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Pharmaceutical Executive

AUGUST 2013
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VOLUME 33, NUMBER 8
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New CEO Flemming Ornskov's simple strategy for success

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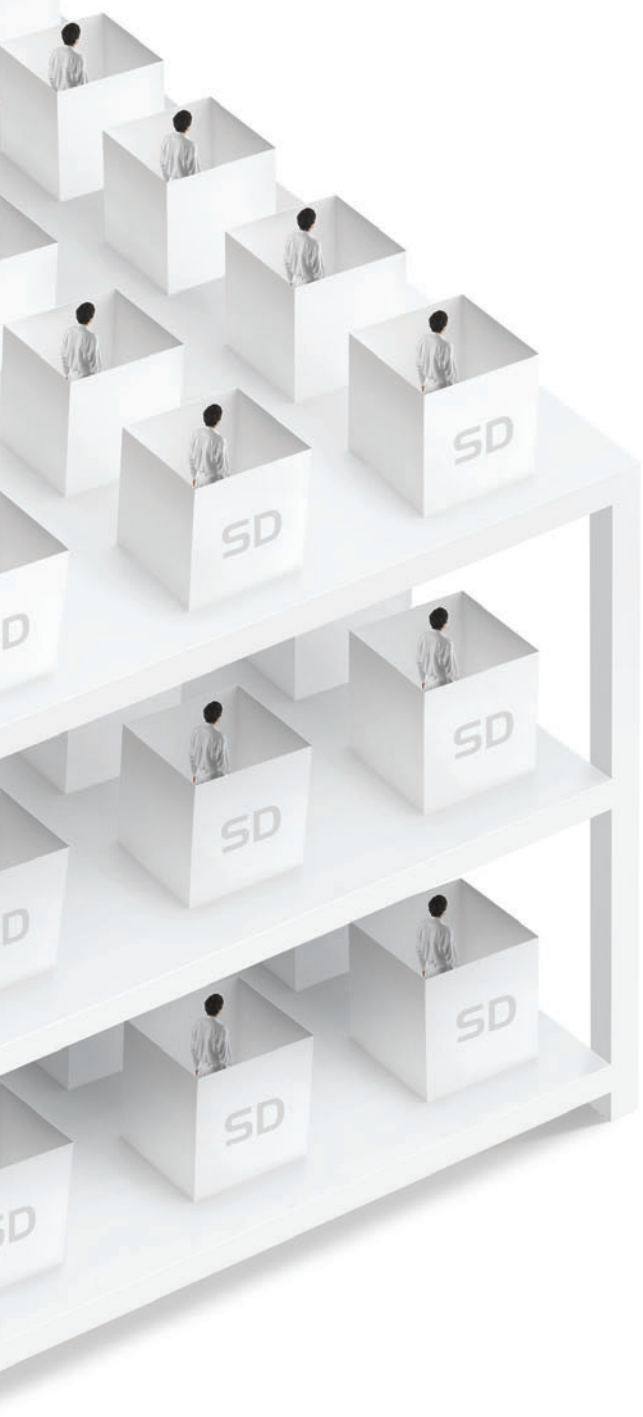

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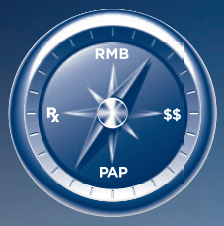

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Jayson Slotnik, *VP, Reimbursement Strategy & Innovation*
Using Technology to Expedite Appropriate Access

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Imbedding Patient Access Services in a Specialty Pharmacy

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William Looney, Editor-in-Chief

New CEO Flemming Ornskov has a simple strategy for his company's continued success: ***Set*** the industry pace on specialty medicines, ***Spread*** the positive buzz and momentum of a growth stock, and ***Seize*** the opportunity to innovate—from sources in-house and outside.

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The Case for Content

Peter Houston, FlippingPages

Reaching skittish consumers through objective, story-driven information is digital marketing's hottest digit, and the numbers around engagement are impressive. But applying this consumer phenomenon in Big Pharma presents some unique challenges, best expressed by the need to test that delicate balance between sharing experiences and the controlled pitch.

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Emerging Markets

New Rules for a New Africa

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Declining revenue growth in the United States and Europe have sent pharmaceutical companies in search of opportunities in the emerging economies of Latin America, the Middle East, and Asia. Now, as growth in these high-flying regions begins to stabilize, companies are finally turning their attention to Africa—a hidden trove of potential that is only as good as you make it.

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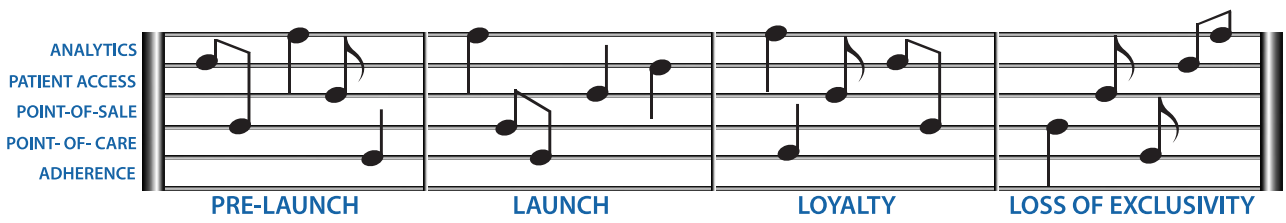

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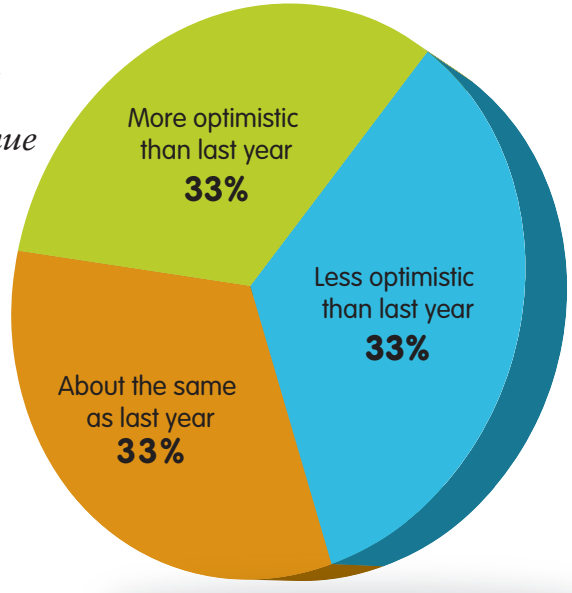
Data Point

Poll data courtesy of online *Pharm Exec* readers between June 24, 2013 and July 17, 2013

Q: How optimistic are you for revenue growth in 2013?



Readers Weigh In

In many cases, co-pay is as bad as no-pay for many people with restricted incomes. Do I eat and keep warm today or take my drugs as prescribed—perhaps I should take half the dose to make the prescription last longer? These are horrible choices to have to make.

Richard Phillips, 7/18/13
"Filling the Rx Gap: Cost Solutions at the Point of Sale"
http://bit.ly/13FSGPk

I agree with the premise that adherence should be a policy issue. However, policy can be molded by both push and pull. To that end, I also believe that adherence is driven by patient education—an area where pharma can play a big part by providing information about the disease, and the benefits and risks of adherence and nonadherence.

Jack Florio, 7/11/13
"Why Patient Adherence is a Policy Issue'"
http://bit.ly/149si9G

Social media can support and add to the meetings experience but the power of face to face cannot be replaced.

Katie Devaney, 7/02/13
"Why Social Media Won't Replace Pharma Meetings"
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Industry Audit

For *PE*'s 12th Annual Industry Audit, Bill Trombetta deploys his custom algorithims to assess the health and merits of pharma's top players.

One Company—One Moment

BEING AN OBSERVER RATHER THAN A PARTICIPANT IN THE DRUGS BUSINESS makes it easier to sense those defining moments when something fundamental has changed, a limit is reached, and a new order emerges to reset the basic license to operate. As *Pharm Exec* goes to press, one such moment appears to have arrived, with the trade media ablaze with lurid accounts of bribery, tax fraud, and other illicit promotional activities in China—ironically, the country touted as guarantor of our industry's future. Equally significant is that the chief target of the Chinese government's assault on corruption in the medicines trade is GlaxoSmithKline (GSK), a favorite of the NGO community and a company well known for positioning itself above the grubby fold of its Big Pharma counterparts.

Those commanding heights around CSR don't look so high right now. Investigation does not automatically incur guilt, but reputation takes a hit when any government—let alone that which manages what is emerging as the world's largest single-payer healthcare system—references you as "a criminal organization." Indeed, GSK appears to have missed numerous signals that the Chinese government was moving to adopt its own zero-tolerance stance on what our industry obliquely calls "transaction costs." Not only was rooting out business corruption a key platform of the recent 18th Communist Party Congress, it is the governing theme of the country's new leadership. It has only to remind the industry of its special place in the local league rankings on capital punishment: the first head of China's FDA, Zheng Xiaoyu, was executed in 2007 for administering his own "pay to play" scheme.

In addition, the magnitude of health system reforms to make China's 1.3 billion citizens eligible for basic health coverage by 2020 effectively requires a huge transfer of income from physician and hospital "profit seeking"—activity that implicitly depends on keeping prices of branded (i.e., foreign) drugs high. GSK's reported mea culpa to prosecutors—to cut prices of its portfolio of drugs in China—puts it on the right side of the central government in terms of reform. But until government finds a solution to compensate and replace the income lost to its key healthcare institutions from the private sale of medicines, the basic economic incentive for graft will continue.

What this means is that Big Pharma has no option other than to unilaterally change its game—and take the hit by lowering expectations on future revenue growth in China and other emerging markets. You can call it leading from behind—by being up front.

A crucial first step is to plug the organizational disconnects that plague all large drug companies. In a recent interview with *Pharm Exec,* former Schering-Plough CEO Fred Hassan said the most important staffing decisions he made were for the country managers in key ex-US markets. He vetted each and retained open channels even when these positions did not report directly to him. It does appear that companies where China management is answerable only to the CEO encounter less of the "field rogue" phenomenon. Another factor that deadens awareness of realities in the field are company cultures that reinforce silo's and negative attitudes between sales staff and management: while the latter is decisive and strategic, the former is often perceived as conformist—and an albatross.

A second, related element is the anticipation of risks through internal controls. "Accountability for relationships with third parties is critical; these need to be 'owned' by an individual, so when that individual moves on, each relationship is reassessed by higher management," says Michael Vermillion, Senior Director at Navex Global, an ethics and compliance service and software provider. He notes that China's Ministry of Public Security has charged GSK with transferring nearly $500 million in suspicious payments through travel agencies, running as far back as 2007. "Not only should business partners be categorized based on potential risk for corrupt behavior—travel agencies are covered under money laundering provisions of the US Patriot Act—but the estimated size and timing of payments should be part of the internal approval process, so these can be constantly tracked and evaluated compared to what was approved."

The scope and duration of GSK's supposed illicit activity suggest these basic elements of an active compliance culture may not have been in place, at least in GSK China. This also raises concerns about an activity that GSK does endorse—metrics of good corporate citizenship. The company consistently scores at the top of the NGO Access to Medicines Index, which requires evidence of "proactivity in fighting corruption, including the extension of ethical marketing practices to all sales agents, local distributors, and contractors." The rub is don't expect any public flogging of GSK from here—the relationship with NGOs is flawed, because it is mutually reinforcing.

What all this discussion says to me is this: if that proverbial defining moment is at hand, then the initiative has to be seized—from the top, and simply because it is the right thing to do. We are at the point where good governance in pharma should be the competitive differentiator of success anywhere, but especially in emerging markets.

William Looney is *Pharm Exec*'s Editor-in-Chief. He can be reached at wlooney@advanstar.com and on Twitter @BillPharmExec.

Understanding the Oncology Market

LIVE WEBINAR: Wednesday, August 28 at 11:00 am EDT

REGISTER FREE: http://www.pharmexec.com/Oncology

EVENT OVERVIEW:

Increasing complexity in the oncology segment, driven by new reimbursement requirements and limited access to oncologists, makes it a difficult market to fully understand. The use of market data can provide valuable insight into market trends, but many factors must be considered when accessing, analyzing and interpreting data. During this presentation, we will examine how product utilization and reimbursement data can bring tremendous value across the oncology product lifecycle from research and development, to product launch and market uptake, to optimizing engagement with providers.

Specifically, we will discuss:

- Key trends affecting the oncology market place
- The growing needs and applications for market data
- Key characteristics of market data

Key Learning Objectives:

- Understand key trends affecting the oncology market
- Understand how to gain a deeper market understanding
- Understand traditional and new applications of market data
- Understand what to look for when selecting data sources

Who Should Attend:

- Any professionals (ie: brand managers, market research analysts or managers, etc…) from pharmaceutical and biotech companies interested in learning more about market intelligence within the oncology field.

Presenters

Heather Morel
Vice president & General Manager of Informatics | Reimbursement, Access and Safety Services (RA&SS)
McKesson Specialty Health

Moderator

Benjamin Comer
Senior Editor
Pharmaceutical Executive

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

Costs and Coverage Challenge Medicare Drug Plans

Rate cuts and fraud concerns create problems for Part D plans and Part B providers.

Medicare Part D either is the most effective recent government health program—providing low-cost access to important medicines for 37 million seniors—or a program open to abuse and uncontrolled costs that has to be reined in. As the Obama administration struggles to roll out its landmark health reform initiative this fall, analysts are looking at Part D as a model for marketing private plans to millions of consumers, as well as a cautionary example of what can go wrong.

Those who orchestrated the Part D launch in 2006 recall widespread fears that insurers would shy away and that beneficiaries would not sign up. Democrats were furious that Republicans had pushed through a market-based program and predicted dire results. Despite initial glitches in computer systems and pharmacy operations, the program is a clear success and has cost the government and beneficiaries much less than originally estimated. The savings result partly from fewer people signing up than anticipated, plus a broad drop in drug costs as fewer new therapies came to market and generic prescribing took off. But competitive plans also deserve credit for promoting generics and for negotiating low prices from manufacturers.

Costs and coverage

Now intense federal budget cutting is prompting closer scrutiny of Medicare outlays for drugs, which total about $70 billion a year for some 1 billion prescriptions. Pharma companies are concerned that plan sponsors are limiting coverage to reduce outlays, as seen in a study by Avalere Health for drugmaker UCB documenting that Medicare plans cover fewer anticonvulsant drugs and impose higher cost-sharing than commercial insurers.

Critics, however, are demanding stronger management of pharmacy benefits to prevent inappropriate prescribing of antipsychotics and other drugs, as described in a May report from Pro Publica (see *Pharm Exec*, "Washington Report," June 2013]. The public interest health researchers also have documented a link between high Medicare physician prescribing and the fees they get from pharma marketers.

Similar issues were raised in a June report from the HHS Office of the Inspector General (OIG) documenting millions in drug program overpayments, underpayments, and undocumented expenditures by Medicare drug programs, largely related to the opioid abuse epidemic and associated fraud and waste. The report uncovered more than 700 doctors with "questionable Medicare Part D prescribing patterns" in 2009, in line with earlier OIG reports documenting inappropriate Part D refills, claims with invalid prescriber identifiers, and questionable billing by retail pharmacies. The Senate Committee on Homeland Security and Governmental Affairs examined these issues at a June hearing where OIG officials further described fraudulent Medicare outlays for prescription painkillers, as well as extensive prescribing by unauthorized practitioners such as massage therapists and home care contractors. Officials from the Centers for Medicare and Medicaid Services (CMS) said they were addressing these problems, but Congress may seek further remedies: Rep. Frank Pallone (D-NJ) has proposed legislation requiring Part D sponsors to verify that an authorized physician issued

Medicare spends about $20 billion a year on drugs administered by doctors, but that could soar with approval of more high-priced therapies for cancer and other critical diseases.

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

the prescription for a controlled substance and to restrict access to opioids for patients showing signs of abuse.

The Senate Special Committee on Aging, moreover, is examining Part D marketing and has asked the Government Accountability Office (GAO) to examine how well plan sponsors provide accurate pricing and coverage details to seniors. Aging Committee chairman Bill Nelson (D-FL.), along with most Democrats, continues to press for pharma companies to pay Medicaid rebates on medicines provided to low income "dual eligible" Medicare beneficiaries, who now receive drug benefits under Part D. Such targeted rebates, according to Congressional Budget Office (CBO) analysts, would cut spending by some $140 billion over 10 years, but probably lead to higher prices on new drugs overall.

Fixing Part B

Medicare spends about $20 billion a year on drugs administered by doctors, but that could soar with approval of more high-priced therapies for cancer and other critical diseases. Fears of unsustainable program costs thus is focusing policy makers on use of particularly high-cost therapies to treat cancer, autoimmune disorders, and chronic kidney disease, such as the 55 high-volume therapies that account for most Part B spending, as documented in another GAO report.

This finding was discussed at a June hearing by the House Energy & Commerce Health subcommittee, along with proposals to fix some of the anomalies in the Part B drug reimbursement formula, now set at 106 percent of average sales price. Physicians complained about losses due to the practice of including prompt pay discounts in rate calculations, plus the half-year lag for CMS to update prices, which leaves providers holding the bag for months. The current sequestration process, with its 2 percent across-the-board cut in Medicare funding, has generated ever louder protests from oncologists, who claim they're losing so much money that they will have to send more patients to hospital clinics for treatment. And that's much more costly for Medicare and often more difficult for patients.

Separately, CMS has proposed to slash reimbursement for kidney dialysis centers by 9.4 percent next year. That means a 12 percent cut in rates for Epogen and other drugs administered as part of kidney dialysis treatment. These reductions come on top of the 2 percent sequester reduction, plus the prospect of additional adjustments in CMS' base payment for these drugs to reflect lower recommended dosages.

Most damaging for pharma, though, is CMS denial of coverage for a new therapy altogether. Eli Lilly was rocked last month by a CMS draft proposal to authorize only coverage with evidence development (CED) for Lilly's Alzheimer screening product Amyvid. That means providing the PET imaging drug only to Medicare beneficiaries who enroll in clinical trials designed to produce more evidence that this type of diagnostic screening is worth the money. Lilly and Alzheimer patient groups are lobbying hard for CMS to be more generous in its final reimbursement decision this fall, warning that restricting coverage could "stifle future innovation aimed at improving diagnosis" of this serious condition. PE

Offsetting Drug Costs

An optimistic note in the drug reimbursement debate is a growing acceptance of the long-held pharma claim that increased use of medicines will reduce other medical costs. A CBO report issued in November 2012 supports changing methods for calculating the cost of prescription drug coverage to reflect drug offset evidence. A number of academic researchers have documented such findings, and newer, more effective medicines promise to yield even greater offset savings. CBO analysts recently acknowledged that the examination of new policies that might affect overall drug use now also evaluate the potential offset effect on spending for medical services.

Such analysis could support policies requiring Medicare drug plans to expand payment for medicines in the Part D "coverage gap" and also reduce the 10-year projected cost of closing the coverage gap. CMS acknowledged the drug offset somewhat in clarifying its policy under health reform for covering contraception as an essential health benefit required for all health plans. In final rules issued in June, the agency explained that insurers will have to pay for contraception for women obtaining health coverage through exempt religious employers, but that contraception services will be "cost neutral" for health plans due to offsetting savings from reduced maternity benefits.

Pharma Bids for European Funding in New Research Program

The €70 billion budget is still subject to final agreement on the European Union's overall spending plans for 2014-2020.

The ink is not yet dry on the European Union's Horizon 2020 agreement to invest some €70 billion ($92 billion) in research over the next seven years, and already contenders for funding are jostling for attention as they prepare their bids. Some of the sharpest elbows are wielded by pharmaceutical organizations, because a large portion of the budget is reserved for life sciences, and the biggest share of that is likely to go to the fittest and fastest in the fray.

Europe's biggest drug industry association, the European Federation of Pharmaceutical Industries and Associations, scored something of a coup by having breakfast with the president of the European Commission on the very day that the program proposal was agreed in mid-July. EFPIA has won support from the commission (and possibly €1.5 billion) for a new and improved version of the Innovative Medicines Initiative (IMI), its public-private partnership with the European Union on early-stage collaborative research. At a special launch ceremony on the upper floors of the commission's headquarters in Brussels, Joe Jimenez, CEO of Novartis and vice-president of EFPIA, announced that industry would match this with €1.5 billion in cash and kind.

Others have moved almost as swiftly to press their case for funding. Before July was out, the European Alliance for Personalized Medicine had announced a major conference in the European Parliament in Strasbourg on "Horizon 2020 and the Future of European Research," amounting to a naked pitch for support for this coalition's ambitions to develop the right treatment for the right patient at the right time. Its members—industry, academics and patient groups—also favor public/private collaborations as "a necessary condition to succeed where individual stakeholders' efforts have failed or were delayed."

EFPIA scored something of a coup by having breakfast with the president of the European Commission on the very day that the program proposal was agreed.

A markedly different approach to utilizing the life sciences budget is being advocated by civil society organizations that are less interested in industry success and, they claim, more interested in patients. Arguing for wider access to medicines, the European Public Health Alliance and its partners, who include Doctors of the World and Health Action International—Europe, are calling for research and innovation that is "needs-driven" and "based on social criteria." The objective, they say, should be "affordable access to R&D outcomes" that can "bring medicines prices down." This is central, they argue, to providing an adequate response to the "dreadful situation faced by millions in Europe regarding access to medicines and the dire health outcomes that result."

Reaching agreement on Horizon 2020 had been one of the priorities that the Irish government had set for its six-month stint in the chair of the European Union in the first half of this year. "It will boost innovation, jobs, and growth," said Ireland's research minister, Sean Sherlock, as he emerged triumphant from the round of talks that clinched the deal. Until the last minute, and through six months of laborious negotiations, questions remained over the size, scope, and emphasis of the program, caught in crossfire from national governments, political parties, and diverse lobbies from science, industry, and consumer and environmental organizations. At the end of 2012, the program looked as if it might be shredded as

Reflector is *Pharm Exec*'s anonymous columnist, a commentator so close to the action in Europe his identity must be kept secret.

the austerity-hit European Union battled over cuts in its long-term budget. But the bulk of the funding was ring-fenced, after urgent pleas from Nobel prizewinners, and industry groupings across Europe representing everything from steelmakers to aviation.

The European Parliament also fought to maintain the integrity of the program against member state penny-pinching, and to champion the role of smaller researchers too. As the agreement was initialled, Christian Ehler, the center-right German politician who piloted many of the Parliament's debates on the plans, praised the deal, and congratulated himself on winning "a new bottom-up mechanism that will allow for small innovative projects to be funded at any time." His Portuguese colleague, Maria da Graça Carvalho, also closely involved in the Parliament's debates, claimed responsibility for "measures aimed at increasing participation by small research groups and smaller firms." But Swedish liberal Kent Johansson greeted the opportunities for innovative smaller firms as a victory for his political group. And so did the chair of the Parliament's research committee, Italian Amalia Sartori. Even then, not all the Parliament's aspirations were satisfied. Belgian Green politician Philippe Lamberts described it as "a timid agreement" that "lacks ambition."

In the program's final form, the funding will be split across three strands. More than a third will go to a segment termed "Excellent Science," which will finance pure research, vital infrastructures, and future and emerging technologies. A second component—"Societal challenges"—will receive a similar amount, and focus on what are billed as "areas of most concern to citizens and business." This segment also offers possibilities for funding research into health— particularly in healthy living and active aging— alongside support for research in climate, food, security, transport, and energy. A third strand—"Industrial Leadership," with about a quarter of the total funding—will back selected industrial technologies, notably nanotechnologies, biotechnologies, and ICT, and will offer particular support to smaller firms.

The research-based drug industry is particularly optimistic about the prospects of Horizon 2020. It believes it can use the program as a vehicle not only for advancing medicines research, but also for gaining broader recognition for the industrial imperatives that lie behind its research activities. IMI-2 will have a focus that goes wider than merely therapy-related categories, or related areas such as biomarker research, innovative clinical trial design, or patient-tailored adherence programs; one of its major ambitions is to bring academia and regulators more closely into the picture, too. EFPIA director general Richard Bergström underlines the attention that Horizon 2020 will devote to the interplay between markets and regulation. This could help ease "the real long-term threat" that innovative medicines face because of the "huge problem of member states and uptake," marked by "increasing reluctance to embrace new products," he says. The drug industry is rejoicing in the elements of the new program that are designed to take account of the need for engagement of authorities responsible for pricing and reimbursement.

The research-based drug industry believes the program is a vehicle not only for advancing medicines research, but for gaining broader recognition for the industrial policy imperatives that lie behind its research activities.

The predecessor of Horizon 2020 won praise in many countries and many sectors. The IMI program, which received €1 billion over the seven years of the EU research program now on the verge of completion, is widely regarded as a big success for pharma and for health. And some countries have done well from the European Union's 2007-2013 program: the United Kingdom will have received around €7.5 billion in funding from it by the end of this year—around 15 percent of the total program allocation. Cambridge University estimates that 20 percent of the work undertaken by its researchers is funded by EU grants. Grants of up to €2 million in life sciences have funded promising projects ranging from high-tech radiotherapy for head-and-neck cancer to supramolecular chemistry.

But there have been frequent criticisms of undue complexity and bureaucracy in previous EU research programs, so this time the mechanisms for seeking support are simplified and the criteria eased, in order to widen access to a greater number of organizations and promote diversity in research. Even so, the final legislative text, covering the detail of the program's operation, will run to more than 1,000 pages. And who gets what will now depend on how effectively the candidates for funding present their proposals in each of the distinct categories of the program.

The program is scheduled to come into operation in January 2014, with the first calls for proposals due to emerge shortly afterwards. But—the Europe Union being the European Union — even a done deal is not a done deal until everyone has signed off on it. The €70 billion budget is still subject to final agreement on the European Union's overall spending plans for 2014-2020—and that process will not be completed until September, at the earliest. PE

VisMedia

Succinctly Shire

New CEO Flemming Ornskov has a simple strategy for his company's continued success: *Set* the industry pace on specialty medicines, *Spread* the positive buzz and momentum of a growth stock, and *Seize* the opportunity to innovate—from sources in-house and outside.

Shire is the standout in the branded industry's lost decade of slowing growth, climbing steadily up the revenue ranks with a strategic focus on the acquisition of specialty medicines, many for orphan indications, which command high margins in a privileged competitive space marked by friendly patients, faster FDA approvals and extended periods of exclusivity. But success in pharma has a notably short lifecycle, so the pressure is on to keep the good times rolling, especially in light of the company's recent transition to new leadership.

Shire is also a perennial takeover target, but with a market capitalization of close to $20 billion its a prize that won't come cheap. Feeding the speculation is Shire's solid late stage pipeline, which features new entries in undertreated conditions like dry eye disease and major depressive disorder.

To take a closer look forward, *Pharm Exec* met last month for a Q&A with new company CEO Flemming Ornskov, an academically–trained physician with a background in pediatrics who has also cut a wide swath through Big Pharma, having served previously in key management roles at Bayer, Bausch & Lomb, Merck, and Novartis. Ornskov recently unveiled a three-year strategy plan that places major bets on undertreated specialty segments in ophthalmology, ratchets up the commitment to leadership in rare diseases, and reinforces Shire's vaunted "just do it" culture through a faster, more agile decision-making structure. The plan positions Shire to take maximum advantage

of opportunities to innovate by effectively forcing the in-house R&D and business development functions to compete in bringing the best assets forward to commercialization. It was also clear from the discussion that a few things about Shire will not change: a determination to stay independent and to avoid the Big Pharma contagion of bureaucracy and bloat. Yes, it's still true: when a Shire CEO shows up for a talk, there is no entourage. —William Looney, Editor-in-Chief

PE: *Under your predecessor Angus Russell, Shire established itself as a high-growth specialty business with a distinctive culture, a key element of which was to avoid the perceived gridlock of Big Pharma. Since taking up the CEO post on April 30, you have been strong on the same mark, with a new strategic plan to guide the company through its next phase of growth. What are the plan's key elements and how do you assess the response of the investment community?*

Ornskov: Our strategy has three components. The first is a commitment to leadership in specialty medicines. The second is to maintain our company's status as a growth stock, with a significant inventory of assets to propel us forward. The third is to become even more innovative in all that we do as an organization, but especially through our expanding in-house capabilities on research as well as Shire's traditional strengths in tapping opportunities through business development and licensing. This latter, dual capability is unique to Shire as a mid-sized company in the pharma space. It is an attribute I intend to emphasize going forward.

Another, overarching aspect of the strategy is the imperative I see to make Shire a truly international organization. We are at the stage now where we need to think seriously about building a stake in markets like China and increasing our presence in Japan. Shire is already in Latin America but we can certainly do more in that region. In Europe, we are well established but there are areas where our footprint can be augmented.

As far as the investor community is concerned, I think the consensus is the strategy is forward looking and prudent: it will keep us lean as we grow and is appropriately balanced between opportunity and risk. Like everything in this business, time—and the market—will tell.

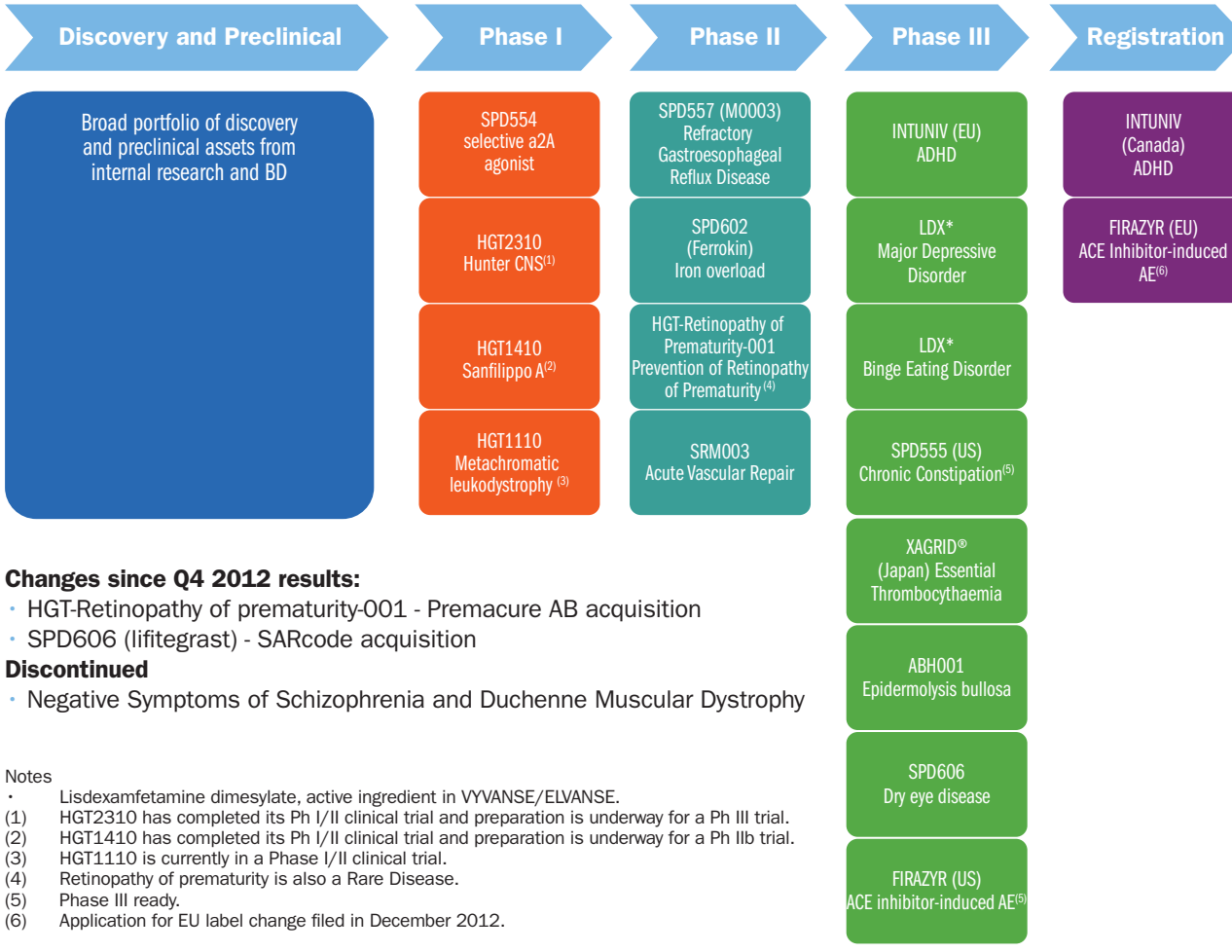
PE: *Shire set a target several years ago to raise sales outside the United States and Europe so that the two regions would account for no more than 50 percent and 25 percent of global revenues, respectively, in 2015. Are you on track to achieve that goal?*

Ornskov: At present, 70 percent of our revenues come from the United States, with the remaining 30 percent ex-US, including Europe. Our aim is to grow the ex-US business significantly. Nevertheless, I think for us to anticipate going too far down that road is unrealistic in so short a period of time. I see the United States as the most attractive pharmaceutical market in the world. It is a high-value geography, with a pricing and reimbursement climate that compares favorably to other countries. We are not going to be "hyper-focused" on the United States, but the reality is that for the foreseeable future it will remain our principal market.

PE: *There is a perception that Shire has grown through a commitment to "search" rather than research, with products derived from vigorous licensing activity rather than in-house R&D. Does the new strategy propose a change in that approach?*

Ornskov: I have experience working in large and small pharmaceutical companies. The lesson I derive from both cultures is that medicines innovation is a difficult quest. There is no fixed formula; in many ways the quest for innovation must be opportunistic. Our approach at Shire is to strive for a balance between in-house opportunities and externally sourced innovation. The key thing we are doing differently is to raise the bar on decision-making by

Shire's Pipeline: A Closer Look



Changes since Q4 2012 results:

- HGT-Retinopathy of prematurity-001 - Premacure AB acquisition
- SPD606 (lifitegrast) - SARcode acquisition

Discontinued

- Negative Symptoms of Schizophrenia and Duchenne Muscular Dystrophy

Notes

- Lisdexamfetamine dimesylate, active ingredient in VYVANSE/ELVANSE.

(1) HGT2310 has completed its Ph I/II clinical trial and preparation is underway for a Ph III trial.
(2) HGT1410 has completed its Ph I/II clinical trial and preparation is underway for a Ph IIb trial.
(3) HGT1110 is currently in a Phase I/II clinical trial.
(4) Retinopathy of prematurity is also a Rare Disease.
(5) Phase III ready.
(6) Application for EU label change filed in December 2012.

effectively asking our business development and research groups to compete in bringing the best assets forward, whatever the source. As part of that, I've created two senior executive-level committees, which I chair, that will simplify, coordinate, and prioritize decision-making around our entire product portfolio. The first is focused on executing around marketing and sales targets for Shire's current in-line products. The second concentrates on opportunities from all assets in the pipeline, whether these come from internal sources, through partnerships with affiliated institutions, or other external channels.

The two committees are designed to work together so that as a new asset comes forward, we can quickly assess how it may impact the balance within the full portfolio, particularly in regard to critical resource allocation decisions we must make in moving compounds into costly Phase III development. An example is our latest acquisition of SARcode Bioscience and its key asset, lifitegrast, an ophthalmologic drug for dry eye disease—a condition affecting 25 million US patients—which is now in Phase III trials. Once the deal was struck, the committees pondered the question: how will this promising asset, in a big therapeutic segment, change prioritization around our existing pipeline, particularly those compounds requiring more resources at the late stage of development? Should we de-commission some work to make room for investments that might augment or grow this high-potential acquisition? The answer is, yes, we did, by scrapping a previous decision to initiate a Phase III trial on an internal compound we were working on to address negative symptom schizophrenia.

The example shows that it is natural and healthy to have competition between these two sources of innovation—internal and external—because it makes the deployment of resources

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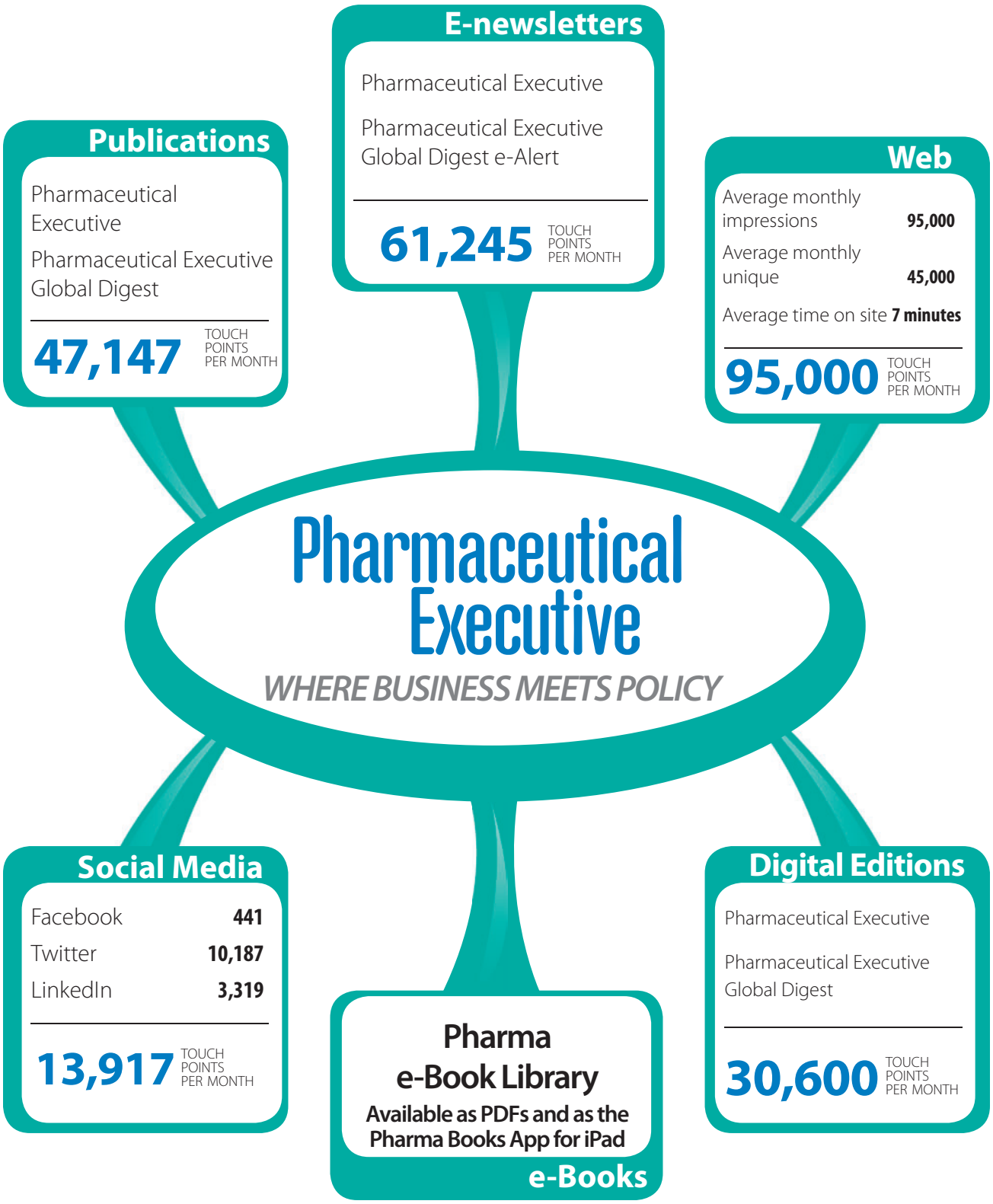
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FUNCTION DIMENSION	QTY
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around the portfolio much more efficient. Execution of our strategy depends on this new decision-making structure I have put in place.

PE: *How do you intend to deploy Shire's in-house R&D capabilities going forward?*

Ornskov: Angus Russell actually did an outstanding job in building up Shire's in-house R&D capabilities. In the field of rare diseases, we are second to none in the work our labs are doing in pre- and mid-stage clinical research. We are improving at the late-stage level as well. I have every confidence that Shire today is able to deliver to the market internally-sourced NCEs for rare diseases. Outside of rare diseases, our preference is to acquire later stage assets, develop them, and win registration. It is also important to note that Shire presently spends about 18 percent of revenues on R&D, or close to $1 billion a year. Hence it's time to change that old image of Shire.

PE: *In what ways does the new organization seek to capitalize on these next stages of growth for Shire?*

Ornskov: Shire has been posting growth rates above the market norm for many years. To manage that growth, we created a number of business units with a keen focus on the therapeutic area and full responsibility for all our activities there. In due course we had a BU incorporating all the rare disease business of our acquired company, HGT; followed by specialty medicines; behavioral science; and later another BU on regenerative medicine. Looking ahead, however, and taking into account the aggressive expansion plans in a number of new therapeutic areas, I concluded it was counterproductive to continue on this path. There was a scalability issue, with multiple duplicative, mainly service, positions for each BU leading to a lot of bureaucratic overhang, not to mention the risk of silo thinking. In fact, during my early visits as CEO to the Shire marketing and sales force, I got feedback that organizational rigidity was starting to constrict the information flow and slow decisions.

So I took a step back, and devised a new organizational structure whose principal feature is to consolidate all administrative, non-commercial functions into a single, corporate, service-oriented unit. The plan integrates formerly separate R&D activities into one organization; business development forms another. Then we sharpened the focus around five reconstituted BUs: rare diseases, consisting of the HGT products we inherited from the acquisition; neuroscience [formerly behavioral science]; gastrointestinal; regenerative medicine; and internal medicine, which mainly covers "heritage" assets that are nearing the end of the product cycle. Building on the SARcode Bioscience acquisition, we are likely to create a new BU on ophthalmology. Hematology could be another future BU for us.

Creating a central, overarching locus for prioritized decision-making across the portfolio are the two executive steering committees, on the pipeline and in-line businesses. I am chairing both committees for now. This is where the buck stops.

Most important, I took heed of what the sales force told me about the danger of letting internal intrigue push us away from the customer. The feedback told me we had to move immediately to remove all barriers between Shire and the customer. That's precisely what we did: the organization is much flatter than it was before. There is a quick way to get the attention of senior management.

PE: *Why did you abandon the name of your acquired company, HGT, and turn it into a BU now called rare diseases?*

Ornskov: We thought the designation of HGT was too confining—not every rare disease is driven entirely by genetics. The criteria should be as broad as possible. I also like to have names that resonate with customers and patients; I don't think the new name of the BU requires much explanation.

I see the United States as the most attractive pharmaceutical market in the world. We are not going to be "hyper focused" on the United States, but the reality is that for the foreseeable future it will remain our principal market.

PE: *Has the strategy plan been shaped by your previous management experience in line operations in big companies like Merck, Novartis, and Bayer?*

Ornskov: Definitely. My years at Bayer gave me a strong grounding in how to manage a BU from the perspective of the customer. I followed the same strategy at Bayer, where I helped set the foundation for its current very strong pipeline through this mixing of internal, in-house R&D and external sourcing through licensing and M&A. Bayer has benefited immensely from its unrelenting customer focus: never strong in ophthalmology, it has broken new ground with the partnership it forged with Regeneron on Eylea, for wet age-related macular degeneration; with Onyx, and Nexavar,

it has made itself a major player in oncology.

The conclusion I draw is that if a BU is closely aligned to the customer base, you can quickly pick up the pace and become a player in segments that historically have been tangential to your core. Whether the asset comes from your own lab or is externally sourced means very little. In fact, allowing both units to compete to identify and develop that asset raises the bar on performance throughout the entire organization. This Bayer model has propelled it from being known mainly for a 19th century product, aspirin, to a company that today has one of the most innovative drug pipelines in the industry. It's not just luck—it's the core focus on learning everything about your customer. This is what is going to drive Shire to the next level as well.

If a BU is closely aligned to the customer base, you can quickly become a player in segments that historically have been tangential to your core. Whether the asset comes from your own lab or is externally sourced by business development means very little. In fact, allowing both units to compete to identify and develop that asset raises the bar on performance throughout the organization.

PE: *Shire has a reputation for being very patient centric, where it leverages extensive outreach to disease groups as well as analytics around data detection, trial design, and indication profiling to secure timely registration and launch. Do you intend to build on this as a driver of competitive differentiation?*

Ornskov: Everyone at Shire has a story about patients—relating to them is part of our culture. In some ways, it comes with the turf: you have to be patient centric if you are active in attention deficit hyperactivity disorder [ADHD], or in extremely rare diseases, where our sales force gets to know many of the patients eligible to treat. I want to bolster this sentiment and keep it as part of our own DNA.

From a strictly commercial standpoint, patients are important but in many ways the key link is to the physician. This is certainly true in our clinical trial work, where physicians are the critical intermediary in the therapeutic segments where we are strong, especially rare diseases. The close interactivity with clinicians is one factor behind our acquisition of SARcode Biosciences. The company had a strong reputation for conducting excellent clinical trials based on real-world input from the most knowledgeable practicing physicians. Again, I cite it: they were very customer-focused. As a physician myself, I could see their capacity to make the connection, from the business to the physician to the patient.

PE: *How are you incorporating the new emphasis on payer value in your growth blueprint for Shire?*

Ornskov: Value is the entry point for all discussions on P&R today. It is harder to obtain access to the market without a careful consideration of cost-effectiveness, impact on overall health outcomes, and analysis of the various tradeoffs important to stakeholders. With prices for many rare disease drugs so high, transparency is a given. At the same time, every negotiation is different. The rarer the disease—and we have an estimated 7,000 such diseases where there are no available treatments—the more important it is to get the value story right. Ultimately, that story has to be persuasive for the patient: does our medicine have a significant impact on his or her quality of life? The industry has to demonstrate that its therapies are life altering. Shire has many products that do precisely that, and the requirement on us is to furnish the evidence base to prove it. We have to do it through better clinical trials but also in the many additional real-life observational studies we are committing to as part of the registration process and through negotiations with the HTA authorities and payers.

PE: *As a European, what is your perspective on the growing reliance of governments on cost-effectiveness measures to control access of new medicines to patients? Do the criteria being used in these evaluation systems adequately incorporate the special social value characteristics of drugs for rare diseases, where Shire is strong?*

Ornskov: I am in regular contact with governments and payer representatives in Europe. All countries in the region are grappling with serious challenges to the sustainability of national health systems. There is no choice but to prioritize. It's fair for them to seek to obtain maximum value for what they can spend. Our industry has to accept and work within that harsh budgetary assessment. HTA is now part of the access process; it's another barrier to market entry that, through rigorous

attention to evidence, we can address and surmount. The onus is on Shire and all companies to provide the documentation needed to help payers make the best judgment. Where Shire wants to play is at the highest level of innovation. Our goal is to be recognized as a company that specializes in innovation and thus deserves a real opportunity to show a benefit to the health system. It is true that for some of the very small patient populations we serve, it is difficult to make our arguments purely on the basis of cost-effectiveness. We want to open payers to a broader discussion around issues like how to adapt insurance programs to serve rare disease patients as well as solidarity and ethical concerns, which are very important in Europe. To varying degrees, we are succeeding in that.

PE: *Do you believe that the quality adjusted life year [QALY] calculus used by the UK National Institute for Health and Care Excellence [NICE] adequately measures the contributions of a biologic drug for a limited rare disease population versus a small molecule drug for a chronic condition designed for a much larger population?*

Ornskov: QALY calculations form only part of what is a clinical guidance that also covers other means for establishing whether a drug is cost effective or not. This is a complex decision-making process, as NICE officials have acknowledged many times. That said, I don't think it is helpful to set arbitrary frameworks that conclude if a cost per QALY is over a certain amount, then the drug won't be made available through the NHS. A QALY should never stand alone. By itself it certainly doesn't serve as an adequate measure of value in rare diseases.

PE: *Many companies today are positioning themselves not as pill manufacturers but as "total health solutions" providers, with a heavy services and outcomes delivery component. Is this part of the Shire strategy?*

For some of the very small patient populations we serve, it is difficult to make our arguments purely on cost-effectiveness. We want to open payers to a broader discussion around issues like how to adapt insurance programs to serve rare disease patients as well as solidarity and ethical concerns.

Ornskov: Shire, for now, is going to stay focused on developing innovative medicines that address unmet medical needs. This is our competitive advantage. We have a decade-long track record in delivering strong growth and returns to shareholders. A singular commitment to developing and marketing innovative drugs is the best way to continue that performance. Anything else would be dilutive.

PE: *What plans do you have for the Shire sales force? Are there changes*

underway in how you intend to introduce and sell Shire medicines?

Ornskov: The sales function is facing significant changes as information technologies create new ways to interact with healthcare professionals. Overall, the climate has become more hostile to the traditional methods in which companies communicate to this group. At Shire, the sales force will remain central to our marketing and information strategies. What we are paying more attention to is the quality of our relationships: Do we have the best educated sales reps? Is there a better balance we can strike between a purely promotional message and more medically aligned and driven opportunities that further enrich these contacts? How can we supplement direct personal contact with the other channels that technology now offers us?

Shire is a company that will continue to take big bets on innovation. I intend to speak out widely, within and outside the company, to relay this message: Shire will only grow if we innovate.

What matters most to me is keeping our eye on the feedback loop we get from prescribing physicians. We must ensure that their exposure to Shire reps is of sufficient quality and meaning to them that they will willingly allocate the time to see us. This feedback is going to be reflected in our compensation system as well as the scale and scope of our investments in the Shire sales force going forward. And feedback is not something limited to our people in sales. Instead, receiving feedback is a cultural imperative for the entire organization. It's the only way to remain attuned to the marketplace. If we aren't rated by our customers as ethical, compliant, and a consistent provider of high service, then this new strategy we have in place will not succeed.

PE: *As a newcomer to the c-suite, what differentiates the role of CEO from that of a line manager?*

Ornskov: As CEO, I must relate to a much wider circle of constituencies. For example, I have multiple outside investors that represent pension funds and depend on our returns to keep their plans healthy and solvent. There is also the responsibility you have to patients, customers, payers and regulators. A successful CEO must be outward looking. He or she must balance these multiple external interests with actions that drive things forward from the inside.

PE: *In addition to being CEO, you are a physician. Are you finding this an asset as you adjust to your new role?*

Ornskov: It has always been an asset. Throughout my career, I have relied heavily on a network of physicians to offer advice on strategic and operational issues facing the business. Being a physician helps retain those essential links to the customer. It's the way I keep myself updated. As an example, my specialization in neonatal care helped inform our due diligence in deciding to acquire Premacure's drug for retinopathy in premature infants. I could see from my experience in intensive care that there was a real need for this indication—that the clinical benefits outweighed the investment risk. I can recall the joy of parents in the successful delivery of a premature baby, only to fade when they find that the child will still be a special needs case because of the blindness or impaired eyesight.

PE: *Are you a believer in corporate culture as a driver of success? If so, what do you intend to do to put your own stamp on Shire's culture?*

Ornskov: Shire has a distinct culture that has been critical to our success. Each of my CEO predecessors have contributed to the strengthening of this culture. I intend to continue doing the same, as I believe that the fate of any company is ultimately determined at the water cooler. If people at the operations level feel good about their work, if there is broad understanding of what the company stands for and where it is going, then you will retain the productivity and alignment necessary to advance in the marketplace.

What we have to do now is to build on the legacy of growth over the past 10 years. We've come to a stage where, as we get bigger, it becomes harder to retain that entrepreneurial spirit, the organizational flexibility, which allows us to grab the best opportunities—quickly. I will challenge the Shire organization to make sure we don't become sclerotic, or too slow in decision-making, or too bureaucratic, with excessive layers of decision-making. We must continue to take a balanced approach to risks, so that we stay ahead of the curve of science and keep the focus on what works best for patients.

This sentiment is reflected in the new strategic plan, where we have metrics to show we are shortening time to action, retaining a flat organization structure, delegating responsibility to the level closest to the customer, rooting out mental fatigue by ingesting new ideas, and not being afraid to take risk in our business development and pipeline decisions. Shire is a company that will continue

to take big bets on innovation. I intend to speak out widely, within and outside the company, to relay this message: Shire will only grow if we continue to innovate. If we stay with innovation, then we avoid the negative side-effects of bigness. I have no plans to stay holed up in a corner office. In fact, I don't have one. Though I am based in Lexington, MA, I am a globe trotter. Shire is many years away from a culture of corner offices.

PE: *What is the biggest external threat to Shire and the industry over the next few years?*

Ornskov: It's the loss of innovative capacity that preoccupies me, from the instant my work day begins to the moment it ends. If we run out of innovation, we also cede our right to exist; society will sever the implicit contract that allows us to perform as a profitable enterprise. In my role at Shire, I have to continue to deliver on innovation—I am first and foremost the company's Chief Innovation Officer. I worry less about the issue that many experts raise—that innovation lacks a reproducible formula and is thus not understood by those who regulate us. To me, innovation is like good design. You can consult the academic experts or write books in an attempt to define it, but in the end innovation is entirely intuitive: those who need it, know it.

PE: *Are you pleased with the management transition thus far? There has been some turnover in senior line positions.*

Ornskov: After more than a decade of success, and with the departure of an outstanding CEO like Angus Russell, some turnover is to be expected; some people felt it was time to bank on that success and consider other opportunities. I'd call that a simple coincidence in time, not a coincidence of causality.

PE: *Finally, how will you define success for you and Shire in three years' time?*

Ornskov: I can cite three. First, that we maintain a strong and distinct organizational culture, attracting great talent. Second, that our in-house pipeline and licensed business development assets execute well in delivering at least several new approved innovative drugs to patients who need them. Third, that all our key constituencies—shareholders, customers, patients, and regulators—will rate Shire as one of the top specialty drug companies. PE

William Looney is *Pharm Exec*'s Editor-in-Chief. He can be reached at wlooney@advanstar.com.

Front & Center

Technology for community-based oncology connects all stakeholders

McKesson Specialty Health's newly designed and highly integrated suite of technology products and services were on view during ASCO 2013. All of the products were designed to connect community practices, oncologists, patients, and manufacturers.

Manufacturers face a highly competitive market for their oncology drugs that includes a complicated interplay of market demand, reimbursement and regulatory pressures. Each of these factors requires expert navigation to achieve present and future commercial success.

As Pharma-Biotech companies, physicians and other oncology stakeholders gathered to attend the 2013 American Society of Clinical Oncology Annual Meeting (ASCO), McKesson Specialty Health took advantage of the opportunity to engage with Pharma-Biotech executives around numerous topics, including many new technology solutions developed to address today's challenges. Marc Owen, president of McKesson Specialty Health, kicked off an invitational briefing at Chicago's Ritz Carlton Hotel, attended by more than 100 Pharma-Biotech executives.

"In 2012, we stepped back and asked manufacturers: What's important to you? What are the pressure points? How can we help you?" he said. "You told us about more targeted trials, continued reimbursement challenges, and more crowded markets with many more products. You raised questions: 'How do I navigate these channels? How do I get a product properly positioned?' And then, we set out to help."

McKesson Specialty Health began by developing a suite of technology products and services, driven by big data and targeted to accelerate the development and successful commercialization of specialty pharmaceuticals across a product's life cycle. Importantly, these products and services help speed patient access to breakthrough therapies.

"The aim with all of our technologies is that the ecosystem gets connected," said Asif Ahmad, senior vice president of Information and Technology Services and chief information officer for McKesson Specialty Health, who presented at the briefing along with his colleague Grant Bogle, senior vice president of Pharmaceutical & Biotech Solutions.

"Whether the technology was developed for practices, patients or Pharma-Biotech companies as main users, it connects and benefits all stakeholders; especially for the Pharma-Biotech manufacturer that is looking at bringing new compounds to market, as well as trying to see how the compounds currently marketed are performing," said Ahmad.

Technology for the practices

A highlight of the McKesson Specialty Health solutions suite was **iKnowMed Generation 2**, a powerful web-based electronic health record (EHR). iKnowMed Generation 2 was developed with input from hundreds of oncologists and by the same team that produced its predecessor iKnowMed—the highest ranked EHR for oncologists and hematologists in the 2012 and 2013 Black Book Rankings.

"With the help of physicians, many of whom are affiliated with The US Oncology Network (supported by McKesson Specialty Health and one of the nation's largest networks of community-based oncology practices)," said Ahmad, "we were able to marry technology with best-in-class, evidence-based clinical content to ensure that iKnowMed Generation 2 meets clinician needs and merges fluidly into a daily practice workflow."

The new platform is ONC-ATCB 2011 Certified as a Complete EHR; Surescripts Certified; HL7 Compliant; and is fully integrated with McKesson Specialty Health's **Lynx Mobile®** inventory management system and **My Care Plus** patient portal.

The system is mobile and can be operated from any web-enabled device, which allows the sharing of information between all oncology specialties, including medical oncologists, radiation oncologists and surgeons, to name a few. iKnowMed Generation 2 includes such features as: detailed cancer diagnosis and staging content; an extensive, up-to-date cancer regimen library; flexible documentation options; e-prescribing; automated charge capture functionality; and auto-sharing of clinical notes. As explained by Bogle, iKnowMed Generation 2 brings many new features and advantages to practices, and to Pharma-Biotech companies. "We anticipate that this will lead to more users and more complete data, with additional searchable fields that will provide more insight, whether it's for a more complete picture of the market or for HEOR studies."

In addition to iKnowMed Generation

2 and other technology-based products on display, the National Comprehensive Cancer Network®, The US Oncology Network and McKesson Specialty Health announced the availability of **Clear Value Plus**, a first-of-its-kind clinical quality and regimen support system which incorporates Value Pathways powered by NCCN®. These pathways establish a new standard for quality oncology care, backed by transparent development processes and recognized by NCCN – the leader in evidence-based content. Clear Value Plus creates a common technology platform for measuring quality and value in cancer care. The combined solution allows a greater insight into the use of evidence- and value-based medicine and how it is incorporated into a practice's workflow. Additionally, Clear Value Plus provides evidence-based treatment options, including peer-reviewed indications of efficacy, toxicity and cost, which are all available to providers at the point of care through seamless integration with iKnowMed Generation 2 and other oncology EHR's.

While both iKnowMed Generation 2 and Clear Value Plus are great tools to help the providers with the treatment selection process based on evidence, **CARE 2.0** was created to help expedite the development of new treatments. "With the emergence of targeted therapies, we needed new ways to identify and recruit patients for clinical trials," said Bogle. McKesson Specialty Health launched its CARE 2.0 functionality, which allows practices involved with US Oncology Research to mine iKnowMed and iKnowMed Generation 2 for specific patient information and match it to study protocols available in the Clinical Trial Management System (CTMS). The process is done in real-time so practices are notified about possible study subjects prior to the patient's next visit, where a more thorough screening can be done. Also leveraging its technology, McKesson Specialty Health uses its new **STAR program**, which leverages the full scale of The US Oncology Network and iKnowMed to find qualifying patients for a clinical trial. The Network sees over 750,000 patients annually and includes approximately 1,000 oncology physicians from across the nation who are dedicated to advancing high quality, evidence-based cancer care. Once qualifying patients are identified as possible study participants, sites are opened in locations where these patients reside.

Technology-based products developed for Pharma-Biotech Companies

As Pharma-Biotech executives attempt to gain visibility and understanding into prescription patterns within more complex and crowded markets, McKesson Specialty Health can help through its **Therapy Sequencing** product. HIPAA-compliant, Therapy Sequencing allows Pharma-Biotech executives to follow patients longitudinally through clinical events and provides a view into the sequence of therapies at the practice, zip code and state levels. "This allows for the users to better understand how their drugs or their competitor's drugs are used, and in what sequence," said Bogle.

It is well known that physicians have less and less time for traditional interactions with Pharma-Biotech companies. As time is becoming more scarce, it is increasingly important that each interaction be optimized, which starts with a good understanding by the Pharma-Biotech company representatives of their customer's world. **eConnect Tour** was designed with just that in mind: to deliver a virtual behind-the-scenes experience of what a cancer patient goes through when he or she is being treated at a community oncology practice.

The Oncology Portal, a physician-facing portal, is both a service and an online connection to other physicians in The US Oncology Network. For manufacturers, The Oncology Portal offers a unique look into a community dedicated exclusively to oncology and hematology. Manufacturers can follow discussions, and gain a greater understanding of the physician thought process that's used for treatment decisions. Through a variety of programs and services, The Oncology Portal provides a marketing opportunity for increasing brand awareness as well as an opportunity to invite direct physician feedback.

Technology for patients

My Care Plus allows for connection between the patient and the practice. Also a portal, it has already attracted more than 40,000 patients one year after its launch, and is growing at a rate of approximately 1,000 patients per week. McKesson Specialty Health expects at least 70,000 patients to be utilizing My Care Plus by the end of 2013. With direct links to iKnowMed, My Care Plus provides patients with access to their electronic health records and is planned to have multiple additional functionalities in the near future. For Pharma-Biotech companies, My Care Plus will provide a way to engage with patients with specific diagnoses in a HIPAA-compliant way to provide relevant and timely information, or to obtain valuable feedback.

The unique, integrated products and services demonstrated by McKesson Specialty Health's at the ASCO Annual Meeting clearly showed that the technologies do indeed connect and feed one another. Those connections form a kind of information chain that could very well foster deeper understanding among oncologists, patients and drug manufacturers, bringing them all closer together in achieving a common goal—curing cancer.

Getty Images/DrAfter123

The Case for Content

Reaching skittish consumers through objective, story-driven information is digital marketing's hottest digit, and the numbers around engagement are impressive. But applying this consumer phenomenon in Big Pharma presents some unique challenges, best expressed by the need to test that delicate balance between sharing experiences and the controlled pitch.

By Peter Houston

Imagine you're at a local shopping center on a Saturday afternoon. I know it's not how you'd choose to spend any of your weekend, but you need something.

You go into the first shop that sells what you're looking for and are immediately accosted by a salesman. This guy is in your face—he's assumed you need what he's selling and he's selling it hard. He assails you with his whole features and benefits pitch and, when you look less than interested, he goes heavy on the price. He sounds desperate, you leave.

When you walk in to the next store, the shop assistant offers a cheery welcome but lets you browse uninterrupted—a pleasant contrast to next door. You think you've found what you want, but you have a question. You catch the assistant's eye and ask if the thing you want is suitable for left-handed people. "Funny story about that… " she says and tells you the tale of a customer who bought two of the items in question for his left-handed twin brothers. She's informative and entertaining. Guess what? You've got your wallet out.

Welcome to content marketing

The biggest buzz in marketing today is a reaction to what some see as the failings of traditional advertising. With something approaching a monopoly on customer attention, traditional media channels once had a tight control on the distribution of information and associated marketing messages. Now, people have options.

Technology, from desktop computers to smartphones, has given everyone direct access to the information they

need across a huge and varied range of sources. This gives consumers the means to avoid the hard sell. "Consumers are in complete control today," says Joe Pulizzi, author of "Epic Content Marketing" and founder of the Content Marketing Institute (CMI).

"Healthcare companies can position themselves as go-to informational sources by answering their customers' pain points," says Pulizzi. But the best known content marketer on the planet says the only way to break through and get attention online is to stop the sales pitches and tell interesting stories that customers will actually engage with.

Digital media means there are more ways to get your message in front of more people than ever before—the web, e-mail, social media, games; they all deliver mind-boggling reach. According to global Internet analytics firm Comscore, there are 13.7 billion searches conducted on Google every month. With 60 percent of US consumers saying they looked for health information online in the last year, that's a lot of potential patients.

The problem is, that reach is available to everyone else, from the "Pharma 50" to your local plumber.

In 2010, Google CEO Eric Schmidt claimed that every two days we create as much information as we did from the dawn of civilization until 2003. YouTube uploads, Facebook status updates, Tweets, Pins, and Instagram photographs. We're all publishers now.

But we're not all publishers, we're authors. Publishers have a baked-in quality control filter and would never allow most of the so-called content that is out there on the Internet out of the slush pile. And it's the white noise of the virtual slush pile that's fueling the flames of content marketing and its focus on creating and distributing relevant and valuable content—content that cuts through the clutter.

One of the biggest drivers of the web-world's newly discovered penchant for quality is Google. The big-beast of online search got sick and tired of people gaming its search algorithms with sub-standard content and changed the rules.

Google introduced its Penguin algorithm in 2012 to combat dubious SEO tactics that delivered marginal search results, more to do with keyword stuffing than real relevancy. Originally called the "webspam algorithm," Penguin is designed to reward websites that offer genuinely valuable content. Google hopes it will improve its users' search experience by demoting websites that won the rankings game but left searchers wondering what the page referred had to do with the search terms they had typed in.

I see brand marketers struggling to create valuable content every day. I see them struggling to engage their audiences.

—Chris Nelson, Intouch Solutions

Pharma should have a head start in this new, improved search environment; healthcare is an industry where high quality, expert-led, evidence-based information has always mattered.

"Patients are going online to seek information about their condition and treatments they are considering or currently taking," says Chris Nelson, Senior Director, Strategic Services at digital marketing agency Intouch Solutions. "The topics can vary across disease states and products, but the foundation of timely, relevant information persists across all of healthcare."

That doesn't mean, however, that the pharma industry has content marketing down.

Late last year, CMI held its Content Marketing World Health Summit. In his keynote address, Pulizzi released new research on how healthcare companies are using content marketing. His big takeaway for the 200 healthcare professionals in attendance was that marketers in the industry were two years behind their counterparts in other sectors.

"I see brand marketers struggling to create valuable content every day," says Nelson. "At the same time, I see them struggling to engage their audiences by taking the broad stroke method to media buying." In June, on his Intouch blog, Nelson challenged the pharma industry to up its content marketing efforts: Take 10 percent of your media spend and reallocate it towards content strategy development and content marketing efforts.

"By issuing this challenge, I felt like it would help get attention to the topic and invoke a real change in their fundamental approach going forward," he said.

Nelson didn't pluck the 10 percent number out of the air. He wanted the budget allocation to be big enough to make an impact, but not to seem an impossibility to marketing managers that need to justify the spend. "I thought long and hard about the amount of budget to shift. I felt like 10 percent was the right target as it gives the challenge enough weight to get proper attention by brand marketers, but does not require a massive shift in the way they are spending budgets today."

"Unfortunately, most of our client's budgets have already been allocated for 2013," smiles Nelson. "This is shaping up to be a 2014 challenge."

Time will tell if brand managers switch a tenth of their budgets to

content marketing, but taking the content marketing challenge isn't just about budget allocations.

"It's a company mindset that must be core to the mission of the organization—to truly solve the pain points of customers, not just through the product, but through information," says Pulizzi.

Nelson says Pharma marketers have always done some level of content marketing, traditionally focused on delivering content to consumers through branded and unbranded campaigns. But these messages are too generic and high level. "There isn't a large content library available to direct people towards other relevant content. This, unintentionally, leaves their audiences hanging with more questions than answers. Gone are the times of the one- size-fits-all marketing approach – that is the key difference that most pharma marketers are missing today."

Pulizzi believes pharma can leverage its long-held expertise and experience in KOL programs and continuing medical education, but needs to go further. The big change is to develop processes that are both authentic and real-time, two things that Pulizzi acknowledges are challenging for Pharma. "It means coordinating the stories in the organization with PR, e-mail, social, and marketing. It means focusing more on the reader outcomes first, and on sales goals second," he says.

Nelson agrees—merging patient needs with brand objectives quickly becomes a win-win scenario. "This type of information can be invaluable to the individual looking for it, likely in a time of greatest need putting Pharma marketers in a unique position, as a valuable and trusted information resource."

Even if pharma has the content, it is struggling to take advantage of the other big benefit that content marketing offers: Social distribution.

Sharing—online distribution by the community that values the content—is a core principle of content marketing. The ideal is to create a regular stream of relevant, timely, and trusted content that customers can find when they need it and then have them pass it on to others in need of similar information.

"As a well-oiled content machine that knows how to build relationships, pharma should thrive in this new era," writes Candice O'Sullivan, of Australia's Wellmark agency. "Here is an industry well used to the rigors of consistently producing high-quality content—the number one challenge for most content marketers—but finds it virtually impossible to 'share.'" She describes the industry as being, "too preoccupied by the risks involved to be able to make the most of this opportunity."

Preoccupied or not, pharma is certainly wary of falling foul of regulations and often puts risk avoidance ahead of innovation in the social sphere.

Mark Evans, Digital Strategy Director at the Langland agency in the United Kingdom, says he often sees companies who feel it is safer to do nothing than risk putting information online. "But all we are doing is leaving patients and HCPs to rely on non-authoritative sources to make serious decisions about our products. When a patient searches for your brand and all they read is unofficial blog posts and unbalanced reviews it is a disaster for pharma companies, HCPs, and patients alike."

Langland recently delivered the "I did this with Idis" campaign for international managed access program provider Idis. The campaign objective is what you would expect—to explain how Idis works with pharma to help

Source: Content Marketing Institute

create access to medicines outside of the clinical trials or commercial setting that otherwise would be unavailable to patients' with unmet medical needs. The approach is a little more unusual.

The centerpiece is a custom website—ididthis.idispharma.com—focusing almost exclusively on six short videos that tell the stories of patients, physicians, a pharmacist, and an Idis executive who have accessed, or helped patients to access, drugs through the company's programs.

"The campaign centers on a series of documentary films and explores the personal struggles of people facing a difficulty when accessing the medicines they need," says Evans. "The really brave thing Idis did was to respect the documentary filmmaking process and to allow real patients and HCPs to give their unbranded, unscripted insight into the process, which led to content that is more authentic than anything I have seen from a Pharma company in recent years."

Evans says the nature of the content, high quality digital storytelling, has allowed Langland to greatly expand the reach of the campaign. "We've been able to make use of a lot of digital media channels not usually employed in this sector, including targeted LinkedIn advertising, Google Adwords, YouTube, and sponsored Twitter activity."

He acknowledges that pharma companies have always had access to a wealth of quality content and expertise. "But I guess there is often still an old 'brand guardian' mentality of keeping this great content either in a branded website or locked away completely. This is quite naturally driven by the feeling of control that is given by an 'owned' website, but I think there are more opportunities for pushing great content out to relevant publications and blogs to get greater value out of our marketing spend."

Value may be the final stumbling block to pharma businesses accepting the content marketing challenge—it's not always easy to measure ROI.

Content Marketing: I Know it When I See it

Content marketing is a catch-all term for marketing activity that relies on the publication of any number of content formats, from blogs to white papers, video to infographics, social media to custom magazines. The approach is defined by an oblique approach to sales promotion, more concerned with communicating information that is useful to customers and building engagement than direct response.

The concept of publishing useful content to create brand loyalty is often traced back to John Deere—In the late 19th century the tractor company launched *Furrow* magazine to help farmers work more profitably. Today, content marketing is seen as a way to aid discoverability online and combat the "banner blindness" that has pushed online advertising response rates down.

American Express is seen as the corporate poster child for content marketing. It's "Unstaged" concert series, which features big-name acts performing for global audiences via online video feeds, is designed to create "memorable experiences" for cardholders. The company is also investing in sports events and has created "Open Forum," a website reminiscent of John Deere's *Furrow* magazine but this time offering advice to small business owners.

In Big Pharma, the Sanofi US Diabetes team creates unbranded content useful to its patients and distributes it through social media. The team has developed a central educational site that covers a variety of topics and helps notify patients of other useful content sources outside of Sanofi. It has also developed Diabetapedia, a Wiki or online reference guide to explain diabetes phrases and concepts and runs a Facebook page to share and discuss content with patients.

"This is something that we as agencies need to be helping our clients with, namely that it can be difficult to quantify the impact and ROI of producing branded content not directly linked to a product," says Evans. "Without this information, pharma marketing executives are rightly nervous in going up against medical to plead their case for taking on some of the potential risks."

Nelson puts another slant on the ROI issue. "The challenge for most pharma marketers is setting and measuring appropriate goals for performance of their current marketing campaigns. Without the ability to see the low impact current marketing efforts are having, they're much less likely to try something different or take action to effect change."

Nelson's advice to any pharma marketer looking to take on content marketing is first and foremost to admit there is an opportunity to improve and be willing to change.

Long term, the fragmentation of traditional channels and the disruption of old-style display advertising models may force brand managers' hands. "It's getting harder and harder to interrupt customers," says Pulizzi. "That means we have to focus on what they care about, not by sending out more information about our products and features. Whether the goals are demand generation, customer loyalty, or creating brand evangelists, healthcare companies can win by selling less and publishing more."

Pharma's content-marketing opportunity is to make sure that when a doctor or a patient goes searching for information—which we know they are doing more and more—the right content is there waiting for them, telling them what they want to know without any hard sell. Heading back to that Saturday afternoon shopping trip, it's the difference between sales and service and when the customer has a choice, service is everything. PE

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Getty Images/David Malan

New Rules *for a* New Africa

Declining revenue growth in the United States and Europe have sent pharmaceutical companies in search of opportunities in the emerging economies of Latin America, the Middle East, and Asia. Now, as growth in these high-flying regions begins to stabilize, companies are finally turning their attention to Africa—a hidden trove of potential that is only as good as you make it.

By Joseph Saba

Africa has long been seen as a caricature of calamity—an object lesson on what *not* to do in making public health a driver of balanced economic and social development. Ravaged by a potent mix of infectious and chronic non-communicable diseases and political conflicts, the region sat neglected by investors for decades, a destination to nowhere even for companies with a business commitment to better health. The greatest mistake was to consider Africa as the "carbon copy" continent: uniformly poor, culturally deprived, and entrepreneurially challenged despite its immense, varied topography and a rich, complex mosaic of ethnic and racial affiliations.

But things change. Africa now deserves a second look, however, especially as growth prospects in the mature markets of Europe and the United States are fading due to aging populations and deepening fiscal constraints in key demand sectors like healthcare. Africa actually now presents a refreshing contrast to this politics of decline, with the world's youngest population and a new highly educated class of business leaders that has benefited from a regional transition to democracy—"regime change" in most countries is now taking place peacefully, through the ballot box.

Just a decade ago, Africa was an uncharted frontier for most of the global pharmaceutical majors. Companies familiar with the structured

world of developed markets found themselves without the necessary tools to identify opportunities and build market share in the region. A key concern at the time for African governments was how best to leverage private sector support to find solutions to system-wide healthcare issues like access to medicines. In one of the first examples of public/private sector cooperation, the Abbott Fund and the government of Tanzania formed in 2001 a joint collaboration to strengthen basic health infrastructure. During this time, many hours were spent working closely with the Ministry of Health to highlight critical areas of needs in the midst of what was a chaotic time for many African nations. With more than 23 million people living with HIV/AIDS in Sub-Saharan Africa alone; skyrocketing case loads of tuberculosis, malaria, and other communicable ailments; and woeful under-capacity in essential primary care services, decision makers struggled to know where to start.

As the HIV/AIDS epidemic grew, so did pressure on the global pharma industry to invest in infrastructure and capacity building projects and to provide free-of-cost or lower-cost goods as a subsidy to patients and governments. This left many companies, whose business model focused on serving urban hospitals and the small slice of the population with the means to pay for medicines out-of-pocket, totally unprepared. With countless non-profit and national and multilateral aid organization playing the lead role in managing the health crisis, the pharmaceutical companies' hands-off stance led to them taking a reputational hit, with a spillover impact on the big Western markets where most of their profits were spun.

While clouded with controversy, some industry investments in Africa did play a role in controlling the disease burden, building infrastructure, and even contributed to policy development, in some cases. For example, as part of the Abbott Fund project, an HIV/AIDS wing was built at the Kilimanjaro Christian Medical College (KCMC) in Moshi, Tanzania. After completion in 2003, the beds were quickly filled with HIV/AIDS and tuberculosis patients requiring in-patient care, and over time, the availability of ARVs led to a significant decrease in HIV/AIDS-related hospitalizations in the district. Another example is a recently published impact analysis (*BMC Public Health*) of Boehringer Ingelheim's Viramune Donation Program, which from 2000-2013 provided free-of-cost the drug nevirapine in 34 Africa countries to mothers and their babies to prevent the transmission of HIV/AIDS. It found that availability of the drug at such a crucial time generated a positive cycle of community demand, which in turn encouraged the uptake of local comprehensive preventive mother to child HIV transmission services and fostered new partnerships with national and international organizations. The feedback helped create the political momentum to institutionalize these services through specific policy directives enforceable at the national level.

A 2011 report by the African Development Bank found that the ranks of Africa's middle class increased to 34 percent of the continent's population in 2010—nearly 313 million people, equivalent to the population of the United States.

Africa arrives

Two decades later, Africa finds itself slowly emerging from the perils it once faced. The key driver is economic growth, which has raised living standards and consequently increased demand for health services. A 2011 report by the African Development Bank found that the ranks of Africa's middle class increased to 34 percent of the continent's population in 2010—nearly 313 million people, equivalent to the population of the United States. The continent's urban population is also projected to exceed that of China and India by 2050, according to UN figures. Along with greater political and fiscal stability and improvements in pro-business legislation, the UN forecasts that foreign direct investment (FDI) in Africa could more than double in 2014 compared to a decade ago.

Since 2000, healthcare spending has grown at a CAGR of 9.6 percent due to government, NGO, and private sector investments in system infrastructure, capacity building, treatment provisions, and specialized services. While infectious diseases like HIV/AIDS and tuberculosis still remain a significant problem, the changing economic profile of Africa has led to an increase in non-communicable diseases (NCDs), such as cardiovascular and respiratory disorders, cancer, and diabetes, and as a result, a growing demand for chronic care drugs. The World Health Organization (WHO) estimates that by 2020, the biggest increases in NCD deaths will occur in Africa.

This observation by a leading local health practitioner is telling. "In 2003, the beds in our new HIV/AIDS wing at KCMC were filled with HIV/AIDS patients whose disease was not under control. Since the introduction of affordable anti-retrovirals that decreased the disease burden, those beds are now

Profile of the African Patient

Understanding consumer preferences and behavior cannot be overstated in the development of effective market access strategies in out-of-pocket markets. Results from two recently conducted studies on the African consumer by Axios International have yielded key insights in a variety of behavioral and preference areas, including brand loyalty and perception, ease of use, and geographic access.

While patient demographics can vary greatly across Africa, consistent throughout the continent is that most consumers fall in the out-of-pocket payment segment. Given that few patients receive reimbursement for medication, the price of medicine at the point of sale plays a crucial role in purchasing decisions. Furthermore, consumers' purchasing decisions are often guided by a range of factors beyond prescription, including pharmacist recommendations or previous successful use.

Many patients display strong brand loyalty given the widespread presence of counterfeit medications, and may be wary of generic products or genuine products sold in unfamiliar packaging. Additionally, higher-priced brands are often viewed as more effective than identical products with lower costs and/or different packaging. For example, when choosing between identical malaria medications, wealthier patients preferred the branded medication based on the belief that the price and packaging difference was indicative of a difference in quality. Furthermore, when faced with two therapies of six or 24 tablets, patients often chose the therapy with six tablets, regardless of the known efficacy for either product.

In regards to the effects of geography, in one study, patients in rural areas often went first to their local drug shop instead of the nearest health center. This choice could derive from either the distance to the nearest health center, the cost of treatment at the health center, or both.

Finally, tempting as it might sound, there is no easy "one-size-fits-all" solution to reaching patients in Africa. Country-specific market research will continue to be a crucial tool for companies looking to navigate Africa's heterogeneous marketplace.

filled with diabetes patients," Mark Swai, MD, former Hospital Director of KCMC, told *Pharm Exec*.

Increasing individual wealth, a somewhat stronger health system infrastructure, and rising demand for drugs treating chronic diseases are driving up sales of pharmaceuticals. By 2016, annual pharmaceutical spending in Africa is expected to reach $30 billion—surpassing the United Kingdom.

But how different is the Africa of today when it comes to healthcare provisions?

There is no doubt that there are promising changes ahead, yet one crucial component of a sound healthcare system lags: a weak infrastructure, especially in primary care, accentuated by a shortage of facilities and trained staff, limited disease awareness, and frequent changes in regulatory and distribution rules. As in most other areas of the African economy, creation of an efficient, boundary-less regional market in medicines remains elusive.

Take the doctor to patient ratio for example: according to the most recent World Bank figures available, Mozambique has less than one physician per 10,000 people, as does Gambia, Ghana, and Ethiopia. South Africa has less than one physician per 1,250. Compare this to physician population ratios of one to 300 and one to 425 for France and the United States, respectively. With such a low physician to patient ratio, prescriber-focused sales and marketing tactics are not practicable. Combine this with a still poorly understood heterogeneous market and a decision chain that is notably hard to navigate and you have to ask if a long-term integrated business strategy is possible within these current infrastructure limitations. It follows that the most important question of the moment for pharma investors is: what commitments and level of spending are necessary to overcome these limitations and leverage the region's full market potential?

"There are clear improvements since the early days of the HIV/AIDS epidemic. However, the needs keep changing. What was put in place to treat infectious diseases is not what is needed to keep diabetes patients out of the hospital today," said Swai. Swai's story illustrates how the evolving disease landscape in Africa has exceeded the capacity of health systems to adapt and respond to a new crisis in chronic care, resulting in unnecessary complications for patients and added operational and financial burden on African hospitals.

One fact for Big Pharma is clear: While the role of the pharmaceutical sector in Africa is undoubtedly changing, the need to ensure that private-sector initiatives support and drive infrastructure improvements remains essential. It is the single most important element in a long-term, sustainable market access strategy for Africa.

Learning from the past

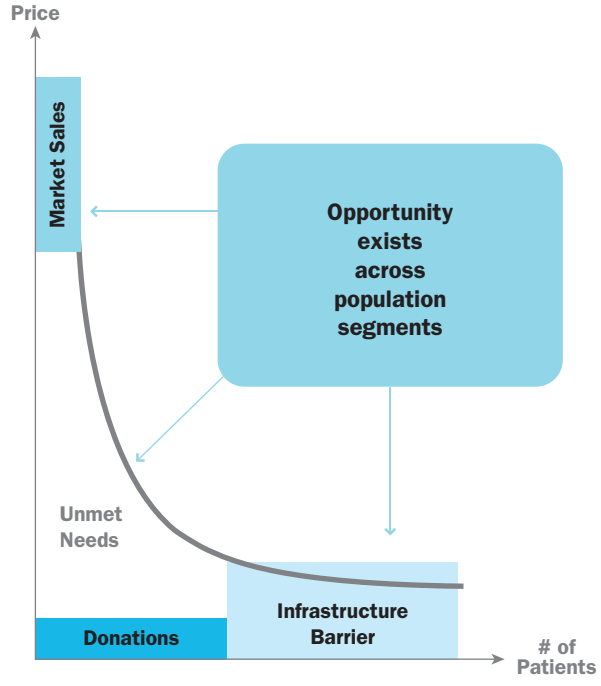
Before addressing key market access considerations in Africa today, it is important to look at what we already know.

Much has been learned from the industry's efforts in Africa to date, and similarly, African governments have grown significantly more informed in their approach to working with the private sector. Gone are the days of "I'll take what I can get." In its place is a new generation of leaders who have overcome epidemics and political instability and now demand smart, actionable, long-term strategies that will address the growing burdens on national healthcare systems. The same goes for the general population. After two decades of external influence from

private companies and donors alike, African patients have grown more sophisticated and have developed distinct behaviors and preferences when it comes to healthcare choices (see Profile of the African Patient sidebar).

The last 10 years have been tumultuous for the pharma industry as it struggled to establish a truly global presence beyond the mature markets of the United States, Europe, and Japan. While each region of the world has its own unique business context, barriers to entry led by low affordability and limited infrastructure are the overarching themes that join all developing or emerging markets. Pharmaceutical companies have built significant expertise on how to overcome these barriers in developing markets through their work in Asia, Latin America, and the Middle East. It is important that this knowledge is leveraged as market access strategies are developed for Africa.

Illustration of Patient Opportunity Spectrum in Developing Markets



Any blueprint for African growth should consider the following:

First and foremost, the ability to pay must take informal sources into consideration. Traditionally, income, expenditures, or wealth have been used as a primary indicator of financial status. However, informal and cash economies, predominant in African countries, make it difficult to accurately assess real ability to pay. An approach that looks at a range of indicators together should be considered.

There is a significant middle income bracket of the population that is not being reached by traditional access solutions. Health insurance in developing countries is neither widely available nor affordable for most people and the majority of patients pay for healthcare expenses out of pocket. Although the very wealthy can afford to pay for patented medications, and the very poor may be able to participate in donation programs organized by pharmaceutical companies, those in the middle of the economic scale face substantial hurdles to accessing needed drugs (see Patient Opportunity Spectrum in Developing Markets figure).

Building up the value of a product in the eye of the payer(s) is essential given the low affordability, limited to no reimbursement, purchasing decisions that are not always dictated by prescriptions, and the availability of generic alternatives. Value building comes in many forms, from setting the right price to utilizing marketing tactics that target informal channels of influence. Regardless of the method utilized, what is important is that your value proposition is locally relevant, applicable to patient preferences and mindful of the competitive landscape in the country.

There is significant competition for how a low monthly wage should be spent in resource-poor settings. Many patients are paid weekly or on an ad-hoc basis, so ability to purchase may vary from week to week. Patients must constantly prioritize purchases based on needs and available financial resources and this plays a significant role on healthcare expenditures.

With low doctor to patient ratios, prescriber-focused sales and marketing techniques have their limits. Deploying a sales force to target key physicians as your primary means of outreach will likely limit your market potential. Instead, coupling a well-trained local sales force with initiatives to educate informal channels of influence, such as community health workers, nurses, and pharmacists, may be more effective in reaching the full patient spectrum across affordability levels.

Strategies for success

How can we apply what we already know to successfully navigate the current African context and establish a fruitful presence in the continent? Consider the following:

Strengthen data to inform the opportunity. There is much we still don't know about the African market. Africa is extremely heterogeneous, and one-size-fits-all solutions are bound to fail. Country-specific market research will be a crucial tool for understanding the path to market, the path to patient, and related barriers.

Stimulate demand. While providing treatment via donations or cost sharing schemes addresses one part of the problem, a sustainable market access strategy, particularly for an innovative drug, should also include disease management, capacity and infrastructure building, and stakeholder engagement components to drive public demand from the ground up. Build-

ing this demand will ultimately affect policy decisions that can positively impact sales in the long-run.

Understand the importance of informal channels and the power shift from prescribers. Decisions in Africa—be it prescribing, purchasing, or policy decisions—are often guided by a range of parties, many outside the formal spectrum of influencers. Key Opinion Leaders (KOLs) are no longer just leading physicians in the field. They include the range of people that make up a patient's "treatment journey"—community leaders, community health workers, pharmacists, nurses, religious groups, aid workers, and NGO representatives. Identifying these influencers is just a first step. The real game changer is a smart engagement strategy that puts stakeholders in the center of the solution.

Look more broadly at the population. By 2015, 221 million additional basic needs consumers (defined as those between the $1,000-$5,000 income bracket) will enter the market in Africa. This represents 55 percent of Africa's population, compared with 39 percent who fell into the basic needs category in 2005. While this income bracket is still low compared to other developing regions, it represents a new market base that will likely not be reached with traditional access approaches. To reach the full patient base, consider how market potential can be maximized by segmenting across the affordability spectrum. For example, by putting in place cost sharing strategies for medium-priced drugs that allow patients to pay only what they can afford and bringing in other parties to cover the remainder, higher income patients are in essence able to "subsidize" lower income patients—thereby growing the patient pool.

Consider the role of willingness to pay. In low affordability environments, willingness to pay must be considered as strongly as ability to pay. Unless the condition is debilitating enough to limit future income generation, preventing or even treating non-essential health issues is not always a priority for a patient that falls in or below the "basic needs" bracket. This is particularly true for chronic diseases that are often progressive in nature. For these reasons, educating patients so they understand the need for prevention or treatment, ensuring that your product value is communicated clearly by influencers, and pricing your product appropriately are key.

By 2015, 221 million additional basic needs consumers (defined as those between the $1,000-$5,000 income bracket) will enter the market in Africa. This represents 55 percent of Africa's population, compared with 39 percent who fell into the basic needs category in 2005.

Select and monitor distribution channels carefully. Availability in pharmacies can often dictate product purchase so a carefully maintained supply chain and distribution system should be in place. In addition, to avoid price inflation, "cutting out the middle man" is an important reality in the African market. Intermediaries and markups can sometimes increase net selling price by four to six times.

Remember the importance of ongoing corporate social responsibility (CSR) efforts. While many companies' presence in Africa to date have been tied to CSR efforts alone, the changing landscape and growing commercial opportunities should not mean the end of these initiatives. Instead, socially responsible market access practices that are sustainable should be seen as complements to CSR practices.

Leverage partnerships with local governments and organizations. Working with governments to support policies and integrated health delivery systems that work in unison with, but not parallel to, existing health systems, is a primary way to ensure that private sector investments in infrastructure garner the proper ROI for commercial sustainability. Instead of detailing products via a local sales force for example, take a step back and consider the need for clinical treatment guidelines and work closely with local governments to develop them. Furthermore, organizations on-the-ground that have local knowledge and relationships can also serve as tremendous assets to establish a footprint and help navigate barriers to market.

Invest in smart infrastructure and capacity initiatives. Focus on skills transfer, and ensure commitment to this at the company headquarters level early in the market access strategy development process.

In time, the results of these initiatives will become the foundation of commercial success in Africa. While it is a longer-term solution, pharmaceutical companies willing to take the effort and make the investment will no doubt reap the rewards. In essence, when it comes to Africa, the market is what you make it. PE

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Breaching the Great Wall

With a revision of China's basic drug approval law now underway, a multinational team of experts is proposing major changes to make the country a world class player in innovation.

Behind the vaulting growth statistics that make China the centerfold in Big Pharma's global playbook is a sobering fact: registering a new drug for local sale is still a slow, dimly lit game of chance. China's regulatory approval system has not kept pace with the needs of an expanding local market, relying on opaque, erratically administered procedures known mainly to staff, many of whom lack the scientific qualifications common among drug reviewers in the United States, Europe, and Japan. You might call it a dated, 20th century pathway to the big market of the future.

A mix of internal reforms, stakeholder insights and foreign pressure has begun to change that. An overhaul of the Drug Administration Law is pending and has been cited as a priority by the Chinese government. In March, the State Food and Drug Administration (SFDA) was reorganized to give drug regulators more independence and a higher profile. The renamed China FDA (CFDA)now reports directly to the government's top executive body, the State Council, instead of the Ministry of Health, and incorporates several formerly separate bureaus responsible for quality and safety inspections.

The question now is—what next?

In a measure of how much China has changed, stakeholders outside the government have decided to weigh in. The most prominent example is the intensive review of the entire decision-making chain behind new drug approvals in China just completed by a cross-functional multinational team of experts convened by the Pharmaceutical Law Institute of Beijing's Tsinghua University. The Institute team, led by its chair, Dean of Tsinghua Law School Wang Chenguang, and with tacit encouragement from the leadership of the CFDA and Ministry of Health, has spent the past year examining process and policy in three specific areas:

- Approval and conduct of clinical trials
- Registration rules and requirements
- Institutional functions and capabilities

Three expert working groups were established around each topic, each led by two rapporteurs, one from China and the other from the United States. A combined report—"Building a 21st Century Pharmaceutical Regulatory System"—was released on June 23 at a Pharmaceutical Law Institute event in Beijing hosted by Professor Wang. The event featured the participation of representatives of the new CFDA as well as the State Council's Office of Legislative Affairs.

A new regulatory roadmap

The report concluded that revision of China's Drug Administration Law should focus on nine integrated objectives. Highlights include the following:

Improve administrative procedures and put additional resources behind efforts to make China a global center for R&D in innovative medicines, including biologics. Greater clarity in rules for the conduct of local clinical trials and allowance for the use of relevant foreign trial data in registration applications are critical if China is to succeed in developing new drugs that will win approval in the global market. "Currently, a Phase I study sponsored by a multinational company can only be conducted in China if the compound is already registered or undergoing Phase II and III trials in other countries. This discourages these companies from including Chinese sites in multinational clinical development programs, which makes it harder for China to realize its objective to be a leader in the registration of new global innovative drugs," said Ken Kaitin, Director of the Tufts Center for the Study of Drug Development in Boston and co-rapporteur for the report on clinical trial issues.

Increased transparency and outside participation in the drug evaluation and approval process. This can be done through such measures as advance notices on regulatory actions and the systematic inclusion of industry, academia, patients, and other stakeholders in decision making. Too often, the report says, regulators operate in "campaign mode," consulting others only as they see fit. An important reference in the report was keeping intact that

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regulatory "firewall" between the market authorization and "value," i.e., pricing. Such differentiation is fast eroding in the mature country systems.

Harmonization of local approaches to trial management, ethical oversight/compliance, registration applications, manufacturing, patient safety, and risk management according to internationally accepted norms—essentially raising the bar on local performance to better prepare Chinese manufacturers to compete in the global market. The team emphasized that China is currently proficient in producing generic drugs, but if the country wants to move beyond that, with new medicines that innovate for undertreated diseases that distort public health, the regulatory system must change—beginning with these and other related approval procedures.

Bolstering the platform is a strong endorsement of IP rights, in which the report noted that China's implementation of the WTO TRIPS treaty still lacked "clarity." The problem of patent linkage was addressed by recommending a new procedure to help originator patent holders ensure CFDA is aware and can respond to infringements by generic producers. Another point was the need to formally confirm that both imported and domestic medicines are eligible for data protection, with advance notice to originators given prior to the registration application.

Improve the institutional capacity and effectiveness of drug regulatory agencies, through actions like better defining the CFDA's legal status; introducing formal science-based review criteria; creating a clear pathway for accelerated review of the most promising therapies, and applying this equally to domestic and imported drugs; and establishing clear lines of authority between CFDA, other central government agencies with a mandate to maintain public health and—most important – the provincial administrative authorities. At present, the Drug Administration Law fails to set a clear demarcation between the functions and responsibilities of the various regulatory bodies for drugs, and local authorities are subject to strong political pressures that limit their independence. Reliance on independent examiners and experts was also cited as a way to raise the skills base and professional qualifications of regulatory staff, which was profiled as being way below international norms.

Raising the bar on talent

The report provided some interesting data points to buttress this reform agenda. It notes that in China it takes on average a year and a half to obtain approval to launch a clinical trial—the less formal FDA notification process in the United States typically takes no more than 30 days. In addition, staffing for regulation throughout China is kept abnormally low by quotas that link hiring to a tiny fraction of the population being regulated. And the professional credentials of regulatory staff lags significantly against the standard in industrialized countries. Only five percent of CFDA staffers hold a master's degree or above; 45 percent of CFDA staffers lack even a bachelor's degree.

Susan Winckler, President of the Food and Drug Law Institute in Washington, who served in a personal capacity as co-rapporteur for the work group on institutional structure and functions, told *Pharm Exec* that what is needed to accompany a new Drug Administration Law is adoption by the regulatory bodies of "an internal culture of continuous improvement." She notes that the challenges facing the Chinese system are actually the same everywhere—it's simply a matter of degree. "The US FDA is also resource-constrained and is under similar pressure to be more predictable and transparent in the way it operates." Winckler believes that the Tsinghua project should thus act as stimulus to a broader dialogue to which regulators in all countries can contribute. "Change will come about if that discussion includes not just the regulatory community, but those who are regulated too."

Project phase II

Looking forward, CFDA officials anticipate that a first draft of a new Drug Administration Law is likely by the end of this year, and it has invited Tsinghua to contribute ideas to help shape the process. In September, the Pharmaceutical Law Institute team will commence a second phase of the project, with three new work streams to address the following topics: pharmacovigilance and risk management standards; a regulatory pathway for biologics, including biosimilars; and legal/product liability reforms. Since the thrust here is to identify and transfer best practices that might prove useful to China, Tsinghua hopes to draw in contributing experts from Europe and other mature countries, in addition to the United States. PE

Prescription for Growth: Embrace a Niche

The best way to grow in the pharma industry is to think small.

In today's payer climate, even innovative products face challenges securing reimbursement if they come with a premium price. The growth of generic products is stunning, and the blockbuster era, with its broad indications, premium pricing, and big marketing budgets, is a thing of the past.

Marketers need to rise to the challenge. The greatest value marketing leaders can provide is to harness the power of strategic thinking. It starts with developing a compelling product positioning.

Positioning is the foundation

Positioning defines how a product competes—who it is for and how it is differentiated versus competitors. In consulting work and teaching Kellogg MBA students, we see case study after case study detailing how companies have significantly steepened their brand's growth curve by developing a compelling product positioning. There are three core elements in a positioning:

Target. Defining your target as simply "patients with X condition" or "primary care physicians" is not enough. The target definition should be grounded in segmentation and customer insight.

Frame of reference. What comparison set do you wish to be a part of? For example, if your product is an asthma drug, are you better off competing broadly against all other asthma drugs or, for example, competing for usage as a preventative therapy in this drug class?

Differentiating benefit and support. Your primary benefit must be narrowed to satisfy three criteria: it must be highly valued by customers, truly unique versus competition, and credible based on the inherent strengths of your product or company. If your product is not seen as "best in the world" at something, your benefit may not be focused enough.

The three elements can be summarized in a positioning statement. This is a fairly fundamental tool for marketing executives. To (target), X is the brand of (frame of reference) that provides (differentiating benefit) because (support).

A common misconception is that a positioning statement is primarily to help create effective advertising or sales brochures. It is much more important than that. Products with no advertising still need a positioning statement. It provides strategic guidance for everything that happens downstream—development of the marketing plans, sales initiatives, legal/regulatory approach, and financial plans.

Pharma's positioning challenge

It's difficult for pharmaceutical companies to develop strong positioning statements. The core problem is that pharma marketers dislike niche strategies; when positioning products, most pharma marketing leaders push for breadth. That's understandable, since the goal at launch is to capture as much revenue and profit as possible before the patent expires. Pfizer, for example, reached a broad audience with Lipitor and that worked very well indeed.

Going after a small group of physicians and patients seems like a bad idea. Why think small? In some organizations, aggressively championing a niche launch could well be a career limiting move.

Broad launches are appealing, but there's a simple problem: they don't often work in today's healthcare ecosystem. In a competitive market, a broad launch often becomes a "me-too" strategy, raising the ire of regulators and payers.

Finding a niche is a far better approach. The key for any pharmaceutical product today is demonstrating a clear benefit, and it's easier to demonstrate a benefit against a small target.

"Niche" doesn't necessarily mean small

A niche strategy doesn't mean sales will necessarily be small. Once a physician is comfortable with a product and appreciates the benefits, she will likely use it with additional patients. It is easy to expand from the initial niche to the broader population of patients that fall within the label. And once the product is in the market, companies can secure additional indications to expand use further.

Eli Lilly's Cymbalta illustrates the power of a niche positioning. Cymbalta entered the intensely competitive anti-depressant category in 2004. By focusing

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medicon valley alliance

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THE NORDICS: A Model for Innovation?

AN INSIGHT INTO DENMARK & SWEDEN

On the Northern fringes of Europe, those who want to believe that there is a sustainable future for the old continent's generous healthcare systems find a beacon of hope.

At a time when the healthcare systems of most of the European Union's member states are going through their biggest existential crisis in post-war history, the Nordics (Denmark, Finland, Iceland, Norway, and Sweden) maintain sustainable yet technologically advanced healthcare systems.

Furthermore, the region's most populous nations (and the focus of this report), Sweden and Denmark, have made impressive contributions to the world's life sciences industry.

Denmark, a country of 5.6 million, brought the world such pharmaceutical champions as Novo Nordisk, Lundbeck, Leo Pharma, and ALK. Sweden, population of 9.5 million, grooms a thriving life sciences industry while its pharmaceutical market, the largest in the region, is often considered the barometer of Europe due to its progressive nature.

Denmark and Sweden coming out on top amid fierce competition, despite their modest populations, is often ascribed to the 'Nordic model.' This slightly undefined concept refers to a consensus-based model with a focus on sustainability and high levels of trust and cooperation between government and industry. Is the 'Nordic model' really the key explanation behind the remarkable success of the Danish and Swedish life sciences industry?

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MAKING A VIRTUE OF NECESSITY?

"The Nordic region—the 'quiet North' as it could have been called—counterbalances the turbulence in Southern Europe," said Zinta Krumins, managing director Nordics, Boehringer Ingelheim, when asked about the relevance of the Nordics to the company. "The Nordics are a very stable region, with small but reasonable growth prospects, very good government structures and frameworks, social infrastructure and a solid economy."

Although attractive for their stable economies and governments, the Nordics do not have numbers on their side. "We cannot compete in terms of volume and economy of scale," said Stig Jørgensen, CEO of Medicon Valley Alliance, a network organization representing human life sciences in Medicon Valley, a region spanning eastern Denmark and south-western Sweden.

From left: Zinta Krumins, Managing Director Nordics, Boehringer Ingelheim; Stig Jørgensen, CEO, Medicon Valley Alliance; Dorthe Mikkelsen, Senior Vice-President Mid-Europe 2, MSD; Mary Di Marzio, General Manager Nordics, Shire Plc

Thus, the countries need to work together in order to increase their leverage. "Other countries often have an individualistic mindset and their culture revolves around competing with each other," Jørgensen continued. "Our collective culture enables us to unite doctors, engineers, and business people to work together. All these disciplines collaborating and working in the same domain is where innovation will flourish."

With Sweden and Denmark taking spot one and three respectively on the European Commission's Innovation Union Scoreboard 2013, it is hard to argue against the effectiveness of the model.

For instance, both Sweden and Denmark are overrepresented in clinical trials. MSD conducts about 10 percent of all its clinical trials in the Nordic region. "The attractiveness of the Nordics is a health care system that is state of the

Biotech as Business—the Bavarian Nordic story

If there is one thing that successful Danish companies have in common with one another, it is the clear recognition of abundant opportunities outside the motherland.

"Danish companies' strengths lie in their ability to build on what they have inherited from Denmark but to also look outward and be international," said Anders Hedegaard, CEO of Bavarian Nordic. His company was established through a partnership with the US government.

With only two years experience of producing biological products in Denmark, building up competencies in a short time has enabled Bavarian Nordic to secure USD 1 billion in contracts from the US government.

"Although we might have started as a more traditional biotech company, smallpox vaccine orders from the US government have helped us to make the leap towards an industrial scale pharmaceutical company," explained Hedegaard. After the Food and Drug Administration (FDA) approval and the clearance to provide the product in 2010, the company had to be steered into a more industrial mindset to deliver on budgets.

Bavarian Nordic also acquired the rights to develop a vaccine for prostate cancer from the National Cancer Institute (NCI) in 2008. The vaccine is in Phase 3 trials after Phase 2 results showed significant improvements in overall survival in a patient group that otherwise had no good alternatives.

In addition to getting more contracts from the US government for the smallpox vaccine, "Bavarian Nordic's strategy is to run Phase 3 of the prostate cancer vaccine until data readout and then hopefully, based on attractive data, we will seek appropriate partners, such as a global pharmaceutical company with the ability to achieve a worldwide product launch," said Hedegaard.

It was a complete focus on execution that enabled Bavarian Nordic to not only survive the typical pitfalls of biotech, but to double its turnover and significantly improve the bottom line. And now it's delivery time. Bavarian Nordic has decided to merge and consolidate their production facilities in Denmark in order to supply both the smallpox and the prostate cancer vaccines.

In spite of all of Bavarian Nordic's achievements, communicating this success to investors has been more difficult. "The government business gives a huge advantage in many ways, but the challenge is to get investors to accept it and rank it on par with a normal commercial market," said Hedegaard. Execution remains the priority to ensure a sustainable business. Bavarian Nordic has a profitable smallpox business but is still shepherding its prostate cancer vaccine candidate through Phase 3 trials and approval.

"The cash flow that comes from a business in infectious diseases gives us a strong market position," explained Hedegaard, who hopes that this will enable Bavarian Nordic "to expand further, either in infectious diseases or cancer. Having infrastructure in place and commercialized products will help us open the business in new areas."

art, with strong medical professionals, a high level of scientific leaders both at the universities and at the clinics, and an overall strong infrastructure for clinical research," said Dorthe Mikkelsen, Senior Vice-President Mid-Europe 2, MSD. Furthermore, the Nordics offer a good data foundation. "Their registries are a goldmine for doing research and developing new products," Mikkelsen said.

From left: Pia Olsen Dyhr, Minister of Trade & Investment, Denmark; Christian Dyvig, CEO, Lundbeck Foundation; Anders Hedegaard, CEO of Bavarian Nordic

Clinical trials are also seen as another avenue for innovation, with many companies breaking out of the traditional sales model. "We see clinical trials as a positive way to collaborate with health care professionals," Tommy Söderman, general manager Nordics, IPSEN, said. "In the Nordics we have many of our own initiatives; for example, we are running clinical trials on rehab patients recovering from strokes at 30 sites in the Nordic region."

The two countries are also a goldmine for acquisitions. Shire Plc recently acquired Swedish biotech Premacure, a biotech developing a therapy for the prevention of retinopathy of prematurity, currently in Phase II.

"Before Premacure became part of Shire, the company was already surrounded by an environment that allowed them to invest, explore and discover, which we then found was a good fit for us. Sweden provides an environment in which government incentivizes companies to be innovative and rewards innovation with favorable taxation," said Mary Di Marzio, General Manager Nordics with Shire Plc. "That is at the core of what the Nordic nations are encouraged to do and are rewarded for doing."

DENMARK: A LAND FLOWING WITH MILK AND PHARMA

How has a nation of a modest 5.6 million been able to build a pharmaceutical industry that exported medicinal products worth USD10.1 billion (DKK58 billion) in 2011? "It is a historical success born through partnership between the industry and the Danish government,"

Denmark VS Sweden

Biogen Idec is building up a strong presence in both Sweden and Denmark. Sweden is a barometer market. Denmark is a manufacturing hub.

Johan Ström, managing director for Biogen Idec Sweden

What makes Sweden an attractive place to invest for Biogen Idec?

"Many of my international colleagues say that changes in the health care systems often happen first in Sweden. One aspect is the value-based pricing & the reimbursement system.

Another aspect is the regional health care structure in Sweden with County Councils focusing on cost-containment measures, e.g. decentralizing costs to the clinics and exploring new innovative pricing models.

There is also a strong ethical focus on the need for open and transparent collaborations between the life science industry and health care professionals. You have to add value to the healthcare system, irrespective of whether you are coming from the medical affairs department or from sales or marketing. That makes the Swedish business model very interesting for a company like Biogen Idec.

Birgitte Thygesen, director, administration & government relations, Biogen Idec Denmark

Hillerod, Denmark is home to Biogen Idec's International Packaging Manufacturing unit, Quality Assurance and Quality Control laboratories, and a newly constructed Large Scale Manufacturing facility.

What makes Denmark an attractive place to invest for Biogen Idec?

"For a pharmaceutical and biotech company, it's extremely important that you manufacture products in a safe and stable environment with access to a well-qualified work force. Denmark has that. The country's long track record in biotech means that there generally is a good understanding of the business conditions needed not only for research and development, but also for manufacturing activities."

CEO-Talk

The two Danish pharmaceutical companies that grew biggest under far-sighted ownership have been Lundbeck and Novo Nordisk. Focus Reports sat down with their CEOs to discuss the companies' recent successes.

Lars Rebien Sørensen, President & CEO, Novo Nordisk

Governments in many of your key markets are pushing to cut expenses. How has Novo Nordisk coped with this situation?

Ten years ago, our overall strategic aim was to introduce new products, but then we realized that because of the financial crisis, societies were beginning to focus more on cost-effective alternatives. If we only looked at the very expensive end of the treatment then we would be foregoing providing our other customers with generic types of medication.

Novo Nordisk manufacturing

This also means that we can now offer the generic versions of Insulin at very low cost; in fact the lowest cost in the world. Because of this we can also offer our products to emerging economies, and even to extremely poor countries.

We like to say that we can offer daily insulin treatment at the same cost as a cup of coffee, anywhere in the world. Coffee is very inexpensive in Brazil, so our insulins in Brazil are also very inexpensive. Starbucks is more expensive in the US, therefore our insulins are more expensive in the United States.

In order to do this well and make a business out of it, large-scale manufacturing is required. Today, we manufacture a little over 50% of all the insulin in the world, providing approximately 20 million people with their daily requirements of insulin, without which they would die.

Ulf Wiinberg, President & CEO, Lundbeck

You mentioned that in the post-blockbuster era, Lundbeck aims to deliver more products to market. To what extent do you need to transform the way the company works to achieve this?

We decided to diversify the business and turn from a European company into a global one. This meant finding products that have a potential of around USD 200-300 million : such revenues still make a product a good one for us.

To use an American baseball term, a blockbuster is a "home run" product. We decided to go for base hits, hoping that some would turn into home runs. Telling your R&D team that they are only allowed to develop blockbusters stifles innovation and the ability to move forward.

Lundbeck Headquarters

As part of the old blockbuster model, all R&D units were self-contained and worked secretly on their own. We are trying to open up much more to partnerships in order to go with the best science, which has led to a number of collaborations and partnerships with academia and small companies.

For instance, we have fantastic partnerships with Takeda and Otsuka. Historically we have had a fantastic partnership with Forrest. It is in this area that you can have a more ambitious agenda, and at the same time get the best knowledge, all while sharing the risk.

said Minister of Trade & Investment Pia Olsen Dyhr.

"Novo Nordisk, for example, benefits from the government's decision to give all patients with diabetes access to free medication. The company has hence been able to build on the domestic market before going global. In the same way, Lundbeck and Leo Pharma benefitted from Public-Private Partnerships to build an export business."

Another shared characteristic of Denmark's top pharmaceutical companies is that they are controlled by foundations. As majority owner, the foundation usually decides who sits on the board, monitors corporate activities, and helps whenever the companies need support, including financial backing for acquisitions. "This model has a lot of potential for innovation and the development of new drugs, something we couldn't do to the same extent if we were just focused on what the stock market wanted us to do," said Lundbeck Foundation CEO Christian Dyvig. The Lundbeck Foundation owns 70 percent of Lundbeck's shares and is majority owner of ALK, a supplier of allergy immunotherapy products with a global market share of approximately 33%.

Can the absence of the stock market as a reality check lead subsidiaries to get too comfortable where they are?

NO CONSENSUS ON CONSENSUS

An essential part of the Nordic model is strong cooperation between industry and government. How do those at the front-lines of the battle, the heads of the industry associations representing innovative companies, judge the strength of the cooperation in their respective countries?

Ida Sofie Jensen, director, Lif Denmark
I think we are good at having a dialogue with one another. Our politicians are sensible; they are not setting up walls against the industry. They are in dialogue with us and are ready to make Danish solutions.

Anders Blanck, director-general, Lif Sweden
It is very good. And it has to be, and that is the problem. We have no conflict in Sweden. We hardly have any political conflict at all; people do not like conflict. Even if you disagree, you still make it sound as if you agree. Because the system is consensus-based, there is no political discussion on where the healthcare system is going.

"That is a risk," Dyvig said. "Academic articles on foundations describe the notion of the dead hand. An owner with a dead hand loses dynamism in the business. That's one of the reasons that we like our companies to be stock listed. The duality between the long-term nature of the foundation and the short-term nature of the stock market brings a lot of benefit. It is in that friction that you end up having the best results."

PUSHING AND PULLING

Most stakeholders in the Danish and Swedish life-sciences industry praise the outcome of concerted efforts to set up the right pull-factors for innovation—the framework to enable pharmaceutical research to flourish. Finding consensus over the push-factors—government's willingness to pay for new innovative products to be used by the healthcare system—is much more challenging.

In Sweden Government spending on academic research has increased significantly even throughout the economic crisis, and in October 2012, the government put forward its Research and Innovation

Stepping out of the shadow, technically speaking

NNE Pharmaplan traces its roots to a technical department within Novo Nordisk. Spun off as an independent entity in 1990 with its parent company retaining 100% ownership, this pharmaceutical engineering and consulting house has enjoyed great success. But as CEO Morten Nielsen, explained the company never forgot its roots—and has always championed the strong ethics and uniquely Danish management style of its parent company. This is NNE Pharmaplan's growth story:

On winning business outside of Novo Nordisk: "Novo's growth phase between 2000 and 2003 precipitated high growth in our own business. However, at the end of 2003, when the project pipeline dried, we were faced with a harsh wakeup call. We had to consolidate our business and significantly reduce our headcount. At that point in time, we realized we needed to build a sustainable business model that was not dependent on Novo Nordisk. In 2006, we celebrated a milestone: for the first time, our quarterly sales to external companies exceeded those to our parent."

On accelerating growth: "In 2007, we bolstered our growth by acquiring Pharmaplan. In that sense, you might say that our company—in its current form—is six years old. Pharmaplan was interesting for us because they had a similar story to our own: they were once a technical department within Fresenius, a German medical care company. Through the Pharmaplan acquisition, we integrated 350 fantastically talented people into our organization, we entered highly attracted geographies such as India and Russia, and we reinforced our presence in markets like France and the U.S."

On differentiating from the competition: "One reason for our success is the fact that both of the entities that combined to form our organization came from within the industry. That heritage gives us a great deal of credibility among our customers. We are not a diversified engineering company. Many of our competitors are engineers that developed expertise in pharma, while we come from the other direction: by heritage, we are a pharma and biotech company, which by coincidence has an interest in engineering and consulting."

On the future: "We want to become the market leader in pharma and biotech engineering. You might say that we are already there—and yes, we are in the top three today, and likely the number one focused company in the industry. But globally, the market is absolutely huge, and our share of it is only approximately six percent. There is still much more of the pie that we can capture."

One for All, All for One

In the search for market share in Europe, the Nordics pose an interesting opportunity for multinationals looking to gain access to additional mature markets outside of the traditional big five in Europe. "The countries of the Nordic region combined form the 12th largest economy in the world," said Anders Löfgren, CEO of Nordic Drugs, one of the biggest homegrown market access companies in the Nordic region. "There are many companies that struggle to deal with the practicalities of having a region that seems to share so many similarities on the surface, but that on a deeper level have significant differences," he said.

"The investments needed to enter each individual country in the region are very high, and the process of setting up local representation has to commence years before the first product can be brought to market," explained Löfgren.

It is this particular challenge that Nordic Drugs has turned to its advantage: since its foundation in 1996, the company has developed the expertise to take a product through each development stage in each Nordic market, as it is currently doing with Teysuno, an oncology product from Japanese company Taiho Pharmaceutical Co.

bill, under which USD 600 million will be spent between 2013-2016 to boost Swedish research capabilities. One of the bill's six focus areas is the life sciences industry.

At the same time, Sweden may soon link its existing value-based pricing system with international reference pricing to cut drug expenditures. The pharmaceutical industry warns this change would have an adverse effect on both the attractiveness of Sweden as a market and as a location for R&D activities.

"The focus is solely on the push-part of the business," said Anders Blanck, director-general of Swedish pharma industry association LiF. "The government wants to build the infrastructure for a well-functioning life-science sector in Sweden, but does not want to talk about markets, about using new products and paying for them."

This is especially surprising for a country with GDP far exceeding EU average. "Even though the Nordic region is better off than the south of Europe," IPSEN's Tommy Söderman, said, "it has still been tough for the pharmaceutical industry, especially in terms of pricing for products that have been around for a number of years."

In some respects the Nordics even lag behind European peers. "In terms of market uptake and penetration, it takes

From left: Tommy Söderman, General Manager Nordics, IPSEN; Tom Rönnlund, General Manager Nordic & Baltic Region, IMS

a lot longer compared to other European countries to get market acceptance for innovative products," Krumins of Boehringer Ingelheim said, speaking of Sweden. "It is much tougher now than it used to be, because of the many stakeholders at national but also regional and local levels. Whilst we can have products authorized and reimbursed, they might not be used by the healthcare system at the regional level or local level."

Tom Rönnlund, General Manager Nordic & Baltic Region for IMS, agrees that the industry faces serious challenges. "Austerity measures and efforts to reign in expenditures on pharmaceuticals are coupled to a longer-term trend of changing rules for the way in which pharmaceutical companies are expected to interact with the healthcare system. This concerns rules for meeting and interacting with care providers, how companies are able to arrange different kinds of activities for GPs, etc in the Nordics."

But this increased scrutiny also offers an opportunity to the international industry. "The change process, especially regarding the evolving business models, has been going on in the Nordics for a little bit longer than in other markets," Rönnlund said. "That allows the industry to be slightly ahead of the game. Many companies have also used the Nordic markets for piloting innovative approaches to act in the best possible way in this environment."

Part of the key to success is realizing that traditional sales models no longer work. "The times are over that you have a detailed aid and sell something—that

TOP 10 COMPANIES IN THE NORDICS BY REVENUE
NOVARTIS
PFIZER
JOHNSON & JOHNSON
ORIFARM
GLAXOSMITHKLINE
ROCHE
MERCK & CO
ASTRAZENECA
SANOFI
ORION

Source: IMS MIDAS Quantum

does not fly anymore," said Markku Santonen, general manager Nordic & Baltic, Amgen. "You need to understand the medicine and the value the medicine can add to a certain group of patients."

Amgen adapted its organization and tactics in the region to meet the new environment. "It used to be more about demand generation; this is no longer the case in Scandinavia. We need to combine the market access, health economics, and the commercial part. It is not easy, but it is the way in which the Nordics as a group are moving," Santonen concluded.

Is the 'Nordic model' really the key explanation behind the remarkable success of the Danish and Swedish life sciences industry? In Denmark, cooperation between government and industry is praised by both sides, and it is safe to say that it supported the industry's focus on the long-term and on niche areas such as diabetes, CNS or allergy.

From left: Markku Santonen, General Manager Nordic & Baltic, Amgen; Morten Nielsen, CEO, NNE Pharmaplan

In Sweden, the situation is more complex. Although the government has set up a solid framework for innovation to thrive and to support the life sciences industry, satisfactory cooperation often seems to be lacking.

"There are good initiatives in Sweden," said Rönnlund. "But they sometimes feel a little bit like a late wake-up call. Only when AstraZeneca shut down a big chuck of its research operations in Sweden the government hurried to drum up plans and policies around innovation. The Danish government and their ambitions, working together with the pharmaceutical industry association and other players, are slightly more concrete."

But the Nordic model is first and foremost cross-country partnerships like the Medicon Valley Alliance which facilitate the convergence of technologies, clever networking and the consolidation of niches in which the Nordics display a strong heritage. "That is the process we are in now—building up beacons, or areas with one shared headline in which we combine different strongholds and disciplines," Jørgensen concludes. As the Swedish band ABBA would probably say, take a chance on the Nordics.

Continued from Page 37

on depression sufferers who also experienced pain symptoms, Lilly could have embraced a broader positioning, but this would have diluted its effort. Eli Lily had a lot riding on Cymbalta; Prozac lost patent protection shortly before the launch, and Cymbalta needed to fill the gap. The depression category already had several blockbuster drugs, and promotional spending was second only to the proton pump inhibitor class for heartburn.

Furthermore, existing SSRIs were all considered similar in efficacy, with no head-to-head clinical trials available for the class. Lilly received a diabetic nerve pain indication on Cymbalta two months after receiving its depression indication in 2004. This niche gave Cymbalta a reason to exist in a very crowded and competitive marketplace. It has since received additional pain indications for fibromyalgia and chronic pain. Prozac sales peaked in 2000 at $2.6 billion—a threshold Cymbalta blew past in 2009.

Narrow to grow

Narrowing a positioning can accelerate growth even once a product is on the market. This repositioning technique can breath new life into struggling products.

One company we've worked with had recently entered the hypertension market with great promise. The category is huge; it's the largest office-based condition treated by physicians with nearly $14 billion in 2011 sales. The new drug attained the coveted regulatory approvals with clear, clinical superiority versus its two branded rivals.

Despite these advantages, the new product struggled in the market. It faced intense rivalry from a host of branded and generic competitors that were already meeting most every apparent need. Adding to the challenge, there was little motivation on the part of physicians to try something new, and intense pressure from payers for them to prescribe generics.

After the new product failed to meet expectation at launch, further research and analysis indicated that a niche positioning could reinvigorate the brand. The marketing team concluded that the best way to gain traction would be to narrow the focus in two ways. First, it would focus on its one main product attribute—strength—where the brand had clinical superiority. Second, it would focus the target audience on those patients for whom strength mattered most—physicians who treat patients whose blood pressure was not being effectively controlled by other medications.

With a clearer positioning focus, the company is now able to intensify the efforts of its sales force against a physician audience that has a more compelling reason to consider the new drug.

Why does it work?

Niche positioning might imply going after a small market. Rather, it means going after a select market that has intense needs. If a niche positioning is executed well, resources will be more focused where they will achieve the biggest result. The benefits of taking an enterprise-wide approach to delivering a niche positioning are significant:

- Better targeting of physicians, e.g., more visits to the highest priority doctors, better visibility in their professional associations and publications
- Better targeting of patients, which is especially important if consumer pull is an important part of the marketing plan
- Reduced concern from payers/MCOs of inappropriate prescribing and risk to budgets
- Clinical data and claim support resources focused where they are most important
- Easier to carve out and defend marketing position from rivals
- Improved financial ROI

Where to begin

To build an effective niche positioning, marketers must focus on doing four things exceptionally well.

Start by understanding all the key players. What are the needs, motivations, and constraints of your targeted audiences, e.g., physician segments, patients, or managed care customers?

Involve your team in developing options. Cross-functional perspectives from all groups are critical to a successful niche positioning. It can be a time-consuming process, but insights and consensus should be obtained from all the key players: legal, regulatory, medical, manufacturing, and finance. This helps to avoid bigger problems that can result from having an un-vetted positioning later.

Conduct rigorous strategic analysis and market research. Your positioning options must be put through a strategic filter. Our framework includes evaluations of three core areas:

- How strong is the value proposition—in particular, how valued, unique, and credible is it with your target audience?
- What is financial opportunity balanced against the risk?
- Is the positioning feasible—can your sales force execute it and will it get legal/regulatory support?

Develop a marketing plan that delivers the positioning. Think through the implications of your positioning options on your marketing strategies and tactics. What levers should you pull? These differ based on the audience you need to reach and the message you must convey. Consider all four key stakeholder groups—patients, physicians, providers, and payers. How will each perceive your value proposition? With which group will you obtain the greatest leverage in gaining awareness and credibility for your new positioning?

The positioning development process takes times and requires thorough use of market research, analysis, and involvement from senior management and cross-functional peers. But if it's done well, your more focused positioning can drive significant sales growth and enhance careers. PE

Take a Chill Pill

The "tawny streaks and shades" of summer sunlight, as Walt Whitman put it, have a mellowing effect; leisurely hours spent in scenic locales, on vacation or just out on the weekend, provide an opportunity for unhurried thought and easy reflection ("heat dome" notwithstanding). In the spirit of lawn chair cogitation and hammock-spun reverie, *Pharm Exec* invites you to submit your own verses—pharma-related, of course—to be published on our website in late August. Send those jottings from the post-conference tarmac, the hotel bar, or the family vacation to bcomer@advanstar.com, if you are so inclined. Our pseudonymous colleague Stix Daley has contributed one of his recent scribblings to kick things off. Summer will be gone soon, so take it slow while you can, and enjoy. *—Ben Comer, Senior Editor*

Pharmacopoetics

by Stix Daley

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adverse events.
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immunity

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in their due time of course.
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that I
well I guess that I
ought to report.

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Even our immune systems are uniting
in mutiny

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or just an encephalographic
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