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VOLUME 38, NUMBER 4

2018 HBA Woman of the Year

Julie Gerberding Unwavering Purpose

UBM

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The New Talent Trajectory

IF YOU HAVE EVER DRIVEN ON THE BACK ROADS OF LANCASTER, PA, you'll see deep ruts on the edge of the roadway caused from the horse-pulled carriages led by the Amish. The ruts have worn the pavement over time. Same principle with the neural pathways in our brain. We do something the same way over and over, and it becomes routine, almost without thought. To create new pathways, you need to change things up and do things differently, which can be easier said than done. This also applies to careers, which used to be long-standing in one company. Now, the average person changes jobs 12 times in their career. In the pharma industry, as noted in the first article of our talent section (see page 16), companies tended to only hire people that were from other pharmas.

LISA HENDERSON
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But that has changed within the past five to six years. Now, executives are seeing an evolving landscape that is creating a need to hire experts from outside of pharma, as well as create new pathways for traditional roles, or roads to another arm of life sciences.

In a recent webcast (http://bit.ly/2GnaGTq), the topic was CRO consolidation, and it covered a lot of ground; suffice to say that issues of venture capital, M&As, and outsourcing were all in the mix. During the Q&A, the question was asked, "When we discuss the increase of expertise and skills in the new 'mega' CROs, does this subtly imply that the pharma sponsors run the risk of losing those skills and expertise as they shift more of their workflow to CROs?"

Jeffrey Kasher, president, Patients Can't Wait, and previous to that a 28-year veteran of Eli Lilly, responded, "That's already happened. It started in the preclinical and toxicology space, when all big pharma outsourced those packages. What they've seen over time is they lose that expertise inside and all of a sudden they don't know what good looks like."

He continued, "You lose capabilities, number one, and, number two, you lose your traditional pipeline of developing people. So, I think what you're going to end up seeing is instead of people going from pharma to CROs, you're going to see more of a cycle where people come in and learn at CROs and go work for pharma companies and go back. … It's not going to be a one-way street anymore."

And it's not only CROs that are gaining more from pharma outsourcing, though development has more penetration at 70%. But with the addition of the "mega" CROs, like the newly renamed Syneos Health and IQVIA, who have added commercial outsourcing capabilities to their mix for end-to-end offerings, it can take advantage of the development relationships sooner in the drug's lifecycle.

If Kasher sees paths from CRO to pharma and back, there is a definite move from pharma to biotech. In our talent section, Senior Editor Michelle Maskaly outlines a few routes that former pharma executives have taken to reach their new future in biotech (see article on page 20). Recruiters that I interviewed said that the world of biotech, full of venture capital and vision, is a very fertile area for former big pharma executives. But one warned that, if you are going to go to biotech, be prepared to wear many hats and not have access to the larger budgets you might be used to.

Pharma companies are also now more open to hiring outside of life sciences altogether. People who are in consumer goods or retail, or those with digital and data experience, may find the doors of pharma more available than in the past. As noted, GSK's new CEO has hired the former CIO of Walmart and appointed its chief digital officer from Google.

The rest of our talent section this month touches on the new role of data scientist; the revamped role of medical affairs; an uptick in the education of and need for HEOR professionals; and how sponsorship, rather than traditional mentorship, has become more necessary for not only diversity but toward helping create opportunities for a more inclusive company culture.

Pharmaceutical Executive regularly profiles executives in pharma and also biotech, healthcare, and related fields, so we see a lot of career paths and trajectories. Most are not hardened into a single line, but flow and move based on mentors, personal decisions, inspiration, or necessity.

As we continue to cover those C-suite executives, again we are turning our eye to the next generation of pharma leaders. Nominations for our annual Emerging Pharma Leaders are now open. You can submit your nominations at www.pharmexec.com/leaders2018.

Who's destined to change the face of pharma? Can you make the tough decisions that face manufacturers? Do you navigate the commercial, financial, scientific, and R&D market landscape with leadership and inspiration? Do you have what it takes to get to the C-suite? Winners will be featured in the October issue of *Pharmaceutical Executive*.

Pharmaceutical Executive VOLUME 38, NUMBER 4

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2018 HBA WOTY: Unwavering Purpose

Michelle Maskaly, Senior Editor

Pharm Exec profiles Merck & Co.'s Julie Gerberding, this year's winner of the Healthcare Businesswomen's Association Woman of the Year award, who, from her early calling as a doctor to assuming critical leadership roles at the front lines of the world's most pressing population health issues, has remained steadfast in her life's mission—help the many, help the one.

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Cover photo courtesy of Merck & Co.

Talent

Rewriting Pharma's Talent Blueprint

Lisa Henderson, Editor-in-Chief

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Julian Upton, European and Online Editor

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From the Editor

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Country Report: Poland

Still motivated by its challenging, underdog past, Poland has strengthened its economic engine in Europe, where the nation's pharmaceutical sector is increasingly pursuing enlightened approaches in areas such as market access and evidence-based decision-making.

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The Revolution in Rare Disease
bit.ly/2F2PXDL

Readers Weigh In

As a SEO specialist, I would like to say that, yes, SEO and social media are interconnected. Both of them work for a site to maintain a good PR and Alexa rank. Choosing the right content that will be able to attract your targeted customer is really important, so you have to choose it wisely.

Tisha, digital marketing manager
"Marketing in the Social Media Stream: The Solution is Personal"
bit.ly/2IblvbQ

Another potential development is that the market or components, e.g., physicians, patients, will view biosimilars approved with interchangeability as inherently better than those that are only just biosimilar. For many, the more clinically tested, more rigorous analytical specs-meeting interchangeable products will be viewed as inherently better than biosimilar versions of the same reference product.

Anonymous
"Will 'Interchangeability' Boost Biosimilar Prescribing?"
bit.ly/2IawfqN

Twitter Talk

■ I too am moved by sports coaches (I have a soft spot for football). Coaching in business, building teams, cultures of excellence—lots of corollaries to sports.

Dawn Bell, @TheDawnBell
"Leadership in All the Right Places"
bit.ly/2ELE6uo

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Episode 2: JPMorgan Healthcare Conference
Marc O'Connor, chief operating officer at Curant Health, and *Pharm Exec* Editor-in-Chief Lisa Henderson give Michelle and Christen an inside look at the 2018 J.P. Morgan Healthcare Conference. bit.ly/2BVV3DR

Episode 3: Pharma's Reputation
Devyn Smith, chief strategy officer and head of operations for Sigilon Therapeutics, talks about the pharma industry's reputation struggles in the US and Europe and potential ways to fix them, from a very personal perspective. bit.ly/2ou14OO

Episode 4: Outcomes-Based Contracting
Michelle and Christen take a deep dive into the issue of outcomes-based contracting, with Editor-in-Chief Lisa Henderson and European and Online Editor Julian Upton. bit.ly/2GAh22z

Episode 5: Medical Affairs Training
Dr. William Soliman shares the story of how the Accreditation Council for Medical Affairs went from an idea in his head to a training program today that has enrolled more than 3,000 people and is setting new standards for medical affairs professionals. bit.ly/2IUZj6Q

Drug Marketing and Advertising Under Fire

FDA moves slowly in liberalizing off-label communications amid outrage over opioid promotion

Even though Scott Gottlieb challenged FDA restrictions on truthful communications about regulated products as a private commentator on pharma policy, he is taking a more measured approach to expanding off-label promotion as FDA commissioner. A high-level FDA working group is "taking a hard look" at how the First Amendment relates to FDA policy, exploring what the agency can do to "refresh" and bring more "clarity" to its regulations, commented chief counsel Rebecca Wood at the DIA advertising and promotion conference in March.

Wood noted that the agency also is reviewing a recently issued —and delayed—new rule on "intended use" of regulated products, which raises important issues on how approved drug labels relate to product use. A final guidance issued in December 2017 clarifies how marketers should clearly and prominently display product names in print, broadcast, and online ads to avoid confusion or deception. This advisory may facilitate FDA efforts to modify current policies that require presentation of long lists of side effects in direct-to-consumer (DTC) broadcast ads, based on agency research indicating that consumers better understand and remember more targeted risk information (see sidebar on facing page).

More safe harbors for additional types of promotional speech also are under review. A draft guidance published in January 2017 would permit marketers to present healthcare economic information (HCEI) to payers, formulary committees, and "similar entities" to help these knowledgeable experts make coverage and reimbursement decisions. A notable section further outlines how sponsors may provide payers with advance information on investigational drugs and devices to facilitate early coverage decisions on important pipeline therapies.

Another guidance presents a strategy for marketers to communicate information that is not in the FDA-approved label for a marketed therapy, but is "consistent with" FDA-required labeling, or CFL. Such messages must be truthful and not cause harm, and may be useful in presenting new product comparative information or discussing additional adverse reactions, patient subgroup analysis, or conveniences in product use. Marketers have submitted proposals to FDA's Office of Prescription Drug Promotion (OPDP) for utilizing this new approach, while seeking further clarification and examples from the agency.

Opioid abuses

FDA's deliberative process for liberalizing off-label promotion also reflects the mounting legal attack on pharma sales and advertising practices for feeding the nation's opioid epidemic. States and municipalities have brought hundreds of lawsuits against opioid manufacturers and distributors for aggressive marketing activities that have spurred inappropriate and excessive prescribing of painkillers. Private plaintiffs' attorneys and Native American tribes are joining the attack, and the Department of Justice recently said it, too, would seek to recover costs for federal government opioid treatment programs by becoming involved in legal actions.

The plaintiffs allege that manufacturers deceived patients and caused harm by underwriting false, deceptive, or unfair marketing practices, often overstating benefits and downplaying risk of addiction, particularly for extended-release formulations. Prosecutors also are probing company use of speakers' bureaus to channel funds to high prescribers, as seen in the case brought in March by the US attorney of New York against five physicians for accepting bribes in the form of speaking fees to increase prescriptions of Insys Therapeutics' fentanyl spray.

Investigations into opioid marketing have raised questions about industry support of medical and patient advocacy groups that promoted broader prescribing of pain medicines. In February, Sen. Claire McCaskill (D-Mo) issued a report on financial ties between opioid makers and distributors and advocacy groups as part of her ongoing investigation into the role of industry sales and marketing in fueling the opioid epidemic. The analysis reported that five firms

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

gave nearly $9 million over five years (2012-2017) to 14 organizations that promoted opioid use for chronic pain, countered claims of addictive risks, and opposed prescribing limits.

Purdue Pharma responded earlier this year by promising to limit marketing activities for opioids, following similar actions by other manufacturers, including Endo, Teva, Allergan, and Johnson & Johnson. Instead of sales reps promoting OxyContin prescribing, Purdue said it will distribute prescribing guidelines prepared by the Centers for Disease Control and Prevention (CDC). Perhaps Purdue hopes to avoid paying millions more in fines, as it has done over the last decade to settle civil and criminal charges related to Oxy marketing. But penalties may mount for all manufacturers as public agencies seek billions to support costly addiction and rehab programs.

Opioid marketing also has drawn rebukes from OPDP, which has cited firms for overstating benefits and limiting or omitting critical risk information in promotional materials. A February untitled letter charges Collegium Pharmaceutical for failing to display important risk information about its Xtampza oxycodone extended-release capsules at a trade show booth.

Investigations into opioid marketing have raised questions about industry support of medical and patient advocacy groups that promoted broader prescribing of pain medicines

Last year, OPDP sent a warning letter to Cipher Pharma for overstating benefits and omitting risk information on its ConZip opioid agonist, despite a boxed warning and specific limitations on product use. Durect Corp. and Pain Therapeutics received letters in September 2016 for using websites to promote an investigational extended-release pain medicine, Remoxy, as safe and effective.

At the beginning of this year, moreover, FDA and the Federal Trade Commission sent joint warnings to 11 companies for producing and distributing dietary supplements and holistic medicines that made unapproved claims for treating opioid addiction or withdrawal symptoms. While OPDP compliance actions have declined in recent years, these warnings illustrate that violative marketing of pain pills and overdose treatments will draw enforcement action. PE

Research drives regulation

FDA made waves last August in issuing a proposal to improve the clarity and value of direct-to-consumer (DTC) TV advertising by permitting commercials to present more concise risk information instead of long recitations of all possible adverse events. A shift to more streamlined presentation of adverse events has support from FDA's Office of Prescription Drug Promotion (OPDP) research indicating that consumers better understand and remember information on product side effects when such messages focus on the most severe or life-threatening risks. No surprise that the controversial plan has drawn comments from more than 50 stakeholders, with pharma companies supporting more limited risk disclosure, and patient advocates predicting it would confuse and harm consumers. A follow-up study by OPDP of older adults with hearing or cognitive limitations finds that fast and complex presentation of risk information has more impact on message retention than do demographics or health status.

More surveys, studies, and focus group queries will provide FDA with additional evidence on how consumers and healthcare professionals (HCPs) respond to promotional materials, as seen in a "sneak peek" of new 2018 research plans presented by OPDP research team lead Kathryn Aikin. In the works is a study to compare consumer perception and responses to disease awareness ads vs. DTC commercials. Two studies will explore how well consumers understand discussions of FDA's accelerated approval process. OPDP also plans to query HCPs on their opinions and attitudes about pharmaceutical promotional pieces vs. claims in scientific publications and how they perceive risk information for newly promoted drugs. And a major survey of prescribers will explore a range of opinions and attitudes on product claims directed at professionals.

A Plus ça Change Feeling on European Pharma

Looking back at the agenda of a 1985 EFPIA conference demonstrates that, three decades on, the European drug industry is still seeking a pill for its own ills

The last 30 years has extravagantly proved how effective drug companies can be in conceiving, developing, and marketing pharmaceutical innovations. Since the 1980s, the range of medicines has been revolutionized. But in striking contrast to this ingenuity, the European biopharmaceutical industry has not shown itself so capable of designing a therapy for its own predicament. From three decades ago, a never-before-published report on a strategic industry meeting reveals some uncomfortably familiar themes—and even more uncomfortable unanswered questions.

Chance and this spring's gales blew the document in through this columnist's window, and its author—a respected journalist—has given me permission to quote from it (although the journalist prefers to remain anonymous). The report shows vividly how the same conflicts over prices, regulation, and political strategy that bedevil today's drug firms were the leading issues at a time when most of today's pharmaceutical executives were still students, or even unborn.

"The Challenge of Medicines in a Changing Society" was the title of the annual conference of the European Federation of Pharmaceutical Industry Associations (as the initials EFPIA stood for before the group changed its name to its current more inclusive form) in May 1985. As the report notes, the high-level exchanges at the meeting included "it is not only medicines that are doing the challenging: society, changing or not, is challenging medicines and the industry that makes them."

Great potential

The potential of science and technology was undisputed: French health minister Edmond Hervé praised recent clinical trials on an anti-malarial vaccine. Nobel Prize winner Michael Perutz recounted his molecular-biology-based approach to treating sickle-cell anemia.

West Germany's (yes, it was that long ago!) economics affairs minister Rudolf Sprung stressed his government's interest in sophisticated biotechnology-derived medicines.

And Pierre Joly, the boss of Roussel Uclaf and president of the French drug industry association, then called SNIP, eulogized Galien, Pasteur, and Mendel as predecessors of the "European therapeutic tradition" that the pharmaceutical industry was now driving forward.

But "discussion of the heady prospects did not induce unqualified euphoria," notes the report. "Exhilaration flickered and all but died in the face of the preponderantly harsh appraisal of the distance separating current reality from future achievement."

Great obstacles

Economics topped the list of obstacles from industry's perspective. Governments do not appreciate the industry's value or promote its development, and instead jeopardizes its research capacity with downward pressure on drug prices in short-term bids to contain healthcare costs, complained Heinz Hannse, the boss of Schering, and president at the time of EFPIA.

Governments and society fail to recognize the need for mutually acceptable relations with the industry if research is to flourish, insisted Ron Wing of Sanofi UK.

> The potential of science and technology was undisputed

Over-regulation, too, came in for industry criticism. Hannse cited tighter controls on testing, clinical trials, drug information, and intellectual property rights as factors stifling progress. Bill Duncan, head of ICI's pharmaceutical division, demanded: "What hope is there of companies backing research if, on top of the intrinsic uncertainty, they are faced with additional risks deriving from incoherent government policies and an unstable regulatory environment?"

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

And political obstacles ranged from the "widespread tendency to seek a 'soft target' for health budget cuts" to a lack of vision: "Politicians, repeated the industry leaders, must be farsighted enough to see that the long-term advantages of allowing innovative products onto the market will outweigh the short-term costs."

Politicians were equally aware of regulatory constraints, the report continues—"but favorably rather than unfavorably." Hervé "spoke warmly of the WHO (World Health Organization) essential drug list, tighter product information requirements, and education to limit abuse and misuse of drugs." Sprung "enumerated the criticisms made of the industry for stimulating overuse and for inadequate quality, safety, and efficacy … and did not find the time to rebut the criticisms."

Austrian health minister Kurt Steyrer urged "adequate safeguards for patients in clinical trials." And Eolo Parodi, the member of the European Parliament in charge of legislative proposals for pharmaceuticals, "urged better prescribing practice and suggested that R&D should be 'directed' to correspond to 'the correct' health needs of populations."

On economics, the politicians coincided in their insistence on finding balance between industry aspirations and "the overpowering need" to control health budgets. And one of the key policy principles they enthusiastically espoused was support for parallel importing.

"In the opinion of the Federal Government," said Sprung, "neither safety nor any other reason suffices to justify statutory measures to make the importation of pharmaceuticals more difficult. The government views parallel imports as an important incentive to competition, which can also contribute to efforts against excessive price demands at home."

Great ambitions

As the journalist ruminated after all this, "What prospects are there for progress in such circumstances? Will the industry be able to convince European governments of the merits of its case?"

The journalist's report concludes by quoting a challenge that Ivor Boden, the boss of Squibb Europe, threw down at the end of the meeting: "We have heard the industry restate the same objectives at repeated meetings of this sort. Is it not time that EFPIA formulates specific policies of how it should move toward achieving them?"

Fueling new discussion?

Few of the individuals from those days are still around, and Roussel Uclaf, Schering, and ICI have been subsumed into other industrial configurations. But in early March of this year, senior figures from Europe's pharmaceutical industry and from national health ministries gathered in Brussels in an adventurous attempt to explore how they might work together in a new collaborative format. And their spring-like intention was to seek new common understandings on issues such as payment models for high budget impact medicines, access to and availability of medicines, and effective competition in the pharmaceutical market.

> The report shows vividly how the same conflicts over prices, regulation, and political strategy that bedevil today's drug firms were the leading issues at a time when most of today's pharmaceutical executives were still students, or even unborn

A solution at last to some of these decades-old questions? Not entirely, it would appear. The heady agenda for this ambitious encounter, designed to give substance to a series of similarly high-level meetings between drug industry bosses and politicians, proved just too challenging. Elaborate draft papers that had been prepared for the meeting on each of these hot-button issues were not even discussed.

Even more strikingly, questions were raised by key participants over whether this forum was even the right way of moving ahead. There was, in effect, no outcome—and no attempt is to be made to resume the talks until the autumn—or even until 2019.

Plus ça change indeed. PE

Julie Gerberding, Merck & Co.'s chief patient officer and executive vice president of communications, global public policy, and population health, speaks during the company's Senior Leader Summit. *(Photo courtesy Merck & Co.)*

Unwavering Purpose

From her early calling as a doctor to assuming critical leadership roles at the front lines of the world's most pressing population health issues, Julie Gerberding, the 2018 winner of the HBA Woman of the Year, has remained steadfast in her life's mission—help the many, help the one

By Michelle Maskaly

Spend just a few minutes talking with Merck & Co.'s Chief Patient Officer Dr. Julie Gerberding about her life, and it is easy to see how her clear purpose and global action help make the world a better place for patients. Throughout her career, first as a doctor, then as the first female director of the Centers for Disease Control and Prevention (CDC), where she led some 40 emergency responses, and now at Merck—where she also serves as executive vice president of communications, global policy, and population health—Gerberding has never lost the sense of who she is and what she is here to do.

Born at the Mayo Clinic in Minnesota, she moved to and was raised in a small, close-knit prairie town in South Dakota, where she understood that one couldn't survive without a strong sense of community and how to function as a network.

"We had our share of blizzards and floods and ice storms and I learned very early on about the interdependence that people have on one another to solve problems," says Gerberding. "When we had a crisis, we did not call FEMA—we called each other. I grew up with a very strong sense of the importance of working collaboratively with other people and to be independent at the same time."

Early on, Gerberding told *Pharm Exec*, she realized her calling. "When I was four, Santa Claus brought me a doctor's kit for Christmas, and from that moment forward, I knew that my goal in life was to be a physician." Gerberding remembers setting up a little intensive care unit for her dolls and rescuing animals. "At one point," she recalls, "we had several rabbits that needed to be fed with an eye dropper every two hours."

Gerberding's story and commitment to patients reinforces why the Healthcare Businesswomen's Association (HBA) selected her as the 2018 Women

of the Year. "I was surprised, and of course humbled," she says about finding out she was selected for the honor. "Immediately, I wanted to think about what I could do in this period of recognition that would create more meaning."

It's an instinct that is well honed from a life spent working with others to forge progress in health—whether that is for individual patients, supporting fellow women in the health industry, or some of the most at-risk populations on the planet.

Foundational inspiration

During her tenure at Merck, Gerberding has been able to fuel her passion for helping others by combining her health and business expertise and collaborating with others. She joined Merck in 2010 as president of Merck Vaccines, where she worked with other leaders inside and outside Merck to help globalize the business and deliver life-saving vaccines to people in some of the neediest countries around the world.

She saw the need for this work. Gerberding shared a story when she was with the CDC and working in a hospital in Vietnam to help battle a SARS outbreak. She saw a little boy in a bed surrounded by his family and others from his village. The boy caught her attention—he was paralyzed, unable to breathe on his own. People were taking turns pumping air into his lungs around the clock by using a hand-held manual ventilator, which was all that was available.

It turned out the boy had tetanus—a life-threatening disease that is preventable by a vaccine.

"They are pumping air into his lungs to make sure he is staying alive, while a tetanus shot costs about two cents," says Gerberding. "Due to the lack of a few pennies, this boy was on the brink of death and had to suffer dreadfully. I was incredibly frightened for him."

> "I grew up with a very strong sense of the importance of working collaboratively with other people and to be independent at the same time."

That was one of the moments that inspired her to take a position with Merck and improve access to vaccines. Her dream job, she says, is to catalyze the elimination of life-threatening illnesses, such as HPV and related cancers, an aspiration that's possible with tools that already exist today.

Lessons in leadership

Gerberding took the helm of the CDC in the middle of chaos—not so much within the agency, but in the world. It was September 2001, and the agency needed to retool itself to protect public health in the post 9/11 era. Gerberding needed to lead through an unprecedented sequence of public health emergencies, from anthrax and SARS, to avian influenza, and a number of devastating natural disasters, like hurricanes.

Even in this constant barrage of public emergencies, Gerberding prioritized her purpose—patients—and structured the agency to manage crises while keeping goals like reducing the obesity epidemic on track.

She knew the work to prepare the nation for a public health emergency couldn't be done by the CDC alone. "You have to build a network, and you have to understand that managing a horizontal network is very different from managing a vertical hierarchy," says Gerberding. "You have to understand what other people are prioritizing, what their capabilities are, what kind of solutions make sense to them, and then lead through influence, negotiation, shared goal creation, and shared resource allocation, rather than through the more traditional mechanisms like power or money."

She adds: "For me, the personal lesson is that the hard problems that we have to solve as a pharmaceutical industry, or really in any organization in today's complex global world, are problems that can only be solved through networks. It's too

FAST FOCUS

» Dr. Julie Gerberding received her undergraduate and MD degrees from Case Western Reserve University. She completed her internship and residency in internal medicine and fellowship in clinical pharmacology and infectious diseases at the University of California, San Francisco, where she is currently an adjunct associate clinical professor of medicine in infectious diseases.

» Gerberding joined Merck & Co. in January 2010 as president of Merck Vaccines and, during her leadership of that business, helped make the company's vaccines increasingly more available and affordable to people in emerging markets and resource-limited countries.

» Gerberding currently serves on the boards of Cerner Corporation, CWRU, MSD Wellcome Trust Hilleman Laboratories, and the BIO Executive Committee.

complicated and too fraught with multiple agendas to expect any one organization or sector to be able to create effective solutions."

Those long days and plethora of public health emergencies while at the CDC also taught Gerberding a lot about self-care, as well as the well-being of her employees.

"During the most difficult of emergencies, I would lose track of time and realize I hadn't eaten a single thing all day," she says. "At one point, it became clear to me that everyone else was also staying all day and night, and I was setting the wrong example. Leaders need to be aware and mindful that people need a mental health balance."

"To not know what to do is terrible—but to not do what you know is absolutely tragic."

— JULIE GERBERDING, MERCK

Putting others first

The foundation of Gerberding's career was built on the lessons she learned from patients at the University of California, San Francisco, where she arrived for her medical residency at the same time the AIDS epidemic was emerging. She saw the evolving dynamic between patients and the medical community—which in many ways started the movement of patient empowerment as we know it today.

"We couldn't really do much in terms of saving lives because we didn't have medicines then," she recalls. "The conversation was about how our patients wanted to live their lives, how they wanted to die, and their participation in the medical process. I became shaped by the force of that epidemic in San Francisco and the powerful engagement with our patients."

Through her work, Gerberding sought to break down the silos of the hospital that had responsibility for treating people with AIDS. She then became a hospital epidemiologist, charged with understanding and preventing the spread of all infectious diseases at San Francisco General Hospital, a step on her path to recognition as a national and global expert in infectious disease and antimicrobial stewardship.

As chief patient officer at Merck, Gerberding feels as if her career has come full circle in such a way, as she states, "combines the discipline of scientific inquiry with the art and wonder of human relationships."

Advice for the future

As a successful business leader, Gerberding is always getting questions about how to achieve professional success. A lot of these questions come from talking with college students who are plotting out their careers and are faced with what, at the time, may seem like life-altering decisions, such as, "should I take this fellowship?" or "should I get a medical degree?"

For Gerberding, working with young women, in particular, is something that has become increasingly important to her. She is involved with a number of diverse programs that support this cause not only within Merck, as the executive sponsor of the Merck Women's Network, but also with outside organizations.

As CDC director from 2002 to 2009, Julie Gerberding led the agency through more than 40 emergency responses to public health crises.

She told *Pharm Exec* that she always replies to these inquires with the same answer: "Put more tools in your tool box because you never know when they will come in handy. Typically, the person with the best and most relevant tools are the ones who are in demand."

Beyond that, Gerberding's call is for aspiring individual talents and leaders alike to recognize that we all have to step up and apply our knowledge.

"To not know what to do is terrible—but to not do what you know is absolutely tragic," she says. "We have a collective responsibility to learn what we don't know, but also to actively and aggressively implement the things we already do know. Sometimes 'doing the right thing' takes moral courage, sometimes it takes financial risk-taking, and sometimes it means you have to exert your own influence and authority in ways that may not create popularity, but hopefully create the right outcome for the people you serve." PE

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Rewriting Pharma's Talent Blueprint

How new models in hiring and recruitment—coupled with the evolution and addition of C-suite functions to keep pace with technology and consumer shifts—are reshaping biopharma's talent path of the future

By Lisa Henderson

If you are searching for the best current example of the future career path of pharmaceutical executives, look no further than the April 2017 appointment of GlaxoSmithKline's CEO Emma Walmsley. While she has been with GSK since 2010, Walmsley joined the pharma giant after 17 years with L'Oreal, where she held a variety of marketing and general management roles, wrapping up as general manager, consumer products for L'Oreal China. Walmsley entered GSK through that consumer door, and is now the first female CEO of a large pharma company.

It may be that consumer door, along with a few additional windows, that will bring the fresh breeze of insights into the traditionally closed-off pharma industry. "Pharma has been very incestuous," says Srini Shankar, vice president, life sciences, with Cognizant, an information technology and services company. "It's only as recent as five or six years ago that they only hired from within the industry. If you didn't have pharmaceutical experience, they wouldn't look at you."

But with the rapid change of digital technology and consumer shifts within the larger healthcare industry, the need to leverage experience from other industries, coupled with new ideas and ability to create synergies, means a new breed of talent is needed.

To that end, many pharma companies are looking for digital or marketing experience from other sectors, be it consumer goods, retailers, or the adjacent healthcare industry—places where the customer experience is central. Srini says professionals


Srini Shankar

from these other industries can translate that consumer knowledge and apply it to the patient journey, for example, or create a more efficient supply chain.

"I don't want to be 'Amazon'd,' the pharma company might say," explains Srini, "but how do you efficiently build a supply chain, from sourcing to delivery to the pharmacy? The conversation has moved away from, 'oh, you don't have pharma experience' to 'we need that.'"

Clearly, understanding the future of pharma means using technology to parse through massive quantities of data for a variety of decisions. Data for understanding patient adherence, informing new drug candidates (or new uses for old ones), targeting physicians, evaluating outcomes and real-world evidence, lean manufacturing…the list is endless. Examples abound in Walmsley's reign. She created the position of chief digital officer, hiring Karenann Terrell, the former chief information officer at Walmart, who will use new technology in data analytics and cloud computing applied to drug development. GSK also added Marc Speichert, formerly of Google, as its chief digital officer for the consumer unit.

Srini notes that half of Cognizant's clients now have a chief data officer. "The CDO has an understanding of data and where that data exists within the context of the industry," he says.

They are then supported by another growing position, data scientists. While biostatisticians are a specialized and familiar role in life sciences, the role of the data scientists that report into the CDO is to find the insights within the data. Specifically, to integrate, mine, and track data patterns using technology (see sidebar on page 18).

R&D to R&C

If research and development were considered the core competency of traditional pharma, experts at Russell Reynolds Associates, the executive search and talent advisory firm, point to pharma's core now being research and commercial (R&C, if you will). "Big pharma is moving out of development and keeping research and the commercial end," says Waseem Noor, a consultant with Russell Reynolds. He adds, "If you look ahead, there is more in-licensing of compounds or technology, and a steady outsourcing trend for development to the CROs (contract research organizations)."

Two growing areas that sit closely together in the new model are medical affairs and market access. The market access function has come into its own over the past five years. Navigating physician access, patient access, country access, and communicating value to payers, providers, and governments for pricing, reimbursement, and marketing purposes is complex—and increasingly more specialized. "We see more and more strategic value for the market access role," says Noor.

The medical affairs function has been around for a long time, but is now getting a makeover, which some call Medical Affairs 2.0. Noor explains that this new role is much more involved in speaking to physicians and physician key opinion leaders (KOLs) to communicate the value of a product, in their language. In


Waseem Noor

place of the sales rep that visits with samples and lunch, medical affairs is now a more focused partner that can help physicians with educational materials, as well as scientific evidence.

"Scientific analysis along with medical affairs provide a lot of market-based input for companies," says Noor. "Medical affairs understands regulatory review and can help transform business models and commercial strategy." (For more about the evolving medical affairs role, see article on page 27).

Executive options

The older model for large, traditional pharma was a system that created a planned succession of leadership. This model, explains Noor, was not just in pharma but a model of the Fortune 500. However, specific to the drug industry, is the last decade of venture capital (VC) making smaller biotechs more attractive to individuals in the C-suite or at the C-minus two level. Add to that mix the large number of M&As in the industry, and two major implications result. "Mergers mean fewer and fewer positions for pharma for the top level, combined with other biotech and small pharma alternatives for people to go into," says Noor. "Both of these forces have led to the upending of the CEO succession planning."

While pharma can take new talent from the consumer worlds, those already entrenched in pharma can find new life in biotech. As Noor notes, VC's impact has been felt in the biotech hubs. Additionally, familiarity with business development and pur-

chasing or in-licensing biotech compounds leads to the further attractiveness of the research end of the business.

John Rynak, a senior HR and staffing consultant located in Cambridge, Mass., noted that many senior executives from traditional pharma have headed into biotech in the last several years. "They are stifled by bureaucracy and the lack of creativity in the large companies," says Rynak. Another difference with the large pharma vs. VC-controlled biotech is the speed with which programs are ended. "In large pharma, you have people who hold onto programs that should have been killed five years ago. They are spending a lot of money chasing a bad idea," explains Rynak. "VC is more willing to pull the plug and sell the technology…pull it quickly if the science wasn't there."

Matt Vossler is a partner with recruitment firm RSA, which handles executive placement for mid-size, specialty, and early stage pharma companies. From his standpoint, there is a balance and a definite window of oppor-

Data Scientist Role Now a Must-Have

Jaleel Shujath, director, life sciences strategy for OpenText, an enterprise information management solutions provider, recently discussed, via webcast (http://bit.ly/2pwpaKb) and through conversation, the role of data and the data scientist. Basically, "many life sciences companies are digital hoarders," contends Shujath, and they don't know which data is worthwhile or how to start organizing their data for actionable insights.

The role of the data scientist is to be the big data analytical expert in a company, says Shujath. Functionally, they may specialize in area of expertise or specific department (e.g., researcher, scientist, statistician, paralegal, clerk, tech writer, financial analyst, accountant). Their day-to-day function would be to look for and collect existing information, write and generate reports, put together comprehensive sets of files, and generate data sets/objects and create data models which can be leveraged by artificial intelligence (AI) systems.

When looking for your data scientist, outside of those specific skills above, soft skills would include inquisitiveness, someone who stays ahead of topics, systems versions, and uses advanced training to remain a competitive expert. A data scientist will also use their experience and judgment to determine what results are useful. And that last determinant is at the heart of the evolving world of data and data "hoarding." Where is the data, how do you bring it together in a meaningful way, how does it affect the question at hand, and what results are useful?

Shujath describes the current enterprise data conundrum where data scientists are now essential. "A company will realize, when approaching its problem from an analysis perspective, that data is at the heart of their challenges and their opportunities," he says. Where it gets challenging is the huge diversity of data sources with different schemas; those exist in disparate formats that are difficult to thread together and merge (e.g., databases, documents, email, IM, IoT, social, XML, etc), and with data that changes, evolves, and increases in volume every day. Shujath explains, "Organizations have a window of time to act on this information, and if they don't take advantage of it, the opportunity is lost." There are different analytic techniques to use with the data, most of which require expertise in data science. That is where the need for the data scientist arises.

> "The data scientist will be the blue-collar job of the 21st century."

In an OpenText survey, "AI in Life Sciences," completed in late 2017, respondents were asked "Does your company employ data scientists?" The results were: Yes, 52%; Not currently, with no plans to hire, 19%; Not currently but plan to hire, 18%; and Don't know, 11%.

With an eye to the current and future needs for innovation in the US, Shujath says, "The data scientist will be the blue-collar job of the 21st century." Life sciences organizations produce over 150 exabytes (150 x 1,018 bytes) per year and Shujath believes that government could play a role in retraining many who have lost jobs in the manufacturing moves overseas and bring necessary technology jobs to the data frontier.

In all aspects of the global life sciences industry, the data scientist's role will only continue to grow demand and opportunity.

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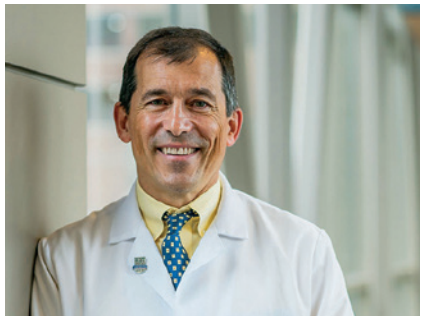

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tunity for fleeing pharma in search of a promising biotech. "A biotech may say we don't want big pharma [candidates], if they have just come from a longer period, say 15 years," says Vossler. "They want someone with that large pharma experience, but maybe a bit removed from that. Say a mid-size pharma or CRO or an institution."

Vossler explains that the smaller companies tend to need individuals to hit the ground running and who wear lots of hats. And maybe someone not used to accessing large budgets. "Sometimes people come in and have no budget for things they used to, and they have to work with that," says Vossler.

In general, so far this year, Vossler has noted a very robust hiring season. "We are seeing demand for combination or hybrid skill sets; for example, a medical leader possessing both an early clinical development and medical affairs background," he says. "And an executive with strong commercial experience, with a PhD-level scientific background, will most likely be using all of their skills daily in these smaller companies."

Vossler says the landscape in pharma today is highly competitive, and one where companies may be looking for a very specific type of executive from a therapeutic standpoint. That can be critical when it comes to interactions with regulatory authorities, or managing a KOL network, for instance, he notes.

On the other hand, it may be that some companies don't know exactly what they are looking for at the outset of a search, but may change or tighten a profile specification after they see a few candidates. For example, Vossler


Matt Vossler

noted a recent West Coast-based chief medical officer (CMO) search that seemed a perfect match for someone with a blend of industry and hospital/academic-based clinical research. Within a few weeks, the company changed its mind, opting for someone possessing a pure academic-based KOL background. On the highly qualified candidate side, Vossler says a recent available position for quality reported into the general counsel, which was not the relationship some of the candidates desired.

"In smaller companies, reporting structures with individuals and teams can be unique based on the skills and experiences of leadership, and things can change quickly, too, depending on timing, as well as who comes in and how they want to structure things," says Vossler.

Rynak agrees that the more senior the executive, the more change that can happen in reporting and organizational structures. "We find that when launching a biotech, it is easier to start with the top-down approach, rather than staffing bottom-up," he says.

Outside of the core CEO, financial, etc., experience, the other major contributors in biotech are the scientists, which is why the biotech hubs have been bubbling along in areas rich with technical and scientific graduates.

The traditional roles

Not to say that pharma has no need for the tried-and-true functions, where a professional pedigree is not only required, but in high demand. Roles such as biostatisticians, or those in the clinical and scientific fields, which can be contracted to offer companies project flexibility and expertise. Thirteen years ago, Jack Schink, former director of procurement within Novartis' business services organization, transitioned from a staffing-aligned managed service provider (MSP) to a vendor-neutral contingent workforce management program not aligned with a staffing agency—with the objective of sourcing, tracking, and managing the company's non-employees (e.g., contractors, temps, freelancers).

In this case, Novartis selected PRO Unlimited as its vendor-neutral MSP, which continues to handle supplier management, on-and off-boarding, market rate guidance, and compliance—all of the areas that Schink says were not part of Novartis' core competency.

"In the pharmaceutical industry, there is so much competition among companies for specific roles that not all large staffing suppliers have access to these specialized workers," he says. "PRO's model leveled the supplier playing field. It allowed for smaller, more niche staffing firms to compete with the larger firms for requisitions. Essentially, PRO's vendor-neutral approach ensured that we identified the right talent at the right time at the best market rate—something that we could not accomplish with our prior staffing-aligned MSP."

Schink adds, "Beyond supplier management, we realized significant cost-savings from outsourcing the program. We managed to bring spend under control fairly quickly and increase program adoption, which helped to consistently deliver around 5%-8% year-over-year savings." PE

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Trading Big Pharma for Small Startup

Senior leaders share the varying intangibles and motivations behind such career leaps

By Michelle Maskaly

After speaking with at least a half-dozen C-suite level executives who made the leap from big pharma to lesser-known startup or biotech companies, it's very clear that there is something deep down in their personalities that propelled them to make the move.

Some of them were at the top of their field when they made the switch. Some were presented with an opportunity they couldn't turn down. Others were searching for something different from what they had done for a majority of their life and were ready for a change. While still others were finally experiencing some financial stability that allowed them to quit the corporate rat race and follow their passion. In each situation, executives were compelled to push out of their comfort zones and embrace change.

Forward thinking

For Dr. Maureen Cronin, the opportunity to join startup Ava, a medical technology company focused on innovations in women's reproductive health and best known as the creator of its cycle-tracking sensor bracelet, hit a number of personal and professional buttons for her, including passion and flexibility.

Cronin has strong pharma roots. She was a member of the executive committee at Vifor Pharma, reporting directly to the CEO, and at Bayer HealthCare, she was a member of a select task force that created the global medical affairs organization after the merger of Bayer Pharmaceuticals and Schering AG. One of Cronin's core interests has been directing numerous large, Phase IV epidemiological studies, mainly in the women's health field, to better understand the medical needs of patients worldwide.

Ava approached Cronin about joining its team full-time as the organization's chief medical officer when the consulting project she was working on with them was over. The San Francisco and Switzerland-based company ended up being a perfect fit for Cronin, who at the time had been running her own consulting business from her home in Europe. She was hired by Ava in February.

"In big pharma, I did some really fascinating things," says Cronin, recalling being on stage with the likes of former secretary of state and presidential hopeful Hillary Clinton, working in Africa to help women get access to contraception, and creating incredible growth in the area of female reproduction.

But, for Cronin, leaving big pharma allowed her to have a better quality of life—both personally and professionally, she says. "I don't have to wear a business suit anymore," she jokes. "I can get up, go do a sport, take a shower, and then go to work in jeans. I like the informality of a startup world and the relaxed atmosphere, while still having the ability to work with highly responsibly, hard-working, and motivated team members who believe in what they do."

Now, Cronin has swapped big meetings for Skype chats and corporate bureaucracy for the ability to make quick decisions with less red tape.

A natural progression

Cronin's story—a big pharma executive being courted to stay on after a consulting project or flat-out poached away from a pharma company—is what a majority of people think of when discussing someone joining a biotech or related startup. However, such scenarios are not always the case.

According to recruiters, such as Alyse Forcellina at Egon Zehnder, the C-suite business skills most desired by biotechs or early startups are those tied to experience with mergers and acquisitions, bringing a product to market, and business development. But, after talking with executives who have made the move, there may not be as much of an active talent grab happening as one might initially think. In fact, many of the people *Pharm Exec* spoke with made the switch on their own because of a career desire that kept gnawing away at them.

Take, for example, Luca Santarelli, the CEO and cofounder of Therachon, a rare disease startup based in Europe. He is also a venture partner at Versant Ventures. Previously, Santarelli was senior vice president and head of neuroscience, ophthalmology, and rare diseases, as

well as small molecule research, at Roche, where he spent 12 years. Prior to joining Roche, Santarelli was a faculty member at Columbia University and a cofounder of BrainCells Inc., a biotech focused on the discovery of novel antidepressants that are able to stimulate the growth of new neurons. He started the company with Nobel laureate Eric Kandel, Rene Hen, and Fred Gage. Santarelli also previously cofounded Synosia and Flexion, two of Roche's asset spin-offs, and led the company to multiple in-licensing deals.

Santarelli has continuously reinvented himself professionally as his desire to be challenged and learn has grown. For the executive, being able to create something from the ground up has been rewarding. As a trained psychiatrist and keen to understanding human behavior, Santarelli knows the type of person who will thrive in a startup biotech environment. After all, he is one of those people.

"It is very hands on," he says. "In big pharma, it's very compartmentalized. In biotech, you do everything. I had to find space [for the office], deal with rental agreements, find an accountant, do payroll, find a lawyer to deal with intellectual property."

Santarelli adds of the distinction: "You don't just do what is on the job description. It's about getting up in the morning and knowing I own the consequences of everything I do."

A successful switch

To make the leap from corporate pharma to a biotech startup environment, it requires a certain type of person. Someone, Santarelli says, who takes motivation one step further, and is not afraid to roll up their sleeves and dive right into areas they might have no previous experience in.

That approach might very well describe Lara Sullivan, president and founder of SpringWorks Therapeutics, who could have one of the more unique stories when it comes to making the jump to biotech from big pharma. SpringWorks was conceived out of a project she was working on while at Pfizer. Sullivan, who holds an MD from the University of Pennsylvania School of Medicine, an MBA from UPenn's Wharton School, and a BA in comparative literature from Cornell University, had joined Pfizer from McKinsey & Company, where she was an associate partner in the pharmaceutical and medical products practice, advising biopharma clients on a variety of strategic and operational issues, with a particular emphasis on R&D productivity.

During her time at Pfizer, Sullivan headed up strategy and portfolio operations for the company's early-stage pipeline. While in that position, she saw, first-hand, programs at various stages of development that held a lot of promise, but through no fault of their own, couldn't be continued.

Pfizer's chief medical officer at the time noticed this, too, and tapped Sullivan to help figure out if something could be done to help these promising therapies stay alive within the pipeline. About two years later, the result was SpringWorks, the startup spun out of Pfizer.

"When we started out, we weren't thinking we would end up with a new company," says Sullivan. "Actually, we didn't know what we would end up with." Once it became clear a new company was the way to go, they conducted an executive search to staff the startup, and Sullivan threw her hat in the ring.

> "We have to do everything from clinical trial design to deciding how to perform HR reviews and talent management."

"I thought to myself, 'okay, I could pull this transition off,' and it felt really exciting and invigorating to have more of a direct impact in a small company, where we have to perform all the functions," she says. "We have to do everything from clinical trial design to deciding how to perform HR reviews and talent management. We don't have to do it at the same level of formality that big pharma does, but we have to have enough of it to guide a team."

That transition Sullivan was referring to was the ability to have enough experience, knowledge, contacts, and confidence to get her through any situation that was hurled at her or her team. It's the reality that a startup may not have a regulations expert, a team to conduct interviews of candidates, or someone to order business cards at their finger tips.

In fact, Sullivan recalls a story where the team was on a conference call and a conversation started about who was

going to design their business cards—something most employees don't think twice about when working for a large corporation. Soon after, the clinical operations person who was on the call took it upon herself to jump right in, design the cards, and then send them to the rest of the team.

"You don't need a job title change for the chance to be stretched professionally," says Sullivan. "You don't need to worry about stepping on someone else's role. No one will tell you to not do something."

Today, SpringWorks is made up of about 50% pharma legacy and 50% biotech, which Sullivan calls "a great balance." She says sometimes pharma alumnae in biotech laugh about the layers and layers of committees they had to previously go through to get things done, as they now usually have a hand in almost every aspect of the company—but quickly adds it's something most employees take for granted when they are in those positions.

Ultimately, Sullivan says pharma and biotech have more similarities than differences, which is why so many people are drawn from one to the other. The fundamental desire to deliver an impact and help patients is the motivating factor in both settings; it's the culture and business structure that is the biggest difference. PE

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HEOR Education: Evolving the Skill Set

Practitioners in the field of HEOR training and education outline how the best courses are responding to advancing industry needs

By Julian Upton

When Gina Ewy, a partner at Jupiter Life Science Consulting, based at the organization's Raleigh, NC, offices, started doing health economics and outcomes research (HEOR) and market access work around 25 years ago, "we didn't really have a name for it," she says. "We called it global pricing and reimbursement. There was no formal training. Most people who have been doing market access for this long came from all walks of life—accountants, doctors, attorneys (Ewy is an attorney herself)—and ended up staying in this work because they enjoyed it."

Dr. Grant Lawless, associate professor and program director, Healthcare Decision Analysis, at the University of Southern California, adds that, traditionally, health economics groups and marketing groups "spoke very different languages." When it came to communicating with the managed care companies and the payers, there was difficulty in putting together clear and relevant arguments that the payers understood and that represented the demanding needs of both the health economics and the marketing groups. "There was no true education that prepared professionals to communicate between those departments," says Lawless.

While health economics "has always been there," says Ewy, it is only in the last 10 years or so that there has been "an increased emphasis on observational research or the kind of perspective studies that we need to do from the pharmaceutical industry to show the drugs work in the real world." Programs have emerged that give young people exposure to health economics, outcomes research, observational real-world evidence, and market access, but the development of such training was initially a slow process. Today, a handful of courses stand out as primers for expert talent in this still-maturing field.

One educator who was ahead of the curve was Dr. David B. Nash, founding dean of the Jefferson College of Population Health in Philadelphia. Back in the early 1990s, when he was a clinical associate professor of general internal medicine on the faculty at Jefferson Medical College and chair of the subcommittee on medication safety at Thomas Jefferson University Hospital's P&T committee, Nash says that all he could see was the escalating cost of drugs. "I was often asked to justify why we were putting particular products on the formulary," he told *Pharm Exec*. "One thing led to another and we noticed we needed additional expertise to make a strong evidence-based case for products and technology, to prepare scientists to help other clinicians make a smart purchase decision."

Hence, in 1992–93, Nash helped to create Jefferson's first post-doctoral, PharmD fellowship program, which offered stu-

dents one year *in situ* within the faculty and a second year on site at a pharma company. With support from the industry—an early supporter being former SmithKline Beecham—the first goal of the fellowship was to create "a cadre of HEOR leaders who could build HEOR shops in pharma internally," says Nash. The second goal was to shape leaders who could contribute to the burgeoning scholarship of HEOR. The longest-duration post-doc, in-person HEOR fellowship worldwide, Jefferson's program now has more than 50 alumni, "spread worldwide, with many at a very senior level," says Nash.

By the early 2000s, it became apparent that there was a need for more practical degree courses in HEOR. Jefferson's Office of Health Policy, however, did not yet have the Board of Trustees' authority to grant a degree until it evolved as a "bona fide" department of health policy in 2003 and then became the Jefferson College of Population Health (JCPH) in 2008. At that point, the college was able to press ahead with launching its formal online Master's degree program. It took two years to create the curriculum and the program debuted in 2010. Since then, JCPH's Applied HEOR program has been really successful, says Nash.

David Nash

"We have students in probably 25 states and a handful overseas, the vast majority, more than 90%, coming from the industry," he says. "They are among our best students, very motivated. Most of our fellows are also taking the degree program. Where the fellowship is more practical, on the Master's they get more formal research training."

The average age of the students coming to Jefferson's online courses is 42, where the average age of the fellows is 30.

Nash says, "The older students are typically mid-career; they're looking to the horizon and thinking, 'What can I do to get to the next level,

Fresh Reset on Diversity, Culture

When it comes to diversifying the pharmaceutical workforce, including the C-suite, industry experts point to sponsorship as the way of the future. *Pharm Exec* recently spoke with Sabina Ewing, Pfizer's vice president of business technology, about this evolution in thinking and approach.

Mentorship is out, sponsorship is in

In the pharma industry, part of the search for talent naturally involves mentorship and networking. From the perspective of a female in the C-suite, Ewing has increasingly tried a newer, more efficient way of building relationships and scoping out talent. "Women, in general, and people of color, have been mentored out," she says. "At this point, what really will matter is sponsorship."

Ewing doesn't refute the importance of mentorship and the many programs that companies offer in the area. But a push toward sponsorship is critical, she believes, as a more direct way of creating opportunities for growth and movement. She defines sponsorship as, "a person using their political equities, capital, and position to directly impact the advancement and movement of an individual." There is a difference, she says, between a cheerleader and a sponsor. A cheerleader is having someone to talk about a person or job candidate positively, while a sponsor will take action to help further and advance another's career. Sponsors are in positions to do the actual hiring or work with peers to hire, or can move an individual to a new role.

Finding a sponsor is an organic process, says Ewing, noting that a person wouldn't typically ask someone outright to be their sponsor. Ewing shares that sponsors, when eyeing for talent, look closely at how a person is engaging and what kind of drive they have—is there a hunger there? "There has to be some reciprocity around this," she says. "With my sponsorship, I am obligated to make sure I show up every time playing to win, and actually making that person look good. And looking at where are their blind spots and gaps. How can I get them engaged in things that can help them address those and be in a position to advance."

Diversifying the C-suite

Ewing says although progress has been made in hiring more women to C-suite roles and treating them equally, there is still more to be done. However, diversity isn't just applied toward women, she points out. Its all-inclusive. "Some people believe that diversity is everything that is non-white male, and that is incorrect," says Ewing, a 2016 *Pharm Exec* Emerging Pharma Leader. "Diversity is the full universe of participants. We can't have white males feel like they aren't a part of this equation."


Sabina Ewing

Inherently, Ewing believes, when companies seek to add talent, looking for innovative and driven people will create rounded teams. In filling high-level positions, a mixture of well-rounded and diverse candidates is critical. To ensure a diverse C-suite, Ewing says that having a continuous pipeline of talent is integral. "It can't be a one-and-done project," she says. "You have to make it a part of your organization's DNA, and you have to hold people accountable for that."

Ewing urges that companies not back away from focusing on diversity and inclusion. In building a talent pipeline, inclusive leadership will instill a sense of belonging within teams, she says, which is key in setting goals and pressing for progress.

Women as CEOs

A recent study was conducted by Korn Ferry examining 57 women who have been a CEO—either currently or in the past. The study was funded by The Rockefeller Foundation, which has a "100x25" initiative to support the hiring of 100 Fortune 500 women CEOs by 2025. The study aims to focus less on why more women aren't in CEO roles, but instead on the traits and factors for success of women who have been CEOs. It is the belief that focusing on the potential of the individual and understanding the organizational impact factors are keys for change.

How can the pharma industry, specifically, help put more focus on women leaders and their success? One way, Ewing says, is for companies to create an inclusive environment where women can be their true authentic selves, and have a sense of value and belonging—important factors in employee retention across the board.

Ewing is also a sponsor for a Pfizer cohort for "Girls Who Code," an effort to close the gender gap in technology. She believes it's important for young girls to see the diversity of roles, the backgrounds, and different women who are in IT to counter-balance the "geeky" or "uncool" stereotypes that some place them in.

— Christen Harm

to get promoted, to play a more active leadership role?'"

About a dozen students a year join the Applied HEOR program. JCPH looks for people who are committed and who can show evidence that they can do graduate-level work. "But the thing we look for the most on our Skype interviews is commitment to the field," says Nash. "It is a course for grown-ups only."

Since Jefferson took the lead, there has been a growth of online HEOR programs, but Nash considers Jefferson's the preeminent domestic program. Providing the course online is vital, he adds, "because we would never be able to get folks from 20 states to come in and make a full-time commitment."

The classroom experience

For his part, Lawless notes that a number of today's HEOR programs out there "tend to be more siloed, as either pure health economics or pure health policy in their training." Lawless decided when setting up the USC's Masters of Science and Healthcare Decision Analysis (HCDA) in 2012 that it would train individuals "with all the skills they would need for both health economics, applied health policy and marketing and the bridging skills that brought those three key areas of knowledge together, to create the kind of story and the data and analysis that payers needed in order to successfully cover new therapies."

Lawless also believes that many of the online programs entering the academic marketplace can miss out on the robust experience offered by the USC classroom-based program. "We're willing to design the programs during weekends, coupled with long, concentrated weeks in the summer," he says, "but we don't believe anything is as valuable as being in the classroom with other students and professors, working on projects and solving problems in real time." Lawless explains that "half the value of our program is the networking. We want the experience to be both academic and professional, and there's nothing more important in your professional life than building your network."

Lawless, an experienced medical doctor and a pharmacist by training, worked in emergency and internal medicine before running the medical and pharmacy affairs departments of Highmark Blue Cross Blue Shield, PA, for 12 years. He followed his clinical and payer experience with 12 years at Amgen, first in the company's health economics group, then in its national accounts marketing group. Lawless's retirement from Amgen was cut short when USC drafted him in to develop and lead its new Master of Science in HCDA. Since then, the program has graduated three classes, "now approaching 100% of students gaining their top choice of jobs or fellowship upon graduation," notes Lawless.


Grant Lawless

About half of USC's HCDA students are healthcare professionals who want to progress onto the marketing side of their companies, he says. The other half come from business and economics. Around two-thirds are starting their careers, using the program as a way to accelerate their core education; a third already work in the broader pharma industry and "want to make a change in the direction of their current career path into a more marketing, value, and access-focused role."

The program is emphatic that the majority of the course's lecturers "do for a living what they teach." Lawless explains: "If we talk about the biopharma and payer industry, we bring in people from Amgen, Pfizer, and even Blue Cross and Blue Shield, to name a few. If we're discussing actuarial sciences and how to design premium rating, we bring in experts from Milliman and large employer groups. If we're learning about pricing and product modeling, we bring in business professionals from the pricing and consulting companies."

According to Lawless, the program doesn't want to limit its lecturers to professional academics without a balance of "real-world" experience. "We encourage students to build their knowledge with real-time experience from expert lecturers who practice what they teach on a daily basis," he says.

Lawless reiterates the importance of students building their business and professional networks and experiences "culminating at graduation and leading to a deeper understanding of the specific skills required for a successful career, along with a broader association of supportive and knowledgeable individuals to help guide them along their career path."

Training into practice: Refining the skill set

Ewy, who occasionally lectures for the HCDA course, notes that while that program is based in USC's School of Pharmacy, the University of North Carolina at Chapel Hill's Global Healthcare Management program, for which she also lectures on pricing, is based in the Kenan-Flagler Business School.

"This kind of reflects the fundamental dichotomy within the industry, a clinical development versus a sales-and-marketing dichotomy," she says. "From an industry perspective, whichever side you are on has an effect on the type of work you can do, the funding you can get."


Gina Ewy

But Ewy notes that the old industry adage that said, "You cannot be a success unless you spent some time 'carrying the bag"' is changing. While getting out and selling to physicians remains important, she points out that companies like Amgen and others are now emphasizing that "You can't succeed unless you spend time talking to payers." Accordingly, companies have established formal market access departments, through which senior executives and executives-in-training rotate, and in countries that are more focused on health economics, companies have taken away full-time equivalents from the sales rep role and placed them within payer-facing roles.

Lawless says that while the location of the HEOR program under Pharmacy or Health Policy can be an issue at some universities, "at USC it's actually become a complement." About a fifth of the USC Master's program enrollees are MBA students, he says. "USC's Marshall School of Business allows students to take electives from our program, gaining full credit toward graduation. We also have a certificate program for the MBA students, where if they take their electives and one extra course, they can earn a certificate of recognition of their core training in HCDA."

Lawless says this program has been very popular with the Business School, especially among MBA students seeking careers in the pharma industry.

The development of cross-functional skill sets is key to sustaining expertise in HEOR and related areas. UK health economist and *Pharm Exec* contributor Leela Barham notes that in the UK it has been "hard to find the people who combine excellent technical skills with the softer skills needed to communicate their work." In the absence of people who "have it all," companies have focused on building small (~10 people) teams that bring these skills together.

Lawless says that one thing he is happy about is that many of the companies that have taken a USC HCDA student, either for summer internships or for full-time employment, have taken a second and sometimes third and fourth student as well. Once the healthcare industry realizes the unique and practical skill sets that the students have, companies say, "That's what we need, someone who can communicate clearly and simply to tout customers balanced with the requirements for technical and functional analysis at the same time."

Lawless adds, however, that, having monitored the direction of HCDA students after graduation, it appears that while the industry likes people "who can speak both languages, it is placing a far greater emphasis on those with well-developed technical training." He says that graduates have tended to gravitate "more toward the two borders of marketing vs. analytics rather than down the middle."

A large group have focused more on the analytical side of marketing—trending, pricing, forecasting, etc—where another has tended to opt for more pure, analytic work, taking "a deeper dive into AI model building, and more data analysis around understanding cost implications in terms of outcomes and utilization," says Lawless. So where the HCDA course began with "a kind of a hybrid program that comprised marketing, health economics, and health policy in roughly equal measure," USC is responding by a launching a second, new Master of Science program in summer 2019, focused on pure biopharmaceutical marketing (BPMK) "but with a more balanced approach to analysis." This will enable some of the marketing aspects of HCDA's established course to be replaced, leaving more room for a deep dive into pure data analysis, research methods, and evidence assimilation.

However the courses evolve, Lawless emphasizes that his program is one where a typical business or healthcare professional can achieve an advanced technical education, while still maintaining a full-time career.

"A lot of people don't have the time or flexibility to earn a traditional PhD in Health Economics, or similar pathways that often require five or six years of detailed research," says Lawless. "Both the MS in HCDA or the new MS in BPMK program can, on average, be earned in two years. You can keep your job, you can still work full time, and control your schedule and personal time, while still advancing your career and goals—if you're willing to put in the commitment and energy." PE

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Med Affairs Building Up its Strategic Muscle

Medical affairs professionals, including the field-based medical science liaisons (MSLs), traditionally report into the chief medical officer and are tasked with disseminating a company's scientific and medical information about its drugs to the larger community. Over the past decade, the role has gained more attention to elevate and leverage the medical expertise of the professionals and become more strategic partners to the C-suite. However, some challenges remain to help these professionals get to the next level.

According to Katie Anders, head of Medical Affairs Strategic Solutions at Medscape, "Today, medical affairs must liaise with their R&D colleagues and fully grasp the science that supports their work. They need access to real-world data. They need the strategic thinking abilities and insights of their marketing counterparts, and the customer-facing skills of those in sales. And they must understand and operate under all of the rules and regulations governing industry interactions."

Anders says, in the face of the changing industry dynamics, companies increasingly are asking themselves, "who do we hire for this role?" She notes some companies consider targeting a sales rep and teaching them science and data management, while others look for a person with science and technology skills and provide them with customer-facing communication skills. "There doesn't seem to be one answer," Anders says.

Simon Mason is chief commercial officer for Medmeme, which houses the most comprehensive, continuously updated, and integrated online repository of disseminated medical science information. He says the medical affairs department is gaining traction—and increased budgets, mentioning one company with a budget in the billions. And, like Anders, Mason says companies aren't sure where to go with this role. "The C-suite doesn't feel that it currently has the right fit or the right skills to take this to the next level. In fact, I know of one company that is replacing half of its [medical affairs] staff."

This is not to scare off current medical affairs professionals, but in the good old days, when therapies tended to be simpler chemicals, medical affairs was seen as a support function. Now, with therapeutics growing in complexity (e.g., biologics) and medicine becoming more personalized, a successful medical affairs department is one that will win by strategically communicating the nuances of sophisticated science with the larger medical community.

Take training. Medscape now offers—based on numerous requests—Medical Affairs Strategic Solutions (MASS). MASS takes its repository of practice performance and clinician behavior data, and offers analysis and insights, personalized training, and solutions that support these professionals in dealing with their HCP clients.

"For example, you can test your messages with Medscape's reach of over 3.5 million active physicians worldwide," says Anders.

With the increased visibility of the MSL and medical affairs professional, comes increased performance measurement. This is an area that has been sorely lacking in the past, says Mason. "It was difficult to measure performance in this area. You could communicate with your external community via publication articles or scientific meetings, but there was no way to measure the impact," he says. "It was hard for medical affairs to prove to commercial its effectiveness."

Medmeme recently launched a platform of solutions called Medmeme Delta. Its measurements use the company's propriety algorithms as an objective solution to validate decisions and measure results. For medical affairs, a department largely involved with writing up and disseminating medical science, Medmeme Delta can evaluate not only internal efforts, but those of the competition, in terms of frequency and quality, and point out the best paths for that scientific dissemination.

Mason explains, "There are tens of thousands of places where [medical affairs] data exist—ClinicalTrials.gov, PubMed—but the rest of the data is all over the place, and getting it together is difficult." Other sources include research grants, patients, clinical trials, meetings, publications, labels, and treatment guidelines. Mason says that it used to routinely take 12-to-18 months to get a paper published in a peer-review journal, however, the mere mention of respectable research can be found in meeting abstracts and online journals a lot faster. "Meetings have exploded," says Mason. "You are reaching KOL (key opinion leader) investigators and researchers much more quickly."

As the role continues to change, Mason notes that many in the C-suite believe that medical should be driving strategy. "It's not there yet, and I thought it would be here sooner," he says. But with the tools, services, and changing skill sets offered to elevate the medical affairs role, it shows promise to reach its potential.

— Lisa Henderson

Medical Affairs: Recent Resources

- "How Can Scientific Dissemination Data Help Medical Affairs Adopt a more Strategic Role?" On-demand webcast, http://www.pharmexec.com/pe_w/medical
- "Maximizing Medical Affairs Impact through Strategic Alignment and Collaboration." On-demand webcast, http://www.pharmexec.com/pe_w/benchmarking
- Accreditation Council for Medical Affairs (ACMA), online article and podcast interview with William Soliman, executive chair. Article, https://bit.ly/2uxBCyb
- For more information about Medscape's MASS, contact Katie Anders at kanders@medscape.net.

Give Them Their Space

To attract the best talent, offer a workplace that inspires

By Roger Humphrey

At the heart of every scientific breakthrough lies the people who made it happen. As the pharmaceutical industry faces increasing pressures to innovate and adapt, the challenge of finding and keeping exceptional talent looms large.

Pharma companies are in the midst of a dramatic transformation, yet the physical workplace has remained largely unchanged. Now, leaders are gaining a greater appreciation and understanding of how places and spaces can help accelerate their business and bring their best ideas to life, according to JLL's latest Life Sciences Workplace Insights report.

Aesthetics matter

Developing an innovative and productive team isn't just about hiring the right people—it's about creating the right kind of environment that will bring the best talent through the door and getting that talent to stay. It's about designing a workplace that keeps the needs of employees front and center so that they feel fully engaged in work and remain productive.

Stark, rigid labs are out. Open, flexible, and welcoming environments are in. Attracting highly sought-after scientists, researchers, and data analysts will require an inspiring workplace where people choose to show up and give their best. Real estate decisions and workplace strategies must be tightly aligned as companies examine the core questions ahead.

Where does our future talent reside? Life sciences clusters such as Boston, San Francisco, and New York City are magnets for industry players of all sizes. And we don't have to look too deep to understand why. Strong ecosystems in these cities support research and funding needs. But perhaps the most critical selling point for companies is the fact that these hubs are breeding grounds for the best and brightest scientific minds, thanks to the region's influential research institutions and universities.

Finding a place to put a stake in the ground is another story. Workspace is scarce in nearly all of the top 10 US life sciences clusters, with vacancy rates under 10%. In turn, the lack of space is pushing up rents. Companies that want to be in the center of the action need to approach their real estate strategies more creatively.

Some companies are moving to the surrounding suburbs of major markets, trading a central location for more competitive pricing and/or better amenities. Waltham, Mass.—on the outskirts of Boston—has lured a number of life sciences companies away from high-priced Cambridge labs. Exosome Diagnostics and Bioverativ, a spin-out of Cambridge-based Biogen, have both recently moved into Waltham. Neighboring Lexington is home to the first-ever speculative suburban Boston lab building, which didn't sit on the market long before Wave Life Sciences leased the entire 91,000-square-foot facility. King Street Property, which built the development, is actively building more new space for life sciences companies in both Waltham, Lexington, and surrounding areas.

Pharma companies are also collaborating with local universities and real estate developers to ignite new hubs. Spark Therapeutics recently signed on as the first tenant of a new $3.5 billion development in Philadelphia called Schuylkill Yards, which is positioning itself as a new hub for technology and life sciences companies. Just blocks away from Drexel University and the University of Pennsylvania, the center aims to bring together leading research institutions with incubators, startups, and established companies in a walkable, work-live-play community.

Some industry giants are finding success with setting up smaller outposts across a variety of hotspots. For example, Amgen is relocating 100 R&D employees from its Thousand Oaks, Calif., headquarters to sites in South San Francisco and Boston. Meanwhile, New Jersey-based Merck & Co. is establishing a West Coast headquarters in South San Francisco, joining companies such as Genentech and Johnson & Johnson.

Regardless of the approach, a presence in or near the major life sciences hubs has become nonnegotiable for growing companies that face increasingly fierce competition for talent. Exacerbating the situation: tech companies have entered the fray. A prime example: Alphabet's Calico subsidiary is going after the same computational biologists and top academic researchers that are already in short supply for the industry.

How do we create an environment that will attract (and keep) the best talent? How can pharma companies compete with major tech play-

ers? While most pharma organizations won't set aside a massage room on-campus or offer free food to employees all day long, there are valuable lessons to take away from the tech world. The underlying philosophy—making work an enjoyable experience for employees—is gaining momentum across all industries.

Newly constructed real estate developments are helping companies lure employees who want a workplace with the latest bells and whistles. The Alexandria at Torrey Pines, which was designed to attract life sciences and tech companies to one of San Diego's hot neighborhoods, gives tenants access to large conference rooms, concierge services, and a restaurant with a celebrity chef.

Relocating to a shiny new office isn't always possible, but smaller measures can have an equally powerful impact on employees. Solutions can be as simple as creating a space where employees can recharge or unwind when they need a change of scenery—whether it's a meditation room or an informal lounge with a fancy coffee station. Giving employees more choices also goes a long way toward influencing work happiness. Employees feel empowered when they can choose from a variety of work spaces or adjust their workspace to fit their unique needs.

How the organization's culture is reflected and supported in the workplace increasingly matters. Even investors are asking questions. PwC's latest CEO survey found that more than 700 publicly traded companies talked about culture with their investors. Open and honest cultures are a distinguishing feature that draws in good people. Workplace design—such as open collaboration areas with glass doors—can help communicate a sense of transparency and honesty.


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How can we create workspaces that boost productivity and efficiency?

Every company has unique needs and can uncover the right solutions by polling employees about their physical workspace. What irritates employees—is it a lack of collaboration areas, limited private spaces, or the office temperature? What features would they change in the office? Understanding frustrations and adjusting the space to reduce or eliminate them can help employees feel more engaged and, ultimately, more productive.

Thoughtfully designed workplaces today offer a diverse mix of spaces that cater to the changing needs of employees, from collaboration zones to small conference rooms to research areas. Genentech and AstraZeneca are reducing assigned seating, moving instead to reserve-able private spaces and open seating. In fact, companies across many industries are adopting more fluid seating strategies to accommodate a workforce that increasingly comprises remote and on-demand workers.

The overall layout of space also needs to be more flexible to accommodate rapidly shifting research needs. Lab space has long monopolized the bulk of life sciences buildings, but as more R&D work shifts to data analysis, companies may need to dedicate more square footage to office space.

The one constant is change. Workplace design must support a culture of constant disruption. Architects and designers can build flexibility into everything from the functionality of rooms down to the furniture, including moveable benches, retractable cords that hang from the ceiling, and plug-and-play research equipment. Shortened research timelines and the pressure to advance products to market quickly means that labs have to be lighter and faster. The ability to use lab space for different projects at the same time or to quickly transition to a new project can help reduce total real estate costs.

Connecting the dots

Constant change makes it difficult to pinpoint which way the wind is shifting. Developing more flexible real estate strategies that are aligned with future workforce strategies can help organizations adjust course more easily. Keeping employee needs in the center of all critical decisions will point you in the right direction and give you the advantage in the war for talent. PE

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Chinese Pharma Trending Up?

Outlining the four major areas driving China's life sciences industry, which may be on the cusp of a new era in R&D and healthcare reform

By Jin Zhang

For the majority of traditional pharmaceutical companies operating in China, 2017 was a tough year. A round of new policies repeatedly challenged and changed the industry status quo. For innovative life sciences organizations, however, it was a different story—a year full of hope and opportunity. Thanks to the steady increase in healthcare need, the introduction of policies favorable to innovation, and capital injections, the Chinese pharma industry could be entering a golden age of innovation and development. In this ever-changing market, where will the industry go now?

Innovation

Supportive and favorable policies

From May to October 2017, the China Food and Drug Administration (CFDA) issued a series of supportive policies—five in all—to encourage innovation in medicines and medical devices. In the past, long drug approval timelines in China were always prominent on the minds of industry experts. This series of initiatives is aimed at carrying out a comprehensive reform of six major aspects: clinical trial management of medicines and medical devices, examination and approval of the listing, drug innovation and development of generic drugs, life cycle management, technical support, and leadership. These are expected to greatly accelerate the drug approval process in China.

Intellectual property is another important area. China has long been criticized by the international community for its lack of IP rights and protection; as a result, the development of China's innovative pharmaceutical industry was heavily restricted. However, things are changing. China made clear improvements regarding this issue in 2017, establishing three anchor points linking drug and patent, patent-period compensation, and data protection. Through this round of moves, China is slated to build a scientific and systematic protection mechanism to effectively protect the patentee's legitimate rights and interests, effectively driving the wave of innovation.

Getty Images: Jeremy Woodhouse

The soaring investment market

Thanks to the new innovative drug-support policies, the pharma investment market in China has become more favorable. At Healthcare Capital Summit 2017, Werner Cautreels, CEO of Selecta Biosciences, said: "China is no longer an emerging market. Instead, to any pharmaceutical companies which are committed to taking the leadership position in the fierce global competition, China is an important strategic priority." After 10 years of domestic development, China's pharma market reached $571 billion in 2016 and is expected to grow to $1 trillion by 2020. An increasing number of local and international investment firms have begun to enter this field, setting up China-focused medical and pharma funds.

According to the annual report on China's equity investment, in 2017, there was a total of 9,120 investment cases in China, of which 1,008 were related to the biotech and pharma industry. In terms of investment number in China, biopharma is second only to

the internet and IT sector; in terms of investment volume, it is ranked fifth among all industries, with a total of $11 billion. Among biopharma investment firms, C-Bridge Capital, Tasly, Temasek Holdings, Shenzhen, and Capitol Group are the most active.

Thanks to the new policies and favorable pharma climate, an increasing number of overseas talent moved back to China, starting new businesses. With the surge of international and domestic capital, a string of new and innovative biopharmas, such as Beigene and Zai Lab, have emerged.

Medical AI

As artificial intelligence (AI) has become more accepted and applied in various fields, the pharma industry is playing catch-up; but there are positive things emerging. Currently, AI has been applied in all three phases of medical treatment in China.

Preclinical treatment stage

The application of AI in the preclinical treatment phase is very broad. It includes a range of services, such as auxiliary diagnosis, medical imaging, and virtual assistant. At present, pharma is the most mature business sector in terms of medical AI application in China, achieving solid success in the past year. For example, if combined with pathology analysis, the accuracy of medical imaging diagnosis has already reached 99.5%.

Clinical treatment stage

In the face of long R&D cycles, large investment, and the high failure rate of new drug development, the pharma industry has long been demanding a more efficient approach to clinical research. The emergence of AI has filled this void. It has been increasingly used to discover novel medications or explore new implications of older drugs. It is predicted that the application of AI in this sector will grow even stronger in China, potentially reaching a market value of hundreds of billions in the coming years.

Post-treatment and recovery stage

AI can also be widely applied after medical treatment, in areas such as health management, wearable devices, risk prediction, and information and data management. A range of biotechs have already joined this field, with the sector likely to become the main force in driving AI's application in the Chinese healthcare and pharma space.

In China, the aging population, the rapid growth of chronic diseases, a serious imbalance between supply and demand, and uneven geographical distribution of medical resources have created a great market need for AI. In contrast, China's large population base, rich business combinations, and a huge reserve of talents have provided fertile soil for AI to grow and flourish. Moreover, CFDA has published over 80 national policies and medical AI-focused guidelines to support and drive its R&D.

As of August 2017, total AI investment in China exceeded $2.6 billion, with 104 companies securing funding in the preceding year. The most active investors include Sequoia Capital, Zhen Fund, North Light Venture Capital, Matrix Partners China, and SB China Capital.

Medical reform

2017 was a major year for medical reform in China. In an attempt to alleviate expensive treatment and the burden for patients and the public healthcare system, the Chinese government introduced a round of policies and measures, including drug control, adjuvant drug monitoring, the two-vote system, drug price negotiation, pay by diseases, and others. The reform has already led to significant improvements.

Healthcare fee control

The rising healthcare fee and how to control it has always been a core issue of the current Chinese healthcare and pharma system. In 2017, that battle was further intensified. Potential ways to solve this problem include, first, expanding the sources of medical funds through the introduction of commercial healthcare insurance, and, then, optimizing the payment structure to meet the new medical needs.

In China, the introduction of commercial health insurance is still in its early days. It remains difficult today to meet the shortage of medical insurance needs, and this likely will not change much in the near future. Under the current structure, all reforms in health insurance, medical treatment, and medicine are moving in the direction of medical insurance payment structure optimization.

Two main approaches can be applied in this setting. First, by reducing the cost of drugs, CFDA aims to effectively cut off the interest chain. Second, through improving the medicine system structure, China is on track to substantially reduce the use of expensive and patent-expired original drugs. Thus, high-quality generics will begin to dominate the market, potentially sav-

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The New (Augmented) Reality in the Life Sciences

Three ways AR can bolster pharma commercialization strategies

Augmented reality (AR) gained widespread attention the summer of 2016 with the addictive game, Pokémon Go. But these days, AR is not just for fun. This disruptive technology is expected to drive significant changes to businesses across many industries because of its ability to combine the virtual and physical worlds. Specifically, AR transmits a live view of a real-world environment that is augmented by computer-generated, 3D images. A digital object can be scaled to fit neatly in a physical environment using an AR application and camera on a mobile device.

In 2018, AR is moving beyond early experimentation, which merely showcased AR's novelty, into more viable business application—especially in the life sciences industry. Innovative companies are developing compelling ways to use AR to enhance customer engagement, improve education of complex topics, and create powerful, even emotive, brand differentiation.

ARNO SOSNA is General Manager, Veeva Systems

Early use cases for AR

AR is becoming more accessible thanks in part to new software such as Apple's ARKit, which is making it faster and easier to develop applications. There are more than 2,000 AR applications available today, and more coming, according to a report by research firm Forrester Research. "Virtual reality (VR) and AR solutions are revolutionizing the way large and complex B2B products get marketed and sold — just as three-dimensional (3D) modeling precursors forever changed the way these products get designed and manufactured," noted Forrester.

Early adopters in the life sciences are starting to use AR to explain complex concepts and treatments. It optimizes today's digital channels by providing an attention-grabbing new content type that allows healthcare professionals (HCPs) and patients to engage directly with 3D images. For example, one company created a 3D heart model to demonstrate how a medicine moves through the organ as part of a new treatment, producing much greater impact for the audience than a simple video. Other AR applications have mapped an individual's body for surgery and shown the exact location of veins in a patient's arm, helping HCPs treat patients better and improve outcomes.

Regeneron is leveraging AR to create deeper empathy and understanding of patients suffering from vision loss. HCPs can experience the blurriness, wavy lines, or black patches caused by different types of retinal disease to better appreciate the challenges patients face from this condition.

As AR continues to gain traction in the life sciences industry, it will be built into core enterprise software such as customer relationship management (CRM) and content management systems—bringing an exciting digital content format to life by making it widely accessible and actionable. Here's how this will make AR a game changer for marketing, sales, and customer service.

1. Enhance personalized customer engagement

AR will enhance customer engagement by creating highly engaging experiences for HCPs and patients. This is crucial today, especially as HCPs expectation increases for digital engagement. Finding new ways to interact with them can serve as a true differentiator and help foster more personal relationships. Using AR to spur emotional reactions such as wonder or surprise can also create a better connection with customers, and help ensure HCPs are fully engaged.

Specifically, AR enables life sciences companies to innovate how they tell and deliver their product's value, as well as demonstrate the outcomes. These demonstrations are extremely powerful, particularly when unpacking complex medical concepts because customers can visualize the product in their actual environment. HCPs gain a clearer understanding of how a treatment works in the body, even in a particularly patient's body. The contextualized experience allows HCPs to more fully appreciate the treatment benefits, too, which also makes the information more memorable.

Consumer brands are already using AR to personalize the customer experience. Ikea Place allows customers to place and move furniture virtually in their own homes. The 3-D furniture appear at scale, with true-to-life representations of the texture, fabric, lighting, and shadows for a true "try before you buy" experience. Similarly, AR can demonstrate exactly how marketing materials might look on display in

a doctor's office, similar to how over-the-counter drugmakers virtually arrange their shelf layout in-store. This simple change not only personalizes the engagement experience, but it also raises the bar from personalized content to a personalized virtual experience.

2. Improve understanding of complex treatments

Unprecedented scientific discovery has led to an increased focus on developing specialized treatments that are highly complex—both in action and, oftentimes, in delivery. With every new discovery, effectively communicating complicated breakthrough therapies or even cures becomes more challenging—particularly just with words. Videos help but are still limited.

Today, AR technology offers a multi-dimensional way to communicate complex concepts for greater comprehension and retention. In fact, researchers have concluded that AR is more effective in demonstrating spatial and temporal concepts, allowing people to engage in the learning process with multiple senses and producing better results. As Benjamin Franklin said, "Tell me and I forget. Teach me and I remember. Involve me and I learn." AR involves the viewer, in multiple ways, so he or she learns faster.

In healthcare, for example, AR can be used to teach medical practitioners complex medical procedures—not just in theory, but also in practice—allowing them to virtually touch and manipulate objects to see the effect or practice the procedure. AR can also provide 3D on-body visualizations of how medicines or medical devices work for both HCPs and patients. Think of the value of virtually demonstrating a unique delivery mechanism for a new drug to HCPs early in the commercialization process. Medical teams could proactively instill product familiarity and avert potential apprehension before the product is even launched. Combining situational and sensorial learning via AR is an exciting way to improve information retention, deepen understanding of benefits, and pre-market complicated products to key opinion leaders.

It offers a new avenue for marketers to engage in storytelling for their brand to communicate product benefits.

A powerful visual experience can showcase important attributes that are different from other products. Differentiation with AR could highlight better efficacy, address new uses or dosing, or build awareness by leveraging an emotional aspect of the product.

Using AR to spur emotional reactions such as wonder or surprise can also create a better connection with customers, and help ensure HCPs are fully engaged

"AR is a wonderful new addition to the visual toolbox and can be spectacular in telling a story with impact. AR is a particularly appropriate medium for cases where a contextual understanding of a medical concept is required," said Yan Fossat, vice president of Klick Labs at Klick Health. "For instance, giving someone the ability to instantly see a disease or skin condition on their own skin or enabling them to see what someone with macular degeneration sees with their reduced vision is more impactful than other forms of visual and textual representation."

3. Create powerful brand differentiation

In an increasingly competitive landscape, AR can provide an important point of differentiation for life sciences companies. Marketers will be able to use AR to stand out in a world saturated with content. With AR, companies can add value to the customers—helping them visualize the product, providing empathic experiences or creating context for the product. Life sciences companies using AR can illustrate these distinctions in a fresh new way. Being first to market with an attention-grabbing AR experience can also strengthen brand awareness in customers' minds.

Life sciences companies are testing the waters in new and exciting ways today and industry analysts expect to see a dramatic climb in AR adoption over the next several years. "The integration of AR applications into conventional workflow, such as through CRM, EMR, and analytics platforms, will lead to even more exciting possibilities for commercial operations," concluded Fossat.

Perhaps the biggest obstacle to AR is simply resistance to change and inertia. Forward-thinking companies will lead the way and provide the industry key learnings while creating broader acceptance of AR as a "killer app" with endless possibilities. Looking to the future, AR will be increasingly important in life sciences commercial strategy, creating extraordinary experiences for HCPs and patients. PE

The Top Barriers to Patient Persistence

And ways pharma can help overcome these hurdles—and boost compliance rates across the full durations of treatment

VICKIE ANDROS is Director of Clinical Services and **JAKE CAINES** is Senior Director of Commercial Strategy and Performance, both at Curant Health

Why don't patients persist in taking their medication as prescribed? This is the nearly $300 billion question about wasted spending the entire healthcare system has yet to solve. Moreover, Capgemini estimates that medication nonadherence accounts for approximately $637 billion in revenue opportunity losses for US pharmaceutical manufacturers. The root causes: lack of initial alignment between provider and patient and inadequate follow-up with patients once the prescription is written.

Time pressure throws off medication alignment

The lack of initial alignment regarding prescribed therapies has many causes. What potentially disrupts the first fill and later, the first refill? It's a matter of time and trust in the precious minutes or seconds the physician shares with the patient.

Physician/patient interaction time is increasingly tightly constrained, with some surveys suggesting that physicians only spent 27% of their total time on direct clinical face time with patients. This time is inclusive of symptom evaluation, diagnosis, listening to the patient, and more.

Frequently, less than one minute spent within those visits is given to the "what and why" about prescribed medication therapies, including side effects. Failure to adequately explain what the medication is and why it is important is a massive barrier to compliance. However, time pressures are very real. Frequently, patients don't want to take any more of the doctor's time than what they perceive as needed. Or perhaps they want to complete the visit as quickly as possible after spending a lot of time in the waiting room. Lack of time with the provider can also tempt patients to consult unreliable outside resources like the dreaded Dr. Google.

Often, even if patients know why medications and compliance are important, they still don't know what to expect from therapy, particularly in terms of side effects and drug-drug interactions.

Competing priorities for patients

Physicians are the experts in intervention and therapies. Patients are experts in their lives and their priorities: their lifestyle, their finances, and emotional factors that inhibit compliance, including depression, perceived stigma, and socioeconomic challenges, just to name a few. Questions like, "How much is my co-pay, and will I have to give up something else to afford this medication?"; "How will this medication make me feel, and is taking this medicine worth my feeling bad?"; or "Will taking this medication serve as a daily reminder that I'm sick?" are examples of potentially competing priorities patients may face. If patients don't receive adequate information about the importance of a newly prescribed therapy, it's possible the drug doesn't come out on the top of the priority list.

Failure to personalize, and persist in, follow-ups

Our colleagues for a large diabetes provider told us that they schedule patients for four visits per year. The average actual number of visits completed: 2.4. The picture is similar for HIV patients. In the US, it is estimated that only 75% of HIV-diagnosed patients are linked to care, and only 66% of those linked to care are successfully retained in medical care. Various US medical sources, including the Health Resources and Services Administration and the Institute of Medicine, define "retention in care" as at least two appropriately spaced visits within one year with an HIV medical provider.

Technology, including patient/provider portals, text messaging, and email (especially if login is required), only works for certain populations. Based on our experience working with thousands of patients nationwide, we know that telephonic patient outreach is mandatory for certain patient populations, for example the elderly and those who require consistent, ongoing support in order to remain adherent. This outreach is time-consuming but effective. It's also likely to be

overlooked in the rush to employ newer technology platforms for engaging patients.

The burden of positively impacting a patient's health cannot be placed entirely on physicians and their staff. Patients must be both interested and empowered to positively affect their health. A trustworthy source is needed to provide patient follow-up to demonstrate care and establish trusting relationships. Patient follow-up is needed on as many ends as possible to demonstrate care and establish trusting relationships, activity that requires a methodical approach over time.

Solutions: What can the brand team do about it?

Improve initial alignment

An honest assessment of the real patient journey to understand what's working and where gaps persist is the first step brand teams should undertake to improve alignment. Ensure that the effort is cross-functional and includes clinicians, healthcare economics team members, and representatives from both sales and marketing. For example, in a hub model, a manufacturer's representative might know that a prior authorization has not been approved or that a refill has not been picked up. This representative may then go back to the provider to let him or her know. In this scenario, however, who goes back to the patient for follow-up?

Our advice: if you've done this assessment and still believe you have filled in all of the gaps, start over.

Optimize follow-up initiatives

Knowing that half of all new prescriptions don't get filled, it's imperative that intensive patient follow-up to address concerns, confirm the accuracy of information they have on hand, and reinforce the value of their therapy and compliance take place before patients go to the pharmacy.

An assessment of patient needs will generate scores of opportunities for intervention, but the following are high-value solutions brand teams can influence for the benefit of patients:

- Patients need constant, regular reminders with good information in the form or format that works best for them: text, phone, email, web, or in person.
- Person-to-person support is the least efficient but most effective. Many manufacturers will not know about prescriptions written or first fills. The physician won't know either. The only people who really know are the patients. If you don't communicate with patients, it is unlikely you will impact persistence.
- The first refill represents pharma's top opportunity to influence behavior. This will require time, resources, a new approach to patient engagement, and assumes the manufacturer and brand team actually have enough contact information to reach patients directly. Ultimately, a sliding scale for follow-up based on patient needs and preferences is optimal. Patient enrollment program investment is increasing, but what are you going to do with it? Start with intensive engagement efforts—person to person—then scale back as needed. If text reminders are enough, great. If not, persist in your own efforts to reach them in a "whatever-it-takes-to-improve-patient-lives-and-outcomes" mindset.
- A multi-channel (HCP/DTC), multi-protocol paradigm. While "population health" is a hot term, actual patient health happens one individual at a time. Texting may work for some, but a phone call may be the best fit for others. Certain patients need a text prior to a phone call to trust the intent of the unknown number. And still other patients want to use their new provider portal. A multi-channel, multi-protocol approach drives population health by recognizing and delivering on individual needs. If you don't have it, you need it. Acknowledge one size does not fit all.

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If persistence is the gold standard by which brand teams measure success, investing the right amount of time in the right type of resources is critical. PE

Digital Innovation: Staying Ahead of the Curve

Key steps to navigating the evolving digital health market, where an influx of new players are looking for a piece of the pie

Organizations in every industry are tapping into digital innovation to increase revenue, reduce costs, and better serve customers. The pharmaceutical industry should be no exception. To date, the healthcare industry has contributed advances to telemedicine, robotic assistance, and real-time monitoring devices, among other technologies. However, the pace of pharma's digital technology adoption remains slow due to the fear of escalating cybersecurity and privacy challenges, strict federal and state regulations, and a need for more digital expertise.

While these obstacles are real, pharma companies need to become more aggressive in adopting digital innovation. Rather than looking at what their peers are doing in digital health, they need to anticipate new challengers in the healthcare industry, including innovative startups and established technology companies who are hungry for new markets.

As we've seen with the recent announcement from Amazon, Berkshire, and JPMorgan, who are forming an independent healthcare company for their US employees, even well-established organizations are partnering with digital disruptors to challenge current industry practices.

KAL PATEL is Senior Vice President of Digital Health, Flex

Here are some steps pharma companies should take to stay ahead of this curve.

Renew commitment to adherence. According to the Centers for Disease Control and Prevention (CDC), one-half of patients cease taking their ongoing medications within a year of being prescribed. As a result, US society loses billions of dollars in hospital bills and other forms of emergency medicine to treat chronic conditions that go unmanaged. Research suggests digital solutions that can improve drug adherence even incrementally represent a huge revenue opportunity. With just a 10% increase in adherence, there is reportedly a $124 billion global pharma revenue opportunity.

While the issue of adherence is not new to pharma companies, there needs to be a different approach to solving it—the current route of creating thousands of standalone mobile apps has not worked for patients nor drug companies. As a group, the top 12 drugmakers have created over 1,000 health apps, yet growth in downloads across these apps has flattened out. One study published in *JMIR mHealth and uHealth* noted that many popular mobile apps don't even capitalize on standard adherence guidelines for encouraging patient compliance.

Adherence solutions work best when they are connected, contextualized, and integrated into a patient's life in a convenient way. For example, a connected inhaler for a patient with asthma can capture and send real-time data regarding the duration of inhalation, amount of inhalation, and location of use, which can inform patients and caregivers on how well the patient is adhering to the assigned treatment regimen and whether it is improving the patient's overall health. With innovations like this, pharma companies can also begin to collect data regarding therapies, patient demographics, adherence, and engagement. This can lead to discoveries such as recognizing patients are overusing their rescue inhalers, which could indicate they may be having acute episodes. How can we better engage patients in a proper adherence protocol to best maintain their health?

Similarly, if a patient receives reminders to take a medication at an inopportune time, this lack of contextualized information may just lead the patient to delete the pharma's app. Companies need to invest in machine learning and advanced analytics to make compelling digital health solutions. Getting a notification to inject your medication while you're in a meeting isn't helpful. An app needs to consider location, timing, and other personalized data that can make simple reminders much more effective.

Broaden the view of ROI. To keep up with the competition, pharma companies must make it a priority to invest in R&D or digital health solutions, in addition to traditional drug research. The current pharma business model of focus-

ing only on new drug development instead of incorporating value-added technology and services is broken. In fact, studies show a steady decline in the productivity and ROI of pharma's R&D investment. This requires a shift in thinking about potential returns that digital health solutions enable in the near term, such as improved adherence and market share, as well as the returns down the road, such as being prepared to operate in a connected world with entirely new business models. The challenge is moving from investing almost all R&D funds up front to a perspective that incorporates the value of software-based services and an approach of continuous improvement.

Partner with digital experts. When it comes to developing life-saving drugs and blockbuster molecules, pharma companies have experience recruiting the best and the brightest. A typical biopharma has thousands of PhDs and MDs, but only a handful of software engineers and data scientists. Building a digital health team from the ground up with a combination of medical and consumer/patient expertise is a significant investment from a headcount and time perspective, not to mention the challenge of reconciling the drastic differences between a fast-paced technology culture and a regulated pharma culture. Instead, look to a partner with a core competency in software development to leverage external expertise, improve patient engagement, and capitalize on better digital insights.

Challenges to be aware of

FDA approval and file management. Approval for new drug solutions and devices can take years. Every day that a drug is not on the market because of development or regulatory delays costs a therapy between $600,000 in lost revenue for niche products to an average of $8 million for blockbuster drugs. As pharma companies move from products that are solely drug-based to product lines that include tech-enabled services, these "beyond the pill" business models carry with them an array of new and challenging regulatory implications. Pharma companies considering the addition of a digital component may rule it out if it may add risk to the launch of their billion-dollar molecule.

FDA approval is required every time a drug formula changes or is otherwise updated, and this is no different for software updates on connected devices. If a therapy is already FDA-approved, but the digital software component is updated, a pharma company needs to update its filing with the FDA; that is, unless there is proper union of the therapy and digital software component that allows independent but complimentary regulatory controls that are sufficient for FDA approval. This can be done by establishing a device master file with FDA for the digital software component. In that scenario, a drugmaker can offload the ongoing file management for the digital component to its technology partner, thereby clearing a significant hurdle.

Potential security and privacy breaches. As more devices become connected, the medical community must ensure the systems handling the medical device and patient data are highly secure to reduce the risk of breaches and protect patient data. While not affecting patient data, just last year, pharma giant Merck & Co. lost more than $135 million in revenue due to a cyberattack that halted drug production. In general, with connected solutions, pharma companies need to be even more vigilant of hacker threats. Personal data, including social security numbers on health records, are frequently sold on the dark web. Drug manufacturers should ensure that security and privacy technical controls, processes, and experts are part of any new system they evaluate.

While the landscape won't change overnight, patients will demand connected, seamless healthcare experiences

Stage set

While the landscape won't change overnight, patients will demand connected, seamless healthcare experiences, and there is a real economic opportunity for companies prepared to bridge the healthcare system/patient divide. Access to information and digital solutions facilitate a more proactive doctor-patient relationship and better health outcomes. To serve the modern patient and secure future revenue streams, major pharma companies need to embrace more meaningful investments in digital health as soon as possible. PE

innovative treatments

Of the estimated 425 million people with diabetes...[1]

about 50% are diagnosed...[1]

of whom about 50% receive care...[2]

of whom about 50% achieve treatment targets...[2]

of whom about 50% achieve desired outcomes, meaning that only around 6% of people with diabetes live a life free from diabetes-related complications.[2]

To break the 'Rule of Halves' we need to drive change where the needs are greatest

The 'Rule of Halves' illustrates the global diabetes situation. Actual rates of diagnosis, treatment, targets and outcomes vary in different countries.[2]

DIABETES IS A GLOBAL HEALTH CHALLENGE

Diabetes is one of today's biggest global health challenges. The number of people with diabetes is growing at an alarming rate and healthcare systems are struggling to match resources with increasing needs. Many people with diabetes are undiagnosed or do not receive adequate care. Even when treated, many do not achieve their treatment targets and risk developing serious health complications.

MEDICINE IS OUR KEY CONTRIBUTION

Since the company was founded in Denmark more than 90 years ago, we have been changing diabetes. Our key contribution is to discover, develop and manufacture better biological medicines and make them accessible to patients throughout the world. Novo Nordisk supplies nearly half the insulin used worldwide and our global presence ensures access to treatment for the 28 million people who depend on it.

IT TAKES MORE THAN MEDICINE TO DEFEAT DIABETES

Producing life-saving medicines is a significant responsibility. However, to defeat diabetes we need to do more. With our Changing Diabetes® commitment we address the biggest unmet needs for people with diabetes. We work for a future where fewer people develop diabetes, everyone with diabetes is diagnosed earlier, everyone diagnosed receives adequate care, and everyone receiving care is able to live a life with as few limitations as possible. Globally, two-thirds of people with diabetes live in urban areas which make cities an important focal point for tackling diabetes.

WORKING TOGETHER FOR A BETTER FUTURE

Success is not something we can achieve on our own. By partnering with patients, policymakers, healthcare professionals and non-governmental organisations we are building capacity for better diabetes care and advocating for people with diabetes. We will continue to take the lead and drive change where it is needed the most with an unfailing belief that it can be done.

PI/CORP/1217/0014

changing diabetes®

1. International Diabetes Federation. *IDF Diabetes Atlas*. 8th edn. Brussels, Belgium: International Diabetes Federation. 2017.
2. Hart JT. Rule of Halves: implications of increasing diagnosis and reducing dropout for future workload and prescribing costs in primary care. *Br J Gen Pract* 1992; 42(356):116-119.

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POLAND

SOLID FOUNDATIONS, GRAND AMBITIONS

The story of Poland is the story of an underdog; savagely battered during WWII by German and Soviet forces, cut off from western markets until the fall of the Iron Curtain in the early 90s, the country has always been forced to get up off the canvas and fight back to prove itself. However, it is difficult to imagine the nation's challenging past, while passing through the European metropolis of Warsaw, the bustling streets of Krakow or the elegant old town of Wrocław.

In fact, the country's economic success has been such that, according to the Central Statistical Office of Poland (GUS), Poland's GDP growth rate reached 4.6 percent in 2017, with this reflected in the Polish pharmaceutical market, which equally experienced substantial growth of 4.2 percent in 2017. This is backed by Poland's 38-million strong population, one of the largest in Europe. Additionally, "the country's favorable location in the center of Europe, where the main communication routes intersect, makes it possible to export goods to all European countries and thus reach over 500 million consumers. Poland's major trade partners are, among others, the power-economies of Germany, Russia, China, France, and the UK," details the Polish Investment and Trade Agency.

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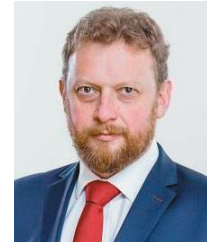
Contrary to the positive trajectory of Poland's energetic economy and pharmaceutical sector, the nation's public healthcare expenditure is still one of the lowest in Europe, projected to languish at a lowly 4.78 percent of GDP by the end of 2018, well below the European average which hovers around 6.8 percent. Recent 2017 hunger strikes by young Polish doctors to increase clinician wages drew worldwide attention, triggering the government to implement long-term plans to increase public healthcare spending to six percent of GDP by 2025. This has been reinforced by renowned cardiologist and recently appointed minister of health, Łukasz Szumowski, who is open to the idea of accelerating progress to reach the mark by 2024, though he also believes that, "there will be no revolution in the health system, though there are most definitely areas that are ripe for improvement."

Marcin Czech, undersecretary of state, ministry of health

This evolutionary approach is being spearheaded by Poland's new drug policy, which "will be completed between 2018 and 2022," explains Marcin Czech, deputy minister of health and undersecretary of state at the Polish Ministry of Health (MoH). "This medicines policy will follow the global methodology of the World Health Organization (WHO) and will be constructed with all the key stakeholders in the public sector…aiming to portray a bird's-eye perspective of decision making for drug policy by taking into consideration both a medical and economic aspect."

ENLIGHTENED ACCESS

This open approach to the idea of pharmaco-economics and evidence-based decision making is not a completely foreign concept, with Poland belonging "to the group of countries that utilizes the cost-effective threshold, which is a solution to ensure healthcare spending of public funds is conducted in the most effective manner possible," according to Iga Lipska, director of the Drug Policy and Pharmacy Department at the MoH. This pharmaco-economic perspective has been implemented for years by the nation's Health Technology Assessment Agency (AOTMiT), which passes on recommendations to the MoH, which then determines market access conditions though, as Lipska indicates, "this HTA competence must now be transferred to the MoH, especially the economic commission for drug policy. This will ensure that price is not the determining factor for reimbursement decisions, and that more factors are assessed, such as the strengths and weaknesses of specific treatments, the target population and if the healthcare system is ready for its introduction."



Łukasz Szumowski, minister of health

The government's strides forward in evidence-based decision making are welcome news for the innovative sector, which is keen to witness "a more holistic approach…where price is not the crucial decisive factor, with health outcomes and indirect costs always being considered," affirms Bogna Cichowska-Duma, general director at the Employers' Association of the Innovative Pharmaceutical Companies (INFARMA). She continues, "through cooperation with the MoH, we have managed to develop non-discriminative solutions with respect to reimbursement budget controls (e.g. payback) and to introduce modern reimbursement tools, such as risk sharing schemes (RSS) and emergency access."

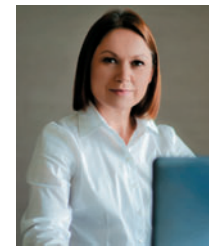
These new methods to improve the market access of innovative treatments have clearly paid dividends and, "in fact, if you look at the last two years, there have been more products reimbursed than the five years prior to 2015," points out country president of AstraZeneca Poland, Jarek Oleszczuk. This strong foundation for the future is equally supported by Dorota Hryniewiecka-Firlej, president of Pfizer Poland and INFARMA, as the Polish pharmaceutical industry is, "not limiting creativity, and is harnessing tools such as risk sharing agreements to adapt to the external environment and reimbursement regulations. In fact, in the last two years there has been a huge openness from the MoH to discussing solutions with the entire Polish pharmaceutical industry, so in the end innovation can obtain market access easier and faster."

TOP 15 PHARMA COMPANIES IN POLAND (2017)

SALES IN PHARMACIES AND HOSPITALS

1	POLPHARMA
2	TEVA
3	BAYER
4	SANOFI
5	ADAMED
6	AFLOFARM
7	SANDOZ
8	SERVIER
9	VALEANT
10	KRKA
11	GSK CONSUMER HEALTHCARE
12	USP ZDROWIE
13	GSK PHARMA
14	BERLIN-CHEMIE/MENARINI
15	MYLAN

Source: IQVIA



Bogna Cichowska-Duma, general director, INFARMA; Dorota Hryniewiecka-Firlej, president, Pfizer; Krzysztof Łokaj, general manager, Chiesi

Deputy Minister of Health Marcin Czech envisions that these aforementioned "risk sharing agreements will be deployed to finance the market entry of innovative drugs, rather than the current model that pushes the generated funds into the general healthcare budget." This, according to Czech, has the ability of creating a more sustainable healthcare system and forcing a change in legislation, so the budget allocated to pharmaceutical spending will be capped at "between 16.5 and 17 percent, rather than a rate up to 17 percent." Nevertheless, Hryniewiecka-Firlej underlines the key, overriding notion that "it is about incremental steps, being more of an evolution than a revolution."

A huge part of this pharmaco-economic push is the utilization of "real-world evidence of how the product is being

Ramping up the Gears

Denis Vujičić, managing director, MSD

MSD stands as one of the world's most significant pharmaceutical innovators, with the company's undeniable global innovative footprint summed up by the slogan: 'Inventing for Life'. Because of this context, the innovative wave currently sweeping across Poland has the potential to catapult MSD's Polish affiliate forward. Indeed, MSD Poland has recently seen the successful market introductions of key melanoma and HCV treatments. Denis Vujičić, managing director of MSD Poland, acknowledges that, "Poland is a market in a constant positive evolution. The ease of doing business is also getting better, and the acceptance of our innovation goes hand-in-hand with the company's push to invest in Poland."

These recent successes lead Vujičić to believe that the market introduction of Keytruda®, a highly impressive first-line treatment for lung cancer accessible in many European markets, will be available to Polish patients in the near future. "However, there is potential for faster growth with other treatments gaining market access, such as in our diabetes portfolio," he notes. This positive business environment and willingness to embrace innovation has triggered the company to invest further into their Polish operations, employing "currently 570 staff with around 350 people working in R&D. Around 260 of them are employed in one of the company's four global data management centers based in Warsaw, which is composed of two different branches – clinical trials support and pharmacovigilance," affirms Vujičić, "An additional staff of around 90 people are part of our Global Clinical Trials Operations (GCTO)," he continues.

This huge investment clearly shows the significant strategic importance of MSD Poland to the company's global R&D ambitions. This importance is furthered, claims Vujičić, by roughly "60 clinical trials ongoing in Poland. Most importantly, the research facilities we work with are world-class and obviously meet the required FDA and EMA standards. The country's fantastic pool of researchers has allowed us to constantly grow our GCTO team," he concludes.

utilized and what kind of effect and outcomes it is subsequently generating in the Polish healthcare ecosystem," expresses Maciej Kuźmierkiewicz, general manager of IQVIA (formerly QuintilesIMS) Poland and the Baltics. This allows companies "to see this financial impact of the product for the entire length of the therapy, not just the initial costs. The full calculation will also include indirect factors such as the time the patient is out work, the length of stay in hospital, and the effect and cost of therapy 'x' compared with therapy 'y'. Our data gives our clients a great opportunity to make such comparisons; and thus, allows them to take real-world evidence to key stakeholders and have a meaningful dialogue around market access and outcomes."

PRICING: TROUBLE BREWING

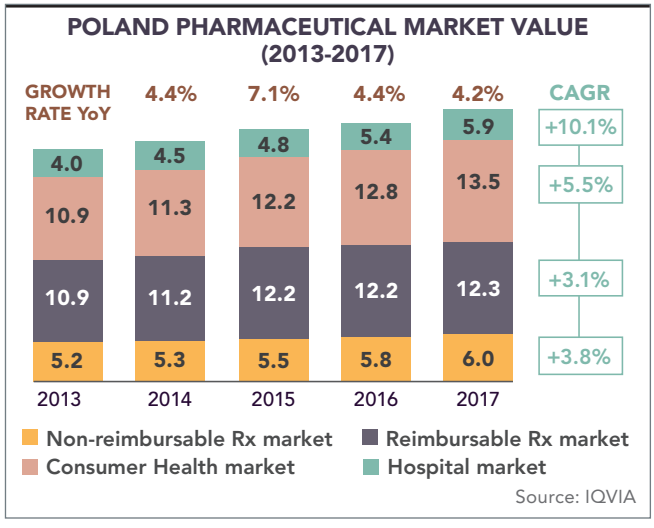
Despite the steps made along this positive path towards a sustainable healthcare model in the future, Krzysztof Łokaj, country manager for Chiesi Poland, argues that still "Poland is a low-price country for pharmaceuticals; therefore, during the negotiation process, there are often disagreements between companies and the MoH over pricing expectations." Nevertheless, the market has given him excitement, especially with the potential to introduce the company's flagship innovation "Trimbow®: a three-in-one treatment for chronic obstructive pulmonary disease (COPD)… this will make us the market leader in respiratory, a first for the company." Furthermore, Łokaj is looking to increase the Italian player's footprint through a "local acquisition, which will take

place over the coming years and can bring significant growth to both sales and the overall organization."

These somewhat mixed feelings towards the market situation are also felt by innovative French ophthalmology specialist, Thea, with Stefan Jaworski-Martycz, country manager Poland and CEE cluster lead believing that "the prices being proposed by the MoH are far too low for Thea Poland to remain sustainable; therefore, we made the decision to not launch some of our new products in Poland." However, Jaworski-Martycz, does offer his opinion on a possible solution to resolve this pricing situation. "Products of the same molecule, but preservative-free, generate higher R&D and production costs… Despite this, treatments are grouped together and priced at the same level. The Polish reimbursement policy should have better differentiation within therapeutic pricing baskets, as currently they are far too broad," he proffers.

Stefan Jaworski, country manager, Thea

This perspective is echoed by eyecare competitor, Santen. Krzysztof Kołodziejski, the company's country manager, laments that, "there needs to be a greater openness to increase the market penetration of innovative products in eye care as many are not on the reimbursement list. Therefore, Poles must pay for these products out of pocket, and generally this is out of the price range for the average person." Despite this, Jaworski-Martycz is hopeful for the future as although "ophthalmology is not a priority for the MoH," he urges the key decision makers to "sit down and discuss the benefits of innovative eye care products for Polish patients…this is not purely based around



Maciej Kuźmierkiewicz, general manager, IQVIA Poland and Baltics

Jacek Glinka, president Europe, Mylan

fair pricing, but the benefits healthy eyes will bring to Poland and this will allow the MoH to reach its core objective of a healthier nation."

AN INVESTMENT MAGNET

Large multinationals establishing extensive Polish footprints is a trend that has been ongoing since "after the fall of communism in the early 90s when many state enterprises were facing bankruptcy and were bought by large foreign players," highlights Monika Constant, director-general of the French-Polish Chamber of Commerce. "The second wave came around 2004 with the influx of smaller business, and the final wave has come recently, with the reinvestments of profits by blue chip companies, a practice equally being conducted by the pharmaceutical industry." This has seen global powerhouse organizations such as Sanofi, Takeda, Teva, Servier and Sandoz position large manufacturing sites in Poland. In the meantime, the nation's recent trademark has been attracting global shared service centers (SSCs), from healthcare multinationals such as Lundbeck, Coloplast, AbbVie and Becton Dickinson, capitalizing on the nation's reputation for delivering low-cost, high quality services within the European Union.

Nevertheless, the perception of Poland as a low-cost alternative to Western Europe is slowly becoming a myth, and the country is stepping up its game, attracting international powerhouses to set up advanced operations, such as global R&D activities. AstraZeneca has positioned its global clinical trials center in the heart of Warsaw, housing roughly 1150 staff. "70 percent of AstraZeneca's global late-stage clinical trials are conducted in Poland, clearly the largest of the company's three global R&D centers," underlines Country Manager Jarek Oleszczuk. These investments have truly cemented Poland as the "second largest country globally for AstraZeneca in regard to patient numbers and the overall leader in Poland," continues Oleszczuk. Furthermore, the company has positioned one of its three global financial centers in Warsaw, conducting activities for 37 countries in Europe, the Middle East and Africa (EMEA)

Countering the Scourge of Diabetes

Drago Vuina, corporate vice president, business area Europe East, Novo Nordisk

According to the Institute of Cardiology in Warsaw, 2.2 to 2.5 million Poles will be affected by diabetes by 2030. These startling numbers go hand in hand with the global trend that projects the number of diabetics to rise from 171 million in 2000 to 366 million in 2030, according to the WHO.

Drago Vuina, corporate vice president of Novo Nordisk Eastern Europe, the global leader in the fight against diabetes, understands the condition all too well and wishes that regional governments applied pharmaco-economics more effectively, especially as "short-term investments will lead to long-term savings and this is especially true regarding diabetes, a chronic and progressive disease. In fact, studies conducted on the life-cycle cost of diabetes in the region show that on average, the initial cost of treatment represents seven to 13 percent of the overall diabetes treatment, while the cost of complications represents the remaining share. We tend to discuss only about this seven to 13 percent, while much bigger savings can be achieved if we treat our patients in the best possible way so they prevent or delay long term complications of diabetes."

This regional view is equally felt by Wolfgang Wagner, regional director of EU and Central Eastern Europe at Wörwag. "It is important to see the situation of diabetics, as the probability of developing diabetic neuropathy in their lifetime is in around 60 percent of patients," he posits. "If they are not treated correctly, their circumstances can go south very quickly and lead to complications such as amputations, an economic issue for overall society. Our job now is to provide pharmaco-economic data on the Polish market to the key Polish stakeholders, and in turn this will help in obtaining greater market access for our high-quality treatments."

Dr. Wolfgang Wagner, regional director, EU and CEE, Wörwag Pharma

The need to integrate with key stakeholders and give a greater voice to diabetic patients is a concept that Novo Nordisk's Vuina understands well, especially considering that "Novo Nordisk employees are not only financially and economically responsible, but also accountable for the local society in which we operate." Actions speak louder than words, and three years ago Vuina and his management team contributed to the rebuilding process after heavy flooding in the Balkans. This social responsibility is evident in the much talked about 'Novo Nordisk Way', with Vuina proclaiming that "it is not a value we claim for promotion - we truly live it. I believe this is a distinguishing factor for Novo Nordisk as; above all, we are a genuine part of the society and want to actively participate toward improving health. It is not only about offering treatment solutions, but equally collaborating with all key stakeholders and engaging with the community. This is what makes me very proud to work for Novo Nordisk and drives my personal mission of helping people live a better life."

as well as one of five global HR offices. As Oleszczuk proudly puts it, "Poland is becoming an important global hub for AstraZeneca."

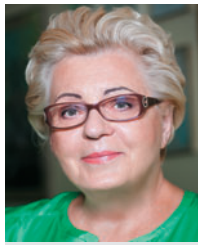
Poland as a centerpiece of activity is equally fundamental to Servier's regional operations, and the nation is "a top-ten market for the company globally in terms of turnover," highlights Joanna Drewla, general manager for Poland. Additionally, the company has positioned its International Center for Clinical Research in Warsaw, which is "a focal point for clinical studies for Slovakia, Czech Republic, Ukraine, Hungary, Bulgaria and Romania with the potential to expand in the future," notes Drewla.

Zdzisław Sabiłło, former president of the management board, PZPPF; Colm Murphy, plant manager, Servier; Joanna Drewla, general manager, Servier; Jacek Mazurkiewicz, general manager, AbbVie

Servier's Polish footprint does not stop there, with Warsaw being home to one of the French company's three main European manufacturing plants and, "since 1997, we have invested over USD 44 million into the Polish production site," ecstatically proclaims Colm Murphy, general plant manager at Anpharm, the Polish Servier production facility. In fact, the facility is projected to export nearly 50 percent of treatments in the future, with a major focus being CDMO operations, especially in the analysis sector within the newly upgraded Quality Control Laboratory. Murphy understands that due to the nation's growing economy, they will not be able to "compete with rock-bottom manufacturing prices," though understands that "Poland fits into the niche of great value" with the nation establishing "a higher-quality product with excellent reliability in terms of service, at a competitive price."

The American biopharmaceutical giant, AbbVie, has also been drawn to Poland and, in mid-2015, achieved "reimbursement of the first non-interferon treatment for HCV in Poland. We estimate that around 10,000 patients have been cured from the disease thanks to this therapy," highlights country manager Jacek Mazurkiewicz. The positivity of the market has had a knock-on effect on other branches of the affiliate, and the Warsaw office now has a "rapidly expanding clinical trials department and in Poland we currently conduct over 40 trials in immunology, oncology, infectious diseases and general medicine. This is a significant increase over last year and is also reflecting on the ongoing increase of staff." This, along with the establishment of one of the company's three global SSCs in Kraków that takes care of financial and accounting operations, shows the great potential of Poland for AbbVie.

However, what really stands out is in terms of AbbVie's Polish operations is its impact in the world of IT, a sector in which Poland has established a recognized global brand. In 2016, Mazurkiewicz met with the CEO of Heart Warsaw and together they "noticed that start-ups from the fast developing healthtech area were not being represented equally. We discussed the potential to grow this area and AbbVie Poland has since helped promote start-ups in this field. We see significant potential here, with digital solutions now starting to redefine diagnosis and care. This cooperation with Heart Warsaw allows us to capitalize on the nation's direct expertise," claims Mazurkiewicz.



Irena Rej, president, Farmacja Polska

Michał Pietraszek, general manager, Apotex

LOWEST-PRICE WINS!

Despite the Polish pharmaceutical industry experiencing an encouraging promotion of innovative therapies, the domestic market is still dominated by generics, encompassing, according to IQVIA data, roughly 77.7 percent of the market share in terms of sales volume and 65.9 percent in sales value. This high generic saturation is not uncommon within the region and, "if you analyze European healthcare markets, 60 to 80 percent of therapies are generics," punctuates Jacek Glinka, president of Mylan Europe. Zdzisław Sabiłło, former president of the Polish pharmaceutical industry employers association (PZPPF) bolsters this viewpoint as, "it is obvious that generics companies are providing a large quantity of affordable products that allow Poland to construct a more sustainable healthcare model." This generics model is based on "a limit price system, in which pricing is based on the cheapest generic within a large limit group," continues Sabiłło.

The issue with this 'lowest-price wins' business model, according to Glinka, is that this system is being created in "a non-sustainable manner," going on to say that, "Europe should take a more holistic view of the importance of the generics sector. If generic volumes in Europe were replaced by innovative products, it would cost Europe USD 122 billion annually.... governments must start looking at the generics industry as the saviors that can help them achieve their healthcare goals." Glinka holds the belief that "the generics ecosystem is becoming more competitive than ever before, despite European governments being exclusively focused on cost containment measures towards generics, rather than innovative therapies." The drastically lowered generics prices have the potential to "force organizations to pull out of the country, that in the end results in the patients losing out," cautions Glinka.

This dire industry viewpoint is not shared by Marcin Czech, deputy minister of health and undersecretary of state at the MoH who does "not see a risk.

The Polish generics market has such strong competition and so many players." His concerns are more centered "around the functioning of the jumbo groups and reference pricing – although – if you have a reference system that rewards reduced prices, it allows more and more generic companies to enter the market; therefore, we are happy with the current model…We are always monitoring products to see when they reach patent cliffs, so we can reduce prices through generics and biosimilars, ensuring on the other end the introduction of innovative medicines."

Nevertheless, these pricing pressures on the Polish market were initially felt over five years ago, with the implementation of the 2012 Reimbursement Act and, "the following year the market dropped nearly 40 percent in value. At this time, the Polish authorities placed tremendous pricing pressures on the market, attempting to lower our prices in some cases by up to 70 percent," insightfully expresses Michał Pietraszek, general manager of Apotex Poland. This tough pricing model forced companies to rethink their strategy and "no longer focus in high volume and older treatments as the price erosion in Poland is immense," notes Pietraszek.

Pietraszek's market tactics for Apotex Poland were to focus on "staying within the niche areas as it allows us to provide to the market innovative generics at a comfortable price point." Furthermore, Apotex, like many generics players, is taking advantage of the nation's incredibly strong over the counter (OTC) and dietary supplement markets, that in 2017 combined for a mouth-watering sales total of USD 2.36 billion according to

IQVIA. Many leading experts expect this to rise in parallel with an increase in Polish people's disposable income, as well as because of "the fact that there are long waiting times to visit doctors and specialists. Therefore, the practical mindset of the Polish population has them going to the pharmacy to purchase their medicines and save time," continues Pietraszek. "These areas are less regulated and allow us to split the risk across the board or our operations. This has given us substantial growth and now makes up 25 percent of our total revenues," he concludes.

ANTAR: Introducing Patient-Centricity into Orthopedics

Andrzej Tarnskowski, owner, Antar

The Polish market offers great opportunities, though Andrzej Tarnkowski, founder and owner of local orthopedic success story, Antar, has eyes on the international landscape as he looks to build on the company's impressive growth.

What is the international strategy for the company?

Our main recent success has been the company's international expansion, which currently represents 40 percent of our total turnover. We have our own affiliates in the Czech Republic, Slovakia, Belarus, and as of 2012, Germany. Furthermore, we operate through distributors across the globe, in nations such as India, Saudi Arabia, Croatia, Latvia, Lithuania, Romania and Bulgaria. Looking ahead, the next countries we are looking to set up affiliates in are India and the US.

What innovation does Antar bring to the market?

In orthotics, we create products that are light and breathable, and we especially avoid using neoprene as a material for our products as this can cause patients to sweat heavily. For orthopedic pillows, we utilize memory foam, a modern but commonly used technology, and concentrate on their unique shape, working closely with physicians in the design process. Lastly, for walkers and rollators we make them as light as possible, as many competitors use heavy materials. Throughout the development process we are constantly in dialogue with the relevant medical personnel and we have a highly-qualified staff with a medical background.

Where do you see the trends of orthopedic devices going in the future and how will Antar adjust accordingly?

The ageing population will be one key factor in growing the market size, but equally people are looking not just for medically accurate devices, but ones that also provide excellent comfort. In this regard, Antar will constantly be looking for ways to meet this comfort need, by utilizing innovative materials and making comfort a cornerstone of our design decisions.

Jarosław Król, president of state-owned player, Polfa Tarchomin has a different approach to the low-priced Polish market, believing many generics "companies are fighting and scraping to generate market share, and many are failing and eventually become bankrupt." He notices that, "the supplier market in the pharmaceutical world is less saturated and has the power in terms of pricing, especially in regard to active pharmaceutical ingredients (APIs)." In this regard, Król's plan of attack is to manufacture and sell APIs and the company has a brand-new facility for this process." He adds that "this strategy will allow us to better navigate the market as a certified western world API supplier, which will in turn allow us to be more profitable." This effort is improved by the company's strong ties with local universities, such as the University of Warsaw, as well as Król's previous career in the banking sector; giving him the astute economic background required under the challenging financial pressures of the Polish generics industry.

THE BRAVE NEW WORLD OF BIOSIMILARS

One pathway out of the world of pure generics is to move into the world of biologic equivalents: biosimilars. In fact, "over the next three to five years, the market in general will experience top performing original products coming off-patent – a great

Jarosław król, president of the board, Polfa Tarchomin; Markus Sieger, CEO, Polpharma; Artur Chabowski, CEO, Mabion

opportunity for biosimilar players and healthcare systems," iterates Jacek Glinka, president of Mylan Europe. Additionally, during this period "based on Medicines for Europe data, there is the potential for Europe to save 61 billion USD annually due to biosimilar launches," he notes.

Now Poland wants in on this area of innovation. Irena Rej, president of the Polish Pharmaceutical Chamber, Farmacja Polska, points out that, "the Ministry of Economic Development and MoH is working closely together to stimulate biologic innovation by supporting biotechnology entities. Polish companies, such as Adamed and Polpharma, are attempting to invest into R&D within this advanced area."

Polpharma is the clear pharmaceutical champion in Poland, having a seven percent share of the overall pharmaceutical market and strong international ties across the region, especially in Russia and Kazakhstan. Seven years ago, the owner, renowned Polish entrepreneur, Jerzy Starak "invested heavily into biosimilars. It was a period of no acceptance for the biologic generics and no reimbursement in this area. He made the brave decision to create a biologic centre in Gdansk and hired top specialists from around Europe. Now, the Gdansk biotechnology site is a Polish R&D hub and houses a fully GMP-certified pilot production plant," affirms CEO of the Polpharma Group, Markus Sieger.

On top of that, Polpharma in 2016 "acquired a Dutch company, Bioceros, that does cell development, the basis of any biologic drug. Furthermore, we are constructing a state-of-the-art biotechnology production plant just nearby Warsaw," continues Sieger. "This means that we have a vertically integrated business model for biosimilars from cell line to the finished product, with the ability to globally commercialise the product ourselves or through partnerships." This R&D approach has the company thinking big, and despite looking to consolidate their Polish footprint, "the real objective of ours is to grow our US presence as this market has incredible potential."

Despite this aggressive mindset by the nation's leading pharmaceutical player, it is another local company, Mabion, that has already put Poland on the international biosimilar map. Their treatment, MabionCD20®, an equivalent for Roche's Rituxan®, has incredible potential with the market for this product being "eight billion USD; four billion USD in the US, two billion USD in Europe and two billion USD in other markets," details Artur Chabowski, president of Mabion. "In April, we will file an application with the EMA and hope to launch MabionCD20 by the end of 2018," he proffers. This has allowed the company to set up a historic partnership with Mylan for distribution in the EU and Baltics and has opened up global doors, with Mabion "finalizing agreements across the globe, such as Australia, New Zealand, Canada, Africa, Asia and South America. It is like a jigsaw puzzle, as some agreements cover more than one country…concerning the USA, we have sent documents to the FDA and will be discussing with them shortly the potential for MabionCD20 to be positioned there."

THE 'SELVITA' EFFECT

The nation's move to become a larger cog in the global innovation chain has been a key strategy of the government strategy, headlined by the much talked about 'Morawiecki Plan':

Witold Włodarczyk, general director, POLMED; Marzena Kulis, managing director CEE, J&J medical devices; Paweł Przewięźlikowski, CEO, Selvita

the government's responsible development plan appropriately named after its creator, current prime minster, Mateusz Morawiecki. This developmental strategy has been dually hammered home by Jadwiga Emilewicz, the minster of entrepreneurship and technology, who acknowledges that "if the pharmaceutical industry is second only to the defense industry, which spends the most on R&D, we would be imprudent if we did not want to develop it if the Polish economy is to become less imitative and more innovative in a short time."

A pure example of this innovation is Selvita, a Polish success and the largest biotechnology company between Germany and India. Thus far they have already "established a partnership with Berlin-Chemie a member of Italian Menarini Group for SEL24, the first ever partnership deal for an innovative Polish molecule," proudly explains CEO Paweł Przewięźlikowski. The next step for the Krakow-based innovator is to complete development of "SEL120, the first-ever CDK8 treatment that targets cancer stem cells and RNA transcription; a completely different mechanism to any molecule ever discovered."

SPILLOVER INTO MEDTECH

The overall increase in Polish healthcare expenditure does not only impact the pharmaceutical industry but facilitates a domino effect on the medical technology industry. "The value of products sold by the Polish medical device market is roughly USD three billion; inclusive of both sales in Poland and exports," expresses Witold Włodarczyk, director general of the Polish Chamber of Medical Devices, POLMED. Witold is excited for the future due to the proposed increase in healthcare expenditure, Poland's ageing population, the drastic increase in people's literacy towards medical devices, and as Poles "now understand what they can have reimbursed and are enquiring constantly with the National Health Fund (NFZ)… in the end, this will result in an increase in sales."

A vital step to improving medical device health literacy is education, an activity that medical device companies are taking to a whole new level. Johnson & Johnson (J&J) Medical's managing director of Central Eastern Europe, Marzena Kulis, understands this is crucial as "Poland needs to understand that bringing a cost-effective solution is not necessarily the cheapest option; there is more to this concept than just the individual price per product unit…this pharmaco-economic approach is not only in the long-term, as cost efficiency can easily be solved by introducing a quicker treatment for a health condition." To demonstrate this effect, Kulis explains that J&J Medical takes a "holistic, full 360-degree picture approach and gives the medical community an opportunity to completely revolutionize and develop care within their therapeutic area." This revolves around "changing the entire paradigm of a certain disease's care by offering programs that cut across the entire specialty, in sectors such as spinal treatment, orthopedics and surgery."

This increased focus on a holistic approach to treatment is shared by Lukasz Korybalski, regional manager of Becton Dickinson who cites the two overriding factors in the market as pricing and healthcare spending. "Both these aspects are interconnected," he notes. "When we approach the medical community with a single product, price is looked upon first. Though if we come to the market with a complete solution to therapeutic areas, such as in oncology and cardio-surgery, it is a completely different story. Our customers, be it the government or hospitals, see the value in spending more funds in one sector, to save in another. The challenge is making these key partners understand our economic models and accept the challenge in helping design a treatment solution that takes in a holistic approach, so patients can benefit in the end."

Continued from Page 31

ing China hundreds of millions in medical insurance funds.

Consistency assessment

A consistency assessment for generic drugs was initiated in 2017. According to CFDA, 17 drugs passed the consistency assessment in the first round. This effort has continued in 2018. A total of 289 products from more than 1,800 manufacturers are slated to complete their assessment this year. Currently, the market price for consistency assessment of a single-species drug ranges from $720,000 to $1.44 million. The high costs have intimidated a slew of small to medium-sized pharma companies. Additionally, the long application process time—one to two years per drug—has further decreased their enthusiasm. Thus, consistency assessment will serve as a complete clean-up of the chaotic generic drug market. Low-quality and inferior products will gradually withdraw, whereas the top performers will further expand their market reach.

Two-vote system

The two-vote system refers to the procedure where a pharma company opens one invoice to distribution companies and another invoice to medical institutes. The arrival of the two-vote system is impacting the traditional marketing model, but, at the same time, it is also increasing the transparency of the drug distribution industry.

The adjustment of marketing models. Currently, two strategies are dominating the Chinese pharma market: low-open and high-open. The former refers to drugmakers selling products to distributors with a low manufacturing price, and then going through layers of subcontracting, eventually reaching the medical institutes. The latter refers to raising the manufacturing price and circulating medicines through exclusive distributors. After the implementation of the two-vote system, all pharma companies are expected to gradually shift to the high-open approach. At the same time, their existing channels will also be compressed, from the original multi-level commercial channel to a single-level channel.

The adjustment of the medicine distribution industry. The most obvious and direct impact of the two-vote system is on the drug distribution sector, in reducing the layers of medicine circulation. Non-standard distributors will be eliminated from the market, raising the entire industry concentration as a result. Down the line, companies with upstream resources, and downstream hospital sales will have a leg-up in the competition.

Internationalization

Joining ICH

On June 1, 2017, CFDA became an official member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). In the short term, the move means China must raise its standards in all aspects of pharma regulation. This will present obstacles to a large number of local pharma companies. However, in the long run, China should benefit. Joining ICH gives the country the opportunity to catch the high-speed new drug development wave in Europe and the US. It is also good news for overseas pharma companies. In the wake of the optimized review progress and international multi-center clinical trials, the listing process and the time to bring products into the Chinese market will be dramatically reduced, saving more costs in the future.

Overseas investments

During the past year, a slew of Chinese pharma companies and investment firms have engaged in mergers and acquisitions abroad, breaking highest-investment-capital records. According to reports, 17 M&As were initiated by Chinese pharma companies last year, of which seven deals exceeded the $500 million mark. In May 2017, private equity firm Pagoda Investment struck an agreement with Queensland and Goldman Sachs to acquire Icon Group, Australia's largest private cancer and oncology services group. Three months later, Fosun Pharma pulled the trigger on a deal to acquire 74% of shares of Indian company GlandPharma for $1.09 billion. Shangdong Weigao beefed up its pipeline with the $850 million buyout of US medical device company Argon. And Sanpower Group acquired Dendreon, Valeant's US biopharma unit, for $819 million.

With the rapid evolution of the Chinese pharma industry and the transformation of its domestic companies, overseas integration has resonated positively across the industry. From a technical perspective, local Chinese pharma companies are still lagging behind the development of European and US pharma giants. It will be difficult for Chinese firms to catch up if they rely solely on their own R&D capabilities. International acquisition helps Chinese pharmas bring back high-quality medical resources and business models from abroad, speeding up their domestic dealmaking, as well as their penetration into international markets. PE

JIN ZHANG is Project and Account Manager at LakePharma, and Editor at The Pharmaceutical Consultant

A Watchful Eye on AI

Looking at the balance of optimism and caution discussed at eyeforpharma Barcelona around pharma's embrace of AI

It's harder to return from an event like eyeforpharma's annual Barcelona conference these days with just one or two key takeaways, as its content streams continue to expand and diversify. This year the range of conference sessions milked the catch-all theme, "Where Pharma Becomes the Solution." But each year a handful of topics inevitably stand out, and 2018 saw artificial intelligence (AI) gain particular attention, as the technology's long-promised "revolution" makes further, tangible inroads into the daily business of pharma and healthcare.

Björn Van Loy, Trilations' global head of advanced analytics, discussing patient use of tools such as Siri and wearables, highlighted that the "boundary of privacy" is finally shifting, with "people becoming more comfortable with AI." Google's Ryan Olohan, managing director, healthcare, showed how mobile activity is continuing to power the increasing sovereignty of AI on the healthcare information stage—mobile devices accounted for 57% of the 160 billion healthcare searches on Google last year. (And if you're interested, Monday was the most common day for searches on depression, he pointed out.) Elena Bonfiglioli, Microsoft's managing director, health and life sciences, EMEA, noted that 30% of interactions with machines today are voice-activated; with that number set to rapidly increase, she underlined how the implications, for patient recruitment and patient activation "with the highest levels of compliance, transparency, and control," for example, are significant. Within the conference's stream of AI facts and insights, Van Loy's question, "Is pharma ready to tap into the well?" seemed rhetorical.

Bonfiglioli pointed to analysis from Rock Health that shows a record $3.5 billion was invested in 188 digital health companies in the first half of 2017. What was once "a very reactive ecosystem" is changing to one that sees "digital health as a new world," she said. And Ben Greenberg, Medscape's vice president of product and user experience, confirmed that AI "isn't just a buzzword, it is going to totally change the planet."

But Greenberg also warned of the gold-rush mentality that is pushing many pharma and healthcare companies into enthusiastic programs of AI technology development before they have fully understood why they are building such products or designing such software. He offered some sobering results of a recent Medscape survey of over 1,500 physicians across the US, Europe, and Latin America, which revealed that there is still an overwhelming resistance, for example, to using voice-controlled smart speakers for professional purposes because "the value isn't there yet." Greenberg explained, "There is not yet a true, voiced-powered clinical decision support tool for physicians," and noted that Amazon's Alexa platform "is yet to really see its killer app." Companies engaged in developing such tools need to understand users' "need states," he said. "If your company is building an Alexa skill just so you can tell your bosses that you are innovating, or because you are checking a box, then don't think you are going to get real scale and meaning from it."

While AI isn't just a buzzword, the problem of "falling down the rabbit hole of buzzword-driven development" will see companies fail to achieve the results they expect. "Building a skill and having it sit in the Alexa store" is a waste of time, money, and resources, Greenberg warned, and will result, again, in the diminishing returns experienced by companies who rushed to develop mobile apps just a few years ago.

Even Bonfiglioli, representing Microsoft, a company that has "supported about 170,000 health organizations with technology solutions," sided with Greenberg's resistance to technology for technology's sake. "It is not about buying the latest device, the latest solution, the latest shiny object," she said. The success of AI in pharma is about buying into "a new mindset, a new culture, new organizational processes, a new sense of trust, and a new ecosystem of solutions and of data." Only in understanding and helping to develop this new "social-digital fabric" will the industry—along with patients, HCPs, and payers—properly benefit from revolutionary technology and truly move beyond the pill. PE

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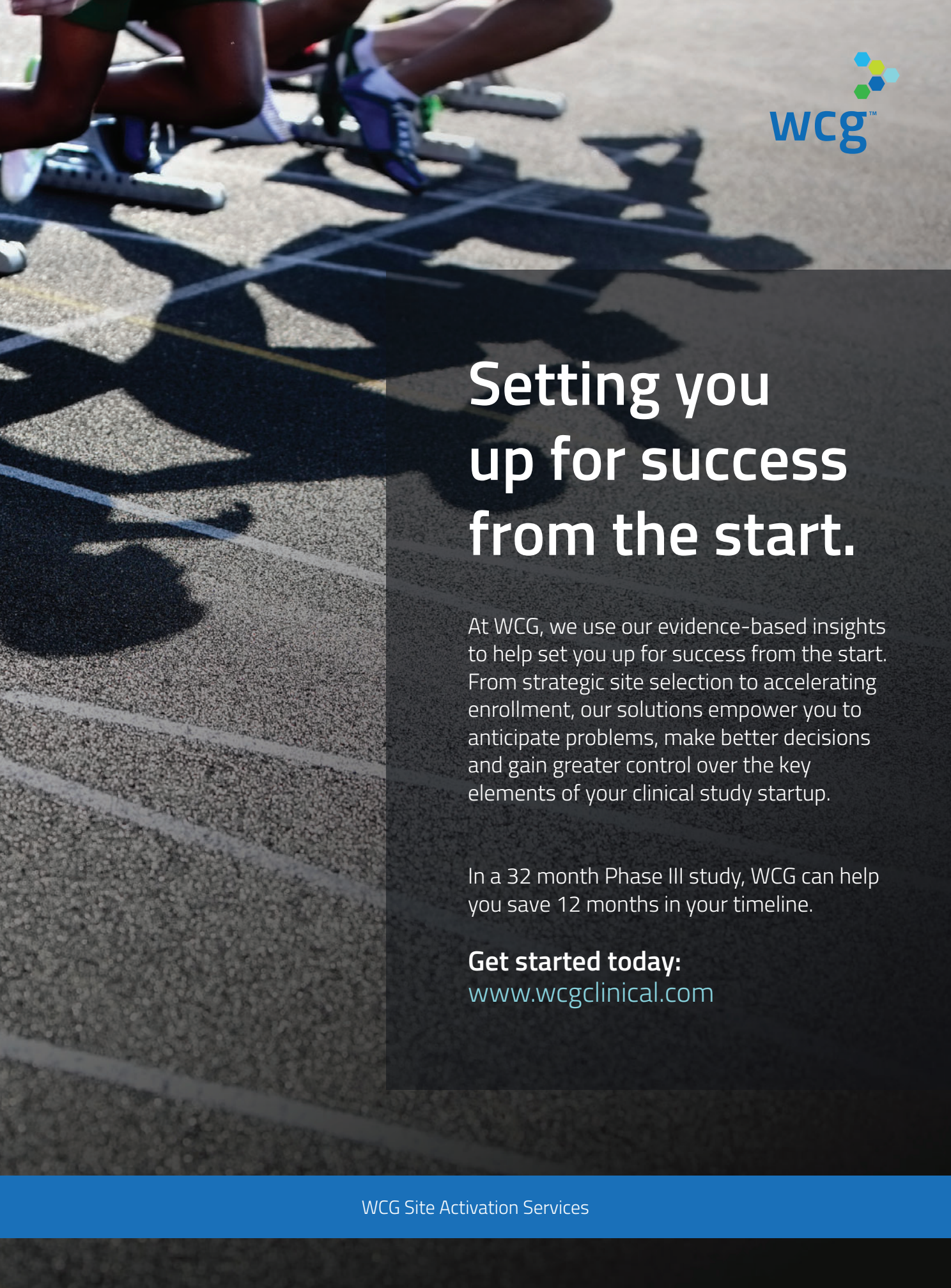

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