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VOLUME 38, NUMBER 6

PHARMACEUTICAL 50 EXECUTIVE

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Insights for the Win

THIS WAS THE FIRST GATHERING OF *Pharmaceutical Executive*'s Editorial Advisory Board since first speaking with them when I took over the reins in January 2017. Over the next months, I met with them in-person, or over the phone, to gain insights into the industry, specific hot topics, and about the *Pharmaceutical Executive* mission. Having the opportunity to have those who could make it all in one room last month was both an honor and a learning experience. And, as in other years, the editorial staff was there to hear first-hand from these experts. And before you know it, we'll be on another teleconference to go over our hot topics and ideas for 2019 editorial coverage. Suffice to say, it's going to continue on the path of providing the "bio" in biopharma.

Board members shared some information from their areas of expertise. Kenneth Kaitin, Director and Professor for the Tufts University Center for the Study of Drug Development, shared remotely what the Center is currently seeing in the industry. The challenges include the continued lack of efficiency in the clinical research enterprise, which contributes to the high costs of developing a drug; the industry shift from high volume/low margin compounds to low volume/high margin products, which contributes to the landscape of high unsustainable pricing; and an increased, more formalized partnering between academia and pharma.

Peter Young, of Young and Partners, provided an overview of industry investments, with an eye toward an anticipated increase in biotech acquisition for 2018. Young also pointed to China as a robust area for life sciences, which led to discussion around investments and financing in that country, as well as reverse activity with China pharma conducting trials in the US.

The EAB and staff also discussed the *Pharmaceutical Executive* magazine and website. The insights ranged from ideas on how to grow our younger audiences, gain visibility into the biotech audience, and offer information that may help the C-suite jump-start its innovation transfer. Like any other business, we are a balance of resources and ideas; profit and sustainability; short-term decisions and long-term strategies.

But with all of those decisions, the editorial staff strives to keep the reader in mind. We routinely send out readership surveys; keep an eye on audience involvement in our social media; know the number of people who are listening to our new podcast; and we monitor our website traffic daily, weekly, monthly, and yearly to find out what you're reading and what's not resonating.

Keep in mind, you can always drop me an email about what you like, or don't like. We received one recently about our April issue, which praised us for our "particularly enlightening" variety of articles. A win for you, is a win for us!

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2018 *Pharm Exec* 50

Pharm Exec's 18th annual listing of the top biopharma players shows that most of the familiar placeholders are holding their ground as they weigh a changing business climate with new opportunities for growth in a potentially resurgent marketplace.

C-Suite Personality: Fit for Future?

By Waseem Noor and Saule Serikova

Exploring new character benchmarks for today's pharma executives, and whether they have the transformational traits to lead through change.

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Executive Profile

Company's 'Rare' Drug Model

Julian Upton, European and Online Editor

Pharm Exec speaks with Joe Wiley, CEO of Amryt Pharma, who is steering a road-less-traveled path for a small pharma—building a sustainable, commercial infrastructure first, with the hopes of accelerating new rare disease drugs to the patients that need them in Europe and beyond.

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Market Access

Piecing Together the Pricing Puzzle

By Sudip Parikh

There is no magic bullet that will dramatically impact drug pricing to everybody's liking. But a stepwise approach involving a series of changes, including taking advantage of the next midterm elections, could point the path toward a solution.

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Increase Impact of HCP Multichannel Marketing
bit.ly/2GfPOkM

Readers Weigh In

I feel this article is spot on. As the customer journey increases in complexity, marketing attribution becomes ever more paramount. Especially true is the case with customer journeys that have especially long "tails," meaning extended buying or converting cycles. This is the case within healthcare. Medical marketers can track full-funnel, cross-channel attribution with a platform, affording teams the ability to analyze return on ad spend in real time.

Anonymous
"Attribution: Mission-Critical for Digital Marketing Measurement"
bit.ly/2sh96xq

Twitter Talk

■ It's a challenge to balance access with affordability—and avoid "racing to a place where there's no profit."

Dr Sohail Manzoor, @manzoorsohail
"Trump Drug Pricing Plan Outlines Rule Changes Pharma Can Live With"
bit.ly/2sfDE2l

■ See the latest article from @Phesi_CT in @PharmExec—a must read for clinical operations executives and CFOs at any company doing life sciences R&D.

Annalisa Jenkins, @annalisajenkins
"Clinical Trials Don't Have to Cost Too Much or Take Too Long"
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The *Pharm Exec* Podcasts are available on all your favorite listening tools such as iTunes, SoundCloud, Google Play, Stitcher, and Overcast. Here's a peek at our recent podcasts, with links to listen!

Episode 5: Med 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

Episode 6: The Pharma vs. Biotech Experience
Michelle and Christen interview Lara Sullivan, founder and president of SpringWorks Therapeutics, about the differences in working for legacy pharma vs. small biotech startups. bit.ly/2EGuvDt

Pharmaceutical Executive PODCAST

Episode 7:Big-Event Insights
Pharm Exec editors discuss key takeaways from a variety of industry conferences that took place across the globe. bit.ly/2Fhfto4

Episode 8: CFO Insights From the Field
Tim Sullivan, chief financial officer of Apellis Pharmaceuticals, provides an inside look at what it takes to be the CFO of a development-stage biotech company, and what business skills are needed to succeed in that type of position. bit.ly/2IIfwig

Episode 9: Brands of the Year
Michelle and Christen host the *Pharm Exec* editorial team to discuss our selections of Brands of the Year and why we chose to highlight these particular products. bit.ly/2ILwFZe

US Maps Strategy to Reform Drug Pricing

Azar and Gottlieb out front in revising rebates, restructuring Medicare, and promoting competition

After months of threats and promises, President Donald Trump finally unveiled his strategy for realizing more affordable prescription medicines in the US. Trump pledged to take on the "tangled web of special interests" that drive up drug prices and chided supply chain middlemen for getting "very rich" under the current system.

The lack of specifics, though, produced a general shrug from industry and the investment community and visible disappointment from public health activists. The administration's "American Patients First" blueprint (see https://bit.ly/2rC3h-JQ), unveiled at a May 11 Rose Garden speech, blasts "global freeloading" by industrial nations and proposes major changes in Medicare and Medicaid drug coverage policies, but stops short of authorizing the federal government to directly negotiate Medicare drug prices and or to permit "safe" importation of prescription drugs from other countries, as sought by Democrats and consumer advocates.

Moving Medicare

In further highlighting the important changes to come under the Trump plan, Health and Human Services (HHS) Secretary Alex Azar blasted the Democrats' approaches as ineffective and unworkable. He emphasized how, instead, the blueprint will achieve such goals by updating Medicare Part B drug coverage and Part D protected classes. This may involve shifting some or all Part B drugs to Part D or revising the Part B payment formula to reflect the wider range of alternative therapies now available in many treatment categories, such as autoimmune disease and inflammatory conditions, as well as cancer, and open the door to Part B price negotiation under new rules. The Centers for Medicare and Medicaid Services (CMS) also may revive the Competitive Acquisition Program (CAP), designed to give physicians an alternative means for reimbursement on Part B drugs.

HHS also is reviewing strategies to gain leverage over prices of drugs covered by Part D, particularly those in the six Part D protected drug classes that account for $30 billion a year in Medicare drug outlays. Proposals include dropping from protected classes those drugs that raise prices too often or too much; permitting coverage of fewer drugs in each class; and authorizing greater utilization management for covered drugs to encourage patient use of less costly medicines.

Less controversial are initiatives to make greater use of value-based payment contracts in Medicare and Medicaid, including a review of whether the Medicaid Best Price reporting requirement blocks such agreements. Reimbursement could vary for additional indications of a drug, and there's interest in long-term financing arrangements for high-cost treatments that promise important benefits over many years. As a first step towards more price transparency, CMS recently expanded its "Drug Spending Dashboards" for Medicare and Medicaid to highlight information on drugs with high price tags or experiencing notable rate increases.

Rethinking rebates

The administration also is taking a hard look at how the current system of rebates negotiated by pharmacy benefit managers (PBMs) and manufacturers creates perverse incentives for higher list prices. Secretary Azar complained that because PBMs receive a cut of paid rebates, they gain from higher list prices, and that this may encourage plans to manage formularies to gain heftier rebates, rather than to lower net drug costs.

HHS wants to examine how beneficiaries are negatively impacted by such arrangements and how Part D plans could block payments or rebates from manufacturers to PBMs. Related questions are whether PBMs should receive any remuneration from manufacturers and how such changes would affect manufacturer pricing behavior and insurance and benefit design. A shift to fixed-price discounts, Azar said, may be needed to "end the corrupt bargain that keeps driving list prices skyward."

FDA Commissioner Scott Gottlieb previewed this discussion in a speech at the May annual conference of the Food and Drug Law Institute, where he cited drug rebates for driving up drug prices to "unaffordable levels for some patients." He sug-

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gested that the federal government may reexamine "the current safe harbor for drug rebates under the Anti-Kickback statute" to help restore "some semblance of reality to the relationship between list and negotiated prices" and boost affordability and competition.

More competition

The blueprint continues to call for more competitive pharmaceutical markets that can put pressure on brand prices by speeding more generic drugs and biosimilars to market. Trump reiterated FDA criticism of brands that block generics makers from access to innovator products needed for bioequivalence testing or stymie negotiations of shared Risk Evaluation & Mitigation Strategies (REMS) required to market competing products. To gain more transparency around these practices, FDA has posted a new database listing about 50 drugs that have received complaints from generics firms about hurdles in obtaining needed test supplies or in REMS participation. The agency also is offering waivers that permit generics firms to create their own REMS if needed. Added competition, moreover, could come from more streamlined approval of over-the-counter drugs and additional FDA guidance to facilitate the development of biosimilars.

A shift to fixed-price discounts, Azar said, may be needed to "end the corrupt bargain that keeps driving list prices skyward"

Moves to enhance market competition at home and to overhaul Medicare drug reimbursement are more likely to alter drug pricing than Trump's call for other industrial nations to pay more for innovative medicines and end the "global freeloading." The Commerce Department would identify the "unfair disparity" between drug prices in the US and other developed countries, and the US trade representative would address this "injustice" in talks with trading partners. However, even if the administration could persuade Germany or Canada to increase rates that their citizens pay for medicines, there's little assurance that pharma companies then would cut prices in the US.

Azar acknowledged that it will take time to make the kinds of "fundamental structural change" in a system of "entrenched market players" that the administration envisions. But he emphasized that President Trump is focused on drug pricing reform and that he expects a visible response from the White House to "the next company that takes a price increase not justified by inflation or change in clinical benefit." PE

DTC disclosure?

Under the heading of increased price transparency is an "American Patients First" blueprint proposal to require pharma marketers to include drug cost information in DTC broadcast ads. With all the time consumers spend watching drug company ads on TV, Health and Human Services (HHS) Secretary Alex Azar suggested that for "a real market for drugs, why not have them disclose their prices in the ads?" Patients hearing about a new wonder drug, Azar explained, should know whether it costs $100 or $50,000.

An FDA working group is examining strategies for requiring marketers to advertise list prices, Gottlieb noted at a briefing, and whether such a requirement could fall under "fair balance" rules. However, there's uncertainty over how useful it would be to post list prices that no one pays, and if requiring price information disclosure would be challenged as unconstitutional "compelled speech."

While FDA proceeds, Azar proposed that drug companies start disclosing prices on their own. Manufacturers should let people know "which drug companies are gouging consumers and which ones are being good actors for our community."

The Centers for Medicare and Medicaid Services (CMS) further is instructing Part D plans to drop "gag rules" that prevent pharmacists from steering customers to less costly products and may encourage doctors to inform patients of the out-of-pocket costs for drugs they prescribe.

Can Trump Plan Serve as Model for What Ails Europe?

Weighing the crossover effect of US's new pricing blueprint

Now Donald Trump has at last made his pitch to tackle the challenge of paying for drugs in the US, speculation is rife about what the impact could be around the world—and healthcare payers in Europe are combing through his 44-page blueprint to see if any of his ideas might be worth a try locally.

That's no surprise. The pressures on health authorities are pretty similar everywhere: how to meet the growing cost of drugs without bankrupting the system. Do Trump's ideas have any relevance for Europe? Is there any value in a transatlantic transfer of thinking?

The heavily-branded proposal—"American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-PocketCosts"—is prefaced by a characteristically assertive quote from the President, but one that is bound to ring some bells in Europe too: "I have directed my Administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down."

Trump has hitched that familiar accusation of unjust drug prices to his own populist approach, so as to present himself as the defender of the victims of drug industry injustice.

His senior health official faithfully follows the same line in his introduction to the proposal—and also sounds some notes that are frequently heard in Europe too. Alex Azar, newly recruited from Eli Lilly as secretary of the US's Health and Human Services (HHS), echoes the criticisms of the system he was a part of until only weeks ago: "Too often, this system has not put American patients first. We have access to the greatest medicines in the world, but access is meaningless without affordability."

And some of the top challenges that the proposal identifies are also habitual elements of the narrative in Europe: high list prices for drugs, payers ill-equipped to negotiate, and "a new era of high-cost drugs lacking competition." The pharma industry stands accused by Trump and his administration of "shifting its attention to high-cost drugs that face little to no competition, because they offer the freedom to set high launch prices and increase them over time."

Shared sentiments

In view of the overlaps between the American and European diagnoses, the remedies canvassed inevitably display some superficial common points. The Trump agenda includes promoting the availability and use of generics and biosimilars—through "educating clinicians, patients, and payers about biosimilar and interchangeable products." In similar vein to European health authorities, it speaks warmly of boosting "physician and patient confidence in biosimilar and interchangeable products" to increase market acceptance.

The Trump agenda envisions improving the accuracy of drug-spending data, including through tighter requirements on manufacturers to report their prices. And closely linked to the pricing system, the blueprint highlights preventing manufacturers from "gaming of regulatory processes" and the need "to address abusive drug pricing by manufacturers"—all well-rehearsed ideas in Europe.

But it is in the area of tackling high-cost drugs that the ostensible similarities are most evident. The blueprint notes that regulations governing the price of prescription drugs "have not kept pace with the availability of new types of drugs, particularly higher-cost curative therapies intended for use by fewer patients." This mirrors closely the spirit of the views expressed by EU health ministers—notably in mid-2016—that new medicines "pose new challenges to individuals patients and public health systems, in particular regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their postmarket surveillance, and patient access and affordability." The same concerns have emerged repeatedly and insistently across a swath of EU policy pronouncements since then.

Matching many of the EU suggestions for responding to these challenges, the blueprint lists a series of possible actions to obtain greater control over drug spending. They range from indication-based pricing to outcomes-based contracts and long-term financing models.

Reflecting some of the current EU discussions of hori-

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

zon-scanning, the blueprint explains that "budgets may be challenged when a new high-cost drug unexpectedly becomes available in the benefit year."

Consequently, "long-term financing models are being proposed to help states, insurers, and consumers pay for high-cost treatments by spreading payments over multiple years." It also buys into the still-embryonic European discussion of value-based healthcare, and focuses on "improving price transparency" as "an important part of achieving this aim."

Dissimilar interests

Not all of the blueprint is so closely aligned to the concerns prevalent in the EU. The profoundly different nature of the US healthcare system means much of the blueprint's discussion is irrelevant—on issues such as requirements to include list prices in advertising, or adjustments to Medicare accessibility.

And even where the diagnoses appear to coincide, the proposed remedies spring from very different contexts—most obviously because the US boasts one health authority with executive power over an entire country, in contrast to 28 distinct governments with national sovereignty over drug pricing, and a European-level authority with virtually no powers in the health arena. In addition, the level of detail in the blueprint's recommendations is not always adequate to judge on their feasibility or relevance to the European market.

However, two other factors set the US approach so far apart from the situation in Europe that comparison becomes almost meaningless.

One is the curious contention that US drug prices are too high

Is there any value in a transatlantic transfer of thinking? … Even where the diagnoses appear to coincide, the proposed remedies spring from very different contexts

because prices elsewhere in the world are too low—based on the belief that "foreign governments are free-riding off of America investment in innovation." "Other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market," says the blueprint—and the loosely-argued justification for this belief invokes an amalgam of "foreign government threats of compulsory licensing or IP theft," "austerity measures in most European countries," "price disparities in the international market," "the growing use of external reference pricing," and "threats of market lockout."

The flaws in both the reasoning and the ambition have rapidly been pounced on by many commentators, who have pointed out that it is far from clear how much leverage the US might have in obliging other countries to raise drug prices, or even how close the causal link is between the prices that drug companies can get abroad the prices they charge in the US. And as James Love, the American consumer guru who is no fan of the drug industry, also observed: "The higher foreign prices are, and the harder it is to obtain low-cost generics outside the United States, the easier it will be to charge higher prices in the United States."

The other major differentiating factor, that stands in stark contrast to the European situation is the level of animosity, even hostility, directed at the pharma industry in the official US pronouncements. Azar has been particularly dismissive of the drug industry in his remarks. "I've been a drug company executive—I know the tired talking points: the idea that if one penny disappears from pharma profit margins, American innovation will grind to a halt. I'm not interested in hearing those talking points anymore, and neither is the President." In his new position, Azar seems determined to settle scores in pursuit of the populist agenda set by his new boss in the White House: "If industry isn't willing to work with us to lower prices, President Trump and his administration will keep turning up the pressure—until the system finally puts American patients first," he said.

Such personalized animus and such coarsely-phrased ultimatums are alien to European officials, even when they express concerns over drug industry performance. Nor does it seem particularly effective, even in the US. Drug company shares rose sharply in reaction to the Trump plan. Right now, the US approach contains little that might be directly applicable in Europe's bid to keep a hold on drug spending.

Paradoxically, the worst that European drug firms may fear as spillover from the blueprint could turn out to be some official pressure to raise rather than to lower their prices! Trump that! PE

2018 Pharm Exec 50

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Pharm Exec's annual listing of the top biopharma players shows that most are holding their ground as they weigh a more challenging business climate with new opportunities for growth in a potentially resurgent marketplace

Amid all the swirling changes in the biopharmaceutical and healthcare marketplaces—from therapeutic advances on one side to access, pricing, and business pressures on the other—our latest annual list of the top 50 global biopharma sales leaders remained remarkably stable. The first 10 spots on the ledger, once again led by Pfizer, were unchanged from the previous full-year rankings. However, prescription sales gains among the entrenched stalwarts were relatively modest, on average, with Johnson & Johnson and Roche experiencing the largest increases at 7.6% and 5.5%, respectively. In assembling the data for the annual listing—now in its 18th year—*Pharm Exec* partnered again with life sciences market intelligence firm Evaluate Ltd.

Sanofi, ranked fifth in sales, boosted its R&D spend the most among the top 10 holders, with a 46% jump in investment versus the previous year. The Paris-based company currently has 28 projects in Phase III development or seeking approval with regulators, and has six programs targeting rare diseases in Phase II or III clinical trials. It's no secret that, overall, industry investment in rare disease drugs—on the investigative and commercial-expansion stages—is on the rise. The FDA, for example, reportedly granted 77 orphan drug approvals last year and 476 orphan drug designation requests.

Among the top 20 sales leaders on our list, other companies with notable spikes in R&D spending year-on-year include Gilead Sciences at 26.8%, Allergan at 69.5%, and Teva Pharmaceutical Industries, which more than doubled its output, investing $4.97 billion in R&D.

Biopharma's bottom line in 2017 was impacted by US tax reform passed late in the year, which limited overall profit for some, with drugmakers having to pay large one-time charges related to the changes. Going forward, however, the tax reform, which lowered the income tax for US companies to 21%, is expected to spur a resurgence in life sciences M&A. It may already have, with several smaller-scale acquisitions announced by big pharma so far this year. Could such dealmaking, combined with larger, global moves, including Takeda's proposed $62 billion acquisition of Shire last month, rearrange some of the positioning in our Pharma 50 listing come next year? The Takeda-Shire combo would thrust the new organization into the top 10, reports say.

Continued focus in political and other circles to curb drug pricing could influence the jockeying as well. Although it's difficult to gauge the immediate impact of some efforts, such as the US Administration's newly unveiled strategy to reform pricing, which didn't include specific timelines on policy implementation. What is more certain is the likely continued penetration of specialty drug products within the overall pharma market—a factor that has contributed to higher prescription medicine costs, even as some reports have predicted branded drug spending in developed countries will actually fall this year and remain flat in the near-term.

With all the different dynamics at play, the importance of having strong and stable leadership has perhaps never been more critical for biopharma. Which brings us again to this year's special Pharma 50 accompanying feature by guest authors at the executive search and talent advisory firm Russell Reynolds Associates. It's clear organizations today are facing mounting market pressures, as the traditional commercial model has become increasingly challenged. The old methods of leadership assessment, therefore, are now myopic, the authors contend, and new perspectives on identifying and benchmarking the character profile of effective C-suite leaders—with the makeup to lead over the long term—are needed. In the pages ahead, Russell Reynolds presents such an approach, using a framework of seven personality dimensions and applying them across all industries to extract those vital and distinctive leadership traits that will best predict "C-suite durability" in the world of biopharma.

— Michael Christel

Rank	Company headquarters [website]	2017 Rx Sales (USD in mln)	2017 R&D spend (USD in mln)	2017 Top-selling Drugs [USD in mln]
1	**Pfizer** **New York, New York** [pfizer.com]	$45,355	$7,627	Prevnar 13 [5,601] Lyrica [5,065] Ibrance [3,126]
2	**Novartis** **Basel, Switzerland** [novartis.com]	$41,875	$7,823	Gilenya [3,185] Cosentyx [2,071] Gleevec [1,943]
3	**Roche** **Basel, Switzerland** [roche.com]	$41,732	$9,181	Rituxan [7,506] Herceptin [7,126] Avastin [6,795]
4	**Merck & Co.** **Kenilworth, New Jersey** [merck.com]	$35,357	$7,563	Keytruda [3,809] Januvia [3,737] Gardasil [2,308]
5	**Sanofi** **Paris, France** [sanofi.com]	$34,397	$8,360	Lantus [5,223] Pentacel [2,065] Fluzone [1,796]
6	**Johnson & Johnson** **New Brunswick, New Jersey** [jnj.com]	$34,078	$6,184	Remicade [5,752] Stelara [4,011] Zytiga [2,505]
7	**Gilead Sciences** **Foster City, California** [gilead.com]	$28,668	$4,978	Harvoni [4,370] Genvoya [3,674] Epclusa [3,510]
8	**GlaxoSmithKline** **Brentford, England** [gsk.com]	$27,743	$4,829	Advair [4,035] Triumeq [3,172] Tivicay [1,810]
9	**AbbVie** **North Chicago, Illinois** [abbvie.com]	$25,662	$3,523	Humira [18,427] Imbruvica [2,144] Creon [831]
10	**Amgen** **Thousand Oaks, California** [amgen.com]	$21,795	$3,482	Enbrel [5,433] Neulasta [4,534] Aranesp [2,053]

Source: EvaluatePharma® May 2018, Evaluate Ltd, www.evaluate.com

How the listings were compiled: 2017 R&D Spend and 2017 Rx Sales analyses were provided by life science market intelligence firm Evaluate Ltd via its EvaluatePharma® service, www.evaluate.com. *Pharm Exec* would like to thank EvaluatePharma for assisting in the development of this year's Pharma 50 listing. EvaluatePharma takes sales estimates from leading equity analysts to create a consensus sales forecast, currently to 2024. Evaluate's Sales and R&D Spend figures represent the fiscal year that ended in 2017. For most American and European companies, that means the year ending December 31, 2017. For many Japanese companies, the fiscal year ending March 31, 2018, was used. Historic averages were used in the conversion of companies' native currency to USD.

SPEED. SCALE. CERTAINTY.

NAVIGATING THE NEW (AND MORE COMPLEX) BIOPHARMA WORLD

Every twist and turn in the bench-to-bedside commercialization journey introduces increasing regulatory complexity, product-specific special handling requirements, and evolving industry guidelines. We've found three opportunities (or pitfalls) that manufacturers must address in their channel distribution strategy to ensure economic success and operational efficiency.

SPEED. HOW QUICKLY CAN YOU GET YOUR PRODUCT INTO YOUR PATIENTS' HANDS?

Logistics can be a matter of life or death. Is your distribution strategy flexible and fast enough to meet complex needs?

For example, your partner should have the right relationships to ship your therapy from and to anywhere, and to do it quickly. "We have established partnerships with freight forwarders, storage facilities, transportation providers, and technology players around the globe," says Danny Williams, Chief Sales & Marketing Officer, Dohmen Life Science Services (DLSS). So, when a Manufacturer required eight-hour delivery of a life-saving therapy for an ultra-rare disease, DLSS customized a solution with existing, successful partnerships.

"Our critical response service provides a configurable system of storage facilities, cold chain capabilities (if required), safety and security solutions, and advanced temperature monitoring via GPS. We coordinate a solution with as few handoffs as possible to minimize errors. Today, our client's therapy reaches patients within eight hours or less, 24/7, with 100% shipping accuracy. The program has saved 600 lives and counting," says Williams.

SCALE. WHAT WILL HAPPEN IF DEMAND DOUBLES TOMORROW?

In this industry, demand can spike exponentially at a moment's notice. An under-prepared partner could cost your organization time and money, so it's ciritical to identify a partner with a solution that can scale accordingly day by day.

"One of our clients won a large government contract that caused a constant flux in demand. Their product needed to be scheduled and delivered to six CDC locations, no matter the size of the order, date received, or time constraints," said Williams. "We needed partners who could handle significant amounts of inventory and execute a detailed project plan to address the government's requirements for the manufacturer. In the end, our flexible solution allowed them to secure the contract, increasing their revenues by 40%."

CERTAINTY. ARE YOU PREPARED FOR REGULATORY SCRUTINY?

Our industry is highly regulated and highly punitive. "Many times, our clients' compliance risks stem from a complex vendor structure. Miscommunication and inefficiencies are exacerbated, and clients are unwittingly vulnerable," says Williams. Partners should have the proper checks and balances in place to maintain standard operating procedures, training and development, and continuous improvement.

What's more, if your organization is called into question, do your partners have the regulatory expertise to course-correct compliance issues without interruption to your business? FDA enforcement escalates quickly and requires immediate action. "DLSS was recruited to assist a client that was facing potential FDA action. They did not have the manpower to meet the rigid FDA deadlines, and their vendors required coaching to speak directly with the FDA," says Williams. "You want to make sure your partner has in-house resources to stand by their work."

For more information, visit **www.dlss.com.**

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C-Suite Personality: Fit for Future?

Exploring new character benchmarks for today's pharma executives, and whether they have the transformational traits to lead through change

By Waseem Noor and Saule Serikova

Leadership's importance to organizational success is clear. Effective leadership focuses companies around strategy and inspires staff toward goals. Whereas, wrong-headed leadership destroys confidence and hinders an organization's ability to adapt to change. It is also clear that today's complex and volatile business environment has dramatically changed the leadership qualities required in the C-suite.

Two leadership topics, however, require more nuanced answers:

» What are the traits that effective and adaptive leaders need in order to lead through change and uncertainty?

» How suited are the personalities of pharma executives to navigating organizations through transformation?

This article describes a new perspective on the character profile of effective C-suite leadership across industries, and benchmarks the specific profile of executive leaders in the pharmaceutical industry.

Rank	Company headquarters [website]	2017 Rx Sales (USD in mln)	2017 R&D spend (USD in mln)	2017 Top-selling Drugs [USD in mln]
11	**AstraZeneca** London, England [astrazeneca.com]	$19,782	$5,412	Symbicort Turbuhaler [2,803] Crestor [2,365] Nexium [1,952]
12	**Allergan** Irvine, California [allergan.com]	$19,258	$4,823	Botox [3,169] Restasis [1,474] Linzess [723]
13	**Teva Pharmaceutical Industries** Petach Tikva, Israel [tevapharm.com]	$18,532	$4,973	Copaxone [3,801] Methylphenidate Hydrochloride [674] Bendeka [658]
14	**Bristol-Myers Squibb** New York, New York [bms.com]	$18,261	$1,848	Opdivo [4,948] Eliquis [4,872] Sprycel [2,005]
15	**Eli Lilly** Indianapolis, Indiana [lilly.com]	$17,715	$3,264	Humalog [2,865] Cialis [2,304] Alimta [2,063]
16	**Bayer** Leverkusen, Germany [bayer.com]	$16,971	$2,129	Xarelto [3,140] Eylea [2,124] Mirena [1,272]
17	**Novo Nordisk** Bagsvaerd, Denmark [novonordisk.com]	$14,906	$2,100	Victoza [3,521] NovoRapid [3,043] Levemir [2,145]
18	**Boehringer Ingelheim** Ingelheim, Germany [boehringer-ingelheim.com]	$14,449	$1,565	Spiriva [3,193] Pradaxa [1,625] Tradjenta [1,506]
19	**Takeda** Osaka, Japan [takeda.com]	$14,262	$3,067	Entyvio [1,800] Velcade [994] Azilva [650]
20	**Celgene** Summit, New Jersey [celgene.com]	$13,335	$2,887	Revlimid [8,187] Pomalyst [1,614] Otezla [1,279]

Source: EvaluatePharma® May 2018, Evaluate Ltd, www.evaluate.com

The challenge of assessing leadership capacity

The last two decades have seen a doubling in annual spending on leadership assessment and development. However, the same time period has been marked by a sharp decline in confidence in leadership assessment. The shortcomings of old leadership assessment methods lie in two major categories. First, they tend to be rather general and not tailored around the unique profiles of C-level positions. Second, old methods are myopic. They may do a fairly good job of selecting leaders able to meet the current demands of an organization and its market, but they are less successful in selecting those able to grow and adapt to the inevitable and rapid changes.

A part of this shortsightedness may be an overinvestment in certain leadership approaches. Specifically, a set of "loud" traits —the competencies that get noticed, such as tough-mindedness and decisiveness—are widely believed to be not just fundamental to but sufficient for successful leadership. When hiring, however, board members and senior leaders should be mindful that when "loudness" is the entirety of an executive's personality profile, it threatens the long-term success known as "C-suite durability."

A unique approach to predicting durable C-suite success

Research on thousands of successful C-suite executives makes it clear that successful executives are much more than a collection of "loud" traits. The capacity to be bold and decisive is certainly critical to effective leadership, but equally necessary is a set of "quiet" attributes—the subtle competencies, like emotional sensitivity and humility.

Rank	Company headquarters [website]	2017 Rx Sales (USD in mln)	2017 R&D spend (USD in mln)	2017 Top-selling Drugs [USD in mln]
21	**Astellas Pharma** **Tokyo, Japan** [astellas.com]	$12,928	$3,017	Xtandi [2,656] Prograf [1,443] Myrbetriq [1,134]
22	**Shire** **Dublin, Ireland** [shire.com]	$11,456	$666	Advate [2,264] Vyvanse [2,161] Gammagard Liquid [2,106]
23	**Mylan** **Canonsburg, Pennsylvania** [mylan.com]	$10,670	$1,984	EpiPen [364] Esomeprazole Magnesium [208] Fentanyl [195]
24	**Biogen** **Cambridge, Massachusetts** [biogenidec.com]	$10,355	$2,254	Tecfidera [4,214] Avonex [2,152] Tysabri [1,973]
25	**Daiichi Sankyo** **Tokyo, Japan** [daiichisankyo.com]	$7,411	$635	Benicar [844] Nexium [781] Lixiana [696]
26	**CSL** **Melbourne, Australia** [csl.com.au]	$7,216	$2,009	Privigen [1,734] Human albumin [930] Hizentra [812]
27	**Merck KGaA** **Darmstadt, Germany** [merckgroup.com]	$6,880	$1,844	Rebif [1,820] Erbitux [964] Gonal-F [796]
28	**Valeant Pharmaceuticals International** **Mississauga, Ontario** [valeant.com]	$5,327	$1,476	Xifaxan 550 [979] Ocuvite [286] Wellbutrin XL [245]
29	**Otsuka Holdings** **Tokyo, Japan** [otsuka.com]	$5,005	$361	Abilify MAINTENA [632] Abilify [600] Samsca [573]
30	**Sun Pharmaceutical Industries** **Mumbai, India** [sunpharma.com]	$4,633	$1,194	Atorvastatin Calcium [163] Absorica [161] Imatinib Mesylate [157]

Source: EvaluatePharma® May 2018, Evaluate Ltd, www.evaluate.com

When "loud" traits are present in abundance but "quiet" characteristics are in short supply, two situations emerge that can lead to an executive's derailment: a) The executive is unable to cope with the new requirements of changing business conditions, or b) The executive's "overuse" of traits once seen as strengths goes unchecked.

It is the combination of both loud and quiet leadership competencies that helps ensure a C-suite executive's long-term effectiveness and impact.

Collaborative research between Russell Reynolds Associates and Hogan Assessment Systems has yielded Leadership Span™—a forward-focused, tailored, and dynamic approach to identifying the traits of C-level executives who experience long-term success (see methodology explainer on page 21). The research identified successful leadership qualities by looking at executive job performance through the lens of over 400 criterion studies and analyzing a data set of 32,000 executives that matched performance data to assessment data. From this, a set of personality dimensions that best predict performance was derived, creating the basis of the framework.

When it comes to the characteristics of executives along four dimensions of C-suite responsibilities, balance, *per se*, is not the key. It is not the "happy middle ground" between two opposing personality styles that is at the heart of successful leadership, but rather very pronounced leanings toward both competing competencies (see Figure 1 on page 20).

Leadership Span™ recognizes that an organization's internal and external environments are not static. The approach to *Setting Strategy*, for example, will inevitably require a leader who is highly

Rank	Company headquarters [website]	2017 Rx Sales (USD in mln)	2017 R&D spend (USD in mln)	2017 Top-selling Drugs [USD in mln]
31	**Eisai** **Tokyo, Japan** [eisai.com]	$4,518	$1,203	Humira [495] Aricept [396] Halaven [369]
32	**Les Laboratoires Servier** **Neuilly-sur-Seine, France** [servier.com]	$4,287	$137	Diamicron [508] Vastarel [464] Aceon [432]
33	**Endo International** **Dublin, Ireland** [endo.com]	$4,279	$1,075	Vasostrict [400] Xiaflex [213] Ezetimibe [187]
34	**UCB** **Brussels, Belgium** [ucb.com]	$4,246	$422	Cimzia [1,609] Vimpat [1,094] Keppra [724]
35	**Abbott Laboratories** **Abbott Park, Illinois** [abbott.com]	$4,058	$473	Drospirenone; Ethinyl Estradiol [26] Ademetionine [21] Choline Alfoscerate [14]
36	**Fresenius** **Bad Homburg, Germany** [fresenius-kabi.com]	$3,876	$326	Heparin Sodium [76]
37	**Chugai Pharmaceutical** **Toyko, Japan** [chugai-pharm.co.jp]	$3,718	$2,075	Actemra [295] Edirol [264] Alecensa [149]
38	**Grifols** **Barcelona, Spain** [grifols.com]	$3,687	$817	Gamunex IGIV [1,163] Flebogamma [720] Prolastin-C [617]
39	**Regeneron Pharmaceuticals** **Tarrytown, New York** [regeneron.com]	$3,684	$804	Eylea [3,702] Arcalyst [17]
40	**Sumitomo Dainippon Pharma** **Osaka, Japan** [ds-pharma.com]	$3,550	$813	Latuda [1,637] Brovana [312] Merrem [182]

Source: EvaluatePharma® May 2018, Evaluate Ltd, www.evaluate.com

inclined to be measured and pragmatic, with an equally strong pull toward being bold and disruptive. When these "competing competencies" are clearly embodied in a single executive, organizations are better able to adapt to the constantly evolving situations of dynamic markets.

Along four dimensions, successful leaders are highly and simultaneously:

» **Pragmatic and disruptive.** In *Setting Strategy*, leadership should bring a level of innovation that shakes up the status quo when necessary as well as a pragmatism that is conducive to focus, priority setting, and a healthy pace of change.

» **Reluctant and risk-taking.** In *Executing for Results*, calculated risk and measured optimism are hallmarks of strong leadership. Leaders should be just as inclined toward strategic hesitation as they are toward bold action.

» **Vulnerable and heroic.** In *Leading Teams*, perseverance and grit are only useful traits insofar as they don't make executives immune to criticism or cause them to deny reality. Leaders need to be open to feedback and external data and adjust accordingly.

» **Connecting and galvanizing.** In *Relationships and Influence*, leaders must be able to rally the organization behind their ideas, but they also need to know when to empower and give credit to others and how to connect the organization in ways that make it greater than an individual personality.

Rank	Company headquarters [website]	2017 Rx Sales (USD in mln)	2017 R&D spend (USD in mln)	2017 Top-selling Drugs [USD in mln]
41	**Alexion Pharmaceuticals** **Cheshire, Connecticut** [alxn.com]	$3,469	$163	Soliris [3,144] Strensiq [340] Kanuma [66]
42	**Mallinckrodt** **Dublin, Ireland** [mallinckrodt.com]	$3,141	$344	H.P. Acthar Gel [1,195] INOmax [505] Ofirmev [303]
43	**Menarini** **Florence, Italy** [menarini.com]	$3,072	N/A	Bystolic [312] Enantyum [148] Uloric [105]
44	**Mitsubishi Tanabe Pharma** **Osaka, Japan** [mt-pharma.co.jp]	$2,733	$693	Remicade [588] Talion [171] Tenelia [168]
45	**Lupin** **Mumbai, India** [lupin.com]	$2,633	N/A	Metformin Hydrochloride [130] Lisinopril [50] Cefixime [41]
46	**Actelion** **Allschwil, Switzerland** [actelion.com/en]	$2,344*	$310	Opsumit [487] Tracleer [258] Uptravi [249]
47	**Aspen Pharmacare** **Durban, South Africa** [aspenpharma.com]	$2,331	$77	Fraxiparine [301] Diprivan [192] Arixtra [119]
48	**Kyowa Hakko Kirin** **Tokyo, Japan** [kyowa-kirin-pharma.com]	$2,272	$438	Aranesp [553] Sensipar [185] Neulasta [179]
49	**Ono Pharmaceutical** **Osaka, Japan** [ono.co.jp]	$2,243	$325	Opdivo [777] Januvia [248] Orencia SC [128]
50	**Ferring Pharmaceuticals** **Parsippany, New Jersey** [ferringusa.com]	$2,214	$201	N/A

Source: EvaluatePharma® May 2018, Evaluate Ltd, www.evaluate.com.

* Actelion sales represent partial-year estimates of prior to the acquisition by J&J in June 2017.

Figure 1: "Competing competencies" are at the core of C-suite performance.

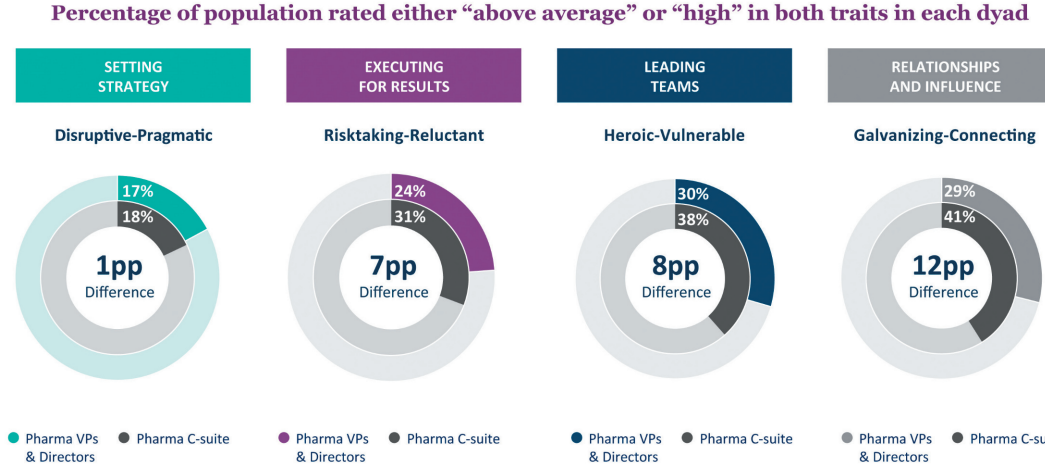

Figure 2: The analysis found that pharma C-suite individuals had a wider leadership span than pharma VPs and directors.

Source for all figures: Russell Reynolds Associates

The degree to which these paradoxical traits are embodied in a single leader is the "span"—the higher an individual scores in both "competing" traits along one of the four dimensions, the bigger the span in that dimension. An analysis of various levels of leadership shows that the size of the span increases as the level of leadership responsibility grows. For example, C-suite leaders exhibit a significantly wider span than global executives, whose span is wider than those of mid-level managers.

Demystifying the personalities of pharma C-suite leadership

Across industries, the correlation between span and leadership level is quite clear, but what does this phenomenon look like for pharmaceutical executives in particular? To explore this question, Russell Reynolds used industry-wide data as a benchmark and then compared pharma-specific results in the following two ways.

C-suite pharma executives vs. other pharma leaders

Across industries, C-suite leaders possess a larger span than other professionals do. That is, leaders at the highest levels score higher in both competing traits along all four dimensions than lower- and mid-level professionals. Our research finds that this is true in pharma as well, but with one exception. On the *Setting Strategy* dimension, the span for C-suite executives is not significantly different than it is for pharma VPs and directors (see Figure 2).

We measured individuals in two groups—pharma C-suite and pharma VPs/directors—on the competing characteristics within each of the four dimensions. We then looked at who was rated either "above average" or "high" for both characteristics within each dimension. For example, along the dimension of *Executing for Results*, about 24% of VPs and directors in pharma rated above average or high in terms of risk-taking and

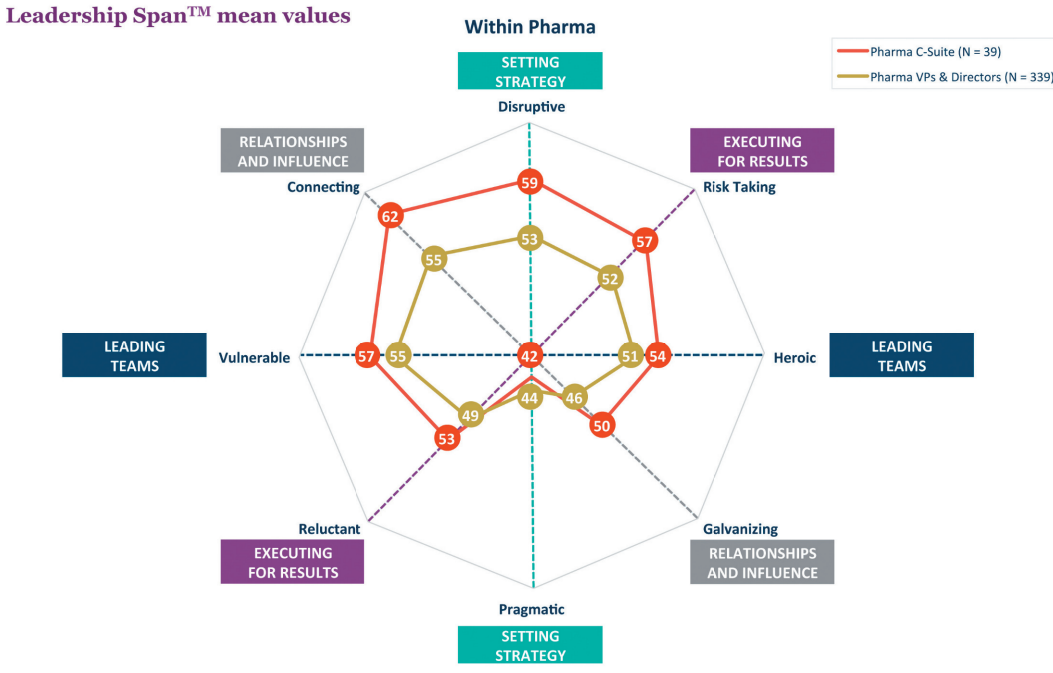

Figure 3: Within pharma, C-suite individuals have a larger span, except around pragmatism.

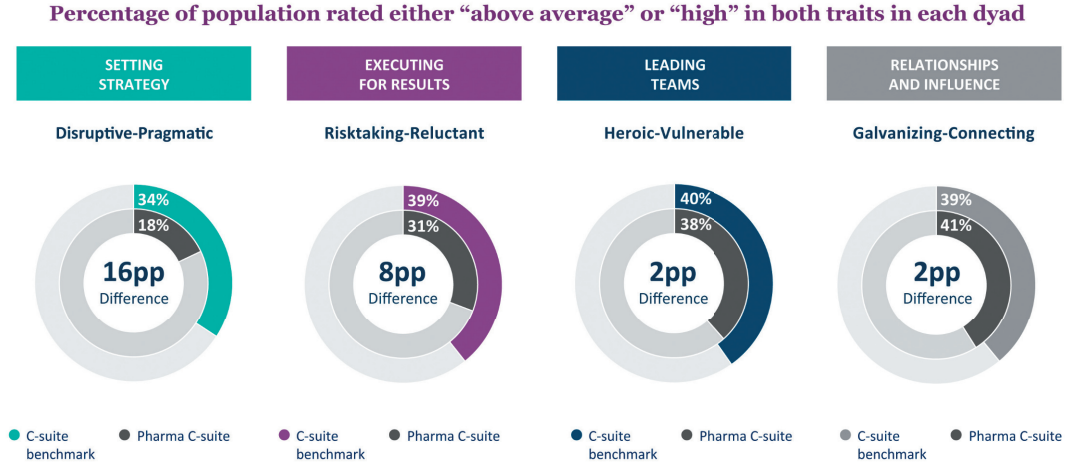

Figure 4: Looking across industries, we found that pharma C-suite individuals differed from benchmark C-suite on two dimensions.

reluctance. Whereas, 31% of C-suite executives scored well on these traits. For the dimensions of *Leading Teams* and *Relationships and Influence*, there, C-suite executives score higher than other leaders in pharma organizations as well. It is only in the *Setting Strategy* dimension that the two groups score about the same.

Methodology

To evaluate the degree to which leaders are likely to display the critical competencies of the Leadership Span™ model, data from the core Hogan assessment approaches were synthesized using a custom meta-analytic algorithm generated from Hogan Assessments data archive. This approach leverages Hogan's gold standard methodology for assessing leadership potential and predicting leadership effectiveness.

Results for pharma executives were aggregated and compared with the senior executive populations. In addition, the strongest traits among these aggregated scores were identified as distinctive of this pharma executive population.

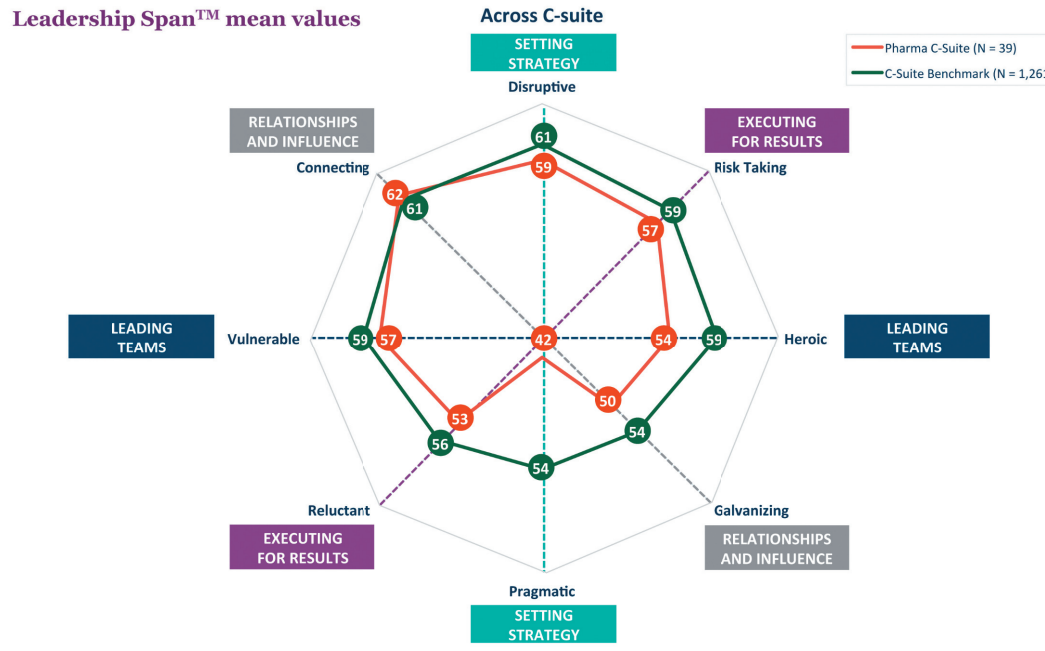

Figure 5: Pharma C-suite seems to be less pragmatic and heroic in their characteristics.

A closer look at scores for the individual characteristics within each dimension is revealing. In Figure 3 (see page 21), we have mapped out each of the dimensions as an axis on a spider chart. The competing traits are mapped on opposite ends of the line. An individual with a larger span across the dimensions will have a larger circle.

It is the combination of both loud and quiet leadership competencies that helps ensure a C-suite executive's long-term effectiveness and impact

Looking at the results, we see that in general, C-suite executives in pharma have a larger span than VPs and directors, in that the red circle is larger than the yellow one. Surprisingly though, we see that scores for one characteristic within *Setting Strategy* depart from the pattern and lead to the two cohorts having similar spans in that dimension. While pharma C-suite executives are more "disruptive" than their more junior colleagues, they score about the same in measurements of how "pragmatic" they are.

We will return to why we believe this effect is happening after the second cohort comparison.

C-suite pharma vs. C-suite benchmark

Examining the data to compare C-suite executives in pharma to their counterparts across other industries further emphasizes pharma's uniqueness. In this analysis, it is also the *Setting Strategy* personality dimension that is the source of the difference, with C-suite leaders in pharma having a narrower span along this dimension than the benchmark group of C-suite executives (see Figure 4 on page 21).

Although pharma C-suite executives are similar to other industry C-suite leaders along the other three dimensions, there is a significant difference along the first dimension of *Setting Strategy*. Once again, if we look specifically at the two traits of this dimension, we find that pragmatism is the culprit, with C-suite executives in pharma scoring just as high on the "disruptive" trait as their counterparts in other industries, but being significantly less "pragmatic" (see Figure 5).

In a nutshell, pharma C-suite executives tend to be less pragmatic than C-suite executives in other industries, and unlike their counterparts in other sectors, they are not more pragmatic than their VPs and directors. In addition, the C-suite seems to be selecting and grooming directors and VPs with similar traits, as is evidenced by "pragmatism" being the characteristic in which pharma's junior leaders also score the lowest.

Tale of Two Leaders

Fictive examples of the wide and contrasting span of traits exhibited by C-suite leaders.

DIEGO is the CEO of a small pharma company. He has an MBA from a prestigious Ivy League school and watches over a pipeline of about four marketed antibiotics with about $1 billion in revenue. His Board has been pushing him to expand into new therapeutics areas, but he does not see this as a realistic goal for the company. He sees that the antibiotics market has become commoditized. He also recognizes that the Board is making a more passion-based decision rather an achievable strategy, since it would be difficult for his sales force to sell products from other therapeutic areas. In addition, given the increased pressure from payers, he understands that he can not stand on the prior achievements of the company. He is aware of the company's and his own strengths and limitations, and so would like to implement continuous improvements rather than an overarching change in strategy. He is looking to set an achievable strategy where he can supplement his pipeline with other anti-infectives, for example, anti-fungals, which his sales force can sell more easily. He then plans to use his considerable charisma and zeal to convince his team and Board to align around this vision.

This is a **pragmatic** leader as he is creating realistic goals and marshaling resources well. Although he is **reluctant** and exercises caution in taking risks, he shows strength in pushing back against passion-based decision-making by exercising a healthy degree of cynicism. He demonstrates his **vulnerable** qualities by being self-aware and increasing standards of the organization. This is a rare quality and should not be mistaken for weakness. He also recognizes that once the strategy is established he can be **galvanizing** to bring together the troops and align follower around the mission.

PRIYA is the CEO of an oncology biotech startup. She has a PhD in genomics and her company's technology is based off work she conducted during her dissertation about 10 years ago. The company has found a novel way to test for genetic markers, and she has received a first round of financing from venture capital and is looking to raise Series B. The first stage of financing did not come easy, and she had to try a number of times before she found the right VC to back her. Given radical innovation in the industry, she is stretching the organization to think in big, long-term, and global perspectives. She has set up 10 new initiatives to promote the technology with larger pharma companies, and is steadfast and relentless in her commitment to take the company to higher heights. She is the first one in the office and the last one to leave and is prepared always for every meeting. She would like to take on more risks given the complex and uncertain environment, but she finds that her people have become exhausted by the changes that the organization is making. To ensure their alignment with the vision, she has decided to let others take on the spotlight of the achievements when presenting to the Board and is thinking about ways to profile the next generation of leaders.

This is a **disruptive** leader. She is a permanent source of ideas and pushes innovation through the exploitation of opportunities. She is willing to be **heroic** in her leadership and displays resilience and grit, which commands respect from her team. She is **risk-taking** and is comfortable with adapting nimbly to situations. She recognizes that to keep her team motivated and engaged she needs to be **connecting** individuals together, so that they are engaged beyond the energy she provides, and, instead, to the greater purpose of the organization.

As pressure builds, pragmatic leadership becomes more important

To examine the "span gap" in pharma, it is important to understand the industry's historical context. Pharma has enjoyed traditionally high margins, and as an industry it has been relatively safe from some of the market pressures faced by, for example, electronics or consumer goods. Specifically, pharma's 15-year development timelines and 20-year post-invention patent protections have created a rather protected commercial model with high hurdles to entry. Given pharma's level of immunity to market threats thus far, it makes sense that pragmatism may not be fostered as an important trait in a C-suite executive.

Looking ahead, however, pharma's commercial model may not continue to enjoy protections, and pressure will likely mount. Disaggregation of the pharma value chain, regulatory compliance, digitization, and value-based reimbursement models are among the trends that are making management issues less static. As pressure grows, pragmatism will become an increasingly important trait of the C-suite pharma executive, and leaders will need to be chosen who demonstrate strength in this trait as well as in the seven others. PE

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A 'Rare' View on Realizing Treatments for Unmet Need

Joe Wiley, CEO of UK-based Amryt Pharma, is steering a road-less-traveled path from the small-pharma playbook—building a sustainable, commercial infrastructure first, with the hopes of accelerating new rare disease drugs to the patients who need them in Europe and beyond

Joe Wiley, CEO of London-based Amryt Pharma. *(Photo courtesy of Amryt Pharma)*

By Julian Upton

UK-based Amryt Pharma launched in 2015 as a commercial-stage enterprise focused on developing and delivering innovative new treatments for rare and orphan diseases. The company pursued a different path in taking a commercialization focus from the start, with the aim of identifying late-stage assets and bringing them to market in Europe, the Middle East, and North Africa. Amryt's in-licensing of and subsequent success with homozygous familial hypercholesterolemia (HoFH) treatment Lojuxta was a milestone in its development, quickly facilitating the company's transformation from a development-stage to a commercial business. HoFH is a very rare and life-threatening genetic disorder characterized by extremely high LDL cholesterol levels.

Pharm Exec spoke to Amryt CEO, Dr. Joe Wiley, to chronicle the rapid rise of this young company, and to discuss how he aims to maintain this momentum in the changing pharma landscapes of Europe and the US.

PE: *Could you outline the Amryt story so far?*

WILEY: I set up the business with my partner, now CFO, Rory Nealon in August 2015 and it's been quite a rollercoaster since then. I'm a medic by training, and before setting up Amryt I worked for Sofinnova Ventures, a US venture capital group, one of the largest investors in biotech in the world. I opened and led the European office for Sofinnova and that role gave me a lot of visibility on all the late-stage drug development companies across Europe.

I noticed some very interesting dynamics, one being that the quality of the assets being developed and discovered here in Europe were every bit as good and often better than the assets being developed in the US. However, predominantly, the com-

panies that are formed and the number of products going through clinical trials to the market is in the US because of access to capital. When you dig into the numbers, there's actually 10 times less capital to support European companies developing these assets. We felt that created an opportunity.

We set out to bring a really great team together, located in and initially focused in Europe. We wanted to be a commercialization business from the start. The way we would get over the access-to-capital issue would be to access the public markets here in Europe faster than you might ordinarily do in the US. In terms of the strategy of that business, the one thing that I've learned in 20 years in this industry, both on the investment side and on the operational side, is that if you focus on areas of really high unmet medical need, that's the best place to be for patients, because you're developing drugs that patients really need.

Of the 7,000-plus rare diseases known in the world, there's only approximately 600 or so drugs available to treat them. Rare disease patients are in desperate need of therapy, as often there's no therapy available for them at all. This also applies for physicians for the same reasons, and for investors and shareholders because there is higher likelihood of success when there are no other drugs. That's particularly true in rare and orphan diseases. So we decided to focus on that.

PE: *What were the challenges and advantages of building a company that avoids early stage R&D? Did setting up a different type of pharma company lead to any obstacles?*

WILEY: We made that strategic choice quite deliberately. We decided early on that we didn't want to be a discovery company. As you know, in the pharmaceutical industry, the average cost of developing drugs keeps increasing; it's now certainly north of a billion dollars. That doesn't mean it costs a billion to develop a product, but it factors in the very high failure rate. Second is the length of time that it takes to develop a drug, an average 14 years to get a drug from discovery to the market. We didn't want to take that path, because that's incredibly long, incredibly capitally intensive, and very hard for shareholders to see a return on their investment in a timeframe that would be appropriate for particularly accessing public markets.

We felt that because there was an opportunity to build a great team with a commercial focus, that would be our core and our niche, and we would be able to identify those assets in Europe and successfully commercialize them and bring them to patients in need. And we've been very successful in doing that from a standing start. In December 2016, we in-licensed Lojuxta, which we leveraged to then build out our commercial infrastructure across Europe and across the Middle East, which constitute the main part of our licensed territories.

When you dig into the numbers, there's actually 10 times less capital to support European companies developing these assets. We felt that created an opportunity

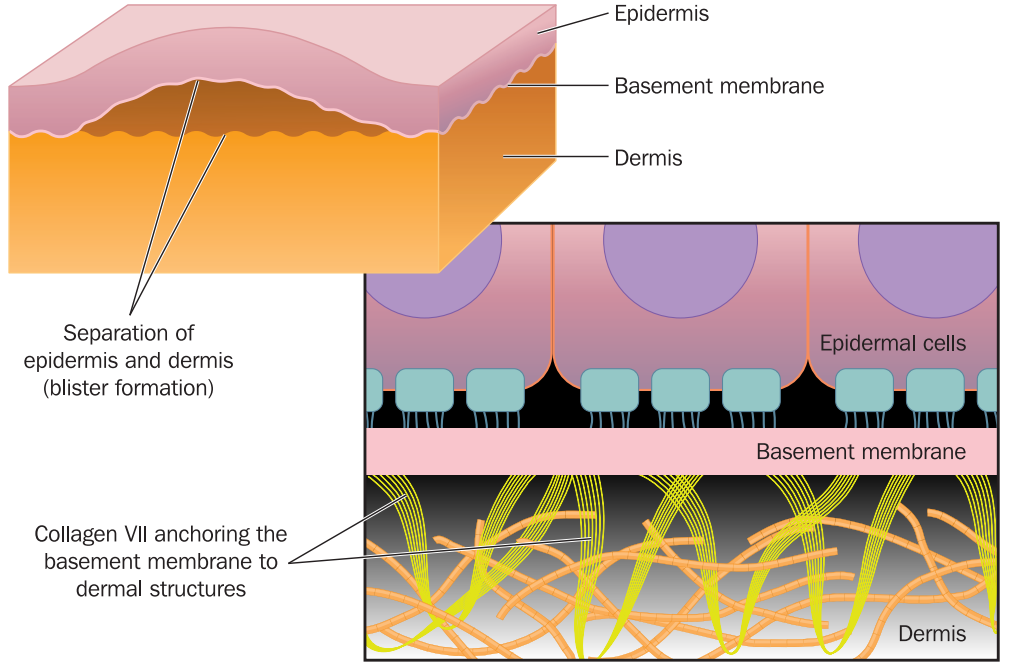
Under our stewardship, we've grown the product very significantly. Most recently, we in licensed a gene therapy platform for the treatment of a rare disease called epidermolysis bullosa (EB), which gives us a high-tech pipeline as a platform and potential to create a number of further products. What we're looking to do now is to add further commercial-stage assets down the channel that we've created. We're truly a billable company at this point because we've built our commercial infrastructure;

FAST FOCUS

» Before joining Amryt Pharma, Joe Wiley opened and led Sofinnova Ventures' European office, was medical director at Astellas Pharma, and held investment roles at Spirit Capital, Inventages Venture Capital, and Aberdeen Asset Management (UK).

» While with Astellas, Wiley liaised with the marketing team and was involved in the launch of a number of specialty pharmaceutical products.

» Wiley trained in general medicine at Trinity College Dublin, specializing in neurology. He is a Member of the Royal College of Physicians of Ireland and has an MBA from INSEAD.



A drawing of blister formation in skin diseases such as epidermolysis bullosa, where the epidermis separates from the basement membrane and dermis.

we've got feet on the ground across Europe, across the Middle East, and we're headquartered in the UK.

Our topical wound care product for EB, AP101, is in a Phase III trial that is being conducted in Europe, South America, Asia, and Australia. It is the largest global Phase III trial ever conducted in EB (a group of inherited connective tissue diseases that cause blisters in the skin and mucosal membranes). We anticipate filing an [investigational new drug application] with the FDA to enable the opening of US trial sites in Q3 2018.

AP101 is a topical product that we gained from acquiring a German business and works by accelerating wound healing. EB is a dreadful disease. It's a defect in the gene that codes for the protein that holds your skin together. Children born with this disease are called Butterfly Children because their skin is likened to the fragility of a butterfly's wings. Even pulling on socks can cause the skin to break. And there's nothing to treat the disease; no drug has ever been approved.

Our product has shown promise in a proof-of-concept study in EB and has successfully completed three positive Phase III studies in broader indications, which in fact led to the approval of that product by the EMA in partial thickness wounds in adults. This is a slightly unusual situation in that the product is actually approved in Europe, but has a very broad label. Our vision and our *raison d'etre* is, however, to focus on the rare disease with the really high unmet need, such as treating patients with the more severe forms of EB, both children and adults. While it's a very large market opportunity for us, it is also feasible to reach as a small company.

PE: *If we could touch on the in-licensing of Lojuxta, how important was that for Amryt's early development?*

WILEY: As I mentioned, from the outset, we wanted to be a commercial business and Lojuxta has enabled that. This is a product that we were able to in-license, which had been launched in Europe in 2013. We saw an opportunity to grow that product, and build out our commercial infrastructure on the strength of that deal. It transformed us from a development stage business to a commercial business overnight. And, importantly, because of how that deal was structured, it allowed us to build out that commercial infrastructure through investing on the back of revenues generated from this product. The revenues of the product actually paid for the roll-out of our commercial infrastructure.

One of the advantages of fo-

cusing on rare and orphan diseases with high unmet need is that the small number of patients affected by the disease means there's usually small numbers of physicians in specialist centers treating those patients; therefore, a commensurately small commercial footprint is sufficient to commercialize the products in this area. That works for us as a small company. Clearly, we can't launch a primary-care drug where we would have to visit every general practitioner in every country. But in rare and orphan diseases, we can. We've signed five new distribution agreements in the last few months, with key partners in the territories for which we have the license.

PE: *Can you talk about how you assembled the first management team and the importance of all their experience in getting the company off the ground?*

WILEY: I was very fortunate in that, from the very outset, I was working with a tremendous partner and CFO, Rory Nealon. Rory and I have very complementary skill sets. We're both very transactional. In his previous career, I believe Rory did 12 acquisitions in 14 years at Trinity Biotech, which was another business that grew through acquisition. And for many years, I worked in the venture capital industry, investing in many companies in this area. We were also blessed to have Harry Stratford on board from the early stages, advising us on how he built his company, Shire, and later ProStrakan, from the ground up. We brought in Mark Sumeray, who has vast experience, fairly soon after we had done our first two acquisitions. David Allmond joined us as chief commercial officer, from Aegerion, and he has been very successful at building out our commercial team.

Somebody said to me that, combined, we have 170 years of experience in the industry. Across the leadership team, we have a great breadth and depth of experience across multiple therapeutic areas and geographies across the globe.

PE: *What is your vision for the next three to five years? Are you concerned that you can keep a track on all that expertise as you grow?*

WILEY: A lot of people say that we've built a company that looks and feels and operates like a much larger company. That's a reflection of that senior team and it flows through the rest of the business. We have a manufacturing facility, we've put the quality systems in place, we have the necessary infrastructure. We are able to leverage that now into a growth trajectory. Our core strategy is to launch our product that's in Phase III ourselves in our core markets. We see our core markets as Europe and the US, so we'll build out our commercial infrastructure in the US on the success of our EB product and we'll launch that in the US.

> [Lojuxta] transformed us from a development stage business to a commercial business overnight

In the meantime, we would like to bring more products into our existing infrastructure, and leverage the infrastructure we've put in place, because then we will take advantage of economies of scale. Our strategy is to build and create a sustainable, European-based business for our shareholders and the stakeholders that will grow into the future.

PE: *Talking of Europe brings us to the obligatory question about Brexit. What are your views on that, with Europe being a major part of your plans and your current operation?*

WILEY: So far, I would say that the impact has been minimal. Obviously, there's a concern, for sure. We're a UK plc operating in a global environment with a pan-European commercial business. So how that separation will work out is of concern.

There are two points, specifically. One is access to talent. We really hope that there will still be ongoing access to the top talent, because right now we are able to access that across Europe. The second area of concern for us is the unknown, specifically, what will happen regarding the regulatory environment? How that will look post-Brexit. Currently, EMA is in the process of transitioning from a London base to an Amsterdam base.

In rare and orphan diseases, products are approved through the centralized process, which means that you have a seamless regulatory process to get products approved across the whole European Union. What Brexit will mean for that remains to be seen. We hope and anticipate that the UK will remain in harmony with this process in the future. PE

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Prescription Price Policy: Targets for Legislative Lift

There is no magic bullet that will dramatically impact drug pricing to everybody's liking—patients, industry, and government. But a stepwise approach involving a series of changes, including taking advantage of the next midterm elections, could point the path toward a solution

Recently, my mom called me with a legitimate complaint affecting her everyday life: the medicine she needs to treat a chronic, yet common condition is too expensive, and the amount she ends up paying for each refill depends on how the pharmacist dispenses the prescription. The frustration and anger was palpable and directed at everybody: the pharmacist, her doctor, the drug company, her insurance company, Congress, and the President. Had she known about pharmacy benefit managers (PBMs), she would have blamed them, too.

The pharmaceutical industry, PBMs, and insurers have vacillated between justifying high costs due to innovation (noting their own programs to lower prices in the process) and pointing fingers at each other in search for the true culprit deserving the blame. While none of the finger-pointing is productive, all of these points have elements of truth.

FDA Commissioner Scott Gottlieb has repeatedly voiced his frustration with increasing drug prices and the lack of competition. And consumer surveys have repeatedly pointed out that pricing is the number one priority of consumers across the US. Congress has channeled the voice of voters when decrying the fact that the US government invests more than $30 billion a year in the National Institutes of Health, yet patients continue to face high drug prices. Meanwhile, in response, President Trump laid out his blueprint for lowering drug prices (see page 8) last month—a long list of policy ideas without specific timelines of implementation.

To begin to address this multifactorial problem, Congress and regulators believe they would have to enact a range of system-wide policy reforms that will spur incentives for both innovation and price competition. As the November midterm elections approach, Congress has a limited window—between now and the end of July—in which to pass legislation. Once the window closes, the next real opportunity for legislation won't arise until a year from now. For complex solutions to work, they require thorough analysis, wise implementation, careful evaluation, and subsequent evolution. Little of this seems likely, but progress is often made when policymakers start with the "gettable good" instead of the "ephemeral perfect."

Why eye midterm elections?

Elections can serve as forcing functions. They may sharpen the focus of politicians as they are eying potential accomplishments on which to run, making the spring and summer before an election a potentially productive legislative period. If no legislation is passed before the election, the results of the Midterms, no matter which direction they go, are likely not going to provide clear outcomes any time soon. Yet, Congress could enact important limited reforms that converge over time to bring about regulatory, market, and cultural shifts required to permanently affect drug pricing.

Getting started on the good is better than waiting indefinitely for the perfect. What limited actions could be the first steps on the long road to lowering drug prices? Two areas of opportunity are generics and price transparency.

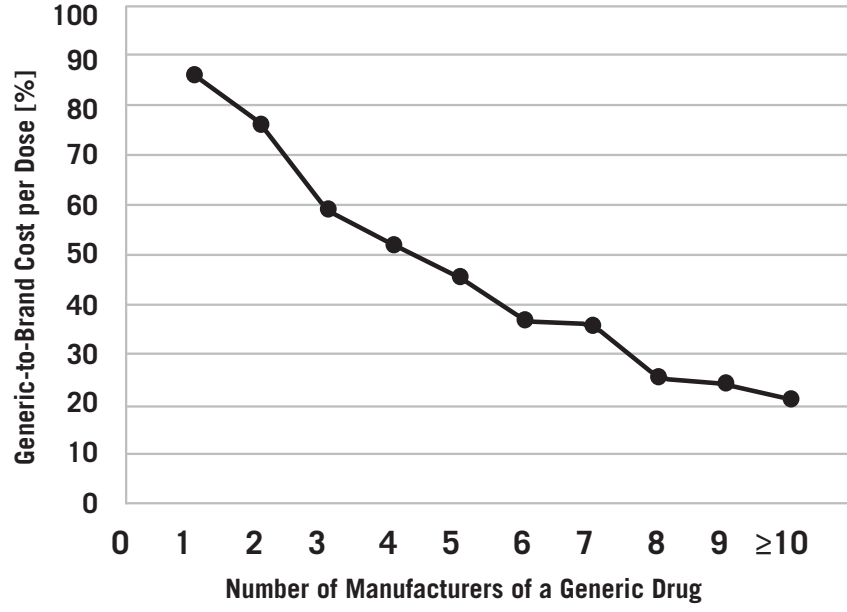
Increased generic competition after patent expiration

At the end of their patent life, every brand-name drug could, in theory, face competition from one or more generic equivalents. Bringing generics to market quickly would increase competition and decrease prices. In fact, available low-cost generics may have generated more than $1.6 trillion in US healthcare savings over the past decade. But as the chart on the facing page illustrates, we need at least three generics for each brand-name drug to significantly impact prices.

The challenges: (1) Pharma companies are incentivized to avoid competition from generics and place barriers to their entry; (2) Complex generics and biosimilars face cultural resistance from large parts of the patient population, who prefer brand-name drugs.

• Vigorous competition lowers prices. In the case of drugs, competition ought to increase once patent protections have lapsed. However, some brand-name drugmakers have gamed the system and prevented generics from entering the market. For example, for a generic to be approved, the FDA requires studies showing that it achieves the same blood levels at a particular dosage as the brand-name drug. Yet, as Gottlieb pointed out in a recent interview, generic companies frequently cannot get access to doses of a branded company's drug, even if they purchase the drug as a regular customer. In other cases, companies have claimed intellectual property on package slips, or moved production plants to a new location. These actions block generics from the market place and keep prices high even after patent protection has ended.

• Cultural barriers remain for uptake of biosimilars. Biologic drugs, which are complex large-molecule drugs grown from tissue, comprise more than 25% of prescription drug spending, yet as of December 2017, there were only nine biosimilars on the US market. In contrast, Europe has approved 33. What's more, the available biosimilars have not been granted "interchangeable" status by the FDA, preventing pharmacists from substituting brand-name drugs with biosimilars when filling prescriptions. The underlying cause for this difference is most likely two-fold: a lack of both trust and incentive. Culturally, there has been a widespread belief that, because biosimilars are slightly different, they are not going to have the same positive treatment effect as their brand-name equivalents. Furthermore, there's no incentive for critically ill patients to enter a clinical trial for a biosimilar (or any generic), if the brand-name drug is widely available and works. With these cultural and regulatory hurdles, it's not always economically attractive to invest in biosimilars.



Source: C.V. Dave, A. Hartzema, A. Kesselheim (2017). Prices of Generic Drugs Associated with Numbers of Manufacturers. *N Engl J Med, 377, 2597-2598.*

To lower drug prices significantly, at least three generics for each innovator drug are needed.

The solutions: The FDA has some ability to affect drug pricing through increased competition and address regulatory loopholes that can be used to subvert the system. Congress can provide legislation to drive this more quickly. There is also an opportunity to learn from how Europe has tackled the biosimilars issue and make it culturally and economically attractive to increase the number of biosimilars on the market.

Congress could enact important limited reforms that converge over time to bring about regulatory, market, and cultural shifts required to permanently affect drug pricing

• The FDA could require companies to provide dose details and prevent brand-name companies from self-imposing Risk Evaluation and Mitigation Strategies (REMS) restrictions. According to Gottlieb, the FDA has already put forward a portfolio with

Only a collection of measures will eventually bring down drug prices and create a large enough market incentive for drugmakers to re-price their products. This will require some amount of experimentation

measures that will impact market competition. Congressional support would help progress this.

• From a regulatory perspective, we need instructions on how biosimilars can gain "interchangeable" status in the US and address the issue of large-scale clinical trials for drugs whose brand-name equivalents already exist. A final FDA guidance on how to reach interchangeable status is currently in the works and expected to be completed in 2019. In addition, the path to approval could be smoothed and accelerated by implementing regulatory harmonization for biosimilars across countries, or limit the scope of clinical trials in some other form, as is done for a myriad other substances, including biodefense molecules. Congress can promote these actions by specifically authorizing and funding them.

Transparency and reimbursement

Value-based and outcomes-based pricing has been proposed to make expensive, innovative drugs more affordable. Furthermore, increased transparency on drug pricing, including rebates, would allow payers to optimize negotiation and hold manufacturers and providers accountable for the prices they charge. It would also help reattribute incurred expenses to the right link in the provider chain.

The challenges: (1) To bring down the cost of treatments with big price tags, we need to create fair and appropriate reimbursement models that maximize treatment benefits per unit cost. (2) Drug pricing transparency will require manufacturers, PBMs, and providers to release detailed pricing information.

The solutions: Tying prescription drug pricing to the value the treatment brings to patients may help price drugs more appropriately while providing the returns that incentivize shareholder investments toward innovative drugs. In addition, states may implement laws that require manufacturers to report cost information, price increases, and patient assistance programs.

• The Centers for Medicare & Medicaid Services (CMS) is currently developing new payment models to curb the cost of highly-priced breakthrough medical treatments. In one considered model, patients would pay depending on treatment success rates for certain conditions, charging extra for a drug that treats one condition more effectively than another. While CMS doesn't negotiate prices or purchase drugs, it can set ground rules for the care companies and state Medicaid agencies that are engaged in price negotiations. Again, these models can be championed by legislation.

• Fair reimbursement models and pricing transparency could be achieved by incremental changes that piggyback on other reforms. For example, every three to four years we see reforms to Medicare. Future reforms may provide an opportunity for piloting proposed changes in individual states. If not championed voluntarily by manufacturers, other states could follow Oregon's footsteps, whose new drug price transparency law requires manufacturers to report certain pricing and patient assistance information for each prescription drug that costs $100 or more for a 30-day supply or for treatments lasting less than a month.

What's to come?

Solving my mom's problem is not going to happen with one policy change. There is no single measure that, with the stroke of a pen, will dramatically affect drug pricing. Only a collection of measures will eventually bring down drug prices and create a large enough market incentive for drugmakers to re-price their healthcare products. This will require some amount of experimentation. Anyone claiming to know exactly how to solve this multifactorial problem is getting ahead of the facts.

However, given the importance of the problem and the limited time to effect significant change before the midterm elections, it makes sense to start with goals that are attainable before August this year and aim for better, if not perfect, solutions next year. To solve the drug pricing problem while maintaining innovation will require a series of market, political, regulatory, and cultural changes that converge on a best solution. My mom, like all Americans, will be best served if industry, government, and patient stakeholders work together toward a solution that takes advantage of the legislative windows before and after the midterm elections. PE

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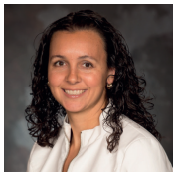
Leveraging Lab Data in Advent of Personalized Marketing

Laboratory testing has become a critical access point for sales teams in the age of personalized medicine

In the past decade, personalized medicine has emerged on the healthcare scene—slowly, at first, then picking up speed and momentum like a snowball rolling downhill. Increasingly, it's no longer enough to deliver every patient who has asthma, or arthritis, or cancer, the same blanket treatment regimen of care and prescriptions. Rather, personalized medicine is about treating the particular patient in front of you for his or her particular illness and how it is manifesting—this means different cocktails of drugs or different biologics, such as immunotherapy vaccines; depending on genetic mutations; biomarkers; stage of disease, and more.

And while personalized medicine has opened up a world of treatment options for patients that have extended and improved the quality of life in many cases, this customized approach has made the job of pharmaceutical sales and marketing teams much more difficult. In a world where blanket treatment plans are no longer appropriate, blanket marketing and sales strategies won't work either.



MELISSA LEONHAUSER
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Lab data takes center stage

Another change in this new arena of personalized medicine is the value and the role of laboratory data. Lab testing is, of course, something clinicians have done for many generations as part of the diagnosis process. As personalized medicine has advanced, however, so has lab testing. Now, lab data can show not only a positive or negative result, but can also reveal each patient's genetic mutations and biomarkers, pinpointing exactly which therapy will work based on the patient's specific genetic makeup and test results.

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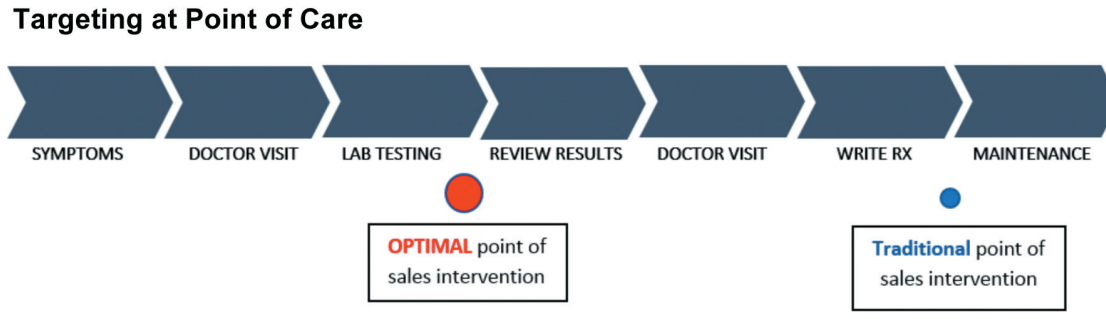
It was only in October of last year, for example, that researchers discovered 65 previously unknown gene mutations that contribute to the risk of developing breast cancer. As researchers continue to learn more about the underlying causes of disease, lab testing will need to keep up with the curve to aide in diagnoses, and pharmaceutical and biotech companies will need to meet demand for increasingly tailored products that treat ever more specific mutations and variations of disease. In this way, medical research, lab testing, and pharma are interdependent. And pharma sales teams must be able to show value as these new medications are being developed.

Timing is everything

Traditionally, pharma companies deploy sales teams and develop messaging based on historical claims data and previous prescription information. They use this data to determine which physicians have previously treated patients in a company's target market, and plan sales strategies and deployment accordingly. In a world of personalized medicine, however, the old ways fall short.

Looking at prescription data tells a pharma sales team where the patient has already been, and conditions a physician has already treated for. However, with lab data, drug manufacturers can gain insight earlier in the patient journey—at the time of diagnosis—and tailor sales messaging and deployment based on what is going to happen next. A lab test that shows a new diabetes or hepatitis C diagnosis, for example, allows the pharma company to reach physicians before they've made their initial prescribing decisions. Operating on insight, rather than hindsight, can benefit the patient as well as the drugmaker by getting the patient on the medicine that is right for their specific circumstance.

In addition to new diagnoses, lab data can also often show when a patient is not reacting well to a particular drug, or if a condition is uncontrolled or progressing. For example, a patient taking one type of statin for high cholesterol may show elevated liver enzymes, prompting a physician to recommend altering the dose or switching to a



different class of medications. Similarly, multiple myeloma patients are monitored using lab tests. An increase in or a returning M-spike—a measure of monoclonal protein—would indicate that treatment is not working or that the disease is progressing. The patient's doctor would likely consider changing therapies. If pharma sales teams have the same information, they can be present for and educate the physician before the moment of decision. It's the unique ability of lab data to provide this insight earlier in the patient journey that allows sales teams to make proactive, rather than reactive, decisions (see chart).

Optimize resources and market share

Using lab data in a sales strategy is also a good way to prevent wasted resources. For example, if a drug is intended to treat only those patients who fit a particular profile, the most logical strategy from a business perspective is to focus the time and resources of the sales team on reaching only those patients. A keen marketing strategy in any industry is not to cast a broader net, but to cast the net in the right place from the start.

Access to timely lab data insights can also help sales teams in both gaining and retaining market share. When a company launches a new drug, knowing which physicians (and, therefore, which patients) to target based on lab data allows manufacturers to ensure their new product reaches the target population as soon as it hits the market. Similarly, using lab data to target physicians whose patients might benefit from an adjusted dose could help retain market share and prevent clinicians from unnecessarily switching to a competitor product.

In rare diseases in particular—where the target population is 500 patients as opposed to five million—overcoming the challenges of reaching the right audience, at the right time, with the right medication is critical for the lifecycle of the drug and for the lives of the patients with these often serious conditions. Hence, in the rare disease space, lab data becomes more important than ever.

Aligning priorities

Lab data, used to its full potential, can point pharma sales teams to the patients that are best served by their brand, and to the treating physicians. No longer must manufacturers rely on data from the past to predict the future; now, sales interventions can happen right at the point of care, before treatment decisions are made. Whether a patient is newly diagnosed, relapsing, or their condition is poorly managed; whether they are on first-line therapy or their disease is progressing; lab data is what physicians are using to make real-time care decisions. Sales teams should be looking at the same information.

> A lab test that shows a new diabetes or hepatitis C diagnosis, for example, allows the pharma company to reach physicians before they've made their initial prescribing decisions

As the future of personalized medicine continues to take shape before our eyes, it's crucial that sales and marketing strategies evolve at the same pace. Lab data is the missing evolutionary link that will get us there—one patient at a time. PE

User-Friendly Urgency

From AI to Alexa, experts in specialty pharma ponder the possibilities for high tech and the patient journey

Consultants are calling it the life sciences industrialization. Others are referring to it as a pharmaceutical renaissance or revolution. No matter what you label it, the pharma industry is going through a transition and those who manufacture—or work with specialty pharmaceuticals—are feeling the pain that usually comes before a big breakthrough.

During Asembia's Specialty Pharmacy Summit in Las Vegas last month, it was very clear that leaders realize the pharma industry needs an overhaul when it comes to certain areas of the business; but they were also very blunt about the reality of making some of those changes happen.

One such area was drug pricing. As one executive put it, "We have hit the breaking point and passed it … the problem is that we don't have a fix." The reason for that, as it was explained, is that the current US healthcare system is fundamentally not set up to sustain one-time, high-cost treatments that have the potential to cure a disease.

In some cases, the science and technology has outpaced the healthcare system. Take the role of artificial intelligence (AI), robotics, and technology, particularly as it relates to patient adherence, as an example. Cory Kidd, founder and CEO of Catalia Health, showed off Mabu, an intelligent, socially interactive robot whose conversations are tailored to each patient that she works with. Mabu is designed to be friendly and approachable, can make eye contact while carrying on a conversation, and is capable of simple gestures with her head and eyes. She holds a tablet-like screen to convey additional information during conversations.

Mabu was first introduced in 2015 after more than a decade of development. Yet, the robot, which Kidd says has shown in testing with patients the potential to transform drug adherence, is not widely available. One of the roadblocks comes down to a simple question, he admitted: Who is going to pay for it?

Kidd says when his company meets with executives, the first question at the end of almost every presentation is, "When does your patent expire?" Catalia Health is currently in the process of working with an insurance company to possibly include Mabu in their risk-based contracting talks.

With popular AI technologies already becoming mainstream in other areas of a patient's life, such as the use of Amazon's Alexa, the pharma industry must step outside of its comfort zone and start treating patients also as consumers. Albert Thigpen, president and chief operating officer of CastiaRx, believes that pharma needs to look to other industries such as hospitality and banking to glean ideas on being more user-friendly. First, is the integration of services.

"We can fill your MS drug, but you need to go somewhere else to get your drugs for depression filled," Thigpen cited as an example of pharma's lack of consumer product integration and how that trickles down to impact everything from patient adherence to rising healthcare costs.

A simple in theory but still futuristic scenario, Thigpen proposed, what if every prescription automatically came with a programmed Alexa? Think about this: Alexa could remind people every morning to take their medication, could keep track of their doctor's appointments, could alert patients when their prescriptions are getting low—it could provide a whole suite of services tailored to the individual and their treatment program.

Admittedly, a great idea on paper, but how would it be implemented? How do HIPAA laws play into the situation if, for example, other people are within ear shot of Alexa? Who would pay for it? Who would program it and what information would be programmed? What if the patient has more than one health concern that spans multiple doctors and pharmacies?

These questions are ones that Thigpen said need to start being seriously addressed and figured out by pharma, because as consumers start paying more for their healthcare out of pocket, as seen with high deductible plans, they are going to want the same consumer benefits they see in other areas of their life.

So, how do all of these issues get solved—and the system move forward? "That's the $64,000 question," is how many speakers at the Asembia conference answered a version of that query when asked during Q&A at an educational session. But during a more serious conversation about the topic at the general session, which brought together a number of top thought leaders, one powerhouse trifecta kept coming up.

"J.P. Morgan, Amazon, and Berkshire Hathaway are going to get together and figure out how to buy healthcare," said Kent Rogers, senior vice president of industry relations for OptumRx. "That may be the catalyst that will force change." PE

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