Belén Garijo, CEO Healthcare, Merck KGaA, Darmstadt, Germany
RP Scherer invents the rotary die encapsulation process, launching 80+ years of innovation

1940 First prescription softgel capsules
1955 In-line printing for softgel capsules
1960 Cough, cold and allergy softgel capsules
1993 OTC Liqui-Gels®

  CosmoPod® topical twist-off capsules

2001 Vegicaps® natural, GMO-free, plant-based capsules
2016 First FDA approved OptiShell™ product with semi-solid fill formulation

2012–2016 New, break-through technologies that help enable more molecules, convenient dosing and better treatments:

- OptiShell™ non-gelatin softgel for extended drug release
- OptiGel™ Bio for oral delivery of macromolecules
- OptiGel™ Lock for multi-level abuse deterrence
- OptiGel™ Mini for concentrated formulations in a smaller size
- OptiGel™ Micro delivers our smallest, micro-sized softgels
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Biopharma Change Agent: Belén Garijo

William Looney, Editor-in-Chief

Pharm Exec visits with Spanish-born Belén Garijo, CEO of Merck KGaA, Darmstadt, Germany’s healthcare business, who shares her steady-eyed approach in transforming a traditional pharma unit focused on small molecules for chronic disease to a high-tech specialty producer of immunotherapy drugs for rare cancers.

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- If it does, it means they weren’t branded, just brandnamed generics ...
  IDEA Pharma, @ideapharma, 12/17/16
  “Loss of Exclusivity Doesn’t Have to be the Death Knell for Branded Drug Revenue Streams”
  bit.ly/2fraise

- Board composition is key for #pharma success in emerging markets
  Damiano de Felice, @damidefelice, 12/14/16
  “The Winning Edge in Emerging Markets”
  bit.ly/2gkMg47

- There are two ways #Africa presents itself to the world — as a powerhouse or a dark continent
  NextBillionHC, @NextBillionHC, 12/9/16
  “Investing in Africa: How to Do It Right”
  bit.ly/2hjDdA8

- @PharmExecutive Indian Govt. not interested in strict implementation of Drugs and Cosmetics Act or any other Health laws
  H R Topiya, @HiraTopiya, 12/5/16
  “What’s in—and Out—of the ‘Cures’ Bill”
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**Latin America Roundtable**
Pharm Exec convenes a panel of executives responsible for the Latin America business to discuss investment, market access and reimbursement issues in this key regional growth market for biopharma companies.
As new faces and agendas emerge in Washington, pharmaceutical companies will face multiple challenges in developing safe and effective therapies that are affordable to patients and payers alike. More biosimilars, cellular and gene therapies, complex dosage forms, vaccines and combination therapies will benefit from innovative research and regulatory approaches. And the imperative of combating the devastating opioid epidemic across America will require formulations able to treat pain while also resisting abuse and misuse, and also put the spotlight on the role of marketers in promoting opioid prescribing.

These issues will be shaped by a new administration that has pledged to overhaul the nation’s healthcare system. The prospect of millions losing coverage has dire implications for drug prescribing and reimbursement, and for maintaining an effective drug regulatory and oversight program. Conservatives in Congress and the White House are looking to scale back federal government operations through budget cuts and hiring freezes. Such actions could be devastating for biomedical research at the National Institutes of Health (NIH) and for FDA, which already lacks sufficient resources to carry out its many mandated responsibilities and struggles to fill some 700 open staff positions.

Pharma companies could gain from corporate tax reform under Trump that lowers rates and facilitates repatriation of foreign revenues to US-based companies. At the same time, Trump’s rejection of the Trans-Pacific Partnership (TPP) trade deal undermines prospects for global harmonization of patent policies and for common standards for conducting clinical trials, producing quality medicines, and ensuring adherence to ethical and legal standards.

While industry hopes to avoid an all-out anti-pharma campaign from the new administration, pharma was jolted last month by Trump reiterating his promise to “bring down drug prices.” Continuing public outrage over too-costly medicines has prompted some pharma CEOs to pledge limits on annual price hikes. They’re also blaming price increases on the need to pay ever-higher rebates and fees to pharmacy benefit managers (PBMs) and wholesalers and calling for greater transparency in how the current distribution process limits manufacturer revenues and harms consumers who lack adequate insurance coverage.

Marketing flexibility
At the same time, a de-regulatory approach that challenges FDA restrictions on industry communications and promotional activities could lead to important policy changes for marketers. In response to legal challenges on several fronts, FDA held a public hearing in November to discuss proposals for revising policies that limit the dissemination of off-label information. Biopharma companies cited the benefits of discussing additional uses of medicines with health professionals, while FDA officials and consumer advocates raised concerns about permitting wider promotion of unproven claims.

Marketers also hope FDA will revisit its regulatory approach to social media communications and current curbs on how companies may respond to queries about unapproved uses at public meetings and through online postings. An early win could come from clarification of FDA policies for disseminating economic information on products to health plans and formulary committees. A more flexible approach was originally proposed in section 114 of the 1997 FDAMA user fee legislation, but never implemented; language in the the 21st Century Cures legislation supports such action (see sidebar).

Trump reformers also could back changes in the Open Payments program that scale back requirements for reporting pharma payments to doctors and hospitals. Critics killed a provision in the Cures bill that dropped reporting on the value of reprints and fees paid physicians for continuing medical education activities; industry
and CME providers will press further for that revision and other changes in the “Sunshine” program.

**Innovation & evidence**

A main theme of Congressional reformers is for FDA and industry to facilitate faster patient access to new therapies, a goal championed by multiple Cures provisions. But regulators can only approve those applications that sponsors submit, and that has slowed down. As 2016 came to a close, FDA officials reported that new drug approvals for the year would fall far short of the near-record set in 2015. Very disappointing is the recent failure of clinical studies for a promising Alzheimer’s disease treatment and patient deaths that shut down clinical trials for a new cancer therapy.

These developments raise questions about how much data and what kind of evidence is needed to bring innovative products to market. FDA has approved numerous breakthrough therapies for cancer and critical conditions based on limited but convincing clinical data, increasingly with input from knowledgeable patient advocates willing to assume added risk. But the agency fears that pressure for speedy approvals despite safety signals and uncertain efficacy could undermine the regulatory process more broadly.

The issue came to a head in the recent debate over approval of Sarepta’s treatment for Duchenne muscular dystrophy. FDA reviewers found the clinical evidence too slim to support approval, but families of ill children saw benefits from the drug and pressed hard for access. Similar questions have emerged related to authorizing a new antibiotic that promises to address growing resistance, but has presented serious safety issues in clinical trials.

FDA officials also are concerned about the proliferation of priority review vouchers. While these may encourage industry investment in medicines with limited financial return, reviewers fear the program will undermine and overburden drug review operations.

Added pressure to scale back oversight of drug safety and efficacy raise the risk that key FDA officials will depart and leave these challenges to others, as seen in the recent retirement of John Jenkins, long-time head of FDA’s drug approval office and widely praised as fair-minded and dedicated to public service. His skill in explaining the complex issues related to difficult regulatory decisions will be sorely missed.

As 2016 came to a close, FDA officials reported that new drug approvals for the year would fall far short of the near-record set in 2015.

**Something for everyone in ‘Cures’ package**

Congress gave biopharmaceutical companies an early Christmas present by enacting the 21st Century Cures legislation with its many provisions affecting drug development and regulation. It bolsters FDA operations and provides significant funding for research at NIH. Congressional sponsors broadened support for the bill by including something for everyone: funding for state opioid treatment programs, expanded mental health services, and support for research on regenerative medicine and on medical countermeasures. A handful of liberal Democrats objected that the bill does nothing to control drug prices, and that it compromises patient safety by permitting wider use of less rigorous data to approve new drug uses and medical devices. Their complaints centered on using novel clinical trial designs and modeling and permitting wider reliance on real-world evidence to support approval of added indications for marketed medicines.

Advocates countered by highlighting provisions in the bill to further pediatric research, patient-focused drug development, qualification of biomarkers, and the development of needed antibiotics and treatments for rare conditions. FDA, moreover, strongly backed language that will help it hire and retain the scientists and experts it needs to evaluate new medical products.

A main disappointment is that the additional $4.8 billion over 10 years for NIH and $500 million for FDA is authorized, but not appropriated, opening the door to future cuts in promised resources. Advocates emphasized that Congress will need to ensure that the funds included in “Cures” will be additive to money provided by the regular appropriations process.
Setting the Pace for the Patient Journey

How Triplefin’s suite of hub-based e-solutions and customized investments in the “human touch” are outrunning the clock on prior authorization claims—a key source of delays in patient speed to therapy.

Biopharma companies are facing a transition in the way their top brands are assessed for coverage and used by patients. The most prominent is segmentation of the growing specialty drug category, from high-priced infusion or injectable biologics for small groups of patients, administered as a “buy and bill” transaction directly by physicians in the clinic; to a more therapeutically diverse array of medicines used in larger chronic care populations, dispensed at the retail pharmacy level, and self-administered by patients at lower price points. An example is in oral oncology drugs, where dozens of new entrants to the market are replacing those traditional clinic or hospital products with higher profit margins.

Another layer of complexity is the varying standards for determining patient eligibility and reimbursement for specialty drugs dispensed either as a major medical benefit or a pharmacy benefit. Because the two categories are associated with different models of patient care, it has added to the time and expense of establishing what’s covered under the rules for various competing commercial plans. Classifying a new medicine as a major medical benefit also raises the stakes in managing patient access to the many supplemental services that manufacturers must provide to ensure these prescriptions are filled and dispensed promptly, as intended. This is particularly true now that cost is a major factor in the product launch cycle, where a strong initial uptake from patients is critical to a new brand’s ultimate success in the market.

Manufacturers want more

As the specialty space adapts to this much larger competitive set, the battle is on for a realignment in the traditional “Hub” patient assistance model used by manufacturers to support the prescription. The bottom line? Manufacturers are demanding more options.

Triplefin, the leading supplier of Hub services, has responded with a customized “Hub-Lite®” model designed to suit each brand’s profile and run at a lower cost. Says Elizabeth Gibson, Triplefin’s Director of Product Strategy, “Hub-Lite® appeals to the growing mid-range segment of the specialty market, covering medicines with retail prices of $400 to $1500 per month. At these lower margins, program costs are an obvious concern for the manufacturer. We’ve been able to use e-solutions in selected areas to obtain savings by making data more accessible to the decision-makers on patient care.”

Gibson stresses that many hub programs still provide the traditional basket of “high touch” services in addition to the savings obtained through efficiencies on the automation side. “Our approach is bespoke, where we work with the manufacturer on a customized program unique to each brand.”

Prior Authorization:

Slow dance to nowhere?

Triplefin has particular expertise in helping manufacturers navigate Prior Authorization (PA) requirements, which emerged as a key concern at the annual Electronic Benefit Verification and Prior Authorization Summit, sponsored by Pharm Exec’s sister conferencing organization, CBI, on October 25–26 in San Francisco. The 150 attendees cited PA as the biggest headache in initiating Hub-enrolled patients on their prescribed drug regimens.

Insurer reliance on this cost management tool is growing: more than 265 million claims in the U.S. required a PA in 2015, a trend which has forced the average physician to spend upwards of 20 hours per week obtaining necessary approvals. More important, statistics show that nearly 70 percent of patients subject to a PA end up not receiving the original prescription, a major drag on medication compliance and persistency.

Many speakers from the manufacturer side noted the stress factor with PAs was highest in the major medical benefit category. Given the slowing rates of up-take for newly launched medicines, manufacturers need things to happen fast. PA requirements interrupt the flow from prescribing to dispensing. The overall cost and complexity of drugs administered through major medical lead to significant variations in eligibility, adding to the processing burden on providers in making their case to insurers. Compliance is impacted by the need to involve the patient in this process, which can be distracting to therapy. And all this is happening while payers focus attention on the disproportionate number of high-priced specialty products classified under major medical. For these
costly products, payers want reliable data on value-based outcomes. But how can the manufacturer demonstrate such outcomes if time, money and resources are diverted to just getting approval for a patient to start taking the drug?

**Fighting back with e-solutions plus**

In a presentation to CBI participants, Triplefin’s Gibson examined the potential of automated electronic verification as well as new tools like predictive analytics in removing PA as a barrier to the ultimate patient solution: speed to therapy. “Better information exchange is the key to understanding the impact of specialty medicines on PA, particularly in light of all the nuances around benefit structure and design for both the pharmacy and medical benefit. The aim is an improvement in the PA workflow: deploying necessary information effectively through the Hub networks, using ePA automation technologies to cut the time and streamline the documentation it takes to get the patient on script.”

That said, progress toward real-time PA determinations made possible through ePA is still too slow, according to Gibson. There are specialty payer limits on the type of transactions covered, failures to coordinate PA requirements with diagnostic/treatment codes, glitches in the inclusion of attachments to ePA application forms, as well as the common practice requiring that any decision labeled “pending” be followed up manually by the provider—which some observers see as a delaying tactic to patient access.

In addition, automated ePA claims management, while important, is not enough to accommodate the larger issue of what insurers and payers really want from the PA process: evidence that a patient’s experience with the drug will contribute to a positive, measurable outcome of therapy. For that to take place, the information flow must evolve from data that is not only retrospective but predictive as well, relevant to resolving a formulary challenge to capturing real-world evidence of value. Says Gibson, “Triplefin believes in predictive analytics. We are investing in a variety of advanced data systems to bring the future to today. I liken our approach to how the hockey great Wayne Gretzky defined success in the rink: ‘I skate to where the puck is going to be, not where it has been.’”

Triplefin is taking a variety of approaches to assist its manufacturer clients of all sizes in managing their way through the PA thicket. Notes Gibson, “for the Hub-Lite® customer, we aim to get them to a fully automated solution set, maximizing the cost and efficiency benefits offered by the latest technologies. We already know that a standardized ePA process would save the industry $5.8 billion annually in health transaction costs. However, piecemeal regulation and other practical realities require added people skills to deflect PA bottlenecks. This is evident at the back-end of the process, where personalized follow-up makes a measurable difference in patient speed to therapy.

Triplefin also pays close attention to advocacy work by engaging in initiatives to build a common set of governance standards on ePA. “The best way to describe the current regulatory situation, with its diverse array of institutional players, is aspirational,” Gibson told CBI. “Like Gretzky, we advise clients where the puck is going—and how to be the first skater to get there.” That’s important due to the glacial place of rule-making in health information, where it can take a decade or more to move from evaluation by committee to final rule adoption and, most important, implementation in the field.

**Reaching out**

Triplefin works directly with key influencers shaping the standards process, including the American National Standards Institute’s [ANSI] “X12” project [www.X12.org] to develop and maintain common industry-wide EDI standards; and the National Council on Prescription Drugs Programs [NCP-DP—www.ncpdp.org], a multi-party forum to connect healthcare services electronically, in the best interests of the patient. The stakeholder network is constantly changing—and likely to shift once again as a new GOP administration takes hold in Washington. “Our goal is to keep the policy process consistent, so that these standards-setting organizations do not end up going down different paths.”

The other plank in the strategy is keeping pace with advances in IT, with an eye on emerging innovations that might work at the Hub level for a particular brand. In that regard, Gibson pledges the virtues of experience. “Back in 2010, Triplefin became the first vendor to offer a Hub-based brand benefit support program at the retail pharmacy level. Over the years, we have been able to expand this base to a truly customized range of services, from basic ‘e-self-service’ programming to a ‘white glove’ approach that handles every stage of the patient journey, including PA.”

In fact, Triplefin’s most important offerings might just be helping clients understand the changing rules of the game in the hard-fought arena of benefit verification—a ratification of its unique, all-in approach to patient engagement. And the growing cost of specialty drugs and the services that underpin them is going to make this inclusive, hands-on service model more vital than ever to brand success.
In conversation, Belén Garijo does not miss a beat. Behind those practical but stylish glasses is a woman with a sharp eye—an eye that travels—observing, processing, and always staying one step ahead of the next question. The impression the 56-year-old physician gives to a visitor ranges from curiosity to empathy to decisiveness. These are character traits that fit well with the mandate she holds as a change agent, responsible for repositioning a traditional pharma business centered on small molecules for chronic disease to a high-tech specialty producer of immunotherapeutic drugs for rare cancers.

Pharm Exec speaks with Spanish-born Belén Garijo, CEO of Merck KGaA, Darmstadt, Germany’s healthcare business, who shares her steady-vision strategy in transforming a traditional pharma unit focused on small molecules for chronic disease to a high-tech specialty producer of immunotherapeutic drugs for rare cancers. Joining Merck KGaA, Darmstadt, Germany in 2011 to lead commercial operations for the Biopharma business, of which Garijo was tapped to be CEO in 2013, she then became the CEO of the overall healthcare business later that year, succeeding Stefan Oschmann, who is now Chairman of the Executive Board & CEO of Merck KGaA, Darmstadt, Germany. Garijo is responsible for nearly two thirds of annual Group turnover, and sits as one of six members of the Group’s Executive Board.

Garijo summarizes her task with a simple mission: To be first in disease. And to be first to market.
There is also a daunting metric laid down by her boss, Executive Board Chairman Stefan Oschmann, to generate $2 billion in new sales over the next five years, mostly from the output of a novel immuno-oncology partnership forged with Pfizer in 2014. That growth must be secured in the midst of a deepening skepticism among payers that new entrants to this increasingly crowded therapeutic field are differentiated enough to justify a premium launch price. It’s an argument about creating a common language on value—can this multilingual advocate for innovation make the case?

In an interview last month with Pharm Exec at Merck KGaA, Darmstadt, Germany US Healthcare headquarters at EMD Serono in Rockland, MA, Garijo holds forth on how the trust of mentors overcame some early resume gaps; the “no rule book” standard for tackling culture conflicts in M&A; lessons from repositioning a conservative R&D organization to take the risks required for breakthrough innovation; and rejecting the notion that women executives, unlike men, must choose between family and career—it’s a myth, she says, a bind on the potential from thinking forward. Here are excerpts from our conversation. — William Looney, Editor-in-Chief

PE: Your career has been focused on the intangibles around business transformation: leading the integration of large organizations, often with markedly different cultures, and moving them to embrace a new way of relating to products, customers and patients. You are also a physician with a strong bias toward professionalizing the practice of medicine. What lessons have you learned from prior assignments at Abbott, Aventis, and Sanofi and how do you apply them in the context of your current role as one of the most senior women line executives in the industry?

GARIJO: I must be honest. My early goals in life had nothing to do with business. I am surprised where I am today, as a global line executive responsible for a $7.7 billion P&L business with operations in 56 countries. I wanted to serve the community as a practicing physician, where I grew up in a small city in southern Spain. I received my medical degree and spent six years tending to patients in clinical pharmacology and internal medicine, where the powers of observation, good judgment, and personality count and you have to improvise a lot.

Still, for me, a life in the clinic was confining and lacked potential for professional growth. An opportunity arose to join Abbott, as medical director for its Spanish affiliate. I took the position because I recognized this function was important to the industry’s future, as stakeholders embraced the medicalization of information in approving drugs for patients. Abbott ended up bringing me to its Illinois HQ, where I was exposed to a diversity of experiences that launched me into the position I hold today.

It was a risk, both for me and for the company, which assigned me an international medical affairs portfolio without any obvious credentials that qualified me for the role. Abbott enabled me to shift from an individual practicing physician, reliant on other people’s innovative ideas for new medicines, to a member of a large R&D team responsible for those ideas in the first place.

One lesson I draw is how much my career has been shaped by people who trusted me more than I was prepared to trust myself. Opportunities arose...
“One lesson I draw is how much my career has been shaped by people who trusted me more than I was prepared to trust myself.”

despite lacking the experience normally associated with the job. For example, trust from others helped me make the second major transition in my career, moving from the medical/R&D function to the commercial side of the business. I had the good fortune to benefit from superiors who acted on hunch and instinct to see beyond the narrow parameters of the job description. My mentors shared a trait in pursuing a personalized view of the world, allowing my own profile to define the job instead of the other way around. They were disruptors in choosing people whose lack of experience predisposed them to act differently.

I follow this precept now that I am responsible for talent development for 20,000 colleagues in the Group’s healthcare business. I want them to benefit from that same open mindset in evaluating potential. Taking a chance on someone is inherently good. How else can a company break the mold and adapt to the changes that now demand an entirely new approach? You can’t follow a prescriptive path to finding good people in an industry where success is so often circumstantial.

PE: You are from Spain, obtained your first significant assignment in Chicago, and held senior roles in a company—Sanofi-Aventis—that evolved as a hybrid of German and French management with a touch of US entrepreneurial spirit, at Genzyme, where you oversaw that company’s integration with Sanofi. Has the experience made you believe that culture is a defining characteristic of organizations today, or in this era of globalization, is it that all organizations are more or less alike?

GARIJO: If your business follows opportunities across regions and markets, then you have to create a culture that unleashes the positive potential of diversity and inclusion. We are an industry highly dependent on human capital. Setting a distinctive culture with strong input from the top tier of management is critical to molding that capital in a productive way—one that bridges the differences induced by geography, demographics, and business practices, reinforced by social values and traditions. Culture is essential when you consider the fundamental fact that tactics that make for success in the US are not necessarily going to deliver the same results in China.

Hence, few people believe that a strong, distinctive company culture doesn’t matter in an industry as globalized as biopharma. My ascent in management is due to having lived and worked in so many different countries, where I was able to experience how to execute priorities, adjust my communication style, and to lead and inspire teams to do their best for the company. One of the hardest tasks in working within a strong cultural mindset is to execute well locally while retaining a global perspective on the big strategic issues. You have to maintain a balance between these two, often conflicting impulses. What will require global engagement and where will a local focus prove optimal? The best managers in biopharma learn how to create this context early on, which then trickles down through the ranks. That’s how culture makes a difference.

PE: Do you believe that women managers are more sensitive to the importance of company culture than their male counterparts?

GARIJO: Women tend to see the issue of culture from a more personal perspective, because women managers—more than men—evaluate family obligations against the day-to-day requirements of their job. This dimension underscores the cultural aspect of living in two worlds. It’s often said that only women executives are obliged to make “choices” between children, family, and their career.

Speaking for myself, I think that view is exaggerated. I work hard to bring other women into senior jobs in the healthcare business, yet I find it a challenge because I see these very women expressing regret that, “if I follow this path, I will have to forego my family.” I’ve heard the remark so many times and I make it an obligation to show that making such an either/or choice is unnecessary. I worried about this at various stages of my career but in the end, my fears proved false. One reason is our company has embraced technology as an internal communications tool. It makes everyone more mobile and employees with children are key beneficiaries—working remotely when necessary is easier than ever.
You have been assigned key leadership roles directing the merger of Aventis and Sanofi operations in Spain, the JV combination between the MSD and Sanofi-Pasteur vaccines businesses, as global integration leader for Sanofi’s acquisition of Genzyme, and, currently, as the senior executive responsible for the oncology development partnership with Pfizer. What insights can you share on creating these combinations and managing them successfully?

The most important goal in any integration is delivering on the hard objectives—and the essential ingredient is figuring out the “how.” The way to do that is adopting a highly inclusive style of leadership, on both sides, which begins with securing a reputation as a good listener. It is also important to remain focused on the ultimate objective in combining the two companies. This involves thinking above and beyond the tactical element of finding synergies, like reducing costs.

Another key task is distinguishing between short-term goals and what you must do to position the combined business for success over the long-term. For the latter, a three-year, step-by-step road map has to be put in place very early in the process. This evaluation has to include a strong commitment to culture change—without that, delivering on the original promise behind the deal will be harder to achieve.

I learned this the hard way, when I worked for Aventis as general manager in Spain while it was being acquired by Sanofi. I was chosen to lead that process, requiring me to scuttle my own business plan and priorities to conform to what Sanofi wanted from the integration of our two operations. I had to abandon several local product launches and take the painful step of moving our offices from Madrid to Barcelona, a “mission impossible” process virtually unheard of in Spain, with its pronounced regional identities.

In addition, I had to lead a management committee composed of two sets of executives used to operating in distinctly different cultures. My Aventis colleagues worked in a decentralized environment with a lot of local autonomy, while the Sanofi people were very buttoned up and expected to be guided from the top.

Sitting at the table in front of these people forced me to change. I had to create a sense of balance and to accomplish that I put an unrelenting focus on the need to make a fresh start. Together, we had to reinvent all the rules, so instead of perusing all the management manuals we devised a simple question to benchmark our progress: will this action create or add value to the combined company? If it did, we did it; if it did not, we went in another direction, even if in doing so it required a cultural adjustment, on either side.

The deal sparked criticism from investors because the big pharma culture of Sanofi was perceived as a drag on the characteristics that made the Genzyme business so attractive.

There was a firm consensus at Sanofi to preserve the independence and entrepreneurial culture at Genzyme. The word came down from the Board: no “sanofizing” Genzyme. Hence, we had a clear assignment to protect and preserve the culture of Genzyme within the larger organization. In fact, we went beyond that and helped drive a new business model for the combined company, founded on what at the time was Genzyme’s unique “patient-centric” approach to the customer. It remains the motivating principle behind all of Sanofi’s stakeholder relationships today.

I joined Merck KGaA, Darmstadt, Germany as chief operating officer for the biopharma business, after the integration with Serono. I discovered no real integration of these two family-owned businesses had taken place. Serono
remained at its former HQ in Geneva; many executives continued to act as if it was still independent. This mindset needed to end, which we accomplished by pulling out of Geneva and redistributing resources to our R&D facility here in Massachusetts. It was another example of fostering a necessary change in culture, emphasizing our tilt to a global, US geographic focus. Closing Geneva, thus, had little to do with just cutting costs.

“One of the hardest tasks in working within a strong cultural mindset is to execute well locally while retaining a global perspective on the big strategic issues. … The best managers in biopharma learn how to create this context early on.”

**PE:** You joined Merck KGaA, Darmstadt, Germany in 2011, taking a series of assignments that have also been transformative for the company. How has the Group changed in the past five years?

**GARIJO:** Merck KGaA, Darmstadt, Germany at that time was at an inflection point: in 2011, we confronted a crisis with the regulatory authorities in the US and Europe declining to approve cladribine, a key successor drug to Rebif in our MS pipeline. Management had to acknowledge that the company was faltering on the innovation, clinical development, and regulatory affairs fronts, not having introduced a patent-protected medicine in more than a decade.

When a big dream disappears, the consequences can clarify the mind—and that’s what happened here. I was tapped to lead the healthcare division, which was, and, at 65% of total Group revenues, remains the largest of our three global businesses. My mandate was to return to the fundamentals: commercializing patent-protected medicines on diseases for which there are few equivalent treatments. The design was to move from being a supplier of traditional pharmaceutical and chemical products, operating mainly in Europe, to a global company centered on innovative science and technology.

The early phase of this transformation focused on operational efficiencies. But we’ve moved well beyond that to create an entirely new business model, with an emphasis on high value specialty drugs for complex conditions like cancer and various immunologic disorders. In that sense, we’ve moved away from small molecule medicines in primary care, characterized by low margins and generic competition. As a company with deep roots in Germany, where we were founded almost 350 years ago, our sales were over-weighted to the region’s low growth cycle, so we decided to pivot to North America and the emerging countries. More than a fifth of our revenues now come from the US, a market that is central to the Group’s future.

All of this is framed in a strategic plan we call “Fit for 2018.” It has put us on track to a different product portfolio as well as a different geographic reach. Our healthcare business is less dependent on Germany and Europe while the product portfolio has broadened beyond our traditional MS franchise to include products in the most promising therapeutic segments, including next generation immuno-oncologic drugs and combinations and in immunology. We are also expanding our base in fertility treatments, a patient-sensitive business where we benefit from decades of expertise.

**PE:** What’s the current state of progress toward “Fit for 2018?”

**GARIJO:** We have completed work on the operational overhaul of the business and are well along in the growth phase, which involves launching new products, including the results of our novel oncology partnership with Pfizer. We’ve successfully introduced a new commercial operations model built around a smaller, more specialized and “high touch” sales force. We have reinvigorated our core franchises, in MS and fertility products, aiming to make these global products, with a pole position in all the major markets but especially the US. We are filing again for EMA approval of our investigational compound cladribine and are looking to do the same in the US.
Innovation is a second element in Fit for 2018’s grow-the-business phase, where we intend to establish ourselves as a leader in specialty medicines for rare and complex conditions like cancer. This required a substantial overhaul of R&D, accomplished in a restructuring we completed in early 2015. More productivity from existing resources was our aim, combined with placing us as partner of choice in in-licensing drugs or leveraging internal assets we could not commercialize on our own.

It started with an extensive pruning of our product pipeline, a high stakes gamble in which we eliminated nearly all that we had in late-phase development while accelerating discovery work in three therapeutic areas: oncology; immuno-oncology; and immunology. The centerpiece of this new strategy is our investigational compound avelumab, the key product in our partnership with Pfizer, with potential indications—as monotherapy or in combination—for a wide range of cancers and tumor types.

The third priority is upgrading regulatory and development capabilities to boost our standing with the FDA. Progress to this objective has been facilitated by the expansion of our R&D presence in the US. The Geneva closure gave us the leeway to recruit more talent here in the US. Half of our regulatory and drug development teams now consist of experts we have attracted from outside. We’ve kept all the talent we had on the discovery side. It has given us opportunity to shake up the innovation process and reinvigorate the pipeline, which I believe is better than anything we have seen in the company before.

**PE:** Is it fair to say avelumab is the inflection point of the “Fit for 2018” strategy?

**GARUJO:** I would say it symbolizes our progress in repositioning the business around patient centered, breakthrough innovation. Avelumab was developed here, in-house; we brought it forward to Phase I. But as we saw its potential, we also knew we lacked the size, scale, and presence to reap that potential on our own. In recognizing avelumab as an important product, Pfizer has ratified our company’s emergence as a player in oncology, particularly in the competitive US market. That’s a game changer for us. It also freed up internal resources that we could devote to the parts of our pipeline outside oncology. And, to be sure, we have other assets besides avelumab.

**PE:** Can you summarize the current state of the partnership with Pfizer? How are decisions made by the two parties?

**GARUJO:** Right now, we have nine pivotal trials underway and 30 clinical programs in multiple indications and tumor types. Avelumab, our anti-PD-L1 antibody, has been accepted for review for a marketing authorization by the FDA and the EMA, as a treatment for Merkel cell carcinoma, a very aggressive form of skin cancer. Regulators have granted breakthrough therapy designation, which means a fast-track status to our applications, and we expect decisions by the agencies later this year.

Beyond this, we are collaborating with Pfizer on more than 30 different investigational programs, including the following cancer types: non-small cell lung cancer; renal cell carcinoma; bladder cancer; third line gastric cancer; ovarian cancer; and squamous cell carcinomas of the head and neck. Each of these represent cancers with few alternative therapies—the unmet medical need is great. We also have a co-promotion program in the US and other countries with Pfizer for Xalkori, launched by Pfizer in 2011 for treatment of ALK-positive metastatic non-small cell lung cancer.

The goals are ambitious, but we are pursuing them as a marriage of equals: it’s a 50/50 allocation right down the line, from development to commercialization. There is a global Executive Committee that decides, with members divided equally between both companies. Discussions are open and each participant is free to bring his or her own ideas to the table. We are looking for exposure to as many sources of expertise as we can manage.

**PE:** Is the partnership focusing on potential post-approval issues, such as strategies on market access and pricing? Are you building a value proposition with appeal to payers? Or is this handled separately?

“When a big dream disappears, the consequences can clarify the mind—and that’s what happened here.”
GARijo: We are very attentive to this area. In fact, I met [recently] with the US commercial and medical teams to underscore the importance of working with stakeholders to communicate our value platform to payers, oncologists, and patients on avelumab as well as the investigational drug M7824, a potential first-in-class bifunctional fusion protein therapy, which is a new approach to immunotherapy beyond the current class of checkpoint inhibitors. All of us are aware that a tolerable risk-benefit profile is not enough to drive market uptake. It has to be accompanied by proof that the incremental value of the product is significant in terms of patient outcomes. That has to drive our entire approach to product development in the US, which is a proxy for the rest of the world, too.

One thing that concerns me is silo thinking between the development teams, which focus on risk-benefit, and the market access teams, which often intervene very late in the journey to registration. I am pursuing a single integrated strategy, with a team responsible for considering risk-benefit and value simultaneously; relying on the best and most novel approach to evidence we can muster. We intend to prove this model on the M7824 compound because of its possible potential as a curative tool in cancer immunotherapy.

PE: One part of your functional portfolio is leading the Merck KGaA, Darmstadt, Germany’s reputation enhancement efforts. What benchmarks can you cite here?

GARijo: I take this commitment seriously. Together with my colleagues on the Executive Board, I took the initiative to create a separate, dedicated Access to Health (A2H) unit that works across the company to bring more of our medicines forward to the patients who need them. Our work has been rewarded by the independent Access to Medicines Foundation Index on industry performance in promoting access, where we rank fourth among the 20 largest global biopharma companies surveyed. Given our smaller P&L footprint relative to the others in the list, we are definitely punching above our weight on this issue.

In a larger sense, it’s important to stay vigilant and recognize how important industry self-regulation through various codes of conduct is to preserving our global license to operate. Our business practices are rigorous and well recognized by our customers, in all markets and geographies. Nevertheless, from an industry-wide perspective, we must be more proactive in presenting the value our products bring to society. The present industry effort around the value argument is not sufficient for the long-term. Our company carries a unique advantage here in moving the industry forward. As a family-owned and family-oriented enterprise, corporate responsibility is a given: it remains integral to our priorities on the business side. There can be no separation of the two.

PE: To conclude, how will you measure success as you lead the Merck KGaA, Darmstadt, Germany’s healthcare business in 2017?

GARijo: Our success will be measured by how well we execute on our strategic priorities to deliver $2 billion in incremental sales by 2022 and the successful launch of the drugs currently in our pipeline. At the end of the day, it is the way we manage these that will decide on the speed and volume that we can provide patients with access to these drugs. We expect the first launch of avelumab in 2017, followed by additional launches each year after 2017 through 2022.

Bio: Belén Garijo, MD

Born: Almansa, Spain
Age: 56
Family: Married, two daughters
Current Roles: Member of the Executive Board of Merck KGaA, Darmstadt, Germany, since January 2015. Responsible for the Healthcare business sector, comprising the Biopharma, Consumer Health, Allergopharma and Biosimilars businesses. Since 2013, has acted as President and CEO of the Biopharma business, where she started in 2011 as Chief Operating Officer. Reach: Responsible for a $7.7 billion P&L business with operations in 56 countries.
Previous Posts: Senior Vice President, Global Operations Europe, Sanofi-Aventis; Global Integration Leader for the Genzyme acquisition in 2011; General Manager of Aventis Spain from 2003 to 2006, subsequently leading the merger of Sanofi-Aventis in 2004; lead International Medical Affairs at Abbott Laboratories.
Early Career: Worked as a practicing physician for six years; is a medical doctor specializing in clinical pharmacology.
Also, our ambition is launch cladribine in Europe and to file in the US, which will hopefully be followed by other promising compounds in the pipeline outside the oncology space. In addition, expect to see the fruits of our special expertise in combining drugs with devices from other parts of the business to create intelligent delivery solutions for patients.

At the same time, we want access to the best external innovations to fuel our discovery engine through creative approaches on in-licensing. I point to our new agreement with Intrexon, a US leader in synthetic biology, to share expertise in CAR-T technology applications geared to expanding the treatment pathways in immuno-oncology.

Other platform-partnering projects are underway with two US-based biotechs, Mersana Therapeutics and Sutro Bio-pharma, to develop next-generation antibody drug conjugates to fuel early-stage discovery and preclinical development activities. Our goal is to be either first in disease or indication to bring innovation to patients in need; this will be our key measure for 2017 and beyond.

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“Our success will be measured by how well we execute on our strategic priorities to deliver $2 billion in incremental sales by 2022 and the successful launch of the drugs currently in our pipeline.”
The pharmaceutical industry has a lot to balance: volatility in its relationship with policymakers, scrutiny over supply chain security, consolidation and public outcry over drug pricing. It’s doing this while continuing to drive innovation and combine broad access with actionable data and real-world evidence.

Casey McDonald, Pharmaceutical Executive (PE) senior editor, caught up with two top AmerisourceBergen executives at ThinkLive 2016, the company’s annual conference for 500+ manufacturers and partners at which industry leaders collaborate on everything from commercialization strategies to next-generation patient-support programs. Steve Collis, AmerisourceBergen’s chairman, president and CEO, and Peyton Howell, executive vice president and president of global sourcing and manufacturer relations at AmerisourceBergen, offered their take on how distributors can best provide value to and relieve some of the pressure on manufacturers.

**PE:** How does AmerisourceBergen approach its relationships with manufacturers in the difficult environment we’re facing?

**Collis:** We start by acknowledging that not all manufacturers are the same and each has its own needs. From big US and European pharmaceutical companies to smaller biotech organizations and, of course, players like generic drug makers to new companies getting ready to launch a new agent, we have built the expertise, connectivity and solutions to help manufacturers of any size maximize their products’ potential. We work across the spectrum, including animal health. We interact at every level down to the community veterinarian and pharmacist on up to the large-scale health systems and chains like Walgreens.

In fact, AmerisourceBergen’s success is intrinsically tied to the success of pharmaceutical manufacturers. Our services are designed around the patient journey to improve product access, adherence and, in turn, create demand for our customers’ products, but they’re also designed to anticipate manufacturer pain points and provide the right solutions.

In the last few years, we’ve focused on building technology internally, like Certio, which provides data-driven insights to generics manufacturers to support their forecasting and production processes. We’re also using our strong balance sheets and cash flows to expand our services and deepen our relationships with manufacturers. We have actively worked to acquire market-leading companies within their categories, such as World Courier and MWI Animal Health, and integrate them into our culture. They have made AmerisourceBergen more robust and dynamic, but more importantly, they’ve given us more ability to support customers at every stage of a product’s life cycle in both human and animal health.

**PE:** Why acquisitions? What are you looking for in partners for AmerisourceBergen or potential opportunities?

**Collis:** The driver for this strategy is two-fold: our business model is built upon our customers’ success and our belief that the way to success is with relentless focus on the patient journey. We’re looking for companies that share that vision and can help us do that better.

One example is how we approached the acquisition of MWI Animal Health, which enabled us to share our knowledge between MWI and other parts of AmerisourceBergen. MWI associates are just as passionate about animal health as others are about human health, but they needed more access to a global market and perspective, which we provided. In turn, we are not only finding opportunities to share new technologies, but they’ve also helped us look at applying a demand-driven sales force, which we’re bringing to our generics business and partners.

I’m especially proud of our ability to find the right acquisitions and to respect and honor their entrepreneurial cultures. Nearly half of the AmerisourceBergen lead team joined through acquisitions, which has continued to bring us fresh perspective. We have developed an expertise in acquiring these complex, regulatory-intense, diverse businesses and integrating them into AmerisourceBergen. And, now, we must ensure all of our customers understand our breadth of services. Looking for a reimbursement partner? You may benefit from connecting with Lash Group. Need strategic consulting? An increasing array of manufacturers are learning about services companies like Xcenda offer—all within one existing partner: AmerisourceBergen.

**PE:** Switching gears, I heard participants at ThinkLive refer to AmerisourceBergen’s role as a “banker” for the industry. What does it mean for AmerisourceBergen to be seen this way?

**Howell:** It’s an interesting analogy. Imagine one central dot on a plane with connections to hundreds of thousands of other dots. That’s us—we’re the central point of contact connecting manufacturers with providers and vice versa. We give pharmacists, physicians, health systems and others one
In the last several years, AmerisourceBergen has become the single invoicing point of contact for pharmaceutical companies, and we do the same for manufacturers. Through us, they access tens of thousands of providers with the benefit of having one entity with whom to interface.

Contrast that scenario with markets outside of the US, where an individual pharma company might have more than a year of accounts receivable with hospitals, doctors and pharmacies. Our ability to relieve this pressure on our partners is a huge value for both upstream and downstream industry members, and yet, it’s the service that’s most often taken for granted because it’s not tangible.

We’re a streamlined resource for products. Pharmacists, health systems and physicians don’t want to purchase pallets of medications; rather, they want daily deliveries of only a few bottles or vials to better manage inventory. So, we take these individual orders—the “ones and twos”—and move them from pallets to providers. We ensure the right medication gets to the right party at the right time. There’s efficiency in our scale, but more importantly, there’s efficiency in the financial support we provide.

We serve as that same streamlined resource when financially connecting manufacturers and providers. It’s a big cost for us, but a huge value for our manufacturing partners. We can sell all products to a hospital, physician’s office, or independent pharmacy—brand, generic, specialty and so on. By doing that, we become “the banker,” if you will, for pharmaceutical companies. We give manufacturers a single invoicing point of contact versus the hundreds of thousands we then manage. We also have a better ability to collect than any single manufacturer would because that provider is buying all, or virtually all, of its products through us. Plus, we work so closely with providers that we truly understand their businesses and can offer terms appropriate for their cash flow. We convert uncertainty and delay into consistent cash flow.

The industry tends to focus on efficiencies. That financial component is extremely valuable to manufacturers and something they could not replicate on their own.

**PE: How does AmerisourceBergen use ThinkLive as a forum for individual physicians and pharmacists?**

Howell: ThinkLive is a terrific opportunity to engage with our customers and foster an open dialogue about how we can create best-in-class solutions to improve patient care, increase product access and enhance supply chain efficiencies. An important conversation from ThinkLive 2016 revolved around affordability. Take the example of the small community pharmacist who was struggling with a big purchase of an expensive oncology drug that only came in a large bottle. He was looking at a big financial loss—dollars he would be throwing out when the bottle expired and might only have been useful for an individual patient. His bottom line would suffer because of a distribution problem. We can work with customers to help manage ebbs and flows and offer them relief; meanwhile, we can be a voice back to the manufacturer to share when there’s a constraint.

**PE: Speaking of constraint, what are some of the new challenges facing the industry today and moving forward?**

Howell: There are so many challenges for manufacturers today, but certainly the pressure is on reimbursement. A drug’s value must be explained in a new way that shows health outcomes benefits to payers, speaks to payers in a competitive environment, and considers all the factors that impact patients at the site of care.

For manufacturers, figuring out the appropriate pricing from a value standpoint is one example of how complex things are getting. You may have a product with 10 uses. From a distribution and pricing standpoint, doses for all indications may all be different, which is challenging.

We’re also hearing about the challenges of commercialization strategy. You must step back and listen to providers. You can’t have a marketing group come up with a marketing solution that’s novel with a competitive advantage if it doesn’t work for the doctor, patient and hospital. That’s totally different than it was in past years when there were few specialty products, and you could focus on one target audience.

**PE: Tell me about AmerisourceBergen’s path forward.**

Collis: In the last several years, AmerisourceBergen has continued to become more global in our footprint and perspective. We’ll continue to pursue opportunities that allow us to bring the benefits of this position to bear for our customers, including expanding our offerings in and helping to shape the Latin American and Asian markets.

We’ll also look to grow our business through our collective specialty expertise, and invest in our core businesses, but continue to look for companies that will help us to be better, longer-term health care partners for patients and our customers.

We must come to an understanding that there are much more important objectives every day than just promoting shareholder value. And a vision that includes long-term shareholder value begins by being moral, making a positive impact in the community and doing the right thing for patients. For AmerisourceBergen, this comes with recognizing that we are truly a health care company, and this is an important differentiator that you’ll see us continue to deepen.
The populist-driven shifts trumpeted from the US to the EU leaves plenty of question marks when trying to size up the trajectory of the global pharma industry. One certainty, however, will be change

By Julian Upton and Casey McDonald

Perhaps more than ever this year, there is no escaping that ubiquitous word “uncertainty” in our annual look at what’s ahead for the biopharma industry. Donald Trump’s victory in the US elections and the UK’s vote to leave the European Union in 2016 were political earthquakes with aftershocks for pharma that could alter the landscape all the way from the already unsteady terrain of drug pricing and trade deals with emerging market countries to the labyrinthine administrative headaches generated by Brexit. In practice, whether the doomsayers or the optimists will see their visions realized will be dependent on how this shift to populism is ultimately strained through political filters, but for 2017, as Pharm Exec Editorial Advisory Board (EAB) member Cliff Kalb points out, pharma should expect that the major environmental constant will be change.

As Kalb reminds us, policymakers in both the UK and US are expected to reflect the will of the voter through their pro-Brexit and Trump victory mandates. Elections in France, German, and Italy may reinforce the trend as 2017 progresses. In the US, pharma is anticipating the demise of Obamacare, repatriation of overseas profits, and reduced regulation and taxes, freeing up cash. In Europe, the environment may change more gradually, but populist/nationalist attitudes place the Euro at risk and could see the potential rise of individual country level policy and regulatory regimes and a return to local currencies.
And there are still industry issues that will cause headwinds to growth, adds Kalb. “New therapies, such as combinations in cancer, a proliferation of orphan drug approvals, and the continuing shift in care from volume to value will offer up ongoing controversies around pricing, market access, and the industry’s public perception,” he says. “In the US, the end of the ‘free money’ Federal Reserve era may stimulate increased M&A, which ultimately results in employee uncertainty and redundancy.”

For Al Topin, president, HCB Health Chicago, 2017 is going to be “a maximum VUCA year.” First used at the US Army War College in the 1990s, “VUCA” was a framework to describe the volatility, uncertainty, complexity, and ambiguity of general conditions and situations of the Cold War. Topin comments: “Even before the election process began, the processes of development, commercialization, and marketing a new molecule was fraught with ever increasing risks. Add a new, unpredictable administration driving a shift in the legislative, regulatory, and financial environments — and VUCA clearly describes circumstances.”

We begin 2017 with more questions than answers, says Topin, among which are:

» Will industry have a clearer path through the FDA approval process?
» How will a potentially simplified approval process add to industry’s risks?
» Will a growing market continue to fund our investment in R&D and reward industry’s successes?
» Will reduced taxes allow for further investment, or will the closing of deductions add to industry’s expenses?
» Can further investments in digital platforms to maximize R&D and marketing continue to deliver savings and increased results, or with rapid industry adoption, will it begin to create a more level market?

Clearly, adds Topin, we are entering the world of “unknown unknowns.”

**Pricing**

Trump caused another upset after the election when he bluntly and, for some, unexpectedly announced that he was going to bring down drug pricing. For ZS Associates’ Ed Schoonveld, however, the pricing trends that were already under way—the shift to value and affordability—will continue irrespective of the US election outcome: “I don’t think anybody believes Trump is going to do things in total isolation,” he says.

Ipsos Healthcare’s Steve Girling, also a PharmExec EAB member, notes that “payers will continue to demand evidence cost savings as manufacturers invest significantly in real-world evidence generation strategies to provide the proof points to match the costs-versus-value arguments.” He points to established, chronic care markets like diabetes, which “will continue to feel the pressure from extensive competition in an ongoing price versus outcomes-driven payer paradigm.”

In oncology, though advances are leading to increased competition for immunotherapy treatments, different pricing dynamics seem to contribute to an escalating and unsustainable trajectory. “Will the new Republican administration’s action(s) regarding possible reforms to (or repeal of) the Affordable Care Act (ACA) and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) impact the overall cancer care of Americans and the cost of it?” Girling asks. Big science, with complex delivery solutions, and hopefully cures, seem like opportunities for “Trumpcare” to win “bigly,” if they can reach patients without bankrupting patients.

As for rare disease, another area where the industry can’t help but make big headlines with dollar signs
and lots of zeros, Biogen and Ionis Pharmaceuticals showed no sign of reversing the trend by pricing newly-approved Spinraza for spinal muscular atrophy at $125,000 per injection, a price point that comes to $750,000 in year one of treatment, and $375,000 per year in perpetuity. Op-Ed sections seem to have been relatively tame in response to Spinraza’s sticker shock, so far hinting at the fact that high science and the pursuit of curative treatments for devastating areas of high need will be rewarded.

But the fact that the news hit during the holiday season might also explain some of the quiet. Except for a mention in the President elect’s profile in Time’s Person of the Year issue, drug prices as a topic seem to be low on the list of priorities. But a well timed article, followed by even a slight comment or retweet, say during early January’s JP Morgan investor congregation in San Francisco, could have a chilling effect.

“The market has become significantly more difficult in terms of getting payers to cover new drugs, and one of the implications is that value communication needs to be much broader,” explains Schoonveld. “A lot of the PBMs (pharmacy benefit managers) and other payers have taken control; they’ve been empowered to make tough decisions.” The 21st Century Cures Act could facilitate easier communication of economic data to payers, but it will also be necessary “to communicate more broadly to provider organizations and medical associations, because the debate around affordability and value of drugs has clearly expanded,” says Schoonveld.

This pushback by payers “is not personal,” says Girling, however. “It’s global. Japan recently announced it would have annual price reviews rather than every two years, and for all products not just a selection. That’s another example of the need for the industry to demonstrate value.”

In Europe, all drug companies are faced with tougher pricing negotiations that are driven by ever-tightener controls on national health system funding across Europe. For Schoonveld, however, most payers in Europe do not acknowledge that the need for pharmaceuticals is growing as the population is aging: “This is a side effect of the aging population, but payers are sticking their heads collectively in the sand.”

In 2017, things will get even tougher, as individual European countries combine their strength to negotiate jointly with drug firms on prices for new medicines. Pharm Exec’s Brussels correspondent Reflector explains: “Ireland is set to join with Austria, Belgium, the Netherlands, and Luxembourg in a new coalition to boost their collective bargaining power, and similar schemes are gathering impetus in the Nordic countries, the Balkans, and in Central and Eastern Europe.”

Emerging Markets: BRIC and ASEAN

Looking toward the emerging markets, questions surround the impending fortunes of the BRIC nations. “There are two schools of thought on BRIC,” Marc Yates, director, Asia-Pacific and Emerging Markets, The Research Partnership, tells Pharm Exec. “One is ‘been there, done that, BRIC is old news.’ But the other is that you can’t isolate BRIC and say it is finished. The number one driver is the global economy and how it impacts those markets.”

China remains a major force. In 2015, it overtook Japan to become the second largest pharmaceutical market. With annual growth rates, as reported by Frost & Sullivan, of more than 18%, the country will reach the top position by 2020. With annual growth rates, as reported by Frost & Sullivan, of more than 18%, the country will reach the top position by 2020. China is seeing growth in the medical device, contract research, and API manufacturing sectors. The relaxation of the one-child policy for the urban middle-class may see a slight increase in the number of children born in China, with a potential impact on pediatric vaccines and private health uptake, says Yates. But, as Reenita Das, partner at Frost & Sullivan, points out, market changes and currency devaluation are having a negative impact on “most of the segments related to
pharma and life sciences,” especially some of the government initiatives. “Therefore, even 2020 care program is progressing slowly and might get delayed by few years,” Das says. There is also the delicate matter of Donald Trump’s resistance to the “One China” principal, and how trade relations will fare if he upsets China’s sensibilities by using Taiwan as a bargaining chip.

In Russia, however, there is “potentially a big upside” if Trump fosters a positive relationship with the country and sanctions are eased, observes Yates. But the country still falls behind western European nations in terms of research innovation and technology development, says Das, primarily due to lack of investment. Even so, the Russian pharmaceutical industry is still one of the fastest-growing across the world.

Brazil’s budget deficit was 10.1% of its GDP in 2015. Stimulating the country’s economy is going to be “a tough ask” if there are curbs on the amount of credit available, says Yates. In the pharma market, Das points out, the generics sector is anticipated to be the main factor for growth. Innovation and improvements in the medical equipment sector have also been consistent, she reports, and Brazil has the largest medical device market in Latin America. Medical imaging also has a large market.

Further, Das adds: “Brazilian hospitals are expanding and modernizing their existing infrastructures in order to improve their services. This is gradually leading to the significant penetration of IT solutions, such as hospital information systems (HIS), electronic medical records (EMR), and picture archiving and communication systems (PACS), especially in private healthcare providers. Technologies such as cloud computing and big data are expected to change the way healthcare is provided in the country.”

In India, the government continues to look at developing the country as a global healthcare hub. Says Yates, “India is looking outwards. If you look at companies like Ranbaxy, they’re looking to be global players, not just value commodity generics companies, so it is interesting to look at India not just as a domestic market but as an exporter of quality medicines.”

And despite its challenges, “India at present ranks amongst the fastest growing countries of the world in terms of GDP growth, a trend which is expected to continue for the next 10 years,” says Das. “The last couple of years have witnessed a large number of multispecialty hospitals coming up in all parts of the country. Driven by the increased domestic demand for high-end services as well as medical tourism, the healthcare sector has attracted high investments focused at making the existing facilities on par with developed nations.”

While technological innovation has an impact on all markets, many patients and providers in the emerging markets are embracing it at a faster pace, observes Yates. There are companies looking to “disrupt the whole model” in emerging markets with e-detailing and telemarketing, facilitating e-consultations or video consultations with doctors, and filing scripts through e-pharmacies. “The growing, urban-elite middle classes are online, comfortable with mobile technologies to a degree, and more willing to pay,” adds Yates. “There is a huge appetite for this in the emerging markets; they are quite open to change, whereas the rest of us may still be a little conservative.”

Further afield, Frost & Sullivan reported last year that Asia-Pac was the fastest growing region globally. In Asia and Southeast Asia nations such as Malaysia, primary care chains are expected to expand integrated services spanning across diagnostic and preventive care, strengthening primary care as the first point for healthcare services. Asia-Pac will also see a growth in private health insurance due to awareness of rising healthcare costs, awareness campaigns by insurance companies, and the push by governments for shared spending.

For Yates, the Association of Southeast Asian Nations (ASEAN) is interesting as it comprises countries such as Myanmar, Cambodia, and Laos alongside medical hubs with centers of excellence such as Hong Kong and Singapore. Thus, medical tourism among the better off in the ASEAN region is still seeing Singapore, for example, “punching above its weight.” Das points out that local manufacturing is gaining importance across the ASEAN environment due to the strengthening US dollar and high percentage of healthcare imports and the increasing presence of Japanese healthcare products and services. And the ASEAN Economic Community’s (AEC) efforts to create an open market place for medical devices, goods, and services across the region is expected to

This pushback by payers “is not personal,” says Girling. “It’s global.”
benefit both local and multinational corporation players in the next few years.

Vietnam, for example, is “definitely fulfilling its promise,” says Yates, despite a challenging environment. Many Japanese and Korean pharmaceutical and device companies have invested in the country and it is “one of the most preferred manufacturing destination in the region.” For Yates, however, Vietnam’s promise as “the next big thing” is still compromised by the fact it has a very young population, and has ongoing issues with red tape and corruption.

“Despite the difficulties, Asia [and Latin America] cannot be overlooked if companies desire to grow faster than their competition,” says Frost & Sullivan’s Transformational Health research analyst Siddharth Shah regarding the company’s recent Vision 2025: Future of Healthcare analysis. “To gain the edge, healthcare players must take the plunge, invest in these regions, find the right local partners, design custom strategies for each country, test them in pilots, and go large-scale.”

Populism and perp walks

At pharmexec.com in December, John S. Linehan, an attorney in the Health Care and Life Sciences practice group of Epstein Becker Green, wrote: “In 2016, the populist trend in American politics was an undeniable factor behind Trump’s election victory as well as the ascendency of Bernie Sanders and Elizabeth Warren within the Democratic Party. During upcoming months, industry observers will be looking for signs as to whether drug pricing is an area in which both parties can agree on instituting significant legislative action at the state and federal levels. The nature and shape of any such reforms will be highly consequential for the US pharmaceutical industry, which has served as a prime source of innovation in medicine. The question going forward is whether cool-headed reform that facilitates patient access to drugs without styming pharmaceutical R&D investment can be achieved in an era of fervent populism and discontent over rising healthcare costs.”

On reflection, Linehan stipulated that populist mentality can take on forms perhaps more extreme than demanding pricing controls. “People want action, and I think we’ll see, in fact we’re already seeing it, reform by enforcement,” Linehan wrote. Where in the past, civil action was being taken against companies, we may see a trend toward greater accountability demanded by charging individual corporate executives. Generics price fixing, kickbacks, illegal and unethical specialty pharmacy buyer relationships, the opioid epidemic, these are all areas where we might see serious charges brought against individuals in 2017.

If 2016 was characterized by one perp walk (Martin Shkreli) and multiple executives being paraded on Capitol Hill for meandering, and rather silly and embarrassing interrogations, perhaps in 2017 we’ll see more politicians attempting to take off the kid gloves.

Government reform can be long and complex, where politicians are tripping over each other to get something accomplished. Underscoring the changes on the national scale were also state-level attempts to strike the industry. Notably, California’s Prop 61 failed, but it received significant attention and resistance from the industry. Other state mandates like Vermont’s “transparency” requirements will make headlines, but results will likely just be more confusing than the laws themselves. Executives in cuffs, perp walks, real criminal enforcement will, that’s a more direct and crowd-pleasing.

An interesting factor to consider could be a halo effect of population questioning “truth in media” (arising from the election cycle) to questioning “trust of the healthcare/pharma industry,” notes Girling. Well known to this audience, survey data places the industry’s approval/reputation numbers near that of the tobacco industry. So could consumer “trust” be
an issue? And what form could the empowering of a populist mindset take? Certainly, strikes directly against the industry could be a result. But as terms like “coastal elite” and “drain the swamp” are in the zeitgeist, don’t expect the FDA to escape upheaval. Last time we checked, the FDA would easily be considered “establishment,” and is pretty close to a coast.

It’s hard to imagine how the industry would react to major FDA changes. And so it’s not surprising that the industry collectively gasped at the mention of a Peter Thiel-associated FDA appointee—managing director of Mithril Capital, Jim O’Neill. Giving a lofty FDA seat to a relatively libertarian mindset, like venture capitalists with a passion for seasteading, could be an industry shocker.

With such a change in FDA’s mandate a possibility, the phrase snake oil salesman surrounds Trump for more reasons than one. Could the fallout, Girling wonders, be an industry in which “pay for performance” would suddenly become a huge question and insurers would be rubbing their hands as the arbiters of efficacy and, therefore, access?

**Technology**

The accelerating pace of technical and scientific change will inevitably drive the industry in 2017 and beyond. “The internet of things (IoT) will spawn the IoMT (internet of medical things),” says Kalb. “We are morphing to a system where patient, pharmacy, doctor, hospital, medical device, payer, and pharma firm are all connected in real time.”

Kalb points to “mega-medical supercomputers” like IBM’s Watson, which “will enable growing virtual interactions, remote care, ongoing database expansion and record keeping, and patient monitoring, and provide pharma with new opportunities well beyond the pill’ for R&D, marketing, and for new revenue sources as well as cost control.”

Pfizer announced in late 2016 that it will be deploying IBM’s Watson for Drug Discovery cloud-based, cognitive tool to accelerate its immuno-oncology research, analyzing “massive volumes of disparate data sources, including licensed and publicly available data to unearth insights at a scale and speed beyond what is manually possible.” Lauren O’Donnell, global vice president of life sciences for IBM Watson Health, tells Pharm Exec: “We’ve been thinking and talking about digital disruption for years and now it’s here. Watson for Drug Discovery is able to do in months and even weeks what it has traditionally taken researchers years to do—that is, sift through large volumes of journals, data, patents, and other information to generate new hypotheses.” The platform has reportedly “ingested 2.5 million Medline abstracts, more than one million full-text medical journal articles, four million patents, and is regularly updated.”

IBM’s Watson Health business unit has launched or is preparing to launch cognitive tools across the healthcare spectrum—from oncology and clinical trial matching to compliance and value-based pricing—aimed at tackling the problem of what to do with the reams of data that organizations have been busily amassing. Wearables, for example, can generate many terabytes of data, says O’Donnell, “but then what do you do with it? How do you get to what is relevant? Cognitive technology can sift through all that and bring out the most relevant pieces.”

She explains: “All the homogenous data, the unstructured data that is not sitting in an electronic medical record, this is the data that’s going to come from the Fitbits, the Apple watches, the diagnostic devices. Add the cognitive capability to that technology and we are going to have wearables that, for example, provide instantaneous data on how a patient is doing based on when they just took their insulin or their activity levels, and can predict a hypoglycemic event hours before it happens.”

Pharma companies may as yet be proceeding with characteristic caution into the cognitive computing arena, but O’Donnell says, “There are those who are leading, like Novartis, who already has a pilot program doing these types of things. Others, while they know they have to do something, they don’t know where to start. But I don’t think companies are going to have a choice. In drug discovery, for example, nobody can afford to spend billion-plus dollars and 10 years to develop a drug. There’s a better way.”

**Preparing for ‘VUCA’**

For all the uncertainty ahead, continuous innovation will remain the lifeblood of the life sciences industry. However, says Kalb, “to remain a leader, pharma will need to expand its myopic view of competition, and routinely broaden partnering activity to actively participate in a wider segment of the overall healthcare space.”

For Topin, in a year of “maximum VUCA,” the industry’s first and most impactful tasks are to reduce uncertainty and minimize complexity so it can effectively reduce its risks. “We could sit out the year and see what happens, but that’s not in the playbook. Now is the time to invest aggressively in learning more about the areas that we can identify for change.”
Opportunity Knocking. Will Europe Answer?

The uncertainties generated in 2016 will multiply and dominate the agenda in Europe in 2017. In the pharma context, this translates to how far Europe is going to remain a market that innovative companies wish to engage with. The business climate, which for many years has been rather benign, despite the frequent cries of “wolf” from drug industry bosses, is now deteriorating rapidly.

At the same time, innovators are increasingly challenged by a rising tide of skepticism—shared now by many senior politicians, as well as by the customary critics in the health activist community. Even the European Union’s normally sedate health council has called for a review of incentives for drug research, alarmed by allegations of rapacious drug firms bending the rules to extract unfair advantage from patent term extensions and market exclusivity deals granted to orphan drugs.

The fragile attempts that had been underway to build a consensual approach to future drug development and regulation are being undermined by the accelerating fragmentation of Europe’s own political structures.

Meanwhile, the fragile attempts that had been underway to build a consensual approach to future drug development and regulation—at the European Medicines Agency (EMA), in the EU’s public-private research venture IMI2, or in closer links between payers, patients and regulators—are being undermined by the accelerating fragmentation of Europe’s own political structures.

The most obvious is Brexit—the planned UK withdrawal from the EU. Not only will this exclude one of the continent’s biggest buyers from the EU’s single market as from 2018 (and consequently oblige companies to start obtaining separate marketing authorizations for products there). It will also remove the expertise of UK government officials from EU deliberations on pharmaceutical policy. And at the practical level, it will oblige EMA to quit its London headquarters and relocate elsewhere in Europe—a prospect that is not only an administrative nightmare in itself, but also is already damaging staff motivation and impeding recruitment.

Brexit will also require major readjustment to existing and pending European initiatives on everything from clinical trials regulation to health technology assessment (HTA), and from digital health to modernized pathways to medicines authorization. What will happen, for instance, to longstanding European attempts to unify the scattered clinical trial authorization procedures that have bedeviled the start-up of multi-country new-drug investigations?

The finishing touches are being put to a single procedure designed to come into effect across the EU, dependent largely on mutual trust among national regulators, and backed up by a legislative framework. Since the UK is the site of so many international clinical trials, and the generator of as many, too, its departure from the EU makes the outlook for a single system now look like a lost dream.

The same will be true for the increasingly troubled bid to modernize European drug authorization procedures—the adaptive pathways project spearheaded by EMA officials, which has enjoyed strong support from the UK. Take the UK away from those deliberations, and the field will be open for countries with a more conservative stance—notably Germany—to block the process. The same fate is likely for the current attempts to find common ground across Europe on HTA, where the UK’s national reimbursement organization, NICE, has been at the forefront in seeking greater coordination.

The European Commission, once the proud defender of EU law, is now unpopular with member states increasingly resentful of being told what to do, and who now also flirt with the idea of going their own way. The Commission, thus embattled, is more hesitant in tackling national governments that ignore legislation for their own national purposes. Will it still dare to promote cross-border care and the planned European network of specialized research and treatment centers, or to push for common approaches to personalized medicine or the orderly development of digital health?

This year, unquestioned opportunities for major healthcare innovations will be taken up in some parts of the world. The question for Europe, however, is whether those opportunities will also still be seized by Europeans, or whether Europe has lost its way and will revert to the parochialism of nationalist views and to division and dissension.

— Reflector, Pharm Exec’s Brussels correspondent
Biopharma’s Tectonic Plates
With unseen forces underfoot, the 7 keys for brand planning in 2017

By Al Topin

It’s a new year with new forecasts informed by last year’s rear view mirror. They’re often insightful. Sometimes misguided. Always interesting.

What many in our industry overlook as they try to identify some new trend are the changes that move below our feet—biopharma’s tectonic plates. These are forces so powerful they will continue to shift our business not just this year, but into the foreseeable future. And they have the potential to disrupt even the most thoughtful marketing plans. So ignore these “seven significants” at your peril as you plan for 2017.

#1 The 10-year century. Change is faster today. Technology moves quickly. Thinking, experimenting, and iterating happen rapidly. And while this acceleration is bringing life-changing therapies to market faster than ever before, it’s also bringing more failed molecules and more “me-too” competitors. Leveraging exclusivity and setting competitive barriers become more difficult. How to succeed at this pace? You can either jump in and swim as fast as you can, or take the time to examine the market and focus your resources on the greatest potential for success. Each approach has its risks, so it’s a matter of which makes you less uncomfortable.

#2 The ubiquitous 800-pound gorilla. 85% of pharmaceutical units sold in the US are generic. Pick virtually any specialty drug category, and sitting right in the middle is a well-known, generic 800-pound gorilla that dominates the market. All are effective, cheap, taught in medical school, and on most formularies.

A new drug with any hope to take down a generic gorilla must offer an advantage so clear, so meaningful that it makes up for a price tag that makes payers instantly nauseous. The game today is outcomes and long-term cost reduction. And it is happening—with high-priced drugs that in some cases turn out to be cures. These are tomorrow’s blockbusters. So as they say in TV commercials, “What’s in your Pipeline?”
#3 **High drama in the exam room.** The key diagnostic questions have been asked, test results are in, and the critical moment is here. The physician informs the patient that he or she has a serious disease and begins to explain treatment options and next steps. A very personal, devastating version of “shock and awwww” begins. The patient is now forced to face the reality of a disease and make treatment decisions they barely understand.

Moments of truth like this have been a part of medicine for centuries. So what’s different today? The opposing forces of a more complex dialogue versus a time-challenged physician. Doctor-patient communication, so critical to therapy compliance, is compromised from the start.

What can be done to improve this moment of truth? More, better patient education and support. But perhaps more important, practitioner training designed to improve sensitivity and clarity when he or she is having that difficult conversation.

#4 **The morphing of the pharma sales rep.** According to Cegedim Strategic Data, the number of pharmacy industry sales reps declined 40% between 2006 and 2014. Not quite last man or woman standing, but dramatic nonetheless.

So in an era of no-see docs and dramatically-priced complex new drugs, what does today’s remaining rep force look like? The “attack of clones” approach is over. No longer will a rep be successful just by delivering the script they role-played at the sales meeting.

The successful rep’s new role has shifted from sales to support: Isolating barriers and patient problems, then providing support/solutions to the physician, the practice, and the office staff. The question for the manufacturer then becomes: What can we do to support our reps in this changing role?

#5 **The Hollywood pharm team.** Have you ever thought about the surprising similarity between today’s Hollywood business model and that of pharmaceutical companies? What was once a studio system in which the directors, writers, and stars were all kept in-house on contract and used for movie after movie is now a business of outsourcing. And what once were the in-house resources of pharmaceutical giants are now a pharm team of outsourced specialties. CROs, medical review, discovery, and more are now orchestrated from best-of-class, proven partners that play well with others.

So the lesson learned here is that in a high-risk venture like launching a new movie or a new drug, it’s best to spread the risk. How can you spread yours?

#6 **The Hollywood opening weekend.** To keep going with the Hollywood analogy, let’s look at the concept of the opening weekend. Many Hollywood movies win or lose on first weekend’s receipts. Expensive blockbusters turn into failures in a few short days, while cheaper independent films with low expectations become heroes by Monday.

Sound familiar? A new drug misses early, sky-high forecasts that management pushed higher. Uptake is slower than expected. All of a sudden, the brand is lucky to keep its initial budget for a full year and risks losing the attention of the sales force.

How can brand teams manage expectations when management, shareholders, and competitors expect a big box office weekend each launch? Thinking long term anyone?

#7 **The missing quarterback.** With all the attention focused on patient centricity, one reality continues to be overlooked. In a world that’s shifted from treatment from primary care to specialties, where drugs are more complicated and expensive, and where illogical insurance coverage continues to frustrate patients, there’s a clear unmet need— for a quarterback.

Specialists focus on a specific body part or set of symptoms, handing the patient to the next specialist once their job is done. Some medical specialties have taken a broader view and adjusted their approach to overall patient care. Neurological teams, diabetes specialists, cancer clinics, and cardiology practices now focus on the whole patient and their treatment. The patient’s specialist becomes the quarterback directing the process. Pharmaceutical manufacturers in these specialties have supported this model with in-depth patient and practice support programs. They should be the ones to emulate.

Seven tectonic plates moving at their own pace, sometimes one at a time, sometimes in combination. Pay attention to how they continue to shift the healthcare landscape, and adjust your plans accordingly.

— Al Topin is President, HCB Health Chicago. He is a member of Pharm Exec’s Editorial Advisory Board. He can be reached at al.topin@cbhealth.com
What makes CuraScript SD uniquely able to serve its broad range of customers? Gayle Johnston, President, CuraScript Specialty Distribution at Express Scripts, says that working with CuraScript SD is like working with a small company, in regards to its approach to customer service. Its offerings can be customizable and highly flexible for even the smallest companies aiming to serve the needs of a very limited number of patients. But CuraScript SD is no small-time player, she adds, and is fully able to leverage the scale and the full faith and credit that comes with its parent company, industry-leading pharmacy benefit manager Express Scripts.

Being able to take the “small company” approach to customer service means that clients are not just a number, she explains. “We don’t try to sell a program that has been used redundantly. We have some very large programs, but they’re all customized to individualized companies, with their unique go-to market strategies and competitive landscapes.”

This ability to draw on its ample, industry-wide payer relationships, while being able to scale from large health systems and big pharmaceutical companies down to the needs of community physicians or a tiny biotech launching a novel treatment in an ultra-orphan indication is what makes CuraScript SD unique, according to Johnston. It enables the company to be truly innovative and flexible in ways that others in the specialty distribution space cannot.

CuraScript SD targets two groups as its core customers. First and foremost, the company aims to service specialty physicians and healthcare providers practicing in a community-based setting. These are doctors prescribing and administering specialty pharmaceuticals. So, this means high-cost, high-touch, intensive therapies which are usually administered intravenously or injected in a clinical office setting. It’s what is commonly referred to as the “buy and bill” segment of the industry. “For these physicians, we strive to make specialty pharmaceutical products available when they need them and where they need them as cost-effectively as possible,” Johnston adds.

The second audience, for CuraScript SD’s specialized services, are biotech and pharma companies with rare, orphan and ultra-orphan products, both those with treatments already on the market, and those planning to launch. “We believe we are well-equipped to meet the highly special and customized marketing and distribution needs of these companies.” It could be large pharma, or an upstart biotech coming to the market for the first time, she says.

Within Express Scripts, an expansive suite of services—CuraScript SD, Matrix GPO, Accredo (SP), and UBC (pharma services)—can offer comprehensive and integrated solutions for manufacturers and their products. This host of offerings often comes together in unique ways for specific customers, Johnston explains. She adds that CuraScript SD can facilitate easy alignment among partners; bringing together unique business expertise and consultative partnerships for smoother launches and, of course, in today’s climate, enabling more competitive pricing.

“What sets CuraScript SD apart, something other specialty distributors don’t have, is the ability to bring in the full force of the large number of relationships that Express Scripts has.” In addition, Johnston notes, CuraScript SD is proud of its exclusive, preferred relationships with large GPOs and deep penetration within specific markets, namely key areas like orthopedics, ophthalmology, neurology and rheumatology. In addition, CuraScript SD’s tools allow customers to better build flexible and integrated programs, importantly utilizing comprehensive reporting and analytic tools like its proprietary Galileo Business Intelligence and Reporting platform as well as more common electronic data interchange (EDI) and Business Objects software.

There are a lot of things in flux right now, including new regulatory requirements and the looming impact of biosimilars, she says. But what is clear is that specialty pharmaceuticals will continue to be a bigger and bigger part of the industry. “We’ve got the depth and breadth, drawing on almost 30 years of experience, and are amply ready for whatever the market might throw at us.”
Pharma and Biotech Markets: Challenges and Opportunities

With the soaring valuations of companies in the public and M&A markets now seemingly a distant memory amid the continuing drama over drug pricing, the challenge for the pharmaceutical and biotechnology industries will be to choose the right overall mix of M&A, licensing, and partnering to accomplish corporate strategic goals.

By Peter Young

The last few years have been a positive period overall for both the pharmaceutical and the biotechnology industries on many fronts. Most importantly, the number of new drugs approved and under development has escalated for pharma and biotech companies. Many of these are driven by new methods, such as immuno-oncology, personalized medicine, stem cells, and biologics. We are also witnessing the development of a greater number of drugs that cure diseases rather than just extend life.

The valuations of pharma and biotech organizations in the public and M&A markets soared up until the end of 2014 in part because of these positive developments, but share prices and public valuations have been volatile since then with the drug-pricing controversies.

Public biotech shares have been hit particularly severely since the end of 2014, and as a result, the IPO market began to cool off in the second half of last year. This is creating a difficult equity financing environment for biotech companies, which, in turn, has affected the choices available to biotech firms to continue to fund their companies.
Pharma M&A

Through the third quarter of 2016, 37 deals were completed worth $117 billion, compared to 56 deals completed worth $200 billion in 2015. From a historical perspective, this is a very strong volume of activity for the industry. However, from an annualized point of view, this represents a decrease in the dollar activity compared to last year, and a slight decrease in the number of deals. The main driver of this moderate slowdown has been the absence of the mega tax inversion-related deals that we saw last year. However, the clampdown on the tax rules by the US Treasury Department strongly discouraged those companies pursuing tax inversion deals and killed a number that were in the works as of the end of last year.

In part because of this action, there were fewer mega deals, with only two large deals completed, the $31 billion acquisition of Baxalta by Shire and the $40.4 billion acquisition of Allergan’s generics business by Teva. Drugmakers are acting as both buyers and sellers, forming strategic alliances and swapping as they shore up their core businesses, exit non-core units, and use or seek tax inversion advantages.

As of September 30, 2016, the value of the deals announced but not closed was $7 billion (20 deals), a solid number of agreements, but a weaker dollar volume in the pipeline. The pipeline was $240.4 billion (16 deals) at the end of December, but the massive Pfizer/Allergan merger was cancelled and took a large dollar amount off the table as a result.

Biotech M&A

Biotech M&A activity has almost always been modest historically, with small spurts of activity from time to time.

Through the third quarter of 2016 there were 29 biotech M&A deals completed worth $14 billion, versus 31 deals worth $19 billion completed in 2015. 2016 activity is on track to exceed 2015 in terms of the number of deals. The dollar volume trajectory is less clear.

This pick-up in activity is partly due to the major dropoff in biotech IPOs since the latter part of last year as the market has turned against biopharma companies. Through the third quarter, only 22 IPOs have been completed this year compared to 61 for all of last year and 72 the year before. On a dollar basis, the picture is even more severe with only $1 billion raised in IPOs during the third quarter, compared to $5 billion the year before. Secondary offerings have also been adversely affected. Sealed off from high valuation equity offerings, the biotech companies are less fortunate than they were in 2013, 2014, and most of 2015, when they were able to raise money at high valuations. In many cases, it is not even an issue of valuation and the biotech companies have

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» The chief contributor to the moderate slowdown in pharma M&A activity in the first three quarters of 2016 was the absence of the mega tax inversion-related deals that occurred in 2015. The clampdown on the tax rules by the US Treasury Department strongly discouraged companies from pursuing tax inversion deals and killed a number of agreements in the works at the end of 2015.

» For biotech, 2016 M&A activity was on track to exceed 2015 in sheer number of deals. The dollar volume trajectory, however, was less clear. What was evident is the pickup in activity was partly due to the major dropoff in biotech IPOs since the latter part of 2015. Through the third quarter of 2016, only 22 biotech IPOs had been completed this year compared to 61 in 2015 and 72 the year before. On a dollar basis, only $1 billion was raised in IPOs during the third quarter, compared to $5 billion during the same period in 2015. The recent slowdown in IPOs will compel many biotechs to either sell themselves or raise funds via partnering deals or discounted private placements.

» Pharmas are modifying their business portfolios to focus on leading positions and to exit weaker positions, and on non-core and mature/established products to search for growth. These are attempts for companies to replace lost or soon-to-be-lost revenues, and to drive for scale and cost reduction through consolidation.
not been able to go public at all. As a result, the biotech organizations who are in Phase II and Phase III clinical trials, where the cash consumption is high, have been forced to either sell or to partner in order to deal with their shortage of cash.

The pipeline of M&A deals as of September 30, 2016 was weak, as the value of deals announced but not closed was very modest at only $600 million on only one deal. However, the movement has picked up, as biotech companies are being picked off as acquisition candidates. There has been a litany of firms who have announced that they are “exploring their strategic alternatives.”

Outside of M&A, the need to fill the shrinking drug pipeline is also facilitated by in-licensing arrangements and the formation of partnerships and joint ventures involving both pharma and biotech companies.

The most promising biotech companies over the previous three years were able to go public first and attract significant interest and high prices later. The surge in IPOs gave biotech companies more flexibility as to whether and when they exit via a sale. However, the recent slowdown in IPOs will drive many companies to either sell themselves or raise funds via partnering deals or discounted private placements.

Therefore, M&A volume and partnering deals will likely increase significantly in 2017, but still be well below that of the pharma industry.

**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 are challenging, particularly for promising drugs in late stage clinical trials and for companies with strong products.

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.

The generic pharma 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.

For biotech companies, public and private, the future is exciting from the drug development side, but troubling on the private funding, IPO, secondary equity financing, and M&A fronts.

Time will tell whether the very public attack on drug pricing will ease up and/or force changes in the industry.
It’s difficult to overstate the importance of patient research in pharmaceuticals, both in relation to improving health outcomes and commercial success.

The ubiquity of connected communications technology, from social networks to wearable apps, has opened unprecedented access to patient populations. Equally, big-data processing facilitates the analysis of patient data for research on a scale unimaginable just a decade ago.

But with increased data availability, capture, and analysis comes increasing concern over patient privacy. Privacy concerns are not unique to pharma research and marketing. Some analysts believe the incredible rise of ad blocking has been fueled as much by privacy and security concerns as the desire to avoid annoying banner ads.

Although the revenue crisis following in the wake of ad blocking is acute for publishing, the industry will find new ways make money, probably improving the customer experience in the process. But pharma doesn’t really have that luxury—patient research is the foundation of improved outcomes and commercial success.

So how can pharma balance the need to access patient data and still respect patient privacy? One approach is to access patients through third-party online communities. Platforms like Facebook can play their part with some disease populations, but community-based platforms provide a more focused level of support and guidance to patients and caregivers going through similar experiences.

Brian Loew, CEO of Inspire, a social network for health that connects almost one million patients and caregivers, agrees that patients, to a degree, should be concerned about online privacy, but he thinks that discussions about privacy often miss the point. “What all of us want and need is to confidently control how our personal information is shared and used.”

He believes loss of control is what upsets patients—being surprised, tricked, or having an implicit promise broken. Inspire tries to avoid these issues with a community team that monitors for spam and possible scams, as well as inappropriate behavior.

Loew describes Inspire’s mission as “to accelerate medical progress through a world of connected patients.” The company seeks to achieve this by connecting community members, in a transparent, opt-in basis, to life science companies for the purposes of research. He gives the examples of creating awareness of an ongoing clinical trial recruitment and conducting market research conducted around how a mobile app can help patients with chronic conditions better manage their disease.

Narrow market research is served well by data from online communities where groups identify with a particular disease state; the online health networks deliver targeted research opportunities based on carefully managed permissions. But there are less personal ways to use patient information to support pharmaceutical marketing with data informing location-based research for pharma companies trying to assess patient populations in specific towns, states, or regions.

Semcasting, a data management platform company based in Massachusetts, helps pharma marketers reach physicians, but has no access to any patient-specific health data. Semcasting works with pharma companies around specific drugs, drug classes, or medical specialties.

“The healthcare data we manage is at the provider level,” says CEO and Founder Ray Kingman. “Our protection of that health data is managed at an aggregated geographic level to shield any reference to individuals.”

Kingman explains that it is possible to deliver accurate targeting without the level of personal data that raises privacy concerns. “Healthcare touches everyone and the volume of data that is generated produces a statistically relevant level of trending and forecasting which informs targeting without ever touching an individual or household,” he says.

Predictive analysis, according to Kingman, is about prioritizing the likely best audience over the least likely. “Our technology, working with de-personalized anonymous data, allows us to do targeting efficiently and safely.”

Patient data is a powerful research tool for pharma—clinically and commercially. But respect for patient privacy is paramount and drugmakers face unique challenges if they are to avoid impeding the valuable exchange of patient-care information. Clever use of third-party geographic and patient community data may be part of the solution.
The ‘Healthcare Internet of Things’

Connected ecosystems will change the future of healthcare; three key value drivers are outlined

The US healthcare system is under constant pressure to reduce the cost of care while addressing the needs of a growing and increasingly unhealthy population. Opportunities to improve the systems that serve this vast industry abound, in particular with emerging technologies that currently address other, seemingly unrelated consumer needs.

It is my belief that, as the Internet of Things (IoT) continues to evolve, healthcare will be able to tap into the potential of an increasingly connected world. The current growth of connected devices is steadfast from wearable devices to in-home virtual assistants, so the dream of a fully connected world is steadily becoming a reality, and it could mean big things for healthcare.

Currently, IoT providers (e.g. Google, Microsoft or Amazon) are developing their solutions in isolation, fine-tuning their own licensed ecosystem of data and connectivity and providing users with an element of data exclusivity for their individual piece of the puzzle. The opportunity for growth and proliferation of these devices and systems, however, will come when we have a standardized, connected ecosystem.

Healthcare is an industry already struggling to reconcile the challenges presented by disparate data versus the possibilities presented by connectivity. Today, health information is scattered and siloed, with healthcare providers, payers and manufacturers often seeing a different version of the truth. However, if we as an industry can create greater interconnectivity in a single ecosystem—a Healthcare Internet of Things—there will be significant benefits to patients, physicians, payers and drug developers. A connected healthcare ecosystem that spans from research and development all the way through to commercialization and treatment adherence could be just the solution for life sciences companies and payers seeking to demonstrate value from new treatment outcomes.

Here are three ways connected ecosystems and IoT can benefit healthcare and demonstrate value to the healthcare system.

1. Supporting patient adherence

With the advent of smart pills, glucose monitors and similar devices, we have already seen how such technology can improve patient adherence. As wearable technology continues to embed itself into everyday life, and life sciences companies seek out more viable and long-term applications for such devices and platforms, adherence rates will continue to increase.

Additionally, manufacturers will begin to integrate elements of gamification in health-related devices as they do in consumer tools, which will also help increase uptake. The underlying principles of gamification, something that triggers the brain’s reward pathways, will be designed to promote positive action and reinforcement for the correct, adherent behavior. This could be as simple as adding a points and badges reward system to a medical app, where patients earn points for taking their medication at the correct times of day. The ability to use this data and analyze behavior patterns for continual improvement will be game changing.

2. Improving patient outcomes

An ecosystem with patients leveraging diverse connected devices will of course create a deluge of new data. In real-time, healthcare practitioners will be able to monitor a patient’s health, activity levels and reaction to treatments. If a patient suffers a hypoglycemic episode or cardiac event, for example, that data can be fed directly back to the physician or specialist to take immediate action.

This goes beyond adverse effects and can include other elements that are often out of view of treating physicians such as sleep patterns, weather conditions, dietary information and any other factors that might impact outcomes. All of these indicators have a cumulative impact on the outcome derived from standard medical interventions. In short, for the first time, healthcare systems will have a complete picture and be able to optimize treatments and the surrounding environment for better outcomes.

3. Accelerating access to new treatments

The significant amount of data generated by a connected ecosystem can do much more than
The significant amount of data generated by a connected ecosystem can do much more than impact an individual outcome—it can influence the future trajectory of research and development. The significant amount of data generated by a connected ecosystem can do much more than impact an individual outcome—it can influence the future trajectory of research and development.
Win Your Brand with Action!
The seven ways for pharma to ensure successful execution of action steps following brand ‘war games’

Many people who have participated in traditional pharmaceutical war games, where internal teams of pharma professionals role-play their and their competitors’ brand teams, enjoy the 1-2 day experience. However, they also share many frustrations with these exercises. The chief complaint with traditional war games is that nothing ever changes following the war games. There are no specific, prioritized action steps executed to help the brand win in the market. In fact, these old model war games are not designed to identify action steps; instead, their primary objective has always been to identify and discuss competitive insights.

Unfortunately, competitive insights—unlike competitive actions—do not win brand wars. Some traditional war games may identify a myriad of sales and marketing tactics, but these also fail because they are too numerous to implement, not prioritized, or are not allowed by regulatory authorities during the pre-launch phase, the most critical time to win in the launch of a new product.

Fortunately, the newer model of pharma war games called “competitive simulations” are specifically intended to rectify all of the major problems associated with the outdated, traditional war games. Most important, these “War Games 2.0” are designed from the outset to identify and ensure implementation of 3-5 prioritized action steps to help brands win. Here are seven ways that competitive simulations achieve this goal:

1. Action steps as the primary simulation objective:
The overriding objective of a competitive simulation is 3-5 prioritized actions, which the extended brand team will align on, own, and execute. All other objectives are secondary to this goal.

2. Client ownership of the simulation and action steps:
Historically, competitive intelligence and war game vendors have tried to make War Games 1.0 as easy and effortless as possible for clients by doing everything for them, including the background briefing documents, template design, on-site facilitation, note-taking, etc. They tell the client that all they need to do is “show up” on the day of the event. Unfortunately, this approach backfires: without any significant involvement or engagement other than filling out off-the-shelf templates on-site, the client’s professionals have no “skin in the game” or feeling of ownership of the war game or its outputs. Consequently, the competitive intelligence or war game vendor owns the workshop outcomes, not the client.

In contrast, competition consultants conducting War Games 2.0 guarantee client engagement and ownership by incorporating a cross-functional simulation planning team to custom design the workshop to specifically address their brand, market, and competitive issues. Competitive simulations are not simply 1-2 day workshops; instead, client professionals usually start their preparation 2-3 weeks in advance by reviewing cutting-edge pharmaceutical competition articles and initiating drafts of highly-tailored templates.

The consultants train client professionals to facilitate their own sessions, like real-world internal corporate meetings. The competition consultant facilities and ultimately direct the overall group to identify, prioritize, and align on a limited number (typically 3-5) action steps that are feasible, impactful, and executable.

3. Senior management engagement, buy-in, and support:
One of the major reasons that traditional war games fail to execute actions is that the client’s senior leadership—including selected C-suite members and the functional leaders of marketing, medical affairs/clinical development, payers, commercial/sales operations, and communications—are not part of the process and only briefed following the exercise. Not surprisingly, since these executives have not been
involved in the process or the event, they often question, challenge, and reject many of the outputs.

In contrast, in War Games 2.0, senior executives are considered part of the extended team from the outset and participate in the entire simulation, including the preparation, template development, discussion, and ultimately the action step selection and prioritization. This high level of engagement ensures their understanding and buy-in for the actions identified, smoothing the way for their support, enthusiasm, and guidance for the subsequent actions.

4. Multi-disciplinary, cross-functional participation: Traditional war games usually include four functions: marketing, sales, payers, and medical. As a result, if any tactics are identified, they are limited to marketing, sales, payer, and medical tactics. Unfortunately, in the current competitive environment, this approach is myopic: pharma companies today compete much more holistically, including actions related to regulatory, legal, supply chain, partnerships, policies, conferences, multiple types of stakeholders, and many others.

Consequently, the new war games consultants work with clients to carefully select and incorporate more cross-functional, multi-disciplinary, and pan-geographic internal professionals to ensure consideration of the numerous ways for either competitors or the company to win. Including regulatory, legal, and other compliance professionals in the simulation process also enhances their understanding of the competitive landscape and the rationale for the recommended simulation actions, thereby increasing the likelihood of their ultimate support and approval.

5. Simulation action planning templates and breakouts: Unlike traditional war games, competitive simulations include action-planning rounds, templates, and breakouts prior to and during the workshop. Teams are forced to identify, prioritize, rationalize, and present their recommended action steps to the senior executives and the other team members. By doing this over several rounds, these action steps are continuously vetted and pressure-tested. The final prioritization of action steps is the result of a highly-iterative and highly-engaged process to ensure the best selection of executable action steps.

6. Action planning process, monitoring, and measurement: Once the group has prioritized the actions, teams are selected on-site at the end of the simulation to prepare detailed plans for execution of these steps. Essentially, the teams are simulating the implementation of the actions, including the supporting activities, roles and responsibilities, resources, timing, final deliverables, metrics, and potential challenges to successful implementation. Following the simulation, these action-planning teams are required to present and update the action plans regularly to either an existing executive team or a newly-created one.

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7. Embedding actions into brand plans: Traditional war games are typically one-off exercises; they are not integrated into brand plans. In contrast, competitive simulation consultants recognize that the team’s selected simulation action steps are an integral part of brand plans and must be embedded appropriately. Since simulations usually identify new or different actions from existing brand plans, senior management and brand leaders must reprioritize and resource these actions as part of the overall plan. They must also help eliminate other current or planned activities that are non-essential to free up resources and time for the new prioritized action steps. War Games 2.0 highlight for brand teams the essential winning actions to execute in the marketplace.
The State of Market Insights in Pharma

It’s time to take advantage of a nascent technology embrace taking hold among market insights professionals

Obtaining a clear market context is harder than ever for pharmaceutical executives today at a time of profound business, regulatory, and technology change. It’s why pharma companies spend an estimated $2 billion on market research annually and retain market insights teams whose real job titles could be shortened to that of “context providers.” The insights they deliver from key stakeholders cut through the market noise and help to ground the hundreds of decisions required to access new drug and treatment markets—uncharted and often unpredictable.

The pharma market insights function, itself, is undergoing change and challenge. Some of it is endemic to the function, like the drive to control costs or do more with less—and some is related to the explosion in technology that has brought big data-sized datasets to every pharma team, without the meaningful context to put them to use with data of the quality the team has come to expect. In the era of the self-driving car and robots for everyday tasks, it’s easy for headline writers to suggest that technology can replace insights professionals and, thus, predict “the death of market research,” or at least its fading away.

But to paraphrase Mark Twain, predictions of the death of market research, particularly in pharma, are greatly exaggerated. A recent survey of Pharm Exec readers performed by InCrowd took the pulse of over 100 pharmaceutical and life science market research executives: who they are; their attitudes toward their work, emerging technology approaches, investments, desired innovations, and challenges. The data show several promising pivot-points with impact on the function’s ability to perform even at a time of historic M&A levels and regulatory uncertainty—when the industry needs timely, quantified market insight more than ever.

1) A new technology embrace

The 2016 Life Science Market Research—State of the Market Report spotlights where organizations are investing today, and major barriers to success in using market research to help meet heightened competition and cope with time-strapped primary research respondents.

The most striking result was a spike in receptivity to new technology—which is particularly noteworthy given industry pundits citing the reluctance to adopt new technology as the No. 1 challenge facing the profession—including such items as more expedient mobile research solutions, “smart sampling,” or technologies that have been well proven in other domains such as cloud computing. Compared with other industries, pharma is slower to adopt new insight technologies. This may be due to a high emphasis on data validity, or a desire to make sure all data is defendable to a p=0.001 confidence level.

In contrast, InCrowd’s State of the Market Report analysis revealed that more respondents characterized their approach to market research as “tech savvy” and “resourceful,” with nearly 50% of life science market research executives surveyed saying they agreed or strongly agreed with these statements. They out-numbered the approximately one-third who agreed or strongly agreed that “traditional” best described their approach.

Perhaps reflecting the ambivalence toward technology, an equal percent of respondents (31% for each) described their approach as “nimble” as well as “conservative.”

This receptivity is a critical first sign that today’s explosion in market research automation, data integration, and visualization technologies is being viewed as a way to streamline some of the profession’s most painfully repetitive tasks such as longitudinal tracking studies, which implicitly demand a seasoned expert to implement them and interpret their results.

2) Investments in an expanded toolbox

The State of the Market Report showed that these pharma market research professionals are putting their sentiments to action and investing accordingly in innovative new approaches.

Respondent organizations identified several new insights technologies that they are currently investing in. Not surprisingly, big data analytics topped the list. However respondents’ investments are diversified and testing new innovations seems to
be commonplace in the industry, including social media analysis, shorter and more focused micro-surveys that can source data in a few hours versus days, and wearable-based research. On the opposite end, mobile ethnography and facial analysis represented the lowest areas of investment.

Even with their present and sizable big data investments, respondents wanted more. Big data analytics still lead the lineup of new research approaches in which the respondents wished they could invest, with predictive markets and behavior economic models falling in second and third, respectively.

3) Staffed by highly senior talent
Life science market researchers are highly educated and older. Seventy-one percent of respondents had a graduate degree or above, with almost 40% holding PhDs—much more highly educated than market research professionals as a whole across all vertical markets (59% holding graduate degrees and only 6% holding PhD, as reported in a 2015 Quirk’s Corporate Report).

Ninety-two percent also were older than age 36, and 71% of respondents had 15 or more years of experience in their field. Eighty-four percent were married, and 80% have children.

4) Teams are stable, with less job-changing
Respondents stay on the job longer than the average market researcher—with 75% staying for three or more years before changing roles within a company, markedly higher than the 49% level for horizontal market research industry, according to Quirk’s report—and 95% saying they typically change companies only after 3-4 years.

5) Twitter doesn’t do it for them
In a social media age, sentiment expressed on Twitter is ubiquitous and is becoming an evermore-frequently used information source. However, it’s not where this community seeks input on the market research challenges they’re trying to address. Over 70% of respondents looked to their peers for information on the market research challenges they face, with less than 2% seeking insight from Twitter.

6) Three big problems keep them up at night
Reaching the right respondents
For more than 60% of Pharm Exec readers in the study, reaching the right physicians is their single-biggest barrier to success. One researcher said shrinking budgets have made it even harder to hire the expertise to ensure only those doctors writing prescriptions for their drug are being targeted.

Getting information fast enough
In two separate open-ended questions, study respondents voiced strong concern about obtaining information fast enough. Obtaining fast data that is also high quality and actionable was another concern, given the traditional toolbox elements of long-term studies, elaborate procurement procedures, and bloated processes that take weeks or months to deliver needed insights.

Overcoming budget issues
Problems of cost overruns and shrinking budgets are endemic to the field—with nearly 40% of respondents listing funding as one of the top three barriers they face to achieving their market research goals. For example, with awareness, trial, and usage (ATU) studies—inevitably a herculean endeavor in time, operational resources, and budget—the initial project cost estimate is only half the picture after those unforeseen questions are folded in. The market has opened up space for more efficient solutions to help address these budget issues.

Speeding ahead
In a market that’s mercurial—when years of product development and multi-billions of market capitalization can be wiped away in a few hours of an adverse drug trial event—pharma executives need to ensure that the business decisions they make help the company evolve ahead of a changing industry—and not trail behind it. Market insights teams are the first line of defense in that effort, and, fortunately, the latest market research on pharma market research teams reflects a new imperative to change with changing times. By “watching where the smart money is going,” these professionals are poised to better structure the many forms of market research they are called upon to deliver, in ways that achieve their goals while saving time, hassle, and costs.
“ALL FOR HEALTH TOWARDS HEALTH FOR ALL”
PHILIPPINES AGENDA 2016-2022

STRATEGIES

A
dvance health promotion primary care and quality

C
over all Filipinos against financial health risk

H
arness the power of strategic Human Resources for Health

I
vest in eHealth and data for decision-making

E
force standards, accountability and transparency

V
alue clients and patients

E
licit multi-stakeholder support for health

3 GOALS

FINANCIAL PROTECTION
Filipinos, especially the poor, are protected from high cost of healthcare

BETTER HEALTH OUTCOMES
Filipinos attain the best possible health outcomes with no disparity

RESPONSIVENESS
Filipinos feels respected, valued, and empowered in all their interaction with the health system
PHILIPPINES

With 7,000 islands from Palawan to Cebu, each adorned with white sand beaches and starfish galore, it is easy to understand the country’s catchphrase, “It’s more fun in the Philippines.” But with enormous growth in the pharmaceutical industry, this slogan is not limited to the country’s utopic beaches. The government’s focus on generics has made healthcare more accessible to the general population, increasing access and driving growth for the industry. This in turn has bolstered the country’s economy. The pharmaceutical industry has contributed more than twice as much towards the economic growth of the country, equaling more than USD 2.9 billion since 2014.

DRIVING MOMENTUM

For exclusive interviews and more info, please log onto www.pharmaboardroom.com or write to contact@focusreports.net
Secretary of Health Paulyn Jean B. Rosell-Ubial has encompassed the government’s plan to increase access in their motto, “all for health towards health for all.” This refers to reaching patients from the most remote archipelago to the densely populated urban jungle of Makati. Secretary Ubial has understood the vital role that the industry can play in addressing Filipino people’s healthcare needs and is urging greater collaboration between the public and private sectors to close access gaps.

**PUTTING YOUR MONEY WHERE YOUR MOUTH IS**

With an economy experiencing seven percent growth, a rate forecasted to continue, and a new administration emphasizing the importance of expanding access to healthcare, it is clearly an exciting time in the Philippines. In order to capitalize on this growth and maintain it moving forward, the government, pharmaceutical and life science industries must collaborate with one another. This will enable the Philippines to continue to drive the country closer to its goal of expanding access to affordable, quality healthcare to all Filipinos, regardless of income or geography.

“President Duterte gave me three main objectives when I was appointed,” declares the new Secretary of Health. “Number one was to address the drug abuse and dependence problem in the country, second was to eradicate corruption and the third was to take care of the poor, which, broadly speaking, is what government is here for.” Additionally, Secretary Ubial explains how the President directed her to work towards achieving the goals of the Department, and to “not worry about resources, to simply do my job and the resources will be provided.”

The importance of having the necessary resources was also highlighted by one of Secretary Ubial’s predecessors, Enrique T. Ona, who observes that “progress in the healthcare system is a continuous process, however, having the funds to support this progress is extremely important.” Ona continues, explaining how during his tenure the government passed the “sin tax” on tobacco and alcohol, with 85 percent of the funds being allocated to healthcare. Ramon Aristoza, the acting president and CEO of PhilHealth, the national health insurance program in the Philippines, also expanded

| SIN TAX (ON CIGARETTES AND ALCOHOL) REVENUE EARMARKED FOR HEALTH (IN MILLION USD) |
|-----------------|-----------------|-----------------|
| **Projection**  | **Actual Collection** |
| 2013 | 2014 | 2015 |
| 610 | 675 | 1,389 |
| 895 | 851 | 1,254 |

Source: Philippine Department of Health
on the increase in funding, stating that during the old administration, we received only USD 745 million in subsidies for the poor, however, now, under the General Appropriations Act, in 2016 we received over USD 880 million, forecasted to increase to more than USD 100 million in 2017.

This commitment to expanding healthcare services, both in past administrations and in the current Duterte government, seems to be helping better the lives of Filipinos as well as drive growth within the healthcare and life science industry.

Expanding Access to Knowledge

The benefits of economic development in the Philippines are beginning to trickle down to the lower economic classes in society through a more comprehensive and affordable healthcare system. Additionally, access to information about healthcare resources, across the sector, is also improving. These advancements are allowing all Filipinos to better understand their health. As the Philippines is looking to maintain the country’s continuously prosperous economic status to make investments that will sustain growth in the future, not only must they invest to increase access to affordable and high-quality healthcare, but there must also be an effort to engage the Filipino population to invest in their own health.

As health literacy and medical compliance are both challenges that currently exist in the Philippines, clearly there is a need to help educate and engage the population. Noel Lantin, president of Medicomm Pacific in the country, expands on this point by stating that “compliance in the Philippines is indeed low.” He elaborates that “there is a need to continue reminding our patients on the importance of taking good care of their health, especially when it comes to completing their medications." To address this issue, the company is investing in innovative ways to engage the population: “Through digital channels, we are developing systems to help people in setting-up personal health records, reminding them to take and refill their medicines, and allowing them to have more regular contact with their doctors” notes Lantin.
COLLABORATION IS KEY: PARTNERING FOR BETTER HEALTH

In addition to the increase in funding from the government, continued collaboration between the public and private sectors is also one of the key drivers of growth for the healthcare and life science industry in the Philippines. Cheryl Maley, managing director of Novartis Philippines, underscores this point, stating that “This is another area where I have been pleasantly surprised, as PHAP and industry collaboration is actually very strong here in the Philippines. The agenda is clear, and it is not simply self-fulfilling, it is very much motivated to create better outcomes for the healthcare system throughout the country. I also have found the collaboration between the private and public sector to be very impressive. Internally within Novartis, this is actually an area where the Philippines stands out as well, as a model for collaboration between the private and public sectors.” She further expanded on the company’s commitment to better healthcare, outlining their efforts to bring 175,000 anti-malaria treatments to the Philippines alone since 2003, as well as an access to medicines program that has served 2,500 patients nationally, totaling roughly USD 400 million. Beaver R. Tamesis, president and managing director of MSD, also elaborates on the necessary collaboration with the government when working to increase access to healthcare for the Filipino population. “Expanding access to the poorer segments of the population is something that we are passionate about,” he explains. Speaking to the company’s efforts to expand access to their vaccines, particularly for HPV and pneumonia, Tamesis adds that “more important than just being a supplier, we needed to work closely with government to make sure that the vaccines get into the body of the relevant population.”

Increasing access to primary care services is another issue currently being addressed in the country. Theresa Martinez, general manager, Roche

The healthcare business process outsourcing industry is estimated at USD 1.8 billion in the Philippines and employed 100 thousand people as of 2015, with this number expected to double to 210 thousand by 2022. The drivers of this growth are increased healthcare expenditures in the US, the UK and OECD countries due to a growing geriatric population and increasing disease burden. With the enactment of The Patient Protection and Affordable Care Act and the shift to ICD-10 coding systems, the pressure to lower administrative costs has only escalated healthcare business process outsourcing. Joe Maristela, Filipino-American venture capitalist and entrepreneur, realized the potential of the Philippines when he began Star Business Centers, a healthcare BPO focused on medical billing for the largest clinic chain in California. The BPO was originally started in Oregon, but as the business grew they began operations in the Philippines as well. Speaking on this transition Maristela states, “The move has only benefited the company.” Star Business Centers (SBC) currently provides services exclusively to the Maristela’s family businesses, but as a prominent figure in the start-up industry, Maristela sees SBC taking on outside clients in the near future. Maristela came back to the Philippines after living in California and Oregon and is confident in investing in the Filipino people, whether through his BPO or his venture capital firm. He sees that the BPO industry is developing the economy and preparing the skilled labor force to start their own businesses, and this year is bringing his investment focus “back to healthcare.”
manager of Roche in the Philippines, explains that “There remain opportunities to broaden access via structural investments for the population to reach healthcare professionals, and then there remains the issue of broader access to innovative drugs.” an area where there has been progress in recent years. In 2015 alone, the Department of Health invested in infrastructure projects in 596 Barangay Health Stations (basic primary care facilities), 138 local government unit hospitals, and 207 rural health units.

In addition to expanding primary care and increasing funding for structural investments in hospitals, there is also a need to expand access to high-quality, yet affordable, medical equipment in the Philippines. To better address the needs of emerging markets, such as the Philippines, GE Healthcare has developed products for such regions. “Products are being developed specifically for this region, with the region’s needs in mind. Obviously these products will be more affordable, but their quality will be just as good as any GE product” explains Ivan Arota, country manager of GE Healthcare Philippines. Through these various initiatives, as well as collaborative efforts across both the private and public sectors, progress is being made in expanding access to all types of healthcare and pharmaceutical services throughout the country, although there many opportunities for future advancement remain.

Let’s Define Our Relationship

Asked about the biggest changes impacting the healthcare system in the Philippines in recent years, Toto Oroceo from the Filipino-owned pharmaceutical company Delex highlights the adoption of the policies of PHAP and the Mexico City Principle on ethical marketing within the pharmaceutical market.

Signed in the Philippines in 2015, the Mexico City Principle is an industry-wide guideline applied to the relationship between pharmaceutical companies and medical professionals. The principle is designed to reduce conflicts of interest and unethical demands as well as to clearly define actions that are globally considered inappropriate or unethical, which could mean changes to traditional cultural practices that are no longer considered ethically appropriate. It outlines six principles that should guide companies: (1) Healthcare and patient focus, (2) Integrity, (3) Independence, (4) Legitimate intent, (5) Transparency, and (6) Accountability. Companies are united under the common goal of ensuring the patient’s needs come first and are never compromised. The Mexico City Principle states that, “Through the promotion of these principles, companies and APEC economies seek to ensure that ethical practices are established.”

The impact of the Mexico City Principle on pharmaceutical companies has been a shift towards a more scientific approach to sales and marketing. Maria Aranas, country manager of Glenmark, describes the change thusly, “We increased the emphasis on scientific events. I shifted the focus to these types of scientific events rather than gifts for doctors, which I do not believe is in line with the Mexico City Principle.” Oroceo also reflects on the impact that the treaty has had on Delex, “These are good controls which we agree to; however, because of this, we at Delex Pharma are working harder to promote our brand more scientifically using daily coverage of our customers and via Continuing Medical Education. With this, we can continue to be consistently ethical in our dealings.”

CHANGING TIDES: THE RISE OF THE GENERIC MARKET

In addition to the drastic increase in health funding in the Philippines, one of the biggest evolutions within the industry has been the rise in prominence of generics, now representing 65 percent of the market. As companies have worked to gain the trust of the population for their generic products, there has been a
dramatic rise in acceptance from the Filipino population. “We have been able to prove through testing and the support of doctors that our generics are of the same standard as the innovative drugs and we have greatly reduced the costs of medicines for the Filipino people,” states Kamal Abichandani, chairman of Ambica, a company that has been able to reduce the prices of some basic medications by over five times. Bert and Alec Van Dierendonck, the founder and country manager of South East Asia respectively at EGI, add to this point, stating that “Once we developed these relationships and built trust, we began to sell large volumes of our products.”

Javish Abichandani, CEO of AGlobal Care, stresses the importance of building trust; “We distribute our products nationwide, and we are known to always have been keen for quality. Even though our products are affordable, we never sacrifice the quality and efficacy of the products. We are known throughout the industry for having quality products, delivered quickly and on time. When our distributors bring our products to the hospitals and doctors find out that it is AGlobal Care, they know it is a quality product.”

The fastest growing generics company in the Philippines, as well as the largest in terms of generic products globally, Sandoz, has brought approximately 80 products to market in the country. “We promote these products in three ways: through in-house promotion, partnerships with pharmaceutical companies and partnerships with retail chains” explains Kuntal Baveja, country head and president of Sandoz in the Philippines. Baveja continues, stating that the company has “expanded in all three of these segments, something that has helped us to greatly expand our reach.”

While the growth in the generic market has been impressive, Teodoro Padilla, executive director and Reiner Gloor, advisor and honorary member, of the Pharmaceutical & Healthcare Association of the Philippines (PHAP) give a reminder that “What is important is that we continuously make more drugs and affordable generics available.” To accomplish this, they highlight the need for there to be a strong relationship between the innovative and generic industries, observing that, “The generics industry would not be able to thrive without innovation, and this is something that the average citizen sometimes does not understand. We have worked to promote the availability of new medicines, vaccines and molecules, as well as to increase the generic output.”

Multicare is a good example of a local company investing in partnerships with innovative companies. “It is very important to always be bringing innovations. There are many needs in the Philippines that we...
do not cover,” insists the president of Multicare, Meny C. Hernandez. He elaborates, “the Philippines has a gap and Multicare is here to fill it with the help of companies such as AstraZeneca, Roche, MSD and GSK. Even though they have their own operations, some lines of products need a third party to be distributed. Our expertise, shown through the fact that we are an affiliate of Lupin, and the local knowhow that we have, makes us the preferred partner of the industry.”

As new generic drugs are continuously made available, companies will need to work to differentiate themselves within the industry to be able to achieve success. Nestor Lumanas, general manager of Sannovex, a local distributor founded in 2010, explains that “The thing that makes us stand-out the most is our customer focus and our sales force. Some medical reps will just visit, but we build the relationship and get to know the doctor including their prescription habits and what their needs are. This allows us to adapt the way we sell to what the doctor most needs from us. We find out what the most prescribed medicines are for certain doctors and then we compare it to what we offer. To put it simply, Sannovex knows how to get the job done.”

**BUILDING MANUFACTURING EXPERTISE**

With the rapidly expanding Filipino healthcare sector also comes ambitions for more local companies to expand into manufacturing. Delex’s Oroceo plans to do just this, both to complement the company’s long-term strategy of focusing on the reliability of their supply chain and to expand into product segments that are more challenging to import from outside sources. “We are actively working at the moment to begin the process of building a manufacturing plant,” attests Oroceo, further explaining that “we Filipinos are capable and competent in terms of manufacturing, research and distribution. There is a wealth of talents we can tap for this purpose.”

Francisco P. Sales, president and CEO of Vizcarra Pharmaceuticals, another local distributor, also affirms the benefits of expanding into manufacturing to better control and sustain the supply of products; expanding on the benefits of partnerships to

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**Going Beyond Distribution**

Gary L. Lee, managing director of Dyna Drug, expands on the challenges that Dyna Drug has been dealing with in terms of distribution, explaining that “we continue to evolve. For us to be competitive and maintain our edge, we have to offer products that are not available with other distributors. Throughout our 40-year history, the company is able to thrive by innovating, and we adapt to the evolution of the market. We are preparing ourselves to be a distributor on a national scale, thus, our continuous development through our branches in Cebu, Davao, Cagayan De Oro, and other areas.” He continues, stating “Dyna Drug is serving 3,000 drugstores in the country, partnership is very important to us, we want to stand by our slogan “Beyond Distribution.” We are making Dyna Drug a diversified company that is active in food, drug, cosmetics, medical devices and equipment.”

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**Making access happen**

Despite the tremendous progress of medical science, a healthy life is not a given for everyone. In fact, access to basic healthcare is still the largest unmet medical need today: 400 million people lack access to essential health services, and 2 billion people cannot afford the medicines they need.¹

At Sandoz, we recognize that improving access to healthcare is one of mankind’s biggest challenges. We have a broad range of medicines that treat the majority of diseases, a leading role in developing innovative cost-savings therapies such as biosimilar pharmaceuticals and targeted health care programs for those most in need. We work towards making sure that access to healthcare is no longer determined by geography, wealth or luck.

At Sandoz, we are committed to making access happen. As a division of Novartis, we discover new ways to improve and extend people’s lives. We pioneer novel approaches to help people around the world access high-quality medicine. This is how we contribute to improving society’s ability to support growing healthcare needs.

¹Source: WHO Health in 2015; Access to Medicine Index 2015

**SANDOZ | Novartis Division**
capitalize on best practices and operational expertise. Sales attests that “we have grown from 10 to 110 employees through product diversification. If we were to go into local manufacturing, we would need external partners that could provide the technology and know-how”

Once Filipino companies expand into manufacturing, they will help to boost the contribution of local companies to the pharmaceutical industry’s manufacturing capabilities, which at the moment is quite low. This is made evident by Higinio “JP” Porte, president of the Philippine Pharmaceutical Manufacturers Association (PPMA), who notes that “the challenge that we are facing as an association is that, even though the pharmaceutical industry in the Philippines is valued at USD 2.6 billion, less than 50 percent of that is supplied by local manufacturing companies, we need to enhance the manufacturing capabilities of these companies.”

What is clear is that the Philippines is a country that is ripe for continued growth, presenting opportunities for companies to expand their operations within the country and further developing the pharmaceutical manufacturing sector.

PascualLab, one of the best pharmaceutical manufacturers in the country and a family-run operation, is investing a lot in new strategies to further their own growth and ensure the growth of the industry as a whole and their many partners. Jose Augusto G. Pascual, president and CEO of PascualLab, elucidates “With a professional family, we are keen to focus on accountability, everybody must be accountable for their efforts and actions. And right now we have the high-quality team that we need to continue our growth in the future.”

CONTRIBUTING TO GROWTH

Looking to the future, considering the booming population of more than 100 million and a growing economy, the Philippines will continue to attract investments. Peter Kompalla, executive director of the German-Philippine Chamber of Commerce and Industry, expands on this, detailing how, “from a company...
perspective, many perceive the Philippines as a very attractive market. We have asked companies across the ASEAN region where our member companies would like to expand, and the Philippines is among the top three.” As companies continue to extend their operations to the Philippines, Kompalla has two pieces of advice, “First, preparation is important before entering the market. There is a lot of market potential, but there is also risk, meaning you must prepare well. Second, you must find the right partners and resources.”

Another example of German experience working to grow a company’s footprint in tandem with developing the Filipino population is Bayer, where country division head of consumer health Alvin So relates how the company is capitalizing on the rising disposable income within the Philippines, helping bring more products to consumers. “We have 100 million people living in this country, all potential consumers for our brands, particularly in consumer care and OTC which serve a much broader range of the population. With the economy doing extremely well over the last few years, we will see a corresponding increase in the incomes and consumption of the population, boosting demand for pharmaceutical products, both prescription and OTC” he states. Luis Mendez, the chairman of the Philippine-Swiss Business Council elaborates on the rising importance of the consumer population in the Philippines. “Not everyone realizes that the Philippines is a huge market of over 100 million people, second only to Indonesia in the ASEAN region.”

What is evident in the Philippines is that this is a country on the move, and to continue to drive the momentum in the healthcare and life science industry, actors across the sector must join together. Secretary Ubial highlights this point, underscoring that “from the Philippines, and from our President, we want to send a message that we are coming together as a country to make sure that our population has access to the best quality health services from the government. The only way that we can achieve this is by engaging all actors in the sector. This effort is not going to be accomplished simply by the Department of Health, we cannot do this alone. Everybody, the government, private sector, NGOs and communities themselves must be engaged. All for health towards health for all!”

As the Philippines is an archipelago, challenges in terms of logistics and access are prevalent in many areas. Working to address these issues is not only the government, but the private sector as well. One example of this is Sandoz’s ongoing corporate social responsibility program in Mindanao, in the southern region of the country. The company has partnered with World Child Cancer to establish clinics to provide pediatric oncology services to children who otherwise would have been without treatment. “Approximately 125 people have received treatment at these facilities through mid of this year, and 80 are still living today! This gives you a great, real-world example of the importance of accessibility; these kids were losing their lives because of things that can be treated” exclaims Sandoz country head and president Baveja, highlighting the company’s efforts to address issues of access in terms of the country’s remote, logistically challenging environment.

Pricing presents a challenge in the country as well, considering that innovative products can be expensive for a market that is predominately out-of-pocket. Working to expand access to innovative and life-saving treatments in this type of healthcare payment structure, Otsuka developed their “ONE Quest” patient program to provide support and price reductions for their products for patients in the Philippines. This program was developed specifically for the Philippines, as Ken Saito, president and general manager of Otsuka Philippines explains, “to both work within the payment structure of the country as well as address the needs of the Filipino patients.”
Connecting the Dots for an Enraged Media

Rethinking views on limited-efficacy approvals may be in order

As with so much this past political year, we all witnessed things we would not have thought possible 12 months ago. Experts had to clear the pie from their faces more than once. The main story for pharma was also one of the top issues nationally, the now very real prospect of repealing/replacing Obamacare. Connected, of course, are the industry’s favorite two words, drug pricing, a topic politicians are all too willing to sound off on, though rarely with much more insight than to incite the mob.

In contrast to repeal/replace and drug prices, the post election story that few saw coming is the implication stemming from a possible Trump appointee: the inkling that there might be a challenge to the FDA itself, calling into question its core mission. The healthcare media threw a fit when Jim O’Neill’s name was mentioned. O’Neill, as we now know, comes from the venture capital world as the managing director of Mithril Capital and is connected to the controversial Peter Thiel. Suggesting a somewhat libertarian lean, O’Neill’s has in the past expressed that FDA ought to approve drugs based on safety alone, easing and speeding up the path to market. Those from venture and tech communities are known to look at healthcare regulatory burdens with a cynical eye. But for those entrenched in the healthcare world, questioning the FDA’s mission to determine safety and efficacy is anathema, downright blasphemous.

The news that O’Neill’s name could be on Trump’s roll call made an earlier panel discussion even more relevant than it had seemed at the time. On December 1, at the Forbes Healthcare Summit in New York, the always ebullient Leonard Schleifer, CEO of Regeneron, stressed the importance of “high bars” for approval while butting heads with Pfizer’s CEO Ian Read. Schleifer’s braggadocious characterization of the company’s science (and disdain for others) came across as supremely confident that the FDA should set bars for approval as high as possible, with Regeneron among the few able to make the leap. The concept of outright eliminating efficacy was not even on the table.

But while many were right to point out that such a change would indeed be a massive shock to the industry, few have connected to the other saga for which industry watchers have blasted the FDA. The approval of Sarepta’s Exondys 51 for a subset of Duchenne muscular dystrophy (DMD) patients came as major headlines for the tragically underserved patient population, but was trashed by those who expect efficacy metrics to be quantifiable. Sarepta’s drug proved very little in terms of efficacy, in a very difficult patient population, where placebo groups are nearly impossible to populate. So the FDA failed, according to many, ceding its objectivity in reverence to a pitiable and animated rare disease advocacy group.

But industry critics failed to connect the next dot, i.e., that the market still worked! Sarepta now faces significant challenges because payers are pushing back. The company’s stock rocketed, doubling after approval, but has fallen back, and is now close to its pre-approval value.

The next step for the FDA, not to mention those in rare disease communities, is anyone’s guess. Few will celebrate the fact that DMD remains a miserable death sentence with minimal options. Do payers want this responsibility and the backlash that comes with refusing an option, even though they can call it unproven?

But the industry, at minimum, needs to be willing to consider different thinking. Many rare diseases seem intractable given the current approval demands. Why not consider for certain diseases lower bars for approval to get drugs to market, then let payers, doctors, and patients sort things out?

Though their voices have rarely been heard at healthcare conferences, there are many of the VC/tech/libertarian ilk who see the FDA fitting the origin story of other bureaucratic regulatory bodies. Starting with a government overreach in reaction to real or perceived disaster, they grow like weeds with few questioning their necessity. A contrarian, outsider taking the helm could be interesting, to say the least.
Three of City of Hope’s most eminent research scientists: Steven T. Rosen, M.D., Linda Malkas, Ph.D., and Larry Kwak, M.D., Ph.D. You’ve just made a promising new molecule or compound. But how long will it take to reach the world? City of Hope is an international leader in cancer research and treatment. Our uniquely collaborative culture offers the most comprehensive translational research model you can find. It incorporates not just phase 1 and 2 clinical trials but funding, patents/legal support and regulatory offers. And our three GMP manufacturing facilities, specializing in viral vectors, stem cell products, T cell therapies and small molecules, are available to external clients. In short, City of Hope can give you everything you’re looking for in a partnership, to help you bring your discovery to life faster. Find out more at CityofHope.org/partner
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Most importantly, however, is the fact that when you partner with inVentiv, you will be working with people who understand each and every step along the way — people who always see the big picture. Your picture.

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