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The Peace Dividend

William Looney
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A SURPRISING TAKE AWAY FROM THE BIO INTERNATIONAL CONVENTION in San Diego last month is the stark contrast between cooperative industry engagement and an unstable geopolitical order marked by xenophobia, drift and active, often violent government *dis*engagement from the hard work of building common ground. While BIO held 29,000 partnering meetings over four days, convened the first meeting of a new 20-member International Council of Biotech Associations (ICBA), and launched an industry-wide commitment to fighting anti-microbial resistance, Convention keynoter Hillary Clinton spent all but six minutes of her 90-minute issues *tour d' horizon* covering the sad breakdown of good governance and peaceful dialogue in virtually every area of public life.

With the state-sponsored sectarian implosions in the Middle East as the main topic, there was little time to talk about all the new science that promises to preserve and extend life—that is, assuming biotech gets the predictable, risk-deflecting operating environment it needs to wait out those long product development cycles.

Consider, however, if current events had allowed BIO to change the conversation with our likely 2016 presidential candidate. Instead of the nuclear option in Iran, how about the public health meltdown in the Middle East caused by the uncontrolled spread of diabetes? One of every 10 adults in the region is now a diabetic, a figure slated to grow to two in ten by the next decade. Some countries, like Saudi Arabia, are already there. The region recorded some 400,000 deaths from diabetes last year; more than half the victims were under age 60, reflecting the fact that many young patients go undiagnosed until it is too late.

Governments are aware of the problem, but priorities remain elsewhere. Combined public and private outlays on diabetes in the region totaled $12 billion in 2012, a small fraction of the nearly $120 billion spent on arms purchases. Significantly, experts attribute the prevalence of the disease and its many comorbidities to the region's damaged infrastructure—in both physical and cultural terms—and the pressure this puts on the stability of families and community. This is reflected in statistics showing that the Middle East has among the world's worst record in drug adherence, with some 70% of patients cycling off a new medicine only four months after the initiation of treatment due to lack of follow-up.

The fact that gets no traction is BIO members have a solution to this and other critical public health challenges. For diabetes, it is biologic therapies promising tighter glucose control, a better safety profile and more patient convenience—with a potentially big payoff from higher rates of adherence to treatment. Industry researchers are also examining the links between type 2 diabetes and stress-related hormones such as cortisol. This is uniquely suited to the Middle East's distinct profile on population health. Millions of otherwise healthy people are suffering from stress due to sectarian strife and randomized violence on a daily basis, not to mention the disruptive effects of urbanization, gender inequities, and other cultural and religious barriers.

The cancer of poor global governance also weighed on BIO's efforts to showcase emerging country markets as a source of future medicines growth and innovation. The grease behind that wheel is captured in one word: partnership. Government officials from country after country touted this, at least in shorthand. However, conducting a partnership dialogue in full paragraphs depends on a punctuated, no-exception commitment to private enterprise and open borders, in finance, information, and especially in people.

A big unknown is how much Russia's budding pharma potential has been driven off course by the country's sudden militaristic push for territorial realignment on ethnic rather than economic lines. There is some government money and a small private sector with expertise in promising fields like regenerative medicine and nanotechnology. Building this base requires extra lift in the form of more foreign multinational expertise, as well as persuading the huge brain drain of experienced researchers from the Yeltsin-era diaspora to return to Russia: but for what? The critical draw is not more government aid or philanthropy. Instead, it's a good commercial opportunity, one that requires a market-incentivized governance structure free of the internventionist distractions that reward brawn more than brains.

Today, there are too many examples of how divisive, dysfunctional governance erodes human potential. It is not a discussion limited to dictatorships. The implications are especially harsh in biopharmaceuticals, one of the few industries with a social impact far beyond its own area of expertise. To me, the message that resonates from BIO 2014 is: let the innovators in this industry do their job!

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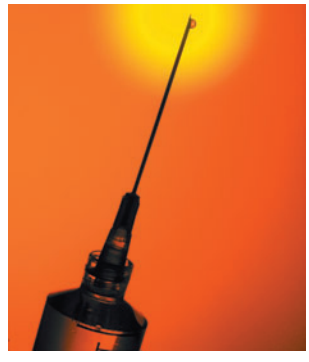

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2014 Pharm Exec 50

June issue online
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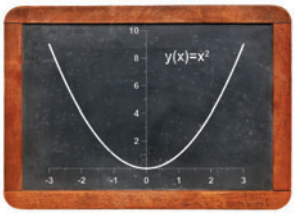
bit.ly/1qkZbyr

Obamacare's 'Unacceptable' Rx Copays

Blog post
Tom Norton
bit.ly/1mpdvoY



The Long Tail: Behind This Year's Pharm Exec 50

Blog post
William Looney
bit.ly/1iOvT5H

The Next List

June issue online
William Looney
bit.ly/TiVqgx

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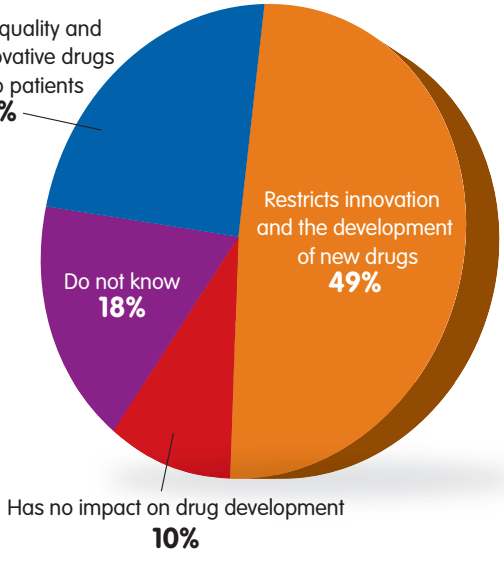
Most-read stories online: May 25 to June 24, 2014

Data Point

Poll data courtesy of online *Pharm Exec* readers between May 14 and June 1, 2014

Q: What impact do mega-mergers of biopharmaceutical companies have on the development of new drugs?



Readers Weigh In

Managed care has decimated the reps' ability to influence physicians, and it will continue to dictate how this industry manages drugs and patients. Bottom line: I don't know of a single colleague in "big pharma" who, if laid off tomorrow, would even want to remain in this industry.

KFM, 6/19/14
"2014: End of the Road for the American Rx Salesperson?'"
bit.ly/1fBKT8v

I'm pretty sure the 30 million estimate originally cited was a CBO estimate for 2022, not the first enrollment season, which was originally 7 million for a long time, then 6 million, with currently estimated actuals at 8 million. And I don't recall that proponents ever conflated the two figures—certainly not to the extent that opponents have.

Scott Gourley, 5/30/14
"Obamacare's "Unacceptable" Rx Copays"
bit.ly/1mpdvoY

As a prescriber, I didn't even know what on label meant. When I first joined a drug manufacturer, they were excited about getting sinusitis added to the Zithromax label. My response was: what are you talking about? I've been treating sinusitis with Zithromax for 10 years. Everybody does that.

Thomas Barsanti, 6/11/14
"What Does "Off-Label" Mean in 2014?"
bit.ly/1pSbfH3

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Pre-emption and States' Rights

Pharma backs federal standards for compassionate use, drug importing, data transparency, and track-and-trace.

As national and international marketers, pharmaceutical companies generally champion federal pre-emption of state laws to gain uniform rules governing drug promotion, research, labeling, and other activities. States have launched various efforts over the years to permit drug importing, regulate drug sales and promotion, require disclosure of certain industry activities, and establish systems for tracking drugs through the supply chain. The usual industry response is to call for national standards, as authorized by the Food, Drug and Cosmetic Act (FDCA).

These issues have moved to center stage recently as states have launched "right-to-try" laws designed to help dying or seriously ill patients gain early access to experimental therapies (see page 14 in *Pharm Exec*'s June 2014 issue). Although FDA routinely approves such compassionate use requests from sponsors, state officials and patient advocates believe their efforts will facilitate the process by allowing a physician to request access to drugs in early clinical trials, eliminating FDA review of these proposals. Local advocates also hope the new policies will put more pressure on biopharma companies to provide a requested treatment, although neither state nor federal agencies can require such action by a private firm.

The larger danger of the new law in Colorado and proposals in Missouri, Louisiana, and Arizona is that they may offer false hope to patients and could erode confidence in FDA's authority to set standards for clinical research and to determine which drugs are sufficiently safe and effective to come to market. Sponsors of new drug development programs generally believe that broader patient access to a promising therapy can be achieved best by completing clinical trials and gaining FDA market approval. FDA, moreover, is not pleased at the potential for state laws to challenge its authority on drug approvals and to raise the risk of patients receiving therapies that turn out to be ineffective and even harmful.

FDA is not pleased at the potential for state laws to challenge its authority on drug approvals and to raise the risk of patients receiving therapies that turn out to be ineffective and even harmful.

Imports & sunshine

Pharma companies and FDA have run into similar concerns with state efforts to permit the import of less costly drugs from other countries. The latest case involves a 2013 Maine law permitting importation of prescription drugs from pharmacies in Canada and other specific countries. Maine officials assert that the program will help local residents obtain needed medicines, but Maine pharmacists and manufacturers have filed suit, claiming that the initiative could bring in unsafe products, and that Maine's action is pre-empted by the FDCA. The case is moving forward following a recent ruling by a Maine judge that local pharmacists have legal standing to bring such a suit— although drug manufacturers do not (see Kurt Karst's FDA Law Blog, May 20, 2014 for more details, www.fdalawblog.net).

And the federal Open Payments program recently went live, largely the result of industry's desire for uniform, national standards governing the disclosure of pharma company payments to health professionals. Although public access to data on "transfers of value" by makers of drugs and medical products is likely to hinder industry interactions with medical professionals and with physicians engaged to conduct clinical research, pharma companies decided that the federal program was preferable to dealing with multiple state laws.

Jill Wechsler is *Pharm Exec's Washington* correspondent. She can be reached at jwechsler@advanstar.com

Under rules issued this past year by the Centers for Medicare and Medicaid Services (CMS), in June companies had to submit their detailed data on payments to physicians and teaching hospitals for the last five months of 2013. CMS will post the information as a way to shed "sunlight" on relationships between industry payments and physician prescribing and treatment practices.

The final Sunshine Act provides only partial federal preemption of local transparency policies, as states still may require industry to report additional data and payments to more health professionals. But industry hopes that over time, the CMS program will establish a disclosure model that satisfies local health authorities.

Uniform drug tracking

Similarly, industry's desire to avoid diverse drug track-and-trace requirements was a prime factor leading to enactment of the Drug Quality and Security Act (DQSA) of 2013, which lays out a 10-year process for creating a national drug tracing system through the Drug Supply Chain Security Act (DSCSA) section of DQSA. After years of debating various options for better securing the drug supply chain to thwart counterfeiters and thieves, supply chain partners lined up behind DSCSA last year to avoid compliance with a California law establishing its own drug tracking system beginning in 2015.

The new law pre-empts California and other state tracking programs, reflecting general agreement that a national system is more capable of identifying genuine medical products and preventing bogus or adulterated drugs from entering the supply chain. The DSCSA requires manufacturers and distributors to establish systems able to transmit information on prescription drug movement in the U.S. from production plant to distributors and ultimately to dispensers. With an initial information-exchange phase set for launch Jan. 1, 2015, FDA is busy consulting with stakeholders on options for data exchange standards able to transmit information, initially via paper or electronically; a fully interoperable system is required by 2023 that can track drugs electronically through package-level two-dimensional bar codes.

The drug tracking measure gained traction in Congress last year due to a sense of urgency among policy makers to strengthen FDA oversight of large drug compounding operations. Although traditional pharmacy compounding is regulated by state law, a lethal meningitis outbreak linked to contaminated injectibles produced by certain compounders generated a groundswell for stronger federal controls.

The new policy walks a narrow line between tighter FDA oversight of those compounders that operate more like drug manufacturers, while retaining state regulation of the many thousands of small entities that provide compounded dosage forms to local hospitals and doctors. Maintaining a balance between state and federal rules is challenging, though, as seen in emerging disputes between FDA and compounders over specific policies, such as limits on the production of "office stock" drug supplies by unregulated compounders—something sought by FDA but opposed by some states. Compounders largely prefer state rules and regulations, and only a handful of large operators have signed up for the new voluntary FDA regulatory regime. PE

State laws and biosimilars

In some situations, industry looks to state laws to protect its turf, as seen in recent efforts by some biotech companies to encourage state action that would limit automatic pharmacy substitution of future biosimilars. While federal policy calls for FDA to set a framework for developing highly similar versions of biotech therapies, some innovator firms are pressing states to enact new laws that require pharmacists to notify the prescriber or obtain patient consent prior to dispensing a biosimilar product in cases where FDA deems the follow-on product highly similar, but not fully interchangeable. Biotech companies promote such requirements as protecting consumers from undisclosed changes in treatment, but health plans, pharmacists, and generic drugmakers strongly oppose these proposals. Such state laws, as well as naming proposals for biosimilars, were discussed at a February workshop organized by the Federal Trade Commission to address concerns that these requirements could discourage biosimilar development. Meanwhile only North Dakota has adopted tighter dispensing rules for biosimilars, and three other states have done so with significant limitations.

Europe Gears Up to Attack Counterfeit Medicines—But Only Some of Them

Cross-sector partnership seeks support for a pan-European system to keep fake drugs out, but obstacles are many.

Just a few weeks ago, in late May, yet another international law enforcement operation uncovered another series of drug counterfeiting outfits, seizing more millions of dollars worth of fake prescription medicines, resulting in the arrest of hundreds more makers and distributors of illegal drug products. Nearly 200 enforcement agencies across 111 countries, led by Interpol, took part in Operation Pangea VII, targeting the criminal networks behind the sale of fake medicines.

While action is heating up at the international level to tackle counterfeit drugs, Europe is making its own efforts to stop fake medicines from entering the legal supply chain. An improbable cross-sector partnership is struggling to secure support for a pan-European system to keep counterfeits out. It's improbable because it brings together not only manufacturers, wholesalers, and pharmacists, but also parallel traders—long treated by drug manufacturers as pariahs and even downright enemies. And I use the word struggling because the system this partnership is advocating will be expensive, complex, and require unprecedented collaboration right across the European Union.

It's a struggle also because time is running out. This is not a spontaneous gesture by the private sector. It is a response to European Union rules adopted three years ago, that are due to come into full effect less than three years from now. There are no options: heavy new obligations will fall on each of these components of the medicines supply chain, and the private sector players are simply trying to set up the most cost-effective way to meet those obligations through a largely self-regulatory system. If they fail, they face legal action for non-compliance, and still tougher—and doubtless more expensive and onerous—obligations under additional legislation and systems that will be imposed on them by the authorities.

In June, the partnership issued a progress report, with an impressive plan of action and an even more impressive appeal for urgent action by the thousands of drugmakers, wholesalers, pharmacists, and traders across the continent. "Start now," urged Lothar Jenne, the managing director of German wholesaler Max-Jenne Artzneimitte, who is one of the key architects of the new system. "Timely implementation requires concrete planning now" was the message from the partnership.

The report listed the many tasks that must be accomplished for the system to work. Specifically, manufacturers will have to modify production lines to affix a 2D data matrix code on each pack that will bear the product code, batch or lot number, expiry date, and a unique randomized serial number. They will also have to apply tamper-evidence features to each pack. And they will have to report the data securely to a national data repository that they will also have to create, along with a Europe-level "hub" that can allow national systems to talk to each other. Pharmacists will have to install equipment and data-transfer links so they can read the 2D code and receive instant verification (or an alarm) via the "hub" on each

The system this partnership is advocating will be expensive, complex, and require unprecedented collaboration right across the European Union.

Reflector is *Pharmaceutical Executive*'s correspondent in Brussels.

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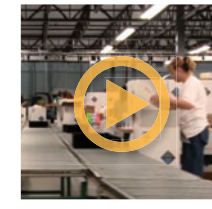

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product before they dispense it. Wholesalers will also have to be plugged into the system so they can keep a check on products going through their hands. And parallel traders will have to work with the system too, affixing new 2D codes and new tamper-evidence features to every medicine they re-label or repackage, and reporting the new data to the system. Everyone will have to be able to receive and respond to queries regarding codes, and make provision for handling exceptions, reverse logistics with recalls, and further queries and investigations.

There are costs as well as long lead-times attached to all these elements. Current estimates range from $100 million a year to double that sum, just for running the system. Unsurprisingly, the question of costs has been at the heart of the discussions—and remains so today. Above all, the cost question has caused a split among manufacturers, with the European Federation of Pharmaceutical Industries and Associations (EFPIA) firmly inside the partnership, and the generics industry still hesitant on the outside.

The European Generic medicines Association (EGA) feels its members are being unfairly treated, since the products they produce are—it claims—so rarely counterfeited that the complex new EU requirements are disproportionate and excessive. There is little reason for them to share the cost burden when the real targets of counterfeiters are the more expensive branded products made by research-based companies, they say.

The generics industry has not given up hope of winning some exemptions under the EU legislation. But it is also hedging its bets, and is exploring joining the partnership if it can do a cut-price deal. What it is insisting on is that the costs—most of which are to be shared among manufacturers—should not be based on volume sales, because that would disadvantage its members, who specialize in large runs of low-cost products. A compromise could be reached soon. EGA has proposed a flat rate approach, under which each company would pay a fixed amount for each of the marketing authorizations it holds. Since big companies with many products in many markets hold more individual marketing authorizations than smaller companies with restricted product ranges, the idea is that this formula would tip the balance the other way.

But it is not yet a done deal. EFPIA has somewhat reluctantly conceded that this methodology might be acceptable. But EGA has yet to win the backing of its board for the approach. And even if it does, there are countless other questions to be resolved to get this system up and running in time for the 2017 deadline that the EU has set—and on which the Commission is refusing to make any concessions.

By a profound irony, the one thing that all these efforts will have no impact at all on is the one thing that Operation Pangea VII was exclusively devoted to: illegal online drug sales. The EU legislation covers only the legal supply chain—leaving gullible patients the world over still just as vulnerable as ever to the purveyors of counterfeit treatments for everything from erectile dysfunction to cancer. PE

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KEEP EXPLORING

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2014 Dealmakers Outlook: Start Early, Stay Late

Experts from big Pharma and biotech dissect the road ahead for M&As, licensing, and partnerships.

After fading to dreary summer stock for the past few years, dealmaking is today back to center stage, but with the major roles reversed—small biotech, yesterday's understudy, now gets top billing, while big Pharma has to work harder for its close-up. As the pacing around the urge to merge picks up, *Pharm Exec* brought partner Campbell Alliance and a select group of West Coast dealmakers to a Sonoma raceway for a test performance on what lies ahead for asset licensing and M&A activity in 2014. The following is excerpts from a full morning of discussion—and despite all the high-octane rhetoric around deals, the key differentiator of success hasn't much changed. It's still that hard—and honestly wrought–evidence of value to payers and patients.

— William Looney, Editor-in-Chief

Roundtable Participants

Igor Bilinsky, SVP, Corporate Development, Vical Pharmaceuticals

Mike Broxson, Head Global Licensing, Takeda Pharmaceuticals

Christophe Degois, VP, Business Development, Geron Corporation

Doug Fisher, Partner, InterWest Partners

Josh Grass, SVP, Business and Corporate Development, BioMarin

Curt Herberts, Senior Director, Corporate Development & Strategy, Sangamo Biosciences

Ravi Kiron, Entrepreneur in Residence, SRI International

Jason Levin, Chief Business Officer, Sorbent Therapeutics

Gail Maderis, President , BayBio

Kimberly Manhard, Co-Founder and SVP, Ardea Biosciences

Neel Patel, Director, Campbell Alliance

Jim Schaeffer, Executive Director, Business Development, Merck & Co.

Dr. Jay Tung, Chief Research Officer, Myelin Repair Foundation

Samuel Wu, Managing Director, MedImmune Ventures

PE: *Campbell Alliance has conducted its Survey of Dealmaker Intentions for six years, one of the most volatile periods in memory. Three of Pharm Exec's top 20 sales leaders—Wyeth, Schering-Plough and Genentech—have disappeared, along with major realignments in the generics and mid-size biotech sectors. What has been distinctive about the past 12 months and how is this weighing on the current business calculations of pharma companies and the host of new partners emerging in this space?*

"Competitive interest in oncology means that mid- to late-stage deals are harder to find; you have to move earlier to find an asset worth licensing."

—Neel Patel, Campbell Alliance

Neel Patel, Campbell Alliance: Our annual survey, which was conducted early in the first quarter this year, is focused on director-level and above executives engaged in key corporate functions, including executive management and business development. There is a slight bias in the survey toward those who are engaged in out-licensing activities, mainly reflecting the fact that right now there are more companies selling assets than buying. Our geographic scope is primarily the US along with a strong sample from Europe. Companies are a mix of public and private, and range in sales from the billion dollar plus big Pharma players to some micro-cap biotechs with revenue below $5 million. In essence, our data is broadly representative of the dealmaking field, which bolsters our ability to accurately gauge forward-looking sentiment.

As far as expectations for activity over the next 12 months are concerned, there is a solid if nuanced convergence around expectations for an increase in the overall volume of deals. Significantly, both out-licensors and in-licensors expect more deals at the early preclinical stage and carrying forward to Phase II clinical trials. At Phase III, there are tempered expectations for deals versus early stage assets. For fully marketed assets, both groups are largely aligned, this time in anticipation that the number of deals will decline. The expectations on marketed assets represent a reversal in sentiment from our last survey, when respondents were expecting an increase in deals. Driving this is the growing confidence among biotech firms in being able to commercialize independently—conditions are more conducive to making that final sprint to the finish line, without any push from big Pharma.

Therapeutic drivers

Christophe Degois, Geron: *Might it also be due to the perception that there are fewer good deals at the later Phase III stage?*

Patel: That has been the prevailing view in our Survey for the past two years. But there is a healthy contrarian view among some buyers that a few real gems are still out there waiting to be discovered. What is determinative is value. Most buyers believe that if an asset can provide real evidence of value, it deserves a premium price. It is emblematic of the "de-risking" sentiment that is driving valuations today in the life sciences.

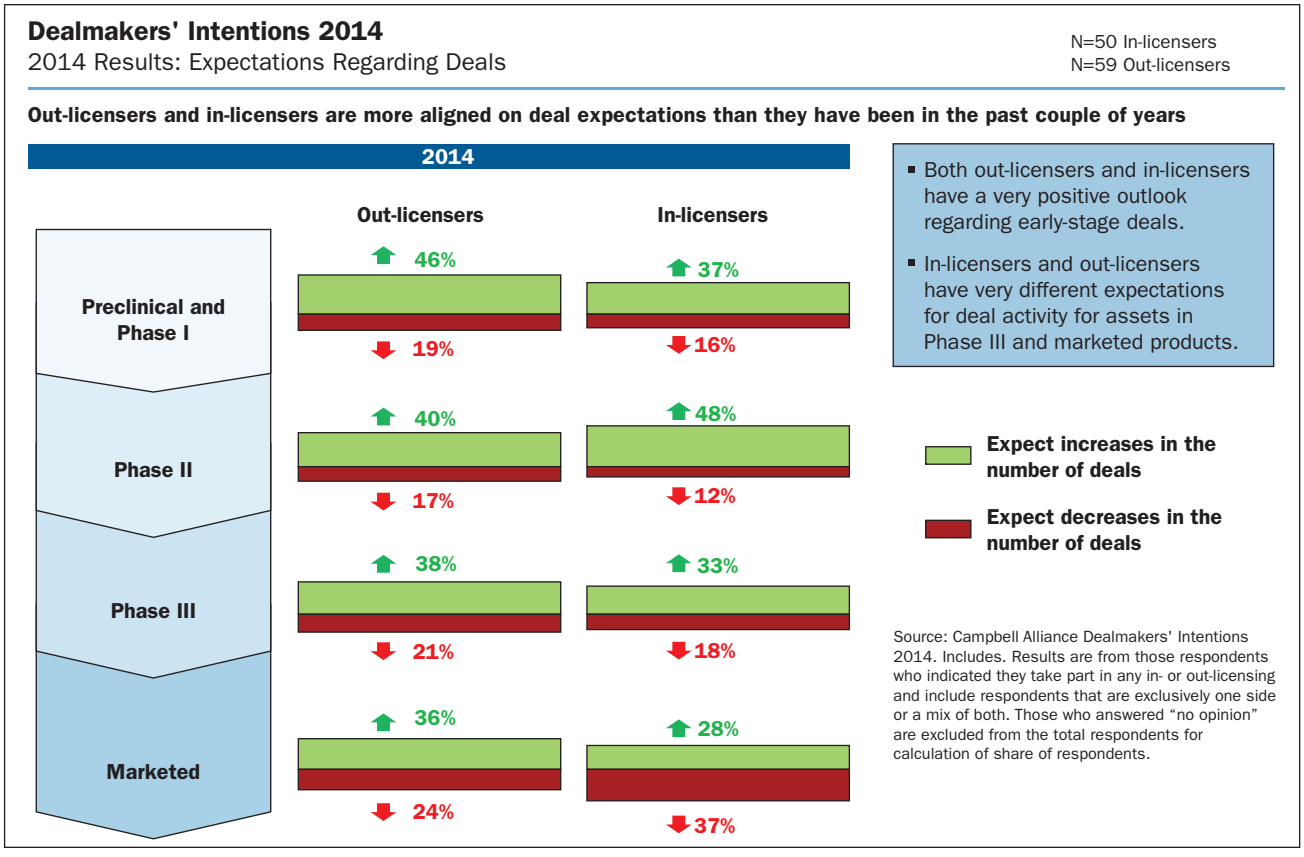
PE: *Which therapeutic areas are attracting the most interest among dealmakers this year?*

Patel: There is relatively little change—oncology assets are by far the top draw; this has been the case since we began the Survey. Both buyers and sellers are committed to signing deals in oncology, which is to be expected, as this is where the science is trending, too. We haven't cut the numbers in detail, but one thing I expect to see is a rise over the years in both out-licensing and in-licensing deals that cover earlier stage, pre-commercial assets. Competitive interest in oncology means that mid- to late-stage deals are harder to find; you have to move earlier to find an asset worth licensing.

What is interesting this year is the therapeutic category we call "Other." Interest is scaling up in this category, which includes mainly orphan drug assets for a growing list of rare diseases. "Other" also includes ophthalmology drugs, which is a favorite for the high pricing flexibility these give to investors. Overall, virtually every company we surveyed—from the biotech start-up to the big Pharma top 10—now includes orphan drugs as part of its business development and licensing strategy. Another intriguing finding is the continuing interest in cardiovascular and metabolic diseases, despite the intense competition and high costs of the large-scale outcomes trials now being required by registration authorities and payers.

Samuel Wu, MedImmune Ventures: *Is the willingness to move earlier to license or acquire oncology assets due to the greater confidence that investors have in the underlying science?*

Patel: Yes. Significant progress has been made over the past 10 years in understanding the biology behind tumor formation and metastasis. Diagnostic instruments have advanced considerably. As a result, treatments being developed are more targeted, resulting in a practical progression of survival rates for many individual cancers. Cancer itself is seen increasingly as a collection



Out-licensors and in-licensors expect more deals at the early preclinical stage and carrying forward to Phase II clinical trials.

of rare diseases, which is advantageous to drug developers because it helps concentrate resources.

Financing trends

Igor Bilinsky, Vical: The greater availability of capital is reshaping the overall strategy of developing an asset. Companies now have more financing options than just relying on out-licensing or an outright acquisition deal, particularly if they have more than one asset to play with. For example, we may be seeing more companies looking to sell some assets earlier in the development pipeline in order to self-finance commercialization of the best of the lot, rather than the formerly common strategy of "selling the first born."

Jason Levin, Sorbent Therapeutics: Capital markets have a big impact on deal strategy because you have additional options to consider. If you are a small company like mine, the strategy is to go first – and get it done fast. If I can raise the capital, I will use it to keep pushing the company forward to generate more value as well as to help fund an expanded, complementary portfolio. Or if someone outside steps up and puts a valuation on the table that my shareholders are willing to take, then I can do that too. Today, the capital markets are open enough that I can do a financing deal much faster than negotiating to sell the asset to someone else.

Doug Fisher, InterWest Partners: The key objective for a seller in exploring any option today is to maximize the value of its most important asset. I would rather have one strong lead asset than a portfolio of runner-ups. Prior to the capital crunch than began around 2007, it was acceptable to fold all the less interesting candidates into a deal, as part of a platform approach. Since then, the dominant perception is that it is folly to waste money developing assets that big Pharma doesn't want. Even among companies that claim to have multiple assets in play, the focus is still on that proverbial "asset A."

Structuring the deal

Patel: Over the last two years, our Survey has seen a significant increase in structured asset transactions built around contingent value rights, leveraged through a "earn out" clause. The "earn out" is a useful way of establishing a contingent value for an asset, which is attractive to companies that want to quantify their risk exposure by tying payment to a goal or an event that has to happen. If you believe we will continue to see a buoyant capital market, then it will be interesting if the availability of funds trumps the

necessity for sellers to negotiate these "earn outs."

Fisher: I don't think future growth in funding through the private capital markets can be assumed. At any rate, what really drives a transaction is not capital but the level of competition for the asset. If this is lacking, the buyer can do whatever he likes. Alternatively, when there are multiple bidders, there is no end to the creative things you can do to seal a deal. On balance, when you can get a competitive bidding situation going, then the likelihood is the seller won't have to settle for a structured transaction.

"Big Pharma remains the biggest buyer, with the deepest pockets, yet we see much more turmoil in the way they manage their pipeline portfolio and therapeutic franchises."

—Jason Levin, Sorbent Therapeutics

Bilinsky: Contingent value rights (CVRs) are typically driven by the differing opinions of the buyer and the seller about the value of the asset. Buyers will often have a more conservative view of the prospects for an asset's market success, while the seller tends to see a higher potential. CVRs are a tool to bridge the gap. Based on what is happening in the capital markets, sellers are becoming ever more confident and optimistic, while buyers in big Pharma cannot always match that. To find that elusive common ground, you have to opt for a structured transaction that can end up being quite complicated.

Levin: It is a tricky process. The deal can include provision for issuing a separate class of securities that are tradable in their own right, which often creates a big drag on the issuing company's own stock. The big Pharma players can afford to take the hit, but the toll on smaller companies can be considerable.

Curt Herberts, Sangamo: CVRs are one of the most useful tools to set terms around a defined event that is expected to occur in the relatively near future. When you are able to identify the specific event and establish the success metrics, then there is less operating risk because you can also set expectations. Otherwise, a CVR ends up being very hard to structure.

Patel: The number and quality of assets available to transact has a strong bearing on the final structure of a deal. What is interesting in our Survey this year is the soaring level of demand for preclinical and early-stage assets in oncology. This is a reversal of previous years, when there was enough supply to meet the demand; now what is available has shrunk, resulting in a much higher level of competition among buyers. Another striking development is the level of interest in products with orphan designations. Everyone wants a stake in this area, to the point where asset sellers are re-classifying products as orphans as opposed to other therapeutic categories.

Levin: One card that is increasingly hard to play is that of the contrarian investor—going against the grain. The reason is the long lead times that still confront any drug developer interested in the ultimate goal of market authorization. Big Pharma remains the biggest buyer, with the deepest pockets, yet we see much more turmoil in the way they manage their pipeline portfolio and therapeutic franchises.

Patel: This is true. We see a clear pattern here: a promising compound fails in Phase III and all of a sudden management decides to exit that entire therapeutic area. Every asset in that zone is declared *persona non grata*, even though the company might have spent many millions in acquiring the assets and even entire companies, seeking a position of leadership. And we are not even considering the churn in management ranks, where there is an innate tendency for newcomers to do the opposite of what their predecessors did.

Market pressures

Bilinsky: Another continuing trend is the growing attention by licensors on whether an asset can command an attractive reimbursement rate from payers, which will ultimately determine whether your investment is going to be successful or not.

PE: *These comments indicate uncertainty about who will be driving the financing for the next generation of biopharmaceutical innovations. No one has cited the involvement of public and philanthropic science. Can this alternative stream fill the gap left by private sources of financing?*

Gail Maderis, BayBio: These sources are absolutely critical, but they represent a drop in the bucket against what is needed. The expectation is that industry should take the lead in developing breakthroughs for medical conditions where there are few or no treatments. Our reputation suffers when we are perceived as not making the effort because of a narrow financial calculation.

Herberts: Some new sources of early-stage capital are arising as a consequence of strategic commitments made by organized disease groups to develop a specific drug for their patient community. Many of these now come in the form of venture philanthropy. It is not occurring on a large scale that will

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change the norm for funding drug development, but in a few instances it is bearing fruit, especially when you can drive expedited development in a small patient population.

Wu: But this is not getting at the critical issue, which is where the money is going to come from for work at the preclinical phase. The pathway to commercialization starts here; if financing is scarce, you never get to the next step.

"The ability of small companies to compete with larger firms has been enhanced by the availability of commercially accessible chemical collections, increased high throughput screening capabilities, and CROs."

—Jim Schaeffer, Merck & Co.

Maderis: There are signs of progress. Just in the last three years, the Bay Area has seen Pfizer, Bayer, J&J, and Merck establish centers of innovation that are designed to incentivize start-up work around promising new areas of science—all at the early-stage and proof-of-concept level.

Jim Schaeffer, Merck & Co.: Merck was among the first pharmaceutical companies to locate a business development group with scientific evaluation capabilities on the West Coast. The objective was to have feet on the ground and to hunt for promising new ideas that might complement what we are doing already or represent something entirely new but is still synergistic to our R&D model. Thirty years ago, all of the action focused on small molecule chemistry which required legions of medicinal chemists. Today, the ability of small companies to compete with larger firms has been enhanced by the availability of commercially accessible chemical collections, increased high throughput screening capabilities, and CROs, in addition to an increased focus on biological therapeutics that do not require large numbers of employees. Consequently, the larger companies are paying more attention to their smaller competitors and now view them as potential partners.

Ravi Kiron, SRI International: The investment in this work is not large, but the payout can be significant. It is all about innovating and then jump-starting a great research idea. J&J was among the first to try it, and I recall we were making bets with as little as $50,000 per grant. The concept is a good one. It has positive consequences for the six billion people outside our mature pharma markets for which the conventional R&D model, based on hundreds of millions of dollars invested per compound, is not sustainable.

Maderis: The areas where deals are being financed—where the private sector demand is—are focused on specialty oncology medicines and orphan diseases. There is less going on in the major chronic diseases areas like diabetes and senile dementia that account for most health spending. This is why major public and philanthropy initiatives can have an impact.

Dr. Jay Tung, Myelin Repair Foundation: Someone clearly has to be addressing the long-term questions that relate to our understanding of the fundamental biologic roots of disease. The Foundation is deeply invested in translating academic research into something that can be applied commercially. We apply a strict standard of rigor to the translation in order to give private investors the confidence they require to take a project forward. The Foundation is non-profit but ultimately our work is dependent on someone finding a way to realize a return on the money invested. It's a way to de-risk some of the costs of starting up in areas of science that have been neglected by the mainstream private R&D model. Clearly, we see big differences in the cultures of academia and big Pharma. For example, in academia the aim of any research is to get it published—there is a single hurdle, called peer review. In contrast, drug companies want to see that research replicated hundreds of times to test, ratify, and reaffirm the faith in their up-front investments. The cultural divide is pronounced; if anything, it is growing wider.

Patel: Nevertheless, options for small companies with good assets to go it alone are improving. They are holding on to these longer than in prior years. We are now being asked to help licensors develop their portfolio strategy, which was rare just two years ago. Biotechs see the potential of remaining independent, with multiple assets that can be developed without necessarily selling out to big Pharma. We are also seeing a more nuanced approach to the footprint companies make in each therapeutic area; there is a lot more "slicing and dicing" of assets, geared to obtaining a very focused market profile that buyers can understand.

PE: *Having viewed the Campbell Survey presentation, is there a takeaway message that is missing or needs to be embellished?*

Mike Broxson, Takeda Pharmaceuticals: The indicators suggest that the second half of this year is going to be

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better for buyers. This is evidenced by the fact that there is more capital available and is being put to productive use. I'd also emphasize including more input to the Survey from Japanese companies.

Levin: Valuations are sufficiently robust that more holders of assets will be ready to transact. The message is on balance very positive for deals in our sector.

"Continuity over the life of a deal is very rare. Changes are to be expected, especially as other M&A activity shapes the external therapeutic landscape beneath your feet."

—Gail Maderis, BayBio

PE: *Looking at the current news cycle, I see three important trends affecting the transaction environment. The first is the three-way distribution of selected assets between Novartis, GSK, and Lilly designed to strengthen each other's position in different franchise therapies. This friendly exchange between avowed competitors was a "no go" only a few years ago. The second is the arrival of hedge funds as a driver of M&A in a sector these speculators find to be undervalued. Valeant's bid for Allergan, with support from investor activist Bill Ackman, is an example here. And, finally, we are seeing a change in payer perspectives, with key PBMs like Express Scripts seeking to create a grassroots coalition to beat down prices of top-selling, highcost drugs. Taken together, where are these developments taking us? Is there a connection between the three?*

Degois: What binds these trends is the primacy of demonstrating long-term value. This work has to be initiated very early in the development of any new asset, with the focus on shaping how that asset is going to be priced and reimbursed several years down the road. It is not an easy task. It requires significant resource commitments, which creates additional burdens for smaller companies like my own. It is interesting that a significant push to provide value is now coming from payers here in the US. Arguably, the pressure is as intense as in Europe, which has controlled prices for years.

Kimberly Manhard, Ardea Biosciences: One positive is that it is easier to obtain a breakthrough designation from the FDA, which is one demonstrable means to prove value.

Herberts: The practical matter is that you no longer have a choice to do it. Potential buyers of your asset expect to have some type of payer/market access assessment even for early-stage preclinical assets. Even if payer discussions are conducted on a high-level conceptual TPP basis, they lay the foundation for both parties to assess the potential commercial value, and thereby the financial value, of the asset. When a small company has these analyses already completed, it creates the credibility that can seal the partnership and lead to a strategic investment. Despite the many potential errors in underlying assumptions, this payer assessment can work to create a common foundation upon which to consummate a transaction.

Grass: The value model itself has to keep pace with the science. The movement toward personalized medicine can make the calculations much harder because pharmacoeconomic data is less meaningful in very small patient populations, especially those with no current therapeutic options.

Maderis: One trend we have not discussed is industry consolidation. Presently, many biotech companies are finding it easier to tap the capital markets and commercialize assets on their own instead of having to rely on partnerships and licensing with big Pharma. But I expect this is temporary; the markets are cyclical. Consolidation is going to make the entire transaction field more challenging, particularly for the smaller players who need to partner, as buyers' leverage increases as the number of potential buyers declines.

PE: *So are the big players getting too big? Is it important for R&D organizations to maintain the flexibility required to act fast, seal the deal, and preserve the intimacy that builds trust and keeps partners in line? Is there anything big Pharma can do to mitigate the negative link between size, organizational inertia, and management uncertainty?*

Grass: You cannot assume that because an organization is large it is inept and remote. As long as the process between partners is clear, and the objectives are understood, then the chances of a junior partner being surprised are limited. When you get bad news, it's usually because of the simple fact that someone was not communicating. This can happen regardless of the size of the organization.

Kiron: It also depends on what you are selling: for example, is it an asset or a platform technology? With the latter, you usually don't get an automatic "in-or-out" decision. It can take time to conduct all the scientific evaluations. Then there are the commercial and market access discussions around an asset. You can finally get it all done and suddenly the big Pharma partner will say a decision has been taken to exit that particular therapy area. But I would say from experience that this

happens rarely and the adverse impact is accentuated by a simple failure to communicate. If a company has strong interest in an asset, it comes across right away; you find out very quickly who the decision makers are. This, in turn, speeds the process. The longer it takes to come to agreement, the bigger the risks.

Maderis: There is so much out of your control. Continuity over the life of a deal is very rare. Changes are to be expected, especially as other M&A activity shapes the external therapeutic landscape beneath your feet. It is hard to take uncertainty and risk out of the deal-making equation.

PE: *Is the need for due diligence becoming more of a drag on speed and timing to execute a deal?*

Levin: Due diligence represents a challenge to the seller side because of the higher resource commitments needed to assure buyers worried about hidden risks. The big companies want to see everything and then this has to be evaluated at multiple decision points. A smaller company interested in buying can move quickly, without having to do things like presenting due diligence evidence directly to a distant Board.

PE: *Is parsing the IP angle still important?*

Manhard: IP protection is our company's biggest category of spend in dealmaking. It is vital to keep track of the changing boundaries of exclusivity in areas like data protection and biosimilars.

Broxon: There are lots of potential PTO problems in any company's portfolio; some issues can be pending for a decade or more. There are varying shades of exposure, and if you don't adequately establish the risk up front it can emerge as a deal killer. You need experts to probe all the patent claims. They should have the experience necessary to pose the right questions.

PE: *Jay, as a representative of a non-profit professional disease organization, what suggestions do you have on how the biopharmaceutical industry can be a more effective partner in advancing the search for cures?*

Tung: The challenge is that each party has different motivations that are based on decades of learned behavior. Companies are reluctant to make early investments in anything that involves speculation against the prevailing grain—but this is often where true innovation begins. At the same time, most non-profits lack the resources and expertise to move these promising ideas into commercial development. What the Foundation has done to address this is to bring this expertise into our staff so we can facilitate the packaging of highly relevant data that takes some of the mystery out of speculative bets. Our data contributions work in the language that big R&D organizations understand; it reduces the number of steps in the preclinical research phase, saving time and money, which in our industry is classified as risk.

To create a permanent infrastructure to drive this concept, we established a translational medicine center with a research agenda specifically geared to myelin repair as a treatment pathway for MS. What we'd like most from industry is more partnering on projects in this area, such as building a consortium of companies to develop new biomarkers that make MS diagnosis more predictable and help narrow and personalize treatments. These biomarkers would boost the clinical credibility of additional investments to find ways to clinically induce repair of myelin rather than the traditional approach, focused entirely on immune response.

Building the business development function

PE: *Is it safe to assume from our discussion thus far that business development—dealmaking—is now a key strategic function for both big Pharma and biotech? What are some of the key internal issues that must be confronted in helping those of you active in this area maximize your contribution to the organization? Where is the best home for business development—in the R&D organization or in the commercial operation?*

Schaeffer: Most pharma companies have integrated licensing and business development activities within the R&D organization. The reason is simple: the most critical component in any licensing evaluation is the scientific assessment. Decisions concerning licensing or acquiring a specific asset will be predicated on this review.

Grass: Business development is a strategic activity and, hence, it should report directly into the CEO. This is the best way to minimize the tendency to overweight the scientific or the commercial view in deals, which happens when you have business development located exclusively in either function. Ideally, you want business development to exist independently of the prejudices and preconceptions that collect when

"Companies are reluctant to make early investments in anything that involves speculation against the prevailing grain—but this is often where true innovation begins."

—Jay Tung, Myelin Repair Foundation

you are located in one area. Organizing business development so that it is independent and directly accountable to the CEO ensures a more balanced view on transactions.

Levin: It's a moot question for smaller companies. Here, business development nearly always reports in to the CEO.

changes in store that might deflect some of the up-front risk in arranging new deals? Or is the climate likely to become even more challenging for those seeking the best assets?

Degois: The search for attractive opportunities at the preclinical stage is going to accelerate. This is reflective of the exciting state of science right now, with more innovations to come as we begin to digest the progress in our understanding of the biologic origins of disease. Big Pharma buyers know they have to cash in on this science at the beginning if they want to seize the competitive advantage around all the emerging platforms. This in turn carries implications for the value debate we are experiencing right now, because if there is no Phase II or III evidence to incorporate, buyers will have no choice but to be more flexible on terms.

"One fact remains constant—the best assets will get funded!"

—Doug Fisher, InterWest Partners

Kiron: It is also important to think in terms of distinguishing your functional corporate/business position as being based on the development stage of an asset. It can be more effective where one team works around assets in preclinical to Phase I, while a separate licensing group handles everything from Phase II onward. You are then able to create that mix between fully understanding the science behind an asset as well as being able to take it forward from a more global, networked orientation that zero's in on market potential.

Maderis: Another key question is to evaluate where in-house corporate venture capital groups fit into the business development picture. We are seeing these internal groups take on a more prominent role; some are fully embedded in the business development function, whereas in the past they operated on the margin—as a separate unit that tended to invest in experimental, speculative things.

Kiron: I'd assess their position within the organization on the basis of this question: can you manage an offbalance sheet activity and still have an impact on strategy?

The next wave

PE: *What will be the major drivers of the dealmaking environment in three years' time? Are there commercial or policy*

Schaeffer: Much of the innovation will still be coming from many smaller biotech companies, which is good for competition. You will likely see the bigger biotechs picking up more assets from the smaller ones. And big Pharma will need to be faster on its feet; deals won't simply fall in their lap.

Bilinksy: We will see higher asset valuations—licensors are better capitalized now and do not have the same pressures to sell just for financial reasons. And there will be more biotech to biotech deals. Many lead programs will inevitably fail in development in the next one to two years, and biotechs will need to deploy the capital that they raised from public markets to fill their pipelines by in-licensing from other biotechs.

Maderis: What concerns me is the continued efficiency of the system that has fueled so much medical innovation over the past decades. The steep decline in public funding of basic research is troubling and not easy to replace, even with the onset of increased independent philanthropic activity. Big Pharma players are outsourcing more of their R&D and overall R&D investment by the industry is falling. Big Pharma wants to do more deals, but will there be enough inventory of good assets? Where is the financing for the innovative start-ups going to come from? It is a long-term process to raise the productivity of the industry's research pipeline. It is inefficient to rely on hope that another cycle in which valuations go through the roof will end up turning that pipeline back on.

Fisher: One cloud I see on the horizon is a drying up in the capital markets, similar to what happened five years ago. If the past is precedent, then you will see many more structured deals, along with a more powerful big Pharma contingent coming to the negotiating table in better shape, especially with the patent cliff behind them.

Wu: I, too, see more deals among smaller companies. Sustainable sources of financing is thus going to be important in preserving the momentum of what is likely to be a new and changing series of niche markets.

Kiron: Another trend affecting deals in the near future is the desire of big Pharma to shed older assets. We will see more dealmaking activity involving off-patent compounds, many of which are no longer being reimbursed, but have real potential as repurposed products with an extended protection of patent life and subsequent product revenues, or in other ancillary portfolio settings.

Fisher: One fact remains constant—the best assets will get funded! PE

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- Characterize patterns of care on Chronic Lymphocytic Leukemia (CLL);
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- Describe total cost-of-care for the treatment of Myelodysplastic Syndromes

Key Learning Objectives:

- At the end of this session, participants will be able to:
- Better understand the expanding influence of Healthcare Economic & Outcomes Research (HEOR) to support specialty brand access;
- Better understand the complexities of projects requiring multiple, disparate data sources to reach meaningful conclusions;
- And visualize analytics output to inform strategy and reduce risk in Specialty pharmaceuticals

Who Should Attend:

- Director – SVP-level pharmaceutical executives
- Specialty Brand Leaders
- Market Access
- HEOR researchers
- Marketing
- Business Analytics
- Chief Medical Officers

Presenter

Bruce Feinberg, D.O.
Vice-President and
Chief Medical Officer
Cardinal Health Specialty Solutions

Moderator

Sara Barschdorf
Webcast Manager
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Fire in the Cold Chain

Vaccines are the business to beat in today's pharma market. By Kevin Fitzpatrick and Nitin Mohan

Vaccines are a proven and cost-effective preventative therapy for numerous disabling and fatal diseases, producing significant public health gains that generate tens of billions of dollars in health system savings each year. Only recently, however, have vaccine producers experienced the commercial returns commensurate with this long record of positive public health performance. Vaccines are now the industry standout in delivering high rates of revenue growth, with double-digit increases of 10% to 15% annually, which are expected to continue for the next several years, significantly outpacing the 6% to 7% growth rate we see in traditional pharma.

The sector's improving prospects are driven by a surge of innovation in the underlying science of disease prevention as well as the increasing importance that national health systems attach to vaccines as their primary tool in the fight against communicable disease. These factors are driving change across manufacturers and their products as well as with markets and key customers. In the era of patent cliffs and shrinking pipelines, the high rates of post-Phase III R&D success in vaccines combined with a long product life cycle—often extending well beyond patent expiry—has forced the broader industry to look at vaccines anew. Nevertheless, companies seeking to benefit from this growth must adapt to a fast-evolving environment that includes lengthy clinical development timeframes, large investments in complex manufacturing platforms, and an often politicized price and reimbursement structure that demands significant attention to building relationships with numerous external stakeholders.

Key growth factors

There is significant untapped potential in the preventive vaccines market. Unmet needs remain since many diseases still have low immunization rates or no available vaccine. Financial analysts have projected the market to reach $39 billion in 2015. The World Health Organization (WHO) expects the global market to soar to $100 billion by 2025, with 120 new products flowing from company pipelines over the next decade.

A range of factors are driving this growth. Our experience in the industry has highlighted three: an increase in awareness of infectious diseases, changes in the global reimbursement landscape, and higher prices for new vaccines.

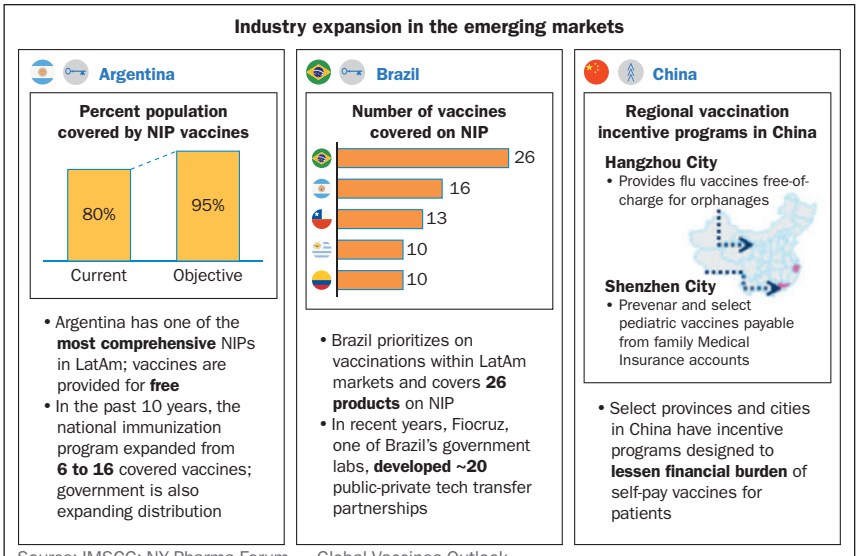
Increased awareness of infectious and communicative diseases: National governments are the dominant customer globally and play a substantial role in purchasing, enforcing safety regulations, and influencing uptake. Over the past decade, governments and supranational organizations have expressed growing con-

cern over public awareness of infectious disease prevention, dedicating substantial investment in mass immunizations and outreach programs in efforts that translate into opportunity for manufacturers.

Global outbreaks of vaccine-preventable diseases have driven much of the growth in public awareness. Seasonal influenza outbreaks like the H1N1 strain have claimed many thousands of lives and taken enormous tolls on national health expenditure. Growing awareness provides the impetus for governments to invest in programs aimed at preventing onset of future outbreaks. These programs supply funding for mass immunization programs, which play an instrumental role in elevating uptake. The WHO, for instance, now supports campaigns that provide not only funding but bottom-up infrastructural support, through numerous public outreach programs for vaccination, including sponsorship of the annual World Immunization Week.

Recent examples of how outbreaks can impact awareness and government policy are the meningococcal B (MenB) outbreaks, which led to meningitis cases and at least one death on a handful of US college campuses. In response, the US CDC and FDA made Novartis' Bexsero vaccine available for use with limited populations despite the product not being broadly licensed for use in the US. In addition, Bexsero and Pfizer's rLP2086 recently received "breakthrough" designation from the FDA, making these two products eligible for accelerated review. We anticipate an updated Advisory Committee on Immunization Practices (ACIP) recommendation for MenB vaccine use. Such a recommendation is expected to compel most payers to cover the product for eligible populations.

Non-profit and non-governmental organizations, such as the Gates Foundation, the Clinton Health Access Initiative, Global Alliance for Vaccines and Immunization (GAVI), as well as many others are increasingly influential as brokers in the negotiation of vaccine purchasing for ministries of health for developing nations and/or as advocates for vaccine use. Each of these groups are receiving more philanthropic support. They also provide access to medications in emerging and developing markets, prioritize vaccination on public health agendas, and help shape national immunization program strategies on coverage, pricing, and uptake.



Source: IMSCG; NY Pharma Forum — Global Vaccines Outlook

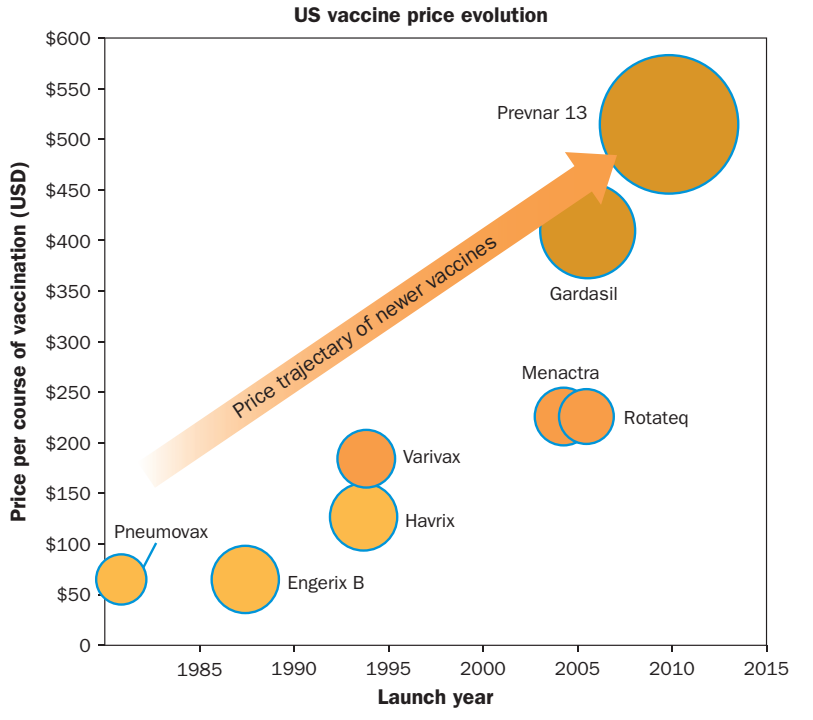
Growth is heavily driven by improved coverage and distribution of vaccines in emering markets.

Improving prospects are driven by a surge of innovation in the underlying science of disease prevention.

Better access and more predictable pricing: Immunization is attracting more attention on national health agendas; governments, in collaboration with supranational organizations, have responded by improving or adding vaccine coverage linked to preventive public health interventions. Provisions in the 2010 US Affordable Care Act mandate all health insurance plans to make recommended vaccines available with no out-of-pocket deductible or co-payment incurred to the patient, a provision that is intended to bring improved prevention coverage for 88 million beneficiaries by 2013.

Other mature markets, including Japan, have increased their emphasis on vaccination as a public health priority. In an effort to narrow the country's historical "coverage gap," Japan's Ministry of Health, Labor, and Welfare (MHLW) has poured investments into the vaccines manufacturing and R&D pipelines of Takeda, Astellas, Daiichi Sankyo, and Mitsubishi Tanabe to promote immunizations against prevalent infectious conditions. The MHLW has provided generous incentives for vaccine manufacturers, funded awareness programs, and by 2015, aims to include HPV, Hib, pneumococcal, varicella, mumps, and hepatitis B vaccinations as part of the national immunization program. The Japanese vaccines market has grown at a 28% CAGR from 2006-2011.

Uptake is also heavily driven by improved vaccine coverage and distribution in emerging markets (see chart above). Argentina, which currently has one of the most comprehensive national immunization programs in Latin America, provides vaccines for free and has expanded the number of mandatory vaccines from six to 16 over the past ten years. Moreover,



Source: US CDC; IMS Knowledge Link; NY Pharma Forum — Global Vaccines Outlook

Prices for new vaccines are increasing relative to traditionally mandated products.

Argentina's Ministry of Health aims to increase the percentage of covered individuals from 80% to 95% and has drafted plans to expand its vaccine distribution system to ensure universal access. Brazil currently leads Latin American countries in immunization protection, with 26 products covered under the national immunization program. In China, select provinces and cities have instituted regional programs for flu and select pediatric vaccines designed to lessen the individual financial burden of vaccines that are not covered for patients.

More evidence of the importance of immunization in emerging markets is the increasing activity of local mid-sized manufacturers and government labs. China's Sinovac, Brazil's Butantan Institute, South Africa's Biovac, Mexico's Birmex, and the Government of India's Serum Institute are developing newer vaccines, investing in more advanced manufacturing technologies, and experiencing higher uptake of in-line products. Brazil has made technology transfer a critical part of its overall national vaccine policy as was seen with Brazil's Ministry of Health agreement to purchase $2.2 billion worth of GSK's Synflorix in return for a gradual receipt of the technology to independently manufacture the vaccine after the end of the 10-year-long contract. Sanofi has partnered with Birmex in Mexico and Butantan in Brazil in a tech transfer agreement for its influenza vaccine. Many of the mid-size institutes have entered into purchasing agreements with supranational organizations such as GAVI, the Bill and Melinda Gates Foundation, and the Program for Appropriate Technology in Health (PATH).

Strong innovation is reflected in elevated price levels: Part of the sector's growth is derived from the higher prices newer first-in-class products have commanded based on the value they provide (see chart above). Wyeth launched Prevnar-7 in 2000 at a price that exceeded most other pediatric vaccines combined while still demonstrating high cost-effectiveness. Merck's Gardasil for human papillomavirus was priced at near $400 upon launch in 2006. With increased value driven by six additional strains, Pfizer's launched Prevnar-13 at a price of approximately $513 per course.

Even in categories that are crowded with competition, innovation has enabled price differentiation, as evidenced by Sanofi Pasteur's Fluzone HD, which is targeted at the elderly sub-segment of the overall flu market where unmet need is most pronounced. While Fluzone HD has not demonstrated greater protection from influenza disease than regular flu vaccines at the time of this writing, it has demonstrated improved immune response in clinical trials. Significantly, the private list price for Fluzone HD is more than twice that of multiple standard dose flu products. AstraZeneca's FluMist was recently able to gain a CDC recommendation at the other end of the age spectrum. The CDC indicated that influenza incidence was markedly lower in the 2- to 8-year-old age group when vaccinated with a nasally administered vaccine. FluMist also commands a premium price in the market.

In addition to the drivers already mentioned, we have also seen growth from successful lifecycle management strategies. The two largest-grossing products in the preventative vaccine industry, Gardasil and Prevnar, are perfect examples. Gardasil for instance, doubled its eligible recipient base after receiving approval for male anal cancer, genital warts, and pre-cancerous lesion indications. In January 2013, Pfizer's Prevnar similarly received a nod from the FDA for an age 50+ expansion, a decision that has led Wall Street analysts to project an increase in sales from $4 billion to $5 billion a year. Vaccines that currently lead market sales have and will continue to provide a steady source of growth, and manufacturers intend to leverage R&D, manufacturing, and marketing capacity and increase year-on-year investments on promotional spend, post-marketing surveillance studies, and indication expansions.

Biosimilars:
Friend or Foe to Healthcare?

ON-DEMAND WEBCAST

Register for for free at www.pharmexec.com/biosimilars

EVENT OVERVIEW:

Referencing recent findings from a physician research study, market access consultant Shrinivas Rao Mukku and marketing research consultant Allison Fleetwood interview a major US payer to look at the opportunities for biosimilars, the possible threats to originator brands, and consider what companies entering the market need to do to effectively launch their follow-on biologic.

During this webinar we will:

- Investigate how the launch of mAb biosimilars in Europe is likely to impact on healthcare strategies in the USA
- Consider the challenges biosimilars face if they are to achieve sufficient uptake and how these may be overcome
- Offer expert opinion on likely future scenarios from a major US payer
- Consider the defence strategies for biologic brands

Who Should Attend:

Executives working with biosimilars or biologics brands such as:

- Marketing executives
- Market research executives
- Brand and Product executives
- Pricing and Market Access executives
- Commercial leads

Key Learning Objectives:

Attend this webinar to:

- Better understand physician awareness and familiarity with biosimilars and the potential barriers to uptake
- Learn about the strengths and weaknesses of biosimilars and the impact they may have on the treatment landscape from the payer perspective
- Gain greater insight into what companies entering the market need to do to effectively launch their follow-on biologic

PRESENTERS

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Director, Therapy Watch
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Global Director,
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Pharmaceutical Executive

For questions, contact Sara Barschdorf at sbarschdorf@advanstar.com

Industry growth has led to M&A activity: Many large-scale manufacturers have turned to vaccines to drive sustained growth and branded revenue. In 2010, the industry reported over 195 vaccine partnering deals, including Johnson & Johnson's acquisition of Crucell, a $2.3-billion deal which strategically introduced the big pharma conglomerate to the mid-size vaccine manufacturer's portfolio of pediatric, endemic, and travel vaccine assets.

Vaccines are no longer a fringe business—it's the "must have" in any public health agenda.

Other notable deals include GSK's recent $5.25 billion initial cash purchase of Novartis's non-influenza vaccine assets, in return for the transfer of GSK's oncology franchise and the development of a distinct consumer healthcare business. This brings to GSK a portfolio of travel assets that includes a promising meningitis vaccine franchise. Sanofi Pasteur's acquisition of Acambis in 2008 augmented the second-largest vaccine manufacturer's flu and tailored multivalent combinations with West Nile and dengue fever travel vaccine assets. In 2007, AstraZeneca acquired MedImmune for $15.6 billion in a deal that through Synagis and FluMist, positioned the company as the sixth-largest vaccines manufacturer. Takeda (see sidebar) launched a new business unit dedicated to vaccines in early 2012, and Mitsubishi Tanabe acquired Canadian company Medicago, thereby getting access to Medicago's innovative technology for producing vaccine-like particles from tobacco plant leaves.

What's next in vaccines

The next generation in vaccines development will rely on platform strategies founded on genomics, reverse vaccinology, high throughput DNA sequencing, new plant and insect based expression and production systems, and new more potent vaccine adjuvants. These developments carry the potential to rapidly produce novel, optimal and cost-effective vaccine targets that carry high chances of success in clinical development programs. Promising new vaccine candidates such as meningococcal-B, GBS, methicillin-resistant *Staphylococcus aureus*, pneumococcal, and pathogenic *E. coli* are already in development. Not only do these new platforms improve the prospects for vaccines against major infectious diseases such as AIDS, tuberculosis, dengue, and malaria, they also provide a basis for therapeutic-based vaccine development against other new and emerging conditions, including allergies, autoimmune disorders, and cancer.

Business points to ponder

New markets and diseases, specialized target populations, and increasing needs for preventive vaccines all lead to new opportunity, but also impose new challenges. The key strategic questions manufacturers will need to address include:

- How to price products whose commercial benefit will rest predominantly in emerging markets?
- How to effectively capture niche populations within an established vaccine disease area?
- Within the structure of public health requirements and recommendations, how can technology advances be effectively translated into commercial advantage?

The benefits that the vaccine market offers will accrue to those who are able to creatively adapt and build on past approaches while incorporating the advances of new science and a more supportive policy environment: vaccines are no longer a fringe business—it's the "must have" in any public health agenda. PE

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Takeda's New

Today's vaccines business represents an almost perfect world for big Pharma. There is a vast landscape of unmet medical need; lots of new science; longer product life cycles, with low exposure to post-patent generic competition; greater stability in pricing and supply commitments; more cost-effective manufacturing and delivery technologies; and the reputational gains that come from fulfilling a highly visible public health mission. While the established players strive to keep their lead, and others contemplate entering the space for the first time, one company—**Takeda Pharmaceuticals**—is moving to up its game, with a commitment to build a truly global vaccines business founded on its historical roots in Japan, where it began producing vaccines for generations of children and adults in 1946, just months after the end of World War II.

Takeda established the new Global Vaccines Business Division in January 2012 as part of an ongoing corporate restructuring to expand its global footprint after several large foreign acquisitions. The objective is to raise the profile of vaccines to complement other parts of the product portfolio and bolster Takeda's overall value proposition to customers, particularly in high-growth emerging market countries. As the dominant industry player in its home market, senior management realized that Takeda's future depended on having an equally strong "rest of world" strategy able to exploit the full range of opportunities in markets with different geographies and income segments. "Expansion of our vaccines business demonstrates Takeda's commitment to address unmet needs in global public health through innovation, with a model that is relevant and sustainable for both mature and developing markets," Global Vaccines Business Division Head Rajeev Venkayya told *Pharm Exec*.

It also makes good business sense. "Our goal is to recoup the significant

Divison Charts Course to Global Growth

investment in R&D while ensuring the broadest access to the vaccine. We will do this through a tiered pricing structure that provides higher margins in wealthier markets with the ability to pay, while offering the same vaccine at lower prices in the low-income developing world." Venkayya, who previously headed the vaccines delivery program at the Bill and Melinda Gates Foundation, stressed it is no contradiction to follow a public health mission based on commercial incentives. "In a company, it is difficult to sustain a business with uniformly low or negative margins. We can guarantee that if allowed to make smart pricing decisions based on a market's ability to pay, we will continue to invest in R&D, and access to our vaccines will not depend on the zip code of one's birth, but on an appropriate, medically recognized assessment of public health need."

Venkayya

The new Division is taking a highly focused approach to the vaccine portfolio, one that relies on the strengths of the Japan business in prophylactics for adult and pediatric infectious diseases. In global markets outside Japan, the objective is to establish a lead therapeutic position in additional infectious conditions that meet two specific criteria: (1) a high level of unmet medical need, led by the absence of alternative therapies; and (2) impact on population health, evidenced by global disease burden.

To achieve this, management has acquired two US-based biotech companies—LigoCyte Pharmaceuticals Inc. and Inviragen Inc.—to leverage promising clinical targets against norovirus and dengue fever, respectively. Both diseases fit the group's portfolio vision. Norovirus is a highly contagious gastrointestinal illness that knows no economic barriers as it exists in both rich and poor countries, affecting children and the elderly disproportionately, and for which there is no existing vaccine or specific treatment. Likewise, dengue fever is a leading cause of disability, hospitalization and productivity loss in tropical countries, with a ubiquitous transmission vector (mosquito) that is steadily moving north, again with no available preventive measure (aside from vector control) or cure. According to Venkayya, the unmet need around norovirus alone is so great that any first in class product the company presents could quickly emerge as Takeda's farthest-reaching product.

And prospects appear promising. A bivalent virus-like particle (VLP) candidate for norovirus is completing global Phase II trials. A live attenuated virus candidate for dengue is also is in Phase II, with support from various public health partners based in emerging markets. However, there is significant competition from rivals in these areas, particularly with dengue, where Sanofi has an advanced candidate in vaccine trials; GSK is active here as well.

The acquisitions also give Takeda access to a new recombinant technology development platform along with a few additional candidates at the preclinical and early Phase I stage, including a vaccine for chikungunya, a mosquito-borne virus similar to dengue, and Enterovirus-71, an important cause of hand, foot and mouth disease, which is associated with skin rashes and polio-like neurological symptoms, mainly in children.

In addition to these new areas, the Division is working to enhance its position in seasonal influenza in the domestic Japanese market, leveraging a partnership with the Japanese Government to establish domestic manufacturing capabilities for pandemic influenza vaccine. A new vaccine for *Haemophilus influenzae* type B (Hib), an important cause of meningitis and upper respiratory tract infections in children, has been submitted for registration and is due for launch hopefully before the end of this year. "We have no intention of neglecting our domestic base. The vaccines business has always been a mainstay of the business in Japan and it is important that this continue," said Venkayya.

Like any player in vaccines, Takeda must confront operational challenges, which Venkayya describes as building a strong, productive mix around "products, people, and infrastructure." Even with its expertise in Japan, scaling up globally continues to take the bulk of his time. "Besides refining and growing the pipeline, we have had to internalize talent from our acquired companies and simultaneously build our team in key areas like clinical development, quality assurance, supply chain & logistics, regulatory affairs, policy, and marketing. The group has to work on aligning the clinical development, manufacturing, and commercial functions, which is critical to any successful launch." For now, the Division is opting to keep important clinical and process development tasks in Japan, which also remains the base for manufacturing. But many of the new vaccines under test are highly complex and will require additional specialized—and costly—production expertise.

In the three to five year horizon, Venkayya states that success for the new global franchise depends on securing two goals. First is the preparation for launch of its lead global vaccine candidates for norovirus and dengue, a task that includes building the necessary partnerships with government, NGOs, and other external stakeholders. He notes that the key element in such partnerships is establishing a scientific and clinical basis for prevention; compiling epidemiological evidence linked to amelioration of disease burden; and modeling for proof of cost-effectiveness, based on accepted population health criteria. "This is a long-term process, enough to test the limits of any planning cycle; I know this from experience," he says. The second goal is to add to the base of the business in Japan, largely through advancement of the pipeline and partnerships to expand the Japanese portfolio further.

— William Looney, Editor-In-Chief

The Patient Value Equation

David Schlanger, a former pharma industry executive, became CEO of WebMD last year. He first joined the company in 1995.

For WebMD CEO David Schlanger, connecting patients with physicians through a robust digital platform delivers the win/win/win necessary to achieve quality of care, cost savings, and better health outcomes.

By Ben Comer

A renewed focus on the costs of healthcare, combined with the Affordable Care Act's incentive structure that attempts to prioritize quality of care above quantity of care, puts WebMD—a household name for online medical information with patients, physicians and caregivers—in a position to connect the dots that draw a picture of tomorrow's patient need.

David Schlanger became WebMD's CEO in August of 2013, but first joined the company in 1995, after serving as executive director, business development at Merck. The commercialization of pharmaceutical drugs has changed a lot in two decades: industry's focus on specialty drugs for smaller populations and patients with chronic disease has supplanted the emphasis on big name primary care products, and the blanket TV buys that propelled them into blockbuster glory. At last month's DIA meeting in San Diego, Lisa Stockbridge, branch chief, advertising and promotional labeling branch at FDA's Center for Biologics Evaluation and Research (CBER), noted that only one television ad for a biologic came through the agency for review in 2013.

Schlanger says he chuckles when he sees Abbvie's TV ad pushing Humira for Crohn's disease—"there's only 2 million people with Crohn's disease" in the US—because it stands as a relic of a bygone era where the biggest media spend all but guaranteed the largest chunk of the market. Money still talks, of course, but fewer patients are all tuned in to the same listening apparatus. Physicians and patients still need to be educated about prescription drugs, but with limited access to the former, and a larger cost burden placed on the latter, drug companies hoping to reach their target audiences (and target sales revenues) do better by concentrating on the quality of interaction, not the quantity of exposure.

PE: *As a well-known online destination for health information for patients, and for physicians through WebMD's Medscape division, what has changed in terms of what your visitors want to see when they visit your website?*

Schlanger: In today's world, consumers are bearing much more financial burden for their care—high deductible health plans, with employers pushing costs off to their employees—so patients really need tools to help them make decisions in a more effective way. Physicians are contracting with health plans in much different ways, and are being compensated differently. The old world of fee-for-service medicine is evolving into one where you're going to be compensated at least partially based on the outcomes you produce, and how efficient you are in delivering care. There's a real need for consumers and physicians to manage care more effectively together, so

Photo: Thinkstock

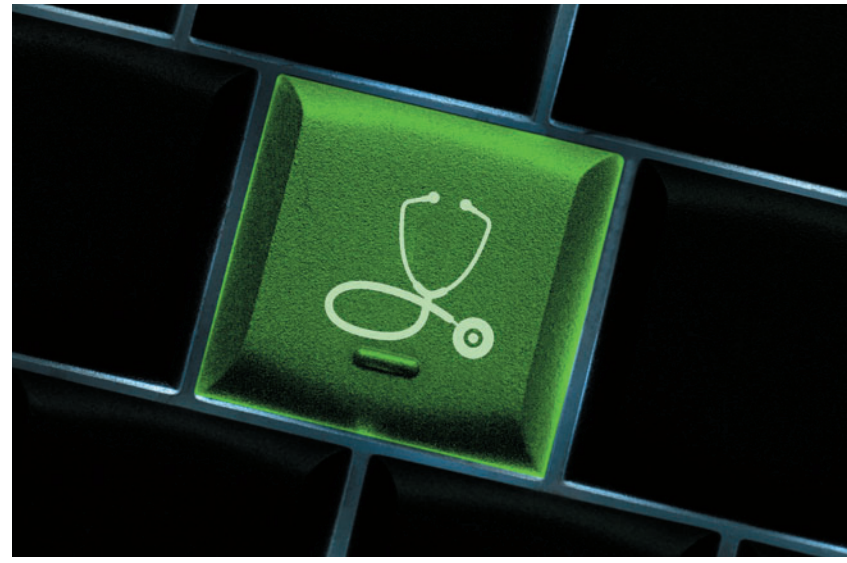
our goal is to help them do that using our platforms.

PE: *What's the missing link in connecting patients with physicians outside of the doctor's office? Several large companies—Google Health, Microsoft Health, etc. – have tried and failed to do exactly that.*

Schlanger: One of our major initiatives is that we're connecting our audiences of consumers and physicians to allow WebMD to be the place where a consumer manages all of their healthcare information. That information doesn't necessarily need to be entered by patients themselves; it might come from biometric devices like glucometers, wearable activity monitors, and electronic health records from healthcare providers—incented by the Affordable Care Act—or even data shared from an employee's health risk assessment. We think that we can be the central place for a truly collaborative care record that enables consumers and health professionals to jointly manage care. We're also building a suite of services for healthcare professionals, administrative functions like appointment scheduling, check in, and copay collection.

PE: *Can you give an example of what that might look like?*

Schlanger: If you're a congestive heart failure patient, you have to go to the doctor frequently to get your weight and blood pressure checked, because those are the two big indicators of a problem. If you have a sudden weight gain, you have fluid build up; if your blood pressure changes, those are signs that your heart is not functioning adequately. In the old world, you'd see the doctor every couple of weeks. You'd step on a scale, get a blood pressure reading, and if everything looks okay, you'd leave and stay on the same medication. Now, with the technology that exists today [if you have a smartphone and a wireless scale], that data could be uploaded through your



smartphone—in a HIPPA compliant way—and sent to your doctor's office every day, instead of every couple of weeks. You can hook up a device to your finger through your smartphone to check blood pressure, and it would go to your doctor's office in real-time. And the doctor doesn't even need to look at it every day—the technology can alert him when something is out of range, or something changes. And the doctor can intervene earlier, to create a better outcome at a much lower cost.

PE: *Last October, WebMD showed up in a lot of high profile tech publications with its acquisition of Avado, a "patient relationship management" software platform and a TechCrunch Disrupt finalist. Can you describe your Healthy Target program (launched on June 16), and how Avado fits in to that product?*

Schlanger: We're starting with wearable devices and biometric data. The reason we're doing that is because there's been a problem with all of those FitBits and UP bands and wireless scales; people use them for a little while, and then stop, because the information provided is just numbers on a screen. I took 6,000 steps yesterday, but what does that really mean to me? How does it help me lead a better life? The answer is it doesn't and that's why people stop using these devices. But we think those devices are really powerful if you take the data and turn it into meaningful insights and action, and put it into the context of a program to actually help you live a better life.

PE: *What's the selling point for the Healthy Target (part of WebMD's iPhone app) program?*

Schlanger: Healthy Target allows you to take data from a whole bunch of wireless devices—scales, glucometers, activity monitors—and use that data in the context of a health improvement program which allows you to set goals that are unique to you. Do you want to sleep better, to eat better, to lose weight, to lower your blood glucose? The app lets you set those goals, and we onboard all of your data from those devices and use it to help you engage in those healthy habits, and monitor your progress against those goals. So it turns all that device data from numbers into insights and action. Once we continue down the development road to connect consumers to their physicians, the data will be shareable so that when the physician says, "You need to lose weight," you can say, "I'm going to use the WebMD Healthy Target program," and the physician can say, "Send me your weekly progress report."

"The old world of fee-for-service medicine is evolving into one where you're going to be compensated at least partially based on the outcomes you produce, and how efficient you are in delivering care. There's a real need for consumers and physicians to manage care more effectively together."

PE: *How does pharma fit in to this new communication platform, and how can individual companies partner with WebMD to reach patients and physicians?*

Schlanger: I've been in the healthcare business for 25 years, and I started at one of the large PBMS, so compliance and adherence has been something that's been buzzing around in my head for over two decades. Physicians aren't equipped to call all of their patients and ensure that they're taking their medications. We can use claims data to find out whether you got your prescription filled, and if not, we can empower your physician to automatically communicate with you, and create incentives for you to be adherent with your medication. Compliance is the doctor forcing you, and adherence is voluntarily knowing that you need to take your medication. I think if people know their doctor is watching and paying attention, they're going to be more adherent.

PE: *As evidenced by the seemingly continuous restructuring of sales organizations at big pharma—and the ongoing scale down of sales forces across the board—access to physicians continues to decrease. How can pharma use WebMD to reach physicians in this environment?*

Schlanger: WebMD has the largest audience of physicians, and they come to us for three primary reasons: to be educated through certified continuing medical education, or just to stay up to date on what's happening in their specialty; for relevant medical news; and for clinical reference. They're very engaged. Our docs spend a couple of hours with us every month, typically across several devices: a PC, a tablet, a smartphone. We provide a really effective way to get to the doctors pharma wants to get to through a host of programs that we push out, and programs that are based on the site that pull doctors in.

Medscape is a registration site so we know who our users are, and just like pharma, we know their behavior patterns and what they prescribe. But on top of that, we also know their proclivity to respond to certain types of things that we ask them to do. Pharma might go visit the top three deciles, knowing that it creates X amount of market lift, but the bottom seven deciles can't be reached in a cost-effective way. But with Medscape, it becomes cost effective, and we can create just as much lift by targeting physicians on the long tail, through an offering of interactive content like patient simulations and virtual speakers programs.

We have a product called Brand Alerts that allows a pharmaceutical company to reach a physician on whatever platform he uses, by any segmentation factor, right into the workflow. We've redesigned the WebMD app, to create a bigger picture narrative. The Brand Alert flows into the news and is integrated into the carousel, so if you click on it, you get an in-line native ad, information from industry. Then you could click through into the content, which could incorporate video assets directly from industry, and of course it is always clearly labeled as such. The engagement and click-through rate is much higher, and it counters what people call "banner blindness." The key is that even if we're going to show something that's native information from the industry, it's got to be relevant to the experience someone is in at the time. We value the trust our users have in us and that manifests itself in a lot of ways.

PE: *A lot of pharma companies spent a lot of money building their own physician portals, and no one really used them. Even though you have the capability to target physicians, and you have the audience, how do you know that you're providing value?*

Schlanger: We can look at who was exposed to a program and how it changed their prescribing patterns. On the Medscape side it's easy to demonstrate that a program is impactful, because we've invested in our marketing sciences and analytics capabilities. On the consumer side, we can measure consumers exposed to a program to find out what percentage of them, on a statistically significant basis, got on therapy after the program. When we report on an ROI, it's a scientifically determined ROI. But WebMD was never the place for a big brand like Lipitor; the target is 50 million people. Consider instead multiple sclerosis. Four-hundred-and-fifty thousand people out of 300 million in the US.

There are a limited number of products in the market, and they each cost over $50,000 a year— everybody's all over Gilead for their

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$84,000 hepatitis C treatment, but MS is $50,000 every year for the rest of your life. But there are 450,000 sufferers, and TV makes absolutely no sense. Why would you advertise on TV? And yet, each patient is so valuable. When pharma comes to WebMD [to target MS patients], they don't care that we have 170 million visitors, or when you eliminate the duplication, about 65 million unique Americans every month. What they care about is that 185,000 MS sufferers are on WebMD every month, plus their caregivers. And [MS patients] aren't just checking their email or checking the sports scores. When they visit WebMD they're dealing with their disease, they're here for a reason. They're in lean-forward mode. We have them at a very teachable moment, at a point in time when it's very impactful to a brand trying to get to them.

PE: *What barriers would you cite as standing in the way of pharma becoming a more active or innovative partner? What gaps could pharma fill?*

Schlanger: The pharmaceutical industry tends to be fairly slow-moving and conservative. I don't think there are any real barriers. Even the rules about fair/balance, and regulatory review of DTC and professional advertising I wouldn't view as barriers to anything because we've learned how to deal with those processes. We just have to continue to do what we're doing, which is to help them understand the value of working with WebMD versus all of their other media tactics. We have certain brands that are very forward-thinking and that have their own mobile-optimized websites, and that leverage our mobile offerings. But that's probably 40 percent of the brands. It should be 100 percent, because they need to understand that's where their audience is.

PE: *Leaving the digital world for a moment, I read that WebMD is now involved in some offline coaching, and that the payment structure is based on patient utilization. Can you explain that program, and why WebMD is dabbling in offline services?*

Schlanger: We have an enterprise business that goes to large corporate employers and health plans and sells them population health management and wellness services. We have a full suite of digital capabilities, and it starts with a health risk assessment, which serves as the bases for a personal health record. We import medical claims and pharmacy claims to pre-populate the health record. There's a digital smoking cessation program, a digital obesity program, and digital condition management programs. These online programs help patients manage their issues, but certain people need more intervention: digital intervention isn't always enough. So we do have a coaching center where we have dieticians, nurses, and exercise physiologists helping people who need more of an intervention. That's typically paid for based on the volume of coaching we provide. This is only offered if you are an employee of one of our corporate customers, or a member of one of our health plan customers.

PE: *WebMD recently scored a Blue Cross Blue Shield Association Federal Employee Program contract that supports over 5 million members. How important is health plan management as a business sector, who are your competitors, and how is it different for your traditional business areas?*

Schlanger: It's more competitive, and it's a pretty fragmented business. It's everything from players like Healthways, Aetna, UnitedHeath through their Optum division, and lots of little players. Castlight Health went public. Cost transparency is a piece of it, a little company called RedBrick Health. But I think WebMD is unique in that people really trust the brand. The [Blue Cross Blue Shield] federal contract is the biggest in the history of that business area.

PE: *What percentage of total revenue comes from that business division?*

Schlanger: Somewhere in the neighborhood of 18 percent of our total revenues.

PE: *WebMD has also made some notable progress toward global expansion, first with your 2009 Boots partnership in the UK, and more recently with DXY, the physician portal in China. How would you describe WebMD's role in China, for example, and what you'd like to accomplish through your partnerships outside of the US?*

Schlanger: Health is very much a local offering. You can't just necessarily assume that because we have an article here or a capability there, that you can just translate the language and have it make sense. The greatest example of this is in the UK. We got into it as a kind of experiment. Boots has been a terrific partner, and now that they're aligned with Walgreens it's even better for us. We're now the largest health site in the UK, but it's solely a consumer package goods opportunity [on the consumer side, since DTC advertising is illegal]. One thing we learned by being there is that even though it's English to English, we had to basically rebuild a new site. Every article is Anglicized, which is a word I didn't know about five years ago. It could be as simple as, in a slide show, showing a picture of Oxford Street in London instead of Eighth Avenue in New York.

To be credible, and to give health advice, you have to be there. If we're giving people advice about eating, the foods have to be available and part of the cultural taste buds. The way that we treat disease might be similar, but it's not exact. On an even higher level, the term "MD" means nothing in these countries. In fact, when I first went to the UK and met with Boots, they said, "You know, no one knows what MD

"We have certain brands that are very forward-thinking and that have their own mobile-optimized websites, and that leverage our mobile offerings. But that's probably 40 percent of the brands. It should be 100 percent, because they need to understand that's where their audience is."

means here. It means Managing Director." They know the term GP, but not MD. On the professional side, with Medscape, it's a different story, because English is the international language of medicine, and many doctors outside the US are educated in English. We engage about 300,000 physicians outside the US.

PE: *What factors precipitated the DXY deal in China?*

Schlanger: China is probably one of the most important growth markets for Western pharma because China is adopting Western medicine. But China's a gigantic country. There are a lot of numbers tossed around, but on the high end, I've heard there are four million doctors in China. Only about a million and a half are classically trained. Some of the rural physicians are more like "my father was the doctor, now I'm the doctor." The government in China is really trying to train these people. But in the cities there's an exploding middle and upper-middle class, so we wanted a greater level of penetration and to be able to reach more doctors. DXY is a very credible, highly academic and highly scientific site; very much in keeping with our brand. We trust them, so that really opened it up for us to expand our reach in China, and we may do that in other places too—the worldwide opportunity for Medscape is definitely one that we are optimistic about, and are pursuing as aggressively as possible.

PE: *How important is it to have a local partner—as opposed to going it alone—in navigating the regulatory system, or local compliance issues, for example?*

Schlanger: In the UK, we leveraged some third-party content, and we approached the *British Medical Journal*. Well, the *British Medical Journal* wasn't so keen on just saying, "Here, take our stuff, you're a US company." In fact, when I first met the CEO, he was very skeptical. But when you go in with the CEO of Boots, and they say "Hey, these are our partners and we trust these guys"—Boots is a 150 year-old British company—it's a lot more impactful. We've had no problems with regulators in the UK. The NHS loves us. I think that's in part because we didn't go in there and just say, "We're Americans, we know what we're talking about, you don't."

PE: *WebMD created a non-sponsored educational site to help people navigate the health exchanges and to understand the Affordable Care Act. What are some of the challenges your visitors are facing with respect to that law, and what business opportunities does it present?*

Schlanger: Most people have never bought health insurance directly before, almost everybody got it through their employer. Now a significant amount of people have to shop for health insurance on their own, and that's a daunting task. And it's daunting for the health insurers because they're thinking, "I've got a bad favorability among consumers because for the last however many years, my relationship with my consumers has been that I'm the denier of care. People hate their health insurance. Now those companies have to be consumer marketers, and no one knows their brands, and if they do, they don't like them. So that's an advertising segment for our public piece of the business.

PE: *Transparency is another key element of the Affordable Care Act, even though the current administration, in many ways, hasn't been as open as voters expected. Is it risky to expect that people will share all of their information digitally, given the developments with the NSA, for one example?*

Schlanger: We're very, very sensitive to HIPPA security and privacy. WebMD has been an industry leader from the very beginning in setting standards and holding ourselves to the highest level. One of the reasons we're working with Qualcomm to enable device data to be onboarded into our [Healthy Target] app is that Qualcomm created a compliant way to take data from a glucometer, load it up into the cloud, and have the cloud send it to your device. HIPPA compliance is a guide for everything that we do; everything is architected in a way to make sure that the highest standards of privacy and security are maintained. That's not trivial, making sure that all those communications are private, secure, and in accordance with all the regulations under HIPAA. We have always believed in the importance of privacy, just like everyone who has come to trust WebMD and the programs we provide. PE

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POLAND: Unlocking Potential

We honestly feel like a member of the richest club of pharmaceutical countries," declares Igor Radziewicz-Winnicki, undersecretary of state at the country's Ministry of Health. Not only is Poland the largest pharmaceutical market in the Central & Eastern Europe region and the sixth largest in Europe (USD 8.1 billion in market value), it is also a hub for production and functional activities. With a GDP growth of 3 percent forecast by the OECD, and the first positive balance of trade in 2013 since its accession to the EU, there are also clear signs of economic momentum. However, Poland has some of the lowest prices of both innovative and generic drugs in Europe. At the same time, as cost containment measures keep the pressure on other European health authorities to reduce drug reimbursement expenditures, the Polish pharma industry is also struggling to deal with the pressure from its own 2012 Reimbursement Act while reasserting its positioning alongside the Big 5 Germany, France, Spain, Italy and the UK.

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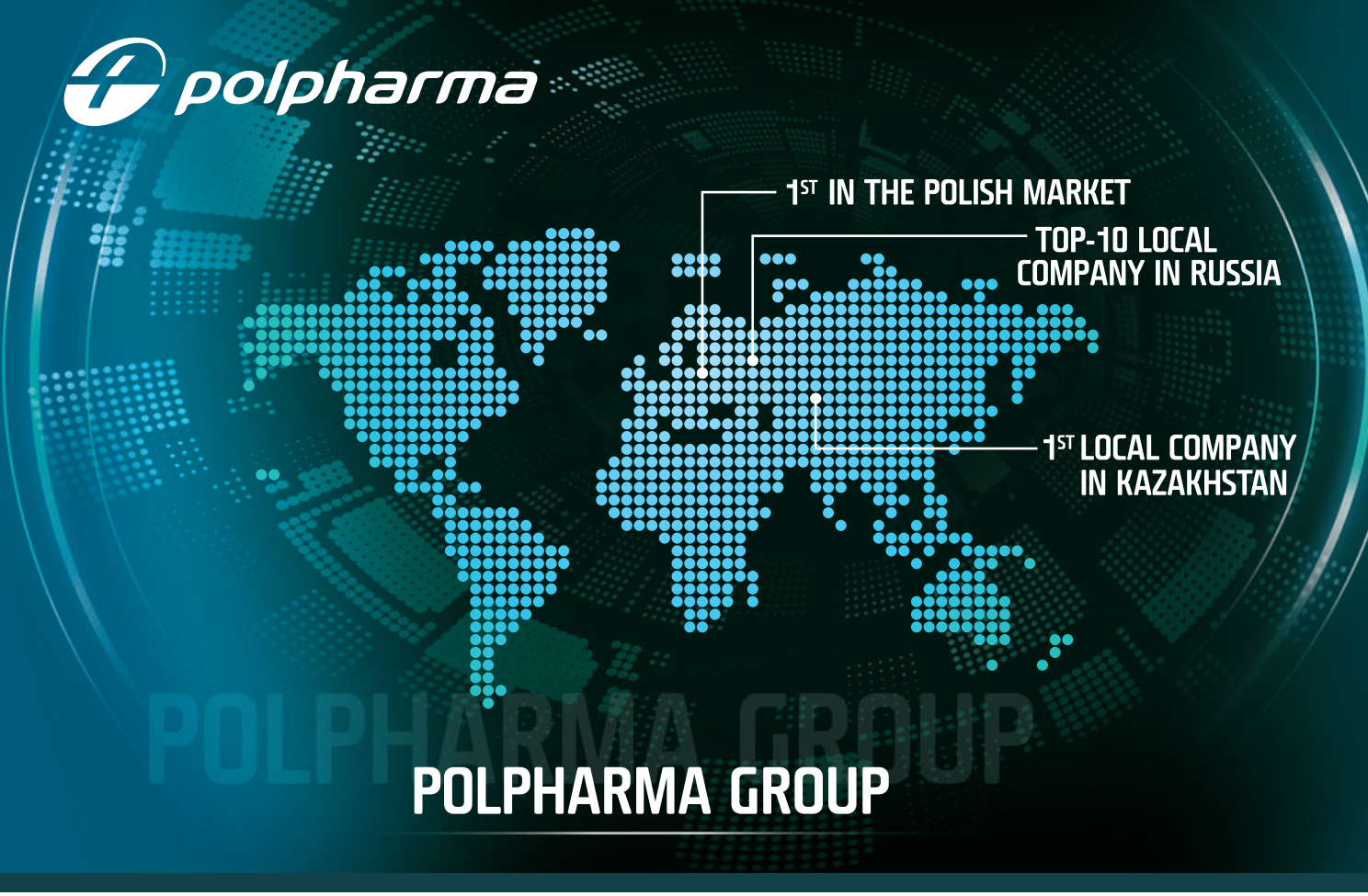

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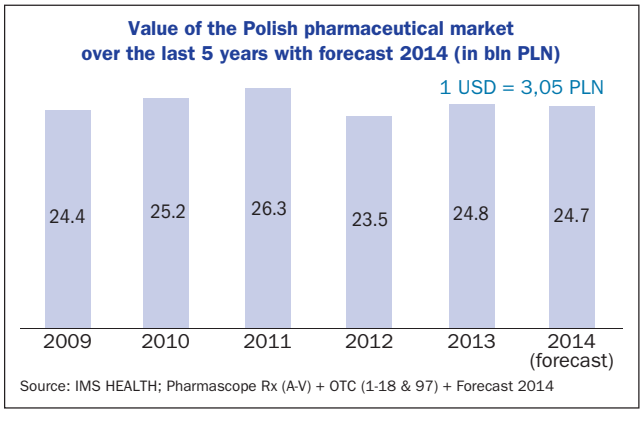
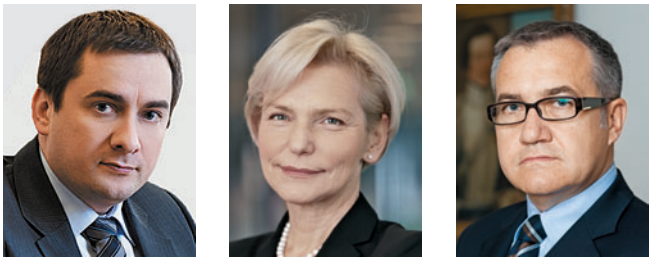
THE REIMBURSEMENT ACT: REVOLUTION OR EVOLUTION?

"Cost containment measures are not just a Polish story, but a European reality," says Marcin Hanczaruk, general manager at Amgen. "The Reimbursement Act is a real revolution, but it has brought both benefits and shortcomings. One consequence is that Poland has the lowest average price of medicine in the European Union," adds undersecretary Radziewicz-Winnicki. In fact, the price of innovative drugs in Poland is 59 percent below the EU average and 43 percent for generics. Poland has historically been a branded generics market and still remains today with 62.5 percent of Poland's market value and 88 percent in volume. "In 2008, the Ministry of Health predicted that by 2015 a gap would emerge between the cost of running the healthcare system and the contributions for health security," says PwC's healthcare sector leader for the CEE region Mariusz Ignatowicz. "In other words, for the first time, healthcare costs would be in excess of the National Healthcare Fund's resources." Poland's Ministry of Health decided to prepare for the future, with the aim of simultaneously improving healthcare access, and bringing more innovative drugs to the market. However, the result was very different indeed.



"With this new 2012 legislation, the situation for patients has deteriorated, as well as that of the industry, doctors, hospitals, pharmacies, distributors, and wholesalers," says Zdzislaw Sabillo, founder and CEO of PBA, a Polish consultancy. "At the same time, copayment has risen, from 36 percent to 40 percent today; but this is only for reimbursed products. However, the total copayment for the whole pharmaceutical sector is at 60 percent." PwC's Ignatowicz adds: "The natural question then is, if they saved this much money, shouldn't it be spent on innovative therapies or in the introduction of drugs that have been waiting years for reimbursement? Such reinvestment has happened to a very limited extent." Indeed, the state budget could earn as much as PLN 5 billion (USD 1.6 billion) by 2015 from the cuts, which has not been reinvested in introducing more innovative drugs.

"Despite the fact that the Polish environment has changed



From left: Igor Radziewicz-Winnicki, Under Secretary of State at the Ministry of Health; Marynika Woroszylska-Sapieha, General Manager, Sanofi Poland; Zdzislaw J. Sabillo, CEO, PBA Consultancy

significantly, access to innovation is still challenging," says Marynika Woroszylska-Sapieha, general manager at Sanofi and president of the board of INFARMA. "This is not because Poland cannot afford innovation but rather because there is no recognition of the value of innovation. INFARMA, the association representing innovative companies in Poland, has been acting since the beginning to change the perception of innovation."

The government is aware of this situation but has many other issues to resolve. "Our biggest priority is to counteract rising waiting lists. Polish society must overcome the burden of health inequality. We believe that a rationalization of health capacities, improved accessibility, availability and adequate health services are the tools needed to enhance the efficacy of our health system," remarks undersecretary Radziewicz-Winnicki. However, Michal Bichta, Merck's country manager in Poland, feels that there is still a long way to go before the industry and the health authorities are aligned. "I personally feel there is lack of long-term perspective in our discussions with health service authorities," he explains. "They are still very much driven by the here and now."

January 2012 Reimbursement Act – Main regulations

- Ceiling on reimbursement expenditure amounting to 17 percent of total public healthcare expenditure
- Fixed pharmacy and wholesaler margins on reimbursed drugs
- Fixed prices for reimbursed drugs
- Introduction of the pay back system
- Publication by the Ministry of Health of a new reimbursement list every two months
- Advertising ban on pharmacies and a ban on discounts relating to reimbursed drugs

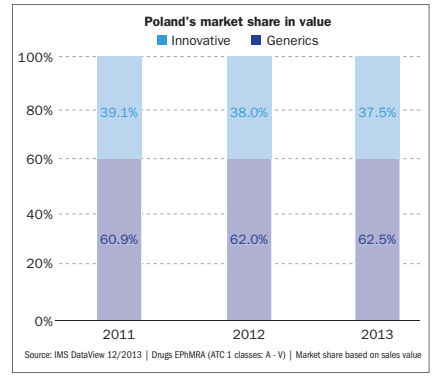
Although this dialogue is only a first step to bringing more innovation and more diversified care for patients, the road ahead is still winding. "In the end, real savings happen with a real revolution and it is not the one we are having right now," says PBA's Sabillo.

SURVIVAL OF THE FITTEST

With a declining Rx market and market access challenges, "companies have to develop new strategies and anticipate change to remain competitive," states IMS Poland's general manager Maciej Kuzmierkiewicz.

Some multinational companies have implemented a three-leg strategy in Poland that has proven to be successful. "Diversifying our business has been essential to our success in Poland," says Sanofi's Woroszylska-Sapieha. "Before 2010, OTC represented 12 percent of our turnover, whereas today consumer healthcare (CHC), which includes OTC, accounts to 20-21 percent. Given these results, last year we were the fastest growing CHC company in the Polish market with 16 percent growth." In such a dynamic environment, the healthy level of diversification that Merck has attained is a critical factor for sustainable growth. Merck has built its nearly 300-year history on diversification. "Merck's market share in OTC, biotech and off-patent products in Poland are well balanced, and we know we can rely on them to outperform," says Merck's Bichta. "We believe this three-pronged setup gives us stability and flexibility in the short-term, making us less dependent on the business environment." Mathieu Fitoussi, country manager of Servier Poland, comments: "We are mostly present in the reimbursed segment; thus we have to diversify; and in the near future, we believe that the prescription non-reimbursed and OTC segments represent the best opportunities."

From left: Michal Bichta, Country Manager, Merck Poland; Mathieu Fitoussi, Country Manager, Servier Poland

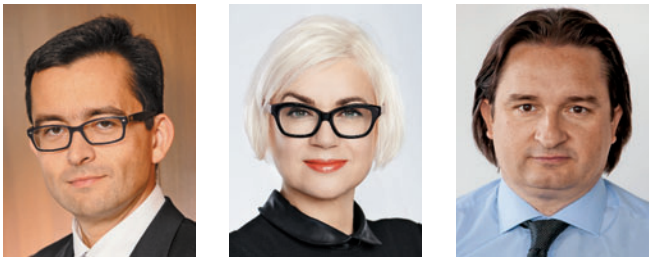


Even for multinational generics players, diversification has been a must. "Actavis is a fully active branded generic company focusing on cardiology, urology, CNS, oncology, hospital products,

and since the new Reimbursement Act was implemented, we also decided to move into OTC. Diversifying our business has been a great strategy, and even though OTC is still small, it is also our fastest growing segment at Actavis Poland today" says Izabela Zimmermann, general director at Actavis Poland.

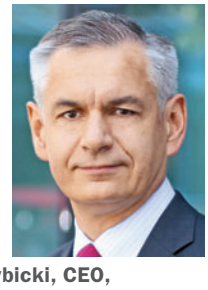
"We are therefore investing our resources and capabilities to increase our portfolio in this area. At the moment we have 250 SKUs on the market, 80 molecules and each of our business units manage between 30 to 40 SKUs. These numbers give us credibility and the assurance that great things are still to be accomplished in Poland," she adds.

Bristol-Myers Squibb has taken another approach; focusing on specialty care with biopharmaceutical cancer research and a new treatment in immuno-oncology. "The goal of immuno-oncology is to change survival expectations and the way patients live with cancer," says Piotr Marciniak, general manager of BMS Poland. Their first immuno-oncology molecule for the treatment of advanced melanoma was approved in March 2014. "In line with our specialty care BioPharma strategy, we aspire to continue delivering the greatest value to customers and patients, with the highest standards of scientific excellence, business ethics and integrity," he adds.



From left: Maciej Kuzmierkiewicz, General Manager, IMS Poland; Izabela Zimmermann, General Director and deputy CEO, Actavis Poland; Piotr Marciniak, Country Manager, BMS Poland

ON YOUR MARKS, GET SET, OTC!



From left: Andrzej Sybicki, CEO, Novascon; Ernest Bartosik, General Manager, Unipharm Poland

With an Rx segment under pressure from the Reimbursement Act, the OTC market was arguably the easiest and fastest option to obtain results. With a market value of PLN 8 billion (USD 2.6 billion), the OTC/dietary supplement market has been booming in Poland, with Aflofarm, USP Zdrowie and Polpharma the biggest market players. Self-medication rates in Poland are high, perhaps unsurprising given that one in every four TV advertisements is for drug promotion.

Novascon Pharmaceuticals and Unipharm are two of the fastest growing OTC companies in Poland with 37.8 percent and 28 percent of growth in 2013, close behind the leader Adamed with 39 percent (IMS data). Novascon is a Polish company, created in 2007 and specialized in the development and implementation of innovative dietary supplements and foods for specific medical purposes (FSMP). Andrzej Sybicki, founder and ceo comments: "We decided to focus on these two areas as it was the fastest way to develop and bring products to the market. With broad clinical trial availability in Poland and the possibility to choose

Best performing companies in 2013 sales growth - OTC segment	
ADAMED GROUP	39,0 %
NOVASCON PHARM	37,8 %
UNIPHARM	28,0 %
OLIMP LABS	24,3 %
OLEOFARM	23,1 %
SANOFI	22,3 %
SCHUELKE & MAYR	21,7 %
AXELLUS	20,2 %
PIERRE FABRE	15,5 %
BOIRON	13,1 %

Source: IMS HEALTH; Pharmascope Rx (A-V) + OTC (1-18 & 97) + Forecast 2014

NOVASCON PHARMACEUTICALS
HEALTH IS MOST IMPORTANT

Novascon Pharmaceuticals is the fastest growing company on the pharmacy market in Poland with about 60% of growth in IMS CMI RWM OTC, over own-developed 30 products in its portfolio and about 100 highly qualified specialists employed in divisions: marketing, sales, business development, regulatory affairs, administrations. **Novascon Pharmaceuticals** is in the TOP 5 of dietary supplementing companies. **Novascon Pharmaceuticals** is specializing in developing new products at attractive market areas.

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the best active ingredients, we were able to develop high quality products, and register them to sell them in pharmacies."

The competitive landscape has increased in this attractive market and finding the right approach is a must. "The OTC market, like other markets, has many entry barriers, and successful companies are the ones which provide new products and solutions and not copies of existing products," says Ernest Bartosik, general manager of Unipharm Poland. "To grasp these opportunities, it is key to master the marketing mix but above all understand the needs of consumers and doctors." Finding the appropriate niche and diversifying the portfolio has also been on the agenda of both companies. Novascon's Sybicki adds: "We are always looking for new opportunities and although dietary supplements and FSMP have a great deal of opportunities, being a real player in cosmetics and medical devices is our next challenge. At Novascon we look to develop any type of product that can be sold in pharmacies; this is our baseline."

POLISH GIANTS

Polpharma has been and still remains Poland's powerhouse and a role model for the domestic pharma sector. How-

Poland's giants

Polpharma Group	Adamed Group
♦ Established in 1936 (Poland) ♦ Privately held ♦ One billion dollar turnover ♦ 7000 employees worldwide ♦ Leader in the polish market with 13 percent market share in value. ♦ Representative offices in Lithuania, Ukraine, Belarus, Vietnam, Azerbaijan, Latvia, Bulgaria, Czech Republic, Armenia, Hungary, Georgia, and Uzbekistan. ♦ 38 percent of revenues come from international markets ♦ 600 products developed and 400 under development ♦ Presence in six continents and more than 50 countries (European producer of API)	♦ Established in 1986 (Poland) ♦ Privately held ♦ 250mn USD turnover ♦ More than 1500 employees worldwide ♦ Second largest local generic player in Poland ♦ Representative offices in Kazakhstan, Ukraine, Spain and Russia. ♦ Sells 250 products across 40 world markets ♦ 25 patents
Main objectives for the future: ♦ Further international expansion ♦ Become the fastest growing regional branded generics player	**Main objectives for the future:** ♦ Develop their own first in-house innovative drug in Poland ♦ Continue expanding internationally

ever, Poland's giant remains humble, and Rajmund I. Martyniuk, president of Polpharma Trade, still sees room for expansion: "Polpharma still has to develop its portfolio to meet current Polish healthcare needs, and this is why a few years ago we decided to invest in biotechnology and optimize our production network. Martyniuk also attributes the company's success in Poland to its "marketing and communication strategy, which has been tailor-made for doctors, nurses, pharmacies, distributors, payers, government and patients."

Rajmund I. Martyniuk, President of the Management Board & Polpharma Trade Office, Polpharma Group

But Polpharma is not only a Polish story and is rapidly growing its international footprint. "We decided to enter markets with similar healthcare systems and business models to Poland. The companies we have acquired in Poland in recent years already had strong connections with CEE and CIS markets, so this is a good starting point for us and we plan to capitalize on this heritage." says Martyniuk. Certainly, Polpharma has the capacity and resources to become better recognized internationally in the years to come.

MANUFACTURING – "I HAVE A DREAM"

"Poland has the means to become a recognized European hub and export platform," says Hendrik Venter, general manager at DHL Supply Chain. "Both local and international manufacturers are present and deliver the highest standards. We are seeing more pharmaceutical manufacturers looking at Poland as a regional hub for CEE rather than setting up individual CEE country warehouses. This allows them better inventory management, the ability to reduce working capital and to exercise better control over their supply chain."

From left: Jerzy Majchrzak, Director at the Department of Innovation and Industry; Hendrik Venter, General Manager, DHL Supply Chain

Of course Poland still has challenges to meet: "Polish infrastructure is still in need of significant development and investment, particularly in the road network," he adds. But there might be a new positive trigger as new investment (overall European Union budget 2014-2020 of EUR 144 billion – USD 195 billion) is arriving to solve infrastructural issues and help the Polish pharma industry and manufacturers blossom. "In the previous budget perspective we had spent a large sum of money, about EUR 10 billion (USD 13.6 million), on capital expenditures for machinery and infrastructure," explains Jerzy Majchrzak, general director at the department of Innovation and Industry under the Ministry of Economy. "This time, up to 80 percent of the budget will be invested in research subsidization. We will also be subsidizing up to 51 percent of the development and engineering of production and installation construction." He goes on to highlight Poland's advantages as a manufacturer: "Poland has significant manufacturing capabilities which, along with a highly skilled and experienced workforce, allow us to specialize in the manufacture of medicines. Polish companies are leading the way with international co-operation in the pharmaceutical industry. Among multinational pharmaceutical companies that have manufacturing facilities in several countries, including Poland, the Polish plants usually perform best in terms of quality, cost-reduction, environmental impact minimization and so on."

With EU accession in 2004, Poland's manufacturing standards have kept on rising, with the Main Pharmaceutical Inspectorate, Poland's supervisory authority, verifying the quality of medicinal products, starting with manufacturing, through to import, distribution and retail distribution in hospitals and pharmacies. "Ten years have passed since GMP was introduced into pharmaceutical law in Poland," says

Polpharma manufacturing plant

Anpharm, Servier production plant

From left: Zofia Ulz, Main Pharmaceutical Director; Dariusz Nowicki, Director, Polfarmed

Zofia Ulz, Poland's main pharmaceutical inspector. With over 200 manufacturers performing to the highest EU standards, plus qualified and affordable labor, Poland has a serious competitive advantage.

"The Polish market is dominated by generics in terms of volume," stresses Dariusz Nowicki, director at Polfarmed, the Polish Chamber of Pharmaceutical and Medical Equipment Industry. "This makes Poland the European leader in generic production – a position that will not change in the near future. Poland is prime real estate for drug production as we can sell high quality drugs at low prices. Our geographical location as a connection point between Eastern and Western Europe puts Polish companies in an opportune position to maximize the benefits of these international connections."

However, some see Poland's accession to the EU as a weak point for manufacturers in the long run. "What is worrying is that because of ever-stricter regulations targeting the pharmaceutical industry, costs are rising drastically to adapt to these new measures, but prices of drugs on the other hand are diminishing," states Cezary Sledziewski, executive director at PZPPF, the Polish Association of Pharma Industry Employers. "No one currently knows exactly how much these costs would represent but estimates indicate costs of EUR 48 million (USD 65 million) for Poland."

Nonetheless, large multinational companies that invested in Poland in the 1990s are still here with their state-of-the-art manufacturing facilities and functional hubs and continue investing to serve the Polish market and export internationally. This is the case for GSK, Sanofi, Novartis, Servier, Valeant, Teva, Mylan and Nycomed "98 percent of the drugs that we sell in Poland are manufactured in Anpharm, a production and manufacturing site close to Warsaw, in Bialolenka," explains Servier's Fitoussi. "Anpharm was the first production site in Poland to receive the European GMP certificate. The Anpharm site is evidence of our commitment to Poland and a clear sign that we are here for the long run." GSK's Toczyski comments: "We are very proud of the state-of-the-art, global manufacturing facility in Poznan. The Poznan facility houses manufacturing and a mas-

Poland: Bridging the gap with Western Europe?

"Having been a member of the European Union for ten years now, we are constantly decreasing the gap in terms of GDP per capita versus the EU average," says Piotr Marciniak, country manager of BMS Poland. "Now, it is time to bridge the gap in terms of investments in healthcare. Today, Polish patients continue to be diagnosed with cancer at later stages than in Western Europe and we all need to work together to change this."

While the country is becoming stronger economically and investing in infrastructure, the latest health reforms and high unmet medical needs are serious obstacles to bridging the gap with the big five European pharma markets. "With our current legislative framework it is highly unlikely we will ever bridge this gap," says PBA's Sabillo.

Indeed, the current legislative framework does not allow sufficient innovative drugs to enter the market, although 40 new drugs were recently introduced into the Polish reimbursement system, which were previously not available to Polish patients, according to undersecretary Radziewicz-Winnicki. "With this new law, the industry has managed to get more products reimbursed than before," confirms Amgen's Hanczaruk. But there are still serious barriers to the development of the Polish pharma industry, which reduces the country's chance to bridge the gap.

Currently, the government updates the reimbursement list every two months and companies have to go through a renewal process for all their innovative drugs every two years. Amgen's Hanczaruk states: "this year is especially important to us as we are going through the renewal process of our entire portfolio, with oncology and hematology as our two main therapeutic areas. Amgen Poland is focused on catching up with market access delays and making sure that our patients finally get first level reimbursement for Prolia, Vectibix, and get any type of reimbursement for Xgeva and Nplate." Bartosz Bednarz, general manager at AstraZeneca Poland, echoes much of the industry when he says: "Many of our products that are reimbursed in other countries have never been reimbursed here in Poland."

These are critical situations to address: Poland's pharma market is still only a third of the value of Spain's, the country's closest competitor in Europe. It will still take some time before the gap is bridged.

Locations of the major investments (production facilities and functional hubs) of pharma companies in Poland

Source: PWC, 2011

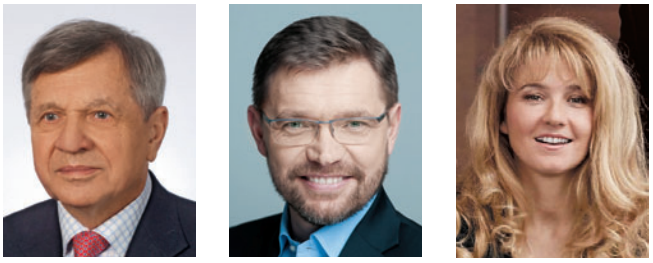
sive multimarket warehouse which serves northern Europe. This facility produces many of our innovative products, which sell to over a hundred markets around the globe."

PREPARING THE NEW POLAND

Poland has the means to work its way into the European spotlight with new encouraging possibilities in biotechnology, R&D and clinical trials. While Poland has shown impressive manufacturing momentum, it will have to develop these other areas to finally be recognized as a giant.

Director at the department of Innovation and Industry Majchrzak comments: "In recent times, we have seen the formation of a number of innovative pharmaceutical companies, including biotech and implants. These scientists have launched their startups, and now they are coming to the market. We have very high expectations for them." Indeed, some startups have blossomed in Poland and two great examples are Selvita and Mabion. "Local innovative companies such as Selvita have a significant role to play in Poland, and we believe that their entrepreneurial spirit, creativity and agility gives hope to the R&D segment in Poland," comments Merck's Bichta.

Indeed this a good start. However, "the very fact that a 200-people team is the largest drug discovery team in a country with a population of 40 million is not something to be proud of," remarks Paweł Przewięźlikowski, co-founder and CEO of Selvita, currently involved in several research projects at the preclinical stage and working in the area of oncology and central



From left: Cezary Sledziewski, Executive Director, PZPPF; Bartosz Bednarz, Country President, AstraZeneca Poland; Malgorzata Adamkiewicz, CEO, Adamed Group

nervous system. "Poland is still a sleeping giant, as we do not have a dozen companies like Selvita carrying out similar drug discovery programs. Poland needs to change if we want to operate on a more value-added level."

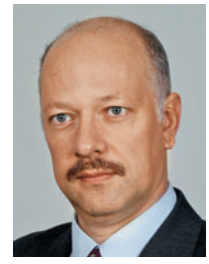
Poland should be able to attract foreign investors because of many advantageous conditions to operate. "Poland has been a good environment to start up because of low-cost labor and many scientists who have the knowledge and experience of working in labs," says Maciej Wieczorek, founder at Mabion, a Polish biotechnology company developing and implementing specialized latest generation biosimilars.

Poland has also shown promising signs in terms of clinical trials but according to Piotr Kolataj, senior director of clinical operations EMEA East Sub-Region, and country manager of Parexel Poland: "Countries like the Czech Republic, Hungary or Slovakia have a much higher number of clinical trials when calculated per capita. Poland has the potential to reach Hungarian or Czech proportions but we have to double or triple the number of clinical trials to reach this level of activity." However, "there is a great interest from pharma companies to enter the Polish market and to invest in clinical trials, especially within oncology and other chronic disease areas. I truly believe that Poland has the potential to develop the next generation of innovative drugs with international CROs offering consulting and clinical services to local clients," he adds.

The MNCs are paving the way in clinical trials and are not afraid to invest their resources in conducting them in Poland. "Our clinical center is our pride," says Bartosz Bednarz, general manager of AstraZeneca Poland. "Having this type of R&D investment in Poland is a real accomplishment."

Praise for Poland's clinical trial capabilities pours in from all sides: "BMS's clinical trials center in Poland can be considered an important hub as we are covering six countries in the CEE region, including Russia and Turkey," says BMS's Marciniak; "Today we can prove that we are one of the best centers, with one of the highest recruitment speeds of medical staff," says Sanofi's Woroszylska-Sapieha; "Poland for Amgen is the second country worldwide in terms of clinical trial recruitment, just behind the US," says Amgen's Hanczaruk; "our International Center for Therapeutic Research (ICTR) is a hub for Poland and the CEE region," adds Servier's Fitoussi.






From left: Paweł Przewięźlikowski, CEO, Selvita; Maciej Wieczorek, President of the Board, Mabion & Celon Pharma; Piotr Kolataj, Country Manager, Parexel Poland; Irena Rej, President, Farmacja Polska

Adamed, the country's second largest local pharmaceutical company, has high hopes that it will soon develop its first innovative drug; clinical trials will then be conducted: "our goal therefore is to prepare and secure our IP and investigational new drug (IND) program to give us the possibility to start the first phase of clinical trials," comments Adamed's CEO, Malgorzata Adamkiewicz. "The future of Poland lies in biotechnology, however costly, risky, long to develop and unpredictable its results may be" says PZPPF's Sledziewski.

Irena Rej has been at the head of Farmacja Polska, the Polish pharmacy sector's chamber of commerce, for over twenty years, and has seen the market evolve over the years. "This is how we are in Poland: pessimistic realists looking for optimism," and perhaps what Poland really needs is more optimism, because CEOs across the value chain have signaled the great opportunities Poland offers and that they are ready to take Poland to the next level with the support of the government.

"Our country is experiencing many changes in the healthcare system and there are still many unmet medical needs that need to be addressed," says Actavis's Zimmerman. "The industry is aware of this and all it needs is the support from the government to help introduce new products as early as possible to meet these needs. Patients should not have to wait to be cured, especially when companies have the right products in their pipeline and are awaiting government approval. However, we believe that better things are coming and this is encouraging."

However, PwC's Ignatowicz believes that the future is less certain than it might at first appear: "Poland is facing two years of permanent political pulls. Right now with the European parliament election, the municipal election in autumn, the presidential election next spring, and the following autumn the parliamentary election. Hence, healthcare will be very high on the political agenda, and in which direction the development will go is very hard to predict."

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Brand Reputation

Capturing the real value from a pharma spinout.

Examine the landscape of pharmaceutical companies and what do you see? A host of new brands—like Abbvie, TWI Pharmaceuticals, and Zoetis—emerging as strong forces in a competitive industry marked by a growing diversity of players. In fact, eight new brands that were spinouts over the last five years are now publically traded and account for $98 billion in shareholder value. These new brands are accelerating the pace of industry change. More important, as companies divest non-core assets in the form of spinouts to unlock value, the role of a strong new parent brand has become increasingly prominent.

This trend will only grow. We see the pharma spin market as poised to move into high gear. While some companies are pursuing merger opportunities, given the complexity of the pharmaceutical industry and the ongoing challenge from post-patent blockbuster revenue decline, most analysts believe that the new norm will be greater focus and that with this, spins will continue. In fact, in March, Baxter Pharmaceuticals joined the move and announced plans to spin out its biosciences business into a standalone company, with the aim of unlocking shareholder value.

Increasingly, pharmaceutical companies see the imperative to tap corporate brand value as a way to retain shareholder confidence. While this industry is often identified through product brands—the "Lipitors" and "Nexiums"—creating real meaning in the company itself holds growing importance.

Why the corporate brand creates value

Customers need a deeper understanding of what the company stands for: When a spin or rebranding takes place, customers want to know that the new brand will preserve the integrity and reputation of the same products, services, and people they are familiar with and have thus come to trust. In today's transparent business environment, understanding what the company is about is critical to bolstering the value of the product—what are the company's values, where is the momentum behind its promises, and, most importantly, what are its intentions for keeping its customers?

Looking outside the pharmaceutical industry, the 2011 spinoff of ITT's water division into a new brand, Xylem, provides an excellent example of a company that's delivering a compelling story about relevant corporate brand meaning. Xylem's tagline, "Let's solve water," sends a very clear and inspiration message about the company's focus on tackling the world's most challenging water problems and how that differentiates from its legacy parent, ITT. It portrays a corporation with the optimism, energy, and focus to be at the vanguard of the big challenges. It rallies the team and gives confidence to customers. And it creates results: Xylem is already a winner in the market, outperforming the Clean Tech indices by almost 10%.

A publicly visible promise of who the company is, backed by real proof points, raises the stakes on performance—those companies courageous enough to make one, under today's media spotlight, send a powerful signal about what they intend to be and deliver.

Increasingly, pharmaceutical companies see the imperative to tap corporate brand value as a way to retain shareholder confidence.

Inside, companies need to win the talent war with current and potential employees: Talent markets have changed forever. Not only are employees less loyal than they were a decade ago, but the information a job hunter can discover about a company has grown exponentially. With hundreds of millions of people using LinkedIn and putting their employer name right next to their picture on Facebook, people are "badged" with their employer's brand like never before. More visible than ever in our social and professional spheres, a company and what it stands for can be as important a public signal of who we are as the car in our driveway.

The need for a corporate brand that connects with em-

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ployees is accentuated in a spinout. Employees who are a part of a spin must face trepidation and uncertainty as they confront the prospect of leaving a strong, stable, and well-known parent brand. This makes employee retention a challenge. Added to this is the need to attract the best research and clinical talent from established pharmaceutical competitors and the importance of creating a corporate brand that connects with employees and recruits is clear.

With investors, a compelling brand story can drive the multiple: In the case of a spinout, a powerful corporate brand will send clear signals to an investor base that's increasingly diverse, and with the power to act instaneously: just one click of the mouse can finalize a $4 trade. For institutional investors searching an increasingly global playing field for the best investment story, a clear corporate brand direction and set of guideposts is an important signifier of attraction. New brands that have invested in a clear growth story get extra credit by garnering P/E ratios in the high teens to low twenties.

Doing it right—A case study example, Zoetis

Zoetis, the new company created when Pfizer spun out its Animal Health business in 2014, provides a case study example of the power of a corporate brand. Its 2013 IPO was the largest since Facebook and third largest of that year, generating strong demand in the market and raising more than $2.2 billion, with an initial market cap of $13 billion. In 2014, the company's branding and communications work was broadly recognized.

How has the new Zoetis used its corporate brand to drive success?

Telling the bigger story: The Zoetis story is not solely about what the new company sells. As a new brand, Zoetis tells a much bigger story—about what the company believes and the role it plays in society. It pushes beyond products and services and describes the critical role of Zoetis in ensuring the health of animals and why this matters —from keeping animals healthy to provide comfort and companionship as well as helping to efficiently create safe, high quality protein to feed the world's growing population

This story is crafted to meet the needs of different audiences, from the livestock farmer and veterinarian who want to partner with a leading animal health company to grow their business, to the Wall Street trader who needs to better understand the attractiveness of the animal health market with a vertical that is outpacing human health.

Delivering a branded experience: While a story is important, it's virtually impossible to lean on messaging alone to build a brand. Experience is critical to support the story and it is this that is often of the greatest concern to current customers and employees. In the case of Zoetis, the company's on-the-ground presence through its network of field representatives and technical specialists is central to its brand's differentiation from the competition. As a new company, it was critical to continue to invest in and support this broad-based network to allow Zoetis to react quickly to local-market needs and be well positioned to help customers increase their business productivity. Since the spinout, not only has Zoetis continued to tell the story of the reach of their team; it has also invested in building out this network. Through this network, Zoetis is able to market its products and to provide value-added services that make its field force feel less like a vendor and more like consultants that help to drive the productivity of their customers' businesses.

Appealing to the team's passion: Employees are the face of the new brand and need to believe in its purpose. Employees must be the ones empowered to bring that purpose to life. In the case of Zoetis, the company's leadership team partnered in the development of a common purpose that focuses on "building partnerships for results that matter" along with a set of six core beliefs that were central in the internal launch of the new company. Together, the idea of "delivering results that matter"—caring for the health of animals to create companionship for humans and ensuring a safe food supply for the world—along with the core beliefs help to motivate employees by demonstrating the link between results and their individual daily actions.

Investing enough: While there may be a tendency to invest heavily at the launch of the new brand and then to scale back, this is a pitfall that should be avoided. Since the launch of Zoetis, the company has continued to invest in the corporate brand, expanding the corporate communications team to better promote the brand externally and initiating partnerships. The latter includes a high-profile sponsorship with the Smithsonian, a nationwide traveling exhibit called "Animal Connections: Our Journey Together." The brand investment goes beyond mere advertising—spanning every touch point, from how the new brand comes to life in workspaces around the world to the detail aids field reps use with customers to traditional publications and activities such as the annual review and annual meeting—all of which are under watchful eye of the brand team.

Keeping the corporate brand at the forefront: As the pharmaceutical industry continues to push for greater specialization and as new brands are created to unlock value, the importance of the corporate brand should not be overlooked. The corporate brand is a powerful asset that can be used to drive loyalty across customers, investors, and employees and win points with potential customers, investors, and recruits. Building a strong corporate brand requires companies to deliver an engaging story, to support the story with a branded experience, to engage employees, and support the brand as a strategic investment in future growth. PE

FDA Abroad

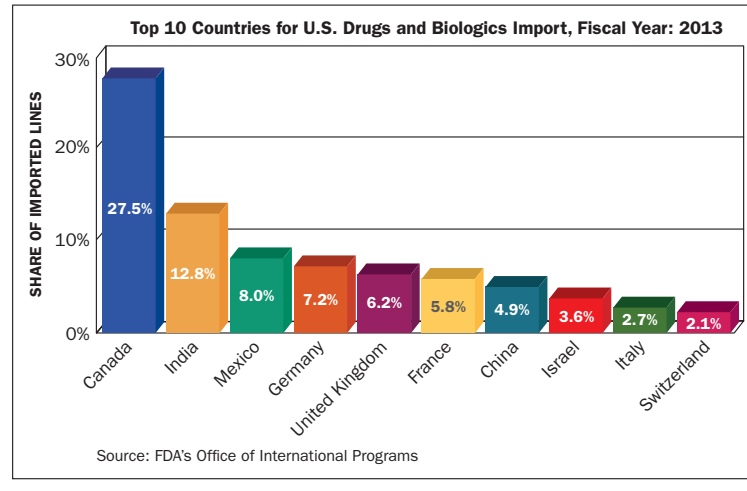
Is FDA capable of sufficiently overseeing global drug imports?

In 2008, FDA sent its first inspectors to live and work full time in global markets, where active pharmaceutical ingredients (API)—and finished drug products—to be used by US patients, are increasingly being manufactured and exported.

That project has since expanded to 11 international offices, but the current level of permanent staffing in some regions in unbelievably, if not terrifyingly small: between 2008 and 2013, just one policy analyst and one inspector worked full time in China, for example, although that number has grown to 11 locally-based drug investigators in 2014, said Christopher Hickey, director at FDA's China office, at DIA's annual meeting last month. Given the fact that China exported $3.25 billion in API to the US last year, up from $410 million 15 years ago, it's in some ways surprising that American patients haven't endured other large-scale adulterations along the lines of the Heparin debacle, which killed 80 people in 2008.

In India, America's second largest global source of API and finished drug products, some 1,965 manufacturing facilities export to the US, but only around 600 sites are registered with CDER, said Atul Agrawal, supervisory consumer safety officer at FDA's India office. Drug manufacturing capability in India doubled to represent 12% of total US drug imports in 2012, up from 6% in 2008. "India is a major player in the prescription drugs Americans take on a daily basis," said Agrawal, much to the envy of Chinese nationals everywhere. And yet, FDA's operation in India currently consists of five full-time Americans, and two locally employed staffers, spread across two offices, one in New Delhi and one in Mumbai.

Challenges remain: reporting structures within foreign governments can be labyrinthine, inspection protocols vary, training is expensive, and economically-motivated adulteration of products, and records, is still in play. In many places, said Michael Rogers, regional director of FDA's Latin America office, additional governmental clearance requirements block out FDA personnel entirely: "We have no information or inspectors" in these places, which means FDA "must partner," or simply hope, blindly, that any problems get sorted stateside, before they end up in a pill bottle or an injection.



Source: FDA's Office of International Programs

As a result, FDA officials in China, India, Latin America, and elsewhere are working tirelessly to form partnerships with "competent authorities" in local governments, to extend the reach of manufacturing inspections. Progress is being made, and the 2012 passage of The Food and Drug Administration Safety and Innovation Act contained critical provisions designed to improve the integrity of imported drugs sold in the US, FDA speakers said. In May 2014, FDA announced the Mutual Reliance Initiative, in cooperation with the European Commission (EC) and the European Medicines Agency (EMA), which aims to deepen the information exchange between inspectors to promote higher quality exports and better manufacturing practices.

FDA officials willing to relocate, often with their families, to far-flung global cities (on modest salaries) ought to be congratulated for their herculean efforts to protect American patients. Patients themselves, particularly those who vote for politicians running on platforms touting lower taxes, economic globalization, and funding cuts to government agencies, ought to be careful who they blame when the next round of adulterated medicine shows up in a loved one's medicine cabinet. PE

Ben Comer is *Pharm Exec*'s Senior Editor. He can be reached at bcomer@advanstar.com.

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