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MAY 2015
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VOLUME 35, NUMBER 5

2015 BRAND OF THE YEAR

HCV: *Faces of a Cure*

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From Care to Cure

William Looney
Editor-in-Chief
wlooney@advanstar.com
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PHARM EXEC'S 2015 BRAND OF THE YEAR AWARD goes to two drugs, *Sovaldi* and *Harvoni,* from one company, Gilead Sciences. Together, the two have set revenue records for newly launched products while revolutionizing the standard of care for the hepatitis C virus (HCV), a dangerous, ubiquitous, below-the-radar threat to public health worldwide.

Not only do they vanquish the virus faster, more completely and with fewer side-effects than previous treatments, *Sovaldi* and *Harvoni* are back-to-back symbols of the innovation chain of continuous improvement—the way new drug R&D is supposed to work. And from a purely commercial point of view, the products are a game-changer, having broken the stereotype of the sclerotic, slow-build launch cycle that appeared to be the industry's destiny just a year ago.

Now it's time to see if the market works its own magic through tougher segment competition that aligns pricing, distribution, and access toward the broader goal of making sure that 160 million patients around the world who need the cure, get the cure. This is where the real story of the pharmaceutical industry gets written, and where the outcome carries significant impact for its reputation.

The situation certainly looks promising. Competition in the HCV drug space has been on a solid upswing since *Sovaldi*'s December 2013 launch. In addition to rendering some earlier, less efficacious treatments obsolete, which is itself a driver of market efficiency, arrival of the two Gilead products was quickly followed by another oral non-interferon-based treatment, AbbVie's *Viekira Pak*. Merck, Bristol-Myers Squibb, and Achillion have drugs in final-stage testing that promise to advance the cure for HCV patients in three distinct ways: (1) a shorter treatment cycle than the current 12 weeks; (2) in all of the virus' six main genotypes; and (3) for victims with specialized comorbidities like HIV and advanced liver disease. Not resting on their laurels, Gilead and AbbVie are doing the same.

Pipelines as flush as this support the broader assertion that true market exclusivity—the period of time when an inventor is a price-setter, rather than a price-taker—is now measured in months, not years. Lack of price transparency aside, discounting of HCV therapies has been intense over the past six months as Gilead and AbbVie vie for share of script in anticipation of the post-launch stretch, with estimated rebates as high as 50% for key US customers like pharmacy benefit managers (PBMs) and Medicaid.

Moreover, almost all the new HCV business in Europe is risk-volume contracting, which caps pricing to a predetermined level of demand. In developing countries, prices have been set at the much lower benchmark of GDP per capita. Gilead has taken the unusual step of licensing *Sovaldi* and *Harvoni* to eight Indian drugmakers who, in return for specified royalty payments, will be able to manufacture and set their own prices for the two drugs in 91 developing countries, a geographic spread that covers more than half of HCV patients worldwide. One licensee, Hetero, launched its version of *Sovaldi* in India in March at a local price equivalent of $11.36 per pill—a tiny fraction of the $1,000 Gilead is said to command here in the US.

Looking ahead, the HCV space offers similarities to the evolution of HIV/AIDS. Innovation, competition, and public visibility gradually transformed that business model, giving payers and patients more options on pricing and greater access to treatment. But there is something distinctive about HCV: it is one of the first major illnesses to make the transition from the chronic care maintenance paradigm to a full, Lazarus-like cure. Among other things, a drug that cures quickly turns the traditional value proposition on its head, at least for some: PBMs, for example, like to spread per patient expenditures over time rather than booking such costs up front. With high turnover in covered lives, PBMs don't benefit from savings that extend long term, so value as defined by outcome fails to resonate.

HCV is complex. Every victim endures its varied symptoms separately. Part of the furor over the cost of these new cures can be attributed to a failure by parties to anticipate how demand would be stimulated by the previous wasteland of options for a hidden, clinically demoralized HCV community. Controversy over the HCV drug rollouts suggest that pharma must put more focus on the epidemiological grunt work of understanding the pathway to disease in different populations, identifying key stakeholders and interpreting their behaviors, anticipating budgetary exposures that impede access, and targeting therapy only to patients whose symptoms fit the indication and the label. Sound familiar? Yes, its personalized medicine, delivered in a multichannel, *not* brand-centric, population health context. Getting this configuration right for the next wave of cures is pivotal to making sure our industry benefits—in revenues *and* reputation—from the sweep of new science.

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VP OF SALES & GROUP PUBLISHER	TEL [732] 346.3018
Russ Pratt	rpratt@advanstar.com
EDITOR-IN-CHIEF	TEL [212] 951.6735
William Looney	wlooney@advanstar.com
MANAGING EDITOR	TEL [732] 346.3022
Michael Christel	mchristel@advanstar.com
SENIOR EDITOR	TEL [212] 951.6635
Casey McDonald	cmcdonald@advanstar.com
EUROPEAN & ONLINE EDITOR	TEL 011 44 [208] 956.2660
Julian Upton	jupton@advanstar.com
SPECIAL PROJECTS EDITOR	TEL [212] 951.6742
Marylyn Donahue	mdonahue@advanstar.com
COMMUNITY MANAGER	TEL [732] 346.3009
Miraj Barodia	mbarodia@advanstar.com
ART DIRECTOR	TEL [218] 740.6411
Steph Johnson-Bentz	steph.johnson@media.advanstar.com
WASHINGTON CORRESPONDENT	TEL [301] 656.4634
Jill Wechsler	jwechsler@advanstar.com
EDITORIAL OFFICES	TEL [212] 951.6600
641 Lexington Avenue, 8th floor	FAX [212] 951.6604
New York, NY 10022	www.pharmexec.com
SALES MANAGER-EAST COAST	TEL [732] 346.3054
Mike Moore	mmoore@advanstar.com
SALES MANAGER–MIDWEST, SOUTHWEST, WEST COAST	TEL [847] 283.0129
Bill Campbell	wcampbell@advanstar.com
SENIOR PRODUCTION MANAGER	TEL [218] 740.6371
Karen Lenzen	klenzen@advanstar.com
AUDIENCE DEVELOPMENT MANAGER	TEL [218] 740.7005
Rochelle Ballou	rballou@advanstar.com
REPRINTS	877-652-5295 EXT. 121
	bkolb@wrightsmedia.com
	Outside US, UK, direct dial: 281-419-5725. Ext. 121
CLASSIFIED SALES & RECRUITMENT	TEL [440] 891.2793
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William Looney, Editor-In-Chief

Pharm Exec's 9th annual Brand of the Year is Gilead Science's back-to-back oral treatments for Hepatitis C, *Sovaldi* and *Harvoni*. Our feature profiles how both drugs have reversed expectations around the listless product launch and revived the industry's reputation for startling breakthrough innovations—from care to cure.

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On The Cover: *Harvoni* patient Gavin West.

Market Access

Pricing's Point Man

William Looney, Editor-In-Chief

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Multiethnic Marketing: The Billion-Dollar Upside

By Steve Millerman

The "multicultural" segment is the fastest growing consumer segment in the US market, with significant treatment gaps that collectively could be worth extra billions in pharma profits. Realizing these riches, however, requires new and more aggressive approaches to brand planning and consumer engagement.

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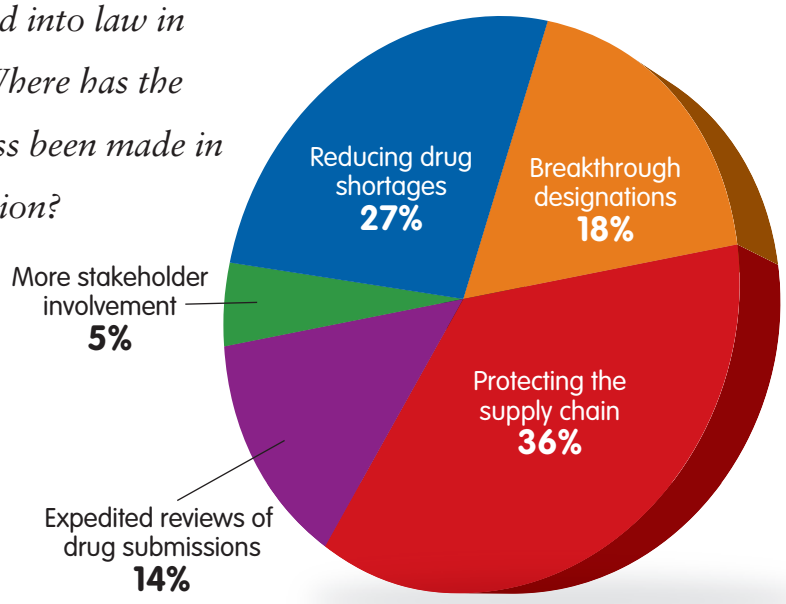
Data Point

Poll data courtesy of online *Pharm Exec* readers between July 21 and August 15, 2014

Q: FDASIA was signed into law in July 2012. Where has the most progress been made in implementation?



Readers Weigh In

Shifting costs to the individual does not change the price pressures, it changes the usage rates. This change in usage rates will result in a decrease of healthcare expenditures. Just as passenger trains were supplanted by cars and airplanes for transportation (and the government took over passenger trains), the current infrastructure for healthcare will be replaced by new industries. People will still need doctors, hospitals, and drugs. How they need them will change. That will be the only universal fact.

Phil Burns, 4/9/15
"Pharma Pricing: Striking a Post-ACA Balance"
bit.ly/1Q2TaTi

Twitter Talk

■ *@PharmExecutive My view is the Cancer Drugs Fund is a "sacred cow." Even when a more measured debate occasionally emerges, tabloids/populist views suppress it.*

Tim Mustill, @Astrocytecomms, 4/21/15
"The UK Election's Hot Healthcare Topics"
bit.ly/1P6PMER

■ *Skeptical, but happy if true.*

Salil Kallianpur, @salilkallianpur, 4/13/15
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Cost & Coverage Challenges for Pharma

Insurers and payers demand lower prices—along with quality and innovation

Rampant concerns about the affordability of, and access to, new life-saving therapies is widening the Great Debate over how much society should pay for new biomedical discoveries. Insurers, pharmacy benefit managers (PBMs), and public and private payers continue to challenge pharma prices, heightened by concerns about covering more new medicines to treat widespread conditions such as high cholesterol and diabetes.

The result is closer scrutiny of product value, pressures to boost discounts and rebates, and support for less costly biosimilars to spur market competition. A sign of the times is a move by prominent hedge-fund operator Kyle Bass to launch a fund that will gain from his challenges of drug company patents that Bass believes are spurious and designed to jack up drug prices. National Institutes of Health researchers recently published an article in the *Journal of the American Medical Association Oncology* (April 2, 2015) documenting that many new, costly cancer therapies fail to extend survival. Medical breakthroughs in the war on cancer continue to make headlines, as seen in the recent PBS special report on cancer. While highlighting exciting scientific discoveries that could transform this "emperor of all maladies" into a manageable condition, it discussed fears that high prices could limit access to innovative therapies.

More transparency

One response from payers is to demand that pharma companies provide more information on development costs and marketing expenditures for high-cost medicines. Oregon legislators recently followed California's lead in proposing legislation requiring manufacturers to file annual cost reports for medicines with wholesale acquisition costs of $10,000 or more a year. The reports would disclose R&D outlays (including acquisition, licensing, and clinical trial costs), marketing expenditures, total profits attributed to the drug, and financial assistance provided to patients. Pharma and biotech companies protested that such proposals ultimately would block sales of covered products in the state, due to the risk of revealing proprietary information, particularly for small, privately held firms.

Insurers also look to gain leverage in negotiating discounts with pharma companies by becoming bigger players in the PBM business. UnitedHealth recently paid $13 billion for Catamaran, which, when combined with its existing OptumRx, will compete more directly with field leaders Express Scripts and CVS Caremark in a more consolidated field.

More transparency in European drug pricing could result from increased collaboration among the national health programs of 27 European nations, according to a March report on "Access to New Medicines in Europe" from the World Health Organization (WHO). Agency analysts urge European authorities to share information on drug cost-effectiveness and to adopt off-label drug uses that save money, such as treatments for age-related macular degeneration. While the report applauded the development of more new therapies, it seeks to ensure that patients "are not provided with expensive new medicines that offer little or no improvement in health outcomes." And where market approval is based on limited preliminary data, WHO advises regulators to utilize adaptive licensing or conditional approval strategies to limit patient exposure pending confirmation of zproduct safety and efficacy.

One response from payers is to demand that pharma companies provide more information on development costs and marketing expenditures for high-cost medicines

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

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Medicare strategies

At home, Medicare is looking to update drug payment and coverage policies to gain more control over outlays for prescription drugs that look to increase significantly. The Centers for Medicare and Medicaid Services (CMS) is encouraging physicians to prescribe new biosimilars headed for market, as seen in its recent statement clarifying that providers will be reimbursed equally for administering a biosimilar therapy under Medicare Part B, as for the innovator product. CMS also issued a unique Q code for Sandoz' recently approved *Zarxio* (instead of waiting a year) to encourage provider uptake.

New CMS guidance also encourages sponsors of Part D drug plans to add a new biosimilar to formularies by noting that such changes can be made at any time. Adding the biosimilar to the reference product on the formulary, though, won't meet the two-drugs-per-class requirement, but that should boost a plan's leverage in negotiating better rates since either the brand and/or the biosimilar could be excluded from formulary altogether, explains Amada Bartelme of Avalere Health.

Meanwhile, the Medicare Payment Advisory Commission (MedPAC) continues to examine a range of strategies for managing program spending on pharmaceuticals. Its analysts are examining better ways to address "polypharmacy," particularly for elderly patients on pain medications, to evaluate how bundling of Part B oncology services may encourage appropriate use of oncology drugs, and to weigh alternatives for how Part D plans assume risk for high-cost beneficiaries.

FDA to examine drug ads that compare costs

Proposals to steer consumers to less expensive therapies assume that more reliable drug pricing information will help patients and prescribers make wiser healthcare choices. FDA's Office of Prescription Drug Promotion (OPDP) will examine this issue in a study on how comparative cost information in drug advertising and labeling influences patient treatment decisions.

FDA explained in a Federal Register notice of April, 3, 2015 that it permits sponsors to provide truthful, non-misleading information about comparative drug prices in promotional materials for both health professionals and consumers. But the agency is concerned that without sufficient context on the similarity (or lack of similarity) of cited drugs, consumers may get the wrong impression that the products are interchangeable, and that price is the main factor to consider in selecting treatment. To find out, OPDP will survey some 3000 people online about how drug price messages affect their perceptions of drug safety and efficacy.

Limiting patient costs

A main response from pharma marketers and some patient advocates is to promote strategies to minimize out-of-pocket (OOP) drug costs for patients. They support bipartisan legislation that requires insurers to charge individuals fixed copayments instead of the 25%-30% cost-sharing on high-tier specialty medicines, which translates into OOP payments of $25,000 on new therapies priced at $100,000 a year or more.

A related tactic is to shift important medicines out of high-cost formulary tiers and to reduce prior authorization and quantity limits that make certain drugs hard to obtain. The AIDS patient community has charged plans that place HIV medicines in high-cost categories with discrimination against HIV-AIDS patients. That prompted Aetna to announce a few weeks ago that it would move most HIV drugs in its CoventryOne operation in Florida from specialty to generic or non-preferred tiers. "Adverse tiering" of drugs for high-cost conditions, such as cancer, diabetes, rheumatoid arthritis, as well as AIDS, may violate anti-discrimination standards for qualified health plans under the Affordable Care Act.

Meanwhile, federal and state prosecutors are keeping a close watch on pharma pricing and discounting strategies to uncover evidence of kickbacks or fraud. In February, AstraZeneca agreed to pay an $8 million penalty to settle charges with the Justice Department involving discounts to a PBM to gain exclusive formulary placement for its *Nexium* heartburn pill. The feds challenged such "hidden financial agreements" and affirmed its continued interest in formulary placement deals. Errors in reporting drug pricing data to Medicare also has led to fines and legal action, as seen in Novartis' agreement in March to pay a $12.6 million fine to settle charges that its Sandoz unit submitted faulty data to Medicare Part B. PE

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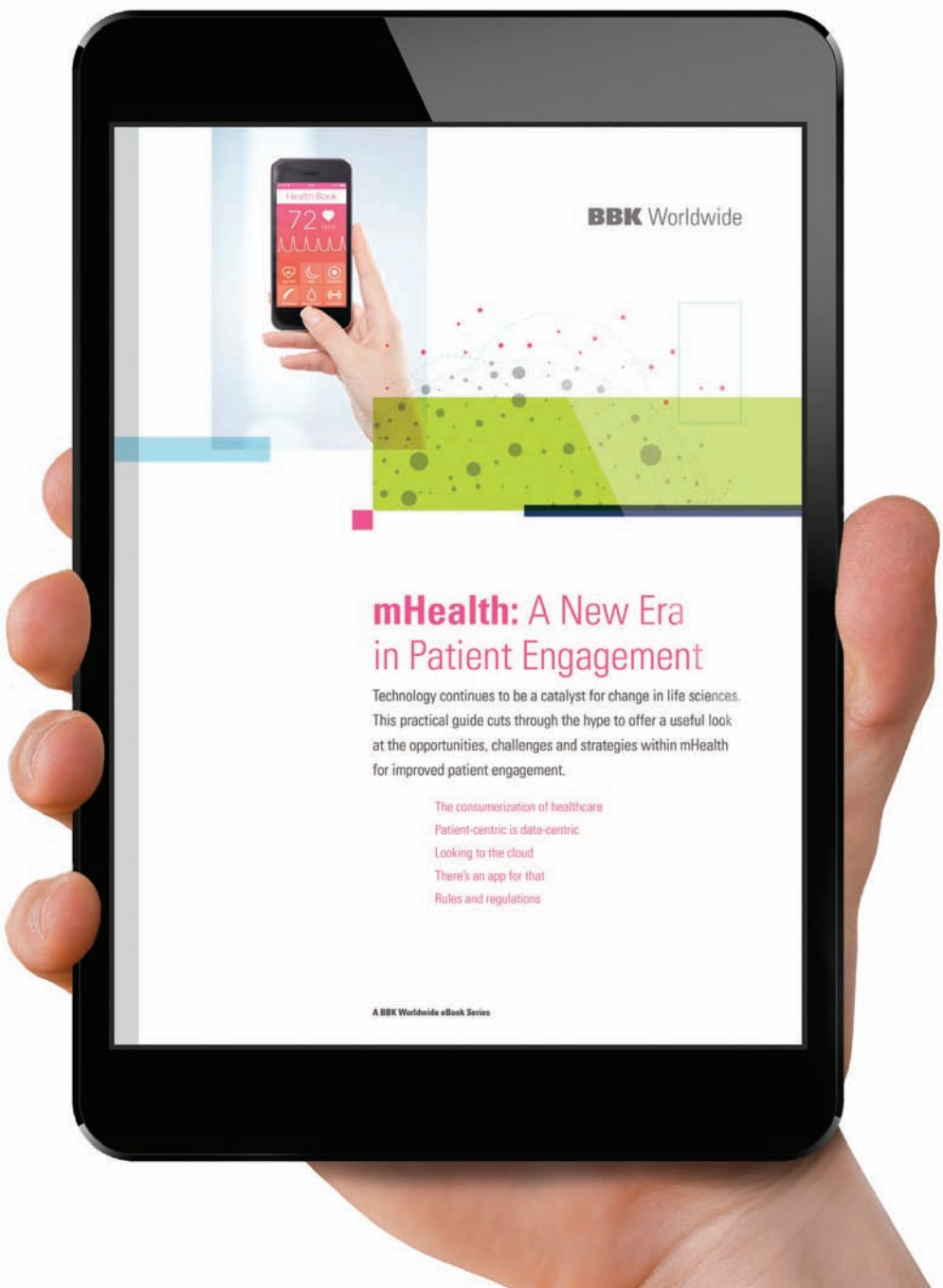

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GLOBAL PATIENT RECRUITMENT AND ENGAGEMENT

Front & Center

A Hub with a Heart

Manufacturers helping patients access expensive, potentially life-saving specialty therapies for chronic diseases and providing support throughout the patient journey is not only good patient care, it is also good business in what's becoming a highly competitive specialty drug market.

The drug pipeline is filled with specialty medications that offer new hope to patients facing complex, chronic conditions. As the fastest growing healthcare drug segment in the U.S. today, specialty pharmaceuticals are expected to represent more than half the total pharmaceutical sales by 2017 with global revenues reaching $236 billion, according to IMS Health.

With growth comes change and with change come challenges. Such is the case with specialty pharmaceuticals and the process of bringing them to market. Expensive to produce and to acquire, specialty drugs present key stakeholders—physicians, patients, payers, pharmacies and manufacturers—with unprecedented cost and access pressures. Manufacturers need a deep understanding of the reimbursement landscape, as well as an ability to work effectively with payers to ensure that therapies are promptly accessible and out-of-pocket costs for patients are managed. And that's just the beginning. Given the nature of the drugs themselves (often requiring special storage and complex treatment regimens, with a limited access network), patients need high levels of support and education to ensure proper administration and compliance.

In response, biopharmaceutical companies have been strategically shifting their commercial approach from product focused to patient-centric; including incorporating nursing support, alternate funding guidance and patient assistance programs (PAPs) into full-service reimbursement Hubs. Currently, annual industry spending for PAPs is estimated at $15 billion, including free drug samples along with $5-6 billion on copay assistance.

Diana Hampton, Product Support & Innovation, United BioSource Corp. (UBC)

"A well-designed reimbursement Hub should serve as the center of activity to help patients, caregivers and prescribers navigate administrative obstacles while offering a variety of support services to patients," said Diana Hampton, Reimbursement Product Support and Innovation at United BioSource Corporation (UBC), an Express Scripts Company.

Hampton was in Baltimore in early March at CBI's Annual Patient Assistance & Access Program (PAAP) conference, where she hosted a panel with industry executives on "New Waves of Patients and Evolving Patient Assistance Models."

As a leader on UBC's Product Support and Innovation Team, Hampton is responsible for the management of reimbursement and clinical services, the implementation and operation of manufacturer-funded centralized referral Hubs, and management of manufacturer-sponsored PAPs. Her 30 years of experience in the healthcare industry include Accredo Specialty Pharmacy and Aetna Health Insurance. In 2004, she joined UBC, a leader in support services geared to the specific needs of specialty drugs and known for its skill in reading market data and generating evidence for their clients.

Uniquely positioned, UBC provides a full-range of integrated, comprehensive clinical, safety, and commercialization services by working with Express Scripts as well as specialty pharmacy and distribution organizations Accredo and CuraScript.

Following the panel discussion, *Pharmaceutical Executive* asked Hampton about UBC's differential: **Specifically, how does UBC provide patients with what, by all reports, is an unusually personal experience?**

"People," she replied. "We first work with manufacturers to ensure that each UBC program manager is someone with whom the client can have a great relationship. It's important they like each other; especially given all the time they spend together on the phone. The same holds true for our people assisting

patients on the phones. We make sure they have a voice of compassion, a voice of understanding, and a passion for what they do."

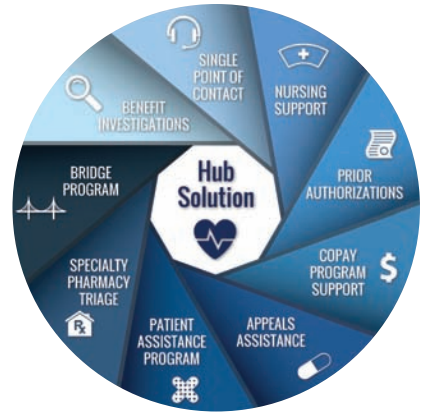
Hampton herself comes across as warm, engaging and utterly accessible. When told she could be the embodiment of the ideal UBC patient-services employee, she laughed. "I talk to a lot of manufacturers about our services. Sometimes one of them will tell me, 'It's so easy to see that you love what you do.' And it's true, I do, but you have to love your job when you're helping patients. Caring is the message we try to impart to patients on the phone —whether it's a very flustered parent who just has found out her child is seriously ill or a caregiver helping his elderly parent. We go to great lengths recruiting, hiring and training the right group of people. It's what sets us apart as a Hub."

Connectivity: 360° patient view

What does centralized and personalized patient support mean?

"At UBC, we recently invested a large amount of capital into creating what I like to call our 360° view of the patient. Other Hubs in the same space might have their reimbursement on one data platform, nursing on another, and patient assistance on yet another, which leads to patient disconnect. We wanted the patient's journey to be as seamless as possible," said Hampton.

"Our technology allows for one entry point for the patient. And from then on whoever touches that patient is able to instantly access a complete, holistic view of him or her and a map of their patient journey so far—whether the patient is on patient assistance and getting free product, or whether the patient needs injection training, or whether the patient is going through a prior authorization or an appeal process," said Hampton, adding that whatever their need, patients always have access to an advocate he or she can identify with who is focused on providing the support needed.



Reimbursement Hub services can be tailored to best support a product's patients, prescribers and payers.

Reading the market

Capture, management, and sharing of patient and product data are of great interest to specialty drug manufacturers. A special concern is with real-time access to various data types in order to be able to monitor and understand the product's performance. How does UBC's technology meet those needs?

"When I first started in the industry, manufacturers were mainly focused on just getting patients on therapy. Now they want to follow the patient's journey in its entirety, to see the barriers and roadblocks patients may encounter, which payers were denying product, and if a product was being denied, why? They want to know if the payers are saying a therapy is not medically necessary for this patient population. Or whether another drug is in the marketplace that's less expensive and the patient's coverage requires them to try that first. With our technology we can provide a manufacturer with data elements to quickly give insights into barriers that need to be addressed," said Hampton.

"Express Scripts, our parent company, manages more than one billion prescriptions per year for tens of millions of patients. HIPAA-compliant data we can gather from these prescriptions provides insights as to how pharma can better serve their patients and how they can better position their product. A manufacturer can say to us, 'I'm one of five manufacturers that offer a drug in this disease category. How can you help me look at my market share within my space?' Not only can we look at one-third of the U.S. population in this disease category, with this diagnosis, and in this geographic location, but we can also drill deeper into the particular space and provide additional data back to our manufacturer. No other organization has the ability to do that."

Speed to therapy

A patient with a newly diagnosed rare disease can face reimbursement challenges and lengthy delays in therapy initiation, which, in turn, reflect badly on the product itself. How can UBC's Hub help?

"Integrating a UBC Hub with Accredo Specialty Pharmacy shortens the lag time between prescription submission and therapy initiation—a success for both the manufacturer and the patients," said Hampton.

"Our connection to Accredo can help a patient who is seriously ill with a chronic disease get onto therapy as soon as possible. So, if UBC is the Hub and Accredo is the SP, speed to therapy is that much faster. And if, during our benefits investigation and prior authorization research, we find that Accredo is the specialty pharmacy, or one of the specialty pharmacies in network, we can send the patient's prescription over to Accredo, and they will not have to duplicate any of our efforts, which another pharmacy would be compelled to do because of risk. Accredo trusts us. After all, we're family."

Welcome to the HTA Jungle

Edging through the complex terrain that is health technology assessment in Europe

"Tell me what your drug is worth and I'll tell you what you can charge" used to be the approach that pricing and reimbursement authorities took when a company came onto the market with a new medicine. It was rarely an easy exchange, but it was relatively direct.

Not any more. The rise of health technology assessment (HTA) has brought new layers and new players into the process. The intention—getting better value for money—is legitimate and laudable. But in practice, HTA is turning what was already tough terrain into a tangle of new complexities.

Naturally, nothing in Europe is ever simple. Companies have always had to negotiate their prices with the pricing authority in each of the European Union (EU) countries. But now they are also obliged to pre-negotiate with the multiplicity of different organs and organizations that advise the authorities. And because there is still no real Europe-level agreement on how to conduct HTA, each of these advisory bodies has been developing its own approaches to evaluating drugs—often reaching strikingly different conclusions and delivering equally divergent advice.

Reuse of joint work

The obvious answer is to see where common ground can be found among these bodies—and that is just what has been going on in Europe for a decade now, ever since the European Commission and Council of Ministers targeted HTA as "a political priority" in 2004.

But it is slow work. The latest in a long line of worthy but limited efforts will shortly see the light of day in the form of a reflection paper on "Reuse of joint work in national HTA activities." This has been in gestation since last autumn, in a French-led working group with a mandate to explore how to "facilitate take-up and reuse at national level of HTA production, including information and joint assessments."

EU insiders were recently given a glimpse of the group's work-in-progress, to see how it was advancing and how national or regional HTA authorities could support its reuse in their own activities. The outline that was presented suggests very reasonably that partial replacements for national assessments could include joint assessments reports, rapid relative effectiveness assessments, and full or comprehensive HTAs—making use of submission templates and methodological standards and coordinated generation of additional evidence.

But the way the draft tries to set out why and how common work should be used immediately demonstrates the delicacy of the exercise; it says more about the obstacles than the objectives, and more about the process than the content. "Recommendations shall not interfere with member states' competence in deciding on the implementation of the conclusions of HTAs and shall not harmonize any laws or regulations of the member states," it states, adding that the recommendations "shall fully respect the responsibility of member states for the organization and delivery of health services and medical care." Thus the group pre-emptively deflects any suggestions that it is deploying its tanks on the wrong lawns. And in case that isn't clear enough, it repeats the need to "respect national responsibilities of member states and their HTA bodies to define their national/

The way the draft tries to set out why and how common work should be used immediately demonstrates the delicacy of the exercise; it says more about the obstacles than the objectives, and more about the process than the content

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

Photo: Getty images / Westend61

regional legal framework and working practices for implementing HTA, and exclude aspects related to pricing and reimbursement issues."

Cold embrace

These sentiments have not gone down too well with some of the constituencies that have seen the outline. Industry, in particular, was hoping for something more operationally useful and more detailed. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has itself been exploring options for making some use of joint HTA work with its own member associations. On the basis of the limited experience so far, the overwhelming industry conclusion is that generalizations are not enough. Any examination of what might be a useful replacement for part of a national HTA will have to be specific about what it replaces in which country's individual system. Also important are what complementary measures might be needed in each case to fit into the idiosyncrasies of each country's way of going about HTA.

In other words, flailing at the challenges with broad concepts is not going to cut a path through the undergrowth. The different and divergent national approaches to HTA already constitute something of a jungle, so adding new lianas is going to make things more difficult, not easier. Something more precise, more surgical, with sharper edges and closer attention to the real conditions on the ground will be needed.

Still time to refine

The game isn't over yet. The working group is still working on its draft, which should appear in finished form later this year, and may prompt a welcome for its content rather than just for its intentions.

Despite all the evident difficulties, there is high-level support for pushing ahead with HTA. The European Medicines Agency (EMA)—one of the most energetic forces in European health policy, despite its strictly limited remit—has been brokering intensive dialogue between HTA bodies, regulators and companies, and most conspicuously in the context of its high-profile adaptive pathways project to bring drug development procedures into the 21st century. And faithful to its remit under the legislation that provided the first firm base for HTA in Europe—the 2011 cross-border patients directive—the Commission is committed to helping the HTA process move forward.

Ladislav Miko, the Commission's acting director general for health, recently confirmed that it plans to launch a new joint project on HTA in 2016. He noted that the Commission is "actively engaged in strengthening cooperation with HTA bodies and other key players in the debate to facilitate access to innovative medicines." The synergies that can be created "are in the best interest of European patients," he said, and "that is also why we have invited the EMA to be part of the HTA network."

Worth the risk?

Bringing EMA closer into the process could bring that sharper edge to the discussions, because—even in its current leaderless state after Guido Rasi was unceremoniously removed from his post—it can offer an unrivalled corps of focused expertise to the issue. It also, however, brings a new challenge. If member states are resistant to aligning their HTA systems in a way that makes Europe look more of a *jardin anglais* than a jungle, and are cautious of any attempts by the HTA network to usurp their authority by offering to trim the excessive growth, how will they feel if an EMA bulldozer comes charging through to drive a highway across their private, if unkempt, domains? PE

Front & Center

Patient Access for Biosimilars: Creating a Differential

Providing a high level of reimbursement services and patient-therapy management support will be a necessary component for creating brand value in the biosimilar marketplace.

Zarxio, the United States' first biosimilar, was approved by the FDA on March 6, 2015 under the new Biologics Price Competition and Innovation Act (BPCIA). Manufactured by Sandoz, Novartis' generics unit, Zarxio contains the same active ingredient (filgrastim) as Amgen Inc.'s Neupogen, which generated sales of $1.2 billion worldwide last year. Zarxio was approved as a biosimilar (not an interchangeable product) for the same five conditions for which Neupogen is used—preventing infections in cancer patients undergoing various treatments.

On the heels of Zarxio's approval, Amgen announced it had filed for a preliminary injunction to block the sale of Zarxio in the U.S. Sandoz has been marketing Zarxio under the brand name Zario for several years in Europe, where biosimilars have been available since 2006. A U.S. District Court judge denied Amgen's motion, ruling that there "exists no substantive bar to market entry for Sandoz's biosimilar filgrastim—and, consequently, no basis on which Amgen is entitled to injunctive relief or other remedies for disadvantages it may suffer due to market competition from Sandoz." Amgen has urged the appeals court to reconsider.

Is this what the future holds for biosimilars—challenges to development and commercialization from an originator followed by further litigation? Should biosimilar manufacturers with drugs in the pipeline be fastening their seatbelts in preparation for a long, litigious road to market?

"The innovators have really brought incredible life-saving medications to market," said Tom Doyle, Executive Vice President, Commercial Solutions H. D. Smith and Triplefin. "And, they are not going to easily step away from those molecules—the investment made in the sites of care or the patient-support services."

Tom Doyle, Executive Vice President, Commercial Solutions, H. D. Smith & Triplefin

While the biosimilar market may not be for the faint of heart, Doyle pointed out the potential rewards. IMS estimates the entire biologic market to be $169 billion, of which the biosimilar market is forecasted by Allied Market Research to reach up to $35 billion by 2020.

"If you take a look at the opportunity from a sales standpoint, the market is going to continue to grow if only from the perspective of the large number of upcoming patent expirations we're going to start to see locally over the next five to six years. Along with the existence of clearer regulatory frameworks for biosimilars, there's a very significant financial reason to be invested in the space, which, I might add, also offers room for innovation, and a chance for biosimilar manufacturers to change the patient experience while on their drug."

Doyle made his remarks to *Pharmaceutical Executive* following his presentation, "Patient Access Offerings for Biosimilars," at CBI's Annual Patient Assistance & Access Program in March.

Doyle speaks from experience. With 25 years in the pharmaceutical industry, his background includes directing trade and U.S. commercial operations at 3M Healthcare and launching its Canadian pharmaceutical business unit. In 2010, Doyle joined H. D. Smith, the nation's fourth largest drug wholesaler, with an eye on building the company's expansion to support specialty products, including biosimilars. Doyle leads H. D. Smith's commercialization for its subsidiaries—Smith Medical Partners and Triplefin. In this role, he leads commercialization teams supporting customers throughout the pharmaceutical supply chain and represents key products and services, which improve patient access to medications. Doyle also helped to diversify and expand the company by launching a third-party logistics business that supports manufacturer's distribution and clinical trial supply needs. In anticipation of the changing healthcare landscape and the proliferation of specialty pharmaceuticals to treat chronic, life-threatening, rare diseases, H. D. Smith acquired Triplefin in 2014, a comprehensive end-to-end brand support, reimbursement and

patient access solutions provider.

"Once we built out the manufacturer service side and the logistics piece was in place, what mattered to our clients was: 'What can you do to get my patients on my drug? And if they can't afford it, what can you do to help?' With Triplefin, we gained a 170-seat call center with experience in patient assistance and reimbursement support programs. We also provide pharmacy services through our own stores, CompleteCare Pharmacy, so we can offer home delivery programs that bring products directly to the patient. Through SPNN (Specialty Pharmacy Nursing Network), where Triplefin has a minority interest, we are even closer to patients. SPNN has more than 4,000 specialty nurses throughout the U.S., providing therapy management for patients with rare, chronic and orphan disorders."

Triplefin is also uniquely positioned to serve the nascent biosimilar market and has enhanced capacity to offer what Doyle believes is a key differential in creating market value for a biosimilar." Biosimilar companies are going to need to offer a wide range of support integration across the patient and product journeys, whether it's clinical trial support, third-party logistics, specialty distribution, patient reimbursement services, pharmacy or nursing services," said Doyle.

"We're starting with a biosimilar company that's bringing its first product to market," said Doyle. "We are currently providing third-party logistics; but we are also in the position to help patients get on therapy. Most often these patients suffer from chronic and rare diseases, and we support them throughout the patient journey from diagnosis to on-going treatment and adherence."

"Under H. D. Smith's umbrella, we can now leverage H. D. Smith's extensive expertise in logistics and what Triplefin offers to provide the high-level of comprehensive support needed to drive market value and differentiate brands."

When choosing a provider to help bring a biosimilar to market, Doyle urged manufacturers to consider two key factors: "Make sure the provider has the bandwidth to support everything that's required in that space, from logistics to patient management. And secondly, make sure the provider is sufficiently flexible to be able to accommodate your plan, especially if it is a creative and innovative approach to differentiating your product. Larger providers often will try to force-fit manufacturers into an existing model. Each program is unique and requires a customized approach."

Inflexibility and high costs are frequent complaints Doyle hears from manufacturers, relative to their experience with larger providers. "Manufacturers are seeking creative and innovative approaches to improve patient engagement, which expand beyond the traditional Hub support models. The current models have been built to support large programs with a cost structure that does not align with the needs of many small or emerging companies.

In contrast, H. D. Smith's motivation behind diversifying and expanding the company is to be able to offer manufacturers comprehensive and custom-designed programs to meet the specific needs of the product, and to do so at an affordable price.

Commercial path

With many different companies currently investing heavily in biosimilar development and nearly 700 different molecules estimated to be in development for biosimilars, Doyle anticipates the competition will be increasingly intense.

"Large players bringing biosimilars to the market will already have the infrastructure in place, along with the experience in providing a full line of services. For some of the small or emerging companies that we've touched, this is a new game for them," said Doyle.

Doyle expects the smaller companies, as unknown entities, to face higher hurdles, not the least being the test of perception from stakeholders who will be assessing the value, utility and possible rejection of the product, even if it is a sole competitor.

"Perceptions of physicians and patients and their preferences will likely play a strong role in the uptake of biosimilars. Traditionally, physicians are most concerned about safety, efficacy and protecting the patient," said Doyle.

"Strategically, even if you're a small player," said Doyle, "you're going to have to engage in key opinion leader development with some very strong clinical studies to build that level of confidence."

Another hurdle is answering the question from patients and providers: "What am I really getting for this?" The answer must address not only the physical product itself, but also support services in the handling and administrating of the product.

What then can be done differently to build patient loyalty? Doyle believes there is tremendous room for innovation in this area which has yet to be realized. "There are ways to provide more. For instance, by using technology to offer easier financial access, or by offering in-office dispensing, or by introducing state-of-the-art devices for administering.

"By demonstrating that you, as a biosimilar manufacturer, are interested in not only providing the same good therapeutic results from your product, but also offering additional and novel ways to support patients and providers on your product, you'll be enhancing the value of the biosimilar and thereby providing better potential outcomes for patients."

2015 Brand of the Year

Sovaldi and Harvoni for Hepatitis C

Gilead Science's two back-to-back cures for a disease with a shadowy public health history has reversed expectations around the listless product launch and revived industry reputation for startling breakthrough innovations that mean something to patients—from death in life, to life restored

By William Looney

Modern medicine is founded more on facts than faith. But for hepatitis C virus (HCV) patient Gavin West, the single pill drug *Harvoni* is not just a virus-wiping cure—it's a miracle. Ironically, it was April 3—Good Friday to millions of Christians—that the 59-year-old singer and retired avionics specialist walked out on a Nashville stage with his musical partner, well-known local songwriter Rob K. Wolf, to celebrate a physical and spiritual restoration of his own. Instead of queuing for a liver transplant, West that Friday resumed his sets with Wolf—live, to a receptive audience of hundreds, who remembered him well. Says West, "*Harvoni* gave me my voice back along with hands that could again feel the strings on the guitar that had sat under my bed, unused, for more than 10 years."

Gavin West

Whether you classify West's case as a clinical outcome or just an arresting anecdote, the facts on *Harvoni* and its companion, first-to-launch predecessor, *Sovaldi*, don't strike the flat encore notes often associated with a breakthrough drug. For the 170,000 HCV patients prescribed the two drugs since the initial US launch of *Sovaldi* in December 2013, Gilead's one-two punch hits home. A trial-certified efficacy rate of well over 90% made *Sovaldi* the first well-tolerated cure for a disease most patients didn't even know they had until it damaged the liver, one of the body's most essential, complex—and costly to replace—organs. With its shortened duration to cure, and an even higher efficacy rate, *Harvoni* does it even better.

Gilead's executive VP for clinical research, Dr. John McHutchison, summarized it this way in a recent interview with *Pharm Exec*. "When *Sovaldi* was approved, it was the first all-oral regimen for genotypes 2 and 3 of the virus, which covers more than a third of the infected population here in the US. In patients with genotype 1, it allowed for a much shorter treatment time in combination with interferon, which cut the severe side-effects associated with previous use of that older medicine. Response rates to *Sovaldi* were all higher than had ever been seen before, in excess of 90%, while therapy discontinuation fell to under 2%—an astounding number, given that the basic characteristic of prior drug treatments was to leave both patient and clinician discouraged by the reality that those side-effects could actually make you feel worse than the disease itself."

Bending the curve

The 31 members of *Pharm Exec*'s Editorial Advisory Board (EAB) seem to agree, tapping *Sovaldi* and *Harvoni* together as our 9th Brand of the Year, in a unanimous vote. That itself is a precedent for this normally contentious group. Our EAB cited Gilead Science's unwavering commitment to a strong franchise in anti-viral therapies through clinically useful drug combinations whose tolerability appeals to patients. Perhaps more important is the psychological boost provided by the $10.3 billion in US sales posted by *Sovaldi* in 2014, a first-year launch record unmatched by any previous brand name drug. Combined with some $2 billion in post-FDA approval revenues from *Harvoni*, this HCV breakthrough duo fell just short of matching the $12.5 billion in 2014 sales of the top-selling US branded drug, *Humira*, first marketed back in 2003.

It's also rare to see any branded med-

icine with such a transformative effect on a company's fortunes and mission. With *Sovaldi* leading the way, Gilead's full-year revenues for 2014 leapt to $24.9 billion, up 127% from the $11.3 billion it posted in 2013. This year, the company will enter the top 10 of our annual Pharma 50 revenues ranking, nosing out century-old R&D icon Eli Lilly & Co. as well as AbbVie and AstraZeneca. Just five years ago, Gilead sat at No. 23 on the list.

And while Gilead remains tightly focused on the anti-viral business, HCV has—at least for the moment—eclipsed the company's traditional weight in the HIV space. In 2013, prior to *Sovaldi*, 76% of Gilead's net revenue growth was attributable to HIV, where the company markets the top three US selling drugs for AIDS; hepatitis (specifically, the B strain) was a distant also ran, at 10%. Today, the situation is on its way to being reversed, with HCV accounting for 48% of total revenue in 2014, compared to 44% for HIV.

The company sees this as a simple confirmation of its business model. From a purely clinical perspective, the two segments are almost complementary. Research insights and marketing precedents from Gilead's two decades of trench warfare against HIV—Gilead launched its first antiretroviral, *Viread*, back in 2001 (a joint indication for HBV was added in 2008)—has helped it secure leadership in the far bigger market for HCV. With 160 million people infected worldwide, the numbers on HCV incidence are more than four times higher than for HIV. "We believe there is substantial room for growth at both ends of an anti-viral business with major unmet medical need," Gilead President and COO John Milligan told analysts at January's JP Morgan investor conference.

Fast and furious

More importantly, the *Sovaldi* story dispels the prevalent view that medical progress always occurs at a glacial pace, measured in multiples of decades rather than years. Instead, the race for a cure for HCV proceeded in a series of predictable relays, borne by the momentum of great science. Once the properties of the virus were identified in 1989 by a team led by the San Francisco-based vaccine company Chiron, researchers focused on creating reliable high-throughput screening systems for use in both the lab setting and for viral detection in the population. That goal was accomplished only a few years later, in 1992. Data and insights derived from these investigations and experience with combination HIV treatments drove awareness that HCV could best be managed through a multiple drug approach, testing combinations of enzyme inhibitors and other molecules along a variety of pathways to suppress the virus' capacity to replicate and develop resistance.

Sovaldi dispels the prevalent view that medical progress always occurs at a glacial pace, measured in multiples of decades rather than years

"Progress in drug development for HCV has occurred at a much faster pace than in areas like HIV. We've moved from a few isolated treatments to a pan-genotype cure in the space of about 10 years, which is remarkable given that there was really no development science behind this disease until after 1989," says McHutchison.

The pace of innovation has been all the more remarkable given the unique epidemiology of HCV. In contrast to HIV, the disease has never attracted attention at a level commensurate to its reach; pundits call it the "stealth epidemic." Before its distinct structure was revealed, the virus was confused with the other, more easily detectable forms of hepatitis, A and B. Spread of the virus was endemic through the donor blood supply until patient screening was widely introduced in the early 1990s, but cases of infection continue through unsafe surgical practices in developing countries as well as unsterilized needle exchanges and injection drug use, tattooing, and other types of unprotected behavior. This latter reflects another aspect of the disease: its largely unfounded association with stigmatized populations like prisoners and drug addicts. The breadth of potential exposures over time has resulted in reduced rates of diagnosis and a historical under-reporting of the actual number of HCV cases.

Moving target

HCV is endlessly inventive in forming new versions of itself, which makes the task of mapping appropriate drug targets very difficult. Composed of a single strand of RNA, the virus has at least six genetically distinct variations. Once in the blood stream, the virus does its work silently. Generalized, non-attributable symptoms like fatigue, body aches, weight loss, and depression persist over many years. Early detection is essential because, in the majority of cases, the virus progressively attacks the liver, often leading to cirrhosis and liver cancer. Treatment for the end-stage of liver disease may require full or partial organ transplant to ensure survival. Besides being a difficult and costly procedure, liver transplants carry a 100 % HCV recurrence rate without effective treatments.

The bottom line is that HCV remains a serious illness with a lasting residual effect on public health. Its impact spans gender, race, age, and economic class. Some 3.2 million Americans are estimated to be infected with the virus; approximately one half, or 1.6 million people, have been diagnosed.

More importantly, the annual US death toll from HCV has surpassed deaths from HIV since 2007, when 15,000 people succumbed to conditions caused by HCV, compared to slightly

Front & Center

Hub Models Align Interests

The growing utilization of narrow networks of specialty pharmacies is fueling the expansion of Hub operations.

Biopharmaceutical manufacturers are moving toward further consolidation of vendor networks in an effort to control costs and risks while improving outcomes and value. This trend toward narrow vendor networks increases the need for end-to-end solutions that meet the interests of manufacturers, specialty pharmacies, patients, providers and payers.

"While manufacturers are moving to a greater utilization of limited specialty pharmacy networks, payers continue to push back by requiring dispensing from their own specialty pharmacies," said Rob Brown, Vice President, Business Development for Omnicare Specialty Care Group (SCG). "The best solutions leverage the relationship between the specialty pharmacy network and the Hub to ensure consistent, high-quality support services with a comprehensive aggregation of data along all points of the patient therapeutic journey."

Omnicare SCG provides access, affordability and adherence commercialization services for the bio-pharmaceutical industry in support of specialty therapies. Their integrated and tailored services include brand support, third party logistics, program pharmacy and specialty pharmacy. Omnicare SCG, hosted a panel discussion on "Specialty Pharmacy and Hub Integration" at CBI's Annual Patient Assistance & Access Programs conference in Baltimore. Following the discussion, *Pharmaceutical Executive* met with Brown to explore his views and ask the following questions:

As manufacturers push for more limited specialty pharmacy networks, who handles such crucial details as benefit investigations, prior authorizations, patient financial assistance evaluation, access, adherence, and so on?

Rob Brown

Specialty pharmacies (SP) that are part of smaller networks (one to three SPs) tend to assume responsibility for support services more so than in larger networks (seven to 15 SPs). These larger networks rely more on a Hub provider. An important key to success in these relationships is to ensure that both the Hub and also the specialty pharmacy have clearly defined roles and responsibilities for a seamless experience in regard to all stakeholders—providers, patients, caregivers and payers.

The Hub acts as the quarterback in communicating initial coverage information with patients and providers and in triaging to the appropriate SP. The Hub handles wrap-around services such as copay assistance, clinical services and educational engagement to ensure a consistent patient experience. The Hub also serves as a central data repository to ensure pull-through of all patients and coordinates HIPPA compliance to collect the required data.

What are best practices in designing a Hub to fit a specific product and patient population?

Individualized engagement is necessary at key junctures along the patient journey. Timing and type of connectivity is defined by the therapy, while method of connectivity should be driven by patient preferences. Some patients and caregivers might prefer phone communications while others prefer text messages. Hub case management systems can accommodate individual patient preferences while still meeting the predefined baseline goals of the program. Data capture of both baseline and additional outreach can provide valuable insights into compliance and adherence protocols going forward.

We recommend basing support services at the Hub, particularly for larger networks with more potential for variation between specialty pharmacies. Sourcing support services from the Hub ensures consistency in processes and in overall messaging. The patient or provider experience, from start to finish, must be totally synchronized in order to eliminate workflow redundancy and increase speed to therapy.

What are the most common Hub designs and how do they affect specialty pharmacies?

Three main Hub designs include:

- Mandatory, where all patient referrals come through a central Hub, and the specialty pharmacy is reliant on the Hub to triage prescriptions to the pharmacy, which can result in increased patient numbers.
- Voluntary, where providers can choose to send a patient to the Hub, and allows the pharmacy to deploy its own sales team to provider offices. As a one-to-one relationship, this can result in increased business and faster speed to therapy.

- Central Service Provider, where one specialty pharmacy within the network is the central intake for referrals.

Hub designs also can evolve over a product life cycle. For instance, a mandatory Hub, appropriate at product launch, could migrate to a non-mandatory model as product access matures. Or a mandatory Hub could change from focusing on product access to patient adherence.

How do Hubs in the orphan drug space differ from Hubs in other product areas?

Orphan drugs typically require a higher level of integrated services focusing holistically on the patient, the caregiver, and the demands of the product itself. Orphan and ultra-orphan Hubs tend to be mandatory to ensure that each patient is accounted for and that all data is completely integrated. Best practices for orphan and ultra-orphan drugs under a single-entity Expanded Access Programs (EAPs) integrate clinical trial conversions, third party logistics, reimbursement support, copay options, patient assistance, clinical services, product dispensing and compliance support.

What is the optimal specialty pharmacy network size?

Specialty pharmacy partners align with the manufacturer's objectives, product attributes and patient characteristics. SPs share the product vision of the manufacturer. They have relevant experience, provide quality data and maintain flexibility in relation to their workflow requirements. At Omnicare SCG, there's no steadfast rule for a right-fit, SP network size. What's critical is that the network is made up of partners that can meet volume requirements and the needs of the product, patient and provider population. It is also critical to determine if prescribers already are familiar with specialty pharmacies. If so, a mandatory network may present problems with practices that have existing loyalties or preferences to a specific SP. If the prescribers are less experienced, the network then must be able to cater to them and to coach them.

What are the critical operational data and reporting elements needed to ensure optimal coverage and utilization in a patient population?

Medication adherence rates, time to fill, turnaround times for benefit investigation, prior authorizations and financial support are all critical. Reimbursement data is also critical for the Hub and SP network to provide. This includes: understanding payer issues and concerns; ensuring that copays align with expectations and evaluating copay support design and utilization; and aggregating payer data points. Adding data on patient out-of-pocket spend and length of therapy may lead to a more complete understanding of patient behavior and trends as they affect prior authorizations and speed to therapy.

How can manufacturers, Hubs and specialty pharmacy collaborate to ensure that the evaluation and operationalization of all the needed elements is part of the program design?

All partners must work together to identify the important and actionable data needed to evaluate commercial success. Scorecards should be used to reflect the operational goals defined by the SP/Hub program. The scorecards also should show which pharmacies are meeting or exceeding the agreed-upon service levels required to deliver an exceptional patient experience. Speed to therapy and time on therapy, as well as the supporting factors, are important markers of success. Other markers include: whether the patients receiving education and additional services are performing better than those who did not receive the services; what is the average drop-off point and why; and what can be done to assist patients with adherence beyond this point?

Are there advantages of partnering with a Hub that is also a specialty pharmacy?

Increasing speed to therapy is the key driver, especially with therapies that are more acute in nature. Connecting the SP with the Hub electronically and objectively aligning their interests produces an exceptional level of continuity and coordination. If there is a retail component and a history of product abandonment, a Hub that can take the patient through to dispensing is another advantage. A heightened sense of accountability also can result when a single vendor operates both a Hub and dispensing service. A negative perception may be the SP operating the Hub is favoring itself but that can be overcome by setting business rules on triaging referrals.

How does Omnicare SCG optimize Hub operations and performance across different products and patient populations?

The Omnicare SCG manages as many as 40 Hub programs across a wide variety of disease states, patient populations, therapy formulations and adherence regimens. The standardization of core tasks is not only possible but also critical in redirecting valuable and costly labor to more value-added activities.

Our quality, training and implementation teams have partnered to identify commonalities across programs and best-practice processes. Documented with standard operating procedures, they serve as the foundation for the standardized data entry screens in our case management system. This core framework allows us to quickly modify processes to accommodate new or transitional programs, each with its own nuanced business rules, protocols and patient/provider contacts.

As a result, case managers are spared administrative tasks. Freeing them to focus on providing individualized, proactive support to both patients and providers helps to create and enhance lasting brand loyalty for the manufacturer.

less than 13,000 from HIV. A February 2012 study published in the *Annals of Internal Medicine* predicted that annual HCV deaths in the US would more than double by 2030, to 35,000, due to the aging of infected baby boomers born before the introduction of blood donor screening requirements. This estimate did not anticipate an effective cure over this period, but it, nevertheless, serves to indicate how broad the potential benefits of *Sovaldi* are from a public health perspective. Globally, the potential payoff is even bigger. World Health Organization (WHO) statistics attribute 500,000 deaths a year to HCV.

Tepid treatments—and half-hearted cures

The interferon class of powerful anti-infective drugs developed in the late 1980s was the first treatment approved for HCV, but its efficacy was low, with severe side-effects for most patients. In 2001, the FDA approved a longer lasting, pegylated interferon for use against HCV. Shortly after, researchers discovered that a combination of pegylated interferon together with an anti-viral drug, ribavirin, proved more effective in suppressing the virus than interferon alone. This quickly became the drug option of choice for the next decade. In 2011, researchers were able to apply learnings from the protease inhibitor class of medicines originally developed for HIV to the HCV space, resulting in the launch by Vertex later that year of *Incivek*, with a relatively higher rate of efficacy in patients with the genotype 1 strain of the disease—but only when combined with the interferon/ribavirin cocktail.

For most HCV patients, drug treatments for their condition proved frustratingly inadequate. All three of the drugs used in combination had potent side-effects, ranging from general malaise and flu to anemia, chronic nausea, cognitive impairment ("brain fog"), serious rash and/or anxiety, and depression. The regimen, which lasted as long as a year per treatment cycle, required weekly painful injections and frequent blood tests. More importantly, cure rates for the average patient hovered around 35% to 65%, depending on individual genotype, and relapse was not uncommon. The side-effects were such that half of all patients had to reduce the dosage of the combination drugs or even discontinue treatment prior to the end of the standard 24-to-48-week treatment cycle. This made the combination regimens even less effective on retreatment.

The larger implication was to perpetuate HCV's status as a low opportunity target, which meant that the flow of money and scientific talent were diverted to more promising areas of research. Patients also suffered due to the natural tendency of clinicians to avoid prescribing medicines seen as causing more harm than good. An active clinical response was often dispensed in favor of "watchful waiting," effectively placing patients in limbo—a slow slide toward disability and worse.

Gilead's gap analysis

For Gilead, this downward spiral of expectations coincided with its own outsized ambitions to raise the bar on unmet medical need. A company whose credo to employees begins with the confident assertion that "being here matters" is not interested in a business model centered on the pursuit of incremental improvements. "Here was a condition affecting 160 million people worldwide where it could fairly be said that the majority of patients felt worse on therapy than without it," Joe Steele, Gilead's vice president of commercial operations, told *Pharm Exec*. "Given our stake in anti-virals, we saw it as a direct challenge that a community this large wasn't being served by the existing drug delivery paradigm."

In HIV, Gilead had eclipsed bigger, more experienced pharma rivals by focusing on patient concerns around efficacy, tolerability, and convenience. In doing so, it revolutionized patient care—and outflanked the AIDS virus—through a novel series of fixed-dose combination products. Gilead believed it could pursue an analogous approach for drug delivery, but this time with the goal to achieve what patients needed most: a quick and certain cure. "From both a scientific and commercial standpoint, a cure that was simple, safe, and free of interferon was the only approach that made sense to us," says McHutchison. "In terms of a clinical approach, the relevant analogy was HIV. We knew we would need multiple drugs, working through multiple mechanisms of action, to prevent viral resistance. We also knew that the most effective therapy for patients is the simplest: a single tablet, administered orally for a short, fixed duration of time. And this oral regimen would have to work across all the different HCV genotypes, ultimately for routine use around the world."

Man with a plan

It was a tall order. Gilead has been active in research on hepatitis B since its founding in 1987. But it was the June 2010 recruitment of McHutchison, a top-ranked researcher and clinician from Duke University, to run the company's liver disease therapeutics program that increased the fixation on an HCV cure. McHutchison formed a multi-functional development team committed to developing a breakthrough product with four characteristics, which he called the "s set:" Safe; Simple; Short; and, of course, efficaciouS. The group mapped a 10-year course toward that ultimate regimen, to be achieved in a series of waves, starting with reduced reliance on interferon and ribavirin and their harsh side-effects; continuing with elimination of interferon from the HCV drug basket entirely; launching a new drug to be taken once a day, selectively targeting different genotypes; and ending with a single oral pill of universal efficacy, providing a cure across all six genotype strains of the virus.

Five years into the program, two new HCV products have been commercialized, and the company is making progress in breaching that last hurdle, on pan-genotypic efficacy. December 2013 marked

the FDA authorization and launch of *Sovaldi* (sofosbuvir), a nucleotide analog formulation that in clinical trials prevented HCV from replicating, with a sustained virologic response or cure rate of more than 90%. Unlike candidates in other classes, sofosbuvir exhibited much higher potency against viral resistance while cutting the required duration of interferon by more than half. This in turn reduced the severity and duration of side-effects, which had for years been a serious barrier to treatment. These advantages were enhanced by oral administration of the drug in a treatment regimen of as little as 12 weeks, compared to the six to 12 month duration of conventional therapies relying heavily on injected interferon.

Two-hole punch

Despite its strong clinical profile, *Sovaldi* was intended as only the first "wave" in Gilead's race to a cure. The medicine still has to be taken in combination with another anti-viral drug, ribavirin; in some cases, interferon is recommended as well.

Within nine months, however, Gilead had a second new product, *Harvoni*, which plugged most of the gaps in *Sovaldi*'s pharmacological profile. Approved by the FDA in October 2014, *Harvoni* is a fixed-dose combination of *Sovaldi* (sofosbuvir) and ledipasvir, a second nonstructural protein 5A (NS5A) inhibitor that came from Gilead's labs. What is significant about *Harvoni* is that efficacy is accomplished without reliance on both earlier treatments, interferon and ribavarin. It avoids the severe side-effects associated with these two drugs, which often led to poor patient compliance.

Phase III trials results also showed *Harvoni* efficacy in about 95% of patients, all on the basis of a single daily pill taken for as little as eight weeks—record timing in the HCV space. More importantly, its FDA-approved label covers genotype 1 patients, the most common in the US.

Gilead is now moving to top the two "waves" in the HCV plan it devised back in 2010. A global multi-site Phase III trial involving more than 1,000 patients is underway to extend clinical progress from *Sovaldi* and *Harvoni* to create a single, safe but more potent oral pill that will work in all HCV patients, regardless of genotype. Results of that study will be available at the end of the third quarter of this year. Finally, the company is testing in parallel these fixed-dose combinations to tackle co-infections with HIV as well as populations of patients with HCV that are most in need.

Initial readouts from some of this trial work were not salutary—in one case, poor numbers on efficacy caused Gilead's stock price to drop 10% overnight

McHutchison attributes the rapid scale up to the Gilead culture. "There are two ways to approach drug development. The first is to do the bare minimum to get the drug approved. The second is reaching beyond the regulatory process to understand the people most in need of the drug, to the full extent of how they might benefit. We chose the latter course." McHutchison tells *Pharm Exec* that some of the biggest challenges were not only clinical but ensuring there was a supply chain at the ready to meet the pent-up demand for a cure. Adds Joe Steele, Gilead's VP of commercial operations, "we faced some tough, time-sensitive issues linked to manufacturing—formulations, batch production and tonnage, volume estimates, quality control, transport—you name it."

Finessing Pharmasset

Culture or not, some observers will wonder just how much sweat equity Gilead actually put in to solving the HCV puzzle. Its 2011 acquisition of rival HCV start-up Pharmasset spawned a discussion best summarized at the time by analysts' consensus that Gilead had paid too much—$11 billion—to buy a drug invented by someone else. And how hard is that?

McHutchison begs to differ. "When we acquired Pharmasset, relatively little had been done to evaluate the full potential of this drug in the field. The clinical and commercial potential was unclear. We knew that Pharmasset's investigatory candidate, PSI-7977, which eventually became *Sovaldi*, had demonstrated efficacy for several genotypes, but there was no efficacy data at all for genotype one, which in the US accounts for almost three-quarters of HCV patients. So right after the acquisition, we initiated two Phase III trials targeted at different subgroups within genotype 2 and 3; a larger Phase III study centered on genotype 1; and a series of exploratory studies on difficult-to-treat patients including those with HIV, efficacy and safety of treatments before and after liver transplants, and other groups including the infected from marginalized populations."

Initial readouts from some of this trial work were not all salutary—in one case, McHutchison relates, poor numbers on efficacy caused Gilead's stock price to drop 10% overnight. Another ripple was the decision, just three weeks after the acquisition was announced, to shut down work on another nucleotide analog candidate in the Pharmasset pipeline after trial data revealed the drug was hepatotoxic. "It shows there was a degree of risk involved in that $11 billion." Insists Steele, "all the agents we are now combining with *Sovaldi* to form the next generation of HCV drugs, including ledipasvir, the lead compound in *Harvoni*, come from discovery and development programs we initiated long before Pharmasset." The deal complimented Gilead's existing strengths; "in that sense it was a good fit."

Beyond that, support from the clinician community proved instrumental in turning all that cumulative research into a highly effective, marketable cure.

"Once we had Pharmasset, the pressure was on," said McHutchison. "We had to move quickly to set up trial sites and recruit." McHutchison leveraged his Duke ties, but he notes it was the "incredible efficiency" of Gilead's in-house clinical development team that proved instrumental. Another factor was support from the FDA in collaboratively broadening recruitment criteria, particularly as interferon, with its many contraindications, was now sidelined from its previous role as a companion drug and comparator. "Based on the new interferon-free therapy, we were able to recruit a new cohort of marginalized patients with comorbidities. In one trial, we were able to enroll 600 patients in six weeks—no one had recruited at that pace before."

It followed, too, that greater diversity in the enrollee pool reinforced the trials' statistical conclusion that a broadly applicable cure was at hand. And it no doubt helps that results of six Phase III trials conducted by Gilead, post-acquisition, now bolster indications found on the labels for both *Sovaldi* and *Harvoni*.

Making the case

With such strong scientific credentials behind it, is it true to conclude that the commercial launch of *Sovaldi* was an anticlimactic event—that rare case of a product so good it could sell itself? Conversations with the Gilead HCV commercial team suggest this premise carries some weight, but ultimately fails to account for those pesky "human elements" that can intervene to either bolster that good case—or suppress it. "There was really no challenge for us to align customers around this product," says David Johnson, VP for US sales and marketing in Gilead's liver disease business unit. "The science was strong and the data we compiled was very convincing." Johnson notes that the HCV clinical community is small and very tight knit; because practitioners were enthusiastic backers of the trial work undertaken by Gilead, they required little convincing about *Sovaldi*'s merits in giving them—and their patients—a real chance for a cure.

The primary driver in the launch was educating physicians on the proper course of treatment for each patient—a complex task. Says Johnson, "With six Phase III trials embedded in the label, we needed to ensure prescribers understood the data on which the FDA based its approval. There are six genotypes of the disease, and different regimens and duration are indicated for some of them." This is where the quality of Gilead's trial work played out: because McHutchison and his team insisted on including a full range of test subjects, especially sequences of subjects with lower and lower blood platelet counts, the results provided a highly accurate indication of how *Sovaldi* (and later *Harvoni*) would work under real-world conditions. The positive readout was recycled back to patients, too, through an unbranded disease awareness campaign urging them to seek help because, for the first time, a cure offered the hope of being able to resume a normal life.

Keeping it simple

Johnson and Steele also point to culture and institutional factors in prepping *Sovaldi* for its debut. Both note that Gilead is a flat organization, with minimal bureaucracy and only a few layers of management. A simple statistic helps back that up: even though Gilead's annual revenue base is now bigger than Lilly's, it has a fraction of the employee count: 7,000 worldwide, compared to Lilly's 38,000. Steele offers, "it's not rocket science. There is very little distance here between the people needing decisions made and the people making those decisions."

Adds Johnson, "we value proximity. The lead marketers for the US organization in every therapeutic area we serve are on one floor in one building. If I have a question for my colleagues in HIV, I just walk down the hall." One committee—the HCV Commercial Planning Group, chaired by Steele —managed all the strategic issues around the launch, including country-level guidance on product profiling, brand messaging, and locally targeted market research.

In addition, early-stage collaboration with McHutchison's clinical development group ensured all clinical study designs included relevant information to support a positive reimbursement decision by local country authorities. "There was a strong quality of life element in our protocols, buttressed by independent health economics and outcomes research from local academics. More than a dozen peer review papers have been published to date that demonstrate how *Sovaldi* is a cost-effective solution to managing HCV," McHutchison said. "In fact, says Johnson, "the clinical team moved so fast in getting *Sovaldi* to market that we on the commercial side had to constantly revise our own timelines. But that's what you get when the product—not the process—sets the pace."

Indeed, the breadth of the data helped Gilead obtain timely—and largely uncontroversial—coverage and reimbursement decisions from single-payer authorities in all the major European markets, including France, Germany, Spain, Italy, and at the UK National Institute for Health and Care Excellence (NICE), where the hard-to-meet quality-adjusted life-year standard is king. *Sovaldi* met that test, subject to a six-month deferred access proviso to accommodate a NHS budget glitch.

Aligning on access

Measured in sales numbers alone, the *Sovaldi* and *Harvoni* rollouts set records—on that score, Gilead's success was undeniable. The one big miss is the reputational hit that Gilead took from US Medicaid and leading private-sector pharmacy benefit mangers (PBMs) for its decisions on pricing the two drugs, in which it was alleged the company failed to reach out in a timely manner to help them prepare for the financial impact. According to Gilead, pricing followed standard industry practice, benchmarked around what was already on the market—with a statistically defensible increment based on evidence of *Sovaldi*'s

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higher cure rate. The bigger challenge was accurately assessing demand for the product, a calculation where few payers appeared to have done their homework.

Gilead itself was caught short. "Right out of the gate, we found an unexpectedly large number of patients whose physicians had postponed drug therapy in anticipation of a new cure." It turned out that *Sovaldi* was not just another rare disease product. "Facing up to that proved tough going," Johnson told *Pharm Exec*. "State Medicaid agencies, in particular, had a difficult time predicting the demand and also had to work within fixed budgets." And HCV had such a low public profile that many assumed it was a rare disease—could it be said the epidemiologists were asleep at the switch?

Despite the kerfuffle over pricing, all the key stakeholders in HCV—industry, payers, providers, and, of course, patients—have still committed to find a way to access these products. Some 140,000 US patients received *Sovaldi* in 2014, the highest ever recorded for a single product in a single year.

The company forecasts that this year more than 250,000 new patients in the US will be prescribed either of the two products, with *Harvoni* out in front of *Sovaldi*. "Payers have gotten to grips with budget planning, so we expect more patients at less advanced stages of the disease will be placed on treatment," said Johnson. Gilead has inked 2015 contracts with all but one of the big PBMs—Express Scripts went with AbbVie's *Viekira Pak*—giving its two products exclusive exposure to around 80% of the covered lives in PBM commercial plans. These arrangements also provide access to more patients with lower HCV fibrosis scores, broadening the potential treatment pool.

Surprise: the market works

What this says is, far from being immovable on price, Gilead is now aggressively discounting its products to beat market competition, particularly with the biggest

Charlotte Stewart

customers. Rebates on the wholesale price of *Harvoni* and *Sovaldi* are expected to average around 46% this year, and more than 50% on the public Medicaid and VA accounts, a segment where Gilead intends to boost its share of scrip. Volume-adjusted pricing is the norm for the HCV business in Europe. Gilead is also ratcheting up Support Path, its subsidized US patient access program on HCV, which offers eligible patients co-pays of as little as $5 per month, particularly among those with no or partial insurance cover.

Acknowledgment of these concessions from top management early this year caused a temporary blip in Gilead's market cap, suggesting that the company will not be immune from investor pressure going forward. Nevertheless, from a strategic standpoint, Gilead can count on four positive currents: (1) leading edge science; (2) a big pool of poorly diagnosed patients; (3) a progressive suite of carefully differentiated products; and (4) a patent fence that, in *Sovaldi*'s case, runs to March 2029.

Last words—three, to be exact

Ultimately, any agenda in pharma should begin around the patient. So it's fitting to conclude our Brand of the Year profile by relaying a *Pharm Exec* dialogue with another HCV survivor, Charlotte Stewart, an avid traveler and active grandparent who was diagnosed with the virus in 1998. "In a routine physical, it was discovered my liver enzymes were elevated, which led my physician to test me for HCV. When the results came back positive for the virus, I finally had an explanation for the fatigue, aches, and recurrent infections I had experienced over the past year, which had me continually popping antibiotics." Soon after, Stewart commenced no less than five different interferon-based drug regimens lasting for another 15 years, all of which temporarily suppressed the virus but ended in relapse, while causing side-effects that simply aggravated the virus's underlying symptoms.

It was a chance meeting with a physician investigator on a clinical trial that brought her to *Sovaldi*. As a trial subject, Stewart received the drug for free. Four weeks into the 12-week, once-a-day, single-pill course of therapy, her viral load fell to undetectable levels; at 24 weeks, post-treatment, she was told she had been cured. "There were no side-effects for me whatsoever; at that four-week stage I knew instinctively that the dead weight on my body I had borne for years was gone for good."

Stewart contends that social factors have diverted resources and attention required to address HCV at its root. In addition to "victim stigma," there is the "physician avoidance trap" induced by the historic lack of treatments that can be tolerated by patients. "My doctors kept telling me that if your symptoms didn't progress, you were OK, which was a completely false narrative. The truth is they didn't want to take ownership of remedies that might actually make me sicker than I was. It is good that the emergence of a cure is finally moving the physician-patient dialogue on HCV in a much more positive direction."

What does the cured Stewart want to see next from the drug industry? "A vaccine would be the ultimate prize," she says, "because ultimately the only way to defeat this disease is preventing it." Second, is supplementing science with active community involvement in educating providers and patients about HCV—and how it now can be cured. "Industry has to become a better communicator," Stewart affirms. "Getting people tested is critical and the policy/legislative agenda must be primed to reflect that fact." A freshly minted patient advocate for the American Liver Foundation, Stewart offers a solution captured in a simple three-word missive: "Discover to Treat."

Companies, are you listening? PE

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

Next Steps on HCV: Gilead's Four-Point Plan

In discussions with *Pharm Exec,* Gilead Sciences offered a single overriding goal for the hepatitis C virus (HCV) franchise over the next 18 months: to drive science that will lead to better regimens for treatment, especially for those patients who have been diagnosed. "Our emphasis is on access, which informs our entire strategy, from physician and patient liaison to price contracting with the major payers," Joe Steele, Gilead's vice president of commercial operations, told *Pharm Exec*. Key initiatives around this goal are:

Expanding and refining the therapy set. Phase III trial results are due later this year on an investigational single tablet regimen (GS-5816) that will cover all HCV genotypes. Development programs are also in place to cover patients co-infected with HIV, and for other non-viral liver diseases, including non-alcoholic steatohepatitis (NASH), primary sclerosing cholangitis, and advanced liver fibrosis.

Promoting HCV awareness. Gilead intends to build on non-promotional campaigns like the "Forget me Not" ads introduced last year to make sure untreated patients are aware of the options now available to them. "We think an empowered patient able to ask the right questions of providers is fundamental to defeating this disease," notes David Johnson, VP for US sales and marketing in Gilead's liver disease business unit.

This month, Gilead will launch a new branded DTP campaign on *Harvoni* that includes television, print, and digital advertising around the message tag "I am Ready to be Hepatitis Cured." According to Mike Rutstein, CEO of STRIKEFORCE Communications, the creative agency for the campaign, the effort seeks to connect with and empower patients through a message based on understanding combined with insight about the condition. "Patients are ready to stop living with the uncertainties of HCV. They no longer want to wonder whether or not they should seek treatment, but to move forward to a cure. And *Harvoni* is what they've been waiting for." Echoing Johnson, Gilead spokeswoman Amy Flood says "our goals in this campaign are to encourage patients with HCV to connect with a qualified health provider and support a better conversation to increase understanding of their condition and explore treatment options."

Elsewhere on the stakeholder front, Gilead is supporting work to update specialty professional practice guidelines on HCV. Finally, it has established ties to HCV advocacy groups like the American Liver Foundation and the National Viral Hepatitis Roundtable to amplify the patient voice on access to HCV cures.

Leveraging the US distribution chain to increase HCV adherence. Gilead works through specialty pharmacies on the basis of an open channel model—any specialty pharmacy can access its HCV products. Says Johnson, "such relationships provide real value in not only helping patients get their script filled but also serving as a go-between with insurers. Together with our own Support Path assistance program, we help patients get what they may be entitled to in terms of co-pay relief and discounts." Solving the payment riddle leads to higher rates of adherence, which is also advanced through work the participating specialty pharmacies do with Gilead in coordinating take-your-medicine call backs and refill reminders.

Through ads such as this one, Gilead hopes to merge understanding and insight surrounding hepatitis C.

Growing ex-US sales. Despite its broad footprint globally, HCV expresses differently at the regional and country level: Egypt, which has the world's highest rate of HCV infection, due largely to needle exchanges during a major outbreak of schistosomiasis in the 1980s, has one prevalent genotype; Japan and Italy have another. Japan is a key market target this year, and regulatory approval of *Sovaldi* in March now gives the company the opportunity to build a major business presence in a country that has the industrialized world's highest incidence of liver cancer, caused by HCV. "Due to the HCV opportunity, Gilead now has a fully-staffed, permanent subsidiary in Japan, and we expect the *Sovaldi* authorization will be followed by approval for *Harvoni* by the third quarter," says Steele.

Gilead is taking a special approach to marketing its HCV regimens in the developing world, having negotiated licensing deals with 11, mainly Indian, drug partners. The arrangements grant licensees authorization to manufacture, price, and market clinically approved versions of *Sovaldi*'s API in 91, mostly poor, countries. The deals exclude many of the larger middle-income emerging countries, which has attracted criticism from the World Health Organization (WHO) and advocacy relief groups like Medecins sans Frontieres.

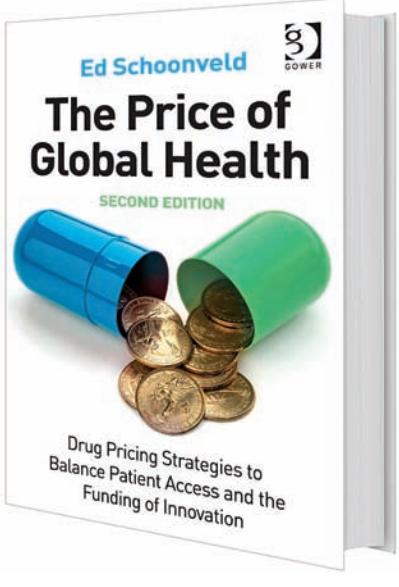
— William Looney

Pricing's Point Man

A leading author and expert reviews what's new in the growing field of global market access By William Looney

Despite its underlying importance to the very survival of the R&D industry, market access has not received the attention it deserves as a living, strategic function, with its own embellished litany of shared learnings and "best practices." One prominent industry practitioner, Ed Schoonveld, currently a managing principal at ZS Associates, has moved to fill that gap with a new, second edition of his 2012 book, *The Price of Global Health*. In the following Q&A, *Pharm Exec* Editor-in-Chief William Looney talks to Schoonveld about the key policy and management issues around market access, and what he sees as a necessary effort to take this relatively new set of pharma capabilities to the next level—from theory to practice.

Looney: ***The second edition of The Price of Global Health was published in January. What in the global pricing environment has changed in the three years since its initial release? Is a comprehensive market access strategy now the norm in bringing a new compound forward to commercialization?***



Schoonveld: Yes, market access strategy is now a regular part of the conversation in pharmaceutical company launch strategy. It has become a necessity due to significant changes in the way all payers—public and private—negotiate market access and pricing conditions with individual companies. Examples include the AMNOG legislation in Germany, which ties drug pricing for new medicines to strict requirements around demonstrated benefits; formalized medical/economic value requirements in France; the launch of a vigorous debate on the definition of "value-based" pricing in the UK; the fiscal crisis in health systems and the subsequent mandated price cuts, coverage restrictions, and patient contribution increases in Europe's economically ailing southern tier; and, of course, reforms in the US designed to drive down health costs through integration of the provider and payer roles, aligning spending to outcomes.

The US remains the lodestone of the global medicines market, so the transitions taking place there will carry a disproportionate effect on future industry profitability. Clearly, the 2010 Affordable Care Act is structured to not only provide health insurance to a broader population, but also to generate savings through new, more efficient players like Accountable Care Organizations (ACOs). ACOs are incentivized to monitor drug spending per indication, with the aim of wresting the fat from high-volume prescribing for major chronic conditions. The idea is that any savings can be shared between payers and providers. With the influx of many new high cost biotechnology therapies, we see more interest in professional medical societies like ASCO in setting ground rules on pricing a new drug therapy—the so-called "value algorithm." It follows naturally that physicians are slowly becoming more comfortable in considering cost as a factor in prescribing, particularly as they face more patient complaints over the high cost of medical and drug therapies.


Ed Schoonveld

Finally, there is the excitement generated by new drug technologies and the opportunities for treatments tailored to an individual's specific disease profile. This means that specialty medicines—high cost drugs for small populations—are going to factor more prominently in the market. The onus will be on the specialty innovators to demonstrate value, not simply in terms of a treatment indication, but on the overall health outcome.

Some of these technologies will actually cure a condition rather than slow or arrest the symptoms. How does society address the budget impact of drugs that cure, but at a high up-front cost? In my view, society is heading for a "perfect storm," between the opportunities driven by better science and the means of paying for them. Much of the burden is going to fall on

the patient, through increased out-of-pocket costs per prescription.

Managing the 'evidence trap'

Looney: ***What about the information revolution in healthcare and the growth of advanced data analytics that give payers greater control over pricing negotiations? How is this trend shaping the market access environment?***

Schoonveld: Good information is a prerequisite—a must have—for an efficient, value-based health system. I am convinced this trend is beneficial overall, because as a research-driven industry, we live or die on the basis of evidence. Nevertheless, there is a danger that the expectations around evidence will exceed what we can test and measure: by definition, the "real-world" evidence that payers want is impossible to provide at the time a new product is launched. We must be careful that this enthusiasm for real-world data does not end up impeding acceptance of new drug agents in the marketplace. It's simple: if you insist on a pure, evidence-based algorithm to determine access, then no new drug will qualify. The industry embrace of big data could come back to bite us by fostering the assumption that we can guarantee a product's value before it is exposed to actual clinical practice.

Looney: ***How prevalent is the transfer of market access precedents from one region to another? Is Europe driving new approaches to cost control that will ultimately be adopted in the US, or are we seeing the opposite?***

Schoonveld: The idea that regulations spread automatically from one region to another is an overstatement of the facts. The US healthcare system, not to mention the culture of medicine and patient care, is different from what exists in Europe; neither region strives to emulate the other. What does exist is a higher level of mutual awareness of what regulators in each region are doing, a trend driven by more and better information. Everyone is acutely aware of trends like comparative effectiveness requirements, or therapeutic reference pricing. But the questions posed will differ and thus so will the answers that national systems enact, in the form of laws and regulation.

Areas where there is alignment tend to occur around procedural definitions at the clinical setting. This includes the way you select an appropriate comparator in a clinical trial, or the promulgation of professional disease guidelines. Industry should be pushing harder for alignment around comparators because when you have common rules across markets, it is easier to manage a clinical trial. Imagine how much more expensive it is to run a clinical trial when France, Italy, or Germany each insist on a different standard comparator within the same protocol.

In a larger context, Germany continues to struggle in making the management of total patient volume exposure a predictable budgeting exercise. The federal AMNOG price control process lacks control over the patient population that qualifies for coverage under a "negotiated" price. The fallback is simply relying on what the drug label says, which is usually very broad language, but this clashes with the strict volume quotas applied by individual sick funds. This perpetuates planning uncertainty around the drug budget cycle. That then becomes an industry problem as well.

"Society is heading for a 'perfect storm,' between the opportunities driven by better science and the means of paying for them. Much of the burden is going to fall on the patient."

Key country developments

Looney: ***Can you point to countries that are currently taking a novel or innovative approach to market access?***

Schoonveld: Germany is struggling with its strategy around orphan drugs for rare diseases. The law provides a fairly generous relaxation from price regulation for these drugs, so long as the annual volume cost of supplying them to eligible patients is below €50 million. What is interesting is the level of support for a more liberal philosophy in increasing the level of access for patients with rare diseases. The desire is to address the ethical aspects without ending up with too many drugs qualifying for orphan status.

What is interesting to me is the evolution of many of the emerging country markets in market access. Many are trying to erect a functioning universal healthcare system from scratch, which means governments are committed to trying new things when it comes to pharmaceutical P&R. China is deregulating pricing for some categories of medicines and it is supporting privately-sponsored funding mechanisms like the alliance between Roche and Allianz on an insurance model to increase patient access to expensive oncology drugs. However, the great majority of patients still pay out of pocket for innovative specialty drugs. In India, you have some interesting multi-branding experiments to segment between markets. In Brazil, the pharmaceutical market is now evenly split between the public Sistemo Unico de Saude (SUS), driven by pure health economics, and the US-style supplementary private insurance market.

Looney: ***What other factors continue to surprise you about the market access environment?***

Schoonveld: A big one is the persistence of European governments in emphasizing price controls to manage the drugs budget. It is thoroughly wrong-headed to put the onus on price. Managing the level of reimbursement exposure is what matters. The prevailing order based on individual country price controls combined with acceptance of third-party parallel trade is nonsensical—akin to explaining something to someone from a different planet. Only the insular academic bureaucracies that manage national health systems in Europe could come up with this kind of inconsistent regime.

No one seems to recognize the contradictions built into almost every dialogue in Europe about reforming access to medicines. You can sit and talk for two years in the UK about institutionalizing "value-based pricing" at the same time as other parts of the system are pressing for the removal of patient access programs that address some of the shortcomings of the current system. Or you can launch a dialogue around more support for R&D innovation without ever addressing local price regulation of new drugs that may end up choking off that drive to innovate. Government payers must actively think about and collaborate on reinstating some very simple market mechanisms that drive consumer and industry behavior at its most elemental.

Narratives trump data dumps

Looney: ***Your book emphasizes "story development" to convince payers a new medicine will deliver value to patients. How do you do it?***

Schoonveld: I make the point that drugmaker communications on value are unfortunately reminiscent of the dossiers that companies submit to regulatory authorities—vast data dumps accompanied by equally prodigious efforts around dozens of power point slides. This is not the way to convince payers to work with you; the mindset is all wrong. Instead, the focus has to be on simple messaging—hooks, really—that link to the individualized interests of the communities you need to convince to adopt and use your drug. The narrative is vitally important. I have seen so many company payer submissions that are organized on the basis of distinct topics, when what you must do is build a compelling story linked to human interest—a story that flows.

"It is thoroughly wrong-headed to put the onus on price. Managing the level of reimbursement exposure is what matters."

Another requirement often neglected is creating awareness about the condition, not just the product. You have to present the product as a solution to an underlying unmet need, which is a challenge because the medical community is resistant to addressing situations that they cannot treat or cure. No physician wants to sow panic in his patients. Thus, the pressure is on the drugmaker to do two things: show that an unmet medical need is actually a problem, and then present a solution that resolves the problem. If you don't succeed in raising that fundamental issue of awareness, you won't have a market for your medicine. And it takes years of effort to achieve it. It cannot be accomplished a few months before launch.

Reputation hit

Looney: ***How well is the industry doing in responding to the changes in the market access environment. What can companies do to up their game in achieving maximum access at prices that adequately reflect their investments in innovation?***

Schoonveld: The talent, expertise, and organizational capacity are strong. Where the industry falters is the continuing hit it takes on reputation. Drugmakers seem to face more public pressure than the gun and tobacco industries. All three industries market products relevant to health status; one industry heals, the other two kill, yet perceptions fail to reflect that stark discrepancy. Failure to turn that sentiment around gives a free pass to critics who advance simplistic arguments about company profiteering at the expense of the consumer.

Reputation is often misrepresented as just a public relations problem—it is much more than that. Reputation affects this industry's basic license to operate. It's one reason why the industry often doesn't get the support of governments in confronting the theft of IP rights through compulsory licensing, as practiced by India. In my view, the US government needs to make its opposition to anti-IP rules more prominent, or we face this becoming a real constraint on the global competitiveness of US companies in emerging country markets, the source for much of the industry's future growth.

Value creation is the best argument drug companies can make. The problem is how the industry engages on this front: the focus is on weighty technical dossiers rather than clear messages tailored toward the stakeholders that count. Those stakeholders are increasingly diverse and differ on the basis of therapeutic segment as well as geography. Getting to the right people with the proper message is more difficult than it appears. It's all about humanizing what we do.

Looney: ***Are you saying that evidence is a secondary factor in the proposition around value?***

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Schoonveld: No. Duality is at the heart of any compelling case for value. You have to make sure you craft a great, audience-appropriate story, and then back it up with solid evidence. Market access people must be acutely sensitive to where the weak spots are in each area of medical practice. For example, in oncology, precedents like the new ASCO value algorithm demonstrate that a new drug offering little or modest differentiation against current therapy is not going to be taken up if its pricing fails to reflect that. Pricing also has to be in line with the position of a therapy within the growing number of clinical practice guidelines; individual physician choice is less and less relevant to what products get used.

A warning on offset coupons

Looney: ***Co-pay offset coupons that companies provide to maintain patients on branded medicines have emerged as a hot topic of debate with payers. How do you see this debate playing out here in the US?***

Schoonveld: The industry has made extensive use of these programs to reduce co-pays and thus eliminate disadvantages associated with an unfavorable formulary tier placement. Their effectiveness has made some drug companies more comfortable with accepting an unfavorable tier, using the coupons to level the playing field against competitors with a lower co-payment. Companies must realize, however, that the market is changing: in competitive therapy classes, outright exclusions from PBM coverage are becoming common. Exclusion lists give plans significant negotiation leverage, provided that the physician community accepts a more limited set of prescribing options. Other healthcare plans are making more extensive use of step edits and prior authorizations to guide the "appropriate use" of drugs, which also effectively blocks co-pay offset programs for their covered patients.

Hence, it is critical that companies prepare for a world where these coupons will be much less effective in preserving share of script. The implication is companies must focus on that robust value proposition aimed at payers, physicians, and patients, rather than relying on the coupon as a fallback. Given the current wave of physician objections over high retail drug prices and the incorporation of cost considerations—the "financial toxicity" proviso—in clinical treatment guidelines, intensive outreach efforts will be required to align the medical community behind favorable inclusion of new treatments in these guidelines and on progressively more restrictive payer formularies.

Payers are not comfortable with implementing precision medicine protocols alone, which is why the intervention of clinical practice organizations like ASCO will escalate. The medical profession is now a more direct part of the market access dynamic—there is no going back

Market access: What's next?

Looney: ***Looking three to five years ahead, how do you see the market access environment for drug innovation shaping up?***

Schoonveld: The biggest change is the requirements around evidence—these are going to be both more numerous and more complex. Payers will continue to develop precise methods to limit a drug's authorized use to that population most likely to experience a positive clinical outcome. That will tend to narrow the size of the potential market, so companies will be compelled to shape the process in a way that enhances the potential for additional indications beyond launch.

Payers are not comfortable with implementing precision medicine protocols alone, which is why the intervention of clinical practice organizations like ASCO will escalate. The medical profession is now a more direct part of the market access dynamic—there is no going back.

Looney: ***What about the activities of PBMs to extend the reach of restrictive or closed formularies for their covered patient populations? Will this prove to be the norm three years from now?***

Schoonveld: We have to examine this trend closely, to see if the exclusion of some therapies is accepted by the medical community and employers who rely on PBMs to manage their drug cost exposure. Indications suggest the number of covered patients actually affected by the exclusions is currently quite small: what is the share of the plans the PBMs are managing that fall under these restrictions? PBMs don't wish to find themselves defending a decision to rely on only one covered drug per indication because they know the medical profession finds this incompatible with their ability to make the best clinical judgment for patients.

We will see a lot of give and take around this point rather than the alternative of "one size fits all" solutions imposed by the PBMs. The politics of medical practice can trump their increasing market power, and more people are aware that PBMs have a narrow, expense-driven, short-term orientation that takes no account of the medical cost savings that new drugs achieve from a health outcomes perspective. Looking ahead, the industry has to be more public and aggressive in bolstering that fact, with messaging backed by evidence. PE

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The Billion-Dollar Upside

Multiethnic marketing in a multicultural world

By Steve Millerman

Today's era of slow, incremental sales growth presents pharma "c-suite" managers with a fundamental question: where—and how—can we tap new revenues to generate the higher profits that shareholders expect? One opportunity with potentially broad reach is the large bloc of consumers represented by the rich ethnic diversity that anchors the US population of more than 300 million.

What we call the "multicultural" or "cross-cultural" constitutes the largest, fastest growing consumer segment in the US market, with significant treatment gaps across therapeutic areas that not only represent potentially millions of new script but also create a strong brand upside as well as a reputational boost from the opportunity for pharma to improve patient outcomes on a national scale. The multiethnic segment is also in the vanguard of the consumer movement when it comes to digital, mobile, and social media use and when communicated to in a relevant way has a higher promotional response. In an effort to gain first-mover advantage, the number of pharma companies investing in multiethnic marketing has tripled within the last decade; but there is still a problem: this pivotal group is not being reached and impacted effectively with the tools of engagement currently employed by big Pharma.

Markets largely untapped

Yes, this is not a new topic for the industry. A "reach out" to multiethnics has probably been included in a brand plan or two, but never quite makes the cut. Perhaps this marketing area felt interesting to you at first, but when it came down to it, the demographics were not tangible enough to fully understand the profit and loss (P&L) impact. I remember years back, as a sales rep in Brooklyn, NY, sitting in a doctor's office amazed at the level of diversity of patients in the waiting room: Hispanics, African Americans, Chinese, Koreans, Russians, to name just a few. But what was most interesting to me was the thirst for information these patients had and the lack of information available that could speak directly to these consumers.

Being an immigrant myself, having moved to the US from Ukraine in 1990, I knew what it was like to be in a new country, with its different customs, language, and processes. That's when I decided to dedicate my time and passion to building methodologies and strategies that help my industry colleagues brand teams see multicultural marketing through a focused pharma lens. Specifically, the dynamics of the multicultural markets needed to be quantified in Rx sales terms and positioned in context of an Rx strategy. After heading up multicultural marketing capability for Novartis Pharmaceuticals Corporation, followed by working at leading multicultural agencies, and working on over 30 Rx products specifically in the multicultural category on the client and agency side, I have found that the sales upside can be anywhere from $100 million to over $1 billion per brand. To clarify further, I do not mean the size of the market; I specifically mean a brand specific, incremental sales upside. Given this scale, the conclusion is obvious: the multicultural segment should not just be a tactical marketing mix consideration, but a strategic business development opportunity, initiated and endorsed at the corporate level.

Clearly, there is much room for growth. Historically, big Pharma has not leveraged the US multicultural market place in the way that the finance, travel, CPG, auto, and communications industries have, investing hundreds of millions annually per company. As an example, in 2012, looking at the top 50 spenders in the US Hispanic market alone, the investment range is $30 million to nearly $300 million per company annually, none of which were pharma companies.

The multicultural segment should not just be a tactical marketing mix consideration, but a strategic business development opportunity, initiated and endorsed at the corporate level

Why? Multicultural marketing models driven by non-pharma industries did not apply as effectively to pharma due to the other industries different stakeholder mix, specialized analytics, highly restrictive regulations, and unique consumer insights and behaviors. Due to these differences, the business case built for pharma brands was not sufficient to persuade managers to invest.

But the question remains, why not invest? Let's put things in perspective. The combined multiethnic segment represents over a third of the US population, a bloc nearly the size of Russia's entire current population. Population wise, the US Hispanic market alone is larger than Spain, and it's expected to more than double by 2050. We literally have an "emerging market" in our back yard.

Pharma investment on rise

The good news is that although the industry is a bit behind, the needle is certainly moving in the right direction. Five to eight years ago, a few of the major

pharma companies started taking a closer look at these market segments. By now, certain organizations have been willing to invest in the multicultural platform as a part of an in-house innovation initiative.

Companies such as Pfizer, Novartis, and Merck & Co. launched a multiethnic or multicultural corporate strategy, while an additional one or two firms have made isolated brand investments in a given year. Fast forward to 2015, we have at least 15 pharma companies now consciously investing into multicultural markets on a brand level; at least 40% of these companies are either exploring or already having a corporate strategy across brands. Hence, labeling multicultural as an exploratory innovation initiative is no longer the case for the industry, but is instead a competitive advantage.

Being first to market is one of the key drivers in securing a leading market share for a given segment. The time is ripe. There are certainly more companies investing, but we are not at a point where the market is cluttered. In other words, there is still plenty of space to gain that first mover advantage and build brand trust and loyalty with this consumer segment.

We literally have an "emerging market" in our back yard

A similar dynamic has been observed in the retail space, and interestingly enough, over the past five years Walgreens, CVS, Target, and Wal-Mart have all established multicultural operations internally with targeted investments in various cultural segments. A coincidence? Probably not. Three major events in the past seven years have significantly heightened awareness and opportunity within the multicultural health segment overall. First, in 2008, the US presidential campaign showed the power of marketing to and building brand loyalty with US minority populations. Second, in 2010, the US Census came out with the latest population projections highlighting the tremendous growth of minority ethnic and cultural communities. Third, the Obama administration's Affordable Care Act (ACA) further heightens the opportunity specific to the multicultural health field.

Prime points for discussion

As we look to expand this opportunity further and prepare for brand planning, common topics that often come up for discussion include the following: are

traditional marketing efforts sufficient enough to impact these populations, in a positive or negative way? Is scalability of the opportunity sufficient, given the company's available resources? What are the misconceptions about insurance coverage and use of technology among these groups? And, lastly, where does the budget come from?

Let's address these in turn.

Incremental reach & impact: One of the most important aspects of pharma marketing is the understanding of the patient journey and how this journey may differ across disparate patient types. After analyzing the differences in the patient journeys for Hispanics, Asians, and African Americans in therapeutic areas such as cardiovascular and metabolic, vaccines, oncology, hematology, respiratory, Alzheimer's disease, rheumatoid arthritis, hepatitis, multiple sclerosis, and others, we find there is a common thread, which points to significant gaps across cultures within diagnosis, treatment, and adherence rates. These gaps are also known as healthcare disparities.

Certainly not in every case, but in most cases, at least one of the key parts of the patient journey has significant gaps. At times, the gap is in awareness levels, or perhaps the treatment rates across cultures compared to the non-Hispanic white patients is a lot lower. These gaps can be quantified in financials down to a brand level with the idea that if the gap can be closed, there is immediate financial upside to the brand.

The key part here is that to close some of the gaps, an incremental investment is needed to specifically target these audiences, since traditional efforts are clearly less effective in these populations. To use a tactical example within media, using Nielsen, when applied to unduplicated TV viewers, in prime time, across the top 10 English language networks compared to top Spanish language networks, about 70 % of US Hispanics 18+ are only watching Univision. The data thus shows that traditional investments like English language TV are under-reaching this audience.

US Healthcare Snapshot

Population Segment	% Covered by Health Insurance
Total Population	87
US Hispanic	76
African American	84
Asian American	86
Caucasian	87

Source: US Census 2013

Furthermore, for the 30% that may be reached by the English language networks, the question is how relevant is the message—can the impact of the creative be even stronger? In a Nielsen study conducted in 2014 across OTC ads that advertised in both Spanish and English, for adults 18+, Spanish language ads outperformed English language ads in brand recall, message recall, and likeability. The takeaway message on this topic is, (1) multicultural audiences are significantly under-reached by traditional marketing efforts; and (2) for the small number that is reached, the message may not be resonating as well.

Scalability of the opportunity: Let's start with the US Hispanic market, comprising about 55 million consumers and which is expected to more than double by 2050. If this bloc were a country, it would be the 16th largest economy in the world. The African American market is about 42 million consumers and is also growing faster than the non-Hispanic white segment. Using the gap analysis exercise from the previous section, a patient journey gap for Hispanic or African American markets can range anywhere from $100 million to $1 billion per brand. What this simply means is that if through corporate marketing efforts these journey gaps can be closed over time, one brand can bring over $100 million annually as incremental sales. If there are multiple brands in a corporation, the upside is in billions.

Let's put this in perspective. From a business development view, a corporation can spend hundreds of millions of dollars on R&D to bring a new drug to market and then make $500 million annually in peak sales, through a loss of exclusivity. Here, you can take an existing brand and invest less given the brand is already in market, but the upside is equal or better, making your overall ROI stronger over time. In addition, this upside is purely from closing the gap between the given culture and the non-Hispanic white population. This does not include any other upside that may naturally come from promotion, which would be icing on the cake.

For the Asian market, the story is a bit different. The scale is not as significant. However, the ROI is tremendous. For example, a standard recommended investment within the Chinese market place is about $400,000 to $600,000 annually, but the ROI seen on these investments could be closer to a 4:1. In this case, the question is not of scalability, but merely choosing a better investment in your current marketing mix (e.g., when looking across all the tactics that are in the $400,000 range, what tactics are returning lower ROIs—or do you know what the ROI is across all the tactics of $400,000 and under?) I challenge everyone to ask this question, as investing in the various Asian segments, or the US Russian speaking market, may drive a stronger ROI versus existing tactics in the marketing mix.

For companies that have invested consistently every year and maintained a strong investment level across ethnic groups and cultures, they possess disproportionate market shares within the cultures they have invested in. What's most staggering is the potential scale upside for the brands and a huge win for patients. The impact of even moving the needle in closing some of these gaps is a tremendous turning point in patient outcomes, from quality-of-life benefits to improving survival rates. This is "patient centricity" at a whole new level, as here we have an opportunity to connect with patients in a highly individual, targeted way.

Health Insurance: This is a really easy one to parse. As of 2013, health insurance coverage rates across population segments are illustrated in the chart on facing page. The biggest question on everyone's mind is the insurance coverage for the US Hispanic group. The rate is actually 76% coverage, compared to 87% in the white population. Certainly it's lower than for non-Hispanic whites, but the real point is that the vast majority of these people are covered. Also, considering the scale and future growth, the numbers are very strong and are from 2013, which does not account for full ACA impact.

Technology consumption: Generally speaking, multicultural consumers are not only on par with non-Hispanic white consumers, but are leading the total US population in various consumption behaviors within digital, mobile, and social platforms. Certainly, there are variations when we start to break consumption down by channel, by age, gender, etc., but overall the multicultural consumer tends to over-index in various areas.

Here are the key highlights:

- US Hispanics watch more video than non-Hispanic consumers, are more engaged on mobile use, and are the most active users of social media networking sites.
- 70% of African Americans and 71% of Hispanics own a smartphone, versus 61% of non-Hispanic whites.
- 73% of African Americans age 18 or over versus 72% of non-Hispanic whites use social networking.
- 22% of African Americans age 18 or over Tweet versus 16% of whites.
- Asian Americans have a higher smartphone penetration and adoption of tablets than the overall population.

Budget source: No question, this is a tricky and potentially sensitive topic. My recommendation is to create an internal risk-share model where the initial investment, "pilot," "test," and "proof of concept," is co-shared between the brand budget and a matched amount of funds allocated outside of the brands. This way, there is shared accountability and a guarantee of internal brand team support, along with sufficient funding for an initial investment.

In allocating your investment, the last thing you want to do is to shortchange your test. Typically, this can cost anywhere from $500,000 to $3 million. But what's most important is the mindset going into this test, which is not only to see whether this works or not, but more to learn, optimize, and scale up. Scaling up can mean finding funding in the millions of dollars, which in most cases the brand budgets will not be able to support alone. This is where we have to make a call beyond the brand teams promotional spend.

Given the significant upside of the opportunity in most cases, an incremental budget allocation is needed. However, the spirit of this allocation is not just about the typical promotional spend increase. It's a business development opportunity. As is the case when bringing a new brand to market and being in a pre-launch stage, new budget is allocated. Similarly, with this potentially being a billion-dollar upside for a company over time, an incremental investment outside of the current brand team's funding is certainly worth the commitment.

We are at a point where not investing is not just a financial miss, but a driver of competitive disadvantage

Engagement signals strong: Don't miss out

In summary, the multicultural segment is the largest, fastest growing consumer segment with significant treatment gaps across therapeutic areas that collectively are worth billions of dollars in pharma revenues and profits. This creates a tremendous opportunity for pharma to improve patient outcomes on a national scale. The multiethnic segment also happens to be a savvier player when it comes to digital, mobile, and social media use, but it's not being reached and impacted effectively by current practices. The evidence does show, however, that when communicated properly, the multiethnic cohort delivers a higher promotional response. We are at a point where not investing is not just a financial miss, but a driver of competitive disadvantage. Changing that dynamic through a solid investment is worth it. It may be the largest marketing mix opportunity for the industry in an era of declining expectations. PE

Steven Millerman is President and Founder of Emcay. He can be reached at steven.millerman@emcay.net.

Refuting R&D Tax Credit Myths

Why executives should make the US R&D tax credit part of their planning discussions

While companies are beginning to plan for the coming year and beyond, there is no time like the present for pharmaceutical executives to evaluate whether they're taking full advantage of the research and development (R&D) tax credit. Recently, President Obama signed into law a bill that retroactively extends the R&D tax credit for expenses paid or incurred in 2014. Even with the potential of substantial benefits, many companies aren't claiming these credits because of common misconceptions.

Let's take a few moments to dispel the most common of these misconceptions.

Calculating the research tax credit just isn't worth the time it takes

In 2011, the last year for which the IRS published data, U.S. corporations claimed $9.24 billion in R&D tax credits. Executives will find value in these dollar-for-dollar offsets against tax liability because the credits can help companies increase their cash flow and earnings per share, reduce their effective tax rate, hire more staff, develop new products, and finance other business objectives. Just how sizable can these benefits be? Federal and state research tax credits can equal 15% or more of a company's qualified spending, and can result in substantial benefits for companies of any size. The credit can result in cash back for previous open tax years and can also represent future savings, as they can be carried forward up to 20 years.

We aren't performing activities that are eligible for the credit

Traditional research activities that take place during the development of groundbreaking drugs aren't the only activities that qualify for the R&D tax credit. Pharmaceutical companies may think they're not performing as many qualified activities as they are because many of the costs that qualify for the credit are accounted for as "R&D expenses." So, as long as companies are attempting to develop new and improved products, product lines, manufacturing processes, or software, they could be eligible.

As long as companies are attempting to develop new and improved products, product lines, manufacturing processes, or software, they could be eligible

As discussed in a roundtable recently on process innovation published in *Pharm Exec* (December 2014 issue), companies are working towards improvements in their production processes—activities that may be eligible for R&D tax credits. Supplies used in these processes might also qualify, including lab supplies, prototypes, and experimental production lots. In addition, some supporting functions like marketing and product safety, may be performing qualified activities that should not be overlooked.

We haven't claimed any credits before, so we've lost the chance

Up until recently, taxpayers who didn't elect the Alternative Simplified R&D Credit (ASC) on an original return could claim only the Regular R&D Credit on an amended return. This may have acted as a deterrent to taxpayers to report the credit, because the Regular Credit can sometimes require financial documentation from tax years dating back to 1984. Moreover, because the Regular Credit and ASC are calculated differently, the Regular Credit is sometimes zero while the ASC may be quite significant. Now, with the ability to claim the ASC on an amended return, the process of both calculating and supporting qualifying activities is simpler. Because of the ASC and this new rule, executives should reconsider

Chai Hoang is R&D Tax Services Senior Associate at BDO USA, LLP. She can be reached at Choang@bdo.com. **Chris Bard** is National Leader of R&D Tax Credit Services at BDO USA, LLP. He can be reached at CBard@bdo.com.

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whether their companies can claim research tax credits in both current and prior years.

R&D tax credits are often challenged by the IRS and difficult to defend

Although it's true that the IRS may challenge research tax credits if a taxpayer is audited, companies have a track record of successfully defending these challenges. The IRS has published the Pharmaceutical Industry Research Credit Audit Guidelines to provide guidance for IRS agents and managers examining pharmaceutical research tax credits. These guidelines provide helpful information to industry taxpayers, as they identify audit areas that have the lowest and highest probability for errors. Executives may consider leveraging this document to prepare for potential audits.

Taxpayers also benefit from a directive released by the IRS in late 2012 that instructs examiners to provide more flexibility in allowing the R&D tax credit for companies developing pharmaceutical drugs. This directive allows taxpayers to qualify their expenses incurred in the discovery and preclinical and clinical stages of development with less federal push back. IRS agents are instructed not to challenge these expenses if the taxpayer certifies that they were (1) incurred in the discovery, preclinical, or clinical stages of development; (2) for "qualified research;" and (3) not for activities excluded by statute.

Additionally, a recently-decided US Tax Court case, *Suder v. Commissioner*, provided several taxpayer-friendly points that can assist companies in defending their claims:

- Activities that tax examiners often disallow as "routing engineering" or "routing software development" were upheld.
- 75% of the CEO's time, and a high percentage of other senior management's time, was allowed as qualified research activities, including time that was spent in strategy meetings coming up with new ideas, in follow-up meetings throughout the product development process, and reviewing and signing off on specifications, among other activities.
- Substantial time for employee activities tax examiners sometimes question was also allowed, including quality assurance and field testing.
- Expenses paid to law firms for patent research and prosecution were also permitted.
- Considerable weight was given to employees' testimony and representations in finding that qualified activities were performed.

Research tax credits aren't substantial enough to invest in developing drugs for uncommon diseases

The government supports further drug development, as Congress has passed the orphan drug credit to incentivize companies to search for the treatment of rare diseases. Regrettably, many pharmaceutical companies aren't claiming this valuable credit, which is equal to 50% of qualified clinical testing expenses paid or incurred in developing the drug. Qualifying costs occur between the date the FDA designates a drug as an "orphan drug" and the FDA's drug approval date. Taxpayers must remember, however, that some expenses may qualify for both the R&D tax credit and the orphan drug credit, but they cannot claim both credits for the same expense.

While these and other misconceptions regarding the R&D tax credit may cause some pharmaceutical companies' tax strategies to underperform, others may take a moment to review and determine whether R&D credits can be leveraged for a positive bottom-line impact. With more capital on hand, such companies will be better poised to innovate, influence, and deliver, which could result in market-leader prominence. PE

Fake Medications, Real Solutions

Tactics pharma leaders can implement to stem the continued global threat of counterfeit drugs

Counterfeit medications remain a top concern in the pharmaceutical industry. Today's complex global economy, rise of online transactions, and increasingly intricate pharmaceutical supply chains have made counterfeit drugs increasingly difficult to discover, track, and police. The good news is that the industry remains more committed than ever to one of the top concerns around the globe. Today, international organizations, law enforcement, policymakers, and the pharmaceutical executives themselves are implementing a number of robust, successful tactics that are curbing and reducing the amount of counterfeit drugs that enter consumers' homes.

The risk: Counterfeiting a top concern

There's a reason counterfeit medications are increasingly spoken about in the industry, and a reason why so much effort is brought forth to curb the practice. Counterfeiting remains a global, prevalent issue that has become increasingly difficult to police. The e-commerce boom has given rise to illegal, online pharmacies that can crop up at a moment's notice and put counterfeit drugs in the hands of unsuspecting consumers in rapid time. Similarly, the expansion of our global economy has created geographically diverse supply chains around the world. A counterfeit operation could occur at any step in the supply chain in any country in which your organization might be located, from manufacturing, distribution, labeling, packaging, and even the printing of the cartons in which it is contained.

As a result, the risks of counterfeit medications remain great. Threat to patient safety, public health, and business continuity make counterfeit medications one of the top threats in the industry today. By the very nature of the pharmaceutical and medical industries, patient safety is of paramount importance to companies operating within the US and around the world. When counterfeit drugs end up in the homes of unsuspecting consumers, there's no telling what active ingredients are in (or not in) their fake medications. A related risk is the business impact of counterfeit drugs. Every counterfeit medication has the potential to damage both company and brand reputation and result in lost revenue.

The industry's response—what's being done?

Combating counterfeit medications is everyone's responsibility, from top pharmaceutical companies right down to individual consumers. The encouraging news is that there are a number of ways the industry is fighting counterfeiting. Today, there are a multitude of groups, programs, and organizations committed solely to fighting and curbing counterfeit medications.

One of the most effective, notable, and successful methods of counterfeit prevention is through international cooperation between pharmaceutical companies, law enforcement, and international organizations such as the World Health Organization (WHO) and Interpol.

Creating market surveys, running product or sales erosion assessments, and regularly training staff and security personnel will reduce the potential threats

This international cooperation is not new. In fact, Interpol's own Pangea program, which was first launched in 2008, has gained significant momentum and is now active in fighting online counterfeit pharmacies in over 100 countries. Online rogue pharmacies pose a different set of challenges altogether. Counterfeiters have the luxury of operating anonymously behind a computer screen, making them difficult to locate and identify. However, by targeting online pharmacies' Internet service providers, their payment systems, and delivery services, the Interpol-lead initiative is

Dave Campbell is a director of operations at Pinkerton, a global risk management agency. He can be reached at dave.campbell@pinkerton.com.

now the collaborative result of nearly 200 participating agencies. According to Interpol's website, a recent operation in May 2014 lead to 9.6 million counterfeit medications seized totaling more than $32 million, 434 arrests, and more than 11,800 websites shut down. The success of these raids and large number of arrests are sending a powerful, aggressive warning to would-be counterfeiters.

There are also a number of regulatory and public policy initiatives currently underway. In the US, policymakers have increasingly proposed new legislation that would impose even greater sanctions on counterfeits, including harsher fines and up to life in prison. Swift action against counterfeiters within our judicial system will naturally discourage criminals from producing fake medications in the first place. When the risk of increased incarceration time and steep fines outweighs the perceived "reward" of counterfeiting, would-be criminals and counterfeiters think twice.

New and encouraging technologies

In addition to an increased emphasis on international cooperation between organizations and a concerted effort in public policy, technology is making the fight against fake medications quicker, simpler, and more organized. As a whole, the business world is becoming more technologically advanced. As a result, new and encouraging technologies continue to emerge to help identify counterfeits and combat criminals more easily and quickly than previously thought possible.

Identifying counterfeits used to be a several-week process, where a suspected fake would need to be identified, isolated, and shipped off to a laboratory halfway across the country for several days of testing. Today, the rise of handheld detection devices enable hyper-quick testing and discovery of counterfeits, speeding up the process and keeping potential harmful drugs out of the supply chain.

Another notable trend that we are seeing with great potential is mass serialization, which is a comprehensive system used to track and trace prescription drugs as they progress through the supply chain. Regulations are in place in several emerging markets, but not in the US, Canada, and European markets, as those are currently pending. It is the belief of some large global pharmaceutical companies that successfully implementing serialization will result in significant reduction of counterfeiting of medicines worldwide.

Staying proactive in the fight against counterfeiting

As previously mentioned, fighting counterfeit drugs is everyone's responsibility. This is especially true for pharmaceutical executives. While there are a number of successful organizations, law enforcement agencies, and policymakers fighting the war on counterfeiting, individual pharmaceutical companies play a vital role in this process as well. The most successful pharmaceutical organizations will be the ones who prioritize proactive investigations and enforcement through a global security plan.

A proactive approach to combating counterfeiters means staying in tune with your customers and knowing the warning signs in consumer behavior. While counterfeiters can be difficult to track, rely on the data that you do have to diagnose a potential problem. Have the sales of a particular drug taken an unexpected and unexplainable dip in a general region? Has a customer reported or suspects that they may have acquired a fake medication?

Similarly, a proactive approach means developing aggressive, sustainable anti-counterfeiting programs and policies within your own operations. Creating market surveys, running product or sales erosion assessments, and regularly training staff and security personnel will reduce the potential threats your individual organization may have.

Lastly, highly successful pharmaceutical companies strive to secure their supply chains. Map every step in the supply chain and test for potential vulnerabilities, from manufacturing, distribution, labeling, and packaging. Crime involving the combined threats of counterfeiting, cargo theft, and economically motivated adulteration is on the rise around the world. While you can never completely secure your supply chain, building a dedicated, global team of investigators, security professionals, and logisticians can help put the right processes in place to reduce the risk and curb the loses due to counterfeiting, trademark and patent infringements, and supply chain security breaches.

The industry must remain vigilant

The unfortunate reality is that counterfeit medications will never go away, and the prevalence of the Internet and e-commerce pose new challenges that were not previously a reality. Sadly, counterfeiters will always look to make a quick profit off of the research of pharmaceutical companies, even at the expense of public health and patient safety. While the statistics will vary, WHO estimates that approximately 10% of all medications are counterfeit. The good news is that the industry as a whole continues to make great advancements in curbing the problem. Deeper partnerships, increased collaboration, and greater resource sharing will keep patients safe and counterfeiters behind bars. New technologies, new programs, and new initiatives, coupled with a proactive risk management approach from individual companies, will continue to address counterfeit medications head on. PE

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HEALTHCARE & LIFE SCIENCES REVIEW

KOREA
BE INSPIRED

"When I left Janssen, I never imagined joining a Korean company," recalls Choi Tae-Hung, sipping a freshly brewed yujacha tea in his office on a crisp autumn morning as he gazes down at the busy, sundrenched streets of Seoul below. "I thought that the global business of Korean pharmaceutical companies would be very limited due to a lack of competitive R&D or marketing capabilities." Choi spent two decades at Janssen before moving on, but when he did, it was to become president of Korean pharmaceutical company Boryung in 2013. "After speaking to a number of people within the industry, I realized that everyone was talking about big changes in strategic direction for domestic pharmaceutical companies. The new focus for these businesses was on the global market," explains Choi.

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Project Director: Cameron Rochette
Project Coordinator: Valerie Baia
Contributors: Alexander Ackerman, Eunseo Kim
Project Publishers: Diana Viola, Julie Avena

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Korea's chaebols, the country's large conglomerates, have in large part been responsible for building the country's reputation in the fields of electronics, shipbuilding and automotive. Today, Korea's government is looking to develop growth in new sectors outside of this traditional base; pharma has been selected as one of these new sectors. The race is now on to position Korea as the Asian hub for pharma R&D and new drug development (NDD), something that only a few years ago would have been unthinkable: a situation mirrored in other Asian countries such as Taiwan and Singapore.

From left: Chung Seung, Minister of Food and Drug Safety; Moon Hyung-Pyo, Minister of Health & Welfare of Korea; Jung Kee-Taig, President, KHIDI; Lee Kyeong-Ho, Chairman and CEO, KPMA

"In the past, Korea's pharmaceutical makers focused mostly on generics," admits Korea's Minister of Health and Welfare Moon Hyung-Pyo. "However, today they are in the process of transforming into brand-name manufacturers by investing more in R&D and developing innovative drugs. The Korean government is very active in helping the drug industry to become truly world-class. With all of these factors combined together, Korea's healthcare industry will soon join the ranks of global healthcare power houses."

"Korea is in a unique position in terms of new drug development," explains Lee Kyeong-Ho, chairman and CEO of the Korea Pharmaceutical Manufacturers Association (KPMA). Indeed, Korea has already successfully brought 22 new drugs to the market between 1999 and 2014, two of which have been approved by the US FDA. "Korean companies have had an interesting experience in developing innovation, but not game-changing innovative new drugs which require significant money and manpower that we do not have enough of yet," Lee continues. "Nevertheless, we do have successful experience in creating incremental innovation, and this has been an excellent experience for Korean companies," he adds.

Leading the charge in boosting Korea's regional competitiveness for pharma and R&D is the Korea Health Industry Development Institute (KHIDI), Korea's sole public institution designed to foster growth in the healthcare industries, like pharmaceuticals, healthcare technology, cosmetics, and health systems. "It has already been eight years since global healthcare was selected as one of 17 growth engines of our nation, and we have been somewhat successful in inbound business like attracting foreign patients and physicians for training," remarks Jung Kee-Taig, president of KHIDI. "In terms of outbound business, we hope to create those success cases more frequently and this business can be a mature and major industry for Korea's growth by 2020." "Koreans really want to win and be number one in everything, rather than being perceived as the little brother of China or Japan," says UCB Korea managing director Tom Roberts.

There is a solid support system behind Korea's Pharma Vision 2020. "The level of quality approval in Korea compared to Europe and the US for products like biologics is usually the same; sometimes it is even better but this is not recognized worldwide," says Chung Seung, Minister of Food and Drug Safety. Since becoming Minister in 2013, Seung has already taken a number of efforts to ensure the Ministry actively participates in forums, working groups and international organizations to promote Korean medical products. In July 2014, Korea officially joined PIC/S, which created a framework where international creditworthiness of domestic medical products' quality can be elevated. "We will actively provide support to develop biological products such as stem cell therapy products by fully implementing a 'Support Scheme for Global Biological Products', which aims at becoming one of the world's top seven powerhouses in the biological product field by 2017. The Ministry will rigorously support commercialization of vaccines, biosimilars, stem cell therapy products and gene therapy products. We will also support domestic pharmaceutical companies advancing into the global vaccine market while also expanding our self-sufficiency rate from 32 to 70 percent in the domestic vaccine market over the next six years."

However, becoming a top-tier nation for pharmaceuticals will take time

Vision 2020: Pharmiracle on the Han River

The idea of Korea becoming a top-tier nation in pharmaceuticals was carefully outlined in 2012 by the government through its Pharma Vision 2020, which details a number of ambitious goals:

- Become a top seven global pharma powerhouse by 2020
- KRW 10 trillion (USD 8.9 billion) between 2013 and 2017 allocated by Korean government for R&D
- 20 new drugs to be produced by 2020
- Two Korean companies in global top 50
- Global market share to increase from 2 to 2.5 percent
- Pharma exports from 12.5 percent to 46 percent of total production

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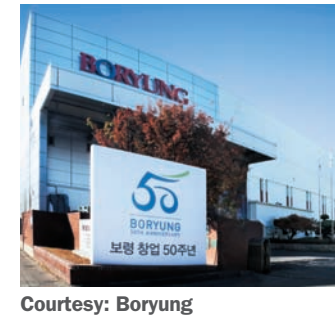
From left: Hakim Djaballah, CEO, Institut Pasteur Korea; Choi Tae-Hong, CEO, Boryung; Lee Gwan-Sun, President & CEO, Hanmi Pharm; Lee Han-Koo, President, Daehwa Pharmaceuticals

and effort. Hakim Djaballah, CEO of Institut Pasteur Korea, believes that without attracting the international know-how necessary for solid tech transfer, the goals of Pharma Vision 2020 are more of a dream than reality. "The infrastructure for basic research is already in place and translational research is beginning to take off, but the infrastructure to take that into a product still does not exist," comments Djaballah. "Compared to other countries with facilities for API production, Korea is still at the starting line. It does not mean they cannot achieve it; Korea is geographically attractive and the country just needs to invest in building the industry scale infrastructure to produce APIs."

KORINNOVATION

Local flagship company Boryung has found success with its newly developed angiotension receptor blocker (ARB) Kanarb. Nine molecules currently exist worldwide in this category of antihypertensives, and Kanarb is currently ranked eighth. "Boryung is the only domestic company that has developed a drug from start to finish, including outlicensing. Of course, other companies have developed new chemical entities (NCEs). But in terms of experience Boryung is different. From discovery and development to product launch and internationalization, Boryung has experiences that other companies cannot imitate," explains Choi Tae-Hong, Boryung's president. "Given Kanarb's competitiveness, multinationals are our new competitors."

Could Boryung be one of the two top 50 companies that are planned in Korea's Pharma Vision 2020? "Our own strategic objective is not to make Boryung a top 50 company in terms of sales size, but rather to make Boryung the best company in Korea in terms of marketing and R&D capability," Choi reveals. "My dream is for Boryung to be at least number one in Korea. I do not know what the company's rank in 2020 will be globally, but that is not so important as long as we achieve our strategic goal year by year."



Courtesy: Boryung

Hanmi is a Korean pharma heavyweight, and is the highest R&D spender in the Korean pharma sector, with KRW 100 billion (USD 90 million) invested in 2013. "We can lead Korean pharmaceutical companies in the R&D field," believes Lee Gwan-Sun, Hanmi's CEO. "We are interactive in some external R&D activities from recent venture companies and from a very early stage we can select some candidates or compounds which can be a synergy with our current pipelines. In that sense, Hanmi can be a role model."

Founded in 1984 and listed in 2002, with three production centers and three R&D facilities, Daehwa Pharmaceutical's anticancer drug DHP107 aims to provide an oral version of Paclitaxel – a new 'Made in Korea' product. As Lee Han-Koo, president of Daehwa, explains, "there is no such thing as a single injection for oncology. One drug has to be used in conjunction with other anticancer drugs, such as enhancers that need to be interactive with each other. DHP107 avoids this situation altogether." After finishing clinical trials, Lee hopes to receive approval for DHP107 by the end of 2015 and start marketing the product first in Korea and then to other emerging markets in the region. Daehwa currently exports to 22 markets worldwide; Lee is bullish about future growth: "Of course we will expand to satisfy all

How can *chaebols* influence Korea's life science sector?

Christopher Ko, CEO, Samsung Bioepis

James Jun, CEO, KT&G Life Sciences

Don Hyun, President, MSD Korea

Korea's economy has been dominated for decades by chaebols, large family-owned business conglomerates like Samsung, Hyundai, and LG, known for their hierarchical structures and success in Korea's traditional sectors. However, a number of these big businesses are today making investments in the life sciences area – and those that started early are leading the pack: LG Life Sciences, for example, was the first Korean company to have a new drug approved by the US FDA.

In 2011 the country's biggest chaebol, Samsung, created a joint venture with Biogen Idec to form Samsung Bioepis, an offshoot of the Samsung group dedicated exclusively to the research and development of biosimilars. By 2016, the company already expects to launch its first product. "Because of the Samsung brand on our back, we have been able to attract the best talent pools and that is where many other Korean CEOs' biggest nightmare begins; attracting the right people," says Christopher Ko, CEO of Samsung Bioepis. "When we announced the foundation of Samsung Bioepis, the development status of our project was at an early stage. But Biogen Idec saw our potential and our willingness to work hard. They believed our story because the Samsung group was behind it, and this has helped in terms of obtaining necessary technology and guidance. The Samsung brand will continue to place us at the forefront of the competition."

Earlier, in 2009 MSD launched a partnership with Samsung to develop biosimilars. "At that time, MSD was just starting in biopharmaceuticals, and Samsung had not done much in healthcare," explains Don Hyun, president of MSD Korea. "Nevertheless, Samsung came up with some in-licensed products and within a year and a half they had three promising molecules. By creating a global partnership, Samsung was able to carry out clinical valuation development and product registration, while MSD retained global commercialization rights. We are looking forward to the addition of those products towards the end of 2015."

Although not a chaebol per se, KT&G, Korea's biggest tobacco company, created its Life Sciences division in 2002 as a venture project that has dabbled in creating drugs across a wide spectrum of indications. James Jun, CEO of KT&G Life Sciences stopped most of these projects to focus on just two products in-depth. "The first project is mainly focused on accelerating biogenesis in mitochondria, which targets MELAS Syndrome," he quips. "Our other project focuses on studying Type-2 diabetes. I believe these two products have very new mechanisms for which the global market is demanding. If these projects succeed, KT&G Life Sciences will go for an IPO, at which point we will consider receiving funding from the outside and manage itself as a venture company." Jun certainly hopes KT&G will develop the first Korean blockbuster.

Jae-Don Park, Chairman, Korea Pharma

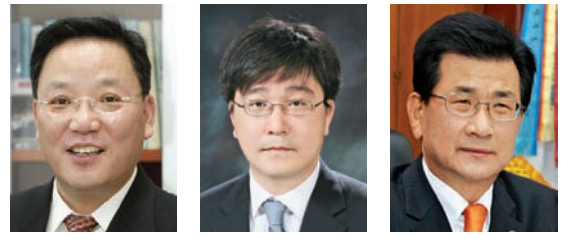
Kim Won-Bae, Vice Chairman, Dong-A ST

people's needs," he explains. "However, the methods of expanding could be diversified. For example, we have recently signed a technical contract with Iran. We send the products first and will build a plant later. We also will have made our spot in Chengdu, China. Furthermore, following the market situation and requests, we will expand our business territory to the whole world."

Ambition and innovation is not limited to the biggest or best funded Korean labs; domestic companies of all sizes and levels of experience are prioritizing R&D investment and planning to develop new drugs in the future. Korea Pharma is a prime example, and Chairman Park Jae-Don explains they have become involved in "several R&D projects with a few different partners" over the past few years. One such project is a "pre-clinical trial for a dementia treatment based on osmotin, an ingredient extracted from tobacco leaves, in conjunction with Kyeong-Sang University," while they are also working with an "overseas partner to develop a product

that treats disease caused by bacteria resistant to CEPA antibiotics, and are currently conducting late phase clinical trials."

"Most Korean pharmaceutical companies think they need to develop new drugs by following a manual, without having the necessary technology or infrastructure first, or in other words, without the capacity to do so," says Kim Won-Bae, vice chairman of Dong-A Pharmaceutical, another Korean giant with ambitions to enter the global top 100 pharma companies in the next ten years. "Rather, we think we should focus on what we are capable of doing. So we deal with traditional drugs that have already been verified and used." In 2014, the US FDA approved Dong-A's antibiotic tedizolid marketed under the name Sivextro, the second ever such approval for a Korean innovative drug.



From left: Oh Tae - Kwang, CEO, KRIBB; Shin Young-Kee, CEO, Abion; Lee Shi-Jong, Governor, Chungcheongbuk-do

BURGEONING BIOTECH

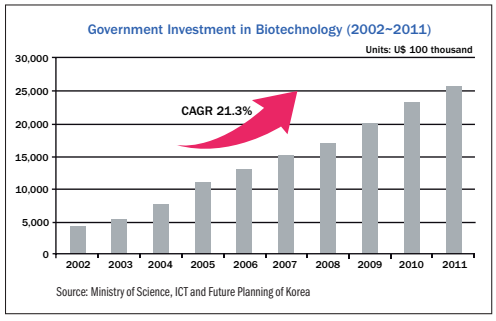
One of the pillars leading the growth of Korea's pharmaceutical industry is biotech, as seen through the large amount of resources being expended in this area by both the government and the private sector. One of the leading forces in expediting Korea's growth in biotech is the Korea Research Institute of Bioscience and Biotechnology (KRIBB). Its current president, Oh Tae-Kwang, has been working to restructure the institute to best fit the needs of Korea's next generation of scientists, by fusing Korea's strength in IT and nanotechnology with biotechnology. "KRIBB wants to serve an important role in composing the bio industry ecosystem," Oh remarks. "We are building a system for 20 major companies and 130 small and medium-sized enterprises to collaborate together over five sectors. Previously, these sectors worked independently and without coherence; now they interact with each other extensively, which will lead them to the global market." KRIBB's vision is to be a global research institute leading bio-innovation by 2018, with a goal of producing five world-class platform technologies by that time as well as having one of the top research infrastructures in the world.

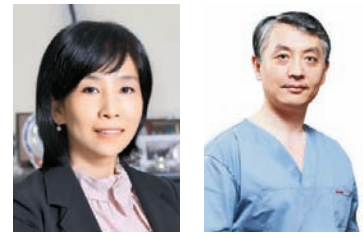
The market in Korea is abounding with numerous ambitious startup biotech companies. Abion, originally a startup venture of Seoul National University to provide molecular pathology analysis services in 2007, is one such example. In 2009, the company began conducting studies for potential new pharmaceutical development and in just a few short years has three new projects in the pipeline, most notably a siRNA therapeutic project for the development of a chemo-radio sensitizer for the treatment of advanced cervical cancer and head and neck cancer caused by HPV. "Our primary target market for siRNA therapeutics is the US market," says Abion's CEO Shin Young-Kee. "The number of patients with advanced cervical cancer is relatively small; however it is a good market to validate whether our concepts on siRNA therapeutic development are correct or not. We consider the key pharmerging countries such as Russia, China or India as secondary markets in the future."

Top 10 South Korean Companies

Rank (Asia rank)	Company	2013 pharma sales ($m)	2012 pharma sales ($m)
1 (35)	Yuhan	862	689
2 (37)	Green Cross	812	721
3 (41)	Hanmi	667	607
4 (48)	Daewoong Pharmaceutical	617	590
5 (52)	Chong Kun Dang	512	415
6 (55)	Dong-A	452	827
7 (56)	Jeil Pharmaceutical Co Ltd	413	379
8 (60)	ILDong Pharmaceutical Co Ltd	376	351
9 (63)	JW Pharmaceutical	361	353
10 (68)	LG Life Sciences	305	290

Source: SCRIP





From left: Yang Yoon-Sun, President and CEO, Medipost; Moon Eun-Sang, CEO, SillaJen

Many of these bioventures have benefited from the support and protection of one of the national or provincial government's various biotech incubator projects. The province of Chungcheongbuk-do has developed the largest and most extensive of these centers, the Osong Bio Valley. "We had set the goal of attracting six national health policy institutes to this cluster and have succeeded, and already have more than 60 different pharmaceutical and biotech companies that have established offices within the Osong complex," explains Lee Si-Jong, governor of Chungcheongbuk-do. "With the health policy institutes in Osong, the ministries and national agencies across the river in Sejong, there is no other city in the world where you can find as much political and regulatory infrastructure in close proximity to healthcare and life science cluster. In two or three years time we will have developed a rectangular belt of R&D clusters for different niches in healthcare," explains Lee. "We expect to see some tangible success of these development projects within that timeframe."

Medipost, one of the 60 life science companies with facilities in Osong, was founded in 2000 as a public umbilical cord blood bank by Yang Yoon-Sun, a former clinical pathologist at Samsung Medical Center in Seoul and medical professor at Sungkyunkwan University and Korea University. In 2012, the company's lead product Cartistem was approved for marketing by the MFDS and is currently undergoing an FDA approved Phase IIa trial in the US. Stem cell therapies such as Cartistem "are such a revolutionary, innovative area of medicine, there is no existing regulatory framework in place," says Yang, who highlights that "Medipost is playing a key role in this process in Korea and elsewhere, because we are working closely with regulators for these regulatory changes."

In the field of oncolytic viral therapies, SillaJen is a global leader and has published several papers in *Nature and Nature Medicine* on their groundbreaking work. CEO Moon Eun-Sang describes their lead product candidate, an oncolytic vaccinia virus that they call Pexa-Vec, as a "bona fide medical breakthrough of immense proportions," one that "doesn't represent just a cancer treatment, but an actual cure for cancer." SillaJen is "the first company to try to develop an oncolytic vaccinia virus," says Moon, who adds that they "can deliver the vaccinia virus to tumors intravenously as well as intratumorally, while the other oncolytic candidates that are suitable for solid tumor cancers must be injected intratumorally." Clinical trials have generated a lot of excitement so far, and Moon explains that "in our phase II A trial, out of 30 patients, 21 demonstrated partial tumor responses, and four were completely cured." "At present," he concludes, "we are preparing to begin a global phase III clinical trial for Pexa-Vec's efficacy as a treatment for hepatocellular carcinoma."

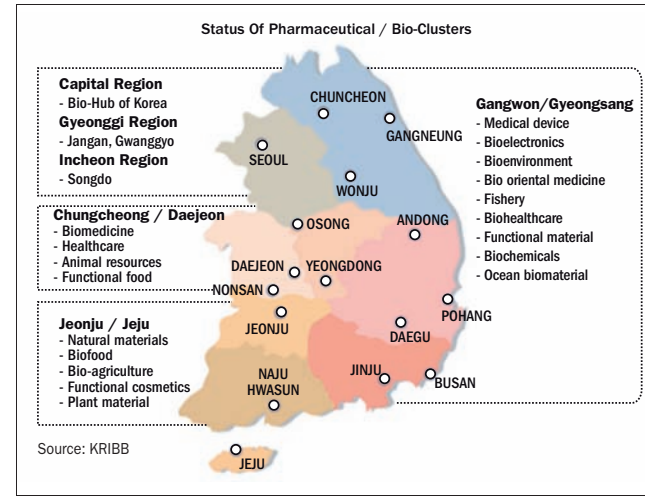
Osong Bio Valley

MASTERS OF THEIR OWN DESTINY

Minister of Health Moon Hyungpyo accompanied Korea's president on a state visit to the Middle East in February. "This was the first time for a health minister to join the president during the state visit to Middle East countries," explains Moon, "which is a testament to the fact that the healthcare sector is one of key pillars of the Park administration's Creative Economy. Some GCC countries have chosen Korea as their healthcare partner as they are becoming more interested in setting up or improving their healthcare systems." Over 150,000 people from across the globe have come to Korea to take advantage of its health services.

Kim Han-Joong, Chairman, CHA Strategy Committee

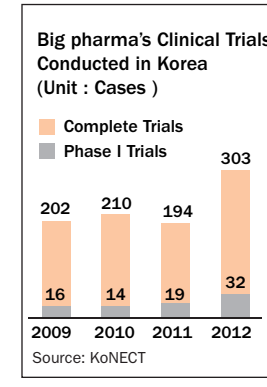
Some countries have begun to look to Korea as a model and partner. Thus far, the most prevalent form of partnership has been that of Korean hospitals opening affiliates all across Asia, the Middle East and even the United States. Kim Han-Joong, chairman of the strategy committee at CHA Health Systems and board member of Samsung, believes that the strength of Korea's future global contribution to health lies in its ability to export health systems and health technology. "We have well-trained health professionals and cutting-edge facilities and equipment in our hospitals. Compared to the population, there is an abundance of hi-tech equipment in Korean hospitals, because the competition among hospitals here is very high. In terms of equipment competition, Korea's strength is in the area of information technology-biotechnology (IT-BT) convergence technologies as well as stem cell research and cell therapy."



Kim concludes with Korea's plan of action for the coming years: "This country has developed healthcare systems based on the welfare model, but now we must turn from a welfare to industry model. Secondly, until now, the government has controlled much of the system, but it must become more market oriented. Thirdly, our interest has been historically limited to the domestic market; Korea must move from a domestic model to a global market."

KONECTING THE DOTS

The growth of clinical trials in Korea has been remarkable in recent years. The number of clinical trials performed by multinationals has shot up from five in 2000 to 303 in 2012, with 367 clinical trials performed by local companies. In the same year, Seoul was ranked the number one city worldwide for clinical trial competitiveness, according to the US National Institute of Health, and Korea is ranked tenth worldwide.



Why has Korea become such a favorable country for doing clinical trials? Liz Chatwin, country president of AstraZeneca Korea, explains: "The clinical research facilities of institutions like Samsung Medical Center or Seoul National University are much better than

anywhere else in the world, even the US. This is because they have a coordinated approach to research with all the phases of research under one roof. The implication of this is that institutions can mix expertise in pre-clinical research, translational science and clinical development in one place. They can then do clinical research very efficiently." Chatwin also attributes a well-tailored patient database to this efficiency. "Hospital patients can be identified rapidly to fit particular criteria for a clinical trial," she remarks. "Because the big institutions treat almost every type of patient with almost every diagnosis in their center, they can recruit individuals for just about any clinical study very quickly."

From left: Liz Chatwin, Country President, AstraZeneca Korea; Deborah Chee, CEO, KoNECT; Jack Lee, President, LSK Global; Albert Liou, Vice Chairman, Asia Pacific Region, PAREXEL

"With 50 million citizens all covered by a single public healthcare system, Korea has a much bigger pool than other countries in term of people exposed to clinical trials," adds Deborah Chee, president of the Korea National Enterprise for Clinical Trials (KoNECT). "The size of our economy and the characteristics of Korea's population as the fastest-growing ageing society worldwide provide us great potential. Our disease patterns are similar to that of western countries; for the elderly, the government focuses primarily on cancer and neurodegenerative diseases."

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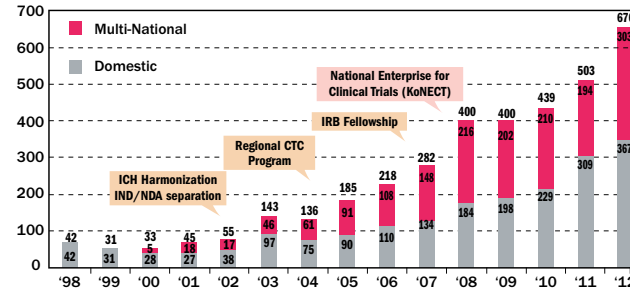
Chee, whose goal is to increase Korea's clinical trial positioning from tenth to fifth worldwide, notes that there are currently 15 supported regional clinical trial centers across the nation with financial support from the government and with matching funds from hospitals. Furthermore, in 2012 the government launched a program to identify new Global Centers of Excellence for Clinical Trials, of which KoNECT has selected five so far. "These centers should further the clinical trial capability of Korea, especially focusing on specialized areas like complex clinical trials, studies in special populations, and patient-oriented Phase I clinical trials," says Chee. "Korea is contracting more global Phase I studies for indications like oncology. So far about 160 sites have been accredited by the Ministry of Food and Drug Safety."

The explosion in number and quality of trials in Korea certainly makes an attractive case to attract multinational CROs; but to what extent do these companies actually contribute to Korean research? Jack Lee, president of Korean CRO LSK Global, notes that the recent arrival of global CROs has drastically changed local CROs' sponsorship base. Moreover, global CROs present in Korea have the financial muscle to hire the best Korean talent, having been trained by local CROs. "CRAs of

Clinical Trials Approved by KFDA



*Source : KFDA, 2013

global CROs do not complete the life cycle of studies as CRAs hop around from one CRO to next," laments Lee. "They spend a couple years at each company and very few see a study from beginning to end. Global CROs do not contribute at all to Korean clinical drug development technology, because all the protocols, data management, statistics and project management are done at these companies' headquarters. It is nonsensical to believe that because we are active in global clinical trials, Korea will benefit from such activities. Global CROs do not teach us anything. They just use our trained labor, stolen from companies like mine. To them, Korea is like a clinical trial assembly plant country."

Albert Liou, Vice Chairman of PAREXEL Asia Pacific, takes a different tone on this issue, arguing that while "the clinical development industry in Korea has become more competitive, but also more collaborative." "Local CROs have their own strengths, including government support and a general 'home team advantage', while we have different strengths and assets as a global CRO, specifically our technological capabilities." As the local CROs have developed, PAREXEL has "greatly developed our role as a healthcare consultant," explains Liou. "Often, the Korean CRO will manage trials conducted in Korea," he says, while "PAREXEL provides eClinical trial technology, safety monitoring, and project management for trials conducted in

An Elderly Crisis

Lee Sang-Suk, CEO, KRPIA

Korea is a large market: with a population of 50 million, the pharmaceutical market was valued at USD 18.6 billion in 2013, making it the 14th largest in the world. "Korea has always been a consumer nation for innovative new drugs rather than a developing nation," says Lee Sang-Suk, CEO of the Korea Research-based Pharmaceutical Industry Association (KRPIA). The market's value is forecast to rise to USD 24.3 billion by 2020; much of this growth caused by the country's rapidly aging population. In 2013, the number of people aged 65 and over in Korea reached six million, or 11.7 percent of the total population. But the real worry for Korean policymakers is the projected growth of this aging population: by 2050, the number is due to rise to 33 percent.

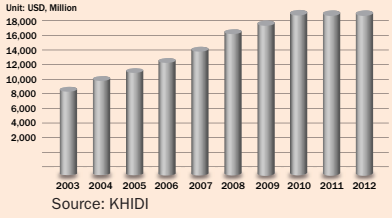
"We forecast that in 2017, Korea will be an aged society and a super aged society by 2026, which tells us to prepare for an aging era in overall society," cautions Kim Choon-Jin, chairman of the Health & Welfare Committee of the National Assembly of Korea. "Especially in the near future, the baby boomer generation of more than 7.1 million people will enter into the senior citizen class. This generation possesses a higher education level and diverse society experience compared to current senior citizens. Considering the changing features of society, it is necessary to reform and implement systems that prepare for the future." On top of that, Korea has been categorized as a "low birthrate country" for the last 13 years, with an average birthrate of 1.13 children in 2013.

From left: Kim Choon-Jin, Chairman of Health & Welfare Committee, National Assembly of Korea; Tom Roberts, Managing Director, UCB Korea

It is perhaps this looming threat that led the Korean government to follow up on its 2006 price cuts with another round of cuts in 2012, which saw prices drop by an average of 14 percent. Consequently, drug prices were reduced to 45 percent of the average of OECD countries. However, the country's drug expenditure compared to 2007 increased by 1.2 percent, still twice that of the average of OECD countries. A pre-emptive price cut could stop this figure rising even higher as the population ages, but it may damage the development of the pharma sector that the government is counting on.

"The government has repeatedly said that it wants to nurture and develop the pharmaceutical industry. However, not recognizing the value of innovation will be ma-

jor hurdle for the government trying to achieve its Pharma Vision 2020," warns the KPMA's Lee. "There is a disconnect between what the Korean pharmaceutical industry wants to do and what the Korean government wants to do," argues Roberts of UCB. "Korea's Pharma Vision 2020 aims to make the country a top seven player within a very small amount of time, but price controls make it almost impossible for some companies to stay in business."



Evolution of the Korean pharmaceutical market in value: 2003 to 2012

Two of UCB's products were launched last year with non-reimbursed status because the Korean health authorities' suggested reimbursement prices were just slightly too low to be profitable (nine percent of US prices). This is not only a big concern for Roberts, but many other multinational CEOs constantly facing similar situations. "Multinationals, who can teach people here about the innovation process, will slowly either withdraw or transform their business into cash cow enterprises and sell old products," Roberts comments. "There are many companies with great products in the pipeline that may not be able to launch due to the current pricing situation. Korea is a modern, fully developed country that is rivaled in size with many European countries. The pricing situation, combined with a 44 percent OECD pricing average, is not conducive to this 2020 Vision." All eyes will be on Korea as one of the first super-aged societies, to see whether legislators can find a sustainable solution that balances access to innovation with good financing.

other countries, and we work to together to maximize the returns from our shared clients' resources."

FREE TRADE EVOLUTION

Following the implementation of the Korea-US free trade agreement (KORUS FTA) in 2012, Korea has lowered its import tariffs, enhanced its regulatory transparency, and attracted an influx investment from multinational pharmaceutical companies, especially in the form of JVs with domestic players. "Korea has signed free trade agreements with a number of parties; one part of that agreement was to ensure a proper IP protection scheme. Most relevant for us is the patent linkage system, implemented in March 2015, which will allow the base requirements to be met for proper protection of IP rights in the pharmaceutical sector." says Lee Sang-Suk, CEO of the Korea Research-based Pharmaceutical Industry Association (KRPIA).

In addition to Korea's excellent clinical trial infrastructure, multinationals also have at their disposal a plethora of local companies and research institutes with which they can work hand in hand to each other's mutual benefit. Novartis, which registered more clinical trials in Korea in 2013 than any other multinational, has found strategic ways to team up with the local community to further enhance Korea's creative economy. "One way is through co-marketing and distribution partnerships," says Brian Gladsden, president of Novartis Korea. "In this way we can complement each others' skills and capabilities in the marketplace

Brian Gladsden, President, Novartis Korea

Executive talks

Chun Young-Chin, CEO, PMG Pharm

The long-term perspective

Chun Young-Chin founded PMG Pharm (Pionex Management Group) in 2001. From its origins as a small medical distribution company, he has successfully built it into a rapidly growing drug manufacturer, specializing in a number of diseases.

"The Korean pharmaceutical industry has experienced dramatic changes regarding its policies and market environment inside and outside of Korea for the last ten years, but pharmaceutical companies have done well to manage these crises. I think that we should recognize that crisis causes problems that the pharmaceutical industry must tackle, and there should be a supporting plan to realize the visions and strategies that the Korean government has proposed through the Pharma Vision 2020."

Lee Kyoung-Ryul, Chairman, SCL Healthcare Group

Korea's big data opportunity

Combining Korea's expertise in technology with healthcare, SCL has grown to become the largest diagnostics service provider in the country: today, the company examines around 30 million cases per year.

"As this is a diagnostic center, we deal with non-patients (healthy people), as well as patients from all of Korea's hospitals. SCL takes all the information we get from every patient to a data warehouse. Thus, in other words, data implementation business is our most important research business today," explains Lee Kyoung-Ryul, chairman of the SCL Healthcare Group. SCL has pioneered some groundbreaking technology in recent years, including a device that tests for 56 different congenital metabolic diseases in newborn babies. "As central laboratory, SCL Lab screens 30 percent of clinical specimens of total newborn babies," Lee reveals. "The data we have covers a broad range of information. It is panoramic data compared to other organizations. The fact that we have the largest market share in Korea means that we have a significant amount of data. We are planning to cooperate with pharmaceutical companies, institutions, and biotech companies in Korea and abroad with this well-organized data."

to offer more to our customers and reach more patients. In addition, potential R&D collaborations could provide huge opportunities for both partners in Korea. Many domestic companies are looking to increase their R&D capabilities and are investing significantly in this area." Through the Novartis Venture Fund, investing in smaller companies in Korea also shows promise. "As of today, we have invested in three local companies and hopefully there will be an opportunity for similar investments in the future," continues Gladsden. "This provides a unique opportunity for knowledge-sharing, R&D capability-building, education and training. I believe that further collaboration between multinational and domestic companies, and investments in smaller Korean companies, are very much aligned with the Pharma 2020 Vision to grow the Korean pharmaceutical industry."

"Many Korean companies can be highly effective partners from the distribution and promotional perspective," concludes Gladsden. "Many of these businesses have long histories here, which provide in-depth local knowledge and expertise. Through mutually beneficial partnerships we can benefit from the local expertise and domestic partners can learn from the global experience of multinational companies as well. This is increasingly important as many domestic companies have aspirations to increase their presence worldwide. In addition, with the increased investment in R&D by many local players, multinationals have an excellent opportunity to partner on innovative new drug development that can ultimately benefit patients globally."

Examples of collaboration

GE Healthcare (2009)

GE Healthcare founded U-Health Global R&D Center in Songdo, Incheon, in 2009, supported by matching funds from the Ministry of Trade, Industry and Energy and Incheon City. The company will invest KRW 6 billion (USD 5.45 million) over six years.

Novartis (2008-2010)

From 2008 to 2010, Novartis selected three of Korea's bioventures (**Neomics, Pharmabcine, Quroscience**) through KOTRA's Global Alliance Project and made equity participation.

GlaxoSmithKline (2010)

GSK engaged in equity participation (9.9 percent) in **Dong-a Pharmaceutical**, establishing a division dedicated to GSK's products through JV, developing and commercializing generic drugs and fostering stronger cooperation.

Samsung (2011, 2012)

Samsung BioLogics with **Quintiles**. It also founded another joint venture company with Biogen Idec.

Ajinomoto and Genexine (2012)

Ajinomoto, a Japanese company specializing in the development and production of food, amino acid and other chemical compounds, has signed an agreement with **Genexine**, a Korean bio venture business, to invest in a joint venture business for the production of cell cultivation media.

Source: Invest Korea

Impact of the potential Korea – China FTA

What are the major implications of the Korea-China FTA that received preliminary approval in February 2015?

Han Ki-Won, Commissioner, Invest Korea

The significance of this FTA is much greater than that of the previous FTAs with the EU and US, primarily because we actually face some significant tariffs in China. Furthermore, since it is physically such a close market, the tariffs are actually the primary barrier, instead of a relatively minor one compared to shipping and transport costs. Thus, the FTA will radically change trade conditions between China and Korea once ratified, and make exporting to China much more feasible for companies in Korea.

Positioned between Asia's two largest markets, China and Japan, and with favorable trade conditions with both, Korea will be an ideal location for business to enter the region and locate manufacturing facilities. Furthermore, the FTA will also make it easier for Chinese companies to enter Korea, and our agreements with the US and EU will make us an attractive platform for them to export their products to the rest of the world. The government is formally promoting this "entry point" mechanism.

Photo: Getty images/Stockbyte

Time Capsule: A New York Pharma Exec, 1960

Inspired by TV's *Mad Men*, Julian Upton puts himself into a 1960 executive's shoes to describe the 'ethical pharma' industry of half a century ago

It's strange to think that the industry as we know it now began only about 20 years ago. It wasn't until after WWII that the wonder drugs really took off. Before that, no ethical drug manufacturer could boast a sales volume even as large as Macy's department store. But by 1946, ethical drug sales amounted to $500 million; last year, it was over $2 billion.

It's a boom time for our company. Worldwide revenue topped $175 million last year, a 14% rise on 1958. We've come a long way since the '51 merger. Back then we were mainly in toiletries and cosmetics; now, pharmaceuticals account for 61% of our domestic sales and we've also expanded internationally, with sales branches in Great Britain, India, China, and Australia.

I oversee our advertising activities. Until recently, the pharmacist was the man we had to target; now it's the physician. This has led to new ways of selling, such as the use of "detail men." The detail man is no ordinary salesman; he has to be an orator, a journalist, a diplomat, and a scientist all rolled into one. It's challenging work—he might have 100 doctors to call on—but he can make $10,000 a year.

We also advertise in the conventional way, but our direct mail campaigns use state-of-the-art color printing. Nothing less will do—physicians are highly educated and artistically discriminating. We also have to find inventive ways of establishing cordial relations with them. This takes more than supplying them with free drug samples or free golf balls. For the launch of *Sedaton*, our tension-relieving drug, for example, we sent doctors free pillows in handy plastic cases, head rests that can be attached to a car, train, or plane seat, and striped slipper socks with the brand name stitched into one side.

I'd say the ethical pharmaceutical business is a young man's game. You just have to look at some of the other companies. Lawrence Barney was president of Hoffmann-La Roche at age 38. Francis Brown took charge of Schering at 40. As for Pfizer, almost two-thirds of its management are under 40. I'm 39 and have been vice president in charge of promotion at my company for four years. Researchers tend to be even younger. Merck & Co.'s Lewis Sarett was 27 when he synthesised cortisone; George Rieveschl, of Parke-Davis, 30 when he helped develop *Benadryl*. We have a vibrant, egalitarian outlook that separates us from a lot of sectors. About 40% of the industry's employees are female, and many of them are engaged in work that is beyond the routine.

The industry has been called to account over its profits. The US Senate subcommittee last year criticized our "1,000% markups." But they did not consider the research, distribution, promotion, and selling costs it takes to get a new product on the market. No other industry plows as much as we do back into research—up to 10% of our sales dollars. Do you know what it costs to research and develop a drug? We're talking upward of a million dollars.

Fortunately, the industry's prestige remains intact. You just have to look at the health changes of recent years to see what it has helped to achieve. Our children can expect to live long lives. There are now at least 7,000 people aged 100 or over in the United States. Antibiotics and sulfa drugs have reduced pneumonia from the leading cause of death to a treatable malady. And in the last six years, tuberculosis treatments have cut the TB relapse rate from as much as 50% to 5%—so much so, Dr. Trudeau has closed his Saranac Lake sanatorium.

Outside work, I live a quiet life in Riverdale, NY, with my wife, Mildred, and our three children. My son Clifford is comic-book crazy and my daughters Janie and Rosalie live for sock hops. We have a maid, Leonda. I drive a '58 Colonial White Ford Country Squire. I enjoy swimming at my country club. We have a small place on Cape Cod where I like to fish for striped bass. I've caught a few twenty-pounders there, but generally I just go for relaxation—a rare commodity in these busy times! PE

Julian Upton is *Pharm Exec*'s European & Online Editor. He can be reached at jupton@advanstar.com.

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