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SEPTEMBER 2017
COMMERCIAL INSIGHTS FOR THE C-SUITE
VOLUME 37, NUMBER 9

Leading FROM THE Front

Cynthia Schwalm, President of North America, Ipsen

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FOR MY FIRST EDITORIAL just a few months ago, I wrote about the experts on the *Pharmaceutical Executive* Editorial Advisory Board, and how fortunate to be able to rely on them as I learned this side of drug development. Now I'd like to take some time to thank you, the readers. We have sent two surveys recently to our readership, one through the SurveyMonkey platform, and one through a third-party provider. They were both geared to better understand your needs, your interests, and how you view *Pharmaceutical Executive*. For everyone who took the time from their busy day to respond, thank you. Please know that we take your opinions seriously.

LISA HENDERSON
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This is what we've learned about you. The majority of you read the cover story of each issue, followed by news, and executive interviews. Globally, the regions you are most interested in learning more about are EU minus UK, UK, Japan, and China. The majority of you—41.8%—have been reading *Pharmaceutical Executive* for one to five years, followed by 21.7% at six to 10 years. Further, 26% of you are in corporate management, followed by R&D, QA/QC management, sales management, and medical/clinical management. A combined 64.5% of you have been in the industry for 11 to 30 years.

Our mission is to give you the information you want, in the format you prefer, with the best analysis, writing, and thought leadership that you have come to expect from *Pharmaceutical Executive*. Along with the information you want, we also want to make sure we provide you with the "you don't know what you don't know until you know it" moment. As journalists, we live for that. When we talk to executives, attend a conference, or see a trend coalescing, we get excited and have to tackle it.

The editorial team currently is planning articles for the last quarter, and mapping out next year. To be sure, next year you will be reading a lot about health outcomes and real-world evidence. That topic, though around for years, is really coming into its own because of technology, and the overall basis for pricing, reimbursement, and value-based contracting.

Traditionally, *Pharmaceutical Executive* has a US bent, but drug development is globalized and that is a reality. Our country reports, which are a mainstay section in every issue, will bring you insights from countries such as Austria, Canada, Brazil, Japan, and Switzerland in the near future. We will also be featuring executives from Japan and the EU to gain their global views.

Pharma's reputation

Another topic we are going to feature early next year is the reputation of the pharmaceutical industry. I've said it many times and in many ways. A few rotten apples don't spoil the bunch. The general public doesn't understand how expensive drug development is. Pharma has the smartest and most even-keeled people I've ever met, and all of them believe they are in it to truly help people. We all have to live the realities of business, but the good stories about the industry just don't readily float to the top. I may be preaching to the choir here, but we really do want to help industry show its better half. And that's you, the readers.

I live in New Jersey. I regularly meet people that are connected to pharma—at the gym, local hangouts, parents of my children's friends. It literally happens all the time. On my daily commute, in all likelihood, of all the people I cut off in traffic, one in five are affiliated with pharma. (Kidding, I'm a great driver.)

But my point is, in this innovative industry, which employs the best and the brightest, and keeps a lot of local and global economies going, it shouldn't get such the bad rap.

Rome wasn't built in a day. As one EAB member recently pointed out to me, people used to spit on US soldiers coming back from Vietnam, and now people offer to buy soldiers coffee or clap as they walk through the airport.

But changing that rep does start with people such as Merck CEO Ken Frazier, who recently stood up for his principles on a very public stage. It starts with companies such as Mylan, which addressed its problems and moves forward for positive change. It starts with sharing stories and learning from others in honest dialogue.

Other topics in the pipeline for next year include emerging biopharma, which builds on an eBook of the same name available this month; where pharma talent is coming from and where they are going to; compliance challenges and specialty pharma, in addition to our anchor reports including the annual industry forecast, the Pharma 50, emerging pharma leaders, and the pipeline report. Also this month, we introduce our new tagline: Commercial Insights for the C-Suite, and we look forward to supporting your endeavors in pharma.

Pharmaceutical Executive

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2011 Neal Award Winner for "Best Commentary"

ANDA Arbitrage & the New ANDA Holder Program Fee Under GDUFA II

By Kurt R. Karst –

The second iteration of the Generic Drug User Fee Amendments ("GDUFA II), which is contained in Title III of the FDA Reauthorization Act of 2017 ("FDARA") (S. 934 and H.R. 2430) currently pending in Congress, will, if enacted, significantly change the current user fee system and structure that have been in place the past five fiscal years under GDUFA I. Not only will FDA collect a greater amount of user fee funding each year ($493.6 million annually adjusted for inflation), but one fee type will be eliminated (i.e. the Prior Approval Supplement fee), while others fees would be modified (e.g. a new Finished Dosage Form ("FDF") facility fee for Contract Manufacturing Organizations ("CMO")). GDUFA II will also introduce a new fee type – the ANDA Holder Program Fee – that will account for 35% of annual fee funding. The annual ANDA Holder Program Fee, along with the annual CMO FDF facility fee, are proposed as "small business considerations," according to FDA.

Under the GDUFA II fee structure, the ANDA Holder Program Fee is set up as follows: a firm and its affiliates will pay one program fee each fiscal year commensurate with the number of approved ANDAs (both active and discontinued ANDAs) that the firm and its affiliates collectively own. The program fee to be paid each year depends on the number of ANDAs owned. Firms will not pay a per-ANDA fee. Instead, the program fee will be split into three tiers that represent different positions held by the firms and their affiliates within the market. Specifically, FDARA would amend the FDC Act to add Section § 744B(b)(2)(E) to state:

(i) Thirty-five percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For purposes of this subparagraph, if a person has affiliates, a single program fee shall be assessed with respect to that person, including its affiliates, and may be paid by that person or any one of its affiliates. The Secretary shall determine the fees as follows:

(I) If a person (including its affiliates) owns at least one but not more than 5 approved [ANDAs] on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a small business generic drug applicant program fee equal to one-tenth of the large size operation generic drug applicant program fee.

(II) If a person (including its affiliates) owns at least 6 but not more than 19 approved [ANDAs] on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

(III) If a person (including its affiliates) owns 20 or more approved [ANDAs] on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large size operation generic drug applicant program fee.

(ii) For purposes of this subparagraph, an [ANDA] shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such [ANDA] by April 1 of the previous fiscal year.

The statute (FDC Act 744B(g)(5)) would also be amended to include certain penalties for failure to pay the new ANDA Holder Program Fee:

(A) IN GENERAL. — A person who fails to pay a fee as required under subsection (a)(5) by the date that is 20 calendar days after the due date, as specified in subparagraph (D) of such subsection, shall be subject to the following:

(i) The Secretary shall place the person on a publicly available arrears list.

(ii) Any abbreviated new drug application submitted by the generic drug applicant or an affiliate of such applicant shall not be received, within the meaning of section 505(j)(5)(A).

(iii) All drugs marketed pursuant to any abbreviated new drug application held by such applicant or an affiliate of such applicant shall be deemed misbranded under section 502(aa).

(B) APPLICATION OF PENALTIES. — The penalties under subparagraph (A) shall apply until the fee required under subsection (a)(5) is paid.

The ANDA fee schedule for Fiscal Year 2018 was just published by FDA on August 28th. For a small or medium sized firm, the annual ANDA Holder Program Fee is a decent amount of cash for some companies to lay out. And for those companies with a modest number of ANDAs, they'll be laying out cash for drug products that they don't currently market, because their ANDAs are in stasis, as identified in the Discontinued Drug Product List section of the Orange Book.

FDA will collect under the ANDA Holder Program Fee initiative as follows - companies in the small tier (1-5 ANDAs) will pay $159,079; companies in the medium tier (6-19 ANDAs) will pay $636,317; and companies in the large tier (> 20 ANDAs) will pay $1,590,792. For a small tier company this can be a dramatic impact in their ability to even retain the assets they worked so hard to obtain!

A new venture might offer some user fee relief and a solution to companies that have discontinued ANDAs for drug products not currently marketed. A company called ANDA Repository, LLC. (info@andarepository.com) is offering what we can only characterize as "ANDA arbitrage." Imagine, if you will, a parking lot. The owner of a car that is not being used on a daily basis needs a parking space for that car. In exchange for that parking space (and an annual fee) the car's owner transfers title of the automobile to the parking lot owner. The old owner of the car can, with appropriate notice, take back ownership when he decides that he wants to use the automobile again. Provided the parking lot owner has enough cars, this can be a beneficial venture for all of the parties involved.

In the imagery above, the automobile owner is an ANDA sponsor, and the parking lot owner is ANDA Repository, LLC. **When ANDA Repository, LLC. obtains title to 20 or more ANDAs, then the company will be identified as a "large size operation" and will pay a full generic drug applicant program fee regardless of how many additional ANDAs are owned.** In exchange for its services, ANDA Repository, LLC. will charge an ANDA sponsor an annual fee, which would be **significantly less than the ANDA Holder Program Fee** such ANDA sponsor would otherwise pay as a small or medium size operation. Not a bad idea! **Fees are due by October 1st** so please contact us at the email or phone below for more information.

Leading With Patients in Mind

Michelle Maskaly, Senior Editor

Former critical care nurse Cynthia Schwalm, now executive vice president and president of North American commercial operations for Ipsen, speaks with *Pharm Exec* about her formula for successful team building internally—and the importance today of stepping outside of the C-suite and into the world of the patient.

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Cover Photo: John Halpern

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Amid political and economic turmoil in recent years, and resulting shortcomings in healthcare budget, medical infrastructure, and drug access, the Ukraine government is championing the introduction of an unprecedented set of reforms, prompting a significant evolution in the country's healthcare system.

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Emerging Leaders

In its annual feature, *Pharm Exec* profiles a selection of rising pharma managers who are poised to help chart the industry's path forward in a new and more demanding business future.

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FDA, Industry Prepare for New User Fee Initiatives

Drug pricing, right-to-try, opioids, and OTC improvements still on legislative agenda

The Senate approved critical legislation early last month reauthorizing important five-year user fee programs that fund FDA review operations, just in time to avoid major agency disruptions. The bill was nearly derailed by contentious Senate debate over revising the Affordable Care Act (ACA), but once the wrangling over Obamacare fizzled out, the Senate quickly adopted the FDA Reauthorization Act (FDARA) that the House had approved in early July so it could be sent directly to the White House without further Congressional negotiations.

By enacting new fee programs for drugs, biologics, generic drugs, medical devices, and biosimilars before they expired on Sept. 30, Congress avoided FDA having to send layoff notices to more than 3,000 staffers supported by industry payments. The Trump administration had created uncertainty by demanding that industry pay much higher fees to fully support FDA review activities. But agency officials had been negotiating with industry representatives and other stakeholders for more than two years on user fee goals and program revisions, making it impossible to revise the agreed-on packages so late in the game. Fees to support FDA oversight of drugs and medical products, moreover, are designed to be additive to appropriated public funding of the agency, a stance that reflects strong convictions that fees should be designed to limit industry influence over the drug regulatory process.

To move the user fee package forward quickly, the Senate adopted a separate "right-to-try" bill (see sidebar on facing page), even though FDARA includes language to broaden eligibility to clinical trials for very ill individuals. The Senate also approved separate measures backing wider use of patient-reported data in the drug approval process and standards for recording patient opioid use in medical records.

'Clean' bill

FDARA, thus, has relatively few policy riders, due both to the tight time-frame for enactment and to Congressional approval of the extensive 21st Century Cures Act last December. FDARA largely builds on existing FDA programs for accelerating approval of new and generic drugs. There are added incentives for developing pediatric cancer therapies and medical devices for children. One provision aims to limit orphan drug exclusivity awards for too-similar therapies, and another requires sponsors to conduct studies on new tropical disease treatments to qualify for relevant priority review vouchers. There's language to deter import of counterfeit medicines and several measures designed to streamline development of innovative medical devices.

Efforts to lower prescription drug prices ended up focusing on strategies for speeding the development and marketing of generics. FDARA establishes a priority review track for "competitive generic therapies" and an accelerated development initiative offering more advisory meetings and fast facility inspections for certain products. Brand manufacturers have to update information on products withdrawn from the market as part of an initiative for expanding information on drugs with limited competition.

The new five-year program funded by the Prescription Drug User Fee Act (PDUFA VI) restructures fees to collect more revenues from product fees, as opposed to applications, while continuing initiatives to accelerate the testing and development of new therapies. As the drug user fee program has reduced review times by increasing first cycle approvals, FDA and sponsors now are focusing on efforts to streamline the mushrooming demand for development-phase meetings, boost resources for the breakthrough drug program, advance the review process for rare disease treatments, and bolster support for combination products. In addition to added provisions for incorporating the "patient voice" into regulatory decision-making, there's continued emphasis on advancing model-informed drug development, clarifying standards for biomarker qualification, and enhancing policies for using real-world evidence in regulatory

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decisions. PDUFA VI also increases resources to improve FDA's electronic submission process and enhance IT initiatives, and to improve systems for hiring and retaining review staff.

The second version of the Generic Drug User Fee Amendments (GDUFA II) also changes its fee structure and operations, largely to accommodate the many small generic drugmakers with relatively few approved products, through lower application fees offset by higher program fees based on approved products and facilities. Stakeholders acknowledge that GDUFA has helped FDA improve the timeliness and predictability of generic drug application reviews and has reduced its formidable review backlog, and the revised program aims to continue those gains. Similarly, FDA's biosimilar fee program (BSUFA II) bolsters annual program fees to support agency advisory efforts during product development.

More to come

A number of key issues failed to make it into FDARA, largely to avoid legislative delay. The Senate rejected a proposal to allow the import of less expensive drugs from Canada backed by Sen. Bernie Sanders (D-Vt). Earlier, House Democrats blocked provisions limiting FDA regulation of manufacturer communication related to unapproved uses, including clearer definition of "intended use" and "scientific exchange" and more leeway for providing economic information and alerts on pending product approvals to payers and formulary committees.

FDA has recently moved forward with a proposal for establishing user fees to support expedited review and approval of over-the-counter (OTC) drugs, too late to be included in FDARA but likely to gain Congressional approval in the near future. FDA unveiled its OTC reform plan in August, and hearings in the House are expected this month.

Generics makers backed a measure to facilitate access to branded drugs needed for bioequivalence testing but withheld under innovator restricted distribution programs. The issue will be part of broader consideration and debate on drug pricing and access. FDARA already includes language that calls for legislative action to lower drug prices, and several proposals before Congress aim to do just that. More are in the works and likely to be combined with legislation on access to experimental therapies and to opioid-rescue treatments, as well as other strategies for curbing opioid abuse. PE

Fees to support FDA oversight of drugs are designed to be additive to appropriated public funding, a stance that reflects strong convictions that fees should be designed to limit industry influence over the drug regulatory process

Right-to-try legislation moves forward

Before approving the FDA Reauthorization Act (FDARA), the Senate adopted a controversial "right-to-try" (RTT) measure sponsored by Sen. Ron Johnson (R-Wis) to avoid delayed action on user fees. Described in the press as a libertarian victory, the bill endorses similar state laws by confirming that patients with terminal illnesses and no other treatment options should have access to certain experimental therapies that have completed Phase I testing.

Patients won't have to apply for FDA approval to access these drugs, even though the agency already approves 90% of "compassionate use" requests. Manufacturers, however, are not required to provide a test therapy, which is important because test products often are scarce and because wider use of an experimental medicine may generate conflicting data and deter enrollment in studies designed to clarify product risks and benefits.

Johnson revised his bill to make it more palatable to critics by permitting FDA to consider safety data from investigational drug use, while also clarifying that pharma companies, prescribers, and dispensers will not be held liable for problems arising from use of such products. To promote transparency, manufacturers have to submit an annual summary of drug use under the program and relevant adverse events. Biopharma companies and physicians did not openly oppose the legislation, largely to keep FDARA on track and appease RTT advocates, and the House is expected to revise the particulars in its version.

UK Unveils Post-Brexit Life Sciences Strategy

Is report worth a look as potential springboard to addressing future EU ties in healthcare—or just more bluster?

The unveiling of the UK government's Life Sciences Industrial Strategy at the end of August was greeted with almost universal acclaim as a credible plan for the British healthcare industry to become a global powerhouse after Brexit. So it seems almost churlish to rain on the parade. But credibility is something currently in seriously short supply with the UK government. And the merits of the government's pronouncements, and still more its commitments–on healthcare as on many other issues—are consequently open to question.

The report itself looks good, of course. It talks eloquently of the need for support for discovery and translational science, National Health Service (NHS) collaboration, manufacturing, and skills. It lists objectives in "moonshot programs," clinical trials excellence, conducive tax arrangements, and the growth of clusters. What's not to like?

And government ministers enthusiastically led the cheers as the report was presented. "The government is committed to helping the sector go from strength to strength," said business secretary Greg Clark. Health secretary Jeremy Hunt said "Britain is well-placed to be a world leader in the life sciences industry after Brexit."

Alongside the publication of the strategy, the government also announced a new $16.8 million funding competition for a medicines manufacturing center, a $85.3 million investment in a vaccines development and manufacturing center, a $38.8 million investment in cell and gene therapy treatment centers, a $15.5 million cell and gene therapy investment in Stevenage, and $32.3 million to support small and medium-sized enterprises and boost innovation.

The plaudits quickly followed. Former life sciences minister George Freeman greeted the "flagship announcement" as "a groundbreaking moment in the development of the 21st century UK economy." The UK BioIndustry Association welcomed the report. Association of the British Pharmaceutical Industry (ABPI) CEO Mike Thompson said the "impressive report" is welcomed by leaders in the sector.

Phil Thomson, president of global affairs at GlaxoSmithKline, said "GSK welcomes the vision." So, too, did the Sanger Institute and the UK's innovation organization, the Knowledge Transfer Network.

The talent dilemma

But it is one thing to put money into research. It is quite another to find the right people to conduct the research. The report does concede that "The potential disruption associated with Brexit could lead to some loss of talent from the sector; as such, creating an opportunity to bring very high-level talent into the country over the next five years is important." So it blithely requests the setting up of a migration system "that allows us to recruit the best international talent"—without any mention of the UK's ongoing travails to identify, and still less to negotiate, any such system.

The Institute of Cancer Research (ICR) dared to highlight the point in its comments when the report was published: "For the UK, and global institutions like the ICR, to remain competitive, we need to be able to attract and retain the brightest and the best. We look forward to hearing more about the government's plans for ensuring the UK continues to be a beacon for skilled scientists from within the EU and beyond."

But the UK is currently teetering on the brink of locking out most of the best brains in Europe, with the government's imprecisions over Brexit generating uncertainty over EU citizens' access to the EU, and threatening to push the country into a barren no-man's land on everything from trade to data, and from research to regulatory affairs.

Details left out

Bizarrely, the report makes hardly any explicit reference to the UK's impending rift with the rest of Europe—although it insists repeatedly on the need for a view that extends across the next five years.

It urges the UK to "work with industry and regulators to establish a working group to evaluate the use of digital healthcare data and health systems and to evaluate

REFLECTOR is *Pharmaceutical Executive*'s correspondent in Brussels

the safety and efficacy of new interventions"—without any acknowledgement of the fact that currently this is precisely what is taking place within the European Medicines Agency (EMA), that is about to be booted out of the UK as one of the many unintended consequences of the rush to Brexit. Similarly, the report recommends creating "a forum for early engagement between industry, NHS, and arms-length bodies (e.g., National Institute for Health and Care Excellence, Medicines and Healthcare products Regulatory Agency) to agree to commercial access agreements," ignoring ongoing EU efforts—that the UK is still involved in—in early dialogue and health technology assessment.

A few other incidental references to Brexit acknowledge potential challenges in continuity of regulation and of import/export regimes—but without any extended attempt to answer them. The introduction opens with the observation that "As the UK plans its future outside the European Union, identifying and supporting specific sectors of the economy to grow and expand quickly becomes a clear priority." The report does note that "the future of regulation in the life sciences will need to be considered in light of the UK leaving the European Union"—but merely suggests that "the focus should be on alignment."

Still in denial?

This vagueness is characteristic of the UK government's current approach to its strategic future, so it is perhaps unsurprising that this commissioned report displays the same insouciance. It is this air of happy optimism that is provoking such dismay on the other side of the English Channel, and prompting comments that are far from complimentary about the way the UK is addressing some of its most pressing issues. A senior EU diplomat described London's proposed customs solution as sounding "like a fairy tale."

> The UK is teetering on the brink of locking out most of the best brains in Europe, with the government's imprecisions over Brexit generating uncertainty over EU citizens' access to the EU

The UK government continues to act as if it is in denial over what Brexit really means. The improbable incumbent of the foreign office, Boris Johnson, hardly the government's most able strategist, has had to recognize that his earlier dismissive remarks that the EU can "go whistle" for any UK money were ridiculous, and he now openly admits that Britain has a duty to pay what it owes when it leaves the EU.

Those UK red lines—so triumphantly declared only months ago—on removing all influence of the European court and abruptly ending free movement continue to suffer drip-drip erosion in the face of dawning realities that Britain will need European workers, and judicial guarantees for trade with the EU or its own citizens living there, even after 2019.

The poverty of the UK government's current stance is emphasized when senior figures in and around the government are reduced to invective as their chief response to criticism of its failings. Backbencher Jacob Rees-Mogg, admirable for his sharp intellect and his wit, could find no better comeback to Jean-Claude Juncker's comment that the UK's position papers are unsatisfactory than to accuse the Commission president of being "a pound shop Bismarck, arrogant and bullying but without the charm."

Cautious support

This dysfunction at the heart of the UK government calls into question any promise it makes. It remains to be seen what the—normally prudent and independent—House of Lords Science and Technology Committee makes of the life sciences strategy; it has just announced an inquiry into it, and is inviting contributions. But there was a small sign of what may be to come even in the eulogistic pre-prepared statement of support from healthcare industry organizations that the government included in its own press release on the life sciences strategy. This incorporated—almost incidentally—a certain reservation, in that it described the report as a "springboard," and pointed out that it would be vital "that the recommendations set out in this strategy are fully implemented." PE

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Lynda Parker
Chief Business Development Officer
Dohmen Life Science Services

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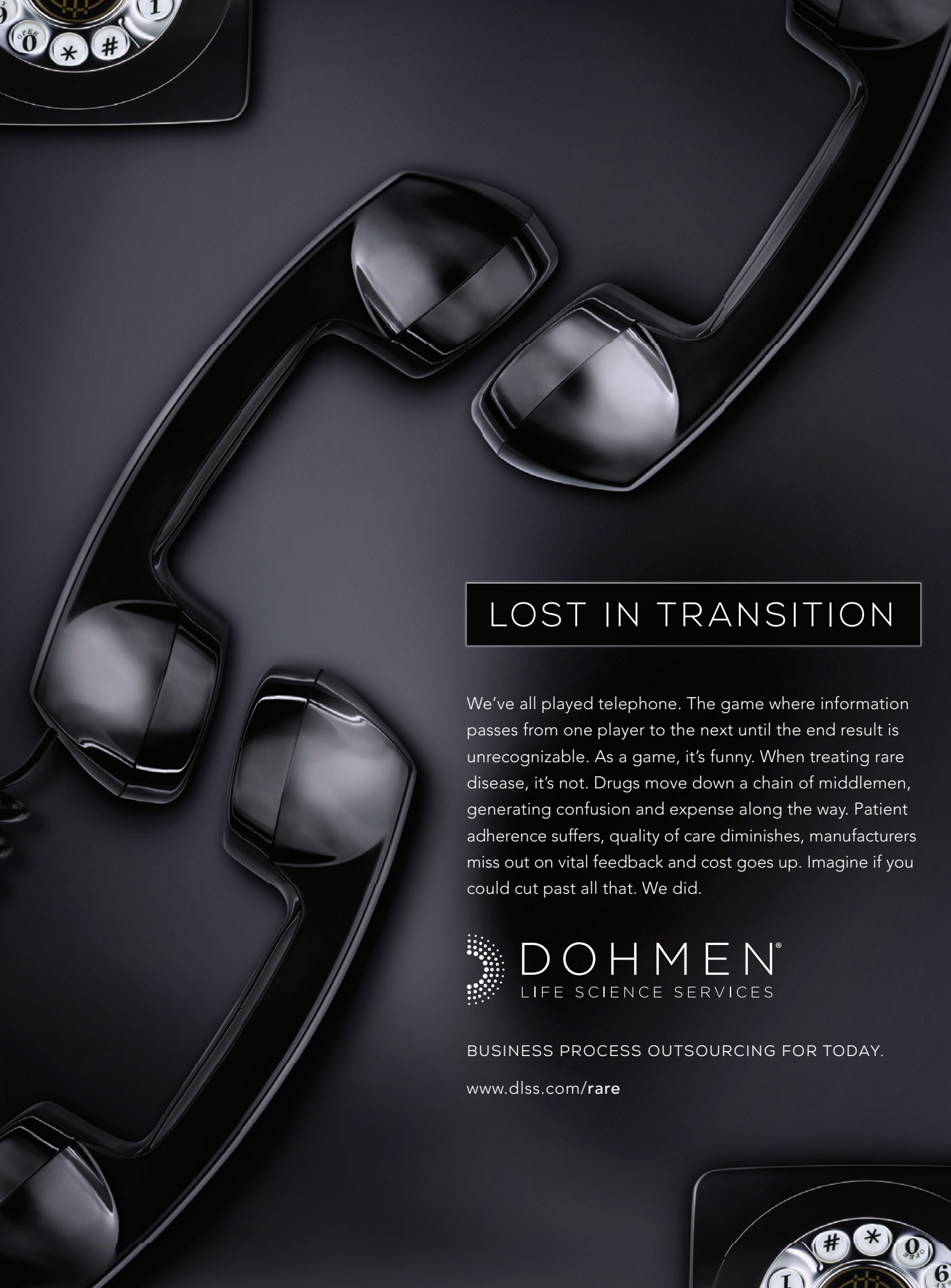
LOST IN TRANSITION
We've all played telephone. The game where information passes from one player to the next until the end result is unrecognizable. As a game, it's funny. When treating rare disease, it's not. Drugs move down a chain of middlemen, generating confusion and expense along the way. Patient adherence suffers, quality of care diminishes, manufacturers miss out on vital feedback and cost goes up. Imagine if you could cut past all that. We did.
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Leading With Patients in Mind

Former critical care nurse Cynthia Schwalm, now executive vice president and president of North American commercial operations for Ipsen, shares her unique perspective on the pharma industry, her formula for successful team building internally, and the importance today of stepping out of the C-suite and into the world of the patient

By Michelle Maskaly

To say that Cynthia Schwalm's ascension to the top wasn't exactly traditional wouldn't be too far of a stretch. Originally an engineering major, the now president of North America for Ipsen, a global specialty-driven biopharmaceutical group, was affected by her mom's cancer diagnosis and switched her undergrad major to nursing. As a nurse, Schwalm was able to see the benefits of quality therapies. She also got to see what could be improved.

This first-hand knowledge stays with Schwalm to this day, and has not only shaped her leadership style, but is also a dynamic she tries to find in candidates looking to work on her team.

Pharm Exec recently spoke with Schwalm about the current state of healthcare, her work at Ipsen, and how she managed a successful merger. With global headquarters in Paris, Ipsen markets more than 20 drugs and employs more than 5,100 people around the world.

PE: *Tell us a little bit about your current role at Ipsen?*

SCHWALM: I have two roles with Ipsen. I am president of North America—our definition of North America is the US and Canada—so I manage all the commercial operations. My team also delivers shared services to some of the global roles that are in the US, such as R&D, manufacturing, business development, regulatory, etc.

I also serve on Ipsen's worldwide executive com-

Opposite: Cynthia Schwalm (sitting left) is pictured with her leadership team at Ipsen's US headquarters in New Jersey. (Left to right) Jennifer Benenson, Ron Graybill, Donny Pearl, Paul Reider, Brad Bailey, and Marisol Peron.

mittee, so that's why I have a second title and act as executive vice president for the Ipsen Group, which is the worldwide family of companies.

PE: *What's a typical day like for you?*

SCHWALM: Instead of a day, because my days can swing greatly, it might be helpful to talk about how I think about my time. I think of my time in chunks. I work toward spending 30% of my time externally. By externally, I mean with patients, with healthcare providers in external settings where I am learning about the evolution of healthcare, etc. It's a lot harder than it sounds, because when you're managing a company there is always something that is pulling you into the home office or something going on with corporate. So I'm pretty rigorous about planning my time at least three to four months in advance.

Another 30% of my time I spend on people and people development, and working with some of our best talent to ensure we have the right team. We have the great fortune of being able to build a talent base from scratch in North America. I have been able to collect high-performing talent across the US and Canada, and we're growing at such a fast rate—over 50% per year—so it's very important that we help these executives come in, grow, and develop.

Another 30% I spend on being a member of my other team, which is the worldwide executive committee working on global projects, global initiatives, thinking through the strategy of the company moving forward, operations globally, mergers and acquisitions, etc. That takes me out of North America and to the global market.

And the final 10%, I try to keep open to just be able to think, because that's where some of the best ideas come from—when I can just have some free time to either take in ideas, spend time with people I might not have normally spent time with, and just be able to think and reflect on the business.

PE: *What do you enjoy most about your position and leadership role within Ipsen?*

SCHWALM: It's going to sound a little clichéd, but what I really enjoy the most is the fact I have been able to build this business as an entrepreneur and fund it by an almost 90-year-old entity called Ipsen. I've been able to build this business, and by that I mean building a great high-performing team that actually has a tremendous team dynamic. The most enjoyable time for me is when I'm being with, watching, and enjoying the efforts of this group that I've put together. It really makes my professional life very enjoyable, and it feels very rewarding.

Keeping a strong team dynamic can be challenging. I've been in the industry for a long time, and people talk about it and I've grown weary of reading—I mean, how many coaching books can you read? There are dozens of publications per year on high-performing teams. When you have the good fortune of living through many experiences, at this point in my career, it's a real blessing, and I don't take it for granted.

PE: *What's the most challenging part of your job?*

SCHWALM: The most challenging part is managing the growth of this business and its contribution to Ipsen. When I was approached by the board at the end of 2013, Ipsen had not been successful in the US, despite investing a significant amount of money since 2009. Now, three years later, we became the major growth engine for Ipsen. We are the largest country, the number one affiliate; we are leading growth and profitability for the company. That challenge does keep me awake at night and it is also requiring all of us to learn how to embrace this level of change and responsibility within the company. The acceleration has been sort of extraordinary.

It's about how you bring people along day-by-day, how you help shape the shift, how you think about resources, how you drive externally, which is now one of my big drivers. It is a very important responsibility.

I do find it challenging because you can become overwhelmed by it, or you can take it step-by-step. For example, I recently presented as part of a team at our annual investor day, where we showcased the growth of the company to our investors. Over

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» Cynthia Schwalm began her corporate career at Johnson and Johnson with Janssen Pharmaceuticals, where she held multiple commercial roles over an 18-year period, including as general manager of Ortho Biotech UK & Ireland.

» Previously, Schwalm served as chief operating officer at Eisai Inc. and vice president and general manager of the oncology business unit of Amgen. Schwalm was CEO and president of Ipsen Biopharmaceuticals Inc. from February 2014 until August 2016.

» Schwalm earned a bachelor's of science degree in nursing from the University of Delaware and an MBA from the Wharton School of Business. She and her husband live in New Jersey, and have two daughters.

the past three years, our investor base has changed: We now have more American investors, our stock price has increased on average by about 50% per year since early 2015, our return to our shareholders is up 150%-plus, and a lot of that has to do with the impact in North America. The expectation is that we continue to drive performance.

These are good problems to have.

PE: *Your undergraduate degree is in nursing. Can you explain your career evolution from a critical care nurse to executive of a global pharma company?*

SCHWALM: I was actually an engineering major in college, and I've always been fluent at math. During college, my mother was diagnosed with breast cancer, and I made the switch to nursing. I was a dual major for a period of time, and then I made the switch to nursing, because I really felt very passionately about it.

At that time, cancer was a death sentence. In the late '70s, there was none of the innovation that we have today. In changing my major and moving into oncology and critical care nursing, I really decided that I was intrigued by what I was seeing happening to my mother, I was intrigued by the whole situation, and I really wanted to get into the clinical aspect of healthcare for a living versus the abstractness of engineering.

After several years as an oncology and critical care nurse, I was studying for my MCATs, because I wanted to continue being able to impact and influence. I was very drawn toward helping populations who were very sick or very challenged, and it was at that time that I was approached to join a device company as a trainer.

I decided to pursue the device role, and that led my career to what I call the manufacturing side. Once I started working my days and nights and working in medical schools all over the four-state area of New York, New Jersey, Pennsylvania, and Maryland, it was exciting to be able to influence at that level. I witnessed all the types of healthcare—and at the time, I was still very close to the patients—I knew that was my calling. It was very clear to me.

This concept has driven my career choice over the past 30 years. Being close to patients and the patient agenda drive my thoughts around strategy and has been what has made me successful, along with having the good fortune of getting my executive MBA at Wharton (University of Penn.) between 1997 and 1999. Business skills completed what I would call the heart-mind connection; I learned the language of finance and use that language to drive the opportunities I see being so close to healthcare.

PE: *How has the nursing background helped you in your corporate roles?*

SCHWALM: I have so many different colleagues who are leading in the industry, and we all come from different backgrounds, but I very clearly see the patient in my mind's eye in every single conversation. That's something that I think is very unique about executives from the nursing and allied healthcare professions. We have been so close physically to so many aspects of life and death with patients and their families. That agenda is front of mind.

It's been very easy for me to see business opportunities where it might not look like an opportunity on paper or logically, but I can see the patient agenda. I think it's also helped me in the evolving world of pharma, where being a compliant organization is so important. I can very easily see the ways to work with patients and providers in a very compliant fashion, and it's not been what I would call a barrier to me, because that's all about responsibility.

PE: *What's the biggest change or shift in healthcare you've seen during your time in the industry?*

SCHWALM: The biggest change in oncology has been the absolute drive and focus now in oncology and rare diseases. These were areas that when I started, the industry wasn't even interested in. There was one company, Bristol-Myers Squibb, that had worked with the government on Taxol; and now most companies, with a few exceptions, have a significant business model in oncology and are also working on subpopulations that are very small populations of people who are ill and need help. That is a dramatic change. Thirty years ago, it was about primary care and big, big patient populations—and oncology wasn't on the agenda.

The other big change in terms of the industry is the influence of Wall Street and driving the behaviors of leaders and executives in our industry around deals, acquisitions, and pricing. I'm hoping that push has run its course, and that we are going to come back to some middle ground about focusing on strong innovation that is obviously profitable for companies, but also extremely effective for patients.

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PE: *What excites you most about the current state of the industry?*

SCHWALM: What excites me is that we are moving to a new level of marrying communication with adherence and consistency. And, of course, technology is in the background. When I say communications, I mean the enabling-technologies.

There are still so many therapies where patients don't adhere, because they don't have the right resources, and then they don't get the optimal outcome. This whole new world—that's not totally complete yet around the patient's ability to communicate, monitor, think through, deliver, and look at their own outcome—is just absolutely fascinating. I look forward to the day when we get a total integration of technology with therapy.

One example that I'm thinking about that we have is Increlex, a therapy for a rare condition called short stature, in which children do not grow, that helps about 500 children in the US. One thing that we noticed is that for some particular reason that we are sorting out, the parents and the children are not getting the injections that are required to help them grow—to help their organs, body, and mind grow. So having that continuous loop with these parents, the children, their doctors, and access to the medicine is something that is going to require a very integrated approach. If we can tackle that, it could profoundly affect many decades of life for children in this country with a rare disease.

That's just one example where I really see an opportunity, if the industry can figure out a way to bring all of these technologies together for a better outcome.

PE: *What do you think is the biggest challenge the healthcare industry will face in the next five to 10 years?*

SCHWALM: In the US, it's still disturbing that about 30 million people don't get access to care, and we are one of the most affluent countries. Recently, there was an article in *The New England Journal of Medicine* that posted statistics that we have states in our country where the average mortality age is decreasing.

We have not tackled fundamental healthcare for our citizens and I think it's a huge challenge—I don't immediately see the way forward with the new administration. I think that we, as industry partners, have a role to play in that. I see that as a huge challenge for the US, and I don't see the absolute way forward, but I'm hopeful that various constituents will continue to partner.

In terms of access to global healthcare, I think access to care in some of the burgeoning countries where the middle class is moving forward and people have disposable incomes but not necessarily adequate access to care, is still an issue. I think about the time I spent in China, where there are also global access issues. In India and Brazil as well.

The biggest challenge for our industry is how we continue to truly innovate and drive value-based pricing, with pricing that meets the needs of the major global markets. The whole issue of pricing has obviously hit an all-time high in terms of being

the lightning rod for our industry. It's going to require global biotech and pharma companies to agree on finally developing value-based pricing in the US. We've talked about it, but we really haven't done it and stuck to our convictions.

PE: *You have a great deal of experience building successful leadership teams. What qualities do you look for in a candidate when you're filling a position?*

SCHWALM: There are some common themes that we look for, all the way from executives to emerging leaders. We look for people who have just as much of an interest in being as high-touch as we are regarding patient care, being focused, aligned, spending our time visualizing, and being with the patients and the people who care for them.

People talk about it, but I want to see that they have done it and that they have enjoyed that aspect of their work. If they have not had that opportunity, certainly there is the ability to be intensely curious about what we do from a patient and innovation agenda.

We look for people who have a real love of this game, of what we do—that we bring innovation to patients, and that are internally curious, whether they are in finance or HR. It doesn't have to just be a field-facing position. You can sense when people have a real love of the game, the love of the industry that we are in, and a love of where they think they can contribute.

The bottom line for us, which we say at Ipsen, is this work is personal to us. So when you interview people, you can very quickly determine whether this work will be personal for them.

PE: *Ipsen recently completed the acquisition of global oncology assets from Merrimack Pharmaceuticals. As a company leader, how do you prepare for a successful transition of bringing a new brand into your current portfolio?*

SCHWALM: The short answer is you don't wait until the acquisition closes. As we went to the board and presented our proposal, we had already identified an integration process, an integration team, and we picked a high potential executive in our company to be that integration leader to make sure all the aspects went well—everything from regulatory, manufacturing, clinical development, and commercial. We actually started that process in December, announced the deal, and then closed the deal in April.

The short answer is you start way before Day One.

PE: *You serve on a number of leadership boards. Why do you feel it's important to volunteer your time in this way?*

SCHWALM: I serve right now on the Wharton Executive Women's Leadership Board and Harvard's JFK School Leadership Board; those are two philanthropic boards. I feel most compelled to do that because it moves outside of just our industry, and we are actually engaging in very thoughtful research about women in leadership globally. The research is beginning to have traction and is beginning to be used not only by private interest, but by government and academic interest.

By thoughtfully engaging in the work of what it means to empower women to be at the table, be part of the conversation, and to deliver on that conversation, is extremely important to me. Also, I have two grown daughters, and I have mentored many people.

I also think it's important for our young men coming up, because as our world evolves and we live longer, a career is longer. To be able to be a leader throughout life's journey requires a different skill set for both men and women. It's a more inclusionary skill set than ever before.

PE: *What advice do you have for younger executives who aspire to a C-suite role?*

SCHWALM: I'm so excited to be here today, because when I started my career it was a bit of the land of "no." I think there are opportunities to manage your career and find the environment where, for both young men and women, you can be highly performing, highly functional, and still have a committed relationship, manage a young family, manage respecting your elders, and moving homes at times. Being able to say, "you know what, I can't move to take this job now, but I certainly can do it at another date." That type of flexibility is what is going to make people successful in the long haul and I encourage people to seek out those environments.

I also encourage executives to get close to the line. I don't believe in strategy alone, I don't believe in operations alone. I think good strategy comes from people who have been close to the customers, been close to patients, and understand what it really takes to ensure that innovation moves forward.

It can be difficult when people get into what I would call classic corporate jobs, and have not had those frequent exposures to the patient agenda at the bedside. I really encourage people to do that. PE

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The Supply Chain: What Price Patient Centricity?

There is a lot of talk about the patient-centric supply chain, but can the pharma industry hope to really achieve it? *Pharm Exec* looks at how some of the pharma services and clinical trial logistics companies are racing ahead in the field of patient centricity

By Julian Upton

Amid increasing regulations and restrictions in access to patients or healthcare providers, pharmaceutical companies need to improve the reliability of their supply chains while at the same time build flexibility and reduce costs in the supply chain, wrote the authors of a 2016 LogiPharma Benchmarking Report.[1] "The watchword is 'visibility,'" the report went on. As demand models shift from push to pull, "businesses must go further than shifting their demand strategies and illuminating all the components of their logistics routes." Companies should get closer to their customers, using analytics to derive insight out of their brand interactions, the report recommended. To gain competitive advantage in the future, they must remodel their supply chain practices using all channels available to them to reach out to patients and prescribers, and invest further into maximizing visibility, improving the visibility of their shipments and the needs and preferences of their customers.

This is easier said than done. In a December 2011 article, Hedley Rees, supply chain expert and author of *Find It, File It, Flog It: Pharma's Crippling Addiction and How to Cure It* (2015), asserted that "the supply chain patient is sick" and that the cause of the "sickness" could be summed up in two words: "parental neglect."[2] The industry's "single-minded drive to meet clinical endpoints and gain regulatory approval has resulted in [it] paying scant attention

to the good practices and processes required to build and manage robust, secure and high performing supply chains," he wrote.

For Rees, the root of this supply chain sickness goes back more than 30 years, when "big pharma began to jettison what it considered 'non-core' activities (clinical/non-clinical research, development, manufacture, logistics) by outsourcing on a massive scale." The move created "a rapidly spiraling contract services sector" but the result was "hands-length, cost-based relationships between the various players in the pharma supply chain, each operating within their own separate organizational structures, quality systems, and information technology investments." As a result, supply chain visibility all but vanished: "There remains very limited two-way interaction at this critical interface between those developing/supplying drugs and the patient experience of their product," Rees concluded in 2011.

Speaking to *Pharm Exec* six years after his diagnosis of the industry's "sickness," Rees maintains that pharma still has no grip on its supply chain. "The industry has become so fragmented in the last 40 years," he says. "The way the supply chain has developed, there are so many different players—product license holders, clinical trial sponsors, contract research and contract development and manufacturing organizations (CRO/CDMOs), third-party logistics providers (3PLs), wholesalers, pre-wholesalers, pharmacies—that the supply and distribution of finished goods is highly convoluted. It is very difficult to keep track of them. Today, the CDMOs are integrating upstream and downstream and taking more control over the supply chain. So too are the CROs, wholesalers, and 3PLs. These contractors are getting bigger, where the pharma companies are becoming smaller. That leaves pharma companies in a weak position."

The irony for Rees is that although drug manufacturers are totally responsible for their products, they have "almost no control" over them. "Pharma doesn't own the CDMOs or any of the other contractors in the chain of custody; they don't see the product when it has left their ownership, when it leaves the plant after being packaged, so they have no access to sales and other information," says Rees. "They have to buy that information back at great expense, and when they receive the sales information, it is about six weeks old. So, when you talk about pull demand, pharma is not going to be able to achieve it."

A changing industry

As Rees indicates, "control" of the supply chain rests outside the hands of pharma itself, so it is worth looking at how certain pharmaceutical services and clinical trial logistics businesses are achieving a more authentic level of supply chain patient centricity. Big companies like Cardinal Health, on the medical and pharma services side, and UPS, on the logistics side, have been investing heavily in patient-centric solutions that show how the space is really evolving.

Hedley Rees

For Jennifer Fillman, vice president and general manager, specialty services, Cardinal Health Specialty Solutions, a patient-centric distribution strategy is one that is "built around the needs of the patients and all the factors that might impact their treatment experience: medical needs, financial needs, social needs. It needs to consider not only how does the pharma company get its therapy to the right patient at the right time, but also how the company can help remove the barriers to access, and help support the patient in adherence and compliance to really optimize the outcome."

Cardinal Heath Specialty Solutions subsidiary, Sonexus, is a hub services company that, according to its marketing, goes "beyond traditional hub services" to help patients and providers access specialty products "with unprecedented speed, efficiency, and empathy." Sonexus integrates non-commercial specialty pharmacy services with direct distribution services to hospitals, practices, specialty pharmacies, and patients, and allows for direct interaction with patients and healthcare pro-

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» There are numerous players involved in today's pharma supply and distribution chain—from product license holders, clinical trial sponsors, contract research and contract development and manufacturing organizations, and third-party logistics providers to wholesalers, pre-wholesalers, and pharmacies.

» The shift to personalized drugs is going to completely change the supply chain system, experts predict, replacing the traditional model of making bulk product in a factory for distribution to warehouses and wholesalers.

» Logistics companies are increasingly experimenting with supply chain automation, such as those leveraging the cloud, big data, and machine learning—looking to tap the ROI promise that Uber, Amazon, and other service models have generated with such tools in other industries.

fessionals (HCPs); it helps patients find financial assistance, explores their transportation considerations, and connects them with support groups and nursing services.


Jennifer Fillman

For rare disease patients, this is particularly important, Fillman told *Pharm Exec*, as "patients and their caregivers are typically managing a lot more complexity." There is increased pressure on pharma companies to ensure they are meeting the needs of such patients, she adds. "There are the physical, psychological, and emotional aspects of the disease, and there are very few resources for people to turn to for support," says Fillman. "Patients and their caregivers are heavily dependent on the services that are provided through the supply chain."

According to Fillman, as some of these niche disease states become more competitive, pharma companies will need to deepen their relationships with patients, caregivers, and HCPs "to help differentiate themselves as well as drive adoption of their products." Although the focus here is on specialty products, Fillman underlines the broader issue of pharma's limited visibility of its own products: "The majority of the clients we work with are launching their very first drug and may have limited supply chain experience. Their product goes from the manufacturer directly to our 3PL facility. We take care of it, we work on behalf of their brand, so we're really an extension of the pharma company."

For Wes Wheeler, CEO of Marken (now owned by UPS), which works in the clinical trial logistics space and offers direct-to-patient services and biological sample shipments, the patient-centric supply chain is "one that respects the life-saving nature of what we do, and respects the fact that we're not just moving boxes, but moving a biologic sample, an organ, a life-saving drug, or a life-saving vaccine, and that there is a patient behind every single one of those shipments."

Described as "the only patient-centric supply chain organization 100% dedicated to the pharma and life sciences industries," Marken is involved with around 100 trials with a direct-to-patient feature. The company assigns a project manager to each of its trials and enlists its delivery drivers in training programs. As Wheeler told *Pharm Exec*, "We get to know the patient by name, we can call the driver on his or her way over to the patient's home, and we make sure the nurse is there. The nurse draws and centrifuges the blood, puts it into tubes, back into the box, and the driver takes it to the central lab."

Now Marken is delving further into the mobile space and developing an "Uber-like technology." Wheeler says it "will offer the patient an Uber experience, where they can go to their app, call up for a delivery, see which driver has been assigned and where the driver is currently located. They can communicate with the driver, whether by phone or text message, and have that very personalized experience."

Wheeler believes that within two years, every significant clinical trial will offer patients the opportunity to take part from their home. "This will greatly increase retention and compliance among these patients, particularly Alzheimer's patients, Parkinson's patients, epilepsy patients, and terminal cancer patients, who perhaps cannot drive, who cannot get to the doctor's office in time," he says.

Wheeler notes that almost 50% of all trials in development now are cancer-related, that most cancer drugs are sterile, and about half of those drugs are biologically derived, requiring very sensitive handling. "But the more exciting thing is the advent of cell and gene therapies, or immunotherapies," he says. "In autologous drug trials, where each patient's tissue is used to create a drug, each treatment is personalized."

The move to personalized treatment is "going to completely change the industry" as far as the supply chain is concerned, Wheeler contends. "The traditional model of making bulk product in a factory for distribution to warehouses and wholesalers will disappear," he says. "We will have banks of small pharmaceutical storage areas in retail pharmacies to store a patient's individual therapy, so when they're ready for the next treatment, they can go to the pharmacy and they get their own personalized medicine. The current system of storing hundreds of millions of drugs in tablets and bottles will go away, and we will move toward small vials of sterile product that are personalized with the patient's name on it."

Where now for pharma?

Where this leaves the pharma industry and its traditional, "20th Century" supply chain model is open to question. For Rees, the onus is on pharma

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to become truly patient-centric. But for all the marketing and communications talk about how important this is, he does not see this happening. "If you look beneath the talk," he says, "the people who develop drugs are not talking to patients and HCPs." What is required is a major shift at the heart of the industry—a complete overhaul of "an ingrained cultural mindset that drives behaviors counter to the needs of patients," says Rees.

That will be no easy fix, of course. Rees believes it will take at least a generation, and probably longer, to achieve. As he wrote in 2014, "CEOs and their executive teams must step up to the plate and drive a new culture of patient engagement, not only talking to them, but building a deep understanding of their needs, across diagnosis, therapy, after-care, and prevention."[3]

Rees adds today that change must be kick-started by governments and politicians. "They should facilitate amendments to medical patent laws, so that companies are rewarded for building much stronger cases for the validity of a molecule before patent application," he says. "The role of patents is to reward companies for bringing a workable product innovation to market. At the moment, given that it takes 10,000 patented molecules to get one to market, the proof of 'workable' is very much to the contrary."

He concludes: "FDA's CDER (Center for Drug Evaluation and Research) Director, Janet Woodcock, has been hanging out opportunities for pharma since 2002, in the form of the 21st Century Initiative and the Critical Path Initiative. Since they are merely advisory, lip service only has been paid to them. These FDA initiatives would make an excellent starting point for advancing a dialogue between the key stakeholders in the industry, but only politicians can get the ball rolling." PE

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Critical Crossroads for Cold Chain Storage

Technology and other trends in medicine are driving the need for new strategies and investments in temperature sensitive packaging

By Michelle Maskaly

A lot of industries have temperature control requirements, but when it comes to the pharmaceutical industry, it can literally be a life or death situation. For example, when grocery products are not kept at the correct temperature, there will be spoilage and a loss of product, potentially costing hundreds of thousands of dollars. But, when it comes to pharmaceuticals, it could mean injecting life-saving vaccines that are no longer potent into patients and not knowing it until it's too late.

"This is the most critical level," says Tom Grubb, manager, cold chain strategy, for American Airlines. "We are talking about the process of transporting medications and treatments in order to keep them safe and effective all the way to the patient."

Temperature control as it relates to pharma generally comes down to ensuring the quality, efficacy, and safety of a product being used to treat a patient—making the journey from manufacturer to endpoint absolutely critical. In the past decade or so, the pressure to keep pharma products in their correct temperature range while being transported has come under heightened scrutiny.

Typically referred to as the cold chain, because there has been an emphasis on the cold temperatures, increasingly that temperature range is also focusing on controlled room temperature. As a result, "temperature sensitive" is being used more commonly than the phrase "cold chain." While it may seem like a small shift in wording, it is a glaring change to those who have worked in this area of the supply chain, because it creates a new emphasis on the need for additional temperature ranges.

According to Jim Bacon, vice president – partner client solutions for AeroSafe Global, in the early 2000s, the US and Canadian governments

became more interested in the integrity of pharma products as the drugs traveled from the manufacturer to the next levels of distribution, including wholesale distributors and doctor's offices. In recent years, he said government interest has expanded beyond just the cold temperatures.

Bacon, a cold chain expert who frequently speaks at conferences on the subject, notes that regulations are changing. Now, when a company registers a new product, it has to talk about the storage and shipping as it relates to temperature and efficacy, making discussions about temperature sensitivity a more important part of the drug development process than it might have been previously.

Factors driving change

The number one factor driving temperature sensitivity is technology—both inside and outside of the lab. As technology allows pharma companies to develop more biologics, the special temperature requirements get increasingly complicated. If you factor in technology-driven trends like personalized medicine, gene editing, and immunotherapy, which all require temperature sensitivity, it's a no-brainer that this subject area is getting more attention.

Another contributing factor is the global marketplace. Susan Li, manager, UPS Temperature True Packaging, said that as pharma companies expand manufacturing and distribution, the temperature ranges that products are exposed to become more extreme. Take, for example, a product that is being shipped to both the Middle East and Canada. The temperature, and weather, in these locations are very different, yet the product needs to be kept in the same temperature range in both places for it to be effective once it gets to the final destination, which has also become more complicated. As Li explains, the final destination can now include a patient's home or doctor's office, compared to a hospital or pharmacy setting historically.

"It adds a lot of pressure to the last mile," she says. "More products are protected, and not just those refrigerated. It has expanded into the controlled room temperature products previously shipped naked."

This can result in a complicated supply chain—multiple lanes, packaging needs, and temperature requirements.

Global influence

Global factors influencing the pharma industry's temperature supply chain go beyond the weather conditions. Although there are global manufacturing standards, the regulations surrounding pharma products legally entering a country can vary greatly, and the results are not pretty.

Shipments of temperature sensitive therapies can be stranded at borders while going through the proper regulatory checkpoints, with no additional ways of keeping the product in the correct range besides what it was shipped in. That makes packaging a critical component in the overall picture.

As a result, pharma companies are increasingly looking for a variety of custom packaging solutions. From working on the front lines, Bacon has observed organizations that need multiple packaging options depending on where they are shipping to in the world. A product being shipped domestically and with a shipping time of about 48 hours may need different packaging solutions compared to if that product is being sent to Europe or Asia and may need to be kept at a certain temperature range for five or 10 days. This is the reason Bacon advises pharma companies to think about temperature sensitive requirements, including how they are going to package and

ship the product as they are developing it.

Environmental impact

When it comes to temperature sensitive packaging, the effects on the environment are increasingly coming up in conversations. "Everyone wants to do better for the environment," says TJ Rizzo, senior vice president of global commercial operations at Cold Chain Technologies. "Also on everyone's mind is cost-reduction factors."

This is where the reusability factor comes into play. Rizzo says technology is allowing packaging companies to come up with new materials that are not only cost-effective and reusable, but also keep the pharma treatment better protected. The reusability component is a feature the end user tends to prefer as well.

As Rizzo notes, the end user, whether a hospital, pharmacy, or doctor's office, has always felt a burden of what to do with the packaging once it gets there. Now, many companies offer a return shipping label that the end user can attach on the packaging and send back to the shipper. Once returned, the shipper's experts can closely inspect the package before allowing it to go back in the system. Being able to reuse temperature sensitive packaging not only helps cut cost, but also trash.

Getting in the game

Airlines, airports, and other transportation companies are getting wise to the fact that if they want to do business in the pharma industry, they need to pay attention to the influence of temperature sensitive drugs and therapies.

At American Airlines, Grubb has been involved in its temperature sensitive program since the beginning and worked to build the company's cold chain program from the ground up. The airline has not only invested significant capital into the infrastructure of its program, but also into the training of the employees who handle the pharma packages. "We make sure each person, according to their role, is trained in a certain way based upon what they do," says Grubb.

This includes everyone from the individual loading the cargo on the plane to the sales person speaking with pharma executives about the services the airline offers. Across the board, American Airlines' employees in this area go through reoccurring training every year to ensure they understand the importance of the procedures.

Temperature sensitive shipping was such a vital area to the airline that in 2015, it introduced a new state-of-the-art, dedicated pharma facility in Philadelphia, PA. Focused solely on healthcare products, the facility was designed specifically for temperature sensitive shipments, and features among other things: A deep frozen area for shipments between -10°C and -20°C; a zoned active container management area with powered charging stations for up to 30 electronically controlled units; advanced technology for 24/7 monitoring of products, including proactive alarming, validated to 0.25°C; and full backup power generators in the event of a power failure.

Shipments of temperature sensitive therapies can be stranded at borders while going through regulatory checkpoints. That makes packaging a critical component in the overall picture

Future outlook

As technology changes, more biologics come to market, and medicines become more personalized, the temperature of therapies when stored and transported is going to become even more important—and complicated. Experts are optimistic about the future of temperature sensitive solutions.

Stephen Laaper, principal of strategy and operations for life sciences and healthcare at Deloitte, says the increasing ability to detect and sense temperatures across the entire supply chain, from the manufacturing, through shipping, and all the way to the final destination, will continue to be critical—and getting those results in real-time will drive innovation.

Being able to collect real-time data about a product's temperature, or other excursion that could adversely impact the treatment, will make a considerable difference in the way companies can respond to these situations in the future. And while the technology might be there, it really comes down to cost.

Laaper points out that, fortunately, the cost of such technology is starting to drop, and temperature sensors that can perform this type of reporting and monitoring are being come accessible. PE

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Drug Serialization for DSCSA Compliance Benefits Everyone

By Peter Sturtevant

A minority of pharmaceutical manufacturers are on track to meet the next big Drug Supply Chain Security Act (DSCSA) deadline—just around the corner. Although the FDA has announced it will delay enforcement until 2018, beginning November 27, 2017, pharma companies are required by law to serialize individual packages of drug products using a product identifier (a GS1 Global Trade Item Number® [GTIN®] or an FDA National Drug Code [NDC]), serial number, lot number, and expiration date, and embed this information in a 2D barcode.

In May, GS1 US, McKesson, and AmerisourceBergen Corporation (ABC) conducted a barcode assessment to gain insight into the industry's readiness for the November deadline. The assessment involved physical scanning over 16,000 actual products in two distribution center locations—and this snapshot in time showed that only a single-digit percentage of products were fully and accurately serialized to meet the upcoming DSCSA requirements. That leaves a majority of companies playing catch-up.

Enforcement delay provides opportunity

Recognizing that some manufacturers may need additional time to ensure that products are properly labeled with the required identifiers, the FDA issued a one-year reprieve in its June 30 draft guidance. That means that while the deadline remains in force, the agency will not take action against manufacturers who do not affix or imprint the product identifier to their packages and homogeneous cases until after November 26, 2018.

The FDA's enforcement delay is intended to minimize possible disruptions in the distribution of prescription drugs in the US. The road to compliance takes time, and by starting now, drug manufacturers have an opportunity to put the necessary systems in place before they will incur any potential penalties. It also leaves time for collaboration with trading partners, system testing, and refinement to optimize results.

Benefits beyond compliance

All the buzz about compliance deadlines shouldn't eclipse the bigger picture, or the reasons behind the DSCSA law. It's important to remember that the DSCSA was enacted to improve patient safety and care, and will also result in benefits to supply chain stakeholders. Compliance with serialization requirements helps move the industry forward with better traceability and accountability for the origin, chain of custody, delivery, and availability of authentic prescription drugs. Patients will benefit from improved access to the drugs they need and assurance that those medications are exactly what their physicians prescribed. The serialized identifiers will help ensure that the drugs delivered match what was ordered and have not been replaced with counterfeit products, which endanger patients and compromise the industry's profile and profits. Patient safety will be enhanced by a granular chain of custody record that permits visibility into the location of the drugs at all times. That also enables quick, accurate recall of product in the event it is needed.

Manufacturers, wholesalers, and dispensers also will benefit from unit-level serialization. Inventory will be better tracked; traceability drives better efficiencies throughout the supply chain. Expedience in solving any supply issues can help prevent negative consequences downstream. Altogether, the work involved in meeting DSCSA requirements is going to benefit all of the legitimate stakeholders in the pharma industry and its customers.

Challenges to implementation

Why are most companies behind schedule in meeting a federal regulation that promises improvements throughout the supply chain—from manufacturers all the way through to patients? Implementation challenges and uncertainties have caused some to adopt a wait-and-see approach. However, making the transition to unit-level serialization, and all the other data requirements specified, won't happen overnight—so the time to "wait and see" is over.

In leading the GS1 Healthcare US Initiative, we have learned from discussions with member companies about challenges and solutions for DSCSA implementation. We'll share some of these here.

Apprehension

While the DSCSA defines the "end game" requirements, the roadmap—procedures and best practices for arriving at the compliance destination—has mostly been left for industry to develop. Some companies have been reluctant to move forward without FDA-specified implementation guidelines to follow.

However, a few companies are leading the way in working out the details and best practices. For example, as reported in the April issue of *Pharm Exec*, Johnson & Johnson Supply Chain (JJSC), ABC, and GS1 US recently published a case study detailing the results of a pilot test they conducted, and offering suggestions for the industry based on their experience. Among other findings, conclusions emphasized the need for repeated testing to identify any potential problems and areas for improvement. The importance of top-level, company-wide commitment and collaboration between business partners were also highlighted.

Grandfathering

The law specifies that manufacturers must serialize their products as of November 2017. Two years from then, wholesalers will only be allowed to receive and ship serialized product. (Pharmacists must meet the same requirements by November 2020). Does that mean the manufacturer cannot produce a product today that is lot-based and has an expiration date after November 2019?

Clarity on this issue will help. Meanwhile, the best solution remains to make the transition to serialized production sooner, rather than later.

Saleable returns

When the November 2019 wholesaler deadline kicks in, saleable returns will have to go through a verification process that is yet to be fully defined. Some industry members have been voicing concern that the verification conditions could change parameters for their implementation of Phase II unit-level serialization requirements. As a result, they may be disinclined to invest in changes that might need to be reengineered in a few years.

Cost

As in any operational transition, converting manufacturing lines from lot-based to unit-based serialization represents an investment in software, hardware, and temporary reductions in productivity while the changes are being implemented. The lead time to install a production line averages six to eight months. Purchasing scanners and inline or label printers to print a clear and concise GS1 DataMatrix, engaging a third-party solution provider to manage the serial numbers, and simple production line efficiencies all contribute to the time and cost of conversion. Some companies are simply waiting to flip the switch—even if they have the machinery all ready to go—until the clock runs out.

Presumably, manufacturers will regain any losses in productivity when the transition is complete. Service providers can help navigate the logistical infrastructure and setup to maximize efficiencies. The best way to optimize the transition process is to stay abreast of guidelines as they develop, and learn from those who have gone before. Stay tuned in to the industry's progress in identifying best practices.

Resources

Time and money always top the list of resources needed to implement changes. Another resource that is in increasingly short supply is the solution providers that manage the transition and serial numbers. There are so many companies just beginning the process that demand for solution provider services is tight.

Start now!

Thanks to the FDA, there's still time to meet requirements before noncompliance is enforced. The best advice offered by those companies who are ready now is:

- Understand it's going to take some time.
- Run pilot tests to identify and resolve the quirks and glitches in your system.
- Collaborate and communicate with your trading partners up and down the supply chain.
- Manage top-down: C-suite level leadership is needed to command integration between departments, divisions, and individuals for a system-wide transformation.

Getting it done

The scope of changes needed to serialize packages with robust data codes may seem daunting for companies that aren't there yet. Recently, a collaborative group of drug manufacturers, distributors, and providers compiled an extensive reservoir of information to help the industry address the DSCSA requirements. The result is a 42-page doc-

ument available for download on the GS1 US website (www.gs1us.org).

To begin, manufacturers will need a GS1 Company Prefix in order to obtain and assign the required product identifiers. The prefix is easily acquired by filling out an online application on the GS1 US website.

Once the Company Prefix is assigned, individual products can be identified with a GTIN to meet the requirements of the law. As a best practice, an FDA NDC number may also be embedded in a GTIN.

The GTIN uniquely identifies not only the individual sale unit of packaging, but also higher-level groupings such as homogeneous cases, homogeneous pallets, etc. So, for example, a 30-tablet bottle of Drug XYZ will have one GTIN, and a 12-bottle case of the same drug will have a different GTIN. The NDC only identifies the drug itself, and does not distinguish between the individual sale unit and higher-level groupings.

Using EPCIS to meet DSCSA requirements

DSCSA requires manufacturers, distributors, and dispensers to capture and share information, using standards for interoperable exchange of information, about transactions in the supply chain in which ownership of pharma products is transferred.

The pharma industry is already using GTINs for product identification, to comply with the first phase of DSCSA requirements. Many companies are also leveraging Electronic Product Code Information Services (EPCIS) to facilitate the exchange and synchronization of data with products' movement through the chain.

EPCIS provides a standard language to express this information in an interoperable manner. Although EPICS is not specifically required, it was selected by FDA as a method that can be used to comply with DSCSA data exchange requirements. Hence, many companies will adopt EPCIS as the preferred method for doing so.

Why use EPCIS

EPCIS is designed to support full track and trace of products for many different purposes. Using EPCIS to meet the requirements of DSCSA lays the foundation not only for compliance, but also for using supply chain data for a myriad of purposes, including tracking and tracing recalled product, anti-counterfeiting, product authentication at point of use, optimization of supply chain routes, and more.

In the JJSC/ABC pilot, the EPCIS data allowed ABC to confirm receipt of every item shipped from JJSC without even opening the boxes. Using EPCIS message standards streamlined the process by establishing similar data file expectations across the supply chain and between the two trading partners.

EPCIS provides visibility to pinpoint a product's location at any time and place in the supply chain, and the possible uses of this data for business benefit are limitless. In this respect, EPCIS is far superior to siloed approaches such as devising a single-purpose data model exclusively for DSCSA compliance. The EPCIS approach allows all companies to maximize the return on the investment made in gathering the data in the first place.

Many of the leading companies in the US pharma market have stated their desire to standardize on EPCIS and the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* as the preferred means to meet DSCSA data requirements. Using EPCIS helps assure best practice for DSCSA data reporting and the greatest degree of interoperability with other trading partners.

Go all in

Some companies will make the November 2017 deadline—some will not. The one-year delay in enforcement gives the rest of the industry time to catch up, and to learn from the experience of those who have gone before. Start now, and you'll be ready when FDA enforcement begins.

Keep in mind while tackling each of the challenges and steps that ultimately, serialization will convey huge benefits beyond compliance. It will ensure continued product access for patients and customers while helping enable investigation of counterfeit and diverted products—adding integrity and security to the supply chain and to brand owners. End-to-end visibility means that recalls, where necessary, can be executed efficiently. The automation of processes and resulting minimization of errors will ultimately increase patient safety, on top of all the brand and supply-chain benefits it holds.

Start now, if you're not already on your way. Manage the transformation from the top down in your organization and make sure all functions and departments are collaborating and communicating. Reach out to engage solution providers and trading partners in your process, and run tests when you're ready. Take advantage of available information resources, including the experiences of companies that are farther along in the process, and GS1 US Implementation Guidelines. The benefits will be worth it. PE

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Mitigating Increased Supply Chain Risk

An agile, responsive operation is key

By Jeff R. Livingstone

The pharmaceutical industry is evolving quickly. On one hand, pharma companies are seeking to reduce R&D costs. On the other hand, thanks to the digital revolution, patients are demanding more personalized care through a multitude of different touch points. And in the middle of it all, compliance requirements are becoming increasingly stringent, while a growing global aging population further burdens supply chains and logistical planning.

In an intricately linked world of researchers, production facilities, logistics providers, care practitioners, and patients, it becomes increasingly difficult to balance these various demands without sacrificing speed or security. Depending upon the resources of today, it may become increasingly difficult to keep up with the demands of tomorrow.

Current challenges

More than ever, there is a need for speed. Consumers are demanding more high-tech care, delivered in-home and when convenient to them. In turn, life sciences and healthcare companies are seeking to accelerate their speed to market, yet must do so against strict regulatory requirements that often limit rapid technological change. Cost also remains a significant barrier to achieving rapid change. While there is huge pressure on pharma companies to deliver through their R&D budget, recent research suggests that only half of them are adopting the right digital tools to achieve this.

Underpinning all of this is a lack of integration behind many supply chain components. Today's top drugmakers are huge conglomerates, made up of divisions, facilities, and research arms located across multiple geographic regions and operating in complex partner ecosystems. To complicate

matters even further, partners may own entire segments of the value chain. Inevitably, data flow is complex and prone to delays. Networks are open to vulnerabilities, and compliance culture is often mismatched. If the industry is to become truly outcome-oriented, then the security of patient data in digital supply chains must be managed in a robust and scalable way.

How security can help

In recent years, the sector has adopted several strategic moves to improve its efficiency, including outsourcing and partnerships. For example, outsourcing clinical trials has allowed pharma companies to reduce their overhead costs, while collaborating with third-party logistics and distribution providers has allowed them to expand and extend existing supply chains. This has reduced costs and improved output. However, it has also opened the door to significant risk.

Cybersecurity has become a huge issue for many companies, and the pharma industry is no exception. Attackers are after all kinds of data, from intellectual property, to private patient health data, to commercially sensitive information. As a result, the digital supply chain is a key target, due to its intimacy with all of the players within the lifecycle. For pharma companies, successfully mitigating this risk demands they protect their entire ecosystem.

The potential ramifications of a breach can be quite damaging. Along with downtime, loss of revenue, and loss of consumer trust, human life is ultimately at stake. In addition, a lack of security can result in the spread of counterfeit drugs. This remains a major issue in many countries. For example, according to the Pharmaceutical Security Institute, the number of worldwide counterfeit drug incidents increased from 196 in 2002, to 2,108 in 2012. Current estimations of the worldwide cost of counterfeit drugs are in the range of $75 billion. In Europe alone, counterfeit drugs cost the pharma industry over €10 billion each year.

New regulations are helping to combat this challenge. From February 2019, all prescription medicines in the EU must come with a security feature allowing drug dispensers such as hospitals, pharmacies, or healthcare providers, to verify their authenticity. In the US, the FDA's Drug Supply Chain Security Act calls for the pharma supply chain to create an "electronic, interoperable system to identify and trace certain specific drugs as they are distributed in the United States."

While regulations are becoming more onerous, pharma organizations should not see this as a threat. Instead, they should see compliance as a reason to improve integration across the entire pharma supply chain. By ensuring adherence early on, forward-thinking companies will reap significant business value from increasingly optimized networks. Success also requires an inclusive approach to security. Pharma companies must consider weaknesses at all points in their relationships, while remediating their own cybersecurity risks and dependencies.

Ensuring the security of the supply chain is just one way drugmakers can cope with the market challenges facing them today. Safeguarding the security of digital patient data is also a significant priority. Making sure these chains are efficient, responsive, and integrated enough to support these journeys is just one step toward this overall aim.

Chain gains: Key steps

However, creating a truly integrated, global supply chain operation is no easy task. There are many critical steps necessary to ensure an agile, responsive and streamlined supply chain.

First, it is important to establish an agreed-upon strategy. This involves demonstrating an understanding of a company's position in the market, where it wants to go, how to operate within local/regional regulations, and how this is likely to affect the operational efficiency of the company's infrastructure.

Second, there needs to be a strong coalescence around this strategy, which starts from the top and funnels down throughout the organization. The company's leadership must support the strategy laid out in the previous step, ensure that any regional teams are set up in a way that aligns within that strategy, and facilitate providing individuals with the training and tools needed to execute.

Third, a wholly integrated global supply chain is dependent upon establishing and using common IT systems and technologies. From warehouse management systems to enterprise resource planning (ERP) platforms and from product and location labeling to quarantine procedures, there must be standardized processes used both internally and externally by partners and vendors.

Finally, industry evolution is unavoidable. When this happens, it is important to not only look at the change happening to the industry, but focus on how one can improve operations to adjust to these oncoming changes. Each enhancement should provide additional avenues for building flexibility into one's processes, as well as seek out ways to leverage the latest technology tools and services available. PE

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16th ANNUAL INDUSTRY AUDIT

Playing the Long Game

With our latest review indicating declines in shareholder value and shareholder value to sales, those companies that score well in critical profit management metrics such as return on invested capital are best positioned to maintain that crucial edge in performance execution

By Bill Trombetta

Compared to the previous year, 2016 came up a bit short when measuring economic performance, according to *Pharm Exec*'s latest Industry Audit examining the business of biopharmaceuticals. The life sciences sector, however, still stands out compared to other industries, as it continues to outpace the overall US economy.

As in past years, *Pharm Exec*'s 16th annual Audit presents a unique perspective on biophama performance, with its focus on shareholder, or enterprise, value—an organization either creates shareholder value or they destroy it. The goal of the Audit is to rank the top publicly traded biopharma companies across 10 metrics, most of them financial. There are 23 publicly traded companies (the "PE 23") that make up this year's rankings.

The metric of sales revenue is used as the starting point. From there, a number of metrics are incorporated that do not commonly appear in other financial output lists. For example, return on assets is highlighted—a much more important metric than simply net profits. Also featured is return on invested capital, which measures how well a company is managed, not just how its stock value can be driven by a feeding frenzy due to activist stock trading that can send the price of stock soaring, but have nothing to do with how a company is managed for profitability.

Annual Sales

Company	Sales 2016	Sales 2015	Percent Change
Johnson & Johnson	$71.94 B	$70.20 B	2.48%
Pfizer	52.82 B	48.85 B	8.15
Roche	51.34 B	50.00 B	2.68
Novartis	48.52 B	49.44 B	(1.86)
Merck & Co.	39.50 B	38.77 B	1.88
GlaxoSmithKline	37.63 B	36.55 B	2.95
Sanofi	37.41 B	38.30 B	(2.32)
Gilead	30.32 B	32.04 B	(5.37)
AbbVie	25.04 B	22.86 B	12.16
AstraZeneca	23.00 B	24.71 B	(6.92)
Amgen	22.68 B	21.34 B	6.28
Teva	21.90 B	19.62 B	11.62
Lilly	21.22 B	19.96 B	1.75
Bristol-Myers Squibb	19.43 B	16.56 B	17.33
Novo Nordisk	16.61 B	16.05 B	3.45
Allergan	14.57 B	15.07 B	(2.65)
Shire	11.40 B	6.43 B	77.57
Mylan	11.12 B	9.47 B	17.43
Celgene	10.93 B	8.90 B	22.80
Biogen	10.19 B	9.32 B	9.33
Valeant	9.67 B	10.45 B	(7.46)
Regeneron	4.86 B	4.10 B	18.54
Endo	4.0 B	3.27 B	13.61
Average	**$25.90 B**	**$24.88 B**	**8.84**

Table 1

Methodology

This year's performance analysis relies on reported information for the 2016–2015 time period. The metrics are also weighted reflecting their relative importance in assessing a company's performance. Some metrics are more important than others. The "Big Three" metrics are: growth in shareholder (enterprise) value; ratio of enterprise value to sales; and return on invested capital. Each of these metrics is weighted at a Three.

The remaining metrics, each weighted as a Two, are: sales growth; gross margin; net profit to sales; sales to assets, and return on assets.

Two non-weighted metrics are used as well. One is sales, general and administrative (SGA) expenses to sales revenue. This metric does not factor into assessing company performance. The reason is that in any one year, or two, a firm may be launching a new product or revising its marketing or branding strategy. For that time period, SGA outlays may need to increase and can be justified as an investment in growth. However, over a longer time period, SGA spend should not outpace sales growth. If that happens, a company is getting bloated and becoming less productive and less efficient. Still, SGA to sales is an important metric to track.

The other non-weighted metric is profit per employee. This metric has less to do with how well a firm is managed, but it does reflect how productive a firm's employees are. The Audit has developed this metric because human capital is a vital differentiator for an industry that relies increasingly on knowledge-based intangibles such as IP to create the most profitable products.

In summary, the Audit consists of three metrics with a weight of Three, which indicates their higher relative importance to shareholder performance compared to the metrics that carry a weight of Two. The higher a company performs on each metric is reflected in a ranking based on the number of

Audit Data Sources & Table Key

( ) Denotes loss
B = Billions of US$
M = Millions of US$
K = Thousands of US$
Figures are rounded up where appropriate
Sources: *Forbes*, *Fortune*, *Business Week*, *The New York Times*, *The Wall Street Journal*, FinanceYahoo.com, EvauatePharma, FactSet, and various 10k and annual reports. The data presented are for the full year, beginning on January 1, 2016 and ending on December 31, 2016.

Enterprise Value

Company	EV 2016	EV 2015	Percent Change
Johnson & Johnson	327.0 B	264.65 B	23.56
Pfizer	227.2 B	215.43 B	5.48
Roche	234.5 B	264.5 B	(11.34)
Novartis	212.0 B	223.96 B	(5.34)
Merck & Co.	191.60 B	160.24 B	19.57
GlaxoSmithKline	123.72 B	123.37 B	0.03
Sanofi	121.4 B	117.20 B	3.58
Gilead	103.96 B	152.0 B	(34.18)
AbbVie	133.20 B	118.64 B	12.27
AstraZeneca	88.75 B	97.56 B	(9.03)
Amgen	128.1 B	122.49 B	9.46
Teva	72.74 B	62.72 B	15.98
Lilly	82.28 B	96.61 B	(6.61)
Bristol-Myers Squibb	97.53 B	117.20 B	(16.78)
Novo Nordisk	104.8 B	148.0 B	(30.00)
Allergan	105.0 B	170.8 B	(38.24)
Shire	$71.85 B	$43.52 B	75.10
Mylan	37.37 B	32.48 B	15.05
Celgene	103.3 B	101.9 B	2.26
Biogen	64.80 B	70.09 B	(7.55)
Valeant	33.36 B	65.52 B	(49.10)
Regeneron	40.83 B	56.09 B	(27.20)
Endo	15.4 B	21.32 B	(27.70)
Average	**$118.8 B**	**$123.3 B**	**(4.30%)**

Table 2

points it receives. The highest placing for each metric is 23 and the lowest is one. For example, if a firm places 22 out of the 23 on a key metric like enterprise value to sales, the company receives 66 points on that metric, given its 22 ranking with a weight of 3 (22 rank × 3 = 66 points). In another example, if a firm comes in at a ranking of six, toward the bottom, on the metric sales growth, with a weight of Two, the company's total points would be 12 (6 ranking × 2 = 12 points). Each of the 23 company's points-based placement per metric are totaled to arrive at an overall ranking to determine which of the 23 receives the most points to become this year's winner.

Finally, in addition to these 10 performance metrics, the Audit includes several benchmarks that compare the biopharma sector as a whole to other industries as well as the 23 individual biopharma companies in this year's list. For example, how do the biopharma sector and the 23 firms figure in comparison to the overall picture of the US economy and inflation? Then there are more specific indices related to economic performance such as the Dow Jones, Standard & Poor, Nasdaq, and others.

'Macro' benchmarks

If a biopharma company can't beat the growth of the US economy and the US Consumer Price Index (CPI), then it is in trouble. For 2016, the US economy expanded about 2% and the rate of inflation also increased about the same. In comparison, the PE 23 substantially outpaced the US economy, growing at 8.8% in sales revenue. The group fared far better than the Fortune 500 in 2016, whose growth was at negative 1%.

Sales growth

Table 1 (see facing page) shows sales growth for 2015-2016. Revenue from sales is always good to have, but it tells us little about how well a company performs. For instance, AbbVie's sales in 2016 are $5 billion lower than Gilead's, but AbbVie's enterprise value, or market capitalization, is $20 billion higher. As the old adage states, "either you grow or you die." Note in Table 1 that six companies experienced negative growth. Mergers and acquisitions also drive increases in sales as opposed to organic revenue generation that come from within a firm's in-house labs.

Enterprise value and enterprise value percentage growth

Table 2 on enterprise value (EV) shows that the average change for 2016 for the PE 23 was negative 4.3%, vs. 6.8% growth in 2015. Twelve of the PE 23 went backward in EV.

EV is directly related to shareholder value, and is derived from market capitalization (the number of common stock shares out-

Enterprise Value to Sales

Company	EV/S 2016	EV/S 2015
Celgene	8.8	11.45
Regeneron	7.89	3.47
Shire	7.16	6.83
Allergan	6.51	11.27
Biogen	6.16	7.52
Valeant	5.97	6.27
Novo Nordisk	5.62	9.47
AbbVie	5.08	5.49
Bristol-Myers Squibb	5.03	7.06
Amgen	4.6	5.74
Merck & Co.	4.37	4.13
Roche	4.23	5.29
Pfizer	4.2	4.41
Johnson & Johnson	4.13	3.77
Novartis	4.02	4.53
Lilly	4.02	4.84
AstraZeneca	3.9	3.95
Endo	3.85	5.5
Gilead	3.59	9.75
Teva	3.36	3.2
GlaxoSmithKline	3.35	3.38
Mylan	3.11	3.43
Sanofi	3.1	3.14
Average	**4.87**	**5.82**

Table 3

Gross Margin

Company	Gross Margin 2016	Gross Margin 2015
Celgene	92.55%	92.15%
Regeneron	91.68	88.61
Gilead	85.49	87.15
Novo Nordisk	84.63	85.00
AstraZeneca	82.63	75.35
Biogen	82.28	82.59
Amgen	81.65	80.43
AbbVie	77.32	79.45
Bristol-Myers Squibb	74.61	77.33
Lilly	73.35	74.76
Roche	70.38	69.34
Johnson & Johsnson	69.92	69.26
Pfizer	69.8	73.07
GlaxoSmithKline	67.94	62.73
Merck & Co.	66.17	62.53
Novartis	63.89	64.8
Sanofi	63.07	61.89
Shire	55.01	75.69
Teva	54.14	57.73
Endo	48.63	36.5
Valeant	45.38	53.37
Allergan	42.9	32.57
Mylan	42.89	46.7
Average	**68.96%**	**68.70%**

Table 4

standing multiplied by the price of the stock on a given day), plus cash and cash-like assets, minus debts and liabilities. The higher the ratio is, the higher the value of the company. The most valuable biopharma firm in the world is Johnson & Johnson, with an EV at the end of December 2016 of $327 billion, an increase of 23.6% over 2015.

As mentioned, EV is analogous to market capitalization and both numbers are close. For example, Pfizer's EV for 2016 was $227 billion; its market capitalization was $203 billion. Across the Fortune 500 list, market capitalization increased an average of 11.7% in 2016 from the previous year.

Enterprise value to sales

The EV/sales ratio reflects a market assessment of future growth and profitability. The higher the ratio suggests that a firm's best days are ahead; the lower the ratio, it means the firm has hit a mature phase where growth and/or profitability has peaked. Table 3, EV to sales, shows the average ratio for 2016 was 4.87 times sales, compared to 5.82 times sales in 2015. This reinforces the drop in shareholder value. Only five companies increased on this critical metric.

Gross margin

Table 4 shows gross margin, defined as sales revenue minus cost of goods sold. This metric reflects a firm's ability to price. The higher gross margin, the more power the company has to raise prices. Average gross margin for the PE 23 in 2016 was 68.96%, a slight increase from 68.7% for 2015. The figure is impressive, nonetheless, given the industry's hostile pricing environment.

Net Income to Sales

Company	2016	2015
Gilead	56.39%	67.61%
Biogen	48.39	51.15
Novo Nordisk	42.76	40.29
Amgen	40.4	37.39
AbbVie	30.75	29.07
Bristol-Myers Squibb	30.45	12.54
Johnson & Johnson	27.53	27.34
Regeneron	27.36	27.51
Roche	25.72	24.90
Celgene	21.72	22.73
Sanofi	16.79	15.18
Lilly	15.9	13.98
Pfizer	15.81	18.35
AstraZeneca	15.59	12.49
Novartis	14.55	15.91
Merck & Co.	11.8	13.93
GlaxoSmithKline	6.93	43.94
Shire	4.27	21.60
Teva	3.76	11.99
Mylan	1.09	9.67
Endo	(11.06)	(23.22)
Allergan	(19.44)	(29.40)
Valeant	(25,17)	(1.49)
Average	**19.92%**	**22.50%**

Table 5

Sales to Assets

Company	S/A 2016	S/A 2015
Novo Nordisk	1.18	1.28
Regeneron	0.77	0.87
Roche	0.66	0.64
Bristol-Myers Squibb	0.59	0.51
Lilly	0.57	0.55
Gilead	0.56	0.74
Johnson & Johnson	0.52	0.53
GlaxoSmithKline	0.5	0.51
Biogen	0.48	0.55
AbbVie	0.43	0.57
Merck & Co.	0.4	0.39
Celgene	0.4	0.4
Mylan	0.39	0.5
AstraZeneca	0.37	0.41
Novartis	0.35	0.37
Sanofi	0.33	0.35
Pfizer	0.31	0.29
Amgen	0.3	0.3
Teva	0.3	0.39
Endo	0.28	0.22
Shire	0.26	0.42
Valeant	0.21	0.28
Allergan	0.11	0.35
Average	**0.45**	**0.5**

Table 6

Warren Buffet characterizes pricing power as "the moat surrounding and protecting your castle." The ability to raise price and keep prices high is seen among the stratospheric pricing levels of Gilead, AstraZeneca, Amgen, Novo Nordisk, Celgene, Biogen, and Regeneron. These companies are masters of their pricing domains.

Net income to sales

Table 5 is an indicator of profitability—earnings before interest, taxes, depreciation, and amortization (EBITDA) in relation to sales revenue. Net profit is arrived at after subtracting operating expenses from gross margin. Net profit to sales is your profit margin.

The profit margin measures how well the company deals with sales, pricing, cost of goods sold for ingredients used in manufacturing its products, operating expenses, and discounts, rebates, and royalties, if any. If a company cannot grow revenues, the appropriate management fallback response is to get a better handle on operating expenses. Overall profitability for the PE 23 decreased from 22.5% in 2015 to 19.92% in 2016. Nevertheless, the biopharma industry is a very profitable sector when comparing the 19.92% profit margin to the Fortune 500 average profitability of about 8%.

Sales to assets

Table 6, asset management, relays how well a firm handles managing its collective assets, including cash, accounts receivable, property, equipment, and inventory. The ratio reflects what a firm gets

Return on Assets

Company	R/A 2016	R/A 2015
Novo Nordisk	40.06	41.29
Gilead	24.81	41.87
Biogen	17.47	20.97
Regeneron	14.23	13.42
Bristol-Myers Squibb	13.62	4.78
Roche	12.55	11.72
Johnson & Johnson	12.05	11.65
Amgen	10.35	9.87
AbbVie	9.94	6.22
Lilly	7.36	6.62
Celgene	7.25	7.22
AstraZeneca	5.67	4.72
Novartis	5.0	5.26
Pfizer	4.25	4.13
Sanofi	4.25	4.42
Merck & Co.	3.98	4.44
GlaxoSmithKline	1.62	17.9
Mylan	1.68	4.44
Endo	1.46	(1.98)
Shire	1.37	8.75
Teva	0.44	3.15
Allergan	(0.71)	(3.05)
Valeant	(5.21)	(0.78)
Average	**9.54%**	**12.60%**

Table 7

Return on Invested Capital

Company	ROIC 2016	ROIC 2015
Novo Nordisk	82.23	79.9
Gilead	31.78	53.98
Roche	24.25	23.02
Biogen	21.44	26.08
Bristol-Myers Squibb	20.87	7.29
Regeneron	20.31	18.13
Johnson & Johnson	18.7	18.25
AbbVie	15.95	22.5
Amgen	13.15	12.24
Lilly	12.19	11.13
AstraZeneca	11.3	9.22
Celgene	9.86	9.72
Pfizer	7.8	7.08
Novartis	7.05	7.61
Sanofi	6.04	6.28
Merck & Co.	5.9	6.53
GlaxoSmithKline	5.04	41.55
Mylan	2.27	6.77
Shire	1.93	14.27
Endo	1.89	(2.89)
Teva	0.63	4.53
Allergan	(0.84)	(3.59)
Valeant	(6.97)	(1.03)
Average	**13.85**	**16.78**

Table 8

back in return for every dollar it invests in these assets. Setting the high bar at the top of Table 6 once again is Novo Nordisk, with a sales to assets ratio of 1.18; that is, for every dollar Novo Nordisk invests in assets, it generates $1.18 in return. The average sales to assets ratio for 2016 was 0.447, reflecting a decrease from 2015 in managing assets on the balance sheet.

Return on assets

When you multiply profit to sales times sales to assets, you get profit to assets, a very important metric. Table 7, return on assets, is much more informative than just the profit margin because it measures how well a company is managed; that is, how good the firm is at not just margin management, but at effectively deploying its assets as well.

Table 7 shows Novo Nordisk with a stunning return on assets metric of 40.06. To put this in perspective, Novo Nordisk's return on assets is on par with other companies' gross margins.

Return on invested capital

As with return on assets, Table 8, return on invested capital (ROIC), is a measure of how well a firm is managed. No financial gimmickry here, just the result of how good management is at investing in assets and getting a return on those assets through solid strategies and execution. ROIC dropped from 16.78% on average for the PE 23 in 2015 to 13.85% in 2016. Gilead's number fell to 31.78% from 53.98% the year before, along with a sharp drop in shareholder value and the EV to sales ratio due to the leveling off of the hepati-

Net Profit to Employee

Company	2016
Gilead	$1.5 M
Biogen	699 K
Amgen	601 K
Celgene	488 K
AbbVie	366 K
Allergan	356 K
Regeneron	265 K
Merck & Co.	233.7 K
Bristol-Myers Squibb	232.2 K
Pfizer	219 K
Roche	203.1 K
Johnson & Johnson	199 K
Valeant	187 K
Novo Nordisk	186.2 K
Shire	142.8 K
Lilly	130 K
Novartis	127 K
GlaxoSmithKline	121 K
Teva	108 K
AstraZeneca	106.6 K
Sanofi	107 K
Mylan	88.3 K
Endo	NA
Average	**$302.9 K**

Table 9

General & Administrative Expenses to Sales

Company	GA E/S 2016	GA E/S 2015
Endo	19.08%	23.80%
Gilead	24.83	19.76
Mylan	28.79	27.72
Teva	32.9	31.81
Valeant	33.4	28.82
Shire	37.93	41.62
Biogen	38.47	44.27
AbbVie	39.12	42.52
Amgen	39.5	41.53
Merck & Co.	39.6	43.43
Johnson & Johnson	40.24	43.1
Roche	40.37	41.2
Novo Nordisk	41.96	42.41
Pfizer	42.78	45.85
Sanofi	43.13	41.69
GlaxoSmithKline	43.69	44.28
Novartis	47.17	46.89
Allergan	47.46	38.11
Bristol-Myers Squibb	47.95	53.55
Lilly	44.11	56.76
AstraZeneca	63.59	60.86
Regeneron	64.3	58.1
Celgene	65.26	66.27
Average	**42.46%**	**42.80%**

Table 10

tis C drug wave. Novo Nordisk's ROIC of 82.23% is almost incomprehensible when you consider that for many biopharma companies that number would be a respectable gross margin; Novo Nordisk hits that number at the ROIC level.

Also, it's worth comparing the ROIC and return on assets that measure performance to financial machinations such as stock buybacks and dividend gifts. Such maneuvers lift earnings per share and, correspondingly, price to earnings—but without necessarily investing in the business for long-term gain.

Net profit per employee

Table 9 shows the profit generated per employee, which is a reliable measure of productivity. Gilead is at the top here, with each employee producing $1.5 million in profit for 2016. There is a dropoff to the No. 2 and 3 spots, where Biogen and Amgen delivered $699,000 and $601,000, respectively, per employee. Put those three company's numbers in perspective, Apple's profit per employee is about $500,000. Big box retailer WalMart's profit per employee is about $7,000.

Selling, general and administrative expenses to sales

Table 10 shows a very important metric: SGA to sales. It's strategically prescient, even though it is less useful in measuring year-on-year performance. In general, SGA growth should not exceed growth in sales or it will

start cutting into profitability. Another word for SGA is "overhead," and when this is above average for the sector or increasing at a faster pace than sales, the firm becomes bloated and less productive. The reason why the Audit does not weigh this metric is that for a given, or short, time period, a company may need to pump more money into promotion or marketing or provide money for litigation and other similar expenses. Hence, over a defined period, SGA can exceed sales growth. In Table 10, we see that the companies on this year's list are slowing the rate of SGA growth incrementally. SGA averaged 42.8% of sales in 2015, slightly decreasing to an average of 42.46% in 2016.

Despite not factoring into the PE 23 scoring, SGA to sales is a critical metric, nonetheless. The total estimated amount that large biopharma companies will need to reduce their SGA from 2016 through the end of 2017 to maintain present levels of profitability is $36 billion, according to the IMS Institute for Healthcare Informatics. This reinforces McKinsey & Co.'s ongoing analysis of healthcare productivity. Productivity rates for healthcare overall since 1990 have dropped by negative 0.8%, while average employment has gone up by 3%.

SGA is comprised of operating expenses such as marketing and advertising spend. As a way to gauge whether SGA expenditures are justified, companies may look at their income statements and scrutinize the number of ad agencies they are working with; if the number can be reduced, that could lead to savings in SGA. The supply chain can be looked to for savings and efficiencies, as each supplier's value chain, or gross margin, impacts operating expenses.

Note how high the SGA is for self-proclaimed biotechs like AstraZeneca, which, in its case, is 20 percentage points higher than the group average of 42.8%. Also look, for example, at GlaxoSmithKline. The company is incurring substantial restructuring costs as it integrates 12,000 employees into its consumer and vaccine businesses while trying to offset those SGA costs by reducing the number of drug packaging variants and streamlining its external supply chain network.

And the Winner is…

Company	Score
Regeneron	340
Biogen	329
Novo Nordisk	327
Celgene	317
Bristol-Myers Squibb	305
AbbVie	302
Johnson & Johnson	291
Amgen	282
Roche	277
Gilead	261
Lilly	232
Shire	231
Pfizer	220
Merck & Co.	218
AstraZeneca	193
Novartis	181
GlaxoSmithKline	171
Mylan	165
Sanofi	161
Teva	151
Endo	113
Allergan	100
Valeant	76

Table 11

Points king

Our final Table 11 reveals the winner for 2017: Regeneron. The New York-based biotech came out on top in 2014 as well. Rounding out the top five companies this year are Biogen, Novo Nordisk, Celgene, and Bristol-Myers Squibb.

Regeneron continues to see sales grow for its flagship drug, Eylea, domestically and globally. Its cardiovascular and dermatitis treatments have growth potential as well. Regeneron's SGA to sales ratio is very high, but the company is in a growth mode.

Biogen's sales growth was stagnant for 2016 and two key metrics, EV growth and EV to sales dropped. Biogen, however, was able to maintain a high markup for its drugs and the company's ROIC was at the higher levels.

Novo Nordisk's performance in EV growth and EV to sales was similar, but its ability to perform at the highest level of asset management was notable. The company increased its ROIC as well.

Celgene was the second-highest sales growth performer. Its EV increased slightly while EV to sales dropped. Celgene's gross margin is in nosebleed territory, even higher than Regeneron's.

BMS demonstrated relatively high sales growth, but shareholder value and EV to sales slid due to what is plaguing all high-cost biopharma firms: payer resistance and downward pressure on pricing. Still, BMS demonstrated the highest increase in profitability, while its ROIC almost trebled. PE

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The Fab 5 vs. the Frightful Five

An annual *Pharm Exec* Audit tradition is to compare the top five, or "Fab 5", biopharma performers from our rankings with the so-called "Frightful Five" from outside the industry. *New York Times* columnist Farhad Manjoo coined the term referring to the handful of American high-tech companies that dominate not just the US economy, but much of the global economy as well. The Frightful Five include Apple, Alphabet (Google), Amazon, Facebook, and Microsoft. How does this year's Fab 5 stack up on the following mission-critical metrics?

Enterprise value

Apple: $843 B	Regeneron: $40.8 B
Alphabet: $660 B	Biogen: $64.8 B
Amazon: $463 B	Novo Nordisk: $104.8 B
Facebook: $397 B	Celgene: $103.3 B
Microsoft: $488 B	BMS: $97.5 B

Shareholder value is clearly one-sided in favor of the Frightful Five. Even J&J, the most valuable pharma firm in the world, at $327 billion, trails Facebook.

Enterprise value to sales

Apple: 2.91	Regeneron: 7.89
Alphabet: 5.19	Biogen: 6.16
Amazon: 2.59	Novo Nordisk: 5.62
Facebook: 10.97	Celgene: 8.80
Microsoft: 4.01	BMS: 5.03

Amazon's potential to grow is figuratively unlimited; its profit is miniscule, yet its potential to enter any market is scary. Jeff Bezos, Amazon's CEO, was asked recently for his take on competition. Bezos's reply was: "Your margin is my business." Wait until Bezos gets a look at the nosebleed 80% to 90% markups for the Fab 5.

Return on invested capital

Apple: 24.27	Regeneron: 20.31
Alphabet: 14.68	Biogen: 21.44
Amazon: 7.64	Novo Nordisk: 82.23
Facebook: 19.68	Celgene: 9.86
Microsoft: 15.22	BMS: 20.87

On ROIC, the Fab 5 more than holds its own, with Novo Nordisk leaving everyone in the dust.

Profit per employee

Apple: $500 K	Regeneron: $265 K
Alphabet: $270 K	Biogen: $699 K
Amazon: $11.4 K	Novo Nordisk: $186 K
Facebook: $600 K	Celgene: $488 K
Microsoft: $170 K	BMS: $232 K

To put this in perspective, Gilead, ranked 10th on the audit winners' list, posted a profit per employee of $1.5 million for 2016. In comparison, the supermarket chain Kroger, for example, posts profit per employee of $10,800.

— Bill Trombetta

Behind the Numbers: Impacting Business Trends

High drug prices. The pressure on high drug prices continues to hang over the sector. Even the classic generic companies, Mylan and Teva, are facing downward competitive pricing pressure as reflected by their decreased gross margins for 2016. Increasing value-based payment models are appearing in cancer drug pricing, focusing on high drug prices and wide variation in cancer treatments.

Lilly, Sanofi, and Novo Nordisk are experiencing pressure on diabetes and insulin drug pricing. Pharmacy benefit manager Express Scripts has removed some of Novo Nordisk's diabetes drugs from its formulary.

The importance of sales growth. Shareholder value and enterprise value to sales tumbled in 2016. The decline in sales growth for some of the PE 23 has taken a toll. Interesting comparisons outside pharma include the auto industry. Tesla, for example, lost about a half-billion dollars, but its growth potential is sky high; its market cap now exceeds both Ford and General Motors, even though those companies have generated considerable profitability in the billions of dollars. Amazon, in its 20-year existence, has barely churned out a $5 billion total profit; compare that to Walmart's profit of $14 billion just in 2016. Yet Walmart has half the market capitalization of Amazon, according to *The New York Times*.

Well-managed companies. There are ways to juice up shareholder value through financial smoke and mirrors. But one metric reflects how well a company is managed: return on invested capital (ROIC). Margin management and asset management are key. Novo Nordisk, Gilead, Roche, Biogen, BMS, Regeneron, and J&J are standouts on operational excellence as reflected by their ROIC numbers.

Another gauge for assessing how well-managed a company is can be gleaned from comparing sales; sales, general and administrative (SGA) expenses; and profit growth. Sales should grow faster than SGA and profit should grow faster than sales.

— Bill Trombetta

Data Inflection Point

The time is now for pharma to take next steps in tech adoption

"Digital transformation" seem to be the buzzwords of this era for the life sciences industry and it's no wonder, given the rise of digital information in healthcare.

Today we find ourselves in an industry that is increasingly complex; a data-rich environment that brings more and more information to the table, with a growing number of stakeholders and a need to draw insights—the right insights—from the multitude of data available to us. These insights drive market readiness decisions and often lie at the crux of a product market strategy.

Just as the technological revolutions of customer relationship management (CRM) tools and big data have changed how life sciences companies do business, machine-guided, predictive insights from that data are the industry's next big opportunity.

The future is here

According to *Forbes*, "Big data is transforming businesses across industry sectors—from industrial systems to financial services, from media to healthcare delivery, from drug discovery to government services, from national security to professional sports."

In her annual 2017 "state of technology" presentation, Mary Meeker, the visionary Internet maven of venture capital firm Kleiner Perkins Caufield & Byers, dedicated 31 pages to digital health and called this moment "the digital health inflection point." We are now looking at an industrial revolution that is driving a need for more sophisticated technologies to manage the intricacies of data commerce.

Similarly, a Bain & Company report underlines the mastery of data and digital technologies as the distinguishing characteristic of the most competitive pharmaceutical companies in the next 10 years.

Furthermore, big tech companies like Apple, Google, and Facebook are increasingly investing in healthcare. In fact, Bill Maris, a Google Ventures founder, left Google this year to raise a new investment fund of over $230 million that will focus solely on healthcare investments.

What's holding us back

The healthcare industry has been slow to adopt emerging technologies, but the cautious pace is understandable.

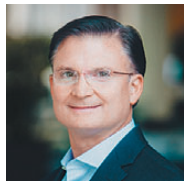
Healthcare companies create and manage exponentially-increasing amounts of highly sensitive data, and must be compliant with the laws and regulations that surround it. "The healthcare industry has very stringent requirements around cryptographic security that dictates how and when the data needs to be encrypted, transmitted, and decrypted," writes Meeta Dash of the Tokbox Blog. "The scope and complexity of healthcare regulation has made it incredibly difficult for organizations to adopt new technologies."

Add to that the changing stakeholder landscape of healthcare, which has become evermore complex. Traditionally, the industry catered to physicians—something that CRM software managed well. Field representative-generated data also helped to provide a more complete view of customers and markets for improved commercial and operational excellence. Yet, even as recently as 2016, according to an Econsultancy and Ogilvy CommonHealth report, up to 44% of biopharmaceutical companies said they were not prepared to use their CRM data in marketing campaigns.

Now, there are more stakeholders than just the physician; payers, prescribers, providers, provider networks, and patients are as relevant as physicians, and physicians' networks of influence are proving increasingly important in decision-making.

Changes in regulations and culture are also redefining what is meant by "product value" for life sciences companies; new treatments are no longer rated in terms of efficacy and cost alone, but also in terms of how well they address customer needs.

As healthcare organizations around the world grapple with increasing price pressures, emphasis on value-based pricing models is becoming more pronounced and providers are under pressure to do more with less as well. Pay-for-performance or value-based pricing agreements with healthcare providers and insurers—much like the one struck between Novartis and Aetna/Cigna early last year for heart drug Entresto—are becoming more commonplace and, in turn, holding greater sway over physician choice.



LANCE SCOTT is President and CEO of Zephyr Health

Additionally, segmented and sometimes siloed company divisions like market access or managed care are also quickly becoming essential sources (and consumers) of data for a more complete and holistic approach to "go-to-market" planning and execution.

To keep up with this growing stakeholder network, life sciences companies require access to deeper and more diverse data sets. They also need more complete, integrated, and cross-enterprise technology solutions that can give them a broader view of the "customer," with relationship and network analytics that provide a cohesive view of their market potential.

The tipping point

The first step for the healthcare industry was to digitize its existing banks of data, replacing analog and paper-based systems with digital versions. The data generated within a given organization then became easier to organize, analyze, and share.

The next step was to collect more data sources—in other words, it was time to put the word "big" in front of "data," and to access more channels of information. According to a McKinsey & Co. patient survey, nearly 70% of US consumers use an online channel to manage health and wellness, and patients can now access their own health records online and log important health data from their smartphones—simple actions that were previously unavailable. This democratization of healthcare information has returned incredible amounts of data to healthcare providers and the life sciences companies that work with them.

Patients are now connected instantly with disease-related information as well as online forums and communities. Meanwhile, apps and wearable technology are recording performance data based on lifestyle, selected symptoms, adherence, and overall well-being.

The result is that patients are more engaged than ever before with their treatment pathway, and frequently approach their physician with ideas and suggestions, making them another important influencing factor for a brand.

Key opinion leaders and healthcare professionals are also using digital technologies that produce real-time insights into customer relations, opinions, and patient needs. At the same time, however, it's still difficult to understand and set digital markers along the patient journey—including the increasingly complicated reimbursement journey—that align with a brand's digital strategy.

These activities all generate high-value data that can be used as a part of a complete brand strategy, and that can be integrated into that strategy for improved customer access and engagement. Now, life sciences companies need to more effectively manage new and existing data sets; to gather, compile, and analyze them in order to better understand how to deliver value for their product portfolio.

Tapping into these data sources and the insights they harbor is vital for life sciences firms to inform and transform their business operations. In order to remain relevant and align with customer values, they must leverage real-time data to make more agile and confident business decisions and predict future trends.

Changes in regulations and culture are redefining what is meant by "product value" for life sciences companies; new treatments are no longer rated in terms of efficacy and cost alone, but also in terms of how well they address customer needs

What's next

This technological adaptation in healthcare reflects our rapidly accelerating ability to adopt new digital solutions. A decade ago, smartphones didn't even exist and now more than half of the world's population uses one. Similarly, in those 10 years, over 80% of the US population now has at least one social media profile. The pace at which new technologies are created and adopted is redoubling again and again.

The next step is to take these massive datasets and put them to work. Having "big data" at our fingertips and knowing what to do with it is another story. Today, analysts still have to know which questions to ask of the data in order to gain any meaning from it. Shifting to machine-guided analytics means letting the data speak to us directly and suggest next-best steps. New technologies are less "human-guided" and

Continued on Page 53

Farmak

Farmak is committed to manufacture of generic products with proved efficacy for Ukraine and 20 European and CIS countries*

All Farmak's production lines received European GMP Certificates*.

Farmak is the biggest pharmaceutical product exporter in Ukraine**.

Farmak manufactures efficient products from almost all therapeutic groups of ATC classification*.

Each year, Farmak launches over 20 new products that have been developed for 5-7 years and proved efficacy*.

In Ukraine, Farmak has been a leader of drugstore sales for 7 years in a row**.

* Internal data of JSC Farmak
** In monetary terms by sales volume, according to Proxima Research in 2010-2016

HEALTHCARE & LIFE SCIENCES REVIEW

UKRAINE

A New Era

Since the breakout of the 2013 Euromaidan Revolution which culminated in the ousting of Ukrainian President Viktor Yanukovych, Ukraine has made global headlines for geopolitical and military strife that includes the annexation of Crimea by the Russian Federation in March 2014 as well as the triggering of an armed conflict in the east of the country. While the critical handling of this tense situation has monopolized a large share of the political agenda of President Petro Poroshenko since his election in May 2014, the country has also been hit by one of the deepest economic crises of its post-independence history. According to the State Service of Statistics, Ukraine's real GDP fell by 6.6 percent in 2014 and by 9.9 percent in 2015, before recovering modestly by 2.3 percent in 2016, while the exchange rate of the Ukrainian currency versus the US dollar has decreased more than threefold since 2014.

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"The industry, more than anything, has been pulled down heavily by currency devaluation," explains Filya Zhebrovska, chairman of the supervisory board of Farmak, Ukraine's largest domestic company and the market leader in the country since 2010. Although it displayed a sustained growth when expressed in local currency and volume, "the value of the Ukrainian pharmaceutical retail market decreased from around USD 5 billion in 2013 to USD 2.3 billion in 2015," documents Dmytro Spitsyn, general manager of TEVA. Although this challenging context led some international companies to leave Ukraine, many players – including both local and international companies – clearly refused to remain insensible to the deep crisis affecting the Ukrainian population. "Although the crisis entailed the loss of a third of our local revenues, we did not reconsider our commitment to Ukrainian patients or abandon the market – far from it! As a matter of fact, we provided substantial humanitarian aid in 2015 and 2016, and over 120 state medical institutions across the country freely received Wörwag's high quality medical products," explains the company's country manager in Ukraine, Victoria Tarabanova.

"Over the last two years, Ukraine has faced serious defense and economic problems, which have moreover drawn a large share of the government's resources – to the detriment of our healthcare sector," relates Dr. Natalya Gudz, the head of the State Service on Medicines and Drugs Control (SMDC), a tricky situation which did not contribute to improving patient outcomes in a country where life expectancy remains ten years lower than the EU average. "Overall, the Ukrainian health system still displays dramatic shortcomings inherited from the Soviet era: a low state budget allocated to healthcare, a medical infrastructure that is not adapted to the management of chronic diseases, as well as an unsatisfactory access to pharmaceutical products because of the absence of a mandatory state medical insurance system,"



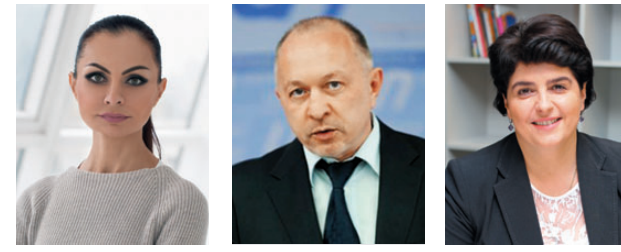
Dmytro Spitsyn, general manager, TEVA Ukraine; Filya Zhebrovska, chairman of the supervisory board, Farmak; Natalya Gudz, head, State Service of Ukraine on Medicines and Drugs Control

adds Wörwag's Tarabanova, "and we have now reached a critical point where deeply reforming our health system has become a vital necessity."

In this regard, President Poroshenko and the government of Prime Minister Volodymyr Groysman have championed the introduction of an unprecedented set of reforms, prompting many industry observers to highlight that Ukraine's health system has evolved more significantly over the past 24 months than it did during the previous 24 years. This encouraging dynamic notably relates to a pioneering reimbursement mechanism covering 21 international nonproprietary names (INNs) in three therapeutic areas (diabetes, asthma, and cardiovascular diseases), which was implemented on April 1 2017. "Nevertheless, this first version of a reimbursement program only covers one percent of the total market value. We deeply hope that this coverage will be expanded year on year; but we need to acknowledge that Ukraine will remain a market mainly driven by private spending in the foreseeable future," warns Liana Maksyoutova, country manager of Polpharma in Ukraine, where out-of-pocket expenses make up around 85 percent of all medicine spending.

"Furthermore, as a result of regulations implemented in 2015, approximately half of the Ministry of Health's USD 151 million drug procurement budget was transferred to the United Nations Children's Fund (UNICEF), the United Nations Development Program (UNDP), and UK-based procurement expert Crown Agents, in an attempt to tackle corruption and rationalize public procurements", explains Volodymyr Redko, the executive director of APRaD, the association gathering 16 international, R&D-driven companies. This temporary reform – a newly created governmental procurement agency is set to take over procurement by 2019 – has drawn a relatively high level of criticism among both international and local companies, notably because it still displays significant technical frailties. "Our European partners in Brussels were particularly surprised to see that our government did not choose to immediately set up an independent national procurement agency instead of transferring a large share of its procurement budget to these NGOs," explains APRaD's Redko, while local players regret that VAT rulings have created an unfair playing field between domestic and international companies. "The laws state that drugs imported to Ukraine are VAT free, while drugs produced in Ukraine are imposed with a seven percent rate. Therefore, domestic companies, which moreover pay all their taxes to the Ukrainian State, are tendering with elevated prices and cannot compete fairly," explains Petro Bagriy, the president of the Association of Manufacturers of Medicines of Ukraine (AMMU), which gathers seven leading domestic pharmaceutical companies. "As Ukraine already holds a mature domestic pharmaceutical industry, it would be more cost effective for the government to construct agreements with local producers," considers Filya Zhebrovska, chairman of the supervisory board of Farmak, the largest domestic company and Ukraine's market leader, before warning that "if the aforementioned international agencies look to work more often with foreign pharmaceutical companies than with local companies, the latter will be less focused on advancing certain critical areas, like vaccines and oncology, as there will be less return on investment."

In this regard, a third axis of reforms chosen by Ukraine's government aims to further open up Ukraine's pharmaceutical market to international products. "A new law was approved in August 2016 to ease the registration of pharmaceutical products already approved by competent authorities in the US, Switzerland, Japan, Australia, Canada, and the European Union," explains Tetyana Dumenko, director of the State Expert Center (SEC), the regulatory agency responsible for product registration, pre-clinical studies and clinical trials approval, about a regulation which also stipulates that the final decision of the Ministry of Health will be issued within only 17 business days. "This reform stands as great news for Ukrainian patients, as we expect it will incite foreign companies to bring a larger number of their products in the country. We have already registered several EMA-approved products via this updated regulatory pathway, and we can testify that stipulated timelines were respected," highlights Victoria Bandyk,



Liana Maksyoutova, country manager, Polpharma; Dr. Volodymyr Redko, executive director, Association of Pharmaceutical Research and Development (APRaD); Tetyana Dumenko, director, The State Expert Center (SEC)

COO of Bioscience, a comprehensive group of healthcare-focused companies which notably includes a branch specialized in product registration and promotion in Ukraine, before adding that "in 2015, Ukraine's Government and Parliament moreover approved the set up of a simplified market access procedure for medicines that are critical for public health (cancer, orphan diseases, HIV/AIDS, tuberculosis, vaccines, and others)." SEC's goal for 2017 is to implement a one-off registration procedure, in place of Ukraine's historical model which implied to re-register products every five years, as well as setting up an electronic application form, while the head of the State Service on Medicines and Drugs

Meeting the global insulin need

Lyubov Vyshnevska, chairman of the board, Indar

Since her appointment in 2012 as chairman of the board of Indar, the only company in Ukraine and one of the few companies in the world operating throughout the entire production cycle of genetically engineered insulin (r-DNA), one of the main missions of Lyubov Vyshnevska has been to bring the company to the next level and significantly increase its international presence. In 2017, Indar finished the ambitious reconstruction plan of its Ukrainian manufacturing plant and just started building a new facility fully dedicated to insulin synthesis, which they plan to complete in July 2019. "This new manufacturing arm will allow us to double our company's production capacity, while international markets already make up more than 90 percent of our company's overall revenues. We export to 22 different countries across Asia, Africa, Eastern Europe and South America and hold products at various stages of their registration processes in 39 countries overall" explains Vyshnevska. "Insulin stands as a life-changing product that is in high-demand all over the world, and we truly see Indar as a global company," she adds.

Brazil holds a strategic importance in this development strategy, as Indar has been closely partnering with the country's Ministry of Health since 2012 for the supply of genetically engineered human insulin, and the quality and affordability of its products have already been widely praised by key Brazilian stakeholders, such as the Brazilian Diabetes Society. "Our commitment to the Brazilian ecosystem actually goes beyond insulin supply, as we established a local manufacturing facility which was GMP certified by ANVISA in 2016. It will allow us to start exporting to Argentina, Chile, Uruguay, Paraguay, Venezuela and other South American countries from our new Brazilian plant," she stresses.

In the meantime, Indar also aims to register three of its flagship products in EU markets as soon as possible. "Our plan is to pass the EU GMP inspection in 2017 and start these products' registration process in 2017 too, while we expect to obtain the required certifications and authorizations before the end of 2018," concludes Vyshnevska.

Control, Natalya Gudz, confirms that "ensuring Ukrainian patients can access an increasing number of foreign, high quality products without lowering quality standards stands as a fundamental objective of the SMDC – and we recently released several regulatory amendments that will contribute to the fulfillment of this objective."

Victoria Tarabanova, country manager, Wörwag Pharma; Taras Velgosh, country manager, Adamed

FROM CRISIS MANAGEMENT TO STRATEGIES FOR GROWTH

This promising reform momentum has undoubtedly provided international companies with both a unique opportunity and a heightened responsibility to propel Ukraine's historical dynamic. "As we hold deep roots in the most advanced health systems, we leveraged this network and invited international KOLs to Ukraine to ensure local stakeholders can benefit from their expertise, while partnering closely with other Wörwag affiliates to bring into Ukraine the best practices already implemented in other health systems," details Wörwag's Tarabanova.

In parallel to this expertise-oriented contribution, going through these extremely challenging times also entailed pharmaceutical executives turning themselves into crisis management experts. "When such a deep crisis occurs, there is no margin for error and a company's ability to quickly adapt is absolutely critical," relates Taras Velgosh, country manager of Adamed, a leading Polish company. "The deep economic crisis led us to concentrate our efforts on a single but critical objective: rapidly increasing our competitiveness in order to survive this crisis," he adds, before elaborating on Adamed's strategy to cope with this crisis: "We successfully introduced a substantial number of new products and – in the meantime - conducted a diligent assessment of our portfolio and got rid of all products that were either non-profitable or not aligned with our affiliate's recently implemented focus on prescription drugs, a field where we can directly work with doctors." This strategy has undoubtedly paid off, as Adamed entered the market's top 100 and increased its sales force by 60 percent, while many international companies have been restructuring their affiliates over the past few years.

In the same vein, international players, including France's Théa and Biocodex, as well as generics-focused Alvogen, took advantage of the deep changes reshaping the Ukrainian market to set up their local affiliates. One of the most eye-catching moves undoubtedly was the acquisition of PharmaStart - Ukraine's ninth largest domestic company at the time – by Switzerland-headquartered Acino Group in October 2015. "At first, industry observers were extremely sceptical – to say the least – about Acino's decision, but thanks to the cultural and operational transformation we have been fostering since the acquisition, we became in 2016 the fastest growing domestic company among the industry's top 20," explains Eugene Zaika, a seasoned pharmaceutical executive who was appointed general director Ukraine and CIS of Pharma Start upon this acquisition.

If these examples prove that gaining market shares in a plummeting market was feasible, one should not overlook the specificities of "Ukraine's new reality." "Since the deep economic crisis started, the Ukrainian market has been characterized by a soaring demand for low price products, which is totally logical considering the importance of out-of-pocket spending in our health system," explains Vladimir Tkachenko, general manager of Amaxa Pharma, a UK-headquartered pharmaceutical



Tatyana Pechaeva, general director, Lekhim; Vladimir Tkachenko, general manager, AMAXA; Eugene Zaika, general director Ukraine & CIS, Pharma Start Acino Group

company focused on life-threatening therapeutic areas such as oncology and neonatology in the CIS countries. "In this context, evaluating products to launch or in-license has become much more difficult than a few years ago, where the quality of the product, the brand reputation, or the product's technology were considered the main differentiators," he adds, before highlighting that Ukrainian patients' decision-making power is probably heightened compared to those in countries where state reimbursement agencies or private insurers hold a tighter control on the patients' healthcare pathway. "This new context also implies to subtly play on our margins to adjust the price of our products, as, in the case of too high pricing, the share of the Ukrainian population that can afford a given product becomes almost nil," continues Tkachenko.

The crisis has moreover triggered substantial changes across the entire value chain, with its full impact for pharmaceutical companies still difficult to evaluate. "Ukraine still holds more than 20,000 points of sales and a very high number of points of sales per capita. Nevertheless, we see that this part of the value chain has been rapidly consolidating over the past two years, as independent pharmacies are steadily replaced by thriving pharmacy chains," explains Adamed's Taras Velgosh.

RANKING OF CORPORATIONS IN UKRAINE (BASED ON Y2016 DATA)

2015 RANK	2016 RANK	Corporation	2016 Sales, MM USD	USD(%)
		Total	1.639	100,0%
1	1	FARMAK	88	5,6%
2	2	SANOFI	59	3,8%
5	3	ARTERIUM	58	3,7%
7	4	DARNITSA	53	3,4%
6	5	ZDOROVJE GROUP	50	3,2%
3	6	MENARINI GROUP	49	3,1%
4	7	GLAXOSMITHKLINE	49	3,1%
8	8	NOVARTIS	41	2,6%
9	9	BAYER HEALTHCARE	38	2,5%
10	10	TAKEDA	35	2,3%
12	11	TEVA	32	2,1%
15	12	KIEV VITAMIN FACTORY	31	2,0%
13	13	KRKA	30	1,9%
19	14	YURIA-PHARM	29	1,9%
14	15	SERVIER GROUP	29	1,9%
11	16	GEDEON RICHTER	29	1,8%
18	17	KUSUM HEALTHCARE	28	1,8%
16	18	ACTAVIS	25	1,6%
98	19	MACLEODS PHARM	20	1,3%
20	20	BORSHCHAHIVSKY HFZ	20	1,3%
17	21	ABBOTT	20	1,3%
25	22	ACINO PHARMA AG	20	1,3%
21	23	STADA	19	1,2%
22	24	MERCK SHARP&DOHME	18	1,1%
23	25	BOEHRINGER INGELHEIM	17	1,1%
24	26	ASTELLAS	16	1,0%
28	27	NOVO NORDISK	16	1,0%
36	28	ROCHE	15	1,0%
27	29	PFIZER INCORPORATED	15	1,0%
34	30	RECKITT BENCKISER	14	0,9%

Source: SMD Retail and Tender data (Rx+OTC), USD (pharmacy purchase price)

Cosmetics: Going global

Victoria Filatova, chair, APCU

Elfa, Ukraine's largest domestic manufacturer of cosmetics and household goods, has steadily increased its international footprint to today offer a wide portfolio of products across Europe and set up factories in Slovakia and Poland to supplement existing facilities in Ukraine. Dmytro Popov, Elfa's director and founder proudly states that "We have a well-established brand in Poland, a wide portfolio in Germany and Belgium, and a smaller offering in the Czech Republic, Slovakia, and Austria. Just last year we exported our products to over 60 countries."

Although Elfa is the leading light in the internationalization of Ukrainian cosmetics, president of the Association of Perfumery and Cosmetics in Ukraine (APCU), Victoria Filatova, feels that this move abroad is an industry-wide trend for Ukrainian companies. With the domestic market remaining stable in recent years, she posits that "almost all Ukrainian producers have significantly diversified their export policies and have been able to replace Russia as their only export market with other countries around the world."

Dmytro Popov, chief executive, Elfa Group

A key driver of the future growth of the Ukrainian cosmetics will be the implementation of EU-standard legislation on cosmetics manufacturing; increasing the quality of Ukrainian products and providing clarity to manufacturers. Filatova explains that the APCU's proposed regulatory changes are now "in the approval stage and I hope will be implemented and come into force by the end of the year." For Elfa, and other cosmetics outfits with international ambitions, this regulatory reform will, if passed, allow for easier and more efficient exports of Ukrainian cosmetics and, according to Popov, "greatly benefit the Ukrainian cosmetics market and create more opportunities for local companies to grow internationally."

"The latter are now looking to set up new standards and processes to further rationalize their activities and optimize their consolidation, as they still struggle to increase the profitability of their points of sales," he continues, while Adamed has been closely partnering with Ukrainian distributors on the large-scale implementation of a Vendor Managed Inventory (VMI) system, a streamlined approach to inventory management and order fulfillment.

In the meantime, the gap between foreign and local product prices has significantly increased during the crisis, which probably explains why domestic companies' market share has increased from 63 to 78 percent (in volume) over the past three years. "In product categories where local companies hold a strong foothold, it is now particularly challenging for international companies to compete," highlights Amaxa's Tkachenko, while four domestic companies were ranked in the market's top five in 2016. Commenting on the recent performance of the Lekhim Group, one the top ten domestic pharmaceutical companies, its managing director Tatyana Pechaeva indeed confirms that "the company has managed to display double-digit growth rates over the past few years, and we expect for 2017 to achieve at least the same results as over the last five years."

BUILDING ON DOMESTIC LEADERSHIP

"2013 marked a turning point in our company's strategy, as we decided to allocate more resources than ever to our international development and opened several representative offices in Kazakhstan, Tajikistan, Vietnam and Russia, while building strategic partnerships to make our products available in high-potential Asian markets, such as Thailand, the Philippines, and Indonesia," explains Mykola Gumenyuk, CEO of Yuria-Pharm, a leading manufacturer of infusion solutions and hos-

Innovation and science beyond Ukraine's borders

Dr. Anatoliy Reder, general director, InterChem

"The true core of our company has always been its scientific expertise," relates InterChem's founder and general director, Anatoliy Reder. Actually, InterChem's history is quite unique among Ukraine's domestic industry, as it started as a chemical company with a very small group of postgraduate students from the National Academy of Sciences, before focusing on the development of finished products and implementing an in-house R&D unit at the end of the 90s. Since then, InterChem has managed to design and launch four original products – an antiviral, two anxiolytics and a sleeping agent, which have gained a remarkable brand reputation in Ukraine and in CIS countries, where two of these original products are ranked among the 50 largest selling pharmaceutical products. "We are now actively advancing the development of three new molecules (two pain killers and a neurotropic drug), which we plan to launch in Ukraine in the near future," explains Reder, "while our strategic vision is to steadily enter higher value, regulated markets, such as the EU." Over the past nine months, InterChem has indeed been diligently searching for the right international partners to guide them through this tricky regulatory process. "We discussed this proposition with over 30 interested companies and ultimately picked an American company based in Czech Republic," he adds.

To fulfil this ambitious internationalization plan, the company just completed a USD 48 million development project which has increased InterChem's overall production capacity fourfold, contributing to double the volume of exports. "Throughout our successive expansion plans, we have moreover paid special attention to continuously upgrading our facility's laboratory, which leads us to consider that we hold one of the most advanced laboratory capacities in the country," explains Reder. InterChem is now at the frontier of a new era, as his founder holds the clear ambition to build an international company. "In this regard, our expansion strategy does not only encompass the marketing registration of our existing products in foreign markets, as we are also interested in the joint development of new original products with international partners," concludes Anatoliy Reder.

pital supplier in Ukraine and CIS countries. "At present, we are not focused on any specific geography, as we are considering expansion opportunities all over the world. We do not hold substantial international experience, so entering multiple international markets at the same time appeared to us as the best way to test the waters and more precisely identify in which countries we hold the greater chances to be successful," he adds, confirming an industry-wide trend among local players to overcome the limitations of the domestic market by expanding beyond Ukraine's borders. "We have been implementing plans to increase our exports in Asian and African countries, while in 2016 we also set up a new subsidiary in Lithuania which will enable us to expand our business into the EU market, in addition to our current 25 export destinations," explains Lekhim's Pechaeva. This approach perfectly illustrates how many leading Ukrainian companies favour a two-fold strategy, which includes entering fast-growing emerging countries – where Ukraine's pharmaceutical expertise is particularly recognized – as well as more mature markets, where they can leverage the country's extremely competitive labour cost, its great scientific capacity, and its proximity to the EU market. "We already hold seven products registered in Poland, while we are positioning ourselves in Western Europe with three registered products in the Netherlands and two in Germany," explains Filya Zhebrovska, the head of the domestic leader Farmak, which recently joined the Drug, Chemical & Associated Technologies Association (DCAT), a global business development association, with the idea to expand its commercial network in the US.

Nevertheless, entering mature markets is no easy task for thriving Ukrainian companies, which have developed themselves within a regulatory framework inherited from the Soviet era. More importantly, these standards, which are completely different than those in force in the EU or in the US, used to shape the entire Ukrainian pharmaceutical ecosystem, from clinical research to product registration. "Although Ukraine has however been rapidly catching up, changing our country's overall regulatory system stands as an enormous task which cannot be completed overnight, and – in the meantime – ambitious Ukrainian companies still suffer from these structural and regulatory discrepancies," points out InterChem's Reder, while Petro Bagriy from AMMU highlights that "Ukrainian companies are however left with no choice but to adapt themselves to the rules of these new markets to fulfill their international ambitions", as Ukraine's government has explicitly chosen a market development approach, ruling out the option to directly support a specific part of the value chain. "In this context, I believe that the best way forward for our country is to strictly implement (unchanged) EU requirements – rather than setting up country-specific regulations which would not be automatically recognized by the most stringent regulatory agencies internationally," states Lyubov Vyshnevska, chairman of the board of Indar, one of Ukraine's most active pharmaceutical companies on the global stage.

"Common efforts of the Ukrainian business and the government to develop the pharmaceutical sector will not only promote the increase in exports, thus having positive effects on the economy, but also deliver higher-quality, timely healthcare to Ukrainian patients which conforms to modern standards," highlights Lekhim's Pechaeva, which moreover underscores her ambitions to "intensify Lekhim's collaboration with multinational companies and fully leverage the company's contract manufacturing capacity." In this regard, cross-border partnerships have truly become a priority in all leading domestic companies' agendas, ranging from CMO and distribution activities to new product development. "Overall, our R&D pipeline targets socially significant diseases, such as HIV/AIDS, malaria, tuberculosis, osteoarthritis, bronchial asthma, and mucoviscidosis, while we are also bolstering

Petro Bagriy, President, AMMU

Mykola Gumenyuk, CEO, Yuria-Pharm

Victoria Bandyk, chief operating officer, Bioscience; Andy Hunder, president, American Chamber of Commerce in Ukraine

the development of several products in the critical care, anti-aging, and advanced antibacterial areas," explains Yuria-Pharm's Gumenyuk. "Although we hold the resources to advance these products' development by ourselves, we are open to discussing with international partners the opportunity to jointly work on these products' next steps, without forgetting potential collaborations for developing brand new products," he concludes.

A NEW ERA – OF GROWTH AND STABILITY?

In parallel to the development of their international strategies, leading domestic companies will also have to consolidate the market shares they gained during the crisis, especially given that the purchasing power of the Ukrainian population is now picking up again, which could prompt patients to switch again from local to foreign products. In this regard, international agencies forecast that the country's GDP will grow between two and four percent until 2020, and above four percent from 2020 onwards. "It is still too early to truly feel the positive impact that such modest economic growth could generate – although our economy is undoubtedly moving in the right direction," highlights APRaD's Redko, while Andy Hunder, president of AmCham Ukraine, also stresses that "we still have to assess the full potential of the recently signed Deep and Comprehensive Free Trade Agreement with the EU and tap into it, as a lot more can be done". Looking at Ukraine's pharmaceutical market, 2017 is also set to mark the long-awaited beginning of a new era of double-digit expansion, while the market's growth rate (year to date) reached 17 percent (in US values) in June 2017, according to the data provider Morion. "Nevertheless, based on our projections, the Ukrainian market may struggle to reach its 2013 level until 2021," cautions Farmak's Zhebrovska, highlighting that the true factor to consider will be the pace at which the economy and the pharmaceutical market will recover.

After years of instability and a frenzy of regulatory updates, pharmaceutical companies are also looking for clear, long-lasting requirements and controls that are acceptable to both sides in order to confidently increase their investments in the country. "Pharmaceutical companies in Ukraine, be they local or multinational businesses, want to operate within a predictable regulatory framework that would allow them to control their operational costs," acknowledges Natalya Gudz, the head of the SMDC, one of Ukraine's key regulatory agencies.

Although most industry observers do not see radical changes happening overnight, they are utterly convinced that Ukraine's situation and the overall healthcare ecosystem will continue to steadily improve in the upcoming years, while the country holds some of the most eye-catching investments opportunities across the continent – from M&A to contract manufacturing or more traditional marketing and sales prospects. "I definitely believe it is now the right time to invest in Ukraine," confirms Bioscience's Bandyk. "As a matter of fact, international companies are now showing a heightened interest in the country and its promising potential, and we truly feel that the number of pharmaceutical players that are eager to bring new products into Ukraine is continuously increasing," she reveals.

Continued from page 41

more "machine-guided," with predictive solutions increasing in importance. This is where life science companies' go-to-market efforts can benefit most dramatically, leveraging data intelligence platforms to guide a data-driven, insights-driven approach to customer engagement through all channels, including personal and non-personal.

The companies who are leading the way in digital transformation are equally focused on increasing their digital and analytic capabilities as well as on supporting these with strategy, culture, and organizational process. In order to be successful, a digital strategy must be embedded into all parts of the business, with customer engagement at the core, and the supporting technology being the means by which teams can holistically and cross-functionally execute to those initiatives.

With a coordinated, cross-enterprise plan to bring currently fragmented and siloed approaches to digitalization together, life sciences companies will get the market, medical, and customer insights they need to transform commercial success with speed and confidence. The implementation of a digital strategy for a brand needs to be a team effort. It is a complex process, involving many moving parts and departments (both internally and externally) and a fundamental switch in mindset around data and the benefits that this will bring to the business. To be effective, it requires the buy-in of every member of internal staff who will be working with, or adjacent to, the new system—and aligned support from the right external partners.

A signal of our industry's commitment to digital transformation is the increasing number of biopharma companies who now have senior leaders in place to lead these efforts—one in five of the top biopharma organizations, according to a McKinsey review of the top 25 global drugmakers. In fact, GlaxoSmithKline recently announced the appointment of a new senior position of chief digital and technology officer, recognizing the need to bring these initiatives to the highest level of senior management.

According to a recent survey from Marketo, almost 70% of all US marketers are planning to use predictive analytics as their primary strategic marketing technology this year. The life sciences industry knows it needs to change and move in a similar direction. A 2015 survey from PwC revealed that 65% of senior sales, marketing, and strategy pharma executives expected to see increased digital interactions within their commercial approach in the near future.

Healthcare companies have entered this new realm of analytics and insights, but so far have concentrated on clinical-centric initiatives. On the R&D side of healthcare, digital technologies are already being deployed to improve the development and adherence of treatments. The commercial and brand side of life sciences companies now has that same exciting opportunity to adopt new technologies to rapidly evolve and accelerate go-to-market—the likes of which we haven't seen since the advent of CRM in the early 1990s.

Commercial teams, for example, can now get real-time alerts on anything from a formulary status change to a drop in prescribing patterns for their target customers. As life sciences brand teams begin to adopt these innovative technology solutions, they will see noteworthy improvements in customer and market engagement as well as improved collaboration between sales and marketing for optimized strategy planning and execution.

> Having "big data" at our fingertips and knowing what to do with it is another story

Medical affairs teams also benefit from this digital transformation, where data and insights-driven medical education programs improve product launch in an atmosphere that values scientific education over sales pitches.

Are you ready?

New digital technologies give everyone access to the art of data science. They transform advanced analytics into everyday insights so that commercial teams can stay one step ahead of customers and operate seamlessly with internal teams for improved brand success.

Now is the time for biopharma and medical device/diagnostic companies to take the next crucial step to adopting innovative technology platforms; platforms that manage and integrate multiple and diverse data sources, in varied and disparate formats, and that produce predictive analytics, powered by domain expertise, to produce relevant, real-time, and actionable insights.

Welcome to the new inflection point in life sciences—the age of big data has now become the age of predictive insights. PE

Charting an Effective Big Data Strategy

Five key considerations when setting up a "data lake"

Big data has proven to be a valuable business asset, but using it to gain competitive advantage requires the right combination of strategy, technology, and execution. Many companies, in their excitement to use big data to solve problems in new ways, hastily search for the latest technologies promising to propel their insights to the next level. Once these technology components have been integrated, project leaders often realize that the organization's expectations and outputs are misaligned. Alongside these disappointments, however, are a handful of success stories in which companies have managed to hit on the right approach to controlled data disruption.

As the life sciences industry continues to incorporate new capabilities like artificial intelligence and machine learning alongside big data, company leaders often find their efforts paralyzed by the many moving pieces. To name a few, there's the sheer amount of data available, the thinking and analytics required to solve the right problems, and the challenges associated with mining existing data sources—not to mention settling on a technology and process that can best serve a variety of stakeholders. To overcome this paralysis, companies can start by considering how the outputs—the resulting insights—of the data will be used.

Many life sciences companies have implemented or are planning to implement a data lake. Now, imagine your enterprise data lake as a town under the jurisdiction of a town planner. The town planner needs to determine who will have access to different parts of the town, map out ways that the town can grow and expand, meet the needs of the town's residents, and identify businesses that can be built to increase the town's productivity. Similarly, if your organization is building an enterprise data lake, the blueprint should include who will have access to what data and insights, how the data and analytics processes can remain agile, how it can suit the needs of a variety of stakeholders, how it will be properly governed to preserve the data's integrity, and how it will improve the organization's business operations now and in the future.

Strategize first, shop for technology later

Just as the town planner wouldn't start with a fully developed town map, your organization shouldn't start by shopping for a new big data solution. Instead, establish a clear plan for how the technology will be used and who will use it before building and integrating a data solution.

Consider the success of Airbnb, a technology company known for its disruption in the hospitality market. The startup began with the end users' needs in mind. It recognized an unmet need in lodging options for travelers, put a plan in motion, and crafted a technological solution around that idea. An alternative to the traditional hotel model, the Airbnb home-sharing app is now in the hands of millions of international users.

In the life sciences, biopharmaceutical giant Amgen took a similar approach when it began its recent data infrastructure transformation. Unable to efficiently access, integrate, and analyze large and complex sets of global data, employee production and company processes were sluggish and ineffective. It abandoned the conventional technology-first approach to its data lake woes in favor of starting with the end users' needs in mind and defining a carefully constructed master plan to accelerate the cycle time from drug discovery to commercialization. Amgen uncovered a thread of common needs across various departments and built a platform to easily access and analyze its commercial operations, R&D, and patient data.

The big data success formula

Life sciences companies often struggle to identify and add the right data assets, access existing data, involve the right stakeholders across the organization, and partner effectively with the right vendors offering the right solutions. To build and sustain big data capabilities that contribute to the organization's overall business goals, life sciences companies need a formula that calls for equal parts planning and execution paired with the right technology. But that combination will vary from company to company. Here are five elements to consider before undergoing a data transformation:

1. Define the strategy with your end users in mind. It's important to determine the impact that the new technology will have on individual roles and plan accordingly. For example, to

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ensure that your company uses big data to solve the right problems in the right way, consult with the people and teams who work with the data every day to identify pain points and system limitations.

In Amgen's case, the team turned to the scientists, business users, and commercial teams to gather a "perfect world" vision for a new data solution, including a list of macro changes that would elevate the company's command of data, speed up projects, and enable data-driven insights. The business team identified its biggest challenges and then scanned all departments for overlapping issues before devising solutions.

2. Invest equally in sustainability and innovation. Data solutions need to be powerful and effective, but also agile enough to withstand future reconfigurations and changing organizational needs. By building solutions incrementally, companies can expand the data architecture and leverage new technologies when needed. For example, the industry is beginning to think about how an already established data landscape will handle a shift to an outcomes-based insight strategy that incorporates predictive analytics.

Of equal importance is balancing these investments in sustainable technology with a focus on bold and fast-paced innovation. Oftentimes, leaders stand in the way of step-change improvements as they wait for the perfect solution to come along. Companies need to make decisions quickly so that they're continually experimenting and cutting their losses when they determine that a particular approach has no value.

3. Expand your organization's capabilities with the right solution. By adopting the right technological horsepower, companies can achieve efficiency gains and fine-tune analytics. Highly educated scientists often spend significant time searching for public data, for example, when it'd be more productive and a better use of those employees' skill sets if the company were to build a platform that automatically gathers public data. Establishing a single data access point and automating manual activities can slash the time needed to complete data-oriented tasks from days to hours, boost employee productivity, and define new efficiency standards.

Automation has solved many of the concerns associated with having humans handle data processes and allows companies to produce more credible insights at a far quicker pace. Each step of manual data entry and analysis activities requires verification, a process that is both time-consuming and tedious. Furthermore, ensuring that data has been handled and entered correctly can prevent costly mistakes.

Beyond improving core processes, new technological systems should be wired to assist companies in their access to—and ongoing pursuit of—more and more data. Companies are learning to access operational data currently not in use, leverage public data sources and tap into previously untappable data sources.

4. Establish effective governance to support your new solution. Big data technology should be open and experimental, allowing end users to tap into their own experiences and backgrounds to expand the impact on business operations. It's equally critical to ensure that the data assets are properly governed. An organized and enforced data governance plan will guarantee that data is both reliable and useful while preparing the organization for future needs.

To be successful, revamping internal processes requires more than building the right solution. It requires a mindset shift. Companies will need a universal and holistic culture change, revamping who's involved in the new data and analytics process, how they work, and how the resulting insights are disseminated and used. To ensure organization-wide trust and buy-in, a "concierge service" training model can be established to meet end user needs on demand. User champions can ensure that everyone is up to speed on new capabilities and can create momentum in the organization.

To be successful, revamping internal processes requires more than building the right solution. It requires a mindset shift

5. Maintain the near-term focus and nurture a long-term vision. Just as a town planner needs the foresight to secure funds to replace the main road's sewer line in five years while recognizing the importance of attending today's town meeting to debate the subdivision of a residential property, those overseeing the data lake need to maintain both a near-term and a long-term view of challenges and goals. With technology advancing at a rapid pace, companies need to simultaneously consider evolving business needs while keeping their eyes on new ways to gather, store, and unlock data. PE

Analytics and the Search for Dangerous Data

Internal oversight is critical for pharmas seeking to avoid CIAs

When it comes to promoting compliance in the pharmaceutical industry, corporate integrity agreements (CIAs) may be the most important—and most onerous—tools in the government's toolbox.

The US Department of Health and Human Services' Office of the Inspector General (OIG) issues CIAs to settle misconduct charges. Failing to comply with a CIA is serious business, as the government can exclude offending companies from all important federal healthcare programs, including Medicaid and Medicare.

Pharma companies subject to a CIA have increasingly stringent obligations, including the duty to hire an outside compliance expert or advisor to assist the board in overseeing management's implementation of a compliance program. In addition to measuring corporate compliance engagement and accountability, CIAs require company-wide training and education plans and provide a framework for monitoring and reporting compliance measures.

The reality is that any pharma company has a high risk of running afoul of the OIG due to the myriad missteps their numerous constituents could take. Employees may inadvertently or intentionally engage in improper pharma sales and marketing tactics, such as off-label promotions, kickback payments, physician referrals, and unreported adverse events. These risks are exponentially multiplied by the exploding growth of corporate data volume and sources, rise in regulatory oversight, globalization of workforces and operations, and increasing use of third-party vendors and suppliers.

This proliferation of risks is driving forward-thinking pharma companies to take new analytics-based approaches to either learn from their mistakes or proactively detect non-compliance issues before they turn into a CIA.

Hidden data risks

A CIA does not limit itself to core data compliance, such as auditing a transactional system with an enterprise risk management approach. Notably, CIAs include provisions on monitoring transactions and electronic communications because email and messaging platforms are rife with opportunities for noncompliance.

Take, for example, an online chat between employees involved in increasing sales:

Sales Representative 1 to Manager: "My goals are not realistic, and I cannot achieve them. Please help."

Manager reply: "You have to hit them! We're counting on you."

Sales Rep 1 to Sales Rep 2: "This is hopeless! I'll never be able to meet my goals."

Sales Rep 2 reply to Sales Rep 1: "The clinical trial is only a few months out…try promoting on the new indicator."

Sales Rep 1 to Sales Rep 2: "Already discussed the clinical trial drug with Dr. Z."

A traditional rule-based compliance process based in enterprise risk management and transaction systems will miss this important communication that could eventually require the employer to pull the drug off the market. It is exactly this type of communication where evidence of non-compliance increasingly lurks, undetected.

New vs. traditional screening approaches

In this case study, a large pharma company planning the launch of a new drug that had encouraging revenue projections was concerned about possible compliance breaches resulting in fines and litigation that would cut deeply into profits and spur a multiyear CIA. Management needed to proactively detect risk in their communications, rather than rely on the traditional—and reactive—electronic discovery approaches legal, compliance, and audit teams use to uncover risk in data once they are hit with an internal or regulatory investigation or in response to litigation.

The pharma company already applied compliance technology on its transactional databases. The challenge was identifying non-compliant email communications between employees and outside parties. This data was in multiple storage systems and email servers, and the company needed to go back as far as five years to satisfy regulatory agencies' requirements. They had to locate and move the data into a central repository and then analyze and review tens of thousands of emails for suspicious communication patterns.

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Traditional methods for mining relevant data would not be sufficient, as these are applied on a case-by-case basis and do not easily transfer data insights. They often rely on tools like keyword searches that can generate hundreds of millions of records, yield high volumes of false positives or irrelevant results requiring significant manual and costly review. Legal teams can further cull data through more sophisticated analytics included in many "eDiscovery" review platforms, such as predictive coding, email threading, and concept clustering. These analytical tools enable prioritization of datasets by potential relevance; present visuals of at-risk activities, such as expensive travel and entertainment for sales reps and doctors; and uncover hidden data patterns and relationships. Linguistic analysis can further identify hidden meanings such as code words and phrases.

A big data analytics approach, however, enables companies to more easily evaluate the real risks and plan appropriate actions by aggregating company data from many sources into a single, secure repository to detect and pinpoint potential compliance infractions, "bad actor" communications, and key document facts and trends. Based on a company's priorities, areas of highest risk are identified, and algorithms run across the data to detect emails or other data indicating potential risk. Specific documents—often less than 1% of the entire document population being mined—are flagged and routed for legal and compliance review and, if warranted, remediation.

In the case study, the pharma company leveraged outside experts and big data technology to consolidate potentially relevant emails into a centralized repository. From there, advanced analytics refined the search mechanisms and applied advanced linguistics, sampling, and statistics to identify suspicious patterns. Company attorneys and third-party review teams reviewed the culled data and identified several risky communications that the company remediated before releasing the new drug. The new compliance process was defensible and repeatable, so the company could consistently monitor communications going forward, as well as run periodic audits.

> The reality is that any pharma company has a high risk of running afoul of the OIG due to the myriad missteps their numerous constituents could take

A three-pronged approach with big data analytics technology was used to achieve the sustainable compliance program:

- **Look-back and validation review.** Look-back processes allow companies to quickly and cost-effectively review very large amounts of data across cases and platforms to detect potential noncompliance. It protects the company when regulatory agencies request a detailed compliance review.
- **Electronic monitoring.** Continuous compliance monitoring gives companies ongoing, actionable insight into corporate communications to enable them to address developing problems going forward. For example, high-risk messaging could include an unusual quantity of emails between reps and a single medical group, sudden deletion of emails within certain date ranges, or emails with competitors that indicate your intellectual property is about to walk out of the building. The process runs continually without impacting data traffic because it does not need to read all employee emails and only flags concepts and phrases that indicate risk. The monitoring may be broad or may be targeted at known pockets of potential noncompliance risk, such as sales or marketing teams.
- **Communications auditing.** Monthly or quarterly audits use the same technology and process to deliver actionable and defensible audits. This level of insight enables the company to understand and to identify compliance issues across multiple areas of company data.

Adaptive training

Compliance doesn't end with big data analytics. The insights generated from electronic communications and monitoring can be used to provide direction into specific issues or regulatory areas that warrant additional and strengthened training. Although outright malfeasance happens, many employees do not set out to be deliberately noncompliant. Education and training alerts employees to activities that are noncompliant. CIAs do not limit training to sales reps but extend it to the entire company, including the executive council and the board. PE

Seizing the Opportunity

How STEM helps women advance from lab bench to boardroom

It's so important for girls to find role models and mentors who share their interests in science and technology. If you can't envision a career involving something you love or are passionate about, you can't pursue it. To secure vital, powerful and influential C-suite roles, girls need to see examples of women who have done so by leveraging their undergraduate and graduate degrees—and related training—in science, technology, engineering, the arts, and mathematics (STEAM).

I recently had the honor of representing Mylan at the Fifth Annual STEAM Fair and Reception hosted by the Women's Congressional Policy Institute (WCPI). I was struck by the energy that filled the Rayburn House Office Building in Washington, D.C. that day, which is typically bustling with congressional activity for the US House of Representatives. So many talented girls in middle and high school eagerly and candidly talked about their ambitions and plans to pursue careers in STEAM, or STEM, as the acronym is more widely known (without the reference to "arts").

Events like these are critical as we try to advance women's participation in STEM-related fields. According to CEB, women make up about 46% of the labor force in the US, yet only constitute 26% of the STEM workforce. That percentage drops even further the higher you go up the corporate ladder in healthcare and tech companies. This disparity is not surprising, as only roughly 18% of women take STEM courses at the university level, with the remaining 82% opting for non-STEM courses.

Early in my career, I wore a white lab coat and goggles, and spent most of my time at work staring down a microscope. I had no idea what else was possible for someone with my professional background until I was exposed to the business side of science—and that's where I found my passion.

I can say enthusiastically that STEM jobs shape our world. They're exciting, critical, influential, dynamic, and never boring. The US Bureau of Labor Statistics closely tracks trends in STEM-related fields and has found that people in STEM occupations, on average, earn higher salaries and higher employment rates than those in who are not in STEM-related jobs. But what is even more exciting for young women is that STEM education and job experience can be leveraged to secure executive leadership roles and positions on corporate boards, where women continue to be vastly underrepresented.

My foundation in science gave me the discipline, problem-solving skills, and intellectual curiosity to pursue a career in the pharmaceutical industry. Growing up in New Jersey, the "nation's medicine chest," made a career in STEM not only attainable, but also, desirable. When I look back at my journey from "bench to boardroom," I now see the inflection points where intervention can be critical for other women. These include advocating for yourself, taking risks, working outside your comfort zone, making personal sacrifices, and most importantly, seeking (and taking) the stretch assignments and special projects that get you noticed by a broad range of people in the company.

In every job that I've had in my 30-plus years, I've been forthright about my career interests. However, I have noticed that women oftentimes aren't proactively asking for more —whether it be in the STEM-related fields or positions within corporations—because women typically don't have the proper role models inside their companies to see what "more" looks like. I'm proud to say that's not the case at Mylan where I was attracted to our CEO, Heather Bresch, as a kindred spirit in advancing women's health and making high quality medicine accessible to all people all over the world. At the most bedrock level, this is the ultimate importance of STEM education and careers: to better the world around us.

We must do our part for the next generation of women and show girls the diverse opportunities that exist. We must help girls see a path to securing positions of authority with operational responsibility. We must lead by example and show girls that women direct how research dollars are spent, which innovations to bring to market, how to prioritize and address patient needs, and which resources to deploy in support of specific projects. I am excited to work alongside Heather to increase female talent and leadership at Mylan, and I feel fortunate to work at a company where I am inspired and encouraged every day to dream big, reach higher, and make a difference. PE

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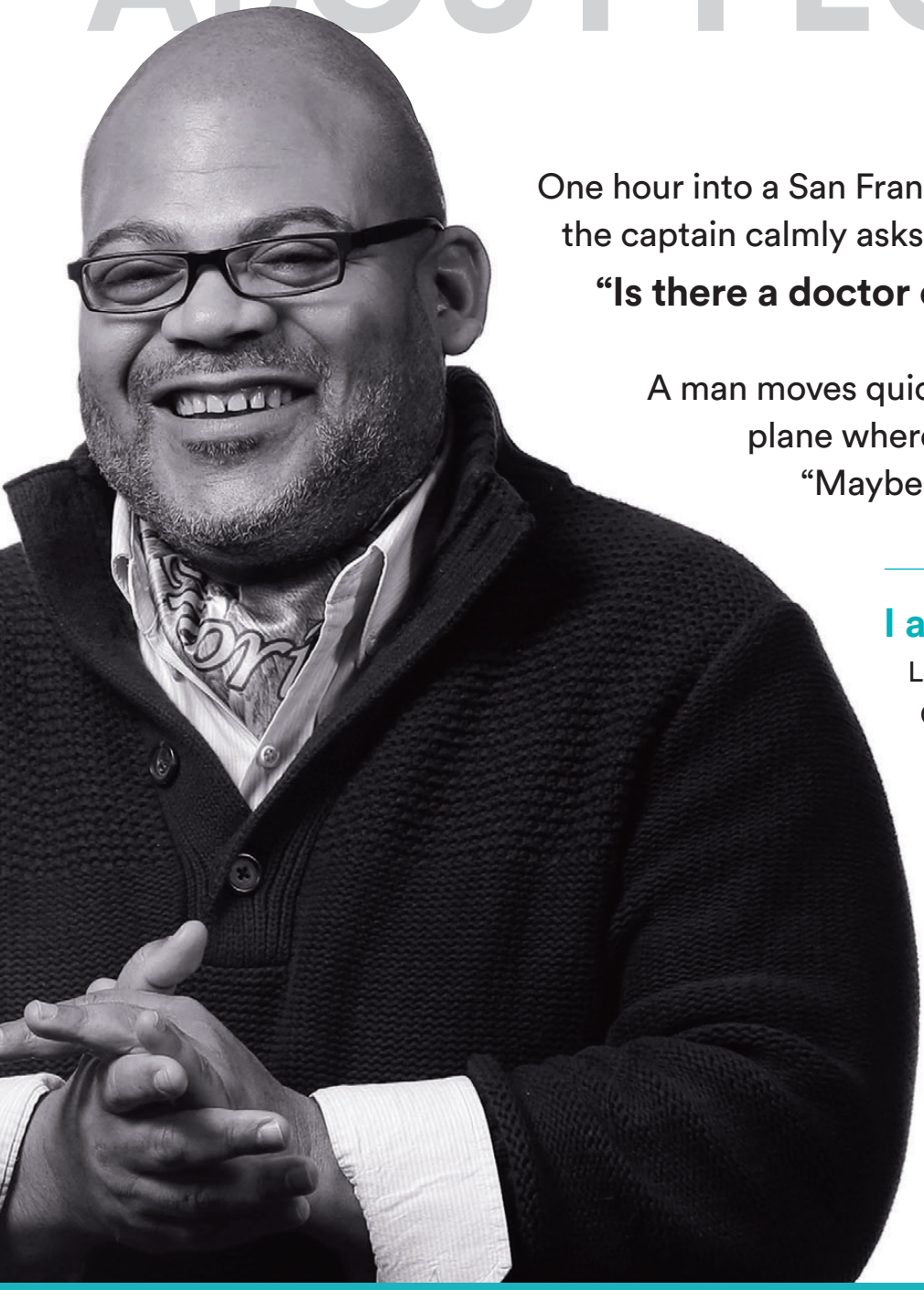

One hour into a San Francisco-to-Newark flight, the captain calmly asks,

“Is there a doctor or nurse on board?”

A man moves quickly to the back of the plane where the curtains are drawn, “Maybe I can help...”

I am Malik Cobb

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Certified Physician Assistant

12 years work experience in a liver transplant unit

My true colors:
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