able to secure scholarships as well as status as head of a student society dedicated to learnings of the medieval period. But it all fell apart when, despite these credentials, I failed to win acceptance to Moscow University. That disappointment pushed me to abandon academic credentials for something more technical." Repik instead trained as an economist, where in 1995 he was introduced to the healthcare field, helping hospitals in the Moscow region manage their costs.

The assignment was short-lived, however, as the upheavals of the Yeltsin era led Repik to join a small, family-owned specialty pharmaceutical company. "When I started in 1997 I was one of only four employees; three years of hard work delivered a worthwhile award, when the company emerged as one of the top specialty drug distributors in the Russian Federation. Unfortunately, this resulted in my second career setback when the owners rescinded a promise to give me a minority share of the company. More than anything, that led to a realization I could trade on the knowledge and contacts I had amassed and start my own company—as an entrepreneur in the new Russia."

Repik founded R-Pharm in 2001, serving the same specialty and hospital segment he had mastered in his previous positions, while also registering as the company's sole owner—a status he retains to this day. Repik is unabashed about calling himself an entrepreneur rather than an executive, repeatedly emphasizing how his company's progress has depended on fusing his "street smarts" and openness to new ideas with the operational and execution excellence of the R-Pharm management team, led by CEO Vasily Ignatiev, an industry veteran with stints at BMS and AstraZeneca. "I'd characterize my role today as unlocking the potential of our 2,800 employees."

Four ways forward

From the start, Repik has held fast to four basic principles in running the business. The first is autonomy, a position guaranteed by his position as R-Pharm's sole shareholder. "With no outside owners, we can make our own investment decisions and take necessary risks to grow the business long-term." Repik employs a rule of thumb requiring three quarters of annual profits to be reinvested in the company. "I also see my youth as a positive because I am willing to wait 30 years to see all this develop, hopefully in a way that sparks the interest of my five-year-old daughter."

Second, R-Pharm is singularly focused on pharmaceuticals. "Sector diversification is the traditional fallback among successful Russian businesses, but we have zero interest in taking that course because you end up ceding your core competitive advantage to others."

A third, and related, objective is looking beyond Russia toward international markets. "Pharmaceutical sales in Russia today amount to less than 2% of the global market. To expand and stay profitable, domestic companies must look outward." Repik notes a tendency of businesses in emerging country markets to strive for designation as a "national champion"—and stop there. "It's a profoundly short-sighted view, which fails to recognize that big Pharma competitors are already active on our own home turf. At some point we need to come forward with high-quality offerings, alone or in partnership, to compete for share on their home bases as well."

The fourth principle is keeping pace with customer needs, largely through

an unrelenting commitment to quality. In fact, Repik tells *Pharm Exec* that customer centricity is pushing R-Pharm toward the innovative side of the market. "The traditional business model for pharmaceuticals is like a tree, growing from the root, which is originator drug innovation, to the branches and leaves, which represent processing or assembly functions like distribution and marketing." R-Pharm is pursuing that model in reverse. "In Russia and throughout the former Soviet Union, we are the leading distributor and manufacturer of a wide range of generic and branded drugs, both for our own account and as a service contractor for others. But the next, and most exciting, phase of our growth is to plant new roots as a developer of medicines, organically from our own facilities in Russia as well as in partnership with other innovative firms worldwide." To push that along, in 2011 R-Pharm established a dedicated Overseas Unit with offices in San Diego and Boston to explore in-licensing and development options with the US scientific, academic and venture capital communities.

Yes to Yaroslavl

Preparation for this expansive step was carefully plotted though a constant upgrading of R-Pharm capabilities in producing a growing variety of medicines—including biologics—all to the highest Western standards. Says Repik, "we are the first Russian company to design production to meet all global GMP requirements, which is unprecedented here." In 2008, when Russia's state finances were in crisis and hospitals—a major source of R-Pharm revenues—were not paying their bills, Repik decided to invest $130 million in new state-of-the-art manufacturing facilities in Yaroslavl, giving R-Pharm expertise to produce advanced APIs and biologics like monoclonal antibodies that previously were not available in Russia.

"Some observers called it a fantasy project located in the middle of nowhere, and it certainly tested our risk limits, but today these facilities are central to our value proposition with an increasing number of international industry clients." In fact, the investments have helped drive new co-production and promotion deals with companies ranging from India's Dr. Reddy and Japan's Meijii Sankyo Kowa (first ever for a Russian company) to most of the Western majors, including MSD, Roche, AbbVie, BMS, Boehringer-Ingelheim, Novartis, and Pfizer. Many of these deals give R-Pharm exclusive rights to marketing new technologies in Russia, as the local partner of choice. Repik notes that another vocal industry actor—the Russian government—likes it too.

Looking forward, Repik will focus his efforts on the international side of the business, particularly in forging ties with local pharmaceutical companies in other BRIC markets, Turkey. and especially with Asia, where he is a strong supporter of President Vladimir Putin's effort to diversify Russia's trade ties into the region. A recent example of that commitment is the $5 million grant R-Pharm awarded in April to Japan's Nagoya University for pharmacological research in oncology.

— William Looney

Sharpening the Learning Curve

Monica Tellado, VP, US commercial operations, Gilead Sciences

With a background that includes one of the largest automotive makers in the country and one of the largest tech firms, Monica Tellado, vice president of US commercial operations for Gilead, brings a needed sense of urgency to pharma's planning cycle.

Born in the US, Tellado left for Spain as a toddler and didn't move back to the States until she enrolled in an MBA program at Carnegie Mellon University's Tepper School of Business. She split her undergraduate degree between Universidad Pontificia Comillas, in Madrid, and Middlesex University, in London. At Carnegie Mellon, Tellado focused on finance, and the Ford Motor Company was a heavy campus recruiter. Ford had initiated a treasury excellence program, and "it seemed like a good opportunity to see different parts of treasury for a big company," says Tellado. "But I didn't stay very long."

Expectations and reality were misaligned at Ford, says Tellado, who next joined Intel, at a time when the company was growing quickly and entering new markets. Six years and several finance department roles later, Intel had "shifted from supporting new initiatives and new areas of growth and opportunity to really focusing on cost-cutting," says Tellado. "So I decided to leave."

Finance is a transferable skill, so Tellado looked out across many industries as she decided what to do next. She interviewed a lot, but ultimately Gilead

won out for a few reasons: it was very small at the time, but growing, and the company was looking for someone to build better processes, systems, and analytics, and to make finance "a true business partner versus just a function

that reports out the numbers," says Tellado. It was also an opportunity to learn a new and unique business sector. Tellado joined Gilead just in time for a series of product launches beginning with *Emtriva* during her first year with the company (2003), *Truvada* in her second year (2004), and *Atripla* in 2006.

After working in the finance department for the first few years, an opportunity to transition over to the commercial side presented itself. Tellado says she was promoted to manage the forecasting function, incentive compensation plan, and the rest of the sales tools and data assessment supporting the sales force. "I was still using my analytical skill set, but also getting much deeper into the business side of things," says Tellado.

In finance, numbers are numbers but "one of my first impressions [upon joining Gilead] was that the lead times are very different, in terms of how you plan out to support a product in the pharmaceutical space versus the high-tech space, in terms of time-to-market," says Tellado. "The planning cycle is a little slower in the pharmaceutical world versus the speed at which things change in the high-tech world, where you're adding new features and you're bring out your next product and wheels are turning very, very quickly."

Tellado says she could deal with longer cycle times because Gilead, despite its dramatic growth in recent years, remains a lean and nimble organization. "We don't have the challenge of having to go to this committee or that committee," she says. "We can bring a product in-house and get it ready to launch in less than two years." Indeed, Gilead announced that it would acquire Pharmasset—and what would become *Sovaldi*—in late November, 2011. *Sovaldi*, which needs no introduction, was approved on Dec. 6, 2013, and made over $2.2 billion during the first quarter of 2014.

Tellado declined to speak on the record about the pricing and commercialization of *Sovaldi* for this profile, but noted that in general, there's an increasing focus on healthcare management and cost—"and there should be," says Tellado. As a result, it becomes "even more important to be able to clearly identify and clearly represent the value of new products and how they address an unmet need, and how they help patients." That means anticipating, early in product development, what health economics and outcomes research will be needed to support a launch, and how to message not just product attributes but also a comprehensive value proposition.

Perhaps even more so for a smaller company, making the right hires, the first time, is a critical skill, one that Tellado emphasizes. "It's important that every single person we bring on to the team is really strong, both from a skill set perspective but also from the perspective of Gilead, and whether or not someone will fit into the culture and environment."

Tellado can manage from 5,000 feet or five inches, depending on the individual. "I think my natural style is more hands off though…it's high level – I'll get involved in questions of what do we need to accomplish and what are the business problems we're trying to solve—but I give the team the flexibility to get there," says Tellado. "Strong players need room and bandwidth and responsibility to make sure they're motivated and feel that they're contributing and making a difference." Tellado also underscores the importance of "very high levels" of accountability as a crucial component of successful management.

Married with three young daughters, Tellado says most of her outside interests have consolidated into simply spending time with her kids; her family likes to travel and play sports. Asked whether she would encourage her daughters to pursue careers in the pharmaceutical industry, Tellado doesn't hesitate: "I definitely would. I'm very happy that I moved from the high-tech world to the pharma world… and I've been here for a while now."

— Ben Comer

Eye for Detail

Hayden Thomas, VP, formulation development, Vertex Pharmaceuticals

When George H. Bush sent troops to Kuwait in August of 1990, Hayden Thomas, PhD, currently vice president of formulation development at Vertex Pharmaceuticals, was aiming high as an undergrad Air Force ROTC cadet.

But the military got downsized shortly thereafter. All the new recruits got cut, and Thomas, an Arkansan, "found myself, in my junior year, looking for something to do." Having also focused on science as an undergraduate, Thomas thought he'd go to medical school. But a conversation with a department chair of medicinal chemistry at the University of Mississippi —Dr. W. Franklin Gilmore—changed Thomas's trajectory. "[Gilmore] was talking about all the great things in medicinal and pharmaceutical chemistry, painting this vivid description of pharmaceuticals…instead of helping one patient at a time as a medical doctor, you can help out thousands or even hundreds of thousands," Thomas recalls.

After graduate school beginning at Ohio State and completed at the University of Michigan in Ann Arbor, Thomas starting working "about a mile down the road" at a Parke-Davis's research facility, a subunit of Warner-Lambert. He landed at Pfizer through that company's $90 billion acquisition of Warner-Lambert in 2000. Pfizer closed Thomas's old Ann Arbor stomping grounds in 2007.

Vertex was a breath of fresh air, "unlike any other company in the pharma industry," says Thomas. With roughly 40 direct reports in his current role, Thomas underscores the importance of being an effective member of a team. Coming from a graduate program centered squarely on himself, Thomas found the transition to teamwork challenging at the beginning of his career. "In grad school it's all about you. You have a tough project in front of you, and four or five years to solve it. You have all the expertise, all the knowledge, it's you, you, you, and then you defend your work in a thesis committee," says Thomas. "That's all good, but then as soon as you step into the industry, it's all about team."

Successful teams are built on "trust and rapport with the folks in your group…you need to build that personal relationship," says Thomas. That means understanding "how each [team member] thinks, what drives them, where their passion lies, what their strengths are, and where they are going."

Observational skills are critical, says Thomas. "I did a short stint in process chemistry back at my former company, and one thing a process chemist must have is very strong observational skills. These skills can be applied in the lab, but they're also important for watching people, in meetings and team settings," says Thomas. "You look for people that are highly effective at what they do, and try to figure out why they are effective. If you can break it apart and take away those learnings and apply them to your own approach, that's a huge skill."

The core objective of Thomas's team at Vertex is to take an active pharmaceutical ingredient and put it into a dosage form that meets a patient's needs. "It doesn't matter if you have the greatest medicine on earth for the worst disease, if it's not in a form that's acceptable"—according to performance metrics—"for patients, then you really haven't delivered anything."

Thomas calls Vertex a leader in quality by design and continuous manufacturing processes. By using "real-time release testing," and linking unit operations together, Vertex is able to finish products, on a continuous basis, that are ready to use by patients as soon as they leave the line," says Thomas. "You're taking a manufacturing process that's highly intensive from a labor and time and materials standpoint, and you're streamlining it down to where you do a manufacturing run in a day, maybe two at the most, and it's released and ready to go." Hayden was instrumental in establishing Vertex's first high-tech continuous manufacturing facility in Boston.

On the manufacturing floor and off, Vertex leadership puts a premium on real-time feedback, connectivity among employees and open communication lines, says Thomas. "Feedback should always be received as a gift. The way I try to give and get feedback is, feedback is given, you listen intently, you don't ask questions about it—you receive it. You say thank you very much, and then you take it away and try to analyze it from multiple angles. What was this individual really trying to tell me? And then you try to apply it in the best way possible."

Asked about the role of failure in pharma leadership, Thomas says failure is simply part of the business. In a way, "there's no such thing as failure… just because an experiment doesn't turn out the way that you anticipated or were expecting doesn't mean that you didn't get useful data, or that you didn't learn. What matters is how you respond to failure," says Thomas.

Even though he never entered the Air Force, Thomas did get his pilot's license. His family and two children take up most of his spare time. Thomas doesn't own a plane, but likes to go boating in the summers, and snow skiing in the winters.

In five years Thomas says he hopes to be solving difficult problems. He says leaders should strive to eliminate their own positions by constantly becoming more efficient. Being perceptive and constantly looking for a better way to do things is what keeps an organization "competitive and innovative, and moves the industry forward."

— Ben Comer

More than a Number

Jocelyn Trokenheim, Head of Global Business Development Office and Strategy,Takeda Pharmaceuticals

Like many data analysts, Jocelyn Tsai Trokenheim was schooled to believe in the pure logic of numbers. Her early history as a "quant jock" clearly helped the 42-year-old immigrant from Taiwan adjust to life in the US, where she arrived in 1991, fresh out of high school and speaking not a single word of English. After obtaining her second Master's degree in Management Science at Queen's University in Canada, she landed her first job at the pharma consulting firm ZS Associates, which introduced Trokenheim to the power of data analytics and the key role it plays in pharmaceutical sales and marketing.

But a larger revelation was at hand in that first industry assignment. "Enlightenment struck when I began to realize that numbers only tell half the story. It's actually people who truly define a business and determine its success. So I decided to get to know the human capital behind the num-

bers—employees, physicians, and patients—as the best way to expand my skills and make an impact where it matters most. This is what led me to seek that larger world beyond consulting and to join Takeda."

After spending 10 years rising through the ranks in Takeda USA's commercial analytics group, Trokenheim chose a new path into the parent company's global Business Development function. It turned out to be an ideal opportunity to hone those combined quantitative and qualitative assets that account for much of the progress she has made in her career. As the company worked to digest two major acquisitions, she was given what proved to be a pivotal assignment: to create an integrated global business process and system operations platform in global Business Development, consolidating activities and processes formerly distributed across three continents. "People skills really counted here, as my job involved working not just within global Business Development but almost all functions across Takeda.

After only nine months, Trokenheim was given the additional task of driving the overall strategic direction for Business Development worldwide, including creating the business development group's strategy as well as managing corporate-level strategic transactions. "Handling both operations and strategy seemed initially like an oxymoron, but as I rolled up my sleeves I began to see it as a position combining the best of two worlds—the ability to contemplate the biggest, most promising ideas of the future while ensuring our day-to-day performance milestones are met through deliberate, hands-on execution."

That swift rise was nurtured by some valuable contacts she has made at different stages of her career. One prominent mentor is Anna Protopapas, President of Millennium Takeda Oncology Company and Executive Vice President of Global Business Development, who Jocelyn met in 2011 when she was part of a small team working on a US acquisition transaction.

On a practical level, Trokenheim cites her biggest accomplishment to date as the creation of a strong in-house commercial analytics capability during her days as head of Business Insights and Strategy at Takeda USA— one that has been recognized as a "best practice" in the industry by TGaS, the group that benchmarks company performance in the market research field. "I was able to recruit and lead a team of 28 talented professionals spanning mission-critical functions—forecasting, market analytics, commercial assessment, decision science, market research, commercial reporting, and data governance—all in support of Takeda's in-market products, pipeline compounds, and business development and partnering efforts. We established close cross-functional ties throughout US Operations and were recognized for providing insights to help patients and move the business forward."

Timing and the right place

Although personal characteristics are a big part of her success, Trokenheim has been fortunate in that her work complements broader environmental trends affecting the industry. "What has really accelerated since I joined the industry 12 years ago is the need to collaborate. Dealmaking and business development continues to drive our industry as never before, with a focus not just on late-stage compounds that are "battle tested" but on earlier stage deals and new forms of pre-competitive exchanges that may offer companies more opportunity for growth, while sharing the risk."

With that in mind, Trokenheim urges younger industry colleagues to gain experience in working cross functionally and with people who can provide a different perspective. "The ability to manage geographically dispersed, virtual teams and to understand different strands of opinion from all over the world is a must. To get others to 'jump on the bus,' you need trust and that trust has to be earned through persuasion and example."

She also has some pithy advice around the popular concept of mentorship. "We need to be clearer about what mentoring means and how it actually develops in the work place. Based on my experience, on both sides of the fence, mentorship develops when the mentor self-identifies the talent and acts to help the talent grow. Any pre-identified or forced arrangement between mentor and mentee typically ends up not working well. So I say the aim must first be to do your best, because once you excel, it will be the mentor who comes to you, not the other way around."

What's next? Trokenheim is open about career possibilities, emphasizing that what she likes about Takeda is the exposure to a broad range of projects. Whatever it is, Trokenheim always returns to the Asian theme of life in balance—"even though I enjoy my work, I don't think my professional life defines who I am." Spending time with her husband and their 9-year-old son, along with another enduring companion—her love of music and family jam sessions on the ukulele—is truly the tie that binds.

— *William Looney*

Photo: Thinkstock

A Mission to Transform

Mid-career students at Brown University's new Executive Masters in Healthcare Leadership program are challenging the status quo with workplace projects designed to do one thing: remove the organizational silos that slow innovations in the delivery and financing of health services.

By William Looney

As the US healthcare system stumbles toward a new consensus built around the "triple aim" of increased access, improved quality, and lower cost, the push is on for new ideas that can test the boundaries of current practice. The Affordable Care Act (ACA) creates a range of incentives to promote this goal, which has added to the momentum around novel reform approaches. Business management schools have jumped with gusto into the fray, providing much of the intellectual heft for integrative, outcomes-oriented programs that stress patient wellness and require medicines to do more than just treat disease.

One institution, Brown University, has gone a step further than many of its counterparts, with a new 16-month Executive Master of Healthcare Leadership (EMHL) program dedicated to empowering mid-career health professionals with the diverse interests, skill,s and capabilities to challenge that status quo and "transform" healthcare as we now know it. The centerpiece of the curriculum is a requirement that each student initiate a "Critical Challenge Project" within their sphere of expertise to address this aim, probing the way healthcare services are currently organized, delivered, or financed.

Strafing those silos: The Critical Challenge project

An underlying goal of the Critical Challenge Project is to attack the bureaucratic or process silos that prevent different parts of the system from cooperating to advance a more holistic population health agenda. The emphasis is as much on doing something differently as doing something important, engaging stakeholders across the system to achieve a measurable result that will allow the student to assess—quantitatively or qualitatively—the effects of its implementation.

The Critical Challenge Project is a key criteria for admission; it also

serves as the basis for much of the EMHL's formal coursework, the student's final grade, and subsequent priorities upon his or her return to the workplace. Students give regular progress reports on their project in a peer group exchange format, allowing diverse points of view to be incorporated in plans and objectives going forward. "This is not a static exercise," says EMHL Program Executive Director Judith Bentkover. "We see it as a way to test theory against practice, with transformative system change as the ultimate objective."

As a complement to this month's cover feature on 15 Emerging Pharma Leaders for 2014, *Pharm Exec* made a recent visit to Brown's first EMHL class of 28 mid-career professionals, most under age 40, and representing a wide range of sectors and occupations in the healthcare field, from traditional big Pharma to health community activists. The purpose? To highlight a few of the more ground-breaking Critical Challenge projects being pursued by this highly motivated class of young entrepreneurs—and thus to open a window on the future of healthcare. A talk with five students indicates a diversity of approaches, but all share the EMHL program objective of exposing the silo thinking that blocks progress toward changes that everyone says they want, but are hard to achieve in practice.

Bridging the information gap

For **Chris Godfrey**, senior vice president at Dallas-based venture capital firm HealthCap Partners, market signals are often missing in healthcare, resulting in more uncertainty and less efficiency in the deployment of human and capital assets. His project revolves around Bloodbuy, a small start-up enterprise he founded to create a more transparent and structurally cohesive process for the exchange of price information and supply of blood products between distributors and hospitals.

"If you want to improve the market," Godfrey says, "the best place to start is with the core commodity of healthcare, which is blood. Essential services literally cannot be provided without it, so I see it as a critical pathway into the health system—and, unfortunately, the logistics of pricing and supply devised by blood center distributors are often non-transparent and lack much accountability to the hospitals that depend on predictability in the supply chain. Godfrey notes that the FDA mandates uniform standardization in the composition of blood products, which means there should be little differentiation in pricing—the product itself is the same. Yet a strong spot market exists in many parts of the country for blood products, with the result that hospitals face wide gaps in what they have to pay for blood, making it harder to accurately account for their needs.

"If you want to improve the market, the best place to start is with the core commodity of healthcare, which is blood."

To remedy this, Bloodbuy has developed data technology to help hospitals overcome the fragmented supply chain and lack of transparency in pricing by broadcasting their blood needs to a broader audience, avoiding the traditional dependence on a few local outlets. "It's essentially about diversifying risk, so that as a hospital I am going to have a better chance of getting the blood products I need, when I need them, at the optimal price point." It also works for the blood centers, which face a strategic dilemma as reform slows acute care utilization, which leads to less demand for their commodity. "Bloodbuy's technology enables them to address this slowdown by helping them penetrate new geographies and acquire new customers." It's a precision response to a gap unmasked by the drive toward system reform, helping customers out of their silo to connect to a relevant area of unmet need, with greater efficiency at each end of the market as the intended result.

Star power: Enlisting the sales force

Debbie McKee, general manager for upstate New York and Connecticut at United Healthcare's Medicare and Retirement unit, works on the front line of the insurance industry's efforts to adapt to new mandates under the ACA on cost-efficiencies in the delivery of health services to seniors. Her Critical Challenge project is based on United Healthcare's commitment to accelerate the number of star ratings it receives for quality of services provided to enrollees in the company's Medicare Advantage beneficiary plans. This is important financially to all insurers because the ACA now conditions reimbursement and bonus payments through Medicare on the quality star rating achieved by each plan, with CMS evaluating plan performance across 53 specific quality measures. "My project confronts

an important silo that can impede our progress against this goal, which is the failure to mobilize United Healthcare sales agents to help win those higher ratings. We have hundreds of colleagues engaged in selling a plan and helping to service the contract with the member, yet having no input around the execution of the company's star rating strategy."

With management support, McKee and her team have initiated a pilot program covering eight markets in United Healthcare's Northeast service area. It gives sales agents assignments to ensure that members in their territories are on target in implementing preventive care programs, especially the wellness checks that patients often fail to utilize. "So far, I have been surprised by the number of people in sales who see this as evidence they are part of the wider solution to the cost of healthcare. Her training at EMHL is helping McKee take the pilot to the next step, which is aligning individual pay and bonuses around this broadened service orientation. "We have to provide a firm response to the root question of economic incentive: what's in it for me?"

The learning organization: Testing old boundaries

Jun Sutherland, worldwide director, education and learning for J&J's Infection Prevention Practice, has built his career helping life science organizations keep pace with the heady pace of scientific discovery and the obligations it places on key functions ranging from regulatory compliance to ethics and reputation management. His Critical Challenge project is arguably the most ambitious in the group, given its scope: bridging what he calls the "learning gap" as big Pharma copes with trends like globalization and high-cost drug development, where the common thread is seeding "the will to cooperate" as a cultural imperative. Says Sutherland, "the way we educate our own workforces is very siloed. Technical training always tends to relate to specific job roles and leadership development is driven largely by internal issues rather than relating to the wider world of healthcare, especially that 'trifecta' of patient/customer expectations around cost, quality, and access."

To address this challenge, Sutherland has secured financial and leadership support for a pilot project in his Infection Prevention Practice, to launch in the first quarter of 2015. The centerpiece is a core healthcare learning curriculum for new employees and managers in three departments of the Practice: sales, marketing, and clinical/provider education. Six to eight course modules are being planned, including an introduction to the ACA and J&J's corporate response to its key provisions; how the innovation process works internally, outlining the distinction between invention and innovation; and what each function can do to engage more productively with the external stakeholder environment.

J&J, as a highly decentralized organization with some 250 separate operating units, might seem averse to any overarching approach to educating employees. But Sutherland was able to address this by securing approval from the company's Global Management Board, and the Board member representing the Infection Prevention Practice authorized the budget to fund the pilot. The Board will decide later next year whether to make the pilot permanent and to roll the concept out to other parts of the company. Says Sutherland, "this is a change management initiative, so it's not unusual that in a large organization like J&J we have to try this out to see how it flies. Where I am going with this is to get our top executives to understand that change in this industry is permanent—organizational learning ultimately can't be applied piecemeal. And we have to be in it for the long haul."

Measuring value that matters

Deborah Pfeifle is CEO of Gould & Lamb, the leading provider of Medicare program compliance services for the global insurance and self-insured markets. Her Critical Challenge is to create a metric that will allow insurance underwriters to accurately value an individual life care plan for so-called "dual eligible" patients who are enrolled in Medicare but receive their care through the Medicaid program for the indigent. These are high-cost patients, usually with multiple chronic ailments, who also have very low incomes.

The Medicaid program has for some time been contracting with private insurers to cover this group and to find ways to deliver care more efficiently—thus creating the rationale for Pfeifle's project. "It is a priority for the insurance industry and actually for government and society as well, to be able to anticipate what dollar amounts will be needed to keep this population well and out of hospital," Pfeifle told *Pharm Exec*. "A life care plan is designed to estimate what the cost will be in services and supplies to help a patient with a chronic disease or condition maximize the ability to function for the rest of his/her life. This is hard to do for those who are ill, but it is particularly challenging for dual eligible patients due to the constraints imposed by the harshness of their underlying economic and so-

cial circumstances." Indeed, evidence shows that failure to anticipate these non-medical needs in a life care plan ends up driving healthcare costs even higher. "We must work to incorporate that fact into our metric."

Pfeifle told *Pharm Exec* she is working with a private non-profit, the Foundation for Life Care Planning Research, to establish a research analytics standard that allow underwriters to build cost estimates for this dual eligible population, which numbers more than 10 million people. Says Pfeifle, "this is something that has never been done before—there is no prior research and we have extremely limited precedents to go on. We are building this metric from the ground up."

Curative power of community

Nicolas Sandoval works for the patient at the most basic level, helping communities of economically marginalized workers to navigate the public health bureaucracy to obtain essential primary care services—services that can make the difference between wellness and disability. A bilingual health educator for Salud Para La Gente, a network of federally designated community health clinics in rural California, Sandoval has a strong interest in the "whole person" approach of population health, especially in identifying the most cost-effective way to treat poor patients with chronic illnesses. His Challenge project centers on the treatment of type 2 diabetes, a condition affecting as many as 60% of farm workers in the areas of the state covered by Salud's network.

"Control of diabetes requires a huge commitment to patient education, a need accentuated in the communities I support by economic troubles as well as cultural, linguistic, and even geographic barriers," says Sandoval. "Many of the people our clinics serve are unregistered immigrants with no fixed address, transient seasonal workers who follow the harvest and speak no English. Getting these diabetic patients to proactively self-manage their condition is almost impossible: how do we do it? This was the essential question deserving an answer. My project seeks to provide it."

Silo-busting precedents: Four lessons

All of the Critical Challenge projects undertaken by this first, 28-member 2015 class of the Brown EMHL program are intended to grow beyond the shelf life of academia; the students expect these will shape their future assignments in the workplace as well. Executing a project designed to establish something tangible around an academic program raises an inevitable question: are there lessons from the experience that can be applied to create a generic lesson plan for business success?

Executing a project designed to establish something tangible around an academic program raises an inevitable question: are there lessons from the experience that can be applied to create a generic lesson plan for business success?

What Sandoval is introducing, with the help of colleagues from Salud, is a structured program of group visits for diabetes patient treated in network clinics. It involves bringing 10-15 patients together for encounters with not only the physician, but a nurse, pharmacist, medical assistant, dietician, and health educator. "It creates a setting where basic messages about health maintenance are reinforced through a structured group exchange built around four behavioral pillars: physical activity, nutrition, medication adherence, and stress management." Sandoval says the training he is receiving through the EMHL program will move the project to the next step, which is developing a list of indicators to demonstrate the program's effectiveness in improving outcomes for covered populations. "Under the ACA, as a federally qualified health clinic, this metric is going to be necessary to scale up and obtain an ongoing source of funding."

The consensus appears to be yes, with *Pharm Exec*'s discussions with the class yielding four strategic principles: (1) understanding the goals of the organization first, to find ways to get others to align with your own goals; (2) avoiding the visionary prison of "thinking small," by going beyond internal politics to identify outside stakeholders who will be affected, for better or worse, by what you intend to do, and planning in advance to address each; (3) consider the underlying social and cultural aspects of health care, in addition to its more prominent scientific and clinical dimensions—that elusive 360 degree picture; and (4) always be transparent, which in the competitive precincts of healthcare is not an instinctive act, but learned behavior. PE

William Looney is *Pharm Exec*'s Editor-in-Chief. He can be reached at wlooney@advanstar.com. Disclosure: he is a member of Brown's EMHL Advisory Committee.

Only Fools Rush In

The Importance of pre-acquisition due diligence.

With the warm days of summer upon us, news of yet one more takeover bid might seem like déjà vu. In late May, US medical-device group Stryker confirmed that it was evaluating a bid for UK-based Smith & Nephew. Before that, GlaxoSmithKline announced a major three-part deal to acquire Novartis' vaccines business. In June, Minneapolis-based medical device maker Medtronic announced a $43 billion bid to acquire Dublin-based rival Covidien. The reality starting to set in is that 2014 stands to be a record year for mergers and acquisitions with a blistering $3.51 trillion in deals estimated to be set by year's end.

What to make, then, of this frenzy of M&A activity, especially with so much of it happening in the life sciences and medical device industries? Mergers not only help boost a company's book value but are also highly attractive to many US companies in search of lower corporate tax rates abroad. Experts have remarked that with many companies facing expiring patents and decreased revenues, the growing M&A trend in the pharmaceutical industry is unlikely to abate anytime soon.

It pays to be cautious

But companies in search of an "easy buck" through an acquisition may end up getting more than they bargained for. That's because successor liability laws transfer a whole host of liabilities from the target company to the purchaser in an acquisition, including criminal and civil liability stemming from past wrongdoing.

For example, a full decade after buying orthopedic device maker DePuy Inc. in 1998, Johnson & Johnson ended up paying $77 million in fines and penalties to the Department of Justice and Securities & Exchange Commission due to the subsidiary's widespread bribery activity in Greece at the time of the acquisition. Expect the latest round of mergers to similarly arouse scrutiny from U.S. government regulators, and those companies that have ignored compliance issues in their pre-acquisition due diligence to suffer buyer's remorse later on.

Long before a deal is signed in ink, a company's compliance and legal team should be involved in the vetting process.

Think compliance early on

Long before a deal is signed in ink, a company's compliance and legal team should be involved in the vetting process. One reason why compliance should have a seat at the M&A table early on is so that they stay informed of upcoming deals in the pipeline in order to marshal the necessary resources prior to the announcement of a takeover bid. Once it is determined that the company is serious about acquiring a target company, the first step should be to assess the target's initial risk profile.

Asking certain key questions at the outset will help determine the target's risk level and the scope of any future due diligence. For example:

- **What, if any, compliance program already exists at the company?** Having zero pre-existing compliance is certainly not fatal to the deal, but is a good thing for the acquiring company to know in assessing risk.
- **Does the acquisition contemplate a full share purchase or just an asset purchase of the target company?** The latter will carry less successor liability for past wrongdoing.
- **What laws is the target company currently subject to?** The acquisition of a company does not create jurisdiction where none existed before.
- **What is the ultimate appeal of the target company?** Acquiring an expanded market share carries different risk from solely purchasing new technologies or patents.

Asses the risks

After this preliminary stage, the buyer should develop a better

Severin Wirz is Manager of Advisory Services at TRACE International. He can be reached at wirz@TRACEinternational.org.

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Cover Art by Ignacio Gana.
Ignaciogana@gmail.com

CHILE: Pharma's Changing Landscape

"2014 represents an exciting time for healthcare in Chile with the implementation of a new national drug law; ensuring the creation of a system that makes access to medications easier and more transparent for patients and, moreover, assures a sufficient supply all over Chile," explains Helia Molina, a doctor specializing in pediatrics and nephrology and Chile's Minister of Health since March 2014. The 'Ley de Farmacos,' or Drugs Law, was passed by Chile's former government in January 2014; its implementation now rests with the new administration.

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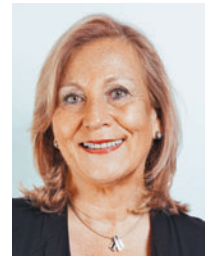
Chile Report

"The new government of Chile has made a commitment to improving the health of the population," Molina explains, "and the Ministry of Health will expand the list of chronic diseases included in the Regime of Explicit Health Guarantees (AUGE) plan, which ensures government-funded coverage for patients regardless of age, class, and ability to pay."



From left: Helia Molina, Minister of Health; Ricardo Fabrega, director of the Public Health Institute

This should contribute to boost a market that is already expected to grow 8.2 percent between 2012 and 2017 according IMS Health. In 2012, the Chilean pharmaceutical market was worth a total of USD 2 billion, according to the latest available data from IMS.

The new government plans to introduce further legislation to improve healthcare in Chile. In her paper entitled '50 Commitments for the First 100 Days of Government,' President-elect Michelle Bachelet builds the basis of her plan for better health services for the nation, committing to invest significantly in the construction of new hospitals, increase the number of specialists to combat long waiting lists in the public sector and provide patients with better access to free drugs.

As it currently stands, Chile's universal healthcare plan covers 80 percent of the population. The remaining 20 percent are entitled to pick their coverage from a number of private insurance companies known as ISAPRES. 80 percent of people in Chile should have access to free drugs under FONASA, the public health insurance system; however, the reality is that there are often shortages at hospitals, and as a result people turn to private pharmacies to fill their prescriptions out-of-pocket. As a result, despite FONASA, out-of-pocket expenditures in Chile are some of the highest in the OECD: A total 4.6 percent of the average Chilean family's budget is spent on healthcare, compared to the OECD average of 2.86 percent.

There is positive news on some fronts however: after years of infamously tense relations between MNCs and the government, both parties finally seem to have found a platform for dialogue. "As an industry, we have an active dialogue with the ministry regarding the expansion of access to innovative medicines, but the discussion is still young and we still have a lot to do," explains Erich Viertel, country manager at Janssen Chile. "Finding the best path to lead Chile toward economic development has been an ongoing task of Chilean governments and leaders over the last century. And if the country is able to sustain its current momentum, at the end of this decade it will probably become the first fully developed country in Latin America."

The Chamber of the Pharmaceutical Industry in Chile (CIF), which represents the international innovators, will carefully monitor the implementation of the new healthcare law, which requires prescriptions to mention the name of the chemical compound. While this is seen as positive for the customer, who will now have access to cheaper alternative products and also their personal brand preference, for, innovators there is still a major concern about bioequivalence.

In Chile, as in other Latin American countries, similares have high market penetration: generic drugs that do not have proven bioequivalence. "If the law would allow physicians to prescribe any generic drug including non-bioequivalents, all efforts made by previous governments would be for nothing," says Jean Jacques Duhart, executive vice president of CIF. "A large portion of products on the Chilean market cannot demonstrate quality, safety and efficacy through bioequivalence studies. Similares are neither generics nor originals and have not demonstrated their quality, efficacy and safety as recommended by the World Trade Organization."

He also warns: "This is not merely a concern in terms of health and risk for patients but it also introduces an important market distortion—different actors are competing with different standards."

LEVEL PLAYING FIELD

Chile is aiming to achieve complete bioequivalence of generics by the end of 2014. Chile's Public Health Institute is leading the bioequivalence testing, aimed at regulating differences between generic and bioequivalent drugs. The recently appointed director of the Public Health Institute, Ricardo Fabrega, echoes the need for drastic change and stresses that: "laboratories that produce generics will have to understand that they must comply with bioequivalence studies; otherwise we will take them out of the market."

The request for bioequivalence could be a game changer. Companies producing similares could be forced out of the market, or to drastically change their practices. According to Carlos Cicogna, managing director of MSD Chile, it could also drive investments from MNCs in the country: currently, MNCs are responsible for more than half of the bioequivalent generics on the market. "The environment is getting more attractive for innovators such as MSD: with the new regulations we will see an equal playing field; fair conditions are being implemented. And as a result there is an increasing interest from the industry to increase investment in the country."

Cicogna, who has been in Chile since 2009, has already witnessed drastic change in the market: "There have been two major developments in the past five years: the implementation of the new drug law and the shift in landscape: the top players on the Chilean pharmaceutical market used to be local players, but today the key players are multinationals."

From left: Jean Jacques Duhart, executive vice president, CIF; Erich Viertel, country manager, Janssen

Another proposal currently being discussed in parliament is the complete overhaul of ANAMED, the national regulatory agency for medicines in order to bring it in line with other regulatory bodies around the world. Elmer Torres Cortes, general manager of ASILFA (the association representing generics companies in Chile) explains, ANAMED is currently part of Chile's Public Health Institute, but should be separated in order for it to stand as an independent regulator of medicines. The current plan being discussed for ANAMED is for it to reach level four of the Pan American Health Organization (PAHO) assessment table, at which point it can be designated a reference authority for medicines. "ANAMED should be autonomous, independent and capable of monitoring the local and international industry. We believe this is fundamental for the pharmaceutical industry in Chile," Cortes adds.

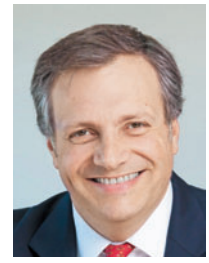
THE R&D INCENTIVE

With the goal of making Chile a hub for innovation, the Chilean Ministry of Economy and CORFO, the Chilean Economic Development Agency, announced last year that four multinational companies would invest in new research and development centers. From the pharmaceutical sector, Pfizer will invest in a precision medical center studying new genome-based diagnostic technologies for cancer. The aim is to enhance Pfizer's precision medicine approach to help understand the underlying biology of disease and identify patients likely to benefit from new drugs.

For the project, Pfizer partnered with the government to develop technology and research: CORFO has contributed USD 7 million out of a total investment of USD 21 million. "Our expectation is that with the initial support of the government, this will be the first of a series of programs that Pfizer will develop in Chile," explains CORFO's executive vice president Eduardo Bitran. "With this subsidy, which we consider seed money, we expect Pfizer to change its view of the country and continue to develop applied research in Chile. As a country we are sending a signal with the aim that other pharmaceutical companies will follow suit."

Chile Report

This strategy seems to be paying off: "The feedback from the industry has been extremely positive and as a result we have received many inquiries about the center," says Ricardo Avila, medical director at Pfizer Chile. "It seems that there is an increasing interest to increase investment in the country." Pfizer's country manager in Chile, Carlos Murillo, feels responsibility to turn this project into a success in the coming years and believes that Pfizer has paved the way for Chile to position itself as a biotech hub for Latin America. "I expect the ecosystem to start flourishing soon," he asserts. "This country is for our company an example of how we can work in partnership with the government."



From left: Carlos Cicogna, managing director, MSD; Elmer Torres Cortes, general manager, ASILFA

Over the past decade, as clinical research activities have been growing steadily within Latin America, Chile has worked hard to become a regional leader for conducting clinical trials. Due to its qualified human capital base and favourable government environment, the country has competitive advantages for developing such a cluster. Currently, Chile lead the per capita rate of clinical trials in Latin America (0.34 per 10 000 inhabitants, threefold of that of Brazil or Mexico).

Roche has a long history of conducting Clinical trials in Chile. Currently the company has 19 on-going trials in 10 different disease stages and is eager to conduct more in the future. According to Ciro Caravaggio, general manager of Roche conducting clinical trials in Chile can be expensive, the process can be slow, and requires significant approval hurdles. "Furthermore, many don't see the value the trials can bring to a hospital or a patient. For a major oncology hospital,

Tecnofarma: an outstanding example

Antonio Avila, general manager, Tecnofarma

With the introduction of the measures to enforce bioequivalence, companies must adapt quickly if they want to continue to compete in the market. Tecnofarma, a Uruguayan company that has been in the Chilean market since 1983, is moving rapidly on this front, and is bullish about its future prospects in the country, having recently secured new Santiago office space as part of the company's continued growth plans.

Antonio Avila, general manager of the company, arrived in 2011, after working experience in Venezuela and Dominican Republic, with a fresh outlook on the business. Avila adapted the business model to the current needs of the market. The company increased its business units and launched new products to the market while focusing on its core products. With a broad product portfolio, Avila is currently focusing on products for oncological and non-oncological therapies. "Tecnofarma launches about 4-5 products per year," Avila says. "This is challenging for a pharmaceutical company and only succeeds with a well-planned business model."

The company has a positive attitude towards bioequivalence and Avila is confident that the company will meet the deadlines for bioequivalence standards for its products in Chile: "The government created three product lists detailing the dates by which the products should have proven bioequivalence and therapeutic efficacy. We are already advancing on each list and I am positive we will reach the objectives," Avila explains.

Chile from a manager's perspective

Ciro Caravaggio, general manager, Roche

Ciro Caravaggio took the helm of the Chilean operations of Roche a little less than three years ago after an experience in Roche's headquarters in Basel, and a career with the same company in his home country, Canada. Caravaggio describes how different Chile and the Chilean environment were from what he expected.

First and foremost I found healthcare was more politicized and in the media than I was used to.

In particular as I arrived we were in the midst of launching Herceptin, a revolutionary product for the treatment of breast cancer. Herceptin was not reimbursed in the public setting at the time and several actors where pushing to get the drug approved. Immediately it became clear to me that there was no formal evaluation process in place. Naturally each country is different in terms of market access and its reimbursement system but what was different in Chile is that the industry is not officially part of the reimbursement or access process.

Cécile Bassereau, managing director, B. Braun

Cécile Bassereau, managing director B. Braun Chile, took over the reins of the Chilean operation in 2012. She describes the challenges and achievements she faced as the head of local operations.

I took the helm of a German company, in Chile while being French. In such a multicultural environment I am trying to transmit that we have to be flexible and tolerant without prejudice.

Chile has been developing extremely fast, with a five percent GDP growth rate in the past decade. Nevertheless public hospitals in Chile do not have access to some state-of-the-art technology and sometimes the cost of a medical device looks like a barrier. But it is important to look at long-term benefits. That being said, it is a challenge and our responsibility to influence decision makers to make them adopt a long-term cost benefit approach to treatments with the help of state of the art technology.

João Simões, head of integration, Grünenthal Chile

João Simões has been with Grünenthal since 2004. Prior to his appointment as head of integration at Grünenthal Chile, he served as CFO for Latin America and country manager, in his home country, Portugal. Simões elaborates on the fundamental differences between a country like Chile and Southern European markets.

I see similar trends in terms of healthcare. In Southern European markets, healthcare is substantially funded by the government. In Chile we see a similar trend as the newly elected government is moving forward with the improvement of the country's healthcare system; increasing coverage for Chileans.

Public healthcare in Chile is improving its quality, but the coverage on medicines is still below the expectation of its people. Chileans want access to medicines for which they do not have enough resources. Universal healthcare is a global trend, which we also see in Chile.

Although I see both worlds coming closer the Portuguese and Chilean market dynamics are still quite different today. Healthcare in Portugal is mostly funded by the government, while Chile still has a high patient out-of-pocket expenditure on health.

clinical research is an integral part of care and not an afterthought; it is critical! So many patients are at the end of their treatment and want new hope."

Historically the clinical trial environment has been seen as a matter for international companies but the CIF is working hard to turn around this situation. "We are working on involving more local partners in clinical trials and research and development. It is our ambition to establish Chile as a leader for clinical trials and research in medicines", CIF executive vice president, Jean Jaques Duhart said.

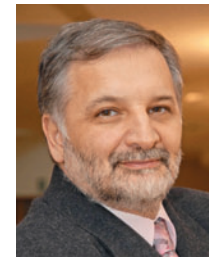
CHANGING LANDSCAPES

Pharma M&As are back with a vengeance. Latin America, which is predicted to grow two to three times faster than developing markets in the years to come, has been a prime target. Chile has not been spared in this recent activity, with several acquisitions in recent months.

The dealmaking in Chile started in December 2013 when Grünenthal Group, an international research-based pharmaceutical company headquartered in Aachen, Germany, completed the acquisition of Andrómaco Laboratories for an undisclosed sum. Andrómaco is a leading Chilean pharmaceutical company with over 70 years in the market that specializes in prescription drugs, but also has a wide range of high technology products, generics and OTC. Grünenthal accepted the public tender offer with respect to the acquisition of all issued and outstanding shares of Andrómaco.

João Simões, head of integration at Grünenthal Chile, explains that the acquisition has been a

major step in the company's growth strategy and has almost doubled its revenues up to USD 450 million in Latin America. In the words of Grünenthal Group's CEO, Eric-Paul Pâques: "With Empresas Andrómaco, we acquire the best regional company to complement our own business and our therapeutic areas in the Andean countries and Central America." In Chile, it propelled Grünenthal into the market's top four companies.



From left: Carlos Murillo, country manager, Pfizer; Eduardo Bitran, executive vice president, CORFO

In May 2014, Alliance Boots, a British pharmacy-led health and beauty group, signed an agreement to acquire Farmacias Ahumada (FASA) Group. FASA is a publically-listed pharmaceutical specialist in Latin America comprising of two retailers: Farmacias Benavides, based in Mexico and Farmacias Ahumada, based in Chile. Together the retailers operate over 1,400 stores, with combined revenues of around USD 1.4 billion: the third largest retail pharmacy chain in Mexico with around 1,000 stores, and one of the three largest retail pharmacy chains in Chile with around 400 stores.

The latest move in a series of multi-billion dollar deals came in May with year, with the acquisition of CFR Pharmaceuticals by Abbott Laboratories. The largest maker of heart stents and adult nutritional beverages joined the wave of mergers and acquisitions with a USD 2.9 billion agreement to acquire Chile's biggest drugmaker. Santiago-based CFR sells a range of products for women's health, heart and respiratory diseases in 15 markets across

Prescription Drug Sales in Units		
Top 5 Ranking 2011		
		(Mkt Share)
1	Laboratorio Chile	6.2%
2	Laboratorio Saval	5.2%
3	Andromaco	4.7%
4	Recalcine	4.3%
5	Laboratorio Bago	3.8%
Top 5 Ranking 2014		
		(Mkt Share)
1	Laboratorio Chile	5.8%
2	Grunenthal Group	4.9%
3	Saval Corp	3.8%
4	Abbott Corp*	3.8%
5	Bayer	2.7%

*Recalcine and Abbott consolidated

IMS Data April 2014

Deutsche Pharma: partner of choice

Luis Aguilera, general manager, Deutsche Pharma

Deutsche Pharma stands out as one of the more interesting cases of a local success story. The company was established in 1992 and expanded internationally to Ecuador in 1995. Two years later, when the Chilean branch got acquired by Sanofi, Luis Aguilera, Deutsche Pharma's general manager, continued leading the company in Ecuador. In 2008 Roemmers acquired the Ecuadorian based company and Aguilera decided to re-establish Deutsche Pharma in Chile. Today the company commercializes its own brands and acts as distributor, supplying the local market with a variety of products for paediatrics and dermatology. Focusing on high value products, Aguilera has found partnering to be an indispensible part of the company's strategy. "There are segments of the market that have unmet needs and that is why we are constantly looking for partnerships that will add value to our portfolio," he said. The company recently partnered with a New Zealand based company for the distribution of the very first bioequivalent isotretinoin, a medication primarily used to treat cystic acne.

Multi Latina

Biosano, a 100 percent Chilean pharmaceutical manufacturer that specializes in injectables, is a good example of the many corporations that start in one Latin American country and spread throughout the region. "A company active in the Chilean pharmaceutical market has to reinvent its business model every three years because today we are competing against some of the largest multinationals," says Maurizio Reginato, Commercial Director at Biosano. Biosano's strategy is therefore to expand its services portfolio and to increase its export markets. The company currently exports to 13 Latin American countries and Biosano is already present with a direct office in Colombia. Additionally the company is in the process of opening offices in Peru and Ecuador. "Given our expertise in manufacturing products under international standards, our current aim is to build a regional network with which we can expand our activities into the fast growing Latin American market," explains Reginato. In order to expand its product portfolio the company is looking at biotechnological products. "We are in the process of concluding partnerships in order to launch biotechnological products into the market place," Reginato adds.

Latin America. The deal will more than double its branded generic drug business in Latin America and establish the company among the top 10 pharmaceutical companies in the region.

A PARTICULAR MARKET

Although Chile is a relatively small market, with only 17 million inhabitants, its geography makes it a challenging environment for logistics and distribution services. Chile stretches over 4,300 km along the southwest coast of South America, a distance roughly the same as that from San Francisco to New York. At the same time, its width never exceeds 240 km, making the country more than eighteen times longer than its widest point. It goes without saying that Chile's harsh geography, typified by the Andes mountain range, is one of the major challenges for the distribution of drugs.

Chile Report

"Reaching the outlying regions for private laboratories is very complicated to achieve," says Edgardo Díaz Navarrete, director of CENABAST, the public purchasing entity and distributor for all public hospitals and clinics, and Chile's de facto largest purchaser. "We reach the whole country, either through own distribution system or that of a logistics operator," says Navarrete. "We have managed to expand our reach by establishing great partnerships with third parties that allow us to conduct our services uninterrupted."

From left: Edgardo Díaz Navarrete, director, CENABAST; Raúl Sánchez, general manager, Peri Logistics

But this is not the only particularity of distribution in Chile. "The Chilean market place is very particular," explains Raúl Sánchez, general manager of Peri Logistics. "For example, the pharmaceutical market is characterized by the vertical integration and dominance of three major pharmacy chains in the country, which control together 92 percent of the market. This is something you don't see anywhere else in the world. And, international logistics providers that decide to come to Chile must take such particularities into account."

"Since 2007 we have been working with the Ministry of Health for the distribution of vaccines and one of our first customers was CENABAST," Sánchez adds.

Unlike large international logistics companies such as DHL and UPS, both of which are present in Chile, Peri Logistics only works with pharmaceuticals or supplements. One of Peri Logistics' strengths is its cold chain expertise. Peri Logistics recently expanded its services to address the need for specialized temperature-controlled ground transportation services. The company's facility accommodates seven cold storage rooms, which allow them to successfully conduct the annual vaccination campaign.

The Overview effect

Eduardo Loyola, general manager, Heel

A company specialized in homeopathic treatments, Heel has had to develop an innovative marketing strategy in order to compete with Western medicine in its chosen markets. Much of Heel's success in the Chilean market can be attributed to Eduardo Loyola, who has been at the helm of Heel's Chilean affiliate for almost a decade, and has, through his innovative view of the market, helped homeopathic treatments be introduced alongside their better-established Western counterparts. "Generally, the person taking family decisions on medicine in Chile is the mother," Lozoya explains. "As a result, we focused our marketing strategy on paediatrics, which is also one of the largest if not the largest group of doctors in Chile. From the doctors we learned that mothers were often looking at a less aggressive cure for their children's illnesses. Doctors were not able to provide such an alternative. This was a huge opportunity," he continues. "We educated paediatricians about our products and consequently reached the doctors."

"Since I was appointed, Heel Chile has grown at a rate of over 20 percent per year. I believe that when I joined Heel, only 30 doctors were involved in alternative therapy. Today there are 3,000 doctors involved and this number is increasing." Lozoya compares his management technique to the Overview Effect, first described by author Frank White in 1987, an experience that transforms astronauts' perspectives of the planet and mankind's place upon it.

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idea of how the target company conducts its business and what are its touch points for regulatory risk. The next step should be to focus the due diligence on those issues that pose the highest degree of risk, be they antitrust, trade and customs compliance, anti-money laundering, anti-bribery, or compliance with applicable local laws. M&A due diligence teams often include anti-corruption specialists, for example, who concentrate on distinct issues from the matters reviewed by the transaction due diligence team.

Each team will want to work alongside the legal department in drafting document requests and interviewing key employees of the target company. In the often hectic days before signing a deal, much of the challenge lies simply in coordinating the various due diligence teams and ensuring that they are not duplicating each other's efforts. Access to one common online dataroom, for example, is practically a must-have for M&A deals in which due diligence teams do not share the same office.

What information should be reviewed during the investigation will depend largely on the type of risk presented. At the very least, the company's legal, accounting, and compliance departments will want to analyze the target's sales and financial data, its customer contracts, as well as its third-party and distributor agreements. For certain heightened risks, compliance may seek to audit selected transactions engaged in by the target or conduct due diligence on the target's primary third parties. The acquirer should also conduct due diligence on the target's key employees, looking not only for evidence of past wrongdoing, but also to understand the culture of the organization and the roles, capabilities, and attitudes of its people.

Photo: Thinkstock

Determining what to do with evidence of prior wrongdoing presents its own unique challenges. Not all wrongdoing will be a deal breaker, of course, especially if the target is already aware of the problem and presents evidence of having conducted its own remediation. But other times, the acquirer may unearth new issues that the target was unaware of, which can be more troublesome and may even require regulatory disclosure. The target's response and degree of transparency in those situations will often dictate the tone of the deal.

Beware of mines

In practice, however, regulatory landmines rarely lie just beneath the surface. Instead, M&A due diligence will usually reveal potential compliance red flags that simply evidence areas of heightened risk. Quite often, compliance professionals may need to rely on a more basic, guttural reaction in deciding whether the company's risk is worth the cost. Done properly, pre-acquisition due diligence can be essential to acquirers in deciding whether to accept a deal and determine the price they are willing to pay.

Developing a post-acquisition plan to fully integrate the target company into the buyer's compliance program may also help mitigate some of these concerns. The acquiring company should ensure that its anti-corruption policies and procedures are implemented within the newly merged entity and that the target's directors, officers, employees, agents, consultants, representatives, and joint venture partners are promptly trained on applicable laws and the company's related policies. All red flags raised during the pre-acquisition process should be thoroughly explored and any employees found to have engaged in prior wrongdoing should be appropriately disciplined.

Be safe, not sorry

In today's heady bull market, many will seek to exploit the M&A boom. But companies would do well to be cautious of who they choose to bed with, lest they wake up with regrets the following morning. Expect compliance officers to play an increasingly important role as gatekeeper, which, in the end, is good news for business. PE

Google Glass—A User's Guide in Healthcare

Three medical affairs experts review the capabilities of Google's latest state-of-the-art technology for delivering information to healthcare professionals in the field. The bottom line? It's a work in progress.

Google Glass represents a technological advance in the form of a wearable computer product. In the health sector, Google Glass is envisioned to provide unique benefits for communicating medical information to healthcare professionals (HCPs). Private communication is achieved via the built-in bone conduction speaker and small screen, which is discernible only to the wearer; therefore, HCPs can privately receive information when others are present. Since the entire device is housed within a glasses-like head mounting, the hands are free to take notes or perform other related tasks while receiving information. The big question for sales professionals is whether this will work well in practice. To test Google Glass in real-world settings, we purchased three Google Glass units and went to work.

We configured Glass by connecting to an existing Google account and installing the MyGlass app on an Apple iPhone 5. Initial configuration was straightforward and took only a few minutes. By default, Glass enables reading email and SMS messages, performing voice-based Google searches, accessing webpages via emailed URLs, recording video, and taking a picture. Additional apps like Evernote and YouTube are enabled using the MyGlass app via mobile device or computer web browser.

Google Glass does not provide any mechanism for accessing private file data on company servers sitting behind a firewall on the corporate network. There is currently no browser access to user-requested web pages as is common on a computer browser or mobile device. Webpage text field entry capability does not exist, inhibiting entry of usernames, passwords, and entering data on web forms. Therefore, information presented in Glass required access to information only from publicly Internet accessible sources.

Files cannot be "downloaded" to Glass in the traditional sense, though they can be accessed as attachments to emails, SMS, or otherwise from the timeline or application. At this time, Google Glass has no built-in capability to display Microsoft PowerPoint slides, which are the standard in the medical industry. To achieve the aim of delivering slide-based data to HCPs, we first converted slides into individual JPEGs so they could be viewed in Glass. These files were then placed on a publicly accessible webserver. Emails with the URL were sent to a Glass attached account so the URL could appear in the timeline. In Glass, clicking on the card and choosing "View Website" allowed the Glass wearer to view this information.

What we found

Google Glass has not yet matured to a level consistent with modern computers, tablets, and smartphones. Its current functionality is limited, in the following ways. Bluetooth and Wi-Fi radios are built-in but it lacks native cellular mobile data capability. There is no menu option for browser access; the browser is accessed by emailing URLs to the account linked to Glass. There is no video player capability, nor can one view PDF or Office documents. Glass cannot be used to complete any type of web-based form and is without a keyboard (at the time of testing). It, therefore, cannot log into private websites and enter any personal information or credit card data; likewise, adding terms to search boxes as if you were searching the medical literature cannot be done. Glass does not browse content well; the card user interface and resolution provide severe limitations. By default, moving from card to card requires hand gestures that require some practice to achieve consistent results. This is problematic for uses that require handing the device to a HCP unfamiliar with the device.

In spite of existing limitations, Glass still has many potential applications across the medical information landscape. In the commercial setting, sales reps can use Glass to access any approved information in response to a physician request and can hand Glass over to the medical information group for off-label requests. Glass can also direct access to patient support services and be used to record on HD video unsolicited requests and all interactions when making office visits. All sales training material can be accomplished through Glass, and, as a hands-free device, the tool may allow people in remote areas to participate in training.

Potential benefits in the area of medical affairs include recording and disseminating presentations in real-time; posters and podium presentations at medical congresses, especially in sharing those with colleagues in remote areas; and gathering competitive intelligence, though, here, caution is advised.

A useful application of Glass in the clinical arena may be through physician-administered quality of life instruments.

In conclusion, given its present configuration, Glass merits consideration for some specific information-based uses. Continued evaluation is recommended. PE

Sean Turbeville is Senior Director, Medical and Scientific Affairs, at Sunesis Pharmaceuticals. He can be reached at sturbeville@sunesis.com. **David A. Wells** is Principal Consultant at Wells Medical Research Services. He can be reached at david@wellsmedicalresearch.com. **Charles Wolfus** is a Biotech IT Leader. He can be reached at cwolfus@gmail.com. Glass is a trademark of Google Inc.

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