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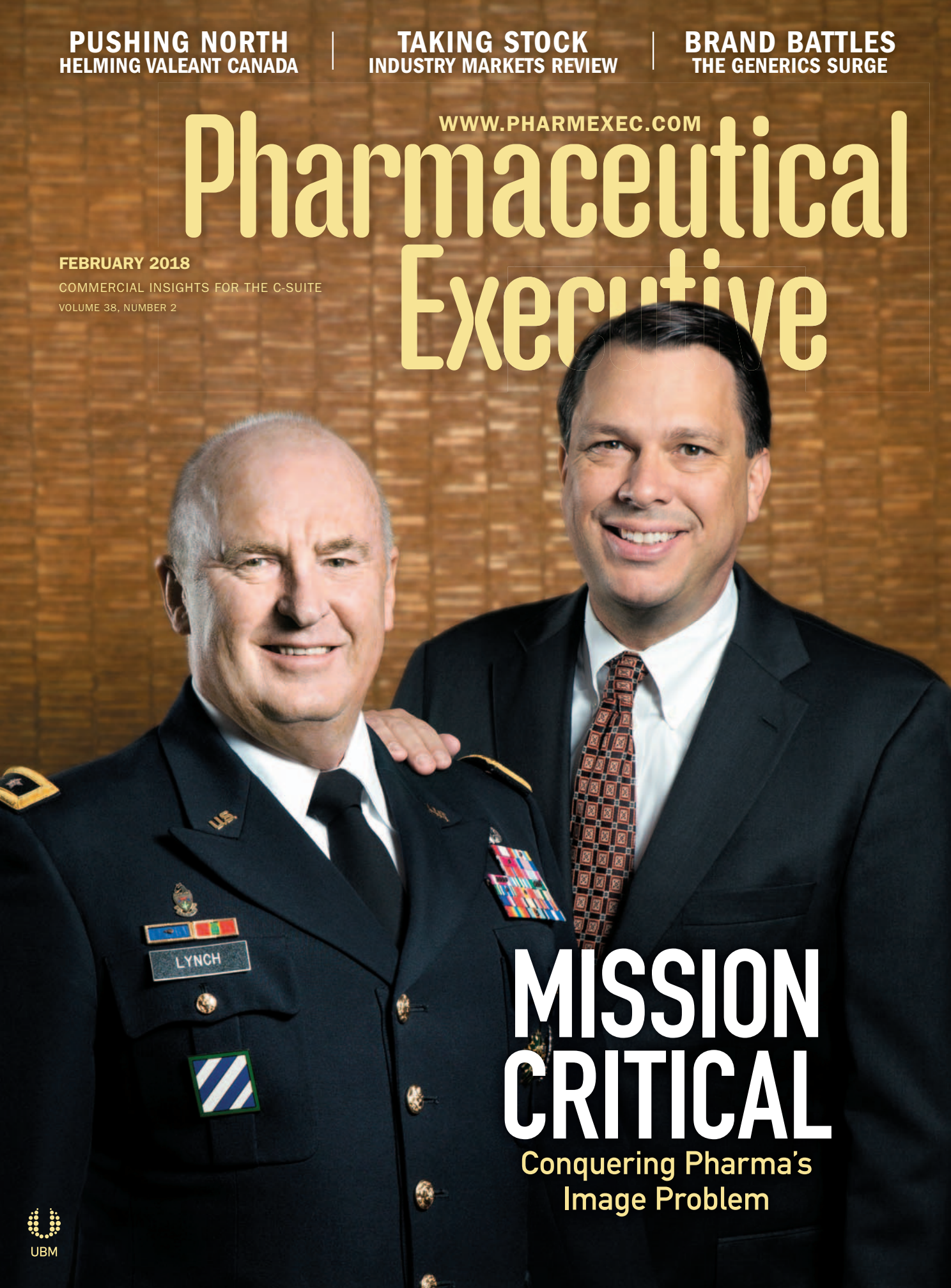

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Leadership in All the Right Places

THIS TIME OF YEAR IS HARD ON FOOTBALL COACHES. There is a mindset that because you were a great college coach, or a defensive coordinator or offensive coordinator, you will make a great head coach in the NFL. But it doesn't always work out. We know that in business, it's called the Peter principle. Basically, people are hired or promoted based on their performance in their current role, not evaluated on their abilities for the intended role. This leads to the quote "Managers rise to the level of their incompetence." Of course, you have to work your way up and be a coordinator on the way to head coach. But we've seen enough examples where someone is excellent exactly where they are, and the next step just isn't for them.

LISA HENDERSON
Editor-in-Chief
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There are very inspirational coaches out there. I happen to be the type of person who is a sucker for movies like *The Blind Side*, *Friday Night Lights*, *Remember the Titans*, and *Invincible*. I saw Coach Don Shula keynote at a conference, and his stories brought tears to my eyes. My colleagues thought I was nuts. But it is a magical thing to watch someone lead a team who really loves their players and the game. And there is also no mistake that some great former coaches have brought in and mentored some of today's great coaches.

So the question becomes how do companies do that for their teams? How can they best evaluate who is going to be the right executive leader to take their company through the challenges facing the biopharma industry today?

As I evaluate the content in this month's issue, and sit it next to upcoming issues on talent (in April) and leadership in June's annual Pharma 50, a theme is emerging. That theme is the ability to change, transform and adapt.

In last year's Pharma 50 (view: http://bit.ly/2Bv1Rnl), the focus was on three new areas necessary to navigate the current pharma terrain —transformative, ecosystem and enablement. The transformative leaders are the ones that help their organizations adapt and grow into ones that can meet the challenges of a new industry landscape—either in regard to digital technology, or big data or innovation. The ecosystem leaders shape the organization's role in regards to its external stakeholders and builds long-lasting partnerships or effectively communicates the value of pharma products and services. And the last group, enabling leaders, can address the issues of administration and operations that may be under duress from M&As or other internal disruptions, and focus on people and culture and organizational efficiency and productivity to breathe new life into hardened processes.

In the upcoming June Pharma 50 article, the authors from Russell Reynolds Associates will tackle the challenges around assessing leadership capability and offer interesting insight into the paradoxical traits that today's leaders need. They present robust data on pragmatism as an increasingly important trait necessary for the C-suite pharma executive as market pressures build.

In April, we are speaking to a number of recruiters and consultants to uncover where pharma and biotech talent is coming from, what experience and skills are most needed, and how employees are mentored or coached to be promoted into new roles.

Finally, in this issue, we are examining the industry's bad reputation and what can be done to fix it (see page 8).

One way, from the eyes of military leader Lt. General (Ret.) Rick Lynch, is to hire "adaptable leaders who possess a strong moral compass." For the article on page 12, I had the privilege of attending an "Adapt or Die" meeting convened in Philadelphia in early December. I was able to listen in on the topic of mentoring and learn how strong mentorships—not the kind that HR mandates as part of its mainstreaming activities—but how mentorships formed on the basis of trust, availability and open advice have worked in pharma and the military. Bob Oliver, a member of the Board of Directors and Chief Executive Adviser of Hyalo Technologies, and his mentor, J&J Chairman and CEO Alex Gorsky, shared their mentoring stories, as well as Alicia Secor, President and CEO of Juniper Pharmaceuticals, who spoke very highly and fondly of her mentor, Henri A. Termeer, former Genzyme CEO, who passed away last year. In many cases, these mentorships look suspiciously like friendships, but with the added value that the mentor has actually walked the path that the mentee is on.

The Adapt or Die meetings focus on a series of topics related to adaptable leadership, and were formed in part "so people can see what right looks like," as Lynch says.

In today's world, there are plenty of examples of what wrong looks like. Which is why we look for stories of hope, people that inspire, or watch football games, where the battles aren't complicated. We simply want to see more examples of what right looks like.

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Pharma's Reputation: Mission Critical

Accentuate the Positive

Julian Upton, European and Online Editor

Whether the pharmaceutical industry is navigating calm or choppy waters, it should be smarter and more assertive in telling its story to its stakeholders—most importantly, patients and the wider public.

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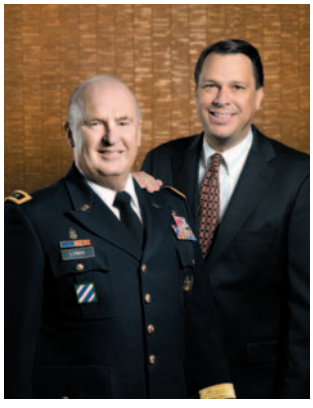

Lt. Gen. (Ret) Rick Lynch, US Army, and Bob Jansen, CEO of Zensights (Photo: John Halpern). A special thanks to Tony Alicea, Philadelphia Marriott Downtown.

'Adapt or Die': Lessons from the Battlefield

Lisa Henderson, Editor-in-Chief

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In its ambition to further strengthen the nation's relationship with the global industry, Brazil holds a valuable, eye-catching asset: the dynamism of its huge pharmaceutical market, the sixth-largest in the world.

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More New Drugs, Generics Reshape Pharma Markets

Low-cost follow-ons and biosimilars please payers but heighten competitive battles with brands

Amidst all the outrage over surging pharma prices, the continued growth in generic drug prescribing has moderated overall spending on medicines, cooling the political heat on industry. Generics now account for nearly 90% of prescription drug use in the US due to policies facilitating their development and regulatory approval. But while generic gains have slowed drug price inflation, the competition has hit brand revenues and profits. The much-anticipated growth in biosimilars, moreover, should further squeeze returns on expensive biotech therapies.

These developments are driving innovators to take advantage of strategies likely to delay the development and marketing of follow-on products. FDA has approved nine biosimilars, but only a few have come to market due to court battles over patents. A major complaint of generics makers is that pharma companies limit access to reference drug samples needed for bioequivalence testing and biosimilar development by abusing FDA-restricted distribution programs.

Competition 'hit list'

FDA Commissioner Scott Gottlieb has responded with a campaign to increase market competition to offset such "gaming" of the drug regulatory and legal system. A main strategy involves encouraging the development and approval of complex generics and combination products, as proposed in a June 2017 Competition Action Plan. FDA also unveiled a "hit list" of more than 250 off-patent, off-exclusivity brand drugs that lack approved generic competition and thus merit FDA assistance in developing alternatives and in expediting product approvals.

At an FDA public meeting in July, manufacturers and health policy experts discussed a range of innovator actions used to block generic marketing, including citizen petitions, labeling issues, late formulation changes, and the use of Risk Evaluation and Mitigation Strategies (REMS) to stymie new generic testing. Similar topics were raised at a November 2017 Federal Trade Commission (FTC) workshop on competition in US prescription drug markets. At that meeting, Gottlieb emphasized the importance of more streamlined development and approval of generic drugs and biosimilars and warned pharma companies to "end the shenanigans" that delay competition and extend a drug's monopoly beyond intended timeframes.

FDA also has published more product-specific guidance documents to help speed approval of complex products, synthetic peptides, and generic versions of opioids with abuse-deterrent features. Agency workshops last fall discussed strategies for developing complex dosage forms where traditional bioequivalency and bioavailability tests may not support approval. Further FDA advisories will address development of difficult formulations, such as ophthalmic suspensions, gels, and inhaled drugs. And FDA is offering to meet with generics manufacturers to discuss R&D issues, such as how labeling can address design differences between a generic and brand.

Equally important are agency efforts to streamline the process for evaluating and reviewing all new generics. FDA approved more than 1,000 new generic drugs last year under a more automated review process supported by generic drug user fees. The added resources helped reduce a huge backlog in unapproved products and achieve a more predictable review process.

Seeking balance

At the same time, FDA approved a record 46 innovative new drugs in 2017, plus landmark gene and CAR-T cellular therapies and vaccines regulated as biologics. With thousands of new medicines in the R&D pipeline, these trends are likely to continue, bolstered by FDA flexibility in the development and review of important breakthrough therapies.

The challenge to FDA and industry is to maintain a balance between encouraging the development of important new medical therapies and assuring access to low-cost follow-on medicines. Biopharma companies emphasize the need for incentives to test new therapies and to develop added indications to an approved product. Yet, driving change through

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increased competition is an uncertain business. FDA support for generics is visible in its recent approval of the first generic version of the leading multiple sclerosis therapy Copaxone, and the rejection of efforts by Allergan to block generic competition to its blockbuster eye drug Restasis. But so far, there has been limited industry response to FDA's list of drugs that lack generic competition, as many products involve small markets and costly R&D processes.

More new drug approvals are good news for sponsors, but that also can spur competition within a drug class, as seen with hepatitis C therapies. And while there's public outrage over steep hikes on drugs to treat rare conditions, as with a 1,400% increase on a 40-year-old drug now used to treat certain brain tumors, such moves have less impact on broader spending than the annual price hikes on big-selling treatments for depression, high cholesterol, and rheumatoid arthritis. Even though industry leaders kept recent increases on such drugs under 10%, as promised, these modest hikes are the main drivers of revenues and profits.

A major complaint of generics makers is that pharma companies limit access to reference drug samples needed for bioequivalence testing and biosimilar development by abusing FDA-restricted distribution programs

Meanwhile, generics makers claim that the squeeze on revenues due to anticompetitive brand tactics, along with distributor and wholesaler consolidation, discourages their investment in modern manufacturing systems needed to ensure product safety and quality and avoid recalls and shortages. Teva Pharmaceuticals is instituting massive layoffs and shuttering manufacturing and R&D facilities to regain financial health. Novartis' Sandoz division says that price pressures may lead to reductions in its US product portfolio and a greater focus on developing biosimilars and complex formulations. And high-profile price increases on older generic products have generated backlashes and allegations of collusion and price gouging, particularly from state prosecutors.

Congress is paying attention to these developments as it continues to weigh proposals for managing drug costs and outlays. The House Judiciary Committee examined barriers to generic drug development at a hearing in July 2017. In December, the House Energy & Commerce Health subcommittee discussed proposed legislation to support access to affordable drugs. Drug prices and exclusivity were hot topics at the recent confirmation hearing for former Eli Lilly USA president Alex Azar to be secretary of the Department of Health and Human Services, and will continue to grab headlines. PE

New payment strategies proposed for costly breakthrough

Spark Therapeutics made headlines last month in rolling out an $850,000 price tag on its gene therapy Luxturna for a rare form of blindness—less than the $1 million anticipated by analysts, but still a huge, one-time outlay. To offset the sticker shock, the company also unveiled some innovative pricing programs. For commercial plans and insurers, Spark proposes to provide rebates to payers if the therapy fails to perform as expected, both for short-term results and over a longer 30-month period. Spark also proposes that payers purchase the therapy upfront, instead of hospitals or treatment clinics buying and then marking up the drug under the usual "buy and bill" model. And for government health programs, Spark is discussing an annuity model with the Centers for Medicare and Medicaid Services (CMS) that spreads payments over multiple years.

This approach may start with a pilot program, as implementation would require changes in the US anti-kickback statutes and Medicaid best price rules. These regulations aim to prevent overuse and excess spending on medical products and procedures, but also block adoption of value-based payment models. Spark is exploring further pricing approaches for one-time therapies with the Duke-Margolis Center for Health Policy Value-Based Payment Consortium of patient groups, clinicians, employers, manufacturers, and public officials.

Accentuate the Positive

Tackling Pharma's Reputation Problem

Whether the pharma industry is navigating calm or choppy waters, it should be smarter and more assertive in telling its story to stakeholders

By Julian Upton

"Merck's Head Defends Drug Prices," ran *The New York Times* headline. *The Times* was reporting on the Merck & Co. president's testimony at the previous day's Senate hearing, part of a high-profile investigation into the price-setting activities of the US pharmaceutical industry. Merck's leader offered a robust defense, stressing that the industry was highly competitive and that it was actually giving the American public "a reasonable bargain." But *The Times* reporter noted that the testimony was an indication "of the drug industry's realization that its reputation was on trial."

The date of this news item? December 9, 1959.

Merck's head at the time, John T. Connor, was one of a number of leaders summoned by the Antitrust and Monopoly subcommittee, zealously headed by Democrat Senator Eftes Kefauver, which brought to the public's attention allegations of drug manufacturers "exploiting the aged, infirm, and sick in the United States by charging more for their products in this country than abroad" *(New York Times*, December 5, 1959). The subcommittee presented evidence that the price of one drug had been increased by its manufacturer by over 1,000%, while the price of another represented a markup of 7,079%. In refuting these explosive claims, Connor and his contemporaries, such as Schering's then-president, Francis C. Brown, attempted to educate the Senate on the realities of the pharmaceutical business—pointing out, for example, that 8% of its sales dollars went into research, compared to 2% for the industry generally—but this did not stop the investigation rolling on for the next two-and-a-half years.

The industry would finally emerge from the official probing "with more damage to its prestige than its purse," wrote John M. Lee in 1962 (although the out-of-pocket cost of defending its reputation was estimated at $5 million, around $40 million today). Lee added that the principal effect of the Senate hearings was "to arouse the industry to a realization that it has to do a better job in telling its story to the public" (*New York Times*, April 22, 1962).

It is somewhat unnerving, although perhaps not surprising, given the industry's inherent conservatism, that Lee's remark from 1962 still applies nearly 60 years later. But the public-relations crises that have dogged pharma in the last decade particularly, whether seized upon by Democrat or Republican politicians, have seen the bouts of official and public anger with the industry—largely contained in 1959 by a more sober and deferential media climate—propelled into a more hostile, 24/7 social media world, where damaging news (real or "fake") circles the globe in seconds, and can destroy careers and derail companies in a matter of days. As Dr. Nir Kossovsky told *Pharm Exec*, the "weaponization of social media" has meant that "the ability of stakeholders to be aware of failures, or even allegations of failures, has increased rapidly, and in this climate, the industry has become a punching bag."

The result is that now, more than ever, pharma has to do a better job in telling its story to the public.

Ethics and expectations

Kossovsky's firm, Steel City Re (Pittsburgh, PA), evaluates, mitigates, and insures corporate and executive reputation risk. For Kossovsky, the issue of reputation is central to the industry's dealings with all its stakeholders. "The notion of reputation can be defined as 'an expectation by stakeholders,'" he explains. "Reputation risk is the risk of

FAST FOCUS

» According to a Gallup News poll of public views on various business sectors, conducted in the US in August 2017, the pharma industry ranked only ahead of the federal government, with a 33% positive rating among the respondents. The healthcare industry received a 38% positive rating.

» Reputation management experts define reputation in the corporate setting as an expectation by stakeholders. Thus, reputation risk is the risk of a company in disappointing stakeholders by not meeting their expectations.

» When it comes to the current debate over drug pricing, experts believe pharma companies should avoid getting involved in the discussion around "is the price right?," but instead take control of the narrative by focusing on the value the treatment creates. That can include, for example, providing specifics on future cost avoidance for the healthcare system in addressing the targeted disease.

disappointing stakeholders by not meeting their expectations. When a company fails to meet expectations, those stakeholders behave in a way that tends to have adverse, objectively measurable economic consequences for the company. Customers don't buy products, don't accept the price points, and they buy less volume; employees charge more to work and there's more turnover; vendors offer less favorable terms, creditors and equity investors charge more for their capital; and regulators will apply a more severe burden, while NGOs (non-governmental organizations) apply more pressure."


Nir Kossovsky

All of these factors create costs or reduce revenue, according to Kossovsky. "The relationship between reputation and meeting expectations and enterprise value are all tightly knit," he says.

Kossovsky points to evidence that superior reputations create additional value. He cites the recent example of Merck CEO Ken Frazier's reaction to the racist protests in Charlottesville, VA, over the weekend of August 12–13, 2017. Early in the morning that Monday, Frazier held a press conference and announced that he was resigning from President Trump's Manufacturing Advisory Council. "That act raised Frazier's profile very quickly," says Kossovsky. "He was known within the industry before that, but not among the general public." There was the expected surge of activity on Google, with people searching for more information on Frazier, but in terms of the market, "for about the next 10 weeks, Merck outperformed the SNP 500 pharmaceutical index, ultimately by about 3.5%, which for a company of its size translates to creating an excess of almost $6 billion in value."

> The "weaponization of social media" has meant that "the ability of stakeholders to be aware of failures, or even allegations of failures, has increased rapidly."

And Frazier's move was no fluke, Kossovsky adds. "He showed that the company had a mechanism where they could take the event of that weekend, process it, and make a board-level decision by Monday morning. That's a lot of activity for a company of that size, and a lot of risk for a company to take. It meant they had a risk management system in place that could handle it." For Kossovsky, Frazier's action was "an incredible example of how a CEO of a pharma company can create value by raising the expectations of stakeholders and signaling that the company is indeed an ethical one."

But surely not all CEOs could hope to act as quickly and decisively as Frazier on a matter of principle? Kossovksy counters this notion: "The companies that really care about reputation and understand what it means will want to follow suit. It creates value; it's not just a 'nice thing to do.' Merck has disclosed what its risk management systems are, and from that you can see that Frazier's action was built into the company's governance structure, into its philosophy."

Still, the positive buzz surrounding Frazier's move was a rare thing in modern pharma. For Pratap Khedkar, principal at ZS Associates, another firm active in the pharma reputation space, the last three years have amounted to "definitely one of the worst period I've seen" for the industry. While nothing has matched the Martin Shkreli–Turing pricing scandal in the last 12 months, the continued pressure from President Trump, the changing of the FDA commissioner and the HHS secretary, and the debate around opioid drugs means that the topic of pharma keeps cropping up in the Senate. And it's not always about price. "There are many ways in which it is possible for the industry to be unfairly portrayed," adds Khedkar.

Kossovsky's organization looks at companies' governance and enterprise risk management processes, rather than their products. "The governance of the company controls such things as ethical behavior and promotion, marketing, and pricing of products," he says. "Because of FDA warranties, stakeholders may feel comfortable about the safety and effectiveness of products, but that is not how they feel about corporate governance."

To this end, Steel City Re offers an insurance solution that "functions like a warranty in governance." This involves, first and foremost, an inspection process that examines governance, enterprise, and operational risks from a reputational perspective. If the processes reflect a sound state of control over both stakeholder expectation management and operational conformance, and if crises management

VIEWS FROM THE TOP

Senior leaders interviewed by *Pharm Exec* in recent months share their thoughts on the issue of industry reputation.

RICHARD SCRANTON,
Chief Scientific Officer, Pacira Pharmaceuticals

We have to change because this image still persists. I was an academic, I was a researcher. As soon as I switched over to say I was working for industry, people had a different perception of me. I built a clinic at Portsmouth Naval Hospital and I couldn't get access back and forth because I was now representing industry.

We've got to figure out how do we get back to a point where we're seen as a solution-oriented group of individuals that are dedicated to the mission of improving the lives of patients. We have to look at our policies, our practices, our procedures. We have to look at the people we are putting into leadership positions, and we have to put the patient first and deliver the value to all of our customers out there. And to think hard about whether we're doing a development process because we can, versus what we should be doing.

VIEWS FROM THE TOP

YARON WERBER, Chief Business and Financial Officer, Secretary, and Treasurer, Ovid Therapeutics

The reputation challenge has been that we've not done a good job explaining how drugs are being financed, where the financing is coming from. Unfortunately, it's not coming from academic labs and then the drug just shows up and a company within a year is profitable. There's enormous risk and enormous timelines that need to happen.

No. 2, we really do believe that companies need to make appropriate decisions to go into areas that have need. You need to tackle a significant problem, which will then allow you to price your drug and really create value. You need to explain that also to your investor base; that it mirrors your strategy. Because it does not translate to a stock that goes up every six months. Your company will be successful if you do your work. That's really where the discussion needs to be and I think the discussion needs to be with the public and, frankly, with management, with the employees, and with the investor base, too.

processes are well articulated, then the company is likely to qualify for insurance. According to Steel City Re's website, Reputation Assurance is triggered, on average, by market cap losses of 24%, anticipated losses in sales of 13%, or anticipated losses in net income of 12%, but it can be triggered when anticipated losses are much lower.

"Reputation risk mitigation begins by pre-positioning an authentic story of managerial quality that will counteract the story that could be used against you, which will be some variation on 'management is incompetent,' 'management is unethical,' 'management is stupid,' etc.," says Kossovsky. "If something bad happens and it's not because the company's governance is bad, or because the board is incompetent, it's because there is a rogue, and rogues will happen. If a company has mechanisms to deal with them, it will recover."

Pratap Khedkar

Kossovsky likens having a pre-positioned story in place to the effect Federal Deposit Insurance (FDI) had on banks when rumors triggered fears that they were about to run out of cash. "You can't argue rationally once fear has taken hold, but if you already have FDI in place, you don't get a run on the banks because FDI assuages stakeholders' fear with a credible counter story: 'There's an authority saying the bank is being run well,'" he says. "Today, that's the critical element of mitigating the anger that underpins reputational risk: the affirmative story that a company is being run well must be pre-positioned, simple to understand, and completely credible."

Customer experience

ZS addresses the issue of reputation in a customer experience tracking study that the firm runs every year. As Khedkar told *Pharm Exec*, "if that does not come out so well, a company needs to ask, 'How do we redesign our organization? How do we create new messaging, new services? What do we need to do to make the customer experience better?'"

Khedkar says that most companies think of reputation as "a PR thing only," but it is something that cannot be managed just with press releases or by reacting to bad news. He explains: "If you have a portfolio of oncology products, you have to remember that there are only about 10,000 oncologists in the US. It is really important that your reputation as a company with those 10,000 people is sustained, is positive, and is based on the fact that they understand your product and that you are helping their patients with good services."

He reiterates, however, Kossovsky's distinction between the product and the company. "For a long time, the product was king," says Khedkar. "If you point to an individual product, people might say it's fantastic, but if you point to the company that makes the product, there's a disconnect. The company gets tarred with the industry view even if their product is associated with the patient benefit. Now we're finding that there are so many products competing in the space, it is customer experience that really matters."

Like Kossovsky, Khedkar recognizes the power of presenting and reinforcing a positive narrative in the public sphere. But in the social media space, for example, he believes pharma has so far been hampered by its extreme conservatism. "If there is the slightest doubt about what the industry might or might not be allowed to say, then it chooses not to say it," he explains. "But this isn't about selling or promotion, it's about owning the narrative, it's about being proactive, and it's about doing it all the time, regardless of whether things are going well for the company or not. This is where pharma needs to be a little bit more aggressive."

Khedkar concedes that, if a pharma company opens up its Facebook page to public comments, then someone, somewhere is going to post a comment about an adverse event. "But the big picture is that you have to open yourself up to some commentary," he says. "People will say things that may be somewhat negative, but then you engage. Engagement doesn't mean just one-way good news. Wouldn't you rather deal with that burden and have good engagement, which prepares you for dealing with bigger issues when they come along?"

Khedkar offers a different perspective on Kossovsky's banking industry comparison. "The banking industry's reputation really just lies with one or two constituencies: the regulators and the general public. Pharma, however, has to worry about its reputation with its patients and the wider public," he says. "It has to think about the government and the regulators. And it also has to worry about the institutional stakeholders: insurance companies, PBMs (pharmacy benefit managers), the large hospital systems. These are not patients or doctors, and yet some of these stakeholders have taken control of the narrative and pushed pharma into a corner."

Where a bank "does not have to fight some other large sector occupied by large companies saying that banks are evil, pharma can get into rows with

PBMs or insurance companies." This has led to "a kind of schizophrenic divide," says Khedkar, with some pharma companies believing they have to get along with these stakeholders at all costs, while others go on the offensive. Ultimately, a pharma company has to be able to say something to protect its reputation, he says. "That might involve challenging, in a measured and reasoned way, what another stakeholder is saying. It can also involve some measure of inviting debate, inviting criticism."

Pricing

Given that the issue of pricing goes back to those Senate hearings of 1959, it is impossible to ignore the subject in any discussion of pharma's current reputation. But Khedkar believes that pricing has

A Bum Rap? Examples of Pharma Giving Back

Pharma's reputation is often overshadowed by drug pricing, access, and reimbursement issues; but we seldom hear about what pharma companies are doing to better our communities. The following is a sampling of such industry efforts at work—designed to improve market access, education, and sustainable solutions.

Genentech: Futurelab
The company's STEM education initiative attempts to inspire and motivate students to reach their potential as the next generation of science innovators. The Futurelab program includes Gene Academy, Helix Cup, and Science Garage for students in South San Francisco's elementary, middle, and high schools. Genentech reports that only one in three students in the South San Francisco district go on to attend a four-year university. And, according to the company, half of middle school students lose interest in science by eighth grade. For the latter, Genentech created real-world, hands-on challenges through Helix Cup, an annual science competition for eighth-grade students.

Science Garage is a four-year biotech program that offers all students in the South San Francisco high school district a chance to explore biotechnology. Students can access the Science Garage biotech lab and classroom, built from a Genentech grant, and are exposed to equipment that is usually only available to professional scientists and researchers.

Mylan: EpiPen4Schools
Mylan reports that an estimated one in 13 children in the US lives with a food allergy that puts them at risk for possible life-threatening allergic reactions. To advocate for awareness and preparedness of anaphylaxis, and ensure access to treatment, the company started EpiPen4Schools. The program provides qualifying public and private schools across the US with four no-cost epinephrine auto injectors to treat students experiencing anaphylaxis in a school setting.

In five years, EpiPen4Schools has aided over 2,000 students in nearly every state to treat anaphylactic reactions. The program offers auto injectors to more than 73,000 schools across America. As of October, over one million auto injectors have been donated to schools.

Novartis: Novartis Access
This program enables wider access to drugs for non-communicable diseases in low-income countries. Novartis Access offers a selection of 15 on- and off-patent medicines for cardiovascular diseases, type 2 diabetes, respiratory illnesses, and breast cancer. Drugs are selected based on significant health needs, medical relevance, and lack of local access programs.

Novartis Access is offered to governments, NGOs, and additional institutional customers in low-income countries and priced at $1 per treatment per month. In addition to medicines, the program provides capacity building activities in support of healthcare systems to prevent, diagnose, and treat noncommunicable diseases.

Better Hearts, Better Cities
Another Novartis initiative, this program is centered on cardiovascular (CV) health in low-income, urban communities. Its main focus is to improve the prevention, detection, treatment, management, and care around hypertension, a major risk factor for CV disease, using a multifaceted, sustainable approach. The model includes strengthening health systems and innovating care provision; encouraging physical exercise through city design and urban planning; creating healthy food environments for city populations; establishing policies to encourage smoking cessation and reduce alcohol consumption; and improving air quality.

— Christen Harm

VIEWS FROM THE TOP

JACK HAMMOND,
Brigadier General (Ret.), US Army, Executive Director, Home Base

I think when it comes to big pharma's reputation, it's a double-edged sword. There are a lot of companies out there doing great things; orphan drugs, for example. Many companies will reinvest funds back into research and set up funding to cover out-of-pocket expenses for those who are financially challenged, and through their efforts, hundreds of thousands, or millions, of people are benefited and lives saved.

Pharma gets a well-deserved bad reputation when you have leaders operating with a broken moral compass trying to exploit these situations for their personal gain, and take advantage of our most vulnerable people without giving back.

I think there's a fine line between recouping your losses so that you have money for future investment, and plain out price-gouging. In those cases, you are one social media report away from becoming viral—and it's tough to come back from that.

VIEWS FROM THE TOP

BOB JANSEN, CEO, Zensights

The American public fails to realize that it is the pharmaceutical industry that springs into action when diseases like the swine flu, Ebola, Zika virus, etc. are identified and present a threat to humanity. The pharma industry reallocates significant resources and deviates from current commercial objectives to do the right thing. However, very seldom do you hear the press talking about these efforts and their benefits.

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tended to overshadow the reputation question. "The reputation management that pharma needs to do is not to get into a debate about 'Is the price right?,'" he says, "but to really focus on the value it is creating." Again, this is about taking control of the narrative. Khedkar points out that in 2016 and early 2017, "about six companies made the pledge, starting with Allergan, that they won't increase their prices more than 10%. But 95% of all price increases last year were actually less than 10%. A generic may go up 5,000%, but that will never happen with a brand. But the public can't tell the difference."

Pharma isn't conveying this message effectively; the same goes for the cost-effectiveness narrative. "The value discussion is not happening enough," says Khedkar. "How many years of life does your product provide? What kind of future cost avoidance does it create? It may be in the PBMs' interest not to let the narrative go there, but pharma really has to take control of it."

On the affordability issue, Khedkar believes pharma may become a victim of its own success. "With an effective, one-shot medicine that works straight away, it is more difficult to convince stakeholders of the long-term value," he says. "Sometimes it may cost a half-a-million dollars over the course of 20 years for a chronic therapy. But if the price is one million dollars for a one-shot medicine that works and is worth 10 million dollars in impact, the customer will still say, 'I don't have one million dollars in my pocket today. Why does pharma want all that value back on day one?'"

These are the pricing stories that pharma needs to get into—and to tell more convincingly.

Defending pharma's honor

As Founding Father Benjamin Franklin once famously observed, "Glass, china, and reputation are all easily cracked, and never mended well." With this sobering thought in mind, the industry needs to handle its reputation more carefully and cleverly, and in anticipation of any mishap, invest in some stronger glue. It is no longer possible to get by on the adage that served the industry leaders of the 1950s and 1960s: "The public doesn't understand what we do." Many people don't understand a lot of things but can still influence others with their opinions.

There is a view from that early post-war era that should still resonate today, however, and still needs to be conveyed emphatically to stakeholders. Speaking to Tom Mahoney, the author of the 1959 book about the burgeoning drug industry, *The Merchants of Life*, Thomas G. Klumpp, a former FDA official and then president of Winthrop Laboratories, put it in a nutshell: "As mother nature fails to create and maintain perfectly functioning bodies, she will need the help of the pharmaceutical industry. The important thing is we have at long last learned how to go about unlocking her mysteries. Give us time and enough profits to do research, and some day we may at least understand them all."[1] PE

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Image Fix: Lessons from the Field

The importance of an 'adaptive' command style in pharma today

By Lisa Henderson

"Leadership starts at the top."
—Morgan Wootten

"How does what you did in the military apply to what we're doing in corporate America today?"
"Leadership is leadership."
—From the book Adapt or Die, Battle-Tested Principles for Leaders, Lt. Gen (Ret) Rick Lynch, US Army

Lieutenant General (Ret) Rick Lynch, US Army and Bob Jansen, CEO of Zensights, *Pharm Exec* Editorial Advisory Board member, and former president and general manager of Source Healthcare Analytics, a Symphony Technology Company (formerly Wolters Kluwer), met at a leadership center in 2009. At the time, Jansen was with Wolters Kluwer and Lynch was commanding the US Army's Installation Management Command (IMCOM) responsible for all 163 Army installations. At

the center, the two discovered they were kindred spirits separated only by a decade, different professional backgrounds, and dissimilar educational direction. But no matter. As Jansen says, "One night, we got to talking and Rick said to me 'Why does the pharmaceutical industry have such a poor reputation?' Then he began to wax poetically about the pharmaceutical industry and what a strategic advantage it is for the United States and the free world, and how the products developed by the pharmaceutical industry saved the lives of our men and women in uniform."

Jansen explained that 99+% of people in the industry, he believes, are committed to continuing to develop breakthrough therapies to prolong and improve patients' quality of life. Jansen said, "And I'm very proud to be a part of the industry—but you have the 1% that come in and take advantage of the pricing inelasticity of the products." Lynch pointed out that the US Army post-Vietnam had an image problem as well. After American soldiers returned from war with visible and invisible wounds, the public turned its back on them, Lynch said. He told Jansen that the only way the pharma industry could change its public perception would be the way the military addressed the issue: by developing adaptive leaders with strong moral compasses. The other challenge discussed for the US military and pharma industry alike is the belief that the press wants to focus on negatives—the mentality of "If it bleeds, it leads"—discouraging coverage of the good things that come from those sectors.

Lynch and Jansen left the leadership center as good friends. Lynch retired from active duty on Jan. 1, 2012, and proceeded to write his first book, *Adapt or Die, Battle-Tested Principles for Leaders*, released in 2013. The book is an interesting and educational look at Lynch's life, chronicling the challenges he experienced and the insights gleaned as he rose the ranks in the Army. The book spans his years in the US Military Academy, to a Master's Degree in Mechanical Engineering from MIT, to command of the Marne Division and Fort Stewart/Hunter Army Airfield, to Commander Third Infantry Division and MultiNational Division Center in Iraq from June 2006 to July 2008, Commander III Corps and Fort Hood July 2008 to November 2009, and Commander Installation Management Command and assistant chief of staff for installation management from November 2009 to November 2011.

A friendship formed between Rick Lynch (left) from the military world and Bob Jansen from healthcare spawned the creation of the "Adapt or Die" leadership meeting series for senior executives in the pharma industry.

Photo/John Halpern

Jansen, meanwhile, left Wolters Kluwer/Symphony and using his extensive experience in pharma, founded Zensights in December 2012 to help biopharma leaders identify "best-in-class" vendors and further create meaningful engagement and partnerships between pharma companies and their strategic vendors.

Lynch began speaking engagements and corporate strategy advising across all industries. But Jansen wanted to bring his friend's expertise on leadership directly to a changing biopharma industry. As Lynch told *Pharm Exec*, "We asked ourselves how we could improve leadership in the healthcare industry. What could we do to help develop more effective, compassionate, concerned, and caring leaders within the healthcare industry."

Thus the brainchild of the "Adapt or Die" series of meetings. Through both of their contacts and networks, Lynch and Jansen launched Adapt or Die in 2014 to a smaller, focused executive audience to spread the word of the importance of developing adaptive leaders in the pharma industry that have strong moral compasses. The goal was to introduce these pharma leaders to military leaders who had already been involved in developing

adaptable leaders, to share their playbook. Military leaders such as former commander-in-chief and president George W. Bush; former secretary of the Army, George Casey; General Fred Franks; General Ben Griffin; secretary of the VA, David Shulkin; and Lt. General Butch Funk have been speakers at these meetings.

The goal may sound lofty, but the meetings have been well-received over the years, and have gained traction with their audience. The list of speakers from pharma who have shared their experiences is impressive. They include Alex Gorsky, chairman and CEO of Johnson & Johnson; Bob Oliver, chairman of Otsuka Pharmaceuticals Canada; Sandy Costas, former president and chief operating officer of Quintiles; Dr. Sandra Milligan, senior vice president and head of global regulatory affairs and clinical safety for Merck & Co.; Mark Alles, CEO of Celgene; Perry Sternberg, head of US commercial, Shire Pharmaceuticals; Ramona Sequeira, president, Takeda Pharmaceuticals USA; Jay Galeota, president and chief operating officer, G&W Laboratories; John Arena, vice president and general manager, US psychiatry, Lundbeck; Victor Vaughn, senior VP of sales and marketing, Supernus Pharmaceuticals; Jack Bailey, president of the Americas for GlaxoSmithKline; and Murdo Gordon, chief commercial officer, Bristol-Myers Squibb.

"Pharma is based on a premise that is innovation-driven, which, by definition, means disruptive," said Galeota. "We tend to think of disruption as agile and fast, but in the case of the pharma industry, many enterprises are more like institutions, and they move slowly; new drug development takes time and care. Ironically, pharmaceutical companies willingly take on risk with development programs, yet are slow to take on risk in other areas like business model evolution, for example. There is a kind of dichotomy; on one hand, there is an appetite for investing heavily in unproven new programs in the labs, but on the other, very little tolerance for novel approaches to how companies are run, go to market, price products, etc."

To that end, Galeota explained that the idea of constant adaptation in order to stay ahead is critical for pharma leaders to understand and, ideally, embrace. "Yet it seems to happen rarely, unless forced," he said, noting the need for current and up-and-coming pharma leaders to consider adaptive leadership principles.

While no one would dispute that the biopharma industry is full of smart, educated, and successful individuals, the skills and ideologies necessary to take the risk-averse industry to a new and necessary level in a shortened timeframe is not lost on many.

Consider the following challenges facing the pharma C-suite:

- Pharma R&D ROI is currently below the cost of capital, and projected to be zero by 2020.[1]
- 2019 represents the pinnacle of the decline for pharma sales over the next 20 years.[1]
- Sales at risk worth $194 billion potentially signal a second patent cliff era with the advent of biosimilars.[2]
- Four-fifths of US health insurers require evidence of cost savings or a clear clinical benefit to include new therapies on their formularies. A further 16% have entered into outcomes-based contracts, while another 33% expect to do so within three years.[3]

Jack Hammond, Brigadier General (Ret), US Army, executive director of Home Base, A Red Sox Foundation and Massachusetts General Hospital program, and a former speaker for Adapt or Die, says, "The whole philosophy of adapt or die is you have to change with the times, and if you don't, you do it at your own peril."

What good leadership looks like

In Lynch's book, he elaborates on his nine leadership principles, and each of the meetings has tackled a specific topic so attendees could leave with a better appreciation of an aspect of leadership. Those topics to date have included values-based

Lynch's Leadership Principles

1. Focus on opportunities, not obstacles. "It can be done."
2. Have fun! "If the boss ain't happy, ain't nobody happy."
3. Achieve a work-life balance. "How are you living your dash?"
4. Decide when to decide. "Take the time to think."
5. Look down, not up. "People don't care how much you know until they know how much you care."
6. Be a mentor. "You must be accessible, you must listen, and you must truly care."
7. Engaged leadership is important. "Love your subordinates like you love your own children."
8. Be demanding but not demeaning. "Everyone must perform to his or her full potential."
9. Always celebrate diversity. "Don't surround yourself with people like you."

VIEWS FROM THE TOP

JAY GALEOTA, President and Chief Operating Officer, G&W Laboratories

There are some basic principles to me that seem to hold true in any kind of effort to rebuild or redirect image, and one of the common threads is communication. How communication occurs, frequency, method, format, etc., matters since image shaping/building requires repetition of messaging.

There is also a high premium on honesty and transparency. Frequently, the absence of communication opens the doors for speculation, often resulting in image ambiguity. But when what is known is communicated honestly and regularly, in a constructive unbiased way, it generally creates a different level of understanding among folks that would typically criticize, or be frustrated, or worse, create and communicate their own messages.

I feel that to some extent, that's what has happened in the pharma industry. The industry has been relatively hesitant to communicate publicly about the good it does, almost in a self-effacing way, as a kind of badge of honor.

leadership; corporate social responsibility; ethical and strategic decision-making; innovative partnerships; and the latest in December on mentorship.

Much of Lynch's book includes what some people would think is common sense. Follow the Golden Rule—treat people the way you want to be treated. Walk the walk. Leaders should look down, not up. Do every job superbly. Be sure that people know you are doing a good job. But in the book, and at the Adapt or Die meetings, Lynch shares examples of poor leadership and how he started to keep a booklet of what not to do when he became a leader.

Lynch says, "In my executive coaching and strategic planning for corporate America, they all tend to have a list of values, but they aren't always living those values. They are not always demonstrating those values, and that's very important."

> "They all tend to have a list of values, but they aren't always living those values."

Galeota said the first time he was introduced to an Adapt or Die meeting, it was on the subject of character. "That caught my eye because it was the first time in my career I'd seen a program dedicated to the topic of character in the business setting," he says. "When I went through military training, there was a lot of emphasis around character, but it has been not a marquee topic in the business sector."

As noted, Galeota has a military background and completed four years in the US Air Force Reserve Officer Training Corps. J&J's Gorsky attended West Point, graduated and was commissioned as a 2nd Lieutenant in Field Artillery and later completed Airborne School. Merck's Milligan was a general medical officer in the Army and Celgene's Alles a captain in the Marine Corps.

In *Pharm Exec*'s most recent Emerging Pharma Leaders issue, two of the leaders profiled have served. Whether or not that is a hallmark of inspired leaders or people who want to continue to contribute, Hammond says, "There are skill sets in the military that translate into good executive leaders. Number one, we institute a very strong moral compass, as this is crucial based upon the type of work we do. Our leaders operate on their own in austere conditions, and have to use their best judgement. If they make bad choices, really bad things can happen and people can die. So we develop a heavily mandated values system which becomes ingrained in them.

"We strive to build agile and adaptive leaders that are good at thinking on their feet and developing a good decision-making process that is well thought out—not just gut hunches," Hammond continued. "They are taught to listen to a variety of people prior to making decisions. Our leaders are trained and constantly reminded to take care of our people, as our soldiers drive success. There is nothing unique to this thinking other than the fact it has been effectively put into practice within the military. I am confident that these are values and practices you would look for in the civilian world as well."

Galeota explained further: "I continue to be struck by the fact that almost independent of mission, whether you are in private enterprise, or government or philanthropy, or a military organization, once you get to a certain level of leadership, the challenges are almost identical and they center primarily around the people-related aspects to running large organizations…how to communicate effectively and efficiently, how to create an environment of engagement, an environment that has high standards, and motivates people to reach for those standards with character, courage, and humility. These kinds of challenges, which are common across all those groups, are brought forward in Adapt or Die."

Lynch and Jansen said about 400 executives in the healthcare arena have attended their series. Lynch continues to believe that adaptive leadership will help companies in any industry respond more successfully to the changes around them. Specifically, for pharma leaders, Lynch says the meetings "challenge the norms and puts life in perspective for these incredibly accomplished leaders, and I do believe these meetings will transcend for these people that attend so that the public understands the value of the pharmaceutical industry." Both Lynch and Jansen have received feedback from attendees who say they have learned valuable lessons, have looked at their behavior, and made changes when they returned to their respective organizations.

Lynch concludes: "We have lots more people to touch. And some people slip back into bad behavior and you have to remind them what we talked about."

VIEWS FROM THE TOP

RUUD DOBBER, President, AstraZeneca US, and Executive Vice President, North America

I strongly believe in the value of this industry and it hurts that the perception is not where it needs to be. We need to take those signals seriously, and we need to do everything that we can to educate governments and societies.

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Adapt or Die, 2018

Gettysburg, PA, and Normandy Beach, France, will be the settings this year. "Leadership Under Fire" will focus on the challenges that pharma leaders face, followed by a walk through the battlefields with historians who will describe what crises the respective generals faced. Jansen and Lynch described: "Pharma leaders may be facing their own pressures, but it's okay to make the right choice and not take the path of least resistance. Nobody is firing a gun at you; they aren't easy decisions, but they aren't life and death. But you could make the decisions that are right by your people, which will positively affect the industry." PE

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The Innovation Distinction

Fair or not, biotech has managed to elude perception crosshairs

By Michelle Maskaly

While traditional pharmaceutical companies are taking a reputational hit, biotech organizations, for the most part, are getting a public-perception pass—for now.

Whether or not it's fair, or accurate, in general, the public views biotech companies as cutting edge, holding the cure to some of the world's most debilitating diseases, and as alternatives to the traditional pharma enterprise, and its characterization by some as greedy, outdated, and only caring about making money.

Biotechs are surrounded by innovation; they make science fiction—a digital pill, 3D printing, wearable technology—a reality; are located in trendy tech hubs like San Francisco, San Diego, and Boston; and most importantly, they offer hope.

This public perception may not be 100% accurate, but neither is the stereotype that all "traditional" pharma companies live in the stone age, hike up drug prices to make an insane profit, and hold the cure for cancer, but don't want to share it with the public.

The driving reputational force

So, where does this public perception come from? Experts who spoke with *Pharm Exec* believe there are several factors, but the most prevalent is a common theme that comes up almost daily when discussing the pharma industry—drug pricing.

"When you talk about the reputation of the industry, the one thing that comes to mind for me immediately is a lot of the rhetoric around pricing, and [the belief] that there is a [price] gouging of consumers by biopharma companies on products that have been placed on the market in the past couple of years," says Ralph Marcello, Deloitte's national biopharmaceutical leader.

Marcello contends that while there are a few "bad actors" who have given the pharma industry a bad reputation, in general, it is not the norm. Of course, that is not the narrative that typically gets told in the media.

This leads to another fundamental difference between many of the biotech startups and traditional pharma companies that experts say is contributing to the reputational differences—commercialization. In most cases, by the time the work coming out of a biotech is ready to be brought to market, those assets have already been acquired by a larger company, who sets the price and everything else around them. That company, not the biotech developer, is the one who gets the public attention, and in recent years, the backlash, that comes with the innovation.

"The delineation comes between companies whose products are on the market versus biotech companies that are in early stages of discovery and development, and are not commercialized," says Marcello. "Once those become products in the market and they commercialize those products, it is the price of the product that causes a lot of heartburn for various people across the industry."

Bursting the happy bubble

Will the golden-child status the biotech industry is currently enjoying ever slip to the levels traditional pharma is experiencing today? It's possible, but it would take a while. Elizabeth Iorns, the founder of Science Exchange, a marketplace for outsourced research, works with biotech and pharma companies. She also works with the general public and sees first-hand how reputation between the two segments differ.

"In some ways, they are sheltered from the criticism of pharma, because they don't have commercialized products," she says. "But, that piece will become more challenging for them as they begin to commercialize themselves. I think Gilead [Sciences] is an example of that."

Gilead, the biotech giant, took heavy criticism in the press for its pricing of hepatitis C drug Sovaldi. However, as *Investor's Business Daily* pointed out, the therapy didn't just treat a disease, but, in most cases, cured patients after about three months. Sovaldi's follow-on drug, Harvoni, also has a high cure rate.

The reason it may take a while for the public to criticize biotechs the way they do pharma is very simple, some say—biotechs are better storytellers. They are nimble enough to fight back when lashed out against and have a compelling story to rest on. For example, Gilead. "They have a really amazing therapy that is helping save the lives of people who might have died," says Iorn. "That's a really compelling storytelling piece."

An inside perspective

Unfortunately, it doesn't matter that pharma companies may also be conducting comparable-type research and coming up with those same life-saving treatments. The public's perception already starts out biased against them. When it comes to the topic of biotech versus pharma reputation, Dr. Devyn Smith has a unique perspective, having viewed the comparisons from both sides. Smith is currently the chief strategy officer and head of operations for Sigilon Therapeutics, a Cambridge, Mass.-based startup whose mission is to develop improved treatments for chronic disease using implanted cells shielded by proprietary biomaterials from immune attack and the foreign body response. But, before joining Sigilon, Smith was part of Pfizer's Medicinal Sciences Division of R&D, where he was head of business operations and strategy.

Pharma companies are an easy target for the public, because people see their copays or out-of-pocket expenses more when it comes to their prescriptions, Smith explained. For example, a patient may go to a hospital and have a $30,000 bill, but they only see $150 of it coming out of their pocket.

Smith said he would experience criticism for working in pharma from friends and family.

> "When you switch to biotech, people love it, because it's the hot new thing. … It's easy to get a pass, because people just see it as promising and are caught up in the excitement of it."

"You would get a lot of flak at times and hear things like, 'you guys are overcharging' and 'they're just in it for the money,'" he said. "When you switch to biotech, people love it, because it's the hot new thing. It's interesting and cutting edge. It's easy to get a pass, because people just see it as promising and are caught up in the excitement of it."

Smith has an additional layer of unique perspective. For a portion of the time he worked in traditional pharma, he lived in the UK.

"They had a very positive view of pharma," he says of the UK. "If you said you worked at a pharma company, they would say things like, 'oh yeah, you guys do really good things.' Coming back to the states you would tell a cab driver or someone you know that you work at a pharma company and you would never know the reaction you would get. Sometimes it was positive, sometimes they would look at you and make negative comments."

Bridging the gap

In the eyes of the general public, it's clear that biotech companies have an advantage when it comes to reputation. They are viewed as a sign of future hope and the public has high expectations for them.

Will this reputation high last? That's a question that experts are not sure about, especially as more biotech companies decide to bring their products to market on their own, and have to deal with issues like pricing.

One thing is certain: whether right or wrong, the public currently has a sweet spot for biotechs over traditional pharma companies. PE

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Valeant's Northern Face

The company's new head of its Canadian business discusses product resurgence, the "made-in-Canada" mantra for pharma, and how Valeant's footing domestically is playing a part in a reputational reboot globally

Richard Lajoie, president of Valeant Canada

In a recent conversation with *Pharm Exec* partner PharmaBoardroom, Richard Lajoie, president of Valeant Canada, shared his main priorities for his tenure as new head of the company's Canadian operations. Those include portfolio rejuvenation through launches of innovative molecules addressing unmet needs in the Canadian healthcare system, growing the organization's manufacturing capacity in the country, and fostering the Valeant culture.

Lajoie was named to his current post in July 2017. He has been a vice president of Valeant Pharmaceuticals since 2013. Before joining Valeant, Lajoie served at Novartis for nine years, starting as a sales manager in western Canada and then rising the ranks in the area of oncology, finishing as Novartis' general manager of oncology in Denmark, Norway, and Iceland.

PB: *What does Canada represent for Valeant today?*

LAJOIE: For Valeant, Canada is home to the global headquarters of the company. We take pride in our Canadian heritage, especially as we have significant manufacturing activity, which is very strategic for Valeant globally. Canada produces CAD 4 billion ($3.11 billion) worth of sales, destined not only for the Canadian market but also for export. Over 30% of worldwide sales are produced here, further underlining that our operations here are key for the global group.

Valeant Canada works hard to ensure and build on the continuing quality and excellence of our two manufacturing sites, through projects such as upgrading of serialization technology that enables specific product tracking. Excellence in manufacturing activity ensures supply, which is critical not just for commercial outcomes but also, and more importantly, for patients.

And finally, across the organization we have great, talented people who are focused on delivering the best outcomes for patients day in and day out.

PB: *Canada is not necessarily perceived to be a manufacturing hub for pharmaceuticals. Having two different sites locally, what are the key arguments for production in Canada?*

LAJOIE: There are several benefits to manufacturing in Canada. We are contributing to the local economy, something we are proud of as Canadian citizens. Our plants are of exceptional quality and both are approved by various regulatory agencies, allowing them to produce for the Canadian as well as other global markets.

Manufacturing here also allows us to demonstrate the important role we play in the overall ecosystem in our interactions with government stakeholders. Our government values jobs, innovation, and healthcare, and we are very much positioned within that triangle due to our manufacturing presence. We employ over 1,000 people and drive innovation through R&D and new technologies, all the while operating in the healthcare sector.

PB: *In your eyes, what does "made in Canada" stand for?*

LAJOIE: While "made in Canada" is a sign of quality, Canadians, as part of their mindset, are often too humble to promote themselves and their achievements on the international scene. We are confident in our quality and would always invite people to visit our plants for them to see our high standards with their own eyes. I can tell you our employees take pride in working for a Canadian company that produces state-of-the-art quality products on local soil.

We see this first-hand when physicians visit our sites, and they come away very impressed by what we do here.

PB: *It appears Valeant is now trying to bring back its reputation and focus on its core business. How important is the Canadian subsidiary in this task?*

LAJOIE: Valeant Canada contributes by continuing to ensure that we deliver innovation to Canadian patients. And of course our manufacturing facilities are key for Valeant to deliver on our promise globally.

It's very important to note that in Canada, when it comes to pricing in particular, every single pricing decision has been taken locally in accordance with the PMPRB (Patented Medicines Pricing Review Board)—and this has been the case ever since I was heading the Rx business over the last five years.

I think a great illustration of our success here in Canada is that in a recent survey, 92% of Valeant Canada employees recommend our company as a great place to work, which is of course the ultimate testimony. Our people are at the core of our company, focused on being trusted partners with healthcare professionals and providing value to patients through our products.

PB: *In times of uncertainty, motivating teams can be challenging. What strategies have you put in place to stay focused and move forward?*

LAJOIE: The leadership team in Canada has agreed on staying focused on what we can control and what we do well. We are committed to doing the right things. By directing our energy toward the things we do well, i.e., making innovation available to Canadian patients, we believe that results will follow and ultimately speak for themselves. Our global CEO, Joseph C. Papa, has been leading the way from a corporate perspective to this end.

PB: *Does Valeant's ranking in the industry reflect the true potential of Valeant Canada today?*

LAJOIE: While we may not be the first in terms of sales in Canada, we are certainly the largest innovative Canadian healthcare company. I believe that our successes have been somewhat understated, but as mentioned earlier, to Canadians there is a fine line between taking humble pride and being overly boisterous.

Our main focus will remain on bringing innovative treatments to patients—and it is thus not our key concern where we are ranked in terms of sales in Canada.

We are proud to be bringing essential products to the market that address real unmet medical needs and improve quality of life. For example, our Bausch + Lomb division is driven to help people see to live better. With this in mind, we are pleased that Canadian consumers have ranked our Bausch + Lomb contact lens solution as the most trusted contact lens solution brand for the second consecutive year by BrandSpark International. We are thankful for the trust people have in our products. We also believe that we can collaborate within industry and with academia for this shared purpose of improving the lives of patients.

PB: *What are some best practices Valeant Canada can export to other affiliates around the world?*

LAJOIE: Something we are particularly proud of is our cardiovascular registry, the largest one for Valeant worldwide with 5,000 patients enlisted.

This allows us to collect real-world data on how products are impacting patients in a relevant manner and brings a commensurable value to our R&D.

PB: *Speaking about innovation, what have been the recent highlights in your product portfolio and what can we look forward to for the near future?*

LAJOIE: The most recent highlight has been the successful launch developments for Jublia, a molecule treating nail fungus. With this launch, Valeant addressed a great unmet need in Canada. Before the launch, the most prescribed treatment for onychomycosis was an oral systemic drug, which is a great drug, but requires liver/enzymes monitoring. By bringing a topical product with great efficacy to the market, Valeant offered practitioners an alternative in their prescription options. Jublia has been a market leader for a few months now, and the market has actually increased by 300%, showing significant acceptance of the product.

In 2018, we are planning to launch two additional highly innovative products. One is a new treatment to manage obesity, and one is a biologic for moderate-to-severe plaque psoriasis. With the obesity treatment, we will introduce an option to help prevent complications related to this condition. We believe that it will bring true relief to the healthcare system, as obesity is often linked with other chronic diseases such as type 2 diabetes, high blood pressure, stroke, osteoarthritis, cancer, and lipid issues.

PB: *How can industry, government, and academia collaborate to foster an innovation ecosystem in Canada?*

LAJOIE: The quality of the workforce in Canada is truly outstanding. Nonetheless, I see a risk in the pharmaceutical industry remaining too focused on our usual ways, not being able to think outside the box. We stick to what we do and see within our own industry, when I believe that we could benefit considerably from exchanges with other industries. Some industries might be more advanced in digital aspects, whereas others might have a competitive edge in export, for example. I dare to challenge us to exchange knowledge with other industries outside of the pharmaceutical world, with the conviction that great results will come of it.

Furthermore, I believe in an ecosystem created and nurtured by partnerships between academia, industry, and government. Academia and biotech companies have the best conditions to discover and conduct preclinical and Phase I trials, while the industry is in good shape to fund Phases II and III trials and ultimately bring products to the market. A supportive government, as seen in recent government innovation strategy announcements, means that we as a country will be in a better position to attract R&D projects, which countries around the world are vying for.

PB: *Canada is oftentimes overshadowed by its Southern neighbor. Why should companies not overlook Canada as a market?*

LAJOIE: Canada might not be a big country and the perspectives for overall sales can certainly not match those of the US. However, Canada has a stable economy, it is very structured, regulated. Exactly because of its size, however, it can actually become an innovation test bed for many companies. In our case specifically, Canada might not necessarily be considered a test bed, but Valeant Canada is more considered to be a leader and pioneer—an agile and innovative part of the Valeant corporation.

PB: *Finally, you assumed your position six months ago. What were the main priorities set for your tenure as president of Valeant Canada?*

LAJOIE: The most fundamental component for us is our culture. I am dedicated to our employees. It is of highest importance to secure our culture internally. What we are striving for is to ensure that Valeant is perceived to be the healthcare partner of choice in Canada. Our priority is to bring value to our customers, and we do this by innovating. Consequently, we can ensure that patients are taken better care of to enjoy what is important to them in their lives, such as having meaningful time with their families and being productive members of society.

Another priority is to grow our manufacturing footprint. Finally, and somewhat overlapping with the previous strategic objectives: portfolio rejuvenation. To be the partner of choice we have to launch new molecules and thus ensure portfolio rejuvenation.

At Valeant Canada we are best placed to achieve this. To illustrate, the freedom for innovation is available within biotech companies, but they often lack the necessary funds, while big pharma companies have the funds but struggle with innovation, as they tend to be less agile with more hierarchical layers. At Valeant Canada, we have the best of both worlds: freedom to innovate and complementary to that, the right funds. We have a global footprint but local decision-making power, which allows us to fully live our goal of creating innovations that benefit patients. PE

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WHERE SPECIALTY PHARMACY MEETS

Industry Engine Check

A year of swings, momentum for biopharma markets

New innovations, a spike in drug approvals, and signs of an M&A rebound point to more stabilized financial roads ahead—but valuations remain challenging amid pricing, geopolitical, and regulatory concerns

By Peter Young

2017 and the last couple of years have been somewhat of a roller coaster ride for the biopharma industry.

There have been a number of very positive developments. The number of new drugs approved and under development escalated for both pharma and biotech companies. A host of new methods, such as immuno-oncology, CRISPR, personalized medicine, stem cells, and biologics have opened up a surge in productive innovation. We are beginning to see drugs that cure difficult diseases rather than just extend life, an extraordinary development. There have even been recent US regulatory and funding changes that are intended to increase government funding and ease the drug approval process. Time will tell if the actual results match the intent.

Amid these examples of industry progress, however, there have been times when heavy clouds have appeared in terms of biopharma stock market volatility, access to private and public capital, pricing controversies, geopolitical challenges, and uncertainties around the ongoing regulatory structural changes in a number of the major markets such as the US and China.

This article will look at what happened in the past year from an M&A, stock market, and financing point of view—and what we expect in the future. We will comment on the implications of these trends for senior executives and investor decisions in the pharma and biotech industries.

Pharma equity market performance

Following 2016, a year where equity markets plunged and recovered sporadically before the overall stock market rallied late in the year, the global equity markets performed well in 2017. The S&P 500 rose by 18.4% and the FTSE 100 increased by 7.1%.

The performance of the pharma and biotech industries varied dramatically by company type and sector. The Y&P US Pharma and European indices did equally well or better, increasing by 17.3% and 17.1%, respectively. The Y&P Specialty Pharma index, however, decreased by 10.4%, as many of the companies have come under attack for price increases for older drugs and for newer orphan drugs. The Y&P Generic Pharma index decreased by 10.9% for a different set of reasons. The generic drug companies are suffering, as the number of drugs coming off patent has slowed and the level of competition in generics has increased many fold.

Pharma equity financing and M&A

Equity issuance in 2017 was a mere $7.7 billion versus $16.4 billion for all of 2016, a dramatic decline on an annualized basis. In addition, there were only 12 pharmaceutical IPOs in 2017. There are generally very few IPOs in pharma, so this is not a change from the past.

In 2017, only 23 deals were completed worth $42.1 billion versus 45 deals completed worth $119.3 billion in 2016. This was a dramatic decrease in both the number of transactions and the total dollar volume. This decrease in M&A activity was a reflection of the great uncertainties facing the industry around pricing and regulation and the loss of the tax inversion-driven deals. The drop was not due to any reduced desire to grow or to enhance business portfolios.

Clearly, there was a sparsity of mega deals. There was only one such deal in 2017—J&J's acquisition of Actelion for $29.2 billion. The next largest deal was only $5 billion in size. The rationale for deals remained the same as pharma companies seek to strengthen their product portfolios, replace pending revenue losses from patent expirations, and restructure their business portfolios.

So why the dampening of M&A activity? Three of the principal reasons were the loss of tax inversions as an alternative for US drug companies, the negative publicity around drug pricing, and the polit-

ical uncertainties associated with the new and unknown policies of the new administration in the US.

As of Dec. 31, 2017, the pipeline of the deals announced but not closed was only $19.6 billion (12 deals), an indication that in the near-term we will be operating at a level that is slightly higher than 2017, but not at record levels. The recently announced acquisition of Bioveritiu by Sanofi for $11.4 billion may be a sign of a pick-up in M&A activity.

Biotech equity market performance

On the biotech stock market front, the Y&P Mid and Small Cap Biotech indices performed exceptionally well during 2017, increasing by 23.2% and 37.4%, respectively. The Y&P Large Cap Biotech index, however, did not perform as well, increasing by a solid but less spectacular 9.5% last year.

This was a welcomed improvement over the poor performance overall in 2016. The growth was driven by the strong overall stock market and by indications by senior Washington officials that the FDA drug approval process will accelerate. However, this was partially offset by the negative impact of the drug pricing issue and signs that orphan drugs will not get a free ride with regard to pricing.

Biotech equity financing and M&A

Equity issuance (secondary and IPO) in 2017 totaled 205 offerings worth $21.1 billion. This was a record dollar amount and a record number of issuances and a significant pick-up in pace compared to the 124 offerings worth $8.7 billion completed in 2016.

There was a partial rebound in the biotech IPO issuance market. Forty-five IPOs were completed in 2017 for a total of $4 billion. This was well above 2016, when only 26 IPOs totaling $2.4 billion were completed. For those companies who struggled to complete IPOs in 2016, it was a partial improvement, but still well below the levels in 2014 and 2015.

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time. This trend continued in 2017, with only 23 biotech M&A deals completed, worth only $14.9 billion. The acquisition of Kite Pharma by Gilead dominated that number with a value of $10.1 billion of the total. That meant that the remaining 22 deals totaled just $4.8 billion.

This was a significant slowdown on an annualized basis compared to 2016, when 41 deals worth $20 billion were completed, driven by six deals that exceeded $1 billion in value. This mirrored the slowdown in the pharma M&A market.

Although the pipeline of biotech deals as of Dec. 31, 2017, was modest at only $4.1 billion (eight deals), there has been a flurry of recently announced large biotech deals, such as Novo Nordisk's €2.6 billion offer (since rejected) to buy biotech Ablynx and Celgene's deals to acquire CAR-T therapy company Juno Therapeutics for $9 billion and cancer drugmaker Impact Biomedicines for $1.1 billion up front and a potential $1.25 billion extra depending on performance.

Outlook: Pharma

Business. The business outlook for pharma companies will continue to be positive in terms of drug development, with promising therapies in the pipeline. The industry's trajectory in drug development innovation and productivity, directly and indirectly through the biotech industry, is strong and should continue to be strong.

There was some concern about the drop in FDA drug approvals in 2016 to only 22, but activity picked up considerably in 2017, with 44 new drugs approved, and there is a push to ease the FDA approval process in the US. In addition, the agency announced in late June that it plans to promote drug competition, including expedited reviews of generic drug applications. This will be helpful to the generic drug companies, but potentially harmful for the ethical pharmaceutical companies.

Drug manufacturers will continue to adjust their business models and strategies, as the environment around them changes and new technologies are discovered. We fully expect big pharma to continue to pursue structural changes to shift the nature and quality of its business portfolios.

Generic pharma companies will continue to consolidate, cut costs, and push selectively into higher value and more protected product areas. They are and will continue to be under intense pricing and competitive pressures.

Specialty pharma organizations will partner, license, and acquire to maintain the strength of their overall business portfolios and scale. However, many of these companies are under severe attack around the drug pricing issue and some are finding that their orphan drug strategies have limitations in terms of insurance company reimbursement policies.

Equity markets. The stock market prices and valuations of the eth-

Continued on Page 49

AstraZeneca

What science can do

Circulating tumour DNA

AstraZeneca has pioneered the use of circulating tumour DNA (ctDNA) in the diagnosis of cancer. Pieces of DNA break off from a tumour and circulate in the bloodstream where they can be analysed to give genetic information about a patient's tumour. This allows healthcare professionals to determine the right treatment for the patient using a minimally invasive blood test.

VEEVA ID: Z4-7001 Date of preparation: September 2017 Date of expiry: September 2018

HEALTHCARE & LIFE SCIENCES REVIEW

BRAZIL
A MUST WIN

"Brazil undoubtedly holds great development opportunities for the global pharmaceutical and healthcare industries," introduces Minister of Health Ricardo Barros, "and we hope to gain the trust of an increasing number of international investors and jointly work on improving the healthcare products and services available to our 207 million Brazilian citizens." In its ambition to further strengthen a win-win relationship with the global industry, Brazil holds a precious, eye-catching asset: the remarkable dynamism of its huge pharmaceutical market. "Very few of the world's largest pharmaceutical markets have been growing at a sustained pace over the past years, and Brazil proudly stands as one of the best performing markets," highlights Jarbas Barbosa da Silva, director-president of the Brazilian Health Regulatory Agency (ANVISA).

"As the second-largest emerging market for Sanofi globally, Brazil is one of the 'Must Wins' in the company's portfolio. It is by no means an easy market, but it is unequivocally a highly attractive market," adds Pius Hornstein, country chair and general manager Pharma of Sanofi Brazil, the largest international company operating in the country. "Brazil today stands as the sixth largest pharmaceutical market in the world, and recent forecasts suggest that it will likely reach the fifth position in the coming years; naturally, this sheer market size has cemented the crucial importance of the country in the overall operations of all pharmaceutical companies with global ambitions," confirms Rolf Hoenger, president and general manager of Roche Pharma Brazil, the largest player in Brazil's non-retail market in 2017.

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AN INDUSTRY ON A HIGH...

To whoever has been following, even from afar, Brazil's economic and political developments over the past four years, the enduring strength and ever-increasing significance of the local pharmaceutical market might seem surprising, as the country just experienced its worst recession in modern history, coupled with a highly mediatized political crisis that resulted in the impeachment of president Dilma Rousseff and widespread dissatisfaction with the political system.

"In 2017, Brazil has exited a particularly challenging two-year recession period, where our country's GDP contracted by 3.8 percent in 2015 and by 3.6 percent in 2016," explains Cleiton Marques, CEO of the domestic powerhouse Biolab and president of the syndicate of the pharmaceutical industry in the State of Sao Paulo (Sindusfarma), which represents around 95 percent of all pharmaceutical marketing in the country and gathers together over 312 associate members overall.

In December 2017, Brazil's Finance Minister Henrique Meirelles indeed announced that the Brazilian economy was expected to grow 1.1 percent in 2017 and 3 percent in 2018. "The country's recent exit from a two-year period of negative growth despite a troubled political context truly showcases how dissociated economics and politics are from each other in Brazil. In this regard, the country's economy has undoubtedly benefited from the quality of the policies implemented by Finance Minister Henrique Meirelles and from the active role played by the country's Central Bank, while some of the reforms and regulatory updates recently implemented have already started to bear fruit," explains Fraser Hall, country president of AstraZeneca in Brazil.

"In fact, in the wake of the crisis, all industry sectors constricted but two, one of them being the pharmaceutical industry. In 2015, at the height of the economic crisis, the pharmaceutical market was actually the fastest growing industrial sector of the Brazilian economy, growing 8.3 percent while all other sectors were largely in decline," reveals Leandro Safatle, executive secretary of the Brazilian Drug Market Regulation Chamber (CMED), which defines ceiling prices, benchmarks for wholesale and retail commercialization, and the minimum mandatory discount for purchases in the public healthcare system. "Our country has indeed been through particularly agitated times over the past few years, but the pharmaceutical industry in Brazil has always accommodated such crises," adds Nelson Mussolini, executive president of Sindusfarma.

Ricardo Barros, minister of health of Brazil; Jarbas Barbosa da Silva, director-president, Brazilian Health Regulatory Agency (ANVISA); Leandro Pinheiro Safatle, executive secretary, Brazilian Drug Market Regulation Chamber (CMED)

Marco Fireman, vice minister and chairman, CONITEC

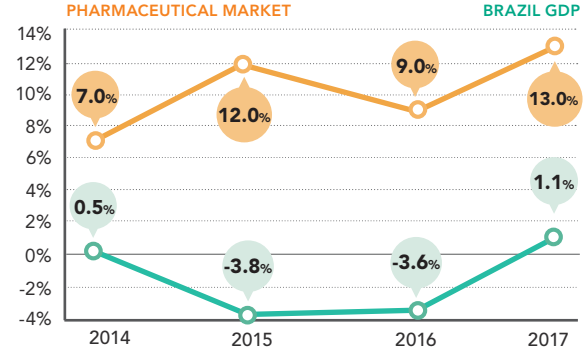
The sustained growth of the Brazilian pharmaceutical market has been nurtured by many different factors, which notably include particularly rapid demographic and epidemiological transitions. "I believe that some external observers still do not fully realize that Brazil is no longer a young country, as its age structure is actually pretty similar to those of European markets," explains Gaetano Crupi, president and general manager of Bristol-Myers Squibb Brazil, while it is expected that more than 30 million Brazilians will be over 65 year old by 2025.

"Furthermore, healthcare stands as a constitutional right in Brazil since the promulgation of the 1988 Constitution, and this specificity has kept our market fully active even during the economic crisis, although we moved from a double digit to a single digit annual market growth" stresses Sindusfarma's Mussolini.

Nevertheless, one should not overlook that the outstanding resilience displayed by Brazil's pharmaceutical industry over the past few years is directly linked with one of the main shortcomings that still characterizes Brazil's public health system: a limited access to pharmaceutical products. "In a country where medicines purchasing

BRAZIL GDP & PHARMACEUTICAL MARKET GROWTH (ANNUAL %)

PMB MAT APR-17 (PHARMACY PURCHASE PRICE) AND NRC BRAZIL MAT APR-17 (2ND PRICE LEVEL)



Source: WorldBank, IQVIA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This is what motivates us every single day.
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SANOFI Empowering Life

Fostering a Winning Mentality

Cesar M. Rengifo, senior vice president and area director emerging markets west, GSK

You headed GSK's Brazilian operations between 2008 and 2015 and established GSK as the fastest growing multinational in Brazil. Now, as GSK's SVP Emerging Markets West, what are your expectations for the Brazilian affiliate, especially given that Brazil makes up 50 percent of GSK's sales in the region?

One aspect that is particularly crucial to GSK is continuously strengthening the eye-catching relationship that we have forged with the Brazilian government. Over the past 30 years GSK Brazil has built a history of success with regards to Brazil's vaccines supply a field where it proudly stands as the absolute leader -, and consolidating this legacy is one of our utmost priorities. We are now leveraging this long-standing experience and plan to expand our collaboration to the HIV area. We also aim at continuously increasing our R&D investment to Brazil, including both pre-clinical and clinical programs, while GSK stands as one of the few multinational companies that has already taken concrete and successful steps in this area. For example, we implemented a comprehensive R&D program called "Trust in Science," through which GSK has been investing millions of US dollars in local, basic science research projects in Brazil.

What do you identify as the main challenges that the Brazilian affiliate will have to overcome in the coming years?

In 2016 and 2017, the growth of the Brazilian market was mainly driven by price increases as volumes plateaued. While the economy is now slowly recovering, market growth in terms of units is set to soar again, but product prices will not increase that much, as the inflation rate has recently reached a historically low level and public spending increases have been capped to the inflation rate for the next 20 years. These new dynamics entail that we will have to be extremely competitive in terms of volume growth moving forward.

In the meantime, Brazil's distribution channel has started to consolidate, which requires developing even more sophisticated partnerships and negotiation approaches, as well as furnishing heightened investments in this part of our operations. In this regard, we will have to be extremely careful when refining our strategies and calibrating our portfolio's critical mass, while our affiliate's talent will be instrumental in terms of execution. In this context, I also see talent acquisition and retention as a key parameter to watch, and we need to create the right environment for our people to continuously develop themselves—from very junior employees to the most senior executives.

Overall, Brazil stands as a very competitive market, where all companies invest significant resources to gain market shares. At the end of the day, fostering a winning culture will also emerge as a crucial success factor to continue outperforming the market and competitors.

comes as out of pocket expenses for around 76 percent of the Brazilian population, the recent economic crisis has had no impact on the growth of private pharmaceuticals sales, because patients cannot live without the medicines they need," adds Antonio Britto, the executive president of Interfarma, the main association gathering together local and international innovators in Brazil.

...BUT NOT A CASE OF BUSINESS AS USUAL.

Nevertheless, a subtler and more challenging reality actually lies behind the unstoppable momentum of the Brazilian pharmaceutical market. "The latter is undergoing rapid and deep changes, and we need to continuously adapt our business approach to the long-lasting consequences of the recent crisis, while seizing new growth opportunities triggered by the long-awaited economic recovery materializing," explains Alexandre França, CEO of Aspen Pharma Brazil, which in 2017 proudly became the best performing affiliate of the Aspen group in spite of the country's profound economic and political turmoil.

Nelson Mussolini, executive president, Sindusfarma; Nilton Paletta, president Latin America, IQVIA

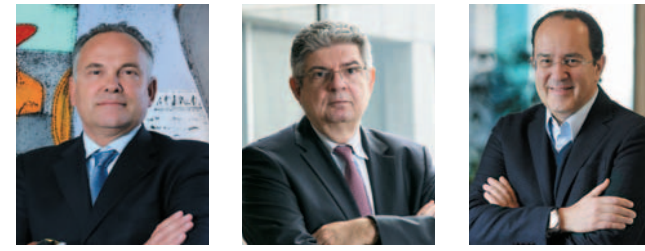
"When refining our analysis, we indeed see that the recent crisis has affected the retail market growth in terms of units, and the annual volume growth of this market decreased from 8.9 percent in 2015 to only 3.2 percent growth in 2017 (MAT April 2017)," documents IQVIA's Nilton Paletta. "Furthermore, high inflation in the 2015–16 period contributed to price growth, but—moving forward—inflation under control at the 3–4 percent level will entail that volume and price growth will be more balanced," he analyses.

According to Sanofi's Pius Hornstein, a new norm is underway. "In this context, companies operating in the retail segment will need to follow a demand strategy, which implies a heightened focus on the quality of their treatments, the quality of their

indications, the quality of their patient population segmentation, and so on. As the economy should slowly recover and Brazilians' purchasing power increases, it is expected that this will foster further demand in the out of pocket segment. Overall, this situation is by no means 'Alice in Wonderland,' but we are seeing a new positive normality, and we don't expect a return to the difficulties of the past few years," he predicts.

While the latest data from IQVIA indicate that the retail market will increase by 7–8 percent in 2018, the latter also forecasts that its mid-term growth should revolve around a CAGR of 7–8 percent between 2018 and 2021 in nominal terms. "While this is lower than the two digit growth we saw in the 2000s, it is still very attractive compared to the global average of two to three percent," highlights Hornstein.

In the meantime, the Brazilian non-retail market has been growing 11.6 percent (PPP and 2nd level—MAT April 2017) according to IQVIA, through the strengthening of a rather complex set of dynamics. In the public sector, which made up around 57 percent of the non-retail sector, the growth has been mainly driven by new product incorporations and increasing expenditures in high complexity diseases (mostly hepatitis C, HIV, immunology, and oncology).



Pius S. Hornstein, country chair and general manager pharma, Sanofi; Antonio Britto, executive president, Interfarma; Cleiton Marques, CEO, Biolab and president, Sindusfarma

"However, the institutional channel in Brazil remains highly volatile and it is hard to predict if the current growth will be sustainable moving forward. So far, the Ministry of Health's budget for medicines has increased 12 percent in 2016 and 10 percent in 2017, but a recent legislation has capped public spending's increasing to inflation rate for the next twenty years. In the meantime, we see that the frequency of incorporation of innovative products into the Brazilian public health system (SUS) has been improving over the past few years, although it is still suboptimal," reasons Paletta.

BRAZILIAN RETAIL MARKET - CORPORATION RANKING

(PHARMACEUTICAL PURCHASES PRICE, CONSTANT DOLLAR / MAT 2017/12)

#	CORPORATION	MAT 2017/12 (in M$)	GROWTH % MAT 2017/12 VS 2016/12
1	NC FARMA	1,490,421	22.41%
2	SANOFI	1,281,305	13.78%
3	HYPERMARCAS	1,257,799	17.39%
4	ACHE	1,195,913	24.76%
5	EUROFARMA	1,195,913	27.65%
6	NOVARTIS	848,703	15.69%
7	BAYER	568,469	11.66%
8	GSK	559,062	21.02%
9	PFIZER	464,963	10.60%
10	TAKEDA PHARMA	454,709	19.97%
11	J&J	444,679	14.72%
12	BIOLAB	424,371	17.25%
13	LIBBS	411,750	22.56%
14	MERCK & CO.	402,283	12.83%
15	MERCK KGaA	343,590	15.62%

Source: IQVIA


Rolf Hoenger, president and general manager, Roche Pharma Brazil; Fraser Hall, country president, AstraZeneca

In this regard, the working of Brazil's institutional system has so far diminished the negative impact of the economic crisis, as the government could not cancel ongoing multiple-year tenders. "As a result, the Ministry of Health has been mainly focused on reaching a greater level of efficiency across the system and differing the payment of medicine-related bills—but no tremendous changes have yet occurred," stresses Interfarma's Britto, before adding that "we nevertheless cannot overlook the fact that the past economic crisis has tremendously decreased budget availability, which naturally casts a shadow on public market's growth prospects."

With 25 percent of its 207 million population covered by private health plans, Brazil holds the second largest private health insurance market by population in the world. "In Brazil, the vast majority of health plans are however contracted by employers, which means that the share of the Brazilian population having access to the private health market is directly correlated to the evolution of the unemployment rate. Over the past three years, this aspect has gained a tremendous importance in the eyes of pharmaceutical executives, as the unemployment rate grew from 5 percent to 13.7 percent between 2014 and 2016, and almost three million people lost access to the private health market," adds Roche's Hoenger.

"Given that unemployment usually impacts entire households, we can moreover extrapolate that at least 45 million Brazilians do not hold the financial means to access products that are only available through the private healthcare system," further highlights Haig Yeghiaian, country manager of LEO Pharma. "Taking into consideration both public and private channels, we expect that Brazil's non-retail market will increase by 5–6 percent in 2018," explains Paletta.

LOOKING BACK WITH PRIDE

In parallel to market growth, the Brazilian ecosystem has clearly distinguished itself over the past years through the implementation of strategic regulations and public programs

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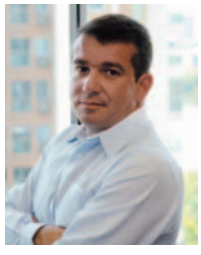
BR/NCOM/1217/0154 - Dezembro/2017

Norberto Prestes, director, ABIQUIFI



Alexandre França, CEO, Aspen Pharma Brazil

that showcase the country's ambitions to tirelessly upgrade its regulatory and healthcare frameworks. "Brazil is truly driving healthcare innovation across Latin America, while many countries in the region (and overseas) could inspire themselves from the policies implemented in Brazil over the past twenty years," highlights José Almeida Bastos, president Latin America at Merck & Co., "and the progress made by Brazil is truly impressive and praiseworthy, while the latter truly comes as a result of an enduring commitment to healthcare displayed by successive governments."

A first aspect that perfectly illustrates Brazil's recent achievements relates to the country's regulatory framework, with ANVISA holding the double mission of ensuring that Brazil meets the highest standards globally while integrating the specificities that come with the Brazilian market's rapid growth and its ongoing consolidation. "In this regard, we have conducted a comprehensive review of our agency's process, having the twofold objective of strengthening our registration processes and making Brazil a more transparent and predictable ecosystem for all stakeholders," explains ANVISA's Barbosa. Although it was only created in 1999, "the agency has made huge progress on the international stage too, as ANVISA joined the International Conference on Harmonization (ICH) in November 2016 alongside the US FDA, the EU EMA, and Japan's PMDA, which stands as an additional evidence of the high level of expertise developed by Brazil's regulator," highlights Bruno Costa Gabriel, managing director of Janssen Brazil. "Being accepted as a regulatory member of the ICH stands as a great recognition of the level of maturity that ANVISA has already been able to reach and highlights the quality of our regulatory processes, while providing us with a heightened influence in the global discussion for regulatory harmonization," continues its director-president Jarbas Barbosa. "Furthermore, we expect that ANVISA's membership to ICH will broaden the export prospects of Brazilian manufacturers," stresses Norberto Prestes, director of the Brazilian Pharmochemicals Manufacturers Association (ABIQUIFI).

On the healthcare side, the Ministry of Health (MoH) has recently implemented a genuine paradigm shift in moving from a top-down approach—where the MoH used to be the sole entity in charge of policy design while the States and the Municipalities were only entitled to these policies' implementation—to a new model based on joint-resolutions including all parties. "This collaborative approach is aimed at enabling a higher level of commitment across all layers of our health system and its four million workers, especially through a more efficient management of the SUS' BRL 250 billion [USD 81 billion] annual budget," explains Minister Barros, "while one should not forget the remarkable comprehensiveness of Brazil's public health system, which provides all Brazilian citizens with access to more than 4,500 medical procedures and 860 pharmaceutical products," he adds.

Furthermore, Brazil can boast of "being the only country in Latin America to strictly base the selection of new technologies entering the public health system on scientific evidence," according to Marco Fireman, vice-minister and chairman of the National Commission for the Incorporation of Technologies (CONITEC), created by law in April 2011. Since its set up until April 2017, 121 medicines were incorporated by CONITEC into the Brazilian public health system (SUS), "including—over the past months—treatments for widely prevalent diseases around the country such as hepatitis C, as well as technologies increasing adherence for Alzheimer's disease and products indicated for rare diseases," highlights Fireman.

Merck & Co.'s Latin America Management Team

A Meaningful Impact

"Although we also work closely with HMOs and the private healthcare market at large, Merck & Co.'s overarching mission is to ensure that the highest number of people and patients can access life-changing treatments, therefore prompting us to redouble our efforts when it comes to these countries' public sectors," explains José Almeida Bastos, Merck & Co.'s president for Latin America. Bastos also highlights how prioritizing the public sector appears to him the only way to build a more equitable healthcare ecosystem and rebalance economic and social disparities in the region.

Scaling up this public health commitment to the regional level however implies dealing with significant access discrepancies across Latin America, as well as with varying levels of government investment in healthcare. "Despite these difficulties, combining the right approach with a strong commitment from our side can entail outstanding outcomes for the population: to give you a concrete example, around two million people across Latin America were immunized with Merck & Co.'s vaccines five years ago, while—in 2016—more than 20 million people benefitted from our vaccines," he continues. "Nevertheless, there is no magic involved in this remarkable performance, it all comes down to our teams' willingness to improve access throughout the region and to work closely with governments to make it happen," concludes Bastos, before stressing that the American company does not plan to rest on its laurels and is currently designing its next objectives in terms of population coverage and vaccine types.

"Brazil can truly pride itself on the excellent level of coverage today available for HIV, hemophilia or hepatitis C products through the SUS," confirms Roche's Rolf Hoenger, while "Brazil's National Immunization Programs (NIP) has now become a global reference in terms of access and coverage," adds José Almeida Bastos, Merck & Co.'s president for Latin America. "One of the great things about Brazil is that once they decide to do something, they do it very boldly and sustainably. Vaccinations are one of the biggest government-sponsored programs, and the government is also building an excellent HIV treatment program, leading the WHO to recently recognize Brazil as a global example in this disease's management," highlights Alexei Kolchin, general manager of GSK Brazil. "HIV is an area where we have some of the most advanced molecules on the market, and Brazil has been recently incorporating some of our innovative products into the public system's reimbursement lists, which stands as fantastic news for Brazilian HIV patients," confirms Cesar Rengifo, senior vice president & area director Emerging Markets West at GSK.

Although these eye-catching achievements must be praised, recent political turmoil and economic turbulence has seemingly delayed the implementation of new, highly needed bold moves that would bring Brazil's healthcare ecosystem to the next level. "This aspect is particularly crucial as Brazil truly stands as a country that requires a clear 25-year vision to further move forward. Day-by-day management will not allow us to face the huge challenges posed by our rapidly aging population, the evolution of our country's epidemiological profile, and the increasing prevalence of cancer or rare diseases, at the moment we definitely need to collectively look at the way the private and public sectors interact," warns Interfarma's Antonio Britto.

MAPPING OUT NEW CONQUESTS

Looking forward, room for improvement lies in both the regulatory and access sides. From a regulatory standpoint, the Brazilian context might seem quite disconcerting for a foreigner, as Brazil has successfully solved crucial issues with regards to legal predictability, the respect of intellectual property, and the strength of the country's pharmaceutical market, but it still lags behind concerning several more minor issues, such as registration timelines and red tape.

"At the end of the day, ANVISA's processes and requirements are closely aligned with those of the FDA in the US or NICE in the UK. What sets Brazil apart from these markets is its unpredictability, and this also applies to registration timelines and the pricing approach by regulatory authorities," explains Celgene's Luciano Finardi. "Speed to market in Brazil is still very slow, whereas we should be surfing the same wave as Europe and the United States. When international companies take into account this unpredictability as they calibrate their product launches, they sometimes favor a wait-and-see approach, observing competitors make the first move," he continues. Leveraging ANVISA's recent admission to ICH, one can however expect Brazil to be evermore aligned with the world's most advanced markets in the coming years.

"In the context of our recent ICH membership, we will work on addressing two of the main challenges that lie ahead for national regulatory bodies: first, ensuring a greater similarity be-

Alexei Kolchin, general manager, GSK

tween the frameworks of different pharmaceutical markets around the world, and, second, building up mutual trust among regulatory authorities in order to favor multiple country processes and authorizations—rather than individual, national requirements," explains ANVISA's Jarbas Barbosa. "In this regard, we recently saw that the US FDA and the EMA jointly assessed the market approval of a new pharmaceutical product—these kind of eye catching initiatives clearly needs to be replicated and expanded in the future," he highlights.

Nevertheless, "one of the greatest challenges at stake for Brazil's ecosystem is to square two competing dynamics: on the one hand, a rising healthcare demand driven by Brazil's rapidly aging population, and—on the other—the integration of new technologies that make health costs increase much faster than the inflation rate," states Minister Barros. "In Brazil, most government and regulatory officials are particularly keen on highlighting that Brazil's SUS stands as the largest government funded universal health system in the world; however, limited budget availability

Luciano Finardi, country manager, Celgene

and the exceptional size of the population covered also implies that only basic products are integrated into the SUS. To give you an example, a cancer patient who exclusively relies on the public healthcare system would most likely only be treated with first-generation therapies," explains Celgene's Finardi. "Nevertheless, we cannot blame CONITEC for this situation; every new innovative treatment reaching the Brazilian market puts the commission in an untenable situation, where allocating resources to include innovative treatments is extremely difficult as our country remains marked by the persisting significance of more basic health issues, such as infectious or cardiovascular diseases," he adds.

Resource allocation at the SUS level has become even more critical with the disruption caused by the rapidly growing judicialization of health, which relates to Brazilian patients filing lawsuits to access a given healthcare product or service through the SUS, leveraging the fact that healthcare in Brazil is a constitutional right. "In 2016, the federal government, the state and the municipalities all together

CORPORATIONS RANKING BRAZIL RETAIL + NON-RETAIL - MAT DECEMBER 2017

(PMB MAT DEC-17 (PHARMACY PURCHASE PRICE). NRC MAT DECEMBER 2017 (PUBLIC PRICES/TENDER)

#	CORPORATION	#	CORPORATION
1	SANOFI	11	BAYER
2	NC FARMA	12	MERCK & CO.
3	HYPERMARCAS	13	ABBOTT
4	NOVARTIS	14	TAKEDA PHARMA
5	ACHE	15	BIOLAB
6	ROCHE	16	LIBBS
7	GSK	17	BOEHRINGER ING
8	EUROFARMA	18	UNIAO QUIMICA F N
9	J&J	19	ASTRAZENECA BRAZIL
10	PFIZER	20	MERCK KGaA

Source: IQVIA

PATIENTS ARE AT THE CENTER OF EVERYTHING WE DO.

Our work is guided by the continuous commitment to well-being and patients quality of life. they are at the center of everything we do! they are the ones who realize our accomplishments and motivate us to be the leader in immuno-oncology and to work hard to bring this great innovation to everyone.

Bristol-Myers Squibb

Immuno-Oncology


Fernando Itzaina, president and CEO, FQM Group; Bruno Costa Gabriel, managing director, Janssen

spent more than BRL 7 billion [USD 2.2 billion] as part of health-related lawsuits, which is particularly substantial," explains Minister of Health Barros. "In this regard, the recently implemented S-code system will provide us with a better control of all legal expenses involving the provision of healthcare and allow us to cross-check information in order to combat fraud," stresses the Minister, " while we also set up expert centers in partnership with the National Council of Justice to help judges for health-related lawsuits," he adds.

In the meantime, CMED's Leandro Safatle is looking forward to establishing a set of rules that will prevent companies from unlawfully taking advantage of judicialization of health, as the latter will receive a penalty equivalent to that addressed to companies selling their product above the regulated, authorized price. In addition to better controlling the excess and fraud related to the judicialization of health, Brazil's Ministry of Health also recently implemented a stringent control and review of the SUS' spending. "As per medicines, comprehensively reviewing all purchasing schemes allowed us to save over BRL 4 billion [USD 1.3 billion] between 2015 and 2016—out of a total budget of BRL 18 billion [USD 5.77 billion] annually allocated to medicine purchasing," stresses Minister Barros.

However, when it comes to ensuring the long-term financial stability of the largest public health system in the world, more radical steps might be needed in the near future. "I believe that the private system will gain in importance in the upcoming years and we will see the implementation of a co-payment system, just like it happens in some European countries like Italy and Spain, as it is a good way to regulate the system: once the individual is helping with the payment of treatments, misuses tend to be tremendously reduced," believes Sindusfarma's Mussolini.

While the recent economic crisis has led Brazil's MoH to take a (relatively unprecedented) stance on public spending, pharmaceutical executives in Brazil have unanimously highlighted the urgent necessity of

Mauro Loch, president and general manager, Amgen

Samuel Mauricio, vice-president, Octapharma

further bridging the huge access gap that exists between the 160 million Brazilians that exclusively rely on the public system and the 47 million that have access to the private healthcare market—especially in some well-identified therapeutic areas. "Brazil stands as one of the Latin American countries where addressing the oncology conundrum is truly a public health necessity, and half-hearted measures will not bring satisfactory outcomes to patients exclusively dependent on the SUS—in a nutshell, Brazil must completely overhaul its oncology model at both the treatment pathway and access levels," stresses Merck & Co's president for Latin America, José Bastos.

While Brazil is a market that still displays huge social needs, there is a strong consensus among the entire ecosystem on the necessity to improve access to innovation, "but this responsibility should not only weigh on the government's shoulders," highlights Fernando Itzaina, president and CEO of FQM Group (FQM), a company that is part of the Argentina-based Roemmers Group, which gathers together multiple pharmaceutical and healthcare companies across Latin America. "When it comes to innovation access in Brazil, we are at the dawn of a new era—this is not an assumption, this is a necessity," states Interfarma's Britto.

TRANSFORMATIVE AMBITIONS

"Although osteoporosis, hematology, and oncology have their own spaces in Brazil's private market, we do not aim to become a private market focused company, and we will remain committed to and continue exploring both segments despite the spending freeze recently decided by the Brazilian government and its negative impact on the budget of the Ministry of Health," states Mauro Loch, general manager of Amgen Brazil, thereby illustrating the efforts of many international innovators to find innovative ways to make their treatments accessible through the SUS.

"Pharmaceutical companies have a crucial role to play in building a more sustainable health system in Brazil, especially through the establishment of Partnerships for Productive Development (PDP)," highlights Minister Barros. These PDPs notably encompass technology transfers and the local manufacturing of patented, in-need products through partnerships with Brazil's public laboratories, therefore significantly lowering prices and extending healthcare access to all Brazilians.

"As we speak, scheduled investments related to PDPs amount to over BRL 6.5 billion [USD 2.1 billion] and will create more than 7,500 new jobs—only for the set-up of manufacturing facilities that will handle these technology transfers. In this regard, we invite new pharmaceutical companies owning strategic products and patents to reach out to the Ministry of Health and set up or develop their footprints in Brazil through PDPs," continues Minister Barros.

As the government identified more than 180 strategic technology transfers, PDPs have become one of the hottest topics among Brazil's pharmaceutical industry, and some innovators have already successfully positioned themselves in this segment. "So far, only one company has actually successfully engaged in a PDP, transferred the technology to the local partner, where the latter has subsequently successfully produced, distributed and sold the resulting products in Brazil. That company is Sanofi, through Sanofi Pasteur, with our flu vaccine PDP. This gives you an indication of not only our commitment to Brazil but our capabilities,"

highlights Pius Hornstein, Sanofi Brazil's country chair. "Earlier this year, the Ministry of Health moreover issued a new PDP list with over 50 priority products, including three core products for Sanofi. After a long internal discussion at both corporate and local levels, we decided to submit a PDP proposal for each of them. This is highly notable as it is not easy for a MNC to engage in such a program, especially for core products. There is still a long path to go as the Ministry of Health needs to do a first selection, then an evaluation, and then the negotiations, but it was a significant decision for Sanofi in Brazil," he adds.

In the same way, Swiss-based Octapharma, one of the largest human protein manufacturers in the world, is ready to embrace the same transformative commitment to Brazil after two PDPs for the supply and technology transfer of recombinant Factor VIII failed to deliver on their premises. "We decided to seize this exciting opportunity and submitted in June 2017 a new, holistic project, whose fundamental approach is to develop a more integrated and complete partnership model, which would allow the government to fully maximize the investment conducted by our company," explains Samuel Mauricio, vice-president for Brazil at Octapharma.

"Furthermore, we truly looked at leveraging Octapharma's technical leadership to develop a tailor-made solution adapted to the specific needs of the Brazilian ecosystem, including the risks posed by the high prevalence of infectious and tropical diseases in the country. As a result, we integrated in our project a proprietary technology that enables the virus inactivation of the plasma for all relevant viruses from a transfusion point of view—including the Zika, Dengue and Chikungunya virus—which will provide Brazilian clinics and hospitals with a heightened transfusion safety," he continues.

"In the grand scheme of things, this PDP would truly allow Brazil to

All Together Now

The Innovation Journey 2017 co-organized by BMS

Wilson Pedreira Jr., executive director, Oncology and Hematology Center, Albert Einstein Philanthropic Society

Gaetano Crupi, president and general manager, Bristol-Myers Squibb Brazil

"While my experience in working with the Brazilian government has taught me that it is absolutely crucial to maintain a continuous communication with public sector stakeholders, we truly want to engage with the entire healthcare value chain in the meantime," explains Gaetano Crupi, president and general manager of Bristol-Myers Squibb (BMS) Brazil. In this regard BMS recently co-organized a hackathon called 'Innovation Journey 2017—#togetherforthecause' with the Oncology and Hematology Center of the Albert Einstein Philanthropic Society, which is widely considered one of the leading healthcare centers in all Latin America, as well as with the technology powerhouse Microsoft and the patient organization Instituto Lado a Lado pela Vida. "This three day meeting gathered together volunteers from all companies and oncology patients, whose testimonials contributed to broadening volunteers' views on the patient's journey. Then, our objective was to collectively work on innovative access solutions and projects to improve the quality of life of cancer patients," documents Crupi.

"This is evermore crucial as cancer already stands as the second most common cause of death in Brazil after cardiac and cerebrovascular diseases, and I expect its prevalence to further gain in importance within our country's rapidly aging population," reveals Dr. Wilson Pedreira, executive director of the Oncology and Hematology Center of the Albert Einstein Philanthropic Society. "The volunteers were divided into five teams, and topics such as the importance of post-treatment actions, family support, and humanization were addressed, while the five groups presented innovative, patient-centric proposals at the end of the event," relates BMS's Crupi. "In line with this Innovation Journey, we truly want to see our relationships with pharmaceutical companies evolving from a purely transactional approach to win-win partnerships—and we are glad that some of the most innovative companies have already accepted joining forces and building sustainable projects in the long term," highlights Pedreira.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Heraldo Marchezini, CEO, BIOMM

move up to a new dimension, as only a very limited number of countries in the world have managed to become independent for the production of plasma proteins and recombinant factor VIII. In the case of Brazil, this aspect is even more crucial as the country holds the third largest hemophilic population globally," concludes Samuel Mauricio, vice-president for Brazil at Octapharma, to illustrate the game-changing potential of PDPs in critical therapeutic areas.

Although 104 out of the 180 PDPs prioritized by the MoH have already been agreed on, only three of them (according to Interfarma data) have actually completed the entire technology transfer process, leading some stakeholders to question these PDPs' design and execution framework. "Interfarma's position is that the government should concentrate its efforts on the most innovative technologies, i.e. the ones for which there is no free market setting. Second, we need to develop a model where Brazilian laboratories are actually able to receive all technology transfers agreed, and—finally—we must ensure PDPs are developed in legal and ethical ways that would bring real technological improvements to Brazil and/or decrease product prices in comparison to a free market situation," summarizes Interfarma's Britto.

Nevertheless, PDPs are far from being the only way forward for pharmaceutical companies aiming to have a transformative impact on the SUS' access paradigm—even in some of the most underserved areas such as oncology. "At Roche, the opportunities that we have been able to seize stem from the structural specificities of the Brazilian market: a federal republic comprising 26 states plus the district capital Brasilia, and over 5,600 cities—and this structure is reflected across the Brazilian model of healthcare," stresses Rolf Hoenger, president and general manager of Roche Pharma Brazil. "In 2014, we therefore set up market access teams entirely dedicated to identifying access opportunities at the state level for products that haven't yet been included into CONITEC's federal reimbursement list. When narrowing the access equation to the state level, we were able to refine our access strategy according to these states' specific healthcare needs. For example, the prevalence of cervical cancer is relatively high in some northern states of Brazil, where these states' secretaries of health would more likely consider cervical cancer as a health priority—and therefore prioritize resource allocation for the reimbursement of innovative treatments in this area," he adds, while some of these state-based access models were actually designed through co-creation workshops gathering together local secretaries of health and animated by Roche employees, as part of the company's *Inovamentes* program.

"In the meantime, we have conducted a comprehensive mapping of the access scenario for breast cancer, lymphoma, and colon cancer in 148 different cities, including the level of disease awareness and the strength of the primary care and diagnostic capacities. Out of these 148 Brazilian cities, we have already been able to implement tailored and impactful access solutions in more than 120," he concludes.

THE HMO EQUATION

Given that private health plans covered almost 48 million Brazilians in 2017, pharmaceutical executives also identify great opportunities to increase innovation access by more closely partnering with HMOs. "At Merck KGaA, we have already managed to successfully include several products in the formularies of private health insurances, but we definitely have room for further improvement in this area," highlights Guilherme Maradei, managing director Brazil and general manager biopharma at Merck KGaA.

"For mental health products, there are only a few

HMOs that are actually open to the idea, as including these products in their reimbursement lists would come at a very high cost for these companies," adds Josiel Florenzano, managing director for Lundbeck Brazil and South Cone. "As per Lundbeck, we have not yet engaged in this process, but I believe it truly embodies the way forward for our country, and I expect that more and more companies' representatives will be focus on private health insurers within the next ten years, especially as the government recently announced that public spending would be capped to inflation rate for the next twenty years, therefore limiting opportunities to increase access in the public sector," he stresses.

Talking about HMOs and private payers, the sector has moreover been consolidating over the past five years, and the total number of private payers has significantly decreased from 973 to 790 between 2012 and 2017. "In the meantime, the share of HMOs covering more than 250,000 lives has increased from 50 to 55 percent and the trend is set to continue in the coming years," highlights Nilton Paletta, president Latin America at IQVIA.

Nevertheless, as the vast majority of health plans are contracted by employers, the latter are typically look-

When Medtech Emulates Pharma

Roberto Alvarenga, general manager Latin America, Biotronik

"When it comes to the complexity of market approaches implemented, I do consider that the pharmaceutical ecosystem in general has reached a higher level of sophistication than the medtech industry, although the latter has been rapidly catching up over the past few years," documents Roberto Alvarenga, general manager Latin America at Biotronik, the leading company globally for cardiovascular and endovascular medical technologies. In this context, it was natural for Alvarenga—a seasoned pharmaceutical executive who previously headed the Brazilian affiliates of Ferring, Shire, and Merck KGaA—to bring to the medtech world his market access expertise forged in some of the most innovative pharmaceutical companies.

"Whether it relates to pacemakers, stents, defibrillators or any other devices, showcasing the added value of our innovative products has become paramount in order to ensure that our stakeholders do not perceive them as commodities roughly equivalent to any other products on the market," adds Alvarenga. "To develop our marketing capacity accordingly and ensure we can become frontrunners in this area, we therefore inspired ourselves from the processes developed by pharmaceutical companies when designing market approval and reimbursement dossiers for innovative drugs, and Biotronik has been applying this new approach to both the private and public healthcare markets," he explains. This pioneering model seems to truly pay off, as Biotronik's award-winning remote cardiac monitoring system, which is capable of detecting and alerting physicians to relevant changes in patient health, was recently accepted by CONITEC and integrated into the SUS, marking the first time ever that such a groundbreaking technology has been incorporated in Brazil's public sector.

ing for the best deals possible and therefore regularly switch contractors. "The average contract length between a company and a HMO in Brazil is around three years, which nurtures two negative dynamics: first, the patient is somewhat disenfranchised from the relationship with his healthcare providers, which generates wasteful spending," explains AstraZeneca's Fraser Hall. "Second, HMOs struggle to track long-term patient records and outcomes, which does not contribute to driving costs down either. When combining the impact of these two dynamics with the fact that healthcare cost in Brazil has been increasing on average by 18 percent a year, it is easy to understand why HMOs are pushing back against the inclusion of new, innovative treatments. We however identify a group of "early adopter" HMOs covering around 15 percent of the 48 millions Brazilians using the private market, which are more open to reimbursing new treatments and use this specificity as a key differentiator vis-à-vis their competitors," he adds.

"In this context, broadening access in the private sector will rely on our capacity to develop innovative schemes with HMOs—and Pierre Fabre Brazil aims to be an active contributor to this approach. Although the private insurance market is still extremely fragmented in Brazil, we can start working with some of the country's largest institutions and jointly design access models, which could then be used as blueprints by other HMOs down the road," explains Alex Carvalho, general manager of Pierre Fabre Brazil.

Nevertheless, in Brazil, private health plans do not cover treatments for chronic diseases and essentially focus on in-patient care, which poses another challenge for companies holding these products in their portfolios. "So far, 100 percent of the sales of our evolocumab for high LDL cholesterol come as out-of-pocket spending, as it is not accessible through Brazil's public health system either. As a result, one of the main priorities of our access teams is to closely work with private insurers to improve the coverage of this product in the private healthcare market," explains Mauro Loch, gen-

Haig Yeghiaian, country manager, LEO Pharma; Alex Carvalho, general manager, Pierre Fabre

Josiel Florenzano, managing director, Lundbeck Brazil and South Cone

eral manager of Amgen Brazil.

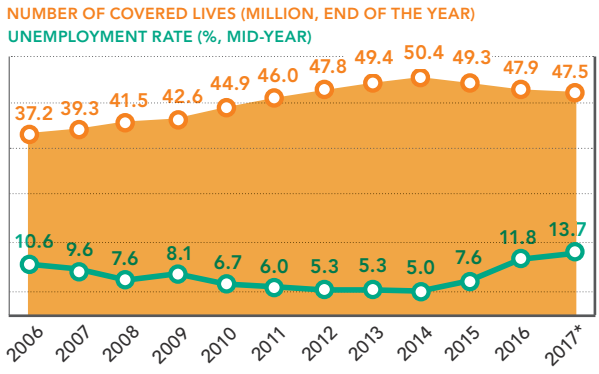
"Fulfilling this objective will however require completing a true paradigm shift that would see private insurers' cost assessment approach evolving from a product- to a disease-centered model, which entails providing our partners with detailed insights into the economic burden of the disease, the average costs associated with emergency events, as well as the savings that could be made thanks to the clinical outcomes offered by our product," he stresses.

While patient-centricity is high on the agenda of most pharmaceutical companies in Brazil, the latter should not overlook the importance of being payer-centric either. "It is extremely difficult for Brazilian payers to assess products based on pharmacoeconomic studies performed in European or North American health systems—whose cost structure is completely different from that of the Brazilian healthcare system. Nevertheless, we see that most companies in Brazil are still reluctant to perform local pharmacoeconomic studies," points out Celgene's Luciano Finardi.

Furthermore, Brazil's private payers seem to still lag behind the US in terms of label enforcement, leading companies to furnish heightened efforts to see approved, life-changing products being included in HMOs' formularies. "Looking at BMS' PD-1 immune checkpoint inhibitor nivolumab which has already been approved in five indications in Brazil, our country's HMOs do not automatically add this ground-breaking product into their guidelines. In contrast to the US, we therefore have to negotiate on an individual basis with HMOs and showcase this product's benefits to ensure they really allow physicians to prescribe nivolumab and reimburse it to their beneficiaries," reveals Gaetano Crupi, president and general manager of BMS in Brazil.

Finally, another identified room for improvement concerns targeted therapies—a model that has not yet been embraced by both the government and private insurances. "As a result, the pharmaceutical industry in Brazil has so far been financing most of the diagnostic costs in Brazil, which stands as another challenge to address when further strengthening our relationship with HMOs," concludes AstraZeneca's Fraser Hall.

EVOLUTION OF THE NUMBER OF PEOPLE COVERED BY PRIVATE INSURERS AND UNEMPLOYMENT RATE



*Covered lives in April-17; Unemployment rate of the 1st quarter of 2017

Source: IQVIA

FINE-TUNING COMMERCIAL STRATEGIES

In parallel to transformative approaches aiming to shift the country's access paradigm in both the private and public healthcare markets, companies cannot afford to lose sight of their commercial performance either—especially given that Brazil's sheer market size nurtures extremely high expectations from headquarters. "Being successful in Brazil and meeting local stakeholders' and patients' needs truly requires building a country-specific portfolio, which might differ from those that companies have in European and Asian markets," warns Haig Yeghiaian, country manager at LEO Pharma.

"Furthermore, from a commercial standpoint, Brazil cannot be approached as "one country," as there are strong cultural, social, demographic, and climatic differences between all the states," explains Fernando Itzaina, president and CEO of FQM Group (FQM). "This diversity has an impact on the pharmaceutical market, as epidemiological and demographic profiles as well as healthcare needs vary significantly from one state to another, which in turn requires pharmaceutical companies to adapt their strategies accordingly. To make the most of the market's huge potential, companies and their management teams must also cover strategic hubs scattered across this huge country, including the political capital Brasilia, the country's economic center Sao Paulo and other large cities such as Rio de Janeiro, Salvador, Fortaleza, and Belo Horizonte" he adds.

"In this regard, it is absolutely crucial to ensure our treatments are truly available to patients, which actually goes beyond affordability: as a company, we hold the mission of guaranteeing to our partners and patients that our life-changing products are easily accessible to all patients across Brazil's huge territory," explains LEO Pharma's Yeghiaian.

Fulfilling this endeavor appears evermore challenging when considering that some parts of the Brazilian pharmaceutical value chain have not matured at the same pace as in other Latin American countries. "Mexico, for instance, is much more advanced in aspects like distribution and pharmacy chains. In particular there is no very dominant

A Unique Story, an Unrivalled Expertise

Jaime Rabi, director, Microbiologica

Founded in 1981, Microbiológica can objectively claim that it has had a pioneering impact on some of the most critical developments of the modern Brazilian and global healthcare sectors. Under the impulsion of its current director, Jaime Rabi, who was a full professor at the Federal University of Rio de Janeiro and a 1A Research Fellow at the National Research Council, Microbiológica became the preferred supplier of the Brazilian government for azidothymidine (AZT), also known as Zidovudine (ZDV), the first antiretroviral medication used to prevent and treat HIV/AIDS at the height of the epidemic of the disease. In this regard, Microbiológica's activities largely contributed to the set up of the National AIDS Program in Brazil, which is now recognized as a global reference.

A few years later, Microbiológica's industrial competences in nucleic acid chemistry led the company to be involved in the development of US-based Pharmasset, which originally developed the HCV treatment sofosbuvir before being acquired by Gilead Sciences for USD11 billion in 2011. "Microbiológica did participate very actively in the development of Pharmasset's pipeline, including products against HIV, hepatitis B and hepatitis C, while I was part of the board of directors of the company from 1998 to 2003. As a matter of fact, the lead structure that gave birth to sofosbuvir was discovered in 2003 and Microbiológica created part of the chemistry for this project in our laboratory in Rio de Janeiro," explains Jaime Rabi. "Simultaneously, Microbiológica entered in a strategic alliance with Boston-based Idenix (originally called Novirio), which was developing nucleosides specific against hepatitis B, before Idenix was acquired by Merck & Co. for USD 3.85 billion in 2014," he adds. Working from Rio as a strategic ally of both Pharmasset and Idenix means that Microbiológica's scientists were directly involved in the invention of new, ground breaking medicines—something that was totally unprecedented in Brazil.

Today, Microbiológica supplies APIs to both European and Brazilian pharmaceutical companies for various international markets and recently established a strategic alliance with an emerging Brazilian pharmaceutical company, in order to jointly develop products that should soon reach the market. "Finally, we forged several promising partnerships with leading Brazilian Research Institutions for the development of new molecules targeting tropical diseases, such as Zika, chikungunya, dengue, and yellow fever, and we will start looking for external partners to move these products' development forward," highlights Jaime Rabi.

pharmacy chain present at country level in Brazil, and I expect to see a significant transformation within the Brazilian healthcare landscape in the next five to ten years," highlights Sanofi's Pius Hornstein.

Although the Brazilian value chain is still under consolidation, one single distributor today holds a market share of over 40 percent, which has negatively impacted the risk exposure of some affiliates. "We are now engaged in the ongoing process of designing a new sales structure for Aspen Brazil, which includes further strengthening our traded marketing division to display a heightened focus on pharmacy chains and distributors," confirms Aspen Pharma Brazil's CEO, Alexandre França.

Furthermore, Brazil's pharmaceutical value chain is still characterized by resistance to change, as recently experienced by Aspen Pharma, which established itself as one the fastest growing pharmaceutical companies in Brazil in 2017 through radical decisions taken at both internal and external levels. "Bolstering structural changes was clearly more difficult at the external level than on the organization side, as most managers across the value chain still seem to prefer accommodating themselves to the sector's ups and downs rather than favoring or welcoming disruptive approaches," explains Aspen Pharma's França. "We however decided to

Guilherme Maradei, managing director, Merck KGaA

question this status quo—at the end of the day, why should we wait for the market to recover, while bold strategy changes could enable us to outperforming the market even during crisis times? Every problem is an opportunity in disguise. While our country was facing its worst economic crisis in many decades, some market niches have still been growing at a rapid pace," he continues.

For innovative products, "it is however much more difficult to reach the same level of market penetration than 15 years ago," stresses Lundbeck's Florenziano: "while the overall size of the Brazilian antidepressant market has soared over the past decade and has now overcome the USD one billion mark, the number of generics competitors has increased accordingly," and the latter have been driving most of the retail market's volume growth since the beginning of the recent economic crisis. Fortunately, innovators can still rely on the strong performance of their mature brands to propel the affiliates' long-term growth. "In the Brazilian CNS market, the brand erosion usually hovers around 15 percent (in market share) in the first year that an innovative product goes off patent, while—in Europe or in the US—it may however reach up to 85 percent in the first year of patent loss," adds Lundbeck's Florenziano.

Another commercial opportunity to seize relates to the fact that—in Brazil—prescribers still hold a real decision power even after generic entry, which is not the case anymore in European countries, where prescribers have to first and foremost comply with payers' reimbursement lists. "In Brazil like in many other Latin American markets, we do see prescriptions changes happening at the point of sales; however, physicians' high influence entails great development opportunities for companies that have managed to build a great reputation for themselves," explains Pierre Fabre's Alex Carvalho.

In this context, fully leveraging one company's leadership in a given therapeutic area and among prescribers also emerges as an optimal way to unlock Brazil's market potential and outperform competition. "In order to further accelerate the growth of our oncology portfolio, we set up in 2015 commercial partnership with EMS, the largest domestic company in Brazil and one of the most significant pharmaceutical companies in all Latin America," continues Carvalho. "As part of this partnership, we are taking care of the marketing and promotion of a very important leukemia product, which is manufactured by EMS before complying with a second quality control at Pierre Fabre's Brazilian distribution center. Our partnership with EMS actually emerges as the starting point of our licensing strategy, and we are currently working on forging other agreements with international companies in the oncology field, which I cannot disclose at the moment," he adds.

Moving forward, distributors and pharmacy chains are not the only part of the Brazilian value chain that may experience significant consolidation, and Brazil's pharmaceutical companies could renew the high level of M&A deals that transformed the industry until 2013—before significantly decreasing when the crisis broke out. "Although it is extremely difficult to predict how the situation will evolve, moving from a double digit to a single digit market growth might prompt companies to consider gaining new market shares through acquisitions," explains IQVIA's Paletta.

In this regard, FQM Group (FQM), originally Farmoquímica, distinguished itself in 2017 with the acquisitions of both DIVCOM's pharmaceutical division in May 2017 and dermatology-focused Melora in January 2016, allowing the company's revenues to grow by 144 percent between 2014 and 2017, with 64 percent coming from inorganic developments (including the acquisitions of DIVCOM and Melora). "Increasing a company's revenues from USD 10 to 20 million is no easy task but it is far from being impossible in Brazil—even if it represents a 100 percent increase of

Broadening Prevention and Treatment Options

Juan Pablo Udry, general manager Brazil & Latin America, Boiron

Juan Pablo Udry, general manager Brazil & Latin America for France's Boiron, the world's undisputed leader in homeopathic medicines, is a man with a mission: to "offer homeopathy as a prevention and treatment alternative to all physicians in Latin America." "One of the company's key priorities over the past decade has been to leverage its domestic leadership and its reputation in European markets to further develop its international presence, while Boiron has already managed to establish a solid businesses in the US and Canada," he explains.

In this endeavor, some specificities of the region truly work in favor of Boiron: "Latin America holds a long-standing history and culture of using natural medicines—in the broadest sense of the term, encompassing homeopathy, phytotherapy, and other natural and alternative treatments. From a physician's perspective, several Latin American countries—including Brazil—moreover recognize homeopathy as a medical specialty per se, which requires following a two-year specialization program and whose practice is fully accepted by these countries' medical associations," he adds. Finally, Latin America is no exception to the global trend where patients and physicians alike are looking for less invasive and more natural prevention and treatment options, which could for example be integrated into mothers' and infants' daily lives without contraindication or high risks. "The latter—as well as pediatricians—have actually emerged as Boiron's entry point in Latin American markets, as our company's portfolio boasts extremely well reputed products for mothers, pregnant women, and infants," stresses Udry.

Nevertheless, there is still confusion between several natural therapies, "so we must address the lack of awareness which homeopathy still suffers from in some countries. However, our objective is not to change the mind of reluctant physicians: if the latter categorically refuse to test homeopathy products, there is nothing we can do about it. Homeopathy is not a medicine based on belief, as it is (unfortunately) often expressed," he highlights.

On the other hand, some regulatory requirements still prevent Boiron from swiftly bringing to Brazil products already available in other parts of the world. "To unlock this situation, we are working more closely than ever with Brazil's regulator and strive to showcase to ANVISA the main specificities of homeopathy products, a field that does not stand as the agency's core area of expertise," he adds. "Brazil holds more than 5.000 compounding pharmacies, which are approved and entitled to produce homeopathy medicines. This truly proves that there is a strong demand for homeopathic products in the country, and our objective is to ensure that we meet Brazil's healthcare needs in this area," he concludes.

the revenues. However, this objective becomes even tougher when these revenues reach a higher level—let's say over USD 300 million," explains Fernando Itzaina, President and CEO of FQM.

BREAKING DOWN BARRIERS

If mergers and acquisitions had the wind in their sails during the BRICS boom, it is partly due to fact that Brazil stands as a very complex and costly market to enter for many international companies. This specificity has not vanished over the past few years: Brazil is still characterized by high operational costs, one of the most complex tax systems in the world, and substantial logistical challenges inherent to the size of the world's fifth largest country. As a result, many international companies have not yet taken the leap of faith to enter the promising but perilous Brazilian market. "In this context, FQM's mission is to ensure that all these companies' products do not remain inaccessible to Brazilian patients because of market barriers, and we established in-licensing partnerships as one of our main development pillars," explains FQM's Itzaina. "We actually decided to go one step further with the set up of our own innovation center, which is mainly aimed to adapt foreign products to the specificities

of Brazilian regulations: although ANVISA's requirements are more and more aligned with those of its most prestigious counterparts, regulatory differences still exist and require investments from our side to ensure foreign products can be swiftly available to Brazilian patients," he adds.

When it comes to bringing to Brazil some of the world's best products, Biomm—the first biotech ever set up in Brazil—recently stood out from the crowd through the inking of two eye-catching partnerships in 2017. "In the early summer of 2017, we entered into an agreement with the US company Mannkind for the marketing and distribution of a very innovative fast-acting, inhaled insulin, which will make Brazil the first country outside the US to receive this life-changing product," reveals Heraldo Marchezini, CEO of Biomm and one of the leading executives in the Brazilian biopharmaceutical sector. "The product was submitted to ANVISA at the end of October 2017 for product approval, and this filing actually includes new label information," he adds.

As a true biotech company, Biomm however does not plan to limit itself to the diabetes field, as proven by the company's recent partnership with South Korea's Celltrion Healthcare for a trastuzumab biosimilar prescribed for the treatment of breast tumors with HER2-Positive receptor status, which affects over 25 percent of invasive breast cancer globally. "As a company, we are particularly proud to have reached an agreement with Celltrion, which stands as the first biopharmaceutical company to have a biosimilar monoclonal antibody approved in Europe. Furthermore, this partnership perfectly embodies Biomm's commitment to explore a variety of critical therapeutic areas, while ensuring that Brazilian patients hold more affordable and accessible options to treat the disease," stresses Marchezini, before adding that "in the oncology area, we see very innovative treatments reaching the Brazilian market, but the latter will remain inaccessible to most patients if pharmaceutical companies do not make the effort to bring biosimilars in the meantime."

PREPARING FOR AN UNCERTAIN FUTURE

Beyond its sheer size or annual growth rates, the most exciting specificity of the Brazilian market in the eyes of pharmaceutical executives probably lies in the creativity and flexibility that it requires on both daily and strategic bases. "That's the beauty of Brazil: the market is big enough to be extremely innovative at the affiliate level, while its strategic importance makes it easier to receive the resources required to experiment with innovative processes and—in turn—increase your chances of success," explains Rolf Hoenger, president and general manager of Roche Pharma Brazil, whose affiliate holds an innovation specialist fully dedicated to fostering creativity and supporting Roche employees in their innovative projects. "However, in such a complex and somewhat unpredictable environment, being resilient and holding firm to your long-term plan is absolutely paramount," advises Janssen's Bruno Costa Gabriel, while Sanofi's Hornstein highlights that "Brazil is a unique and fairly complex country that will constantly surprise you. As a company, if you can embrace how Brazil works and add something further of value, you can be successful."

Furthermore, operating at the executive level in Brazil requires constantly monitoring external trends and being extremely agile to adapt a large-scale organization to ever-changing industry winds. "As a result, I always keep a close eye on our affiliate's numbers, the performance of the industry through various indicators as well as other market data, and I believe this approach works well to anticipate changes in the environment, define and implement actions that help ensure our business is best positioned for growth at any given scenario," adds Guilherme Maradei, managing director of Merck KGaA Brazil, which grew by over 20 percent in volume in 2017, compared to a market increase of just over four percent.

"I also consider that the most successful global executives of the future must have an in-depth understanding of high-growth, strategic emerging markets—just like experience in developed markets has been important in the last decades. As countries like Brazil have gained importance in multinationals' growth plans, holding on-the-ground experience in this country is a valuable asset when it comes to shaping the global strategy of a multinational company," adds Maradei. "Finally, my suggestion to all executives coming to Brazil is to find ways to make a lasting impact in the country: we are truly privileged to work in an industry that changes lives, and Brazilians truly welcome foreigners that are eager to improve their country's healthcare paradigm—so do not miss this great opportunity," recommends AstraZeneca's Fraser Hall.

While the Brazilian economy is expected to recover at a pace that would make most European countries recently affected by economic recession green with envy, the key parameter to watch moving forward will be the impact of the November 2018 general elections, which so far display a very unpredictable scenario. "In the grand scheme of things, I believe that the future growth of our country's pharmaceutical industry will also largely depend on Brazil's capacity to further attract foreign investments," forecasts Sindusfarma's Nelson Mussolini. "Overall, all the conditions have been met to allow Brazil to become the third or fourth largest pharmaceutical market in the world; I am confident that this will happen one day, and those companies that will have been able to build strong operations and a long-standing presence in Brazil will indisputably reap the rewards of their commitments," he concludes.

Continued from Page 23

ical pharma industry suffered for some time, but rebounded nicely in 2017. We expect that to continue in 2018 as long as the overall stock market performs well.

Specialty and generic pharma company stock prices have suffered heavily due to industry pricing issues and competition and will continue to be under pressure in 2018. It is our expectation that the negative news will continue to counterbalance the positive news for these two sectors of the biopharma industry.

M&A. Young & Partners expects M&A activity in 2018 to see a major uptick, as the recent overhaul to the US tax code reduces R&D credits but lowers the penalty for repatriating cash, encouraging pharma to buy rather than build. Volume will also be driven by the restructuring and strategic needs of pharma companies, as they continue to acquire to enhance their product pipelines and strategic thrusts, while selling off non-core businesses.

The need to fill the shrinking pipeline will also fuel in-licensing arrangements, partnerships, and joint ventures with biotechs and other pharma companies.

Outlook: Biotech

Business. The development capabilities of biotech companies have been and should continue to be positive overall. Although there will be successes and failures by individual companies, biotech organizations have demonstrated their ability to develop new drugs at a faster pace than larger pharma firms. There is also the hope that novel drugs and arrangements with payers will allow biopharma companies to achieve attractive and sustainable pricing.

Equity markets. The stock market favored biotech companies for a number of years, but that sentiment weakened starting in the second half of 2015 with a number of negative stories hitting the biopharma industry around pricing and other issues, impacting the IPO and secondary equity issuance volume. We expect the recent moderate improvement in the stock market and equity issuance market to continue for the biotech industry, with the positive regulatory changes being discussed. This will help the stronger biotechs raise equity capital, but we do not expect a near-term return to the frenzy of 2014 and 2015.

M&A. Although the pipeline of deals announced but not closed at the end of 2017 was relatively modest, we believe there will be a significant pick-up in the biotech M&A market this year. With the ability to repatriate cash at reduced tax rates for US firms, the ongoing successes of biotech companies in their drug development programs, and the validation of a number of new technologies, pharma organizations will likely become more aggressive in their pursuit of biotech acquisitions.

However, their interest will be focused on specific targets in favored therapeutic and technology areas and on biotechs that have made strong clinical progress.

Implications for senior management

For ethical pharma companies, there will continue to be a wide variety of tools to acquire revenues and pipeline drugs, but the valuations will continue to be challenging, particularly for companies with promising products in late-stage clinical trials or FDA approval. The challenge will be to pick the right overall mix of M&A, licensing, and partnering to accomplish corporate strategic goals and defend and deliver shareholder value.

For specialty pharma companies, the key will be a rethinking of their strategies, since it is not clear that the pursuit of niche and orphan drug markets will continue to bear fruit in the same way they have in the past. The high price of acquisitions and the pressure on drug pricing, even for orphan drugs, will have a disproportionate impact on specialty pharmas.

Generic drug companies will continue to face a number of industry challenges. This will result in a continuation of the current industry consolidation and selective strategies around diversification. The CEOs of generic drugmakers must be prepared to shift to very different strategies to survive and to thrive.

For biotech companies, public and private, the future is exciting from the drug development side in terms of the approval environment and innovation and the improvements they have seen in the IPO, secondary equity financing, and M&A markets. Unfortunately, the markets have been volatile and have played favorites with regard to therapies, technologies, and stages of development.

The key for biotechs will be to properly assess their cash flow requirements and to create and execute a flexible financing/M&A plan that properly assesses how much capital and at what cost of equity the various alternatives will provide, whether it is private placements, partnering, IPOs and secondary offerings, royalty monetizations, or sources of non-dilutive financing. PE

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Brexit's Sunny Side

Assembling a few rare slivers of pharma positivity on UK's future

The life sciences industry has now been reacting to and processing the UK's imminent withdrawal from the EU for 18 months, and as the historic transition moves closer into view, many commentators have begun to temper their initial resistance with a pragmatism geared to accepting the inevitable. Nevertheless, their repeated warnings to the Brexit negotiators and their ongoing calls for caution remain an emphatic part of the discourse.

However, there have been voices within the pharma debate that take a more upbeat and optimistic view of the UK's future, and while these voices are still very much in the minority, it is worth taking a look at some of their arguments. It's an admittedly reductionist exercise, but in the midst of Britain's winter gloom, a few rays of sunlight can have an edifying effect.

In November last year, Tom Cowap, a pharmaceutical specialist in Catalyst Corporate Finance's healthcare team, argued that "the opportunities of Brexit far outweigh the potential risks." He pointed to seven factors that will "positively contribute" to the UK pharma sector in the lead up to and aftermath of Brexit. Among them, he said, was that the UK will remain a global center of academic pharmaceuticals research, boasting three of the 17 most important clusters of life sciences research facilities in Europe. R&D spending on pharma in the UK remains strong, he added, noting that almost half (47%) of all R&D spending in the UK is in the pharma sector, with the Wellcome Trust awarding £600 million ($831 million) of new research grants in the UK last year alone. He argued that the UK's Medicines and Healthcare Products Regulatory Agency (MHRA)—which is "among the world's most highly-respected and authoritative regulators" and "currently undertakes more cross-border authorization work in Europe than any other country-based institution"—"will flourish outside of the EMA system." Post-Brexit, MHRA "supremacy" will be a major boost for the UK, as it seeks to develop individual trade and authorization agreements with the US, the Middle East, and Asia. "Regulatory harmonization is key to trade agreements… and this will be simpler and quicker to agree on a one-to-one basis."

Finally, Cowap pointed out, the UK's tax regime is especially favorable to the pharma sector, with the UK government's promise to reduce corporation tax to 17% by 2020 making it "one of the lowest rates in any western economy."

MHRA's ex-chairman, Sir Alasdair Breckenridge, offered his own positive spin in the *Financial Times* (May 16, 2017). "Current [UK] systems for regulating healthcare products date from the 1960s," he wrote. "The opportunity exists to modify these specifically for the UK. The creation of a single UK agency for medicines, medical devices, and veterinary medical products would be pivotal."

Pointing out that the current European regulatory system for medical devices depends on assessments made by more than 70 commercial organizations of "varying ability," Breckenridge said, "a new generation of products incorporating both pharmaceuticals and medical devices is rapidly evolving, which presents the opportunity for new forms of regulatory practice unencumbered by European considerations." He concluded that a new single agency, one that includes health technology assessment, could "create a model system equipped for real advances in regulatory science and making the UK an attractive site to launch new products."

Writing in *The Pharma Letter* (June 20, 2017), Michael Jewell, healthcare partner at Cavendish Corporate Finance, argued that Brexit could boost M&As and investment in UK pharma. The "need to stay on top of EU regulations and the prospect of having to move a significant number of staff to the continent could well prove to be drivers for an uptick in sector M&A," he wrote, "as UK pharma companies might opt to acquire firms in the EU so they can more easily stay abreast of changes to regulation, trade with their European neighbors, and continue to benefit from the advantages of being part of the EU." While greater clarity concerning the relationship with the EU after Brexit is required, "there is potentially good value to be found by both buyers and sellers, as sector restructuring and consolidation continues," Jewell concluded.

Readers will note a conspicuous absence of industry leaders in the chorus above; it's fair to say that these slivers of sunlight should be taken with a dose of salts. But as the debate intensifies ahead of the UK's March 2019 departure-time deadline, a few shots of Vitamin D may prove a welcome boost in maintaining the required energy and sustenance. PE

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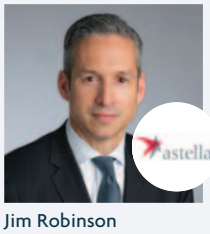

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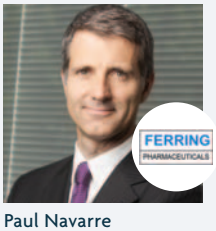

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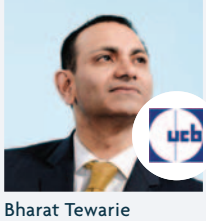

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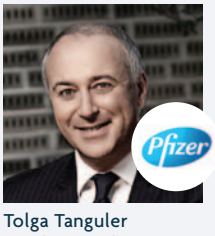

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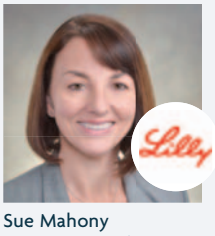

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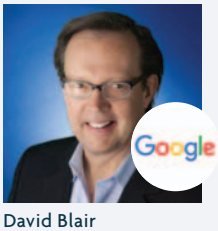

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