THE REINVENT STORY:
FRED HASSAN REFLECTS

PAYERS LATEST PINCH
ON FORMULARY ACCESS

ETHICS OF EDUCATION
A CODE FOR PATIENTS?

Pharmaceutical Executive

MAY 2013
WHERE BUSINESS MEETS POLICY
VOLUME 33, NUMBER 5
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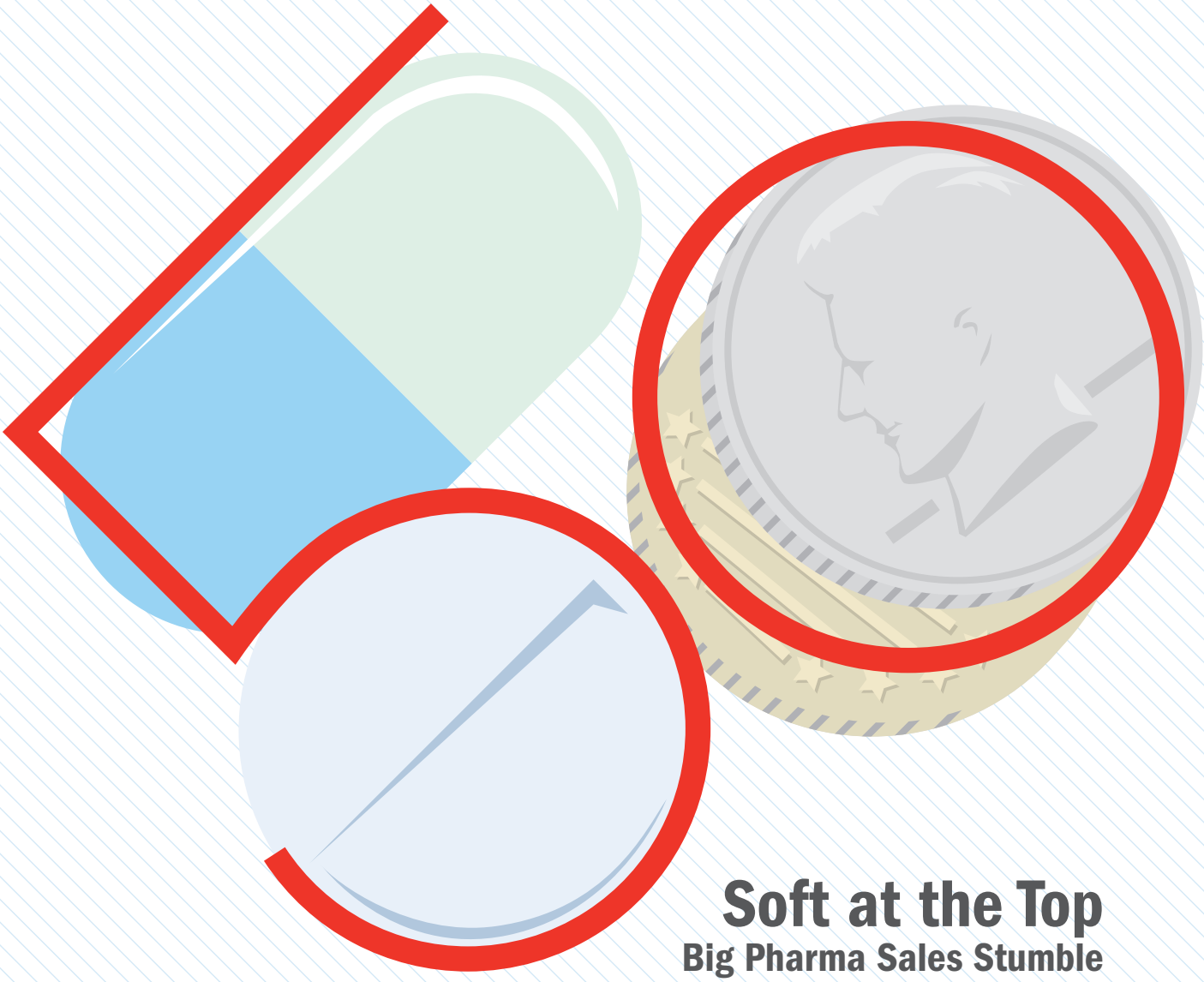

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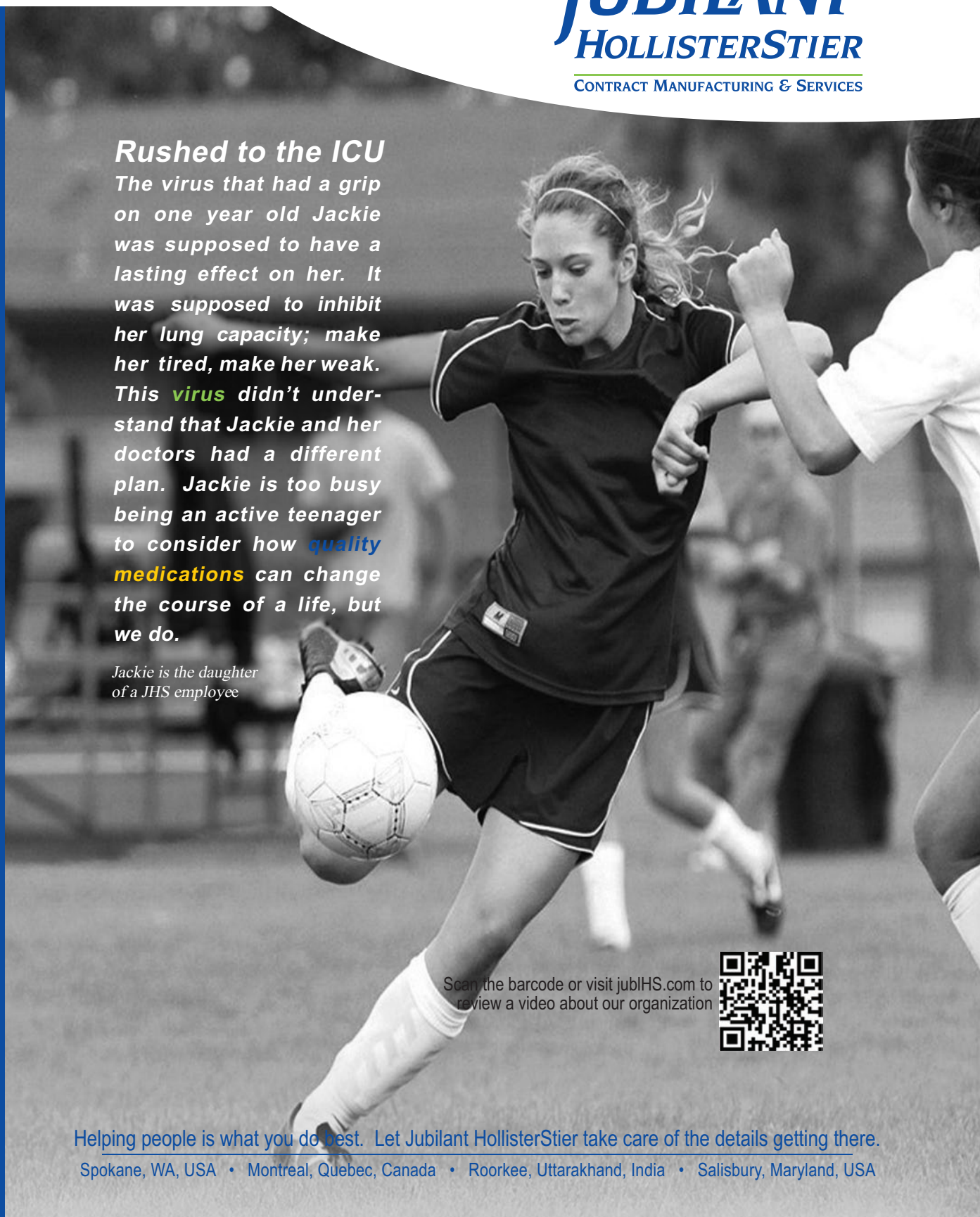

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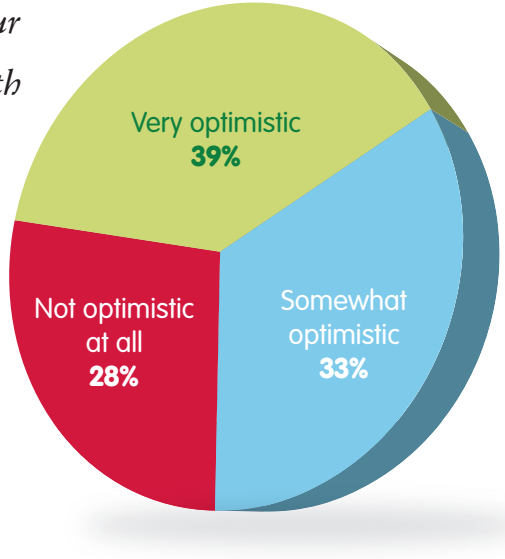
Q: How optimistic are you about your company's revenue growth in 2013?



Readers Weigh In

Pharmaceutical policy in India is not social policy—it is industrial policy. India spends less GDP than most countries in Sub-Saharan Africa to make drugs available for the poor. Despite claims that these policy decisions are intended to improve access and affordability today, less than a week after the Gleevec decision, India announced that generic producers would be absolved from price controls if their products claim "indigenous innovation."

James Ward, 4/4/13
"Six Side-Effects of India's Novartis Glivec Ruling"
http://bit.ly/ZURXH1

Instead of attacking the verdict, Western countries should raise their standards, too. Their over liberal grant of patents has led to the tiniest design changes becoming patentable. One example is last year's ridiculous battle between Samsung and Apple on whether features like a rounded rectangular cellphone screen and finger movements are patentable.

Suma Menon, 4/11/13
"Six Side-Effects of India's Novartis Glivec Ruling"
http://bit.ly/ZURXH1

Why would anybody that works for the federal government be exempt from [Obamacare]?

Scottie V, 4/29/13
"Congress 'Tip Toes' Around Obamacare"
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LAST MONTH'S DECISION BY INDIA'S SUPREME COURT TO DENY A PATENT for the top-selling oncologic drug Glivec took nearly a decade of litigation to resolve—but the implications in and beyond India are both immediate and lasting. Here's a list of four that *Pharm Exec* thinks are most important:

Patenting is a political act. Technical details of patent law aside, the Glivec ruling highlights the most contested issue in medicine today: what constitutes true innovation in an age where scientific advances are transforming the very definition of a drug? This is a question that extends far beyond patent law into basic value judgments like how society should spend limited resources on medical technologies, in a way that balances patient access with the economic incentives needed to seed their development in the first place. The external demand for value—the pressure to prove it beyond doubt—is driving every aspect of the pharma supply chain today. Seeking to raise the bar around the basic patenting criteria of novelty, non-obviousness and an innovative step, as the Glivec decision just did, is but one expression of this broader challenge facing the industry.

India has made a choice—on industrial policy grounds. What is interesting about the 112-page court judgment is not the cursory review of whether Glivec's chemical reactant composition delivered an "enhancement of known efficacy"—a requirement for recognition as a patentable innovation—but the emphasis it places on broader issues of policy and economics. The ruling quotes approvingly from the academic literature that "rules and regulations of the patent system are not governed by civil or common law but by the interest of the national economy." A third of the text traces the rise of the domestic drug industry, noting that "development of the bulk drugs sector is the most important achievement of the pharmaceutical industry in India," an outcome made possible by the absence of full patent protection for pharmaceuticals prior to the country's accession to the World Trade Organization (WTO) TRIPS agreement. It bears noting that many decades ago some industrialized countries pursued precisely this line of argument about patents—until they became themselves major sources of innovation. But this may simply beg the question in today's environment, where knowledge assets are instantly transferable across geographies.

The case suggests there is not much heft left to Big Pharma's reliance on insider lobbying and technical expertise to defeat the anti-patent access lobby.

No alms for the poor. Nothing in the court ruling suggests that the plight of those without access to essential medicines will improve. The decision simply maintains the status quo for Indian generic producers, most of who manufacture primarily for export—because the money is better abroad than at home. As the world's largest exporter of bulk drugs, Indian producers bear some responsibility for a recent World Health Organization (WHO) survey that found prices for even the lowest-priced generic products sold through the private sector were at least nine to as much as 29 times higher than the agreed international organization reference price, in most WHO regions. Even in the public sector, provision of essential generic medicines covers only about 42 percent of the potential target population in developing countries. Access to medicines is complex—it is a cliché that bears truth. Generic production, particularly for profit, will not by itself deliver what the court ruling claims is the commitment underlying India's patent law to "provide drug access to the rest of the world."

Industry strategy needs a re-think. The Glivec case suggests there is not much heft left to Big Pharma's reliance on insider lobbying and technical expertise to defeat the anti-patent access lobby and governments who apply IP as a discriminatory trade barrier. The case has shredded much of what was left of the industry's multilateral IP agenda, a decline that started with CEO acquiescence to the November 2001 WTO Doha Ministerial Declaration on TRIPS and Public Health. The Declaration, whose principles are embedded in the 2005 Indian patent law, limited the scope of drug patents where public health considerations intervene—a gap wider than a Mack truck—and thus had the effect of inhibiting enforcement of relevant TRIPS provisions. Recovery must start with a better message. If what the industry describes as India's patent "theft" can be justified by activists as providing more access to the poor, then most observers will say it is a vice that is easy to live with—especially when the top six Big Pharma patent holders are currently sitting on an idle cash pile of nearly $70 billion.

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Generic Drug Gains and Grumbles

Legal battles and regulatory missteps undermine access to low-cost generics, at home and abroad.

All the reports on the rise and fall in drug spending have one common feature: most savings come from increased use of generic drugs. Low-cost copycat medicines now account for more than 80 percent of US prescriptions, the number rising in recent years as more blockbuster therapies have lost patent protection.

The trend has heightened competition between generics and innovator products, as seen in heated battles over access to brand supplies for testing purposes and efforts by brands to delay approval and sales of biosimilars. A controversial Food and Drug Administration decision last month blocked generic makers from selling copycat versions of the original OxyContin painkiller when its patent expired April 16. The agency instead approved labeling citing anti-abuse features of a newer formulation of the product marketed by Purdue Pharma since 2010. Considered a "gift" to Purdue, the decision reflects pressure from state and federal officials who opposed FDA approval of cheap, easily abused drugs that would further fuel the epidemic of prescription drug abuse raging across the nation.

The fight for market share is just as intense on the international front, as seen in the recent landmark patent case in India (see sidebar). In the United States, though, generic makers and brands are allied in contentious Supreme Court cases. Meanwhile, generic drug manufacturing problems have led to serious shortages in key therapies, prompting FDA to propose new strategies for ensuring product quality that have disrupted regulatory operations.

Supreme decisions

Generic and brand companies are watching closely for two key rulings from the Supreme Court in June. The FTC v. Actavis case (docket no. 12-416) has received extensive media attention as it challenges "pay-for-delay" patent settlements between brand and generics manufacturers that determine when a generic competitor comes to market. The Federal Trade Commission has long attacked "reverse payment" deals as anti-competitive and harmful to consumers and now wants the court to declare them per se illegal. Both brand and generics firms counter that the arrangements avoid costly litigation and actually permit generics marketing prior to patent expiration. Democrats have proposed legislation to ban these settlements and will try to move forward if the high court fails to squash the deals.

The Mutual Pharmaceutical Co. v. Bartlett case (docket no. 12-142) is more technical, but raises important questions about whether lower courts can challenge FDA regulatory decisions, here involving when and how generic drug makers can revise labels to reflect important new safety information. A patient who took Mutual's generic drug and suffered hideous adverse events sued and won a $21 million judgment based on the company's failure to warn of the drug's potential dangers. Mutual argues that the long-marketed, anti-inflammatory and its label were approved by FDA, and the Justice Department agrees that states can't override federal regulatory policy, which would undermine the FDA approval process and open the door to multiple drug liability cases. This is the third case in recent years that has raised generic drug safety labeling issues, and there's growing pressure for statutory revisions that allow—or re-

Generic drug companies have suffered in the court of public opinion from manufacturing lapses and product quality problems that have led to critical shortages in important medicines.

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

quire—generics makers to add warnings to labels, even if the information differs from a reference product.

Shortages and competition

Generic drug companies also have suffered in the court of public opinion from manufacturing lapses and product quality problems that have led to critical shortages in important medicines, particularly for sterile injectable cancer therapies, analgesics, and anesthetics. FDA has strengthened its monitoring of shortage problems and taken steps to make alternative therapies available to patients, but low prices on these hard-to-produce drugs have deterred competitors from entering the injectables market.

Now the economic picture seems to be attracting new players to the field. Becton Dickinson (BD) recently announced FDA approval of an injectable antihistamine in pre-filled syringes, the first of a new line of pre-filled generic injectables.

Similarly, Jordan-based Hikma has expanded sterile injectable production capacity at its New Jersey plant following FDA approval of several injectable generic therapies, and Teva is expanding production of injectables at its facility in Hungary. BD acknowledges that its prefilled products will be more expensive than existing generic injectables, but claims they will be safer and easier to administer. The company is betting that providers and payers will accept higher prices for a more reliable, high-quality supply of necessary therapies.

FDA changes

Meanwhile, FDA's regulatory program for approving new generic therapies has been shaken by a series of organizational changes affecting the Office of Generic Drugs (OGD). The head of that office, Gary Geba, departed suddenly in March after less than a year on the job (see PharmExec.com posting, March 2013), apparently unhappy about a reorganization at the Center for Drug Evaluation and Research that would combine generic and new drug review chemists in a new Office of Pharmaceutical Quality (OPQ). Ever since the OPQ proposal emerged last fall, OGD staffers have raised concerns about decimating the generic drug review process. The change also appears to counter a move by CDER director Janet Woodcock last September to elevate OGD to "super office" status directly reporting to her.

Similarly, staffers in CDER's Office of Compliance are leery about OPQ swallowing up much of its Office of Manufacturing and Product Quality. The idea is to combine operations responsible for evaluating manufacturing data in applications for new drugs and generics with those overseeing compliance with good manufacturing practices, but that seems to involve stepping on a lot of toes.

To lend stability to the situation, Woodcock recently named agency veteran Kathleen Uhl as OGD acting director. Uhl faces the tricky task of implementing a more efficient application review process, overseeing more timely field inspections, whittling down an enormous review backlog, and establishing the new generic drug user fee program. She comes to the job with experience as a CDER reviewer, as head of FDA's Office of Women's Health and most recently deputy director of CDER's Office of Medical Policy, where she was involved with negotiations related to FDA's new biosimilars program. Uhl will need all her experience navigating the drug regulatory arena to meet public demand for high quality—and affordable—generic therapies. PE

Generics Rule in India

The global innovator pharmaceutical industry suffered a major blow last month from a decision by India's Supreme Court rejecting patent protection for Novartis' leading leukemia therapy, Gleevec (Glivec outside the United States). Generic drug makers in India and patient advocates around the world cheered the ruling arising from Novartis' seven-year fight to prevent generic sales of its leading product. The court decided that the current drug represents only a minor improvement to an earlier version and thus does not qualify for continued patent protection under India's 2005 patent law.

The ruling further supports compulsory licenses granted to Indian firms to produce generic versions of other leading drugs for cancer and serious chronic conditions, actions applauded by public health activists as necessary to ensure access to life-saving medicines in low-income countries. But for Novartis and other pharma companies, the decision clouds prospects for building lucrative sales in emerging markets and for negotiating treaties that better protect intellectual property in Asia and other regions.

Front & Center

Examining the Future of Patient Access

One expectation of health care reform implementation is millions of uninsured Americans gaining some form of insurance coverage. Manufacturer-sponsored patient assistance and access programs face unprecedented challenges as they evolve their models to best address the changing needs in the market. This was the overriding topic of CBI's 14th Annual Patient Assistance and Access Programs Conference on March 13-15.

Anthony B. Piagentini, Executive Director of Operations for Brand Support Services at Omnicare Specialty Care Group, discussed the access challenges facing specialty products post-health care reform. His talk included basic macro-economic principles affecting healthcare, an examination of the evolution of health insurance in the United States, results from the implementation of Massachusetts health care reform, and finally, a prediction on future specialty access. Following his presentation, *Pharmaceutical Executive* talked with Mr. Piagentini about some of the issues he raised in his presentation.

Why did you begin your talk by reviewing macroeconomic concepts and presenting the history of how health insurance has evolved? Why is this pertinent for pharmaceutical professionals?

Having a basic understanding of how the economy might react to various market shifts can help brand managers and others in the pharmaceutical industry better plan for various potential outcomes. One example of this is understanding how consumers (patients) will make decisions as costs continue to increase. Consumers make tradeoffs based on value. As cost-sharing for specialty pharmaceutical products increases, convincing consumers of the value of their medication compared to alternative options will become more important.


Anthony Piagentini

I reviewed the evolution of health insurance in the United States to remind us that many of the ideas put forth today have roots in insurance experiments of the past. For example, the only health insurance model that bent the cost curve down in the United States was Health Maintenance Organizations (HMOs). One of the issues with HMOs was the dual role of health care practitioners. They were supposed to advocate for their patients but were also financially incentivized to keep overall costs low since they were paid a lump sum per patient instead of per procedure. This has some parallels to Accountable Care Organizations (ACOs). These organizations will receive financial incentives to keep overall costs down by ostensibly eliminating unnecessary procedures and doing a better job of keeping the patient healthy and out of the hospital.

Finally, there is evidence that health insurance is moving back into a model that mimics how it started. Originally, insurance was only designed to protect against major hospitalization or other significant health related costs. Now we are seeing the rapid emergence of 'consumer driven health insurance'. This is a plan that covers patients for more catastrophic health problems but shifts costs to patients initially to financially incentivize them to make better decisions. The net outcome of these changes is that specialty manufacturers must prove and deliver value to various stakeholders (e.g. patients, ACOs) so they are willing to pay for the higher costs.

Assuming consumer-driven health insurance models continue to grow, what types of changes will specialty product manufacturers need to make in how they approach their customers?

Proving product value to patients will increasingly become the focus. The current model provides value propositions to healthcare practitioners and payers. Now, you will have to prove it to patients.

A recent McKinsey study examined patients' behavior when they were brought into a consumer-driven health insurance model. Patients were twice as likely to have a conversation with their healthcare practitioners about the cost of services being provided; three times more likely to choose less expensive alternatives when the value proposition didn't justify the increased expense; and more likely to follow treatment regimens.

Over the years, the economic incentives to patients have distorted proper decision making. One example of this economic distortion is medical versus

pharmacy benefit design in Oncology treatments. Due to benefit design, there are economic incentives for the oncologist to infuse drugs in an office setting rather than utilizing oral oncology therapies at home. In a consumer-driven health model, payers are doing a better job of protecting against this and better aligning financial incentives.

If accountable care organizations (ACOs) continue to expand post-health care reform, what might they ultimately look like; and how would that change the contracting and the value-landscape for specialty manufacturers?

When I think about ACOs I think 'big box retailer' healthcare service. Imagine going to a Wal-Mart-sized organization for your healthcare: In aisle 10, is primary care; in aisle 11, there's surgery; and so forth. This will be the one-stop-shop that includes everything from hospitals, to primary care, to mental health, and everything in between.

Over time, we can expect that ACOs will benefit from economies of scale. Given the significant overhead costs of operating health services, larger organizations will be more stable and profitable. These could evolve into large, regional healthcare organizations that cover entire geographies such as a Central New Jersey Healthcare System that included multiple hospitals, primary care offices, specialists, etc. Eventually, these organizations may evolve into insurers themselves, similar to what Kaiser Permanente has done in some regions of the United States. In our example of a New Jersey Regional Healthcare System, employers and their families in that area would contract directly with the organization. Since people rarely leave their local area and health care reform may make insurance more portable, the economic value argument for a specialty manufacturer changes. Currently, commercial payers generally care about a 2-year return on value since their assumption is that a patient will leave them and go to another insurer that quickly. If a large, regional ACO is acting like an insurer and is covering patients over a longer period of time, they will be more interested in a specialty product's 10-year, 20-year, or lifetime economic benefit.

The value to the organization of using a drug is more important than the actual cost of a drug. This will affect specialty decision-making from research to commercial deployment and change the discussion about the value a product brings to a payer. The one organization that does this well is the VA. Once a patient is in the VA, he or she is in for life. What's assessed then is lifetime value. Commercial insurers don't do it that way. The shift to ACOs might change that.

Right now the whole payer scheme is very complicated, and in the next 5 years, it stands to become even more complex. You're going to have exchanges, ACOs, commercial insurance, and a shifting Medicare and Medicaid landscape. Specialty manufacturers must create strategies and corresponding service-based tactics to help support their value argument and assist their patients in navigating the change.

How will the specialty pharmaceutical safety net evolve after health care reform completely takes effect?

Patient assistance programs will still be needed. Even several years after health care reform in the state of Massachusetts, there is still a portion of the population that cannot access insurance, even with the mandates and premium support.

The biggest change for specialty safety nets will be the need to manage patient cases more holistically. There will be a need to understand the dynamics of patients who are falling through the cracks and then assist each patient individually.

Currently, patient access services are important but generally not a primary driver of intelligence or value. In the future, specialty manufacturers must use these services as a key component of patient-relationship management. Patient-relationship management in the specialty space includes mining the information in the program to glean key customer insights to continue developing the patient value proposition, create true patient loyalty, and help with future marketing efforts through patient segmentation. These services will develop into a critical part of brand strategy trumping more traditional and increasingly shrinking marketing tactics like sampling or professional marketing.

How is Omnicare Specialty Care Group evolving to help manufacturers through these kinds of challenges?

Omnicare Specialty Care Group is a manufacturer-focused organization. Our unique suite of services is our first focus for creating platforms manufacturers need to help navigate the future. We accomplish this by placing operations at the head of the organization. Very early in the process, we're putting operations out there to help guide the manufacturer and partner with them to solve problems. We don't subscribe to the traditional sales model where the sales team passes the client to operations after the contract is signed. We examine our partner's brand strategy, match it up with our operational expertise and when we put that together, we get a solution that exceeds the demands of patients, aligns with the manufacturer-focused goals, and provides real value in the marketplace.

Is That VBP on the Horizon, or a Mirage?

Value-based pricing in the United Kingdom is getting closer, but it remains out of focus.

The news in late March this year that NICE will be responsible for the "full value assessment" of medicines under the United Kingdom's proposed new value-based pricing (VBP) system came after growing concerns that the government has remained worryingly unclear—and is betraying a lack of confidence—about how VBP will actually work.

VBP is set to launch when the United Kingdom's existing Pharmaceutical Price Regulation Scheme (PPRS) expires in January 2014. The PPRS, established over 55 years ago, is a voluntary agreement between the UK government and the pharma industry that controls the profits made by pharma companies from selling branded drugs to the National Health Service (NHS), but allows them to set their own prices within the constraints of the profit cap. It aims to serve both industry and NHS procurement policy, while allowing patients access to the best medicines. The flaws of the system have come into sharper focus in recent years; as well as suffering under the weight of—in the words of Mike Birtwistle of MHP Health Mandate—the "inherent conflict between the role of purchaser and champion," (August 24, 2011) there is the fact that the PPRS does not focus its price cuts on drugs that are deemed to deliver less "value." The new system aims to address this by setting prices that reflect the value of the drugs to society.

But, despite VBP in the United Kingdom being talked about as far back as 2007 (and formally presented in 2010 by the current coalition government as a replacement for the PPRS), by the beginning of this year critics were still accusing the government of failing to make any progress on it.

While the "last minute" confirmation of NICE's role within VBP may have satisfied the short-term demands of the Health Select Committee, it has not done much to clarify the key issues surrounding VBP.

In January, MPs on a House of Commons Health Select Committee declared that it was "unacceptable that the arrangements for VBP have still not been settled and that those who will have to work with those arrangements are still unclear about what [it] will mean in practice." The committees called for a decision on VBP to be taken "no later than the end of March." This call was honored—but only just.

On March 21, the Department of Health (DOH) announced that the new VBP system will build on NICE's existing appraisal processes but will also be "capable of incorporating a broader assessment of a medicine's benefits and costs, taking into account factors such as burden of illness and wider societal benefits."

But while this "last minute" confirmation of NICE's role within VBP may have satisfied the short-term demands of the Health Select Committee, it has not done much to clarify the key issues surrounding VBP.

The desire on the part of the DOH to demonstrate progress on VBP is understandable, says Birtwistle, but genuine progress isn't apparent. He adds that much of "the running (and thinking) remains to be done," (March 27, 2013).

For one, the term "value" itself remains elusive. As Meir Pugatch of Pugatch Consilium asserts: "Value is perceived very differently by the different players involved in the process, namely policymakers, producers, and, not least, patients."

Policymakers have displayed a tendency to attach a "more static meaning" to value, says Pugatch—"defined narrowly as value for money at a given point in time and in light of the desire to reduce or control costs." Such an approach to VBP, he

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goes on, "presumes *a priori* that a new drug has already been created. Payers do not attach value to the time, costs, and risks associated with the creation of the new drug, but rather only to its therapeutic outcomes compared with other treatments."

For Pugatch, the decision to place VBP firmly within NICE suggests that "the traditional 'realpolitik' approach to value is most likely to hold sway." The result will be that the United Kingdom is less well placed to become the source of the next new wave of innovative medicines.

Pray for delay?

NICE itself hasn't exactly helped to soothe the ongoing VBP anxiety; two weeks after the DOH's announcement, its own chief executive, Sir Andrew Dillon, told reporters: "I don't know very much more than what is in the public domain and the statements that have been made."

He went on to speculate that if VBP is to be "a radically different system, then whoever is involved in it is going to have to move very quickly." On the other hand, if it is "more of an evolution of the current arrangement, then it may be easier to see how 2014 is a more realistic prospect."

Such comments are unlikely to placate those calling for transparency and urgent clarification of the VBP process. Indeed, "evolution of the current arrangement" suggests that those predicting VBP will simply be a modified version of the PPRS may be right. Certainly, Dillon's uncertainty gives rise to the argument that a delay to the proposed January 2014 start date for VBP is inevitable.

For health economist Leela Barham, however, delaying VBP "could make a lot of sense." It would allow for efforts to improve access through innovation, health and wealth, such as automatic updating of formularies, to become established. Unfortunately, the opportunity to delay VBP "quietly" is impossible now following the Heath Select Committee's high profile criticisms. There is a chance though, she adds, that VBP could be introduced "in a phased way, tested on a few new products rather than all new products from January 2014." But one of the problems with this method is how to decide "who gets to be the guinea pig!"

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A delay would however mean further uncertainty with regard to medicines funded by the Cancer Drug Fund (CDF), which, like the PPRS, is set to close in 2014. The fund covers the cost of cancer treatments that NICE has either rejected or not yet decided on. (By December 2011 the fund had made around 10,000 treatments available to patients in England, covering 34 products.) "The CDF is supposed to be a 'bridge' to VBP," says Barham. If VBP solves the perceived problems with NICE in making recommendations on new medicines, then such a fund would not be needed. But the current lack of detail on VBP again leaves this situation unclear.

Whatever the progress (or lack of it) on VBP, NICE's future, at least, seems assured. With effect from April 1, its status changed from a strategic health authority to an executive, non-departmental public body, with new, added responsibility for developing "guidance and quality standards for social care" and encouraging the "better integration of health and social care services." The acronym remains the same, but NICE now stands for National Institute for Health and Care Excellence (after eight years as the National Institute for Health and Clinical Excellence). And with the new remit comes new blood; Sir Michael Rawlins, NICE's chair since its formation 14 years ago, has stepped down to make way for Professor David Haslam, who, alongside more elevated positions, spent 36 years at the coalface of general practice as a primary care physician.

In Haslam's first announcement as chair he admitted that tough challenges lie ahead for the expanded NICE. Forging ahead with workable approach to VBP will be just one of them. PE

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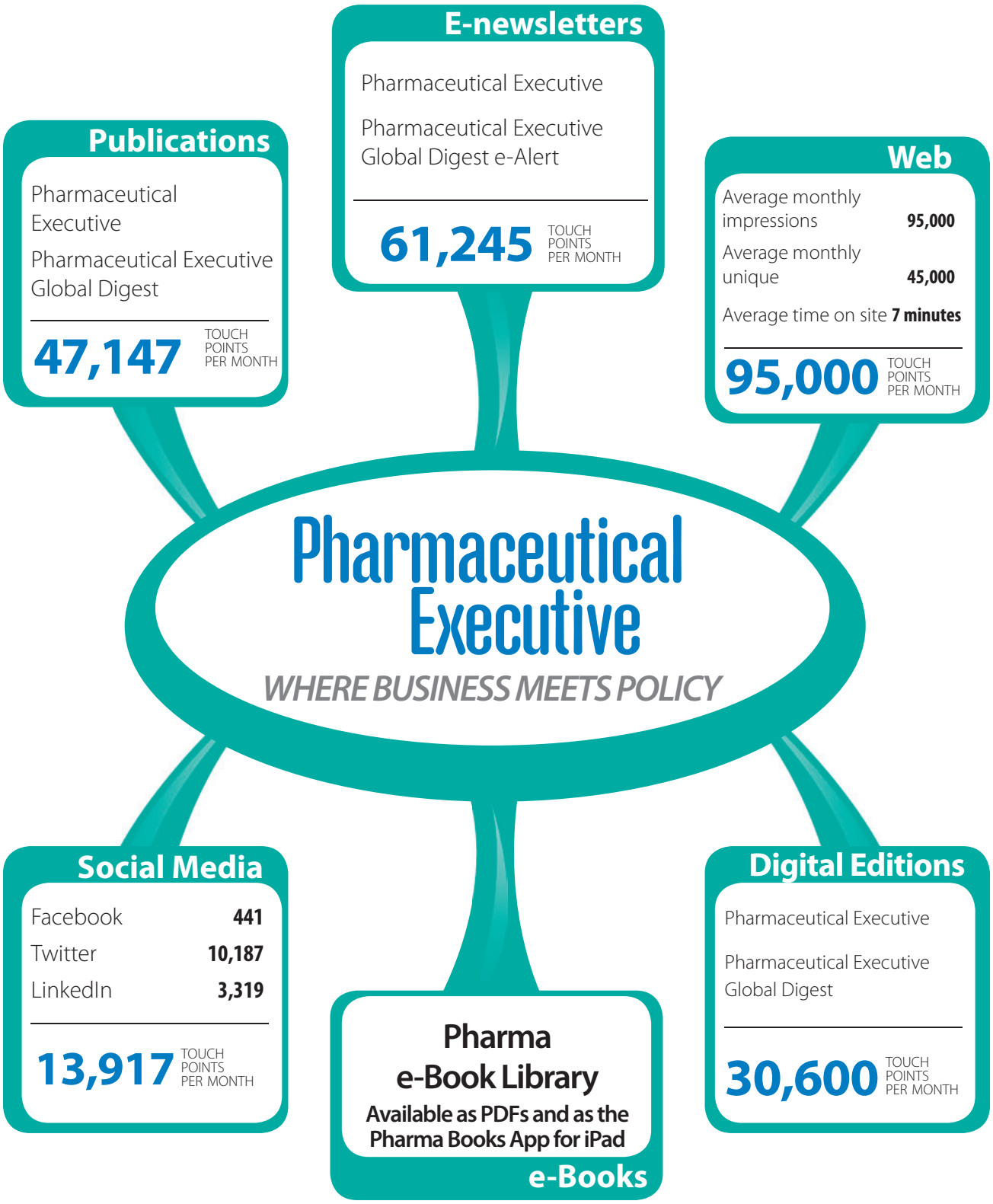
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TOTAL UNIQUE SUBSCRIBERS	**90,929**

FUNCTION DIMENSION	QTY
Business Development	3,797
Consultant	3,197
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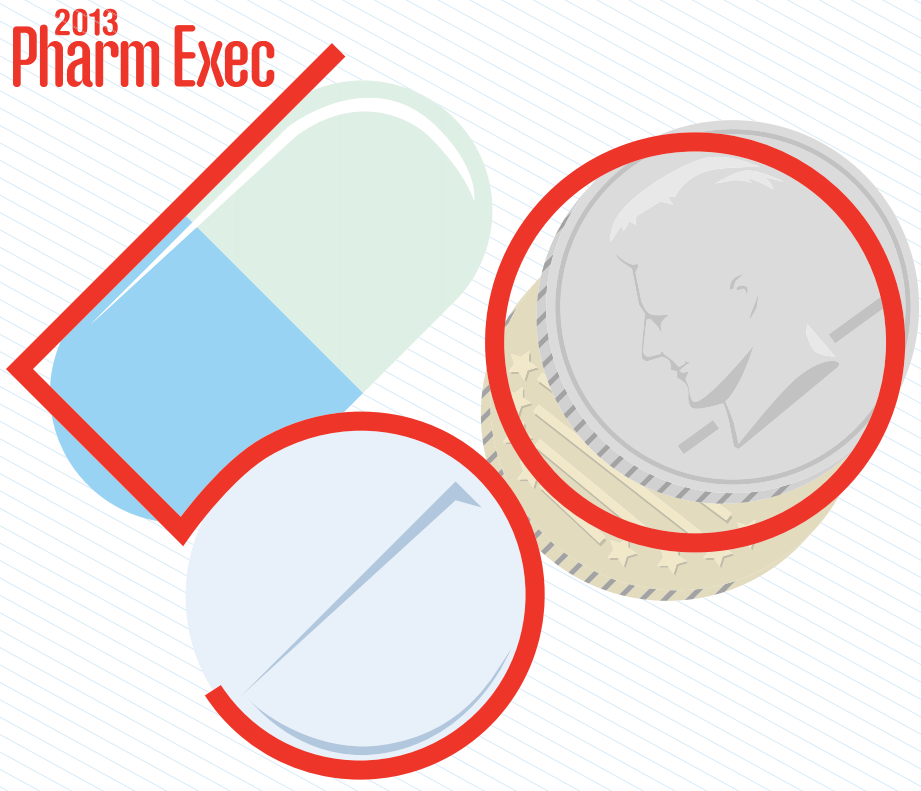


Patent expiries dampen revenues for some of the biggest Big Pharma, but deep pipelines and the geographic play on emerging country markets soften the blow—while growth continues unabated for a few nimble "stealth" players moving steadily up the list.

By Waseem Noor and Michael Kleinrock, IMS

Disruptive market change in the biopharmaceutical industry is a given—but individual company performance is rising to the occasion through efficient deployment of a still considerable inventory of product, process, and knowledge assets. If anything, uncertainty has helped push the Big Pharma players to put their own houses in order, chiefly by slowing the hemorrhage in R&D costs, which has deflected the negatives from the transformation of healthcare as a budget buster—for both households and governments. True to form, *Pharm Exec's* 2013 ranking of the top 50 pharma companies worldwide finds few variations from last year, with the notable exception being the Rx success of global generic firms as they benefit from innovative portfolio diversification: Teva is nipping at the heels of Eli Lilly, at just one slot short of the top 10, while Ranbaxy joins the Pharma 50 list for the first time. Overall, however, only a relatively small set of companies—BMS, in particular, which drops to 17th in global Rx sales, from 11th last year—have been affected by the rush of patent expiries, contributing disproportionately to the weaker industry sales performance over the past several years.

Another enduring truth is the startling lack of concentrated market power in pharmaceuticals. What has not changed since we began compiling the Pharma 50 in 2000 is the top 10 still comprise less than 50 percent of the global market (their 2012 global share is 42 percent, compared to 43 percent in 2007). Other industries less reputationally vulnerable than pharma see much more concentration at the top; certainly this is true in the payer community, where governments increasingly hold sway. Even in the patent protected market, the core competency of Big Pharma, the top 10 players' share remained at 52 percent in 2012, the same level it was in 2007. The bottom line? For pharma, business is still an intensely competitive game of chance.

—William Looney, Editor-in-Chief

20 Pharma 50

To identify what's driving the numbers, we examined the top 50 as a group and in comparison to companies outside the top 50. We see five trends shaping current sales performance across the geographies where the pharma group competes:

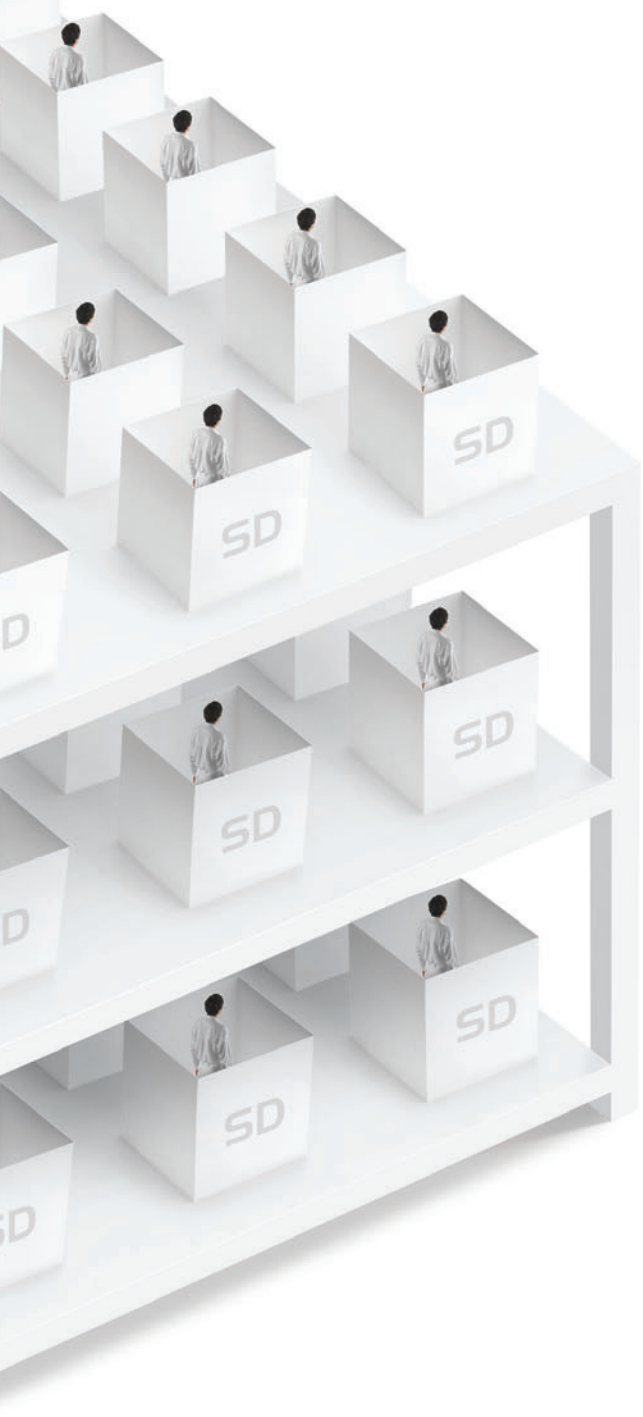
Perhaps most notable is the contraction in the US market—the first in more than 50 years. This contraction comes not only from several patent expiries of billion dollar blockbusters—including Plavix, Seroquel, Lipitor, and Zyprexa—but also from increased scrutiny by payers for reimbursement and regulators for approval. The negative growth is driven by a few companies, each of whom had exposure to over $5 billion in revenue loss due to patent expiration of their major products. In the United States, there were 13 such companies in the five year period of 2008 to 2012: Pfizer, GSK, Takeda, Merck, J&J, BMS, AZ, Novartis, Sanofi, Lilly, Forest, Boehringer-Ingelheim, Eisai, and Roche. Thus, in Figure 1, we see that year-on-year growth for the entire market was negative for the first time.

For the 13 companies, year-on-year performance for 2012 amounted to a close to 10 percent contraction in revenues against 2011. Excluding these companies, we see that US growth performance for the remainder of the top 50 was actually slightly higher compared to last year. The 13 companies thus represent the brunt of the loss to the industry, with the remaining companies in the top 50 performing fairly well. The top line in Figure 1 represents the growth of all other companies with revenue in the United States, comprised of over 600 companies outside of the top 50. The growth in these companies is significantly more than the top 50, and includes companies with extremely varied portfolios, including branded products and generics. In many ways it is not surprising to see such growth, given that they are starting from a smaller base of revenues than the top 50 and that some are posting new revenues from newly launched generics, at the expense of those facing patent expiries.

The second trend is the impact of the recession in Europe, where we see a zero growth situation rather than an outright contraction. The lagging performance of the pharmaceutical industry in the five major EU countries is due more to austerity and government fiscal issues rather than inherent company dynamics. In these countries, patent expiration does not have as striking an effect on

2013 Rank	Company HQ [website]	2012 Rx Sales (USD billions)	2012 R&D spend (USD millions)
1	**Pfizer** **New York** [pfizer.com]	$47.404	$7,046
2	**Novartis** **Basel, Switzerland** [novartis.com]	$45.418	$8,831
3	**Merck** **Whitehouse Station, NJ** [merck.com]	$41.143	$7,911
4	**Sanofi** **Paris, France** [sanofi.com]	$38.370	$6,117.8
5	**Roche** **Basel, Switzerland** [roche.com]	$37.542	$8,032.2
6	**GlaxoSmithKline** **Brentford, England** [gsk.com]	$33.107	$5,255.7
7	**AstraZeneca** **London, England** [astrazeneca.com]	$27.064	$4,452
8	**Johnson & Johnson** **New Brunswick, New Jersey** [jnj.com]	$23.491	$5,362
9	**Abbott** **Abbott Park, Illinois** [abbott.com]	$23.119	$2,900
10	**Eli Lilly** **Indianapolis, Indiana** [lilly.com]	$18.509	$5,074.5

Sources: Company financial statements, SEC 10k reports, other *Pharm Exec* estimates, and contributions from the EvaluatePharma industry sales surveys.



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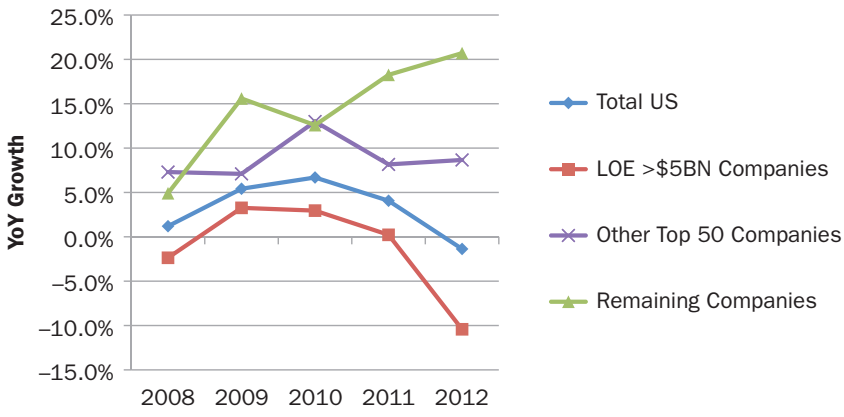

Figure 1: Performance of US pharma market by company type.

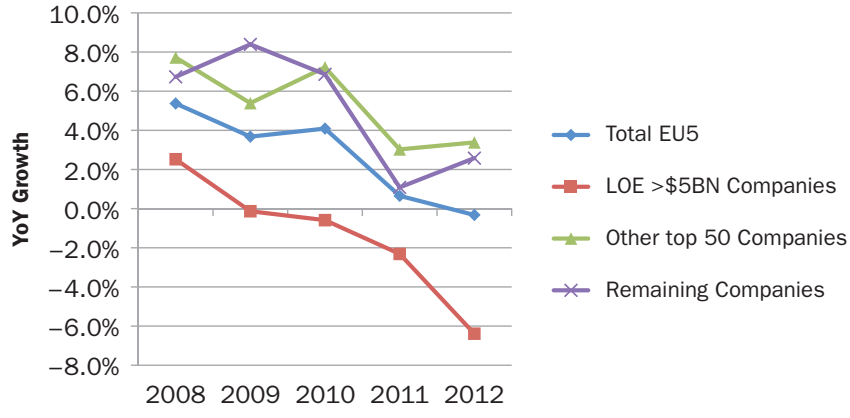

Figure 2: Performance of EU pharma market by company type.

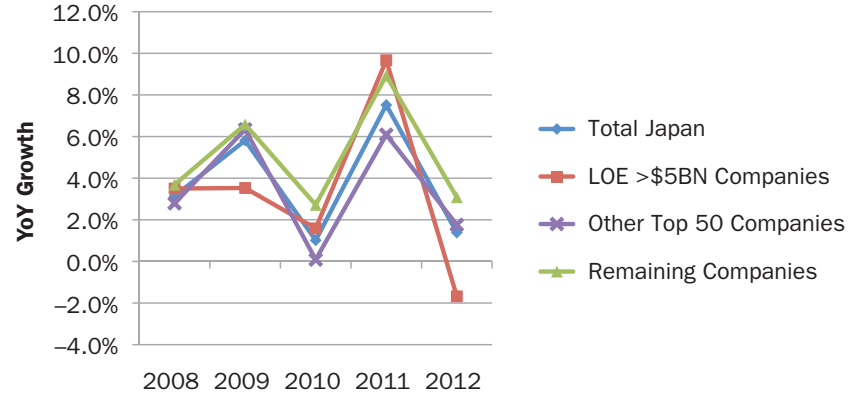

Figure 3: Performance of Japan's pharma market by company type.

company sales after loss of exclusivity (LOE) because the branded product's retention of sales is much higher compared to the United States. Many companies retain significant sales from off-patent products in the EU five as government reimbursement treats off-patent brands and generics similarly. Nonetheless, policy changes in the last five years have changed this pattern substantially and there is significant reduction in sales for off-patent brands as well as steeper erosion of new patent expiries.

In the European countries, industry performance is thus a bit better than in the United States, with sales relatively flat and zero growth. Once again, a handful of countries are driving stagnant growth of the industry overall. In this case, by splitting the performance of the companies that had over $5 billion in patent exposure in the European Union alone—Novartis, Pfizer, Sanofi, Merck, GSK, AZ, and Takeda—we see that as a group these seven contracted by about almost 6 percent in 2012 (Figure 2). The remaining companies in the top 50 actually had an uptick in growth compared to 2011 with almost 3.5 percent growth in 2012, which is also stronger than the growth experienced by all the other companies with sales in Europe outside of the top 50. These remaining companies constitute about 1,600 small companies spread through all of the EU five markets.

Third, in the other lead mature market, Japan, we see more positive growth for the industry, albeit at low single digits. The every-other-year mandatory price cuts on pharmaceutical products imposed by the government, defines the zig-zag nature of Figure 3. We can see, though, that by separating the performance of those five companies that had patent expiry revenue exposure close to $5 billion—Pfizer, Merck, Sanofi, Dainippon Sumitomo, and Eisai—performance of the other members of the top 50 was slightly higher than the group as a whole. Once again, performance of companies outside of the top 50 was even higher given the small base for growth.

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24 Pharma 50

The relatively higher growth in Japan for these five against their global norm was attributable in part to better performance of new launches and to the lower price cuts applied to protected brands under Japan's current NHS price control system. The Japanese government imposes a 5 to 6 percent price cut every other year, in April. In 2010, a revised policy provided lower price cuts for protected branded products, and steeper cuts for off-patent products and generics, amplifying the impact of more recent patent expiries and providing a boost to innovative companies, many

2013 Rank	Company HQ [website]	2012 Rx Sales (USD billions)	2012 R&D spend (USD millions)
11	**Teva** **Petach Tikva, Israel** [tevapharm.com]	$17.681	$1,283
12	**Amgen** **Thousand Oaks, California** [amgen.com]	$16.639	$3,318
13	**Takeda** **Osaka, Japan** [takeda.com]	$15.173	$3,720.5
14	**Bayer** **Leverkusen, Germany** [bayer.com]	$14.734	$2,522.7
15	**Boehringer Ingelheim** **Ingelheim, Germany** [boehringer-ingelheim.com]	$13.686	$3,012
16	**Novo Nordisk** **Bagsvaerd, Denmark** [novonordisk.com]	$13.478	$1,882.3
17	**Bristol-Myers Squibb** **New York, New York** [bms.com]	$13.155	$3,715
18	**Daiichi Sankyo** **Tokyo, Japan** [daiichisankyo.com]	$11.019	$2,287.2
19	**Astellas Pharma** **Tokyo, Japan** [astellas.com]	$10.835	$2,224.3
20	**Gilead Sciences** **Foster City, California** [gilead.com]	$9.398	$1,682.7
21	**Baxter International** **Deerfield, Illinois** [baxter.com]	$8.857	$1,015
22	**Otsuka Holdings** **Tokyo, Japan** [otsuka.com]	$8.385	$1,869.5
23	**Merck KGaA** **Darmstadt, Germany** [merckgroup.com]	$7.709	$1,551.6
24	**Mylan** **Canonsburg, Pennsylvania** [mylan.com]	$6.697	$388.9
25	**Eisai** **Tokyo, Japan** [eisai.com]	$6.181	$1,423.5

Sources: Company financial statements, SEC 10k reports, other *Pharm Exec* estimates, and contributions from the EvaluatePharma industry sales surveys.

How the listings were compiled: The Pharma 50 rankings were compiled using figures taken from companies' annual reports and SEC filings, in addition to data provided by EvaluatePharma, for which we are grateful. In the case of privately held companies and in some other instances, the numbers reflect a best estimate, based on a consensus methodology that includes forecasts from brokers covering these companies. All figures represent the fiscal year that ended in 2012. For most American and European companies, that means the year ending December 31, 2012. For many Japanese companies, we used the fiscal year ending March 31, 2012. Historic averages were used in the conversion of companies' native currency to USD.

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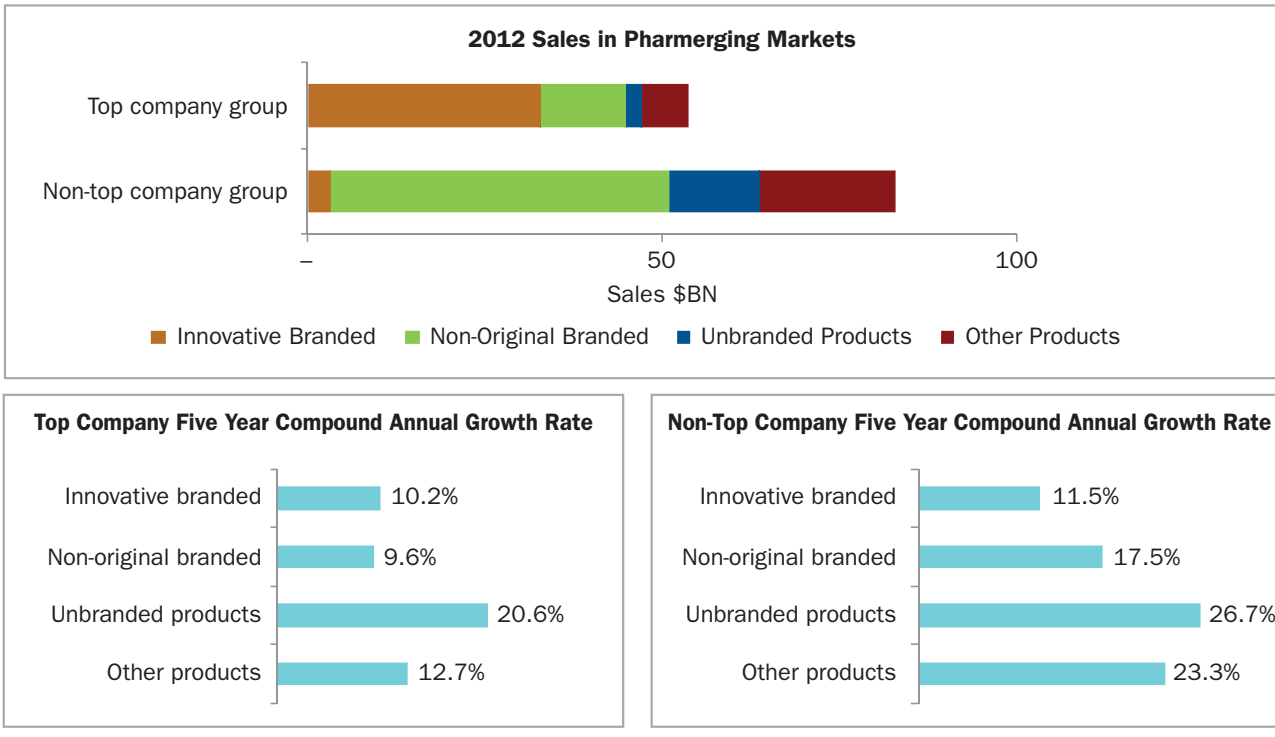

Figure 4: The performance of the companies within the top 50 compared with performance of all the other companies selling in emerging markets.

of whom are responding by launching products in Japan earlier in their global launch sequence than they had in the past. Vaccines are another bright spot, aided by more government support for immunization and access.

Fourth, the strong economic growth platform provided by the emerging country markets are helping to differentiate revenues for those companies with a solid commitment to establishing a local presence (Figure 4). Not all the top 50 are playing in the emerging markets; the sales performance of those who are competing in these markets has been in the double-digits. Many of the top 50 are selling both original and branded generic products since growth in both of these sectors has been exceptionally strong in the past five years. However, despite the promise of continued double digit sales growth in many emerging markets, the gains have not been able to offset weaker performance in the United States and Europe.

In Figure 4, we see the performance of the companies within the top 50 compared with performance of all the other companies selling in emerging markets. The top 50 companies primarily are selling innovative brands along with branded generics and annual growth in these two segments has been close to 10 percent over the past five years. Companies outside of the top 50 are primarily selling branded generics (non-original brands that have some unique branding and where the company marketing the products is not the originator) and regular generics. The "other products" category includes OTC medicines as well as products like homeopathic or traditional Chinese medicines as well as vaccines. For companies outside of the top 50, the growth in all these segments has been incredibly strong, although the innovative brand growth is off a smaller base.

The fifth and final trend on performance of the Pharma 50 is the broad move away from relying on mergers, acquisitions, and divestitures to replace or supplement organic growth (Figure 5). The pace of mega-mergers since the start of the century has begun to slow—Pfizer/Pharmacia (2003), Sanofi/Aventis (2004), Roche/ Genentech (2009), Merck/Schering-Plough (2009), and Pfizer/ Wyeth (2009). One might argue that Sanofi-Genzyme (in 2011) could be the last of the mega-mergers.

Science dividend

Looking ahead, although industry performance in the mature market countries is slowing compared to historical rates, a trend moderated by the growing support from emerging markets, there is still a silver lining. More New Molecular Entity (NME) drugs were approved in the United States last year than in any year since 1999, continuing a rebound in approvals that started in 2011 and appears set to continue.

The right model?

The relative stability of the top 10 companies and the fact that many in this set

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have a predominant impact on the slow industry performance overall provides insight into the current discussion over alternative business models to drive future success. As companies look to fill the gaps in their portfolios by patent-expired blockbusters, most are finding that it takes several mid-sized products with appeal to a well-defined disease segment in the specialty class. This is because it is becoming increasingly difficult for drug makers in the small molecule, primary care markets to demonstrate the benefit of new drugs against the existing standard of care. A strength in specialist-driven markets provides better prospects up front, especially for those therapies that initiate use in the in-hospital setting. Regardless of whether it is a recent strategic choice, or if the company was one of the early few who began with a rationale to serve this segment, a visible presence in specialty seems to be working in the current environment.

2013 Rank	Company HQ [website]	2012 Rx Sales (USD billions)	2012 R&D spend (USD millions)
26	**Celgene** **Summit, New Jersey** [celgene.com]	$5.369	$1,412.1
27	**CSL** **Melbourne, Australia** [csl.com.au]	$5.345	$423.5
28	**Les Laboratories Servier** **Neuilly-sur-Seine, France** [servier.com]	$4.931	$1,232.7
29	**Allergan** **Irvine, California** [allergan.com]	$4.756	$926.8
30	**Actavis** **Zug, Switzerland** [actavis.com]	$4.716	$401.8
31	**Mitsubishi Tanabe Pharma** **Osaka, Japan** [mt-pharma.co.jp]	$4.547	$853.2
32	**Shire** **Dublin, Ireland** [shire.com]	$4.407	$848.8
33	**Chugai Pharmaceutical** **Tokyo, Japan** [chugai-pharm.co.jp]	$4.359	$761.1
34	**Biogen Idec** **Weston, Massachusetts** [biogenidec.com]	$3.783	$1,326.3
35	**Dainippon Sumitomo Pharma** **Osaka, Japan** [ds-pharma.com]	$3.625	$723.2
36	**UCB** **Brussels, Belgium** [ucb.com]	$3.566	$1,064.6
37	**Fresenius** **Bad Homburg, Germany** [fresenius-kabi.com]	$3.445	$270
38	**Menarini** **Florence, Italy** [menarini.com]	$3.045	$220.7
39	**Grifols** **Barcelona, Spain** [grifols.com]	$3.000	$137.7
40	**Valeant Pharmaceuticals International** **Mississauga, Ontario** [valeant.com]	$2.957	$79.1

Sources: Company financial statements, SEC 10k reports, other *Pharm Exec* estimates, and contributions from the EvaluatePharma industry sales surveys.

Strategic choices aside, the extent and pace of future growth depends on a great number of factors including if and how those who pay for pharmaceuticals around the world make provisions to afford the wave of innovations that is coming from researchers' greater understanding of molecular biology and the genetic origins of disease. The signs of this rebound are there to see, so don't get too distracted by the industry-wide slowdown currently underway—this is one cycle that, like all others in the industry, will eventually play itself out. PE

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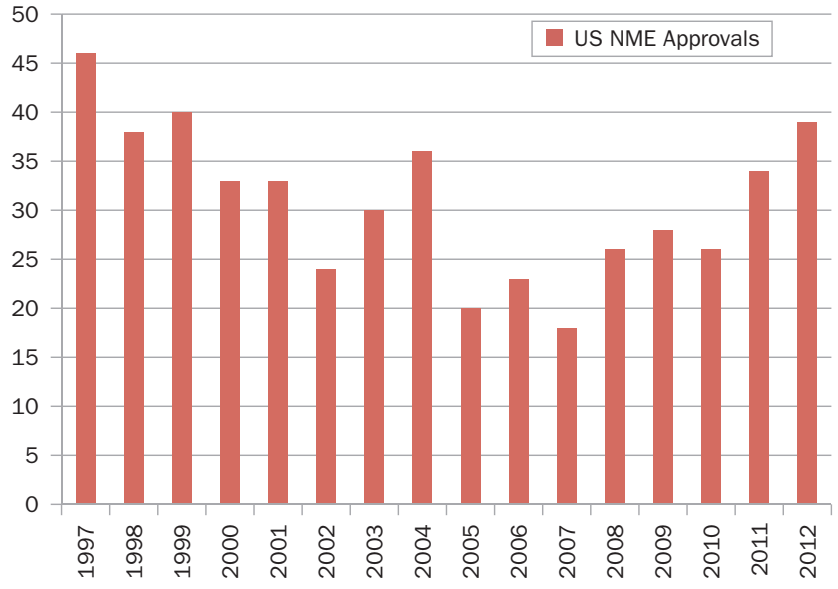


Figure 5: More new molecular entity drugs were approved in the United States last year than in any year since 1999.

2013 Rank	Company HQ [website]	2012 Rx Sales (USD billions)	2012 R&D spend (USD millions)
41	**Forest Laboratories** **New York, New York** [frx.com]	$2.903	$891.4
42	**Purdue Pharma** **Stamford, Connecticut** [purduepharma.com]	$2.678	$434.4
43	**Kyowa Hakko Kirin** **Tokyo, Japan** [kyowa-kirin-pharma.com]	$2.575	$551.2
44	**Hospira** **Lake Forest, Illinois** [hospira.com]	$2.570	$303.6
45	**Lundbeck** **Copenhagen, Denmark** [lundbeck.com]	$2.349	$503.5
46	**Endo Health Pharmaceuticals** **Malvern, Pennsylvania** [endo.com]	$2.329	$137.7
47	**Warner Chilcott** **Dublin, Ireland** [wcrx.com]	$2.306	$103
48	**STADA Arzneimittel** **Bad Vilbel, Germany** [stada.de]	$2.241	$69.0
49	**Shionogi** **Osaka, Japan** [shionogi.com]	$2.162	$647.5
50	**Ranbaxy Laboratories** **Haryana, India** [ranbaxy.com]	$2.049	$112.9
	Total	$594.804	$107,314.3

Sources: Company financial statements, SEC 10k reports, other *Pharm Exec* estimates, and contributions from the EvaluatePharma industry sales surveys.

Getty Images/Tim Teebken

The Big Squeeze

New payer-driven approaches to managing reimbursements for pharmacy benefit programs are testing Big Pharma efforts to get closer to the patient. By Adam J. Fein

US drug manufacturers face significant risks from a trend toward a more controlled approach to the operation of pharmacy benefit networks (PBNs) that deliver medicines to patients. Instead of letting patients choose to fill their prescriptions from an open network that includes a wide range of pharmacies, these benefit designs use financial incentives or explicit restrictions to direct consumers to specific pharmacies that agree to meet the PBN's conditions. The popularity of these new pharmacy network models is exploding in both commercial and Medicare Part D plans.

The risk is the shift in the balance of power to payers in the decisions on if, how, and when patients get access to medicines provided under their pharmacy benefit plans. These so–called narrow networks will give more control to third-party payers, alter promotion and marketing activities, and shift market share between different payers and pharmacies. Payers' use of the more tightly controlled pharmacy network model will keep growing as they seek additional drug spending savings. Over the past two years, plans have taken further steps to enforce formulary control and limit manufacturer marketing practices, such as copay offset programs. More important, consumers are accepting the new plans, encouraged by the out-of-pocket savings opportunities on their prescriptions. Likewise, community retail pharmacies are willing to accept lower reimbursements in exchange for the increased store traffic.

To preserve market position and access, manufacturers must start by recognizing that the economic interests of payer-defined pharmacy channels are diverging from traditional branded drug makers. It is thus important to analyze this crucial trend, highlight its economic appeal to payers and pharmacies, and outline how manufacturers can best prepare for and respond to the challenge.

A crucial distinction

For consumers with third-party insurance, pharmacy benefit managers (PBMs) assemble networks of pharmacies. In an open pharmacy network, a consumer's out-of-pocket costs and copayments are identical regardless of which pharmacy in the retail network dispenses the prescription.

An open pharmacy network, which remains the most common network design, includes nearly all of the approximately 62,000 US retail pharmacies. Network pharmacies compete on service, convenience, and location to attract consumers within a particular plan. Under this approach, there are no financial incentives for a consumer with third-party coverage (and a flat copayment) to shop at the pharmacy with the lowest cost per prescription for the payer.

Today, payers are rapidly adopting networks that differ significantly from the traditional open network design. More than four out of 10 seniors are now enrolled in a Medicare Part D Prescription Drug Plan (PDP) with a narrow pharmacy network design. A survey by the Pharmacy Benefit Management Institute reports that one out of five employers have started utilizing narrow networks. For instance, more than 1,000 commercial plans with 14.5 million covered lives use the Maintenance Choice narrow network program of retail chain and PBM CVS Caremark. Walmart, the third-largest retail pharmacy, estimates that nearly 25 percent of its 2012 prescription volume derived from its participation in narrow networks, compared with less than 1 percent in 2009.

There are two types of narrow networks. A preferred network gives the

consumer a choice of pharmacy, but gives consumers financial incentives to use the particular pharmacies that offer lower costs or greater control to the payer. In other words, a consumer with a preferred network benefit design retains the option of using any pharmacy in the network. However, the consumer's out-of-pocket expenses will be higher at a non-preferred pharmacy.

One of the first commercial preferred retail networks was the trial program between Walmart and Caterpillar, which began in September 2008. As part of the pilot program, 70,000 Caterpillar beneficiaries (employees, retirees, spouses, and dependents) had a $0 copayment on 2,500 "tier 1" (lowest priced) generic drugs that are filled at any Walmart pharmacy. However, the copayment was $5 if the beneficiary chose to fill a prescription for one of these drugs at any other pharmacy in the network. Caterpillar has subsequently broadened its preferred network to include Walgreens, Kroger, and a group of independent pharmacies.

Medicare Part D beneficiaries, for example, annually choose their own new plan, rather than having a benefit administrator or insurance plan provide a few choices for them. Thus, preferred network adoption directly demonstrates consumer appeal. According to the Center for Medicare and Medicaid Services (CMS), preferred pharmacy networks are permitted under the law that created the Medicare Part D benefit.

Table 1 highlights the largest payers that sponsor Part D prescription drug plans. In plans administered by such large payers as UnitedHealth and Humana, the vast majority of seniors are now enrolled in plans with preferred networks. For the 2013 benefit year, plans with preferred pharmacy networks enrolled 9.5 million people, or 42 percent of the total 22.4 million seniors in a Medicare PDP.

The Humana Walmart-Preferred Rx Plan illustrates the popularity and rapid adoption of this network model.

Parent Organization	2013 Enrollment (millions)	percent of Enrollment in Preferred Networks
UnitedHealth Group, Inc.	4.9	92%
CVS Caremark Corporation	4.5	11%
Humana Inc.	3.1	98%
Express Scripts Holding	2.8	0%
Coventry Health Care Inc.	1.4	47%
CIGNA	1.2	0%
WellCare Health Plans, Inc.	0.8	0%
Aetna Inc.	0.6	79%
All Others	3.1	10%
Total	**22.4**	**42%**

Source: 2012-13 Economic Report on Retail, Mail and Specialty Pharmacies

Table 1: Enrollment in Medicare Part D PDPs, by parent organization, January 2013.

In October 2010, Walmart and Humana launched this PDP with 4,200 preferred pharmacies (including Walmart, Sam's Club, Neighborhood Market, and Humana's RightSource mail pharmacy) and 58,000 non-preferred retail pharmacies. In 2013, Humana Walmart-Preferred Rx Plan is the fourth-largest PDP, with 7.8 percent of total PDP enrollment. Compared to 2012, total enrollment grew by 355,279 seniors (+25.5 percent).

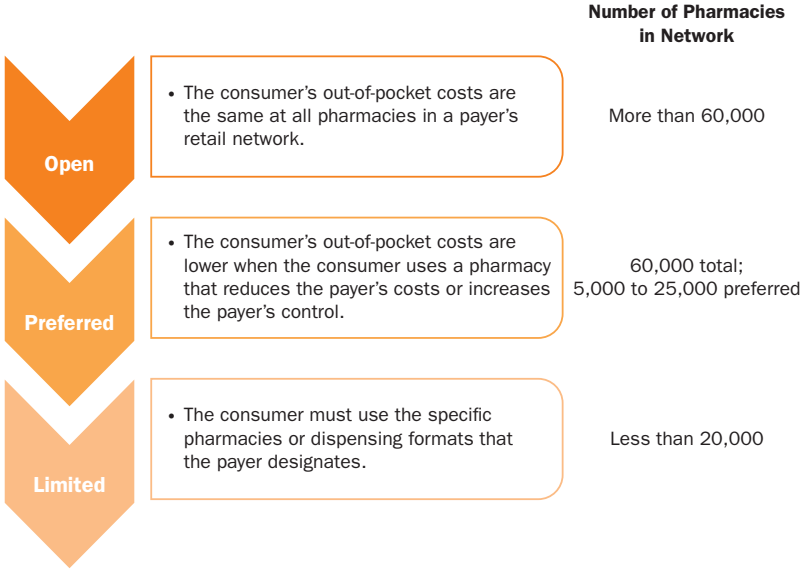
The second type of narrow network is a limited pharmacy network. This more restrictive model designates the particular pharmacies or dispensing formats available to a patient when filling her prescription. A limited network gives a payer the greatest degree of economic control over prescription fulfillment. Payers will include only those pharmacies with the lowest costs of dispensing and/or the highest service levels. In exchange, the pharmacy becomes one of the selected members in the network and increases its market share.

A typical limited retail pharmacy network is 50 percent to 80 percent smaller than an open network. Thus, the consumer can choose any pharmacy within the network, but the network has only 10,000 to 30,000 pharmacies (versus more than 60,000 total retail pharmacies). An example is Restat's Align network, which includes national chains (Walmart, Target, and many supermarkets) and a number of regional chains. In 2013, Express Scripts, the largest PBM, launched the Express Advantage Network, a limited network with about 20,000 pharmacies. Payers also establish limited networks for specialty drugs by restricting pharmacy choice to just one or two payer-designated specialty pharmacies.

Mandatory mail benefit designs are the most common application of limited networks. They require consumers to fill 90-day prescriptions through a mail pharmacy without the option of using a retail pharmacy. About 25 percent of employers require that some or all maintenance medications be dispensed by a mail pharmacy.

CVS Caremark's Maintenance Choice program is the most prominent limited network model for commercial plan sponsors. Under the Maintenance Choice program, a beneficiary can obtain maintenance medications from a CVS retail pharmacy or a CVS Caremark mail pharmacy. This model lets consumers choose the pharmacy channel (mail or retail) but limits that choice to CVS Caremark outlets.

With the exception of the Maintenance Choice model, limited networks have been much less widely adopted than preferred networks. We speculate that commercial plan sponsors may believe there are bigger savings opportunities in



Source: Pembroke Consulting, Inc.

Figure 1: The number of participating pharmacies in narrow retail pharmacy networks broken down by category.

other areas that have less potential beneficiary disruption, such as increasing cost-sharing requirements.

Rationale for going narrow

Many interrelated factors are supporting the adoption of narrow networks:

- Plan sponsors save money with narrower networks. An independent analysis conducted for the PBM Restat concluded that an employer would achieve savings of four percent to 13 percent. Walmart claims that employers achieve average savings in the 13 percent to 18 percent range from its limited network models, but savings can go as high as 45 percent. CVS Caremark recently stated that its limited Maintenance Choice model will save payers four percent of drug spending. Almost one out of five Managed Medicaid plans now uses a limited network, driven by intense cost pressure due to state government shortfalls.
- Consumers have access to many alternative community retail pharmacy outlets. More than nine out of 10 Americans live within five miles of a retail pharmacy. Consumers in a core based statistical area (CBSA)—an urban center of at least 10,000 people and its adjacent areas—live within 1.2 miles of a community retail pharmacy. In many major metropolitan markets, up to 50 percent of market share is held by pharmacies beyond the largest four retail chains—CVS/Pharmacy, Walgreens, Walmart, and Rite Aid. Given the ready availability of pharmacy outlets, plans can establish narrower networks with minimal consumer disruption.
- Consumers are willing to switch pharmacies to reduce out-of-pocket expenses. A preferred or limited network causes the consumer some degree of inconvenience. However, surveys demonstrate that consumers are willing to shift pharmacies for even very small monetary rewards. In a recent national survey, 85 percent of consumers said they would switch pharmacies to avoid higher copayments at their usual pharmacy.
- Pharmacies are willing to boost store traffic in exchange for accepting lower prescription reimbursements. Since overall prescription growth remains very low, pharmacies are trying to remain competitive and attract consumers in a relatively saturated market. Consequently, they have been willing to accept reduced reimbursement rates in exchange for participation in a preferred or limited network. A majority of these savings comes from reduced pharmacy margins, because pharmacies compete to be in a payer's narrower network.
- Narrow networks are consistent with broader healthcare insurance models. Insurance plans have long used preferred provider models for medical services. Many use tiered network models that categorize medical providers in the network based on quality, cost, and/or the efficiency of the care they deliver. These networks encourage patients to visit more-efficient doctors—either by restricting networks to certain providers or by having different copayments or coinsurance for providers in different tiers in the network. In 2011, 20 percent of employers that offered health benefits included a high performance or tiered provider network in the health plan with the largest enrollment.

A dispute between Express Scripts and Walgreens demonstrates the viability of a limited network model. In January 2012, Walgreens exited PBM Express Scripts' retail pharmacy network. Walgreens' prescription sales declined sharply, but the effect on Express Scripts' PBM business was minimal. A small number of plan sponsors switched away from Express Scripts to keep Walgreens in their network, but most accepted the narrower network. After the September 2012 resolution of the Walgreens-Express Scripts dispute, such plan sponsors as the Department of Defense's TRICARE program and Blue Cross of Idaho declined to add Walgreens back to their networks.

Impact on manufacturers

The "narrow network revolution" will affect pharmaceutical manufacturers' commercial activities, in the following ways:

- Narrow networks give more control to third-party payers. Today, a pharmacy's participation in a payer's narrow network is based primarily on the pharmacy's willingness to accept reduced reimbursements. As these networks become more common, payers will begin considering additional selection criteria linked to a pharmacy's compliance with a payer's benefit management plan. For example, payers could select pharmacies with higher generic substitution rates or a greater willingness to block copay cards.
- Narrow networks shift market share between payers. When negotiating for formulary access, manufacturers should be aware how payers can leverage new network models to gain market share. In October 2010, Walmart and Humana launched this PDP with 4,200 preferred pharmacies (including Walmart, Sam's Club, Neighborhood Market, and Humana's RightSource mail pharmacy) and 58,000 non-preferred retail pharmacies. As of 2013, the plan is the fourth-largest PDP in the United States, with about 8 percent of all Part D enrollees.
- Narrow networks shift market share between trading partners. Existing programs can be disrupted or altered as networks evolve. When Walgreens exited the Express Scripts network, rival pharmacies gained from Walgreens' sales losses. Until September 2012, year-over-year sales declined by 10 percent to 15 percent at Walgreens pharmacies, while sales increased at the other chains. CVS's retail pharmacies gained 6.5 million to 7 million new prescriptions from former Walgreens' customers. It expects to retain 60 percent of these customers. Many other pharmacies also reported picking up new business from defecting Walgreens' customers.
- Narrow networks teach consumers to shop for prescriptions by price. Thanks to prescription drug insurance, US consumers' out-of-pocket expenses—cash-pay prescriptions plus copayments and coinsurance—account for less than 20 percent of total US outpatient prescription drug spending. Historically, consumers have considered only service and location when choosing a pharmacy. Narrow networks ask consumers also to consider which particular pharmacy has the lowest out-of-pocket cost. This trend accentuates consumers' price sensitivity for prescriptions.

Three ways to respond

Narrow retail pharmacy networks are created by payers for payers, with the patient coming in second. Thus, pharmaceutical manufacturers have a very limited ability to influence the adoption of this new design. However, companies should take action to understand and prepare for the ongoing growth of these networks.

- *Build cross-organizational insight.* Narrow networks challenge conventional organizational arrangements within most pharmaceutical manufacturers. This can make it harder to spot brand-specific sales implications of narrow networks. Usually, the trade function that manages pharmacy distribution channel relationships is organizationally separate from the managed markets function that interacts with payers. Functions that handle payer relationships, such as managed markets and payer marketing, must understand the product movement and payment functions, and vice versa. For instance, are copay offset programs being blocked with greater frequency in certain networks? Is patient access being compromised or affected by a payer's adoption of this new network model?
- *Be prepared to alter promotion plans.* As new pharmacy network models proliferate, patients will begin moving prescriptions from one pharmacy to another. In some cases, these shifts will require changes to traditional geographic promotion planning activities. For example, membership-warehouse club retailer Costco operates Costco Health Solutions (CHS), a pharmacy benefit manager targeting self-insured employers located near Costco stores. These employers are encouraged to set up a preferred network model, in which the beneficiary has a financial incentive to choose a Costco pharmacy to reduce the employer's drug costs. This movement may or may not correspond to existing sales and marketing plans. Sales teams should understand managed care coverage and new retail provider networks so they can have meaningful discussions with practices and tailor messages accordingly.
- *Develop a coherent policy position.* Manufacturers should be prepared to manage divergent opinions generated by the narrow network trend. Payers support narrow networks, while many pharmacies oppose them. For instance, the National Community Pharmacists Association (NCPA), which represents owners of independent pharmacies, has claimed that preferred network PDPs in Medicare Part D are being "deceptively marketed to patients and lack adequate pharmacy access for rural Americans." While no objective data yet support these assertions about patient access, the sentiment has already led to pharmacy-led lawsuits against CMS. In contrast, larger pharmacy chains are active participants in the new networks. Balancing these competing perspectives is difficult as payers and dispensing channel consolidate.

The narrow network revolution is accelerating—its time is now. Pharmaceutical manufacturers have no choice but to prepare for the coming changes in product and consumer access.

Adam J. Fein, PhD, is president of Pembroke Consulting, Inc., and CEO of Drug Channels Institute. This article is adapted from his new "2012–13 Economic Report on Retail, Mail, and Specialty Pharmacies," which is available at http://bit.ly/VnqMzt. He can be reached at afein@pembrokeconsulting.com.

Photo: Thinkstock

Tracking Trial Cost Drivers: The Impact of Comparator Drugs and Co-Therapies

New research from the Tufts Center for the Study of Drug Development identifies a significant contributor to the rising cost of clinical trials—the first step in meeting a growing strategic imperative to help management and regulators make trials more efficient in delivering results to clinicians and patients.

By Mary Jo Lamberti, Terry Walsh, and Kenneth Getz

Drug supply professionals concur that the increasing use of comparator drugs and co-therapies in clinical studies acts as a strong counter to company efforts to rein in the rapid growth in drug development spending. TransCelerate Biopharma, a consortium of 10 Big Pharma companies committed to improving the overall efficiency of the R&D process, is putting new focus on the high cost and incidence of comparator drugs and co-therapies in clinical trials.

The current climate reflects intensifying market competition and regulatory reform as more trials are being conducted to compare the safety and efficacy of investigational treatments against a standard of care. Although comparative effectiveness studies of new drugs are still relatively new, sponsor companies are including commercial comparator drugs in their clinical studies to position their drug against a competitor. In some cases, regulatory authorities still require comparisons with a placebo. However, as sponsor companies target more difficult chronic and terminal illnesses, comparisons with a placebo may be unethical, making a commercial comparator drug necessary. Moreover, many clinical trials now test the efficacy and benefits of co-therapies on diseases that have historically not responded well to single therapies (e.g., HIV and oncology).

Based on a decade of experience, investigational drug supply chain professionals note that sourcing and managing comparator drugs and co-therapies is difficult, risky, and costly. The cost to acquire comparator drugs and co-therapy drugs is high as study sponsor companies often must pay retail prices instead of wholesale or discounted prices. In many instances, sponsor companies are unable to secure comparators and co-therapies directly from a competitor. As a result, sponsors must rely on vendors/wholesalers and the principal investigators at each research center to purchase comparator and co-therapies, and also through local pharmacies. As newer and more sophisticated therapies enter the market (e.g., biotherapeutics and stem cells), the cost for comparator

and co-therapies is expected to escalate sharply. Also, the supply of these products will likely be curtailed due to the complex manufacturing processes.

Sourcing comparator drugs and co-therapies often results in substantial delays and increased study cycle time. Planning and managing decentralized global sourcing activity poses logistical challenges—particularly with comparator drugs and co-therapies requiring unusual storage and shipping requirements. Obtaining comparator and co-therapy product documentation, handling resupply shortages and delays, and maintaining supply chain security particularly against counterfeit drugs are but a few of the many challenges introduced by comparator and co-therapy sourcing.

Despite mounting concern and increased attention to the rising prevalence of comparator and co-therapies in clinical trials, little data exists that quantifies current practices and characterizes the current situation and key trends. In response, the Tufts Center for the Study of Drug Development (CSDD) conducted a study among 11 major pharmaceutical companies in late 2012 to gather benchmark metrics.

Measuring the problem

A three-part data collection tool was designed by Tufts CSDD to collect general company information, overall perceptions about sourcing comparators and co-therapies, and company-specific study data and costs. Tufts CSDD researchers collaborated with participating companies in developing the data collection instrument for the study. Definitions for specific types of trials using comparators were agreed upon by participants and included with the data collection instrument.

General company information included comparator function capacity; the overall reporting structure within R&D or commercial operations; and strategies typically used for sourcing comparators (e.g., the use of central, local, or mixed models).

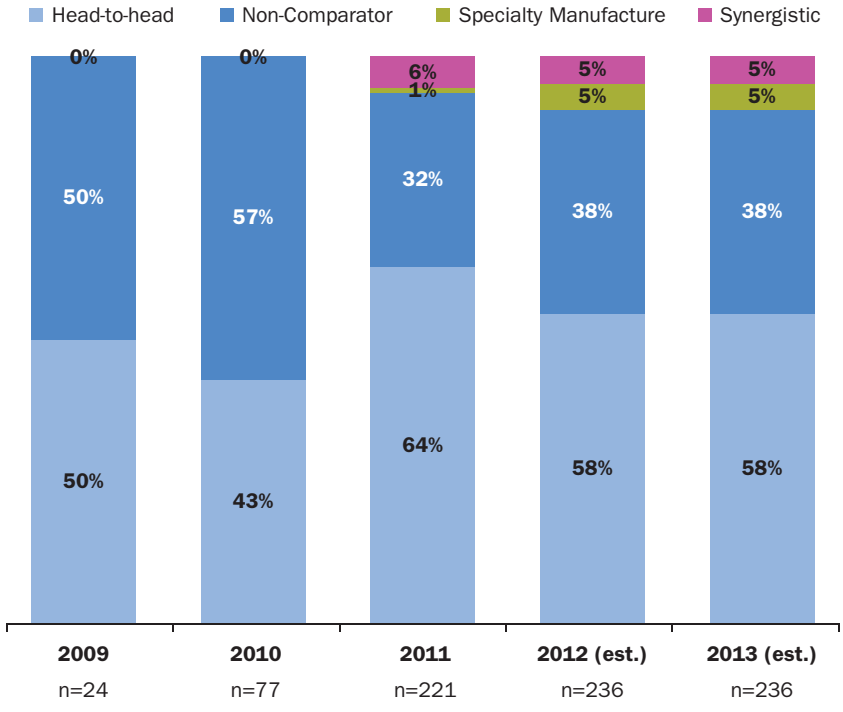


Figure 1: Percentage of studies conducted using various comparators from 2009 to 2013.

Participating company perceptions were gathered using open-ended responses and focused on the challenges associated with sourcing comparator drugs and co-therapies. Areas of impact that were explored included regulations concerning IMP versus non-IMP and the use of generics as standards of care. Company practices and approaches to sourcing comparators were assessed as well as strategies for purchasing products from third party buyers or other pharmaceutical companies. Cycle-time data—including the average lead time from order placement to product delivery—was collected. Data on the timing and frequency of receipt of CoAs and CoCs was collected and examined for global differences and by manufacturers.

Specific study and cost data was gathered for clinical trials conducted in 2009, 2010, and 2011. Sponsor companies were also asked to estimate and forecast study time and cost data for clinical trials conducted and planned for 2012 and 2013. Data was gathered for head-to-head; co-medication; and standard of care trials. Study data was also examined for use of branded and generic drugs. Participating company budget data was collected including the total amount spent on clinical supplies and proportion of budgets spent on comparators and co-therapies.

Tufts CSDD also sought to collect data on the total volume and cost of co-therapy and comparator drugs not used during the course of the clinical trial. Additional data included total number of studies and revenue received from other companies (through use of their company's drugs); and total full-time equivalents (FTEs) or number of hours per month dedicated to working with other biopharmaceutical companies and third party buyers. Company strategies regarding purchasing products from third party buyer services and other biopharmaceutical companies were explored, as was company receptivity to selling comparators directly for use in head-to-head clinical trials. Data on 370 studies was collected and analyzed.

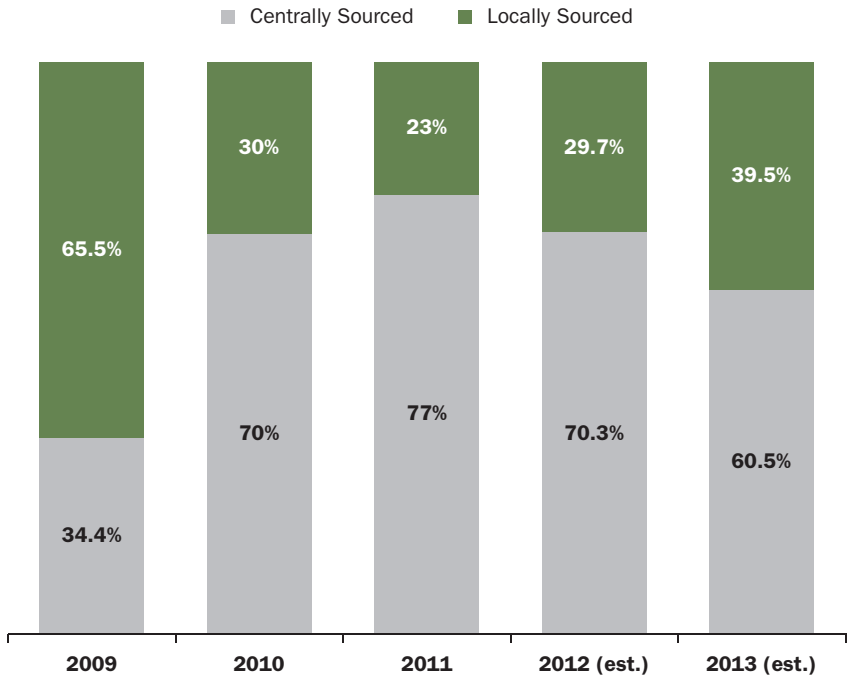


Figure 2: Percentage of studies conducted using centrally and locally sourced comparators.

Comparator and co-therapy sourcing practices

Overall, the clinical supply function is managing varying levels of comparator sourcing using a variety of approaches. The average clinical supply chain function has 246 full-time employees with three full-time staff dedicated to comparator and co-therapy sourcing. Participating companies note that clinical supply functions typically report into clinical operations.

Clinical supply functions have increased the number of personnel dedicated to working with other biopharmaceutical companies and third party buyers. Participating companies indicate that they have added on average one new FTE between 2009 and 2012 to work with wholesalers, for example.

Participating companies indicate that there is wide variation year-over-year in their comparator and co-therapy sourcing costs. Few organizations are routinely collecting metrics on the specific use and expense of comparator and co-therapy drugs. Estimated participating company spending on comparators in 2012 alone ranged from as little as $10 million to as much as $120 million. On average, participating companies spent a total of $50 million per year on clinical supplies with half of the entire clinical supply budget spent on comparator drugs and co-therapies. For several participating companies, 2011 forecasts for budget planning purposes fell in the $150 or $200 million range, but *actual* spending was typically lower. Participating companies were unable to breakdown spending by clinical research phase.

Less than 40 percent of clinical trials did not include a comparator or co-therapy in 2012—a proportion that has been gradually declining during the past four years. During that same period, the proportion of studies involving head-to-head comparator drug trials has been rising to nearly 60 percent of clinical studies in 2012. (Figure 1). And the percentage of studies using non-commercial presentations (e.g., bulk supplied or active and placebo) supplied by the competitor and co-medication commercial comparators (e.g., HIV cocktail) has increased from 0 percent to 5 percent of clinical studies between 2009 and 2012. The total proportion of comparators and co-therapies represents nearly two-thirds of all clinical studies in 2012.

The study results indicate that a growing proportion of comparator and co-therapy drugs are centrally sourced (Figure 2). Whereas participating companies locally (via investigator) sourced 66 percent of their studies involving comparators and co-therapies in 2009, only 30 percent did so in 2012. At this time, participating companies report centrally sourcing comparators and co-therapies for 70 percent of clinical studies that require them.

A number of factors reportedly influence whether to source comparator and co-therapies locally or centrally. Commercial availability within a given market, risk of counterfeits, and local regulations and infrastructure are top factors dictating which sourcing strategy is required.

Branded comparator and co-therapy drug use in clinical trials is far more common. Nearly 90 percent of all studies are sourced with higher-priced branded co-therapies and comparator drugs. This proportion has not changed between 2009 and 2012.

Data on the amount of comparator and co-therapy drug wasted or unused in clinical studies could not be gathered. Participating companies are unable at this time to reliably provide this metric. But anecdotal reports based on conversations with senior sourcing managers suggest that a substantial proportion—ranging between 30 percent and 55 percent—of purchased comparator drugs and co-therapies are leftover and unused when clinical studies are completed or terminated.

Problems exposed

Participating companies indicate that one of the top challenges and a major cause of delays in sourcing compara-

tors and co-therapies is associated with obtaining required documentation (e.g., equivalency documentation, certificates of conformity, certificates of analysis, and BSE/TSE statements) from the manufacturer and temperature excursion data (e.g., stability data).

Comparator and co-therapy product availability is another top mentioned difficulty, especially for products that represent a sizable portion of a manufacturer's revenue and supply. Oncology products, rare disease products, and anti-inflammatory MABs, for instance, are closely monitored and protected by the manufacturer as they contribute a large portion of that company's revenue.

Comparator sourcing managers note a particular difficulty in obtaining comparators when supply is limited or when expiry dates are of short duration. Other notable problems include increasing complexity of trial design, variation in approved indications globally, and increased regulation. These factors can lead to longer lead time in defining comparator requirements prior to purchasing the comparator drug. Multiple requests for proposals to third-party buyers may signal secondary markets to inflate drug pricing or limit availability. Sourcing managers also find that establishing reliable pricing forecasts can become an issue, as there is not always sufficient information on availability of a product within particular regions or countries. Counterfeiting, particularly in remote emerging regions with limited regulatory oversight and law enforcement, is another challenge of note. Another factor at play is rapid expansion of the market and the number of players involved in the pharmaceutical supply chains. The regulatory and law enforcement agencies are also responding in an effort to keep pace with this expansion.

The results of this Tufts CSDD study indicate that a surprisingly high proportion of clinical studies now involve comparator drugs and co-therapies and that these drugs are typically branded products. Based on average spending levels per company, we estimate that the industry overall is spending $1.5 to $2 billion annually to include comparators and co-therapies in their clinical studies.

Looking ahead

Participating companies anticipate that the operating challenges and costs associated with sourcing comparators and co-therapies will continue to worsen and they are eager to identify improvement opportunities.

Among participating companies, senior sourcing executives have indicated high receptivity to establishing a pre-competitive comparator consortium that would create a transparent, centralized forum for companies to be paired efficiently when one is seeking the other's comparator or co-therapy drug. Such a consortium might have its members agree to adhere to standard documentation and supply practices in addition to preferred pricing levels. A consortium model—although often suggested at industry meetings and conferences—has yet to be formally embraced and championed by a pharmaceutical or biotechnology company.

Concerns about competitive pricing, antitrust, and collusion have prevented the precompetitive sourcing consortium concept from gaining momentum.

This Tufts CSDD study is an important first step in compiling and presenting metrics that begin to characterize the prevalence and cost of sourcing comparator drugs and co-therapies. The conclusions drawn in this study are based on a limited sample of clinical studies. More data, from a larger number of companies, should be gathered to establish more robust measures.

Through metrics and the identification of shared challenges, pharmaceutical and biotechnology companies would be advised to begin a discussion about potential solutions to be implemented across the drug development enterprise. To date, organizations have had limited opportunities to establish long-term sourcing arrangements with a single peer company. Some companies have indicated that they are entering into discussions between company R&D functions—particularly those where there is therapeutic area alignment—to establish a more direct exchange of drug supply. In most companies, however, the commercial division is responsible for handling and fulfilling requests for approved drug products.

Concerns about competitive pricing, antitrust, and collusion have prevented the precompetitive consortium concept from gaining momentum. Overall patent expiries and challenges in R&D productivity make some companies reluctant to partner, as there is a perception that it may erode sales of marketed drugs faster. TransCelerate BioPharma has established a working subcommittee to consider how to build and launch a reliable, rapid source of commercial products for use in clinical trials. A pilot is planned for this year. Tufts CSDD is committed to working with TransCelerate and others to measure the impact of new solutions to address this costly challenge. PE

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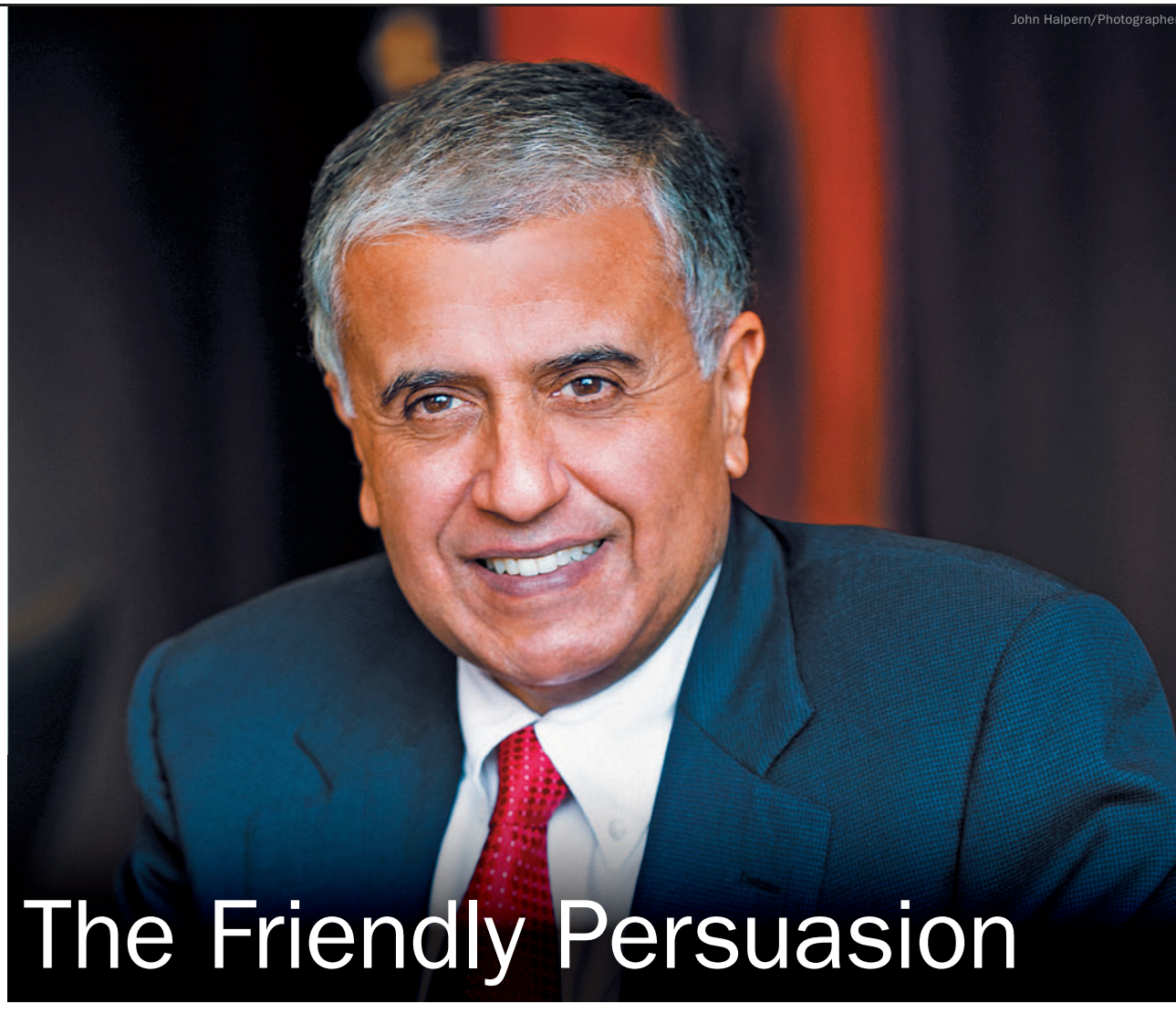

The Friendly Persuasion

Industry icon Fred Hassan's management formula for staying fresh in an era of market churn: be culturally aware, engage the team, make respect the currency of reputation, keep it simple—and repeat often.

While it is widely known that the biopharmaceutical industry is confronting disruptive changes to a business model that dates back well into the last century, less is said about the generational shift taking place among managers at every level of today's pharma organization. Knowledge transfer—the handing down of substantive skills and process awareness, combined with individual learned intuition—has never been more important to successfully charting a new path forward. One key source of insights for this next generation of c-suite climbers is "Reinvent: A Leader's Playbook for Serial Success," written by former Schering-Plough CEO Fred Hassan, whose long career as the driver of no less than six well executed business turnarounds was punctuated by three successive slots on the cover of our magazine. His book's advice is written in the active tense, and is neatly categorized into the three elements of "Me"—authentic, purposeful, and connected—and "We"—leading, raising expectations through example, and winning, not just once, but often. As part of our planning for this year's latest crop of Emerging Pharma Leaders, *Pharm Exec's* Editor-in-Chief William Looney met last month with Hassan in his new role as non-executive chairman of Avon Products Co., whose own customer-centric business model might just be one fragrant shoot for reviving Big Pharma's tired brand. The following is an edited version of our discussion.

Looney: *Based on your 30 years of experience in biopharmaceuticals, do you believe that the ebb and flow of the business cycle is the driver of ultimate success—how much does leadership intervention count?*

Hassan: Industries and companies are not fixed objects but living, breathing organisms that must continuously adapt to survive. All industries evolve; the biopharmaceuticals business is no exception. The classical model of the lifecycle of a business runs from the embryonic stage, to the growth spurt, to maturing competition, and then finally to commoditization. Most observers today see our industry at the competition stage. We are not yet a commoditized business, but growth has faded and we are certainly no longer in an embryonic state.

In my view, the peak era for growth started to fade after the year 2000, coinciding with the fading of the small molecule therapy platform focused on serving a mass market of patients with chronic diseases. Much of this segment of the business is headed toward outright commoditization. What we fail to realize, however, is the very process of decline opens new corridors of growth. Science is going to succeed once again in providing new and lucrative markets for those companies that recognize opportunity and seize it first. I recall how, in the 1980s, monoclonal antibodies were praised for the science but panned for their commercial potential—too many potential side-effects and too hard to manufacture, it was said. But industry found ways to surmount these hurdles, resulting in a flood of new breakthrough products, from Rituxan and Remicade to Humira and Enbrel. That success has spurred more competition, and a new cycle of growth. Entirely new product segments, like targeted medicines with companion diagnostics, will take the industry in different directions. Shaping and directing change in a way that creates new opportunities depends entirely on the human element—a strong leader, by definition, is never a mere captive of the business cycle.

Successful leadership depends on the larger context in which it is exercised. Can you identify some of the external challenges that confront today's CEO—and how they might be different than 10 or 15 years ago?

A key skill required of today's CEO is securing first-mover leadership in these new corridors of growth. The CEO and his team must have the strategic vision to look where others have not. Doing that in large organizations, where there is no danger in simply upholding the status quo, requires a high tolerance for the discomfort zone and for risk. That tolerance for risk has to be passed down the ranks. Because if it was true in the past, it is truer now: no single person has the capabilities to pursue a vision that will transform the business. A CEO must surround himself with people whose talents compensate for his or her own weaknesses. To find those people, you have to start by knowing who you are, and who you are not. It is harder than it sounds: self-awareness is a character trait that can fall into disuse after you have made it to the top. For example, many CEOs today don't know what they don't know about the economics of drug reimbursement. The value of medicine equation is very important in winning prompt access to the market. So it pays to keep that source of expertise close at hand.

Your book spends little time on the topic of creating a winning strategic vision. Is this because strategy is hard to teach? Is it because there are no set lessons: every set of circumstances a company faces is unique?

I chose to focus on executing around a strategy. Implementation is where most companies and their leaders fail, even when the strategy is appropriate. Nevertheless, strategy is vital. A good strategy builds a line of thought that punctuates good decisions. If I write another book, it will be geared toward strategy, which I define as a structured exercise designed to help a company play in the right places and deploy resources so it can win. Good teams that leave nothing off the table in terms of frankness are critical to a strong strategy. Building such a team, where the strengths and weaknesses of each member combine to form a well-balanced whole, is probably the biggest challenge facing a new CEO today. Individual hubris is still the number one reason why CEOs fail.

When you get to that place where you have a strong team in hand, the group should be guided by three actions: analyze, test, and act. I first had the opportunity to apply this

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approach when I took over as CEO of the failing merger between Pharmacia and Upjohn in 1997. The combined business was mired not only in internal fights among different groups, but also there was an impasse around competing strategies. Upjohn, a leader in primary care, had just lost exclusivity for its key product, Xanax, while Pharmacia was convinced the future lay in specialty drugs. The team I established was purposely balanced around both contrasting views, forcing each side to learn to think differently. One of the first things we did was to take a Pharmacia specialty drug—Detrol, prescribed for a very narrow urinary incontinence indication—and expanded its positioning to serve a much larger potential treatment population, for what we called the "overactive bladder" market. In other words, we took a Pharmacia therapeutic innovation and harnessed it to Upjohn's marketing expertise in primary care, resulting in the combined company's first blockbuster. There was a big risk involved here, because we had to move from the "analysis"—where we could only hypothesize the market potential—to the "test," which required substantial up-front investments in expanding the primary care field force to be able to sell the repositioned Detrol.

The positive result we got from leveraging two apparently contradictory capabilities to score a convincing market win gave our team confidence to pursue the third action, to move forward. We did that with Monsanto, where we able to acquire the rights to Celebrex, which was the first Cox 2 product in the arthritis and pain market. We had the expanded field force already in place to hit the ground running with Celebrex, which became our second blockbuster.

What was distinctive about these examples is the reliance we put on testing and acting. Strategists tend to over-analyze, which can force people to focus on the wrong questions and lead to decisions that are overly complex, resulting in a muddled mess of execution. Too much analysis becomes an end in itself; it means that people aren't making decisions. On the other hand, I am suspicious of the CEO who relies too much on intuition. That often becomes an excuse not to seek out the expertise of other colleagues. The notion of the CEO as a sole strategist is the ultimate anachronism. The group mindset, and the positive energy it generates, is critical to everything drug companies want to accomplish today.

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How do you foster that sense of esprit at the top? How do you spread its benefits throughout the entire organization?

The most important task of a CEO is to build a management team that pulses with the force multiplier of collective energy. This is an intangible, almost spiritual asset. It cannot be achieved through an organization chart, divided into boxes that say "this is what you do." At this level, functional responsibilities are really beside the point. What matters instead is the dynamic energy that comes from contributions as a group, where the CFO is not there just to provide accounting advice but has something to say about reputation management as well. The strategy is richer because it is grounded in diversity. This is a point that many experts in organization management have missed.

Has company "culture" become a cliché? Is an effective business strategy possible without CEO leadership in building out the roots of a distinctive culture, one that can be understood by every employee?

Companies do have distinctive cultures. Awareness of this is vital to CEO success in executing around strategy. In all the corporate turnarounds I have been involved in, changing the culture played a huge role. A positive culture attracts talent and serves as a motivator of superior group performance. Unfortunately, the tendency in recent years has been to treat culture as a "soft" topic, one that can be safely relegated to the human resources function. This is a mistake. Today's most effective CEOs consider their HR representative a full partner in business strategy. But your HR leader has to be someone who understands the workforce beyond the "c suite" and can promote a culture that is geared to helping every individual win. Culture must be communicated as something positive and jargon-free. Too often, it is mistakenly applied as part of a PR exercise, filled with empty messaging. People will apply themselves if they believe in what you, as CEO, are saying. Yet most companies are falling short, on that score. Surveys show that more than half of the workers in corporate America are disengaged, with little regard or understanding of where management seems to be taking them, and many workers don't feel free to speak up. This festering alienation is a drain

on initiative and leaves a lot of spare capacity sitting on the table; when companies address it and fix it, productivity rates go up considerably.

Is the human resources function ready for an overhaul to place it higher in the "c suite" pecking order?

It is rare to find in any CEO today a background that has exposed him or her to the HR function. That is a pity. The emphasis in HR today is very passive: recruiting talent, calculating benefits, and providing information to employees. What is really needed is a function that leads at the right hand of the CEO in shaping a productive, positive culture, assessing talent [not just finding it], building succession plans at every stage of the decision-making chain, and finding ways to engage and make colleagues feel valued for being part of an amazing organization, poised to profit from the future. Big Pharma needs to pay even more attention to this skill set than other industries because we are a talent driven industry. Instead, we often let patent driven product exclusivity cycles make us more complacent than we should be. That attitude must change because keeping top talent in place is going to take more effort in the future. The best people have more options and the younger generation no longer believes in lifetime employment.

Moving beyond organizational dynamics like culture, what in your experience are the characteristics that determine individual success in pharma today?

Nothing has changed. Attitude is key. I am often asked if my background growing up in Pakistan and studying in the United Kingdom helped me succeed in the United States. My answer is only partially—what really mattered is that, in moving from a very distinctive culture like Pakistan to the West, I was forced to work outside my comfort zone. I had to adapt on the fly rather than just move along at cruising speed. This had an impact on my attitude toward work. At periodic stages of my career, I was always ready to try something different. I had a built in corrective from my life experiences that prevented me from assuming that something could not be done, just because I was not familiar with it. Attitude is also about being positive. Over the years, I have seen that people who simply point out problems without suggesting a solution rarely gain traction. No matter how dire the circumstances, your personal brand is burnished when you stay constructive and avoid tearing others down.

What insights about our industry have you uncovered in your current role as non-executive Chairman of Avon Products? Is it true that consumer goods companies have a much better grasp of what the customer wants?

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As a heavily regulated industry, pharmaceuticals are characterized by a strong process discipline. Getting the details right is the pre-condition for our license to operate. Companies like Avon are more focused on a continuing brand identity as the guarantor of a strong market position. In pharmaceuticals the right to exclusivity tends to make that a given; once a patent expires, brand identity tends to fade due to the intense generic competition. We can learn from Avon how valuable a good branding strategy is to stretching out the lifecycle of a product and keeping our customers loyal and engaged. Avon has also much to teach us about building share in the emerging country markets, which it treats with a distinct attitude and where it has been active for decades. For new medicines, the United States will continue to dominate, but the BRIC countries and others are going to be critical in giving a second wind to our mature brands. These markets are also sources of reverse innovation and thus a good way to keep tabs on future competition. For these reasons, when I was CEO of Schering-Plough, I was directly involved in concurring with the selection of almost all our country managers in the emerging regions.

Finally, Avon has taught me to look at the field force in a new way. All their sales people are independent vendors and the company looks at them as their first line of customers—you must win their hearts to succeed in selling to the masses. In our industry, sales people are paid mainly through a base salary, plus a bonus usually weighted against the performance of others in the group. It is interesting how the mindset changes when you treat each rep as accountable and trusted ambassadors for the brand. If you look at them as the first line of customers, their results in the marketplace will be quickened and their feedback link to marketing will be sharper.

What's needed to invigorate the drug pipelines of the major pharma companies?

There is no single answer and in many ways it depends on the imponderables of organization dynamics. In the late '80s, I was at Sandoz (now Novartis) when oncology was our next gleam in the eye after our successful reinvention into immunology with the launch of the transplantation drug Cyclosporia. Novartis has now succeeded in creating a successful franchise in oncology over a 20-year period. From the beginning, there was a commitment to working in small groups around specific projects based on a clear medical need and potentially enriched populations from genetic science and biomarkers. They also mix people very easily, so that there is less disconnect between the researchers and commercial development teams. The premise has always been to lead with the science; if the science is good, the market will follow. The Novartis story suggests you can build a big business around small opportunities, without having to chase after the premise that every success means a blockbuster. Small bets can add up, and spread through multiple indications.

Much has been written about the barriers to innovation in big Pharma, but one I have not heard is mentioned in your book: "forestalling victimhood." What does that mean?

In the large R&D cultures that still characterize the industry today, there is a cultural signal to play defense rather than strive for a positive outcome. Job security in these R&D organizations is better assured if fewer risks are taken. Managements have to stop the productivity drain where people think less about innovation and more about keeping their job. People must be taught through example that you can be an innovation leader and also a strong matrix player, and be rewarded for seeking out that area of common ground, working as a catalyst rather than a critic. Again, small groups can help drive this mindset better than more bureaucracy. Scientific leaders able to instill a positive sense of purpose are a prized commodity. They are especially needed now as the R&D enterprise adjusts to a long period of transition toward new modalities such as personalized medicine.

There are two contrasting futures for the industry. The first is that aging demographics combined with strong science will require more medicines and thus keep revenues and profits high. The second is that the industry has lost control of the pricing and value equation to payers and thus faces a decline through relentless commoditization. Where do you stand on this?

Payer power is the big issue right now. However, I am optimistic that the industry has the answer to this challenge—new and better drugs. Even in those therapeutic categories subject to commoditization, such as cholesterol, hypertension, and diabetes, the gravity of the public health threat means that society requires continuous improvement in treatments just to keep up. And this doesn't even address the conditions where there are still no effective treatments at all, led by Alzheimer's and Parkinson's. There is no other industry right now where society has that level of unmet need.

The other response to the payer community is the value of medicines in terms of the overall cost burden from healthcare. In most countries, drugs constitute a relatively small share of total costs, well behind hospital charges, physician fees, and long-term care. What is most exciting is how much of the new medicines innovations coming on stream in the next 10 years will actually contribute to reducing costs through less reliance on these other health services. Personalized medicine is finally beginning to show its mettle through precise targeting of drugs around an individual's unique genetic profile, for a superior therapeutic effect that prolongs life and is cost effective through lower rates of therapy failure and institutionalization. More important, there are major spin offs from this revolution in the biology of disease and the processes that underpin it: R&D becomes more cost efficient in linking a compound to a specific disease target; the long haul of drug registration becomes faster and more focused, because it is easier to identify and assess the population most likely to benefit from a NME (new molecular entity); payers are positioned to obtain better evidence of real-world outcomes; and the patient experience is individualized rather than subject to the hit or miss randomization of a population effect.

This last point is very important. The reason why payers have the upper hand is that they can treat us as manufacturers of products for big populations; for many in this population, there is no clear evidence that

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our products even work as intended. As long as that mindset continues, payers can commoditize us. However, if we succeed in making this a purchase that carries a measurable value unique to each patient, the conversation changes. With the increased information about the clinical effectiveness of our drugs, the initiative moves back to the patient's interest in receiving the most appropriate therapy for his or her clinical condition, rather than just what a formulary says. I think we are getting to that point now, where payers will be forced to give ground.

Do you believe that the new science and personalized delivery will give industry a greater measure of pricing freedom?

What I am saying is that we will have more pricing discretion when the momentum shifts back to the informed patient. At the same time, we need to remain sensible in our pricing behavior. We all can cite examples of egregious pricing decisions that tainted the industry's reputation. Oncology products, in particular, have to be priced strictly in line with the value they deliver. I am a strong believer in the market as providing the necessary discipline. When someone overprices, the market will make a noise, providers will shut you out, and then you have to go back and adjust it—with an extra levy imposed on your reputation.

You were involved in a total of six major corporate turnarounds in your career. Looking back, what was the one skill that mattered the most to your success? Alternatively, in which areas did you feel you were deficient?

The trait that made the most difference was figuring out the "how" behind the "what." The strategy could be set; what was hard is making it all happen. What I learned is to sequence actions so that one would reinforce the other to move things forward. For example, if I concluded that culture change had to drive the strategy, then I would take deliberate steps to demonstrate the need for change and to convince people they were ready for it. Every statement had to be reinforced with action—repeatedly and in a way that everyone from the receptionist on up could understand. Yes, there are some negatives in a turnaround but I have always been careful to put the emphasis on what success down the road would look like. Getting the foundation laid and seeded was something I did well in every restructuring plan. Once the green shoots came—the carefully staged "early wins"—it actually became easier to move the flywheel and launch a chain reaction that would eventually start humming on its own, because the sparks came not from me, but the entire company.

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With regard to what I might have done better, the most important was a failure to move early to correct mistakes I made about people being right for the job. I was sometimes slow to act. The worst players in any turnaround situation are the passive aggressive personalities. I could have done a better job in rooting them out quickly, because passive aggressive behavior is probably the biggest single drain on culture change.

To conclude, what advice do you have for younger managers in building a career in the midst of a business model that is morphing in so many unpredictable ways?

You will find most of your peers have the right credentials, beginning with a good education and exposure to others with a similarly competitive nature. But what is often lacking—and is certainly missing from business school curricula—is learning how to be more self-aware and connected; do you understand how people may view you differently than you do yourself? This is a trait that develops as you grow older in life, when the scars start to show. If younger people can learn to drink from that well of self-awareness earlier, they will do better in coping with the ups and downs that accompany any successful career. When I was recruiting people, I rated "EQ" as important as IQ. In fact, I developed at Schering-Plough what I call the "knockout" assessment system: if a candidate scored perfectly on all the surface attributes, like big titles and a prestigious degree, he or she still failed the cut if we uncovered just one instance of hubris, or rudeness to staff, refusing to work in teams, or taking energy out of the system through self-promotion. Great organizations only survive when we work just as hard for others as we do for ourselves. It requires traits of human character that I believe are permanent and immutable. PE

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It's Time For a Code of Ethics in Patient Education

Medical education for healthcare professionals has a stringent governance structure in place to ensure that every healthcare provider has access to unbiased education. There are regulations around the commercial support of medical education, as well as an accreditation process for both educational activities and the organizations that develop the education.

Transparency is imperative; if an educational intervention is deemed promotional in nature, it must be disclosed as such. This ensures that healthcare professionals have access to a spectrum of options and are essentially making informed medical decisions based upon all the facts and sound judgment. The aim of structural governance in medical education is to protect healthcare professionals from information that may steer them down the wrong path for a particular patient, without a full understanding of all the options.

In the world of patient education, processes, policies, and oversight differ vastly. There is no overarching governance structure. There isn't an accreditation process for educational interventions or patient advocacy organizations that develop the education. There is no mandate, for instance, that patient advocacy organizations put in place a content validation process or a conflict of interest policy to ensure that patient education truly puts every patient first. There aren't formal instruments or regulatory bodies to assess bias (or to even define it) in patient education, or requirements that patient education undergo peer review prior to dissemination.

The "participatory medicine" movement is underway where networked patients are shifting from being mere passengers to responsible drivers of their health, and clinicians are encouraging them as full partners. To encourage this partnership, the tools and resources we use to educate, empower, and engage patients in their care are essential. Each patient deserves access to all the facts through unbiased interventions to allow for informed medical decisions that will ultimately affect their outcome. Patients are key decision makers and should be given the equivalent of what healthcare professionals receive, but in laymen's terms. Patients navigating chronic illnesses may not have the skillset to understand how to detect bias or distinguish between promotional and independent education, where the distinction can be subtle.

In addition, trusted entities such as patient advocacy organizations don't always have the training or policies necessary to ensure content validation processes and to address conflicts of interest. There is often a misconception that all ".orgs" are trusted sources of information and this is simply not the case. A .org is not always indicative of a non-profit, and a non-profit is not always indicative of unbiased education. Patient advocacy organizations often serve as lifelines for patients and caregivers, helping them navigate complex processes, understand options, and obtain a support system.

However, standards across patient advocacy organizations vary, and this variation can affect patients who may not have the trained eye of a media critic, or understand the need to ascertain the credibility of educational resources. With the advent and flexibility of the Internet, where a majority of patients access health information, it's more important than ever for us to arm patients with credible information. Finding valuable and reliable information on the Internet is like mining for gold; patients must sift the nuggets from the garbage.

How can we apply what we've learned about ethics in research to ethics in patient education? For decades, research ethics have benefited from the development of various codes and guidelines, but no similar code exists to guide in the ethical involvement in education. The World Medical

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Association Declaration of Helsinki states, "Even the best current interventions must be evaluated continually (through research) for their safety, effectiveness, efficiency, accessibility, and quality." Principles of continuous evaluation should equally apply to educational interventions.

What can we learn from the compliance-driven, continuing medical education/continuing education industry, which was a reactive model enforced due to legacy practices and resulting regulation? How can we implement a more proactive self-regulation model with more flexibility to allow for strategic partnerships between industry and patient advocacy organizations? How can patients and patient advocacy organizations better leverage the medical expertise and knowledge that pharmaceutical companies have access to in an appropriate and transparent manner? How can we strategically partner across healthcare sectors to improve patient outcomes?

Over the next few months, ideas will be crowd-sourced to gather standards for a code of ethics, a set of guiding principles for those committed to ensuring every patient is put first. The goals of the code of ethics are:

- To establish a set of overarching guiding principles around the development and support of patient education that can be adopted across the healthcare spectrum to ensure every patient is put first.
- To put in place the appropriate processes, policies, and training for those developing patient education to alleviate bias.
- To put a spotlight on the issues and make patients and caregivers aware of some of these gaps and the need to ensure they are searching for information from credible resources.
- To prominently recognize those organizations that have committed to the code of ethics making this information available to patients.

Healthcare professionals, who have had years of rigorous training, have the appropriate safeguards in place to ensure they have access to unbiased education, but who is protecting our patients that might be navigating the healthcare system for the first time? When patients access education, they need to understand the origin of the information and how it's managed, the funding source, the medical accuracy review process, how current the information is, and privacy policies if any information is being collected. All of that must be done—on top of managing their condition. The adoption of an industry code of ethics would allow patients to focus on what's most important—managing their condition and getting well. A few guiding principles follow.

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Draft code of ethics

- *Unbiased.* Education must be scientifically rigorous and credible with a standard or tool for defining and assessing bias in education.
- *Evidence-based.* Decisions on patient education content must be made in the best interest of patients and based on validated evidence and accepted standards of care.
- *Transparency.* Supporter and sponsor involvement must be disclosed in the development and support of education. If education is developed in collaboration with another organization, education should be disclosed as "developed in collaboration" rather than solely depicting a logo, which can also be linked to "independent" education. Leveraging the medical expertise of pharmaceutical companies can be extremely beneficial, as pharmaceuticals companies are well positioned to develop exemplary resources, but this should be disclosed to those receiving the education. Transparency around involvement is important.
- *Conflict of interest.* Any conflict of interest must be disclosed to patients. It is understandable that conflicts of interest may surface from time to time and organizations should have conflict of interest resolution processes in place to address them.
- *Content development.* Procedures should be put in place to ensure that educational content developed is reviewed and endorsed from a scientific standpoint by medical experts.
- *Need based.* Education should be based on measured and documented needs that address specific educational gaps—not perceived needs.
- *Peer reviewed.* Education should undergo rigorous peer review prior to dissemination to ensure information is objective.
- *Outcomes-based.* Interventions should incorporate a plan to measure outcomes with standard approaches for assessing retention or behavior change.

We ask *Pharm Exec* readers: What else would you suggest including in the code of ethics? What other ideas do you have? What barriers to adoption do you foresee? PE

The New Commercial Model Myth

Pharma professionals need to find new competitive—not commercial—models to succeed in the competitive stage of the industry's lifecycle.

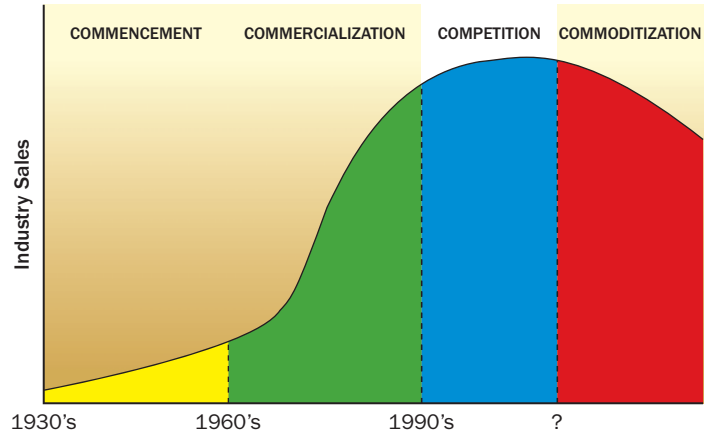
A recent Cegedim Relationship Management survey revealed that the number one concern of nearly three-quarters of pharmaceutical executives is the "changing commercial business model." Desperately seeking new commercial models, many executives have experimented with a myriad of approaches, including corporate restructuring, sales force realignments, customer-centric account management, multi-channel marketing, and new emerging markets strategies. Unfortunately, these commercially-focused efforts were doomed to fail. Because the pharmaceutical industry has transitioned from the commercial to the competitive stage of its lifecycle, companies seeking new commercial models in the competitive stage are fighting today's battles with yesterday's battle plans and weapons (Figure 1). Pharma companies need new competitive—not new commercial—models.

The industry's commercial or growth stage extended from the 1960s to the 1990s. During that period, there were significant unmet clinical needs, many new products and indications; expanding markets, pricing flexibility, and relatively little competition. Numerous companies, products, and brand teams experienced double-digit sales growth resulting in many pharma "winners." However, that changed in the 1990s when the European and the US markets transitioned from the commercial stage to the competitive stage of their lifecycle. This stage has been characterized by brutal competition among a countless number of brands, generics, and substitute products; significantly reduced R&D productivity resulting in fewer new products; more sophisticated payers focused on cost minimization; and increasing industry consolidation and contraction.

The transition to the competitive stage in the United States was marked by two key indicators: the peak number of new molecular entities (NMEs) in 1996 and the end of double digit sales growth in the late 1990s. IMS projects that the US and European markets will have low single-digit growth rates ranging from 3 to 6 percent and 1 to 4 percent, respectively, through 2014. While emerging markets remain in the growth or commercial stage, companies are recognizing the competitive challenges these markets represent for innovative brands, especially biologics and other higher-priced medicines.

Several industry CEO's have acknowledged this important lifecycle transition. In 2008 Andrew Witty, CEO of GlaxoSmithKline said, "The environment we find ourselves in as a pharmaceutical company is so different from seven or eight years ago that it is almost unrecognizable." In the same year, then-CEO of Merck Richard Clark stated in a corporate press release that, "Next year will continue to be a period of fundamental transformation that establishes Merck as a different competitor for the next decade....This new Merck will be built for the new era that our industry has entered."

In this environment, companies need a new competitive



Source: Bernard Associates, LLC; www.BernardAssociatesLLC.com

The four lifecycle stages of the pharmaceutical industry.

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model to outperform rivals and thrive in these challenging conditions. Here are five examples of such models that demonstrate winning approaches:

Technology model. Beginning with its majority ownership of biotechnology pioneer Genentech in 1990, Roche has leveraged its leadership in biotechnology—specifically monoclonal antibodies—to become the world's largest oncology company, with its $20 billion in pharmaceutical sales representing one-third of the industry's total in this category. The company is the global leader in tissue-based cancer diagnostics and cancer therapeutics, including blockbusters Herceptin (breast cancer), Avastin (colon and lung), and Rituxan (blood cancers). According to market research firm Evaluate Pharma, Roche is expected to dominate oncology, the industry's biggest therapeutic area, for at least the next five years.

Diversification model. Beginning in the mid-1990s, Novartis adopted a "focused diversification portfolio" strategy by incorporating pharmaceuticals, vaccines, generics, and consumer health. Novartis invested in new areas of healthcare, such as generics and eye-care, highlighted by its $52 billion acquisition of US eye-care company Alcon. According to CEO Joseph Jimenez, "A broad, diversified portfolio is going to become increasingly important as more and more payers look for low-cost generics and preventive vaccines as complements to innovative pharmaceuticals." By leveraging this unique competitive model, Novartis will generate sales exceeding $60 billion and become the world's largest pharmaceutical company by 2017, according to First Word.

Specialization model. Gilead Sciences (viral infections), Novo Nordisk (diabetes), and a number of other pharmaceutical companies have built dominating disease specialty companies. Gilead, the current leader in anti-HIV product sales, is expected to command an over 40 percent share of the anti-viral market by 2018 by adding new Hepatitis C anti-viral agents. Similarly, Novo's insulin and non-insulin (Victoza) franchises will represent nearly 30 percent of the entire global diabetes market over the next five years. Such focused disease models offer numerous competitive advantages, including product portfolio co-positioning and segmentation; potential portfolio product combinations; enhanced corporate reputation and recognition; potential pricing and contracting leverage; substantive, longer-term relationships with key stakeholders, including regulators, thought leaders, and prescribers; and better business development and licensing opportunities. A 2011 Oliver Wyman study revealed that leading disease specialty companies complete 2.2 times more business development deals, achieve 70 percent higher development success rates, and generate 5.5 times more revenue than non-specialty companies.

Execution model. Teva Pharmaceuticals has become the world's largest generic company by relentlessly focusing on better execution to outperform its rivals. Over the past 15 years, the company has been the global leader in acquiring and integrating numerous generic manufacturers, including Taiya; Barr Pharmaceuticals; IVAX; Scios; Novopharma; Copley; and Ratiopharm, a pivotal European player for which Teva beat out Pfizer, the world's largest pharma company. In the United States, Teva routinely beats its generic rivals to market by filing abbreviated new drug applications (ANDAs) for its generic products much earlier and with fewer revisions than competitors. Teva has been an implementation innovator in supply chain management, information technology, and research and development. For example, Teva effectively developed its branded multiple sclerosis blockbuster Copaxone for one-fifth of the average cost of innovative products. The company is increasingly leveraging its efficiency model for developing and commercializing other innovative products as demonstrated by its recent investments in Cephalon and CureTech. Execution excellence has catapulted Teva this year into the top 10 of global pharma companies, according to Evaluate Pharma.

Virtual outsourcing model. Several biopharma companies have adopted a competitive model characterized by a small number of full-time employees directing a virtual network of support vendors responsible for core corporate functions. In 2006, NPS Pharmaceuticals was a floundering, nearly bankrupt biopharma company with over 400 employees, a failed lead development product, and four research and operational facilities. New CEO Francois Nader dramatically transformed NPS into a virtual pharma company by outsourcing most of its non-core functions to third-parties. NPS closed all but one of its facilities, including its research laboratories and original headquarters in Salt Lake City, effectively eliminating the firm's discovery, manufacturing, and commercial operations. Nader slashed the workforce to 40 people and focused on the development of two key orphan drugs. Today, NPS is a thriving competitor which recently gained FDA and European approval of Gattex, a treatment for short bowel syndrome, and is submitting a biologic license application (BLA) to the FDA in the second half of 2013 for Natpara, a novel treatment of adult hypoparathyroidism. The company recently regained the worldwide rights to these two products from Takeda, making the company a global player in the orphan diseases space. Similarly, Ferrokin Biosciences was a virtual pharma company comprised of seven home-based employees who for several years directed an outsourced group of 60 vendors and contractors developing a novel, once-daily, oral iron chelator for treating transfusional iron overload. In March, 2013, Shire Pharmaceuticals bought the highly successful virtual biotech company in a deal valued potentially at over $300 million. PE

The Affordable Care Act Will Boost Private Managed Care

Public access expansion under the ACA isn't really a "government takeover."

Over 30 million newly insured patients under the Affordable Care Act (ACA) will receive coverage through the mandated Health Insurance Exchanges or the now-optional Medicaid expansion. Sounds like government expansion, right? Well, not exactly.

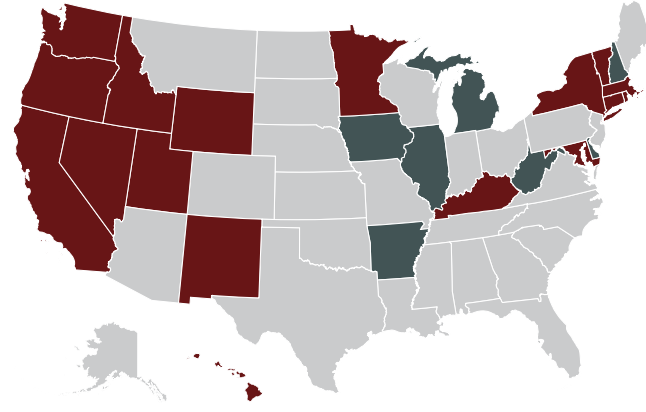
Healthcare reform may not actually lead to the vast expansion of government that some have claimed. It turns out that privately-owned Managed Care Organizations (MCOs) will be the ones providing insurance plans on the exchanges. MCOs are also increasingly being relied on to manage benefits on behalf of state Medicaid. It is somewhat ironic that what many decry as government overreach will actually result in an expansion of patients managed by private insurers.

Now, is this good news or bad news for the life sciences industry? This column will explore these two key ACA provisions to explain how private MCOs are getting more closely involved, and what this could mean for pharmaceutical and medical device manufacturers.

State Medicaid: the trend toward managed Medicaid

One of the provisions in the ACA that has drawn a lot of attention is the expansion of the Medicaid population. The law offers incentives for states to increase their Medicaid eligible population to all patients over 65 years old with incomes below 133 percent of the federal poverty level. States opting to expand coverage receive 100 percent federal funding for these new enrollees in the first three years, with funding then tapering down to 90 percent through 2020. There has been mixed reaction from individual states with some rejecting the expansion (e.g., Texas and Georgia) others embracing it (e.g., California and Illinois) and others still undecided. While the funding for these new patients certainly comes from the government, the administration of benefits for Medicaid has been increasingly shifting toward MCO managed Medicaid.

Already, it is estimated that ~65 percent of Medicaid patients across the United States have their benefits administered via managed Medicaid. This figure will only increase in the future as more states determine that they do not have: the budgets to carry the overhead needed for administering these benefits or the expertise and infrastructure needed to manage care and control cost. By expanding the Medicaid population, the ACA is indirectly increasing the number of patients being managed by private MCOs.



State vs. Federally-operated exchanges	Tally
State-operated exchange	18*
State-partnership exchange	7
Federally-operated exchange (default)	26

* Includes Washington DC

Figure 1: Current status of insurance exchanges, by state.

Innovative cost containment tools are being applied to managed Medicaid populations by MCOs just as they are for privately insured patients. MCOs have an incentive to deliver care in a cost effective manner because states typically pay them

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a fixed amount per patient. Benefit requirements vary from state to state, but in general, managed Medicaid is usually allowed to offer benefits that either match or exceed the state's minimum requirement (such as their preferred drug list). This flexibility opens opportunities for MCOs to implement new payment models with physicians such as capitated contracts with accountable care organizations (ACOs). A frequent criticism of government-run programs is that they tend to be too bureaucratic and inefficient. By allowing the private market to manage Medicaid patients, states are able to take advantage of the latest innovations and cost containment trends from more nimble MCOs and ACOs.

Insurance exchanges: public market for private plans

Even more controversial than the Medicaid expansion is the ACA's provision requiring patients buy insurance or pay a tax penalty, commonly known as the "individual mandate." Most insurance today is purchased as group plans through employers. However, individual insurance plans will gain in importance with the ACA mandate as a greater number of individuals and small employers now look to get coverage. To facilitate this shift, the ACA will establish insurance markets through state insurance exchanges. In the words of HHS, the goal is to provide "consumers a consistent way to compare and enroll in health coverage in the individual and small group markets, while giving states and insurers more flexibility and freedom to implement the ACA." It is expected that these exchanges will provide coverage for as many as 24 million patients by 2016.

Figure 1 shows the current state of the insurance exchanges as of April 2013. Insurance plans offered on these exchanges must meet minimum requirements for essential healthcare benefits and patient cost sharing. Requirements will vary across state lines, and are currently in the process of being established—so far, only California has released details on their proposed benefit design. A key open question for these plans will be to what extent each state allows highly restrictive MCO formularies. What we do know is that the general structure of the offerings will be stratified into four metal-themed categories: bronze, silver, gold, and platinum. The Bronze plans will offer the lowest monthly premiums, but have high patient copays and deductibles. Platinum plans might offer even richer benefits and lower patient copays than typical employer insurance offerings—but this comes at the cost of higher monthly premiums. Given the demographics of patients expected to enter these exchanges, we predict that the lower premium plans (bronze and silver) will end up seeing the most enrollment.

However, insurance exchange requirements set by the state are merely the "rules of the game" within which MCOs will be competing for members. The MCOs themselves will ultimately decide what kinds of products to offer within the guidelines, and how best to differentiate their offerings from competitors. The Massachusetts State Health Connector, a model used for the development of the insurance exchange concept, has numerous companies offering plans. For example, there are 10 plans currently offered at the "silver low" tier with premiums ranging from $330 to $485 per month. Variations between the offerings include differences in regard to physician networks, copay for ophthalmology visits, coinsurance levels for lab imaging, and more. Fallon Community Health Plan even has an offering leveraging their relationship with Steward Health Care (an ACO) where patients pay $100 less each month if they agree to receive care exclusively within the "Steward Community Care" network. The Massachusetts example shows that even within the benefit constraints of a given tier, there can be clearly differentiated plan options and competition.

There is no question that federal and state governments have been the catalysts for the creation and operation of these exchanges. On the other hand, what is also clear is that the private sector will be the group actually managing these new patients and competing for their business.

Implications of the newly insured

The specifics around the scope of Medicaid expansion and designs of insurance exchanges are currently being ironed out. However, there are already a few key implications for pharmaceutical companies and medical device companies to consider:

- The expanded insured US population broadly benefits the industry through greater sales potential, particularly in indications where patients may have previously been uninsured or underinsured.
- MCOs, already the key customer for many products, will become an even more important partner for manufacturers to build relationships with.
- Management trends seen in commercial plans (e.g., capitated payments) are likely to be used more broadly in Medicaid as greater management responsibilities fall to MCOs.
- Insurance exchange plans may look like a new commercial payer channel if MCOs end up structuring their benefits and making decisions differently compared to their employer-sponsored group plans. While we may not see significant differences in the number of drugs covered compared to their current plans, MCOs may look to manage covered products more restrictively in the exchanges.
- Patients enrolling in insurance exchanges may open more doors for patient assistance programs, especially if most patients (as expected) enroll in the bronze plans that have high deductibles and copays

While it was indeed the federal government that passed the Affordable Care Act, it is important to consider that private MCOs will continue to lead the way in ensuring appropriate care and implementing cost containment strategies for these patients. PE

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AUSTRIA: An Ensemble of Collaboration

Historically, Austria was the dominant political power in Central Europe under the Habsburg dynasty which ruled until World War I. Although the 20th century has been marked by significant shake ups and power shifts between countries in Europe, Austria remains today a key strategic market thanks to its steady economic development and inclination for innovation. Because of its dynamics and ideal location, it is often argued that Austria is still a gateway for the Western World to Central Europe. But to what extent? What other roles does Austria play in the regional and global pharmaceutical landscape?

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It only takes a matter of minutes walking down the streets of Vienna to envisage a time when the city, placed at the center of Europe, was the focal point of an entire empire steeped in rich and magnificent history. From the premiere of Mozart's most recognized works to the decisive Congress of Vienna, the city has had a wealth of cultural, political, and scientific experiences that make it truly stand out. While the entire country today is a different place compared to centuries ago, life for the average Austrian has consistently been excellent.

The standard of well-being in Austria is second-to-none. Vienna was rated by Mercer in 2012 as the number one city in the world for quality of living. Overall, Austrians enjoy very high standards in terms of infrastructure and public services, and healthcare could indeed be described as outstanding. 99 percent of all Austrians are protected by statutory health insurance as a result of the General Social Insurance Act of 1956, which created a simple insurance structure that promoted solidarity and social cohesion.

Alois Stöger, Austrian Federal Minister of Health

Alois Stöger, Federal Minister of Health, believes that good health is considered a truly invaluable asset in Austria, which is reflected in healthcare spending and health system resources. "In 2009, about 11 percent of gross domestic product was spent on health, of which 78 percent was generated from public sources," comments Stöger. "A high density of easily accessible health care facilities exists, and patients have considerable choice of provider. Access to high quality medical care is ensured for all citizens. Equitable health care for all patients is of great importance; services provided by social health insurance do not depend on social status or income." An example of this high quality care is demonstrated through the implementation of the "electronic health card" in 2006, whereby citizens' information on medical history and insurance are electronically stored on a personally issued card that can be used by physicians for a variety of purposes ranging from diagnosis to billing. In the coming years, Stöger will be working hard to increase the lifespan of the average Austrian by two years.

In order to create reform, the Ministry of Health, which oversees all of the social security institutions in Austria, established the Federal Health Commission, which is composed of representatives of the Federal Government, the social insurance institutions, the federal states, the physicians' chamber and other advocacy groups. Stöger is excited about the efforts that these various associations have recently made in an effort to improve the quality of healthcare in Austria. He explains that they have "agreed to negotiate a common and co-operative governance system for all relevant levels of health care delivery based on public health goals as well as financial targets for in- and outpatient care on a national as well as regional level." Therefore, the Ministry plans to "raise the effectiveness of the health care system via the further development of the regional health care structure in line with public health needs and to enhance the efficiency of the system by adopting an integrating care perspective and ensuring health care delivery at the best point of service," remarks Stöger.

The macroeconomic environment for the Austrian pharmaceutical industry is quite positive: economic recovery is strengthening, with modest GDP real growth projected in 2013. With its 8.5 million people, Austria sits amongst the largest pharmaceutical markets in Europe, ranked 12th in 2011, with a market size of EUR 3.2 billion (USD 4.3 billion). The pharmaceutical industry in Austria represents between 10,000 and 11,000 individuals working for roughly 220 companies. Additionally, Austria serves as an important research hub. Vienna alone has 22 research institutes, five universities, two technical universities, and an impressive life science student population of around 35,000.

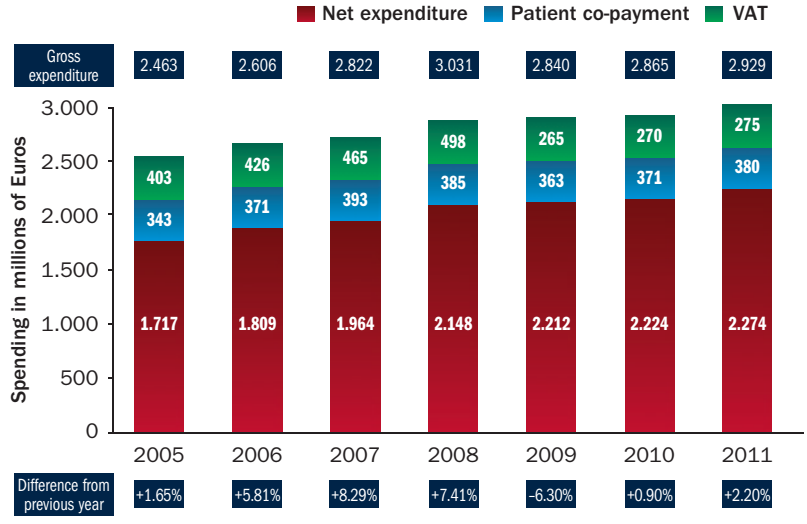
Austria's entire pharmaceuticals market is expected to grow in the next few years. According to the Austrian Federal Chamber of Commerce, business volume is estimated at EUR 1.9 billion (USD 2.54 billion) and rising. More than 60 industrial pharmaceutical companies operate in Austria. Multinationals such as Sandoz, Eli Lilly and Roche not only have production facilities in the country, but have set up research and competence centers. However, despite Austria's reputation of wealth, it is one of the more low-price countries for pharmaceuticals in Europe. Baxter Healthcare's managing director in Austria Andreas Kronberger laments that "in terms of per capita sales for each product line, Baxter is selling more in other countries than in Austria. In the end, the commercialization of our R&D and production strengths ends at the price level of the European market."

The principal challenge facing the Austrian healthcare system is an increase in costs due to a growing population and the uptake of new, more expensive pharmaceuticals. Many countries around the world face similar issues resulting from their ageing population. According to various sources, an additional 30,000 to 40,000 people join the 60+ age group annually in the country. Austria's health system therefore follows an increasingly price sensitive model, which is becoming the number one criterion for health stakeholders. Additionally, as Frank Wartenburg, president of IMS Health Central Europe points out, "Loss of Exclusivity and the patent cliff are impacting the Austrian pharmaceutical industry in general. We expect the market to lose 250m Euros in revenues in the next two years, and half a billion in the next five years."

Elisabeth Prchla, managing director of Merck Austria, points out that "the pharmaceutical industry has been the prime target for cost containment measures which has meant that patient access to innovative medicines is difficult." Prchla believes that, together with the Austrian industry associations, it is fundamental for companies like Merck "to cooperate with politicians and payers in order to develop conditions that allow easier patient access to innovative medicines."

One way in which pharmaceutical companies are dealing with this is by voluntarily paying back EUR 82 million (USD 111.1 million) into Austria's health system until 2015, which will then be reinvested by the Austrian government into various pilot healthcare projects, mainly

Net health insurance expenditure for medicines 2005 - 2011



Source: PHARMIG in 2012

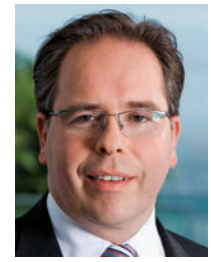
Austria Report

focused on prevention and child healthcare. This historic deal involved all stakeholders in the pharmaceutical industry consenting unanimously to this agreement, which is rarely seen in other countries.

TRAFFIC LIGHTS

In 2004, a new "traffic light" system for reimbursement was implemented that significantly altered the way in which pharmaceutical companies are reimbursed for their products. Essentially, products can be placed in one of three boxes. The green box includes all drugs that are automatically reimbursed by the government. The yellow box consists of drugs that are only reimbursed under special conditions that meet tightly defined rules for reimbursement, and the red box contains drugs that are highly unlikely to be reimbursed.

According to Jan Oliver Huber, general secretary of the Austrian pharmaceutical association PHARMIG, this change in the system caused slower growth rates in subsequent years because of stakeholders' natural cautiousness and the time needed to adapt to this new structure. Like other European countries, Austria's population is ageing. "Considering two thirds of all prescriptions paid by the reimbursement system are destined for this age group, there is a natural, organic growth in Austria because of the demographics," remarks Huber. "But this growth has not been steady: in 2005, the market grew by 1.65 percent whereas it grew by 8.29 percent in 2007 and by 7.41 percent in 2008."



From left: Jan Oliver Huber, General Secretary, PHARMIG; Frank Wartenberg, President Central Europe and General Manager Germany and Austria, IMS Health

Entering this reimbursement system is not an easy process either. Karl Peter Schwarz, managing director of LEO Pharma Austria describes the system as being rigid. "It is very difficult to discuss the added value for patients, which is reflected in any product price," he notes. "The maximum price of a drug within the reimbursement system in Austria is the EU average price," continues Schwarz. "If your product is already on the reimbursement list in other European markets, you have to inform the Minister of Health, after which a price commission gives you clearance." Karl Nikitsch, country manager of Menarini Austria, notes that "the market shares of some products are relatively high compared to other, much bigger, European markets. In spite of the hurdles Menarini faces in terms of market access, such as new products

Top 20 ranking pharma companies in Austria by 2011 Revenue

COMPANY	Revenue EUR/2011
NOVARTIS PHARMA	194,567
PFIZER	190,763
ROCHE AUSTRIA	182,326
SANOFI-AVENTIS	143,607
ASTRAZENECA	130,292
GLAXOSMITHKLINE PH	125,200
BAYER AUSTRIA	106,971
FRESENIUS KABI AUS	86,693
BOEHRINGER I.A	85,168
JANSSEN-CILAG PH	80,880
RATIOPHARM	72,894
MERCK SHARP DOHME	71,096
SANDOZ	67,299
ELI LILLY	66,523
AMGEN GMBH	58,393
NYCOMED PHARMA	49,944
TAKEDA PHARMA	48,187
MERCK	46,890
GENERICON-PHARMA	44,356
CSL BEHRING	43,667

EURO MAT/12/2011

Source: IMS Health in 2011

instantly falling into the yellow box category with many restrictions, there are green lights once this difficult stage has passed. In other countries, companies may need to renegotiate the presence of their product in the reimbursement system, such as Germany," Nikitsch says.

A NEW GENERATION OF GENERICS

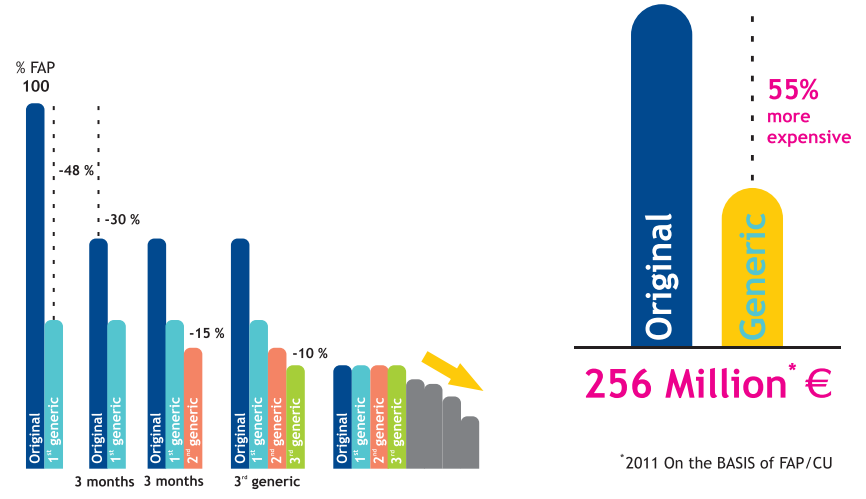
This new reimbursement scheme and price referencing system has resulted in a lower generic market share. The clash between originators and generics is an unusual situation in Austria. In 2005, the Austrian Sick Funds put into place a new system for generic market entrance. If a product is to be reimbursed, generics companies have to lower the price of a product by 48 percent compared to the originator. The second generic that enters the Austrian market subsequently has to reduce the product's price by an additional 15 percent and the third generic product a further 10 percent. To make matters even more confusing, three months after the third generic hits the market, originators have to decrease the value of their product to the price of the third generic.




From left: Robin Rumler, Managing Director and Business Unit Director Primary Care, Pfizer Corporation Austria; Elisabeth Prchla, Managing Director, Merck GmbH; Karl Peter Schwarz, Managing Director, Leo Pharma GmbH; Karl Nikitsch, Country Manager, A.Menarini Pharma GmbH

In 2000, the Austrian Generics Industry Association (OEGV) was created to represent the interests of generics companies in Austria. Compared to many other countries in Europe, the penetration rate of generics in Austria is still relatively low; although compared worldwide Austria finds itself in the middle of the road. IMS data from 2010 indicates that generics only had 26 percent of the market share, putting Austria as one of the lowest in Europe. Bernd Leiter, president of OEGV, notes that until recently, most Austrians were not even aware of the existence or the role of generic drugs. His main task as President is to "raise the awareness of the other stakeholders in the pharmaceutical

Savings in Austria for generics in 2011



From left: Bernd Leiter, President, Austrian Generics Association; Martin Spatz, General Manager, TEVA Austria

industry about the existence and actions of an association entirely focused on defending the interests of generics companies in Austria." Leiter feels that through convincing authorities, physicians and patients about the quality and safety of generic drugs, the potential savings by switching to generics in the future could equate to roughly EUR 256 million (USD 344 million), which represents a 55 percent difference in price between patent-free originators and third generics.

Alexander Papanikolaou, managing director Austria, Czechia, Slovakia & Switzerland, HOSPIRA Austria GmbH

Dr. Martin Spatz, general manager of generics company Teva Ratiopharm is optimistic about the future of generics in Austria. "Whereas the total pharmaceutical market in Austria is expected to grow by 1 or 2 percent, the generic market could grow by 5 to 7 percent. If it is not spoiled by voluntary price cuts and by fully exploiting the potential, it could even grow by 10 to 15 percent," remarks Spatz. "If your brand is not known, you will need huge upfront investments; if you are here as an established generic player, the market is rather protected. Barriers to entry are rather high because it is a branded market."

Dr. Robin Rumler, CEO of Pfizer Austria and president of PHARMIG, is also aware of the shift towards generics that is

BOSTON CONSULTING GROUP: A Fresh Perspective

Focus Reports had the opportunity to sit down with Ewald Kreid, partner and managing director of BCG Austria. Kreid offered some insightful viewpoints about the pharmaceutical industry in Austria. According to Kreid, cost efficiency and being effective with fewer resources is one of the main challenges currently facing the industry, and that the collaboration between the DACH countries can create interesting structures. "Austria is a relatively small and uniform country with many 'basics' in place for data systems," Kreid notes. "However, due to tight data protection rules and strong traditions among physicians, when it comes to analyzing, applying and tying decisions and budgets to certain quality outcomes, it is not being done." Kreid likens the mindset of physicians in Austria to those of 19th century workshop models. The "small is beautiful" attitude, according to Kreid, means being "close to the patient and not industrializing, centralizing or specializing as other countries do."

Ewald Kried, Partner & Managing Director, Boston Consulting Group Austria

In terms of the Austrian generic regulatory system, the market is characterized by price decay and the volume of off-patent generic penetration. "Austria has very strong price decay, but originators keep the volume share, which sometimes increases because regulations are more attractive for originators than generics after patent expiration. If a physician can prescribe an originator for the same price as a generic, why bother switching?"

"In five years' time there will be more pressure on the generics side to make it more attractive. That will continue. Longer term, if countries watch how successful from a payer perspective the German system is with these tenders, our expectation is that there will be a greater concentration of purchasing and price decay."

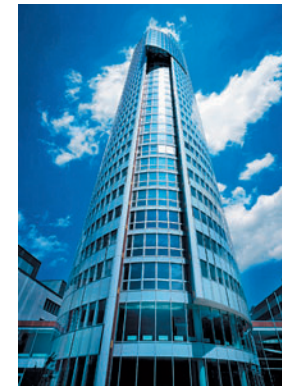
Austria Report

From left: Alfred Grün, managing director, Schülke & Mayr GmbH; Michael Norman, General Manager Austria, Czech Republic, Hungary, Romania, Bristol-Myers Squibb GmbH

From left: Robert D. Lefebvre, Vice President Commercial Operations Europe, Middle East and Asia, Kedrion International; Gerald Schrot, Managing Director, Biotest

gradually taking place. "With respect to the cost of drugs, Austria belongs to the low cost countries in Europe," Rumler remarks. "Drug costs are approximately 18 percent below the EU-15 average. Nevertheless sick funds and payers still put pressure on drug cost to decrease health care expenditure. The so called 'block-buster' era is over; the future belongs to more targeted therapies. The industry is talking about the patent-cliff, which means that many of the block-busters are losing their patent these days."

Additionally, there has been some evidence in Austria that biosimilars tend to be treated as generics. Alexander Papanikolaou, managing director of Hospira for Austria, Czech Republic, Slovakia & Switzerland, says that "the biggest development in the future lies in monoclonal antibodies. If these are treated as generics, we start to destroy a future market that has huge potential for hospitals and for patients. You will not launch a product if you do not have the potential to get a return on investment. If you do not launch these products in the first place, there will be no 'generic' solutions for the market."



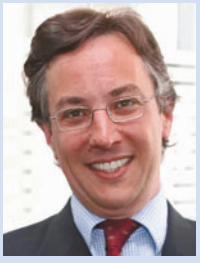
Floridotower, Pfizer offices

THE GATEWAY TO THE EAST

Following the end of the Second World War, Vienna served as an important hub that connected Western and Eastern Europe for many industries. However, following the end of the Cold War, and

KWIZDA: Generations of success

Kwizda was founded in 1853 by Franz Johann Kwizda. 160 years later, the company still runs on a model similar to its original format. Richard A. Kwizda, the fifth generation to run the business and current managing director of Kwizda, noted that over time the company has adapted to changes in the socioeconomic structure through industrialization. Several industrial divisions, such as pharmaceuticals, logistics, and agrochemical have been set up. These all still exist today and have grown in size substantially. In most divisions, Kwizda is positioned as number one or two in Austria. Like other family-run businesses in Austria such as Croma or Chemomedica, Kwizda has the advantage of working independently. Without the burden of having to reach expected targets that shareholders demand, family-owned companies in Austria can set their own goals. "Kwizda has a strong will to control its own destiny," stated Kwizda. "We want to have 100 percent decision power. The company does not need capital or outside support to expand for any particular competence. We have what we need, and are happy with what we have." While Kwizda intends to keep the company within the family, he also realizes that he will have to look beyond Austria to expand his business. "Kwizda's current aim is to enlarge the company's industrial operations beyond Austria and to find regional geography, perhaps expanding some of those units to a European dimension. The company's first focus is to expand to a regional focus of either Central and Eastern Europe, or Western or all of Europe, depending on the division. The pharmaceutical division is a prime focus for the business; Kwizda is strong in the OTC business where it is the number two player in Austria."



Richard A. Kwizda, Owner, Kwizda Holding GmbH

particularly in recent years, the emerging markets of Eastern Europe may give the impression that Vienna's status as a hub or gateway is becoming somewhat obsolete.

Gerald Schrot, managing director of Biotest Austria, believes that "centralizing talent in Vienna is good for Austria. With competence comes a network of talented individuals as well as capital, particularly in the financial world, where Austrian companies have been very successful in former Soviet satellites. Austria is a small country with a history of diplomacy, and I believe that resonates with individuals when doing business in other parts of the continent."

From left: Berthold Cvach, General Manager, Astellas Pharma GmbH

Such an example of this success can be seen with hygiene specialists Schülke and Mayr. Alfred Grün, general manager of the company's Austrian affiliate, says that Austria is "the leading country

in the Schülke group, by 40 percent more than the next country. This is important as the mentality in Austria is very sensitive and flexible, which allows it to cover the Eastern European market successfully."

Michael Norman, general manager of Austria, Czech Republic, Hungary and Romania for Bristol-Myers Squibb, noted that while many international companies still use Vienna as an operations center, "more companies are putting satellite organizations in cities like Bratislava, due to lower costs when compared to Vienna. Additionally, moving across borders is much simpler today, and so the sensitivity that comes with asking a North American CEO to put a significant plant or office in Bratislava or Bucharest has diminished."

Robert Lefebvre, vice president of commercial operations for Europe, Middle East and Asia for blood-plasma derivatives company Kedrion International, notes that "as the markets of countries like Poland, Romania, Bulgaria and the Czech Republic continue to evolve and their healthcare systems strengthen and mature, their ability to start accessing rare disease products that we make is growing. They need to be able to access them in a way that allows for stable and consistent supply."

From left: Johannes Sarx and Peter Halwachs, Managing Directors, Life Science Austria Vienna

Günter Cseh, managing director of Meda Pharma Austria, also says that smaller Eastern European countries will probably continue to use Austria as a hub, but will require more independence. In a region like the Balkans for example, "distance between countries is far less. Doing business remotely does not always work in this region, despite modern communications. Face-to-face relations are essential, and the farther east you go, the more important it becomes. Companies must be able to make decisions in those countries without constantly having to consult headquarters in other nations."

ON TOP OF ONCOLOGY

A significant amount of revenue is invested in Austria by pharmaceutical companies into research and development. Oncology serves as one of the most important and active areas of therapeutic research in Austria. Berthold Cvach, general manager of Astellas, a merger of Japanese pharmaceutical companies Yamanouchi and Fujisawa, says that "for oncology, as Yamanouchi was not present in the Austrian market before the merger, we had to launch the portfolio from scratch in 2006. In a couple of years, I expect that we will be leading in this therapeutic area as well. I can only make predictions, but I am very confident. We will introduce the molecule enzalutamide (branded Xtandi in the US), which is a significant breakthrough and is expected to become a blockbuster drug." Teva has also managed the acquisition of Cephalon to strengthen their oncology business, and Takeda Austria has a hospital and oncology franchise where the company distributes and manufactures TachoSil® patches in Linz. Pfizer is currently working on a personalized treatment for lung cancer. Many other companies in Austria also have a strong research focus in this therapeutic area, making the country outstanding in this segment.

BIOTECH'S PATH TO GLORY

Historically, Austria has provided an attractive environment for innovation. "For over a hundred years, Vienna has always been a center for talented scientists and groundbreaking medical research, as well as having strong hospital infrastructure" says Ingo Raimon, general manager of Abbott spinoff AbbVie GmbH. "From the perspective of AbbVie, we are represented with the best scientific research in the country." The organization runs clinical programs for some of the most widespread and serious diseases, such as Hepatitis C and uveitis.

Life Sciences Austria (LISAvienna), a joint venture between the City of Vienna and the Austrian government, is an organization dedicated to helping upcoming life science companies get started financially through public and private funding. Johannes Sarx and Peter Halwachs, both managing directors of LISAvienna, are optimistic about the future of biotech in Austria. "The Austrian government understands that although we do need to put austerity measures in place like other countries to balance the budget, these cuts are not being made in innovation and startup support. In an economic recession you need to invest in innovation."

Additionally, the environment for biotech in Austria is very welcoming in terms of bringing a wide variety of international people to the scene. Even without being able to speak German, it is possible for individuals to move to Vienna and get started in the life sciences industry with a startup, putting Austria in a very easy and welcoming position compared to its Eastern neighbors.

That being said, the road to success for biotech companies in Austria is not a piece of Sacher torte. Only 3 to 4 percent of biotech companies actually manage to bring a product successfully to the Austrian market. Additionally, the environment in failure in a clinical trial for biotech companies in Austria is generally one of intolerance. Thomas Lingelbach, CEO of Intercell, notes that this is an attitude that is specific to the German-speaking world. "This is not only public perception, but also the perception among the investor community. Investing in biotech means investing in risk. High risk and high return is not something very much appreciated in the German-speaking world." Compared to the more forgiving atmosphere in the United States, the perception of failure in clinical research in Austria and its German and Swiss neighbors tends to make the Germany-Austria-Switzerland (DACH) region hazardous. Sarx points out that, particularly among serial entrepreneurs, "It is important not to judge people if they fail. It is not about names or brands; biotech is about people and talent."

From left: Ingo Raimon, General Manager of AbbVie GmbH; Thomas Lingelbach, CEO, Intercell

Furthermore, with a relatively small population, Austria may not always have an adequate number of people with a certain disease to justify developing a drug to treat the disease. Jürgen Balthasar, country manager of Austria and Switzerland for Genzyme, says that "proportionally, the numbers in Austria are smaller than other European countries. Sometimes, there are diseases that affect about

five to seven patients in this country and we have to decide whether we want to launch a product here, or whether to have Genzyme's German counterparts take care of such a product. If a disease is extremely rare, Genzyme may not be able to handle it in Austria alone. Then we can work with bigger teams in Germany and look for a way to bring the product to Austrian patients."

While certain organizations are in place to help provide private funding for biotech companies, many of these start-ups could benefit from additional funding from big pharmaceutical companies. The founder and CSO of local biotech company Polymun Scientific, Hermann Katinger, points out that it is often the case that unless a biotech company has solid Phase II data from clinical trials in place, the large pharmaceutical companies will not display interest unless the biotech company has something truly groundbreaking.

Perhaps one of the most interesting and popular subjects of study among biotech companies is the development of monoclonal antibodies. The antibody market is currently estimated at between USD 50 and 70 billion worldwide. Polymun Scientific, based just north of Vienna, is noted for having developed the first human monoclonal antibodies to neutralize HIV. However, Katinger noted, "during these studies, it was extremely difficult to raise money, partly because of the lack of organizations that seemed to truly care about this critical issue."

From left: Jürgen Balthasar, Country Manager Switzerland and Austria, Genzyme; Hermann Katinger, CSO and Founder, Polymun Scientific; Hans Loibner, CEO, Apeiron Biologics

Despite big pharmaceutical companies having the capital to invest in such companies, according to Hans Loibner, CEO of Apeiron Biologics, there is great potential for symbiotic relationships between big and small in Austria that is being passed up. "I do not understand why big pharmaceuticals are not investing more in these small companies, as it is a win-win situation. By doing so, you have access to potentially new developments which would help young

companies and also create a significant return on investment. It is much cheaper than using money for internal research, which is inflexible and poorly run. With the money big pharmaceuticals have, this could be done for hundreds of biotech companies, who would consequently be motivated to work even harder."

CLINICAL TRIALS: JUSTICE IS SERVED

The clinical trials environment is generally considered quite attractive in Austria. While capital invested in clinical trials only amounts to between EUR 200-400 million (USD 271-542 million), and the number of trials performed annually has declined in recent years, the reason it is generally attractive is its efficiency. As PHARMIG's Jan Huber states, "Physicians, ethics commissions and legal bodies here work in a very professional and timely manner." If a company needs to perform clinical trials in a setting that allows the company to get a product on the market faster without compromising on quality, then Austria is a shining example in comparison to its fellow European counterparts.

János Filakovszky, vice president of Quintiles Eastern Holdings, noted that this is also due to "the very favorable regulatory environment and a well-regulated clinical research industry. Austria usually obtains regulatory approvals before most European countries." This is beneficial not only to clinical research organizations but also major pharmaceutical companies that invest in this kind of research, such as Bayer, which conducts a number of Phase II-IV trials in Austria. Bayer Austria managing director and senior Bayer representative for South East Europe, Martin Hagenlocher, notes that "the country has high quality research institutes, university clinics, and the hospitals outside of universities have very high standards and qualified personnel to run clinical studies. There is a good base for clinical research in Austria combined with reasonable support from government."

There are some minor limitations. Austria's population consists of approximately eight and a half million people, and thus obtaining a high number of patients for a clinical trial for one disease can be quite difficult in comparison to countries with larger populations. As Klaus Fischer, CEO of Austrian contract research organization Assign Group, points out, sometimes only a dozen patients will have a certain disease in Austria's largest hospital. "If you want to demonstrate efficacy, safety and quality, you need 400-



From left: János Filakovszky, Vice President, Quintiles Eastern Holdings GmbH; Martin Hagenlocher, Managing Director, and Senior Bayer Representative South East Europe, Bayer Austria GmbH; Klaus Fischer, CEO, Assign Clinical Research GmbH

1000 patients and this would take an extremely long time in Austria. In China there are hospitals with thousands of patients with such conditions. If you want to have those diseases treated, you have to go to those hospitals where treatment is offered."

While there may be a number of hospitals in Austria that offer treatment, these hospitals may be spread across the country, thus making Austria a rather decentralized environment for conducting such trials. "In order to obtain patients," Fischer continues, "you have to talk to many smaller potential study centers and this is an additional cost factor in clinical studies. This is also recognized by pharmaceutical companies. If you know the right study centers, then you can compete against larger recruiting countries with larger populations."

The pharmaceutical industry in Austria, while growing slowly, is still ahead of many of its European counterparts simply because of this growth. The quality of healthcare, innovation, and drugs themselves are extremely high, and there is certainly a positive feeling and direction within the Austrian pharmaceutical community. While not the biggest market in Europe, the collaboration between the industry and academia, as well as private and public partnerships, makes Austria a particularly favorable and exciting place to work. As Papanikolaou notes, "Personal relations tend to be very important in Austria. Even if what you are offering does not match entirely with customer expectations, they will be satisfied at the end of the day because of the relationship management involved. Austrians are a little bit more flexible in both thinking and working. There is usually only one way to cross a river — but Austrians can find several!"

The Health Information Advantage

For the hard-pressed oncology practice, new technologies hold the key to surviving—and thriving

In the face of market and regulatory pressures, oncology practices are embracing technology as a solution to enhance efficiencies, increase profitability, and improve patient care. From adopting comprehensive electronic health record (EHR) platforms to providing patients with medical record access and the ability to engage with their providers through online portals, oncology practices are working to improve the quality of patient care. Opportunities for powerful insights into the oncology market are also on the rise.

Challenges facing the community oncology practice include increasingly complex clinical decisions, larger patient loads, declining reimbursement, and increased costs. With the growth of targeted therapies and companion diagnostics, as well as the proliferation of new therapies available for several types of cancers, physicians are turning to technology to assist in treatment selection. Targeted therapies have fueled most of the recent growth in the oncology market and "will dominate the top 20 cancer therapies by 2017," according to a report from GBI Research. These market trends will require clinical systems that support physicians in selecting the most appropriate treatments.

Another issue is declining revenue since the passage of the Medicare Modernization Act in 2003, as reimbursement shifted to average sales price plus six percent for Medicare patients. According to ASCO, "Medicare patients make up 61 percent of new cancer cases in the United States today and that proportion is expected to rise to 70 percent by 2030" leading to further erosion of practice profitability stemming from lower reimbursement rates for Medicare. Drug costs are also on the rise; many cancer treatments approved in the last two years came with a price tag north of $100,000; often, multiple therapies are concurrently prescribed, compounding the cost of treatment. These dynamics will erode practice profitability, increasing the need for practices to effectively capture charges, reduce drug loss, and maintain optimal inventory levels.

Finally, health reform will increase patient loads in a specialty that is already short of physicians: "An aging and growing population, increasing numbers of cancer survivors, and slower growth in the supply of oncologists will result in a shortage of 2,550 to 4,080 oncologists by 2020," according to ASCOs *Journal of Oncology Practice,* 2007. Physicians will have to turn to technology to support the increased patient demand and maintain optimal levels of patient satisfaction and outcomes.

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IT boosters

Adoption of health information technology will lead to improved efficiencies and assist with the challenges facing the community oncologist. According to *Information Week*, "spending on electronic health records [will] grow from $2 billion in 2009 to $6 billion in 2015." The acceleration is the result of federal programs created to support technology adoption with a goal to drive down the cost of care and improve patient outcomes. The Health Information Technology for Economic and Clinical Health (HITECH) act that is part of the American Reinvestment & Recovery Act provides up to $44,000 per provider for the adoption and "meaningful use" of a certified EHR system. The first stage of the program launched in 2011 and the subsequent stages two and three are set to launch in 2014 and 2016, respectively. The goal of the HITECH Meaningful Use program is to "promote the spread of electronic health records to improve healthcare in the United States," according to HealthIT.gov. The primary benefits include complete and accurate health information regardless of the setting, better access to health information to improve outcomes, and boosting patient engagement.

Supporting patient treatment

Technology must support the most critical function of the oncology clinic: providing high quality care for patients. This process is supported by a number of systems, including the EHR, inventory management system (IMS), practice management system (PMS), and financial reporting system (FRS). These systems are connected by interfaces that facilitate the transfer of data to sup-

port the patient treatment process from diagnosis, to treatment decision making, to claim submission and financial review, ensuring efficiencies to increase revenue, decrease costs, and improve patient care. The patient demographic information is entered into the PMS by the practice staff and is sent to all practice systems via the interface. The ability for the PMS to send important data elements impacts the quality of the information that is generated from all other systems in the practice. This information can then be extracted to provide insight into the patients' clinical and financial data.

Before treating the patient, the oncologist enters diagnosis and staging information along with any other relevant clinical data required to create the treatment plan in the EHR. McKesson Specialty Health's iKnowMed EHR presents the physician with the appropriate treatment regimens based on the patient's clinical factors. McKesson's collaboration with the National Comprehensive Cancer Network to launch value pathways will allow oncologists to assess treatment options against evidence-based standards at the point of care, enhancing the physician's ability to support increasingly complex clinical decisions. The EHR captures rich clinical data that can also be used by brand managers to develop effective, targeted educational and marketing efforts. Finally, this data can answer comparative effectiveness and other outcomes questions that support the overall value proposition of brands within the marketplace.

Once the patient's order is reviewed and approved by the physician in the EHR, the order is sent to the IMS. McKesson Specialty Health's Lynx Mobile, allows the user to match the EHR order with the item(s) pulled from the Lynx Mobile cabinet reducing errors to optimize charge capture and practice revenue. In a study conducted in 2011, physician revenue from charge capture was improved by $70,000 per physician annually after the implementation of Lynx Mobile. The system also provides a mechanism for auto replenishment of drug and supplies, ensuring optimal inventory levels and reducing the capital required to run the business, which is critical in the high drug cost, low reimbursement environment. The data captured in Lynx Mobile can be leveraged to create intelligence for pharmaceutical-biotech companies, payers, and other healthcare stakeholders around product utilization patterns providing insight into how their drugs are being prescribed and used.

Patient engagement

After the patient treatment information is signed off by the provider in the EHR, the treatment information is made available to the patient in the portal. According to Deloitte's Center for Health Solutions, 10 percent of Americans currently use patient portals, but that number is predicted to rise as patients begin to expect access to their clinical information online. Patient engagement is a top priority for the government through the HITECH Meaningful Use program. Stage one of the Meaningful Use program required physicians to provide patients timely access to their health records. Stage two increased the patient engagement mandate requiring physicians to provide secure messaging between patient-physician, enabling patients to view, download, and transmit their health information and educating patients on their conditions and treatments. McKesson Specialty Health's My Care Plus patient portal's connection to the iKnowMed EHR provides real-time access for patients to view their health records. My Care Plus enrolled over 25,000 patients in the first year alone, an example of the strong demand for online health record information. My Care Plus also provides a new way for pharmaceutical-biotech companies, payers, and other healthcare stakeholders to engage patients in a HIPAA compliant way, through prescribed content, surveys, virtual advisory boards, and focus groups.

Tracking financial health

After the treatment plan is completed, it is sent to the practice's management system, to the clearinghouse, and ultimately the payer. The claim and remittance data can be extracted from the PMS and imported to a FRS. A big challenge for the oncology practice is generating analytics that provide a view into the financial health of the practice. Understanding reimbursement challenges, denial rates and reasons, and cash flow is critically important for these small businesses in this tough economic environment. McKesson Specialty Health's Lynx TotalView solution provides the ability for practices to glean financial intelligence that offers greater insight into critical financial metrics. The system also provides benchmarks at the regional or national level, providing insight into reimbursement rates across those areas.

Better health 2020: the outlook

Oncology practices are facing tough headwinds, but the oncology market continues to present strong opportunities, and health information technology will provide efficiencies needed to survive and thrive in the marketplace. Spending on health information technology will continue to accelerate as providers look to improve operational efficiencies and meet government regulations. Community oncology clinics have a number of tools available, including EHRs, IMSs, FRSs, and provider and patient portals. These solutions also provide invaluable information and insight for pharmaceutical-biotech companies, payers, and other healthcare stakeholders into the oncology market around product utilization, segmentation and targeting, comparative effectiveness, and reimbursement challenges. Equipped with the right insight, brand managers can better provide assistance and education to providers and patients. We have only scratched the surface on the intelligence that we can collect from these systems; as health information technology products become more pervasive, the quantity and quality of data will continue to improve, providing powerful insights to the user. PE

Whistling Past the Graveyard

A night of comedy in support of a chronic disease.

The best comedians can seamlessly transition from one subject to just about any other, but it was jarring to go from Larry Hausner, CEO of the American Diabetes Association, and the harrowing statistics he presented—along with silhouetted patients entering the stage every 17 seconds, symbolizing the frequency of new diabetes diagnoses—to New York comedians Colin Quinn and Jerry Seinfeld. Luckily, the ever-ebullient Fox New York television anchor Rosanna Scotto, and Novo Nordisk's Camille Lee, SVP, US diabetes marketing (Novo sponsored the concert, and a pre-party held nearby) helped keep the packed theater from getting too depressed before the comedians took the stage.

It was the third time Seinfeld has performed at a Stand Up for a Cure show (SUFAC), and the April 17 event at The Theater in Madison Square Garden represented the first of a series of shows happening under the SUFAC name this year. The Seinfeld/Quinn double bill for charity brought out famous and not so famous celebrities, including Martha Stewart, Sasha Cohen (the Olympian figure skater, not Borat), and several Real Housewives of New York, in addition to diabetes activists and bloggers. Neither Quinn nor Seinfeld did any jokes on diabetes specifically, although Quinn worried about New York City Mayor Michael Bloomberg's legacy, which is lamentably switching from the guy who cleaned all the guns off the streets of New York, to the guy who took away extra-large sodas.

The evidently soda-loving Quinn also had some choice remarks on how much Brooklyn has changed since he was a kid: "It used to be tough Italian guys with tattoos and wife-beaters… now it's young women with tattoos and wife-beaters." Seinfeld riffed on being married with children, and dusted off a couple of old digs on televised drug ads. After viewing an ad for Lilly's erectile dysfunction drug Cialis with his children, Seinfeld said he had to explain that an erection is "like an erector set." Seinfeld said he understood why the couple in the Cialis commercial was having intimacy problems; they'd just carried two extremely heavy cast iron bathtubs all the way up a hill to watch the sunset, without plumbing. On the oft-japed four-hour erection warning, Seinfeld worried about the awkwardness of the hospital waiting room in that situation (he advised wearing a parka), and then, what a physician would actually do about it.

From all appearances, the event was a success, and the idea of employing comedians to help raise funds for research into cures for deadly diseases is a good one. Chronic disease isn't funny, of course, but laughing beats crying. PE

Left to right: Camille Lee, SVP, US diabetes marketing; Diana Blankman, director, US corporate giving and social impact; Jerry Seinfeld; and Antonio Coppola, director of corporate relations, ADA.

Jerry Seinfeld performing at Stand Up for a Cure.

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Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC)
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Track 15	Statistical Science and Quantitative Thinking	Statistics (ST)
Track 16	Professional Development	Professional Education, Training and Development (PETD)
Track 17	Rare/Orphan Diseases	Rare, Orphan Diseases (ROD)
Track 18	Global Regulatory	All
Track 19	Communities Showcase	All
Track 20	Executive Program	All
Track 21	Late-breaker	All
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Monday, June 24
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MONDAY, JUNE 24 11:00 AM-12:30 PM

● *Basic-level content;* ■ *Primarily intermediate-level content;* ◆ *Primarily advanced-level content*

TRACK 01A LEVEL: ■
Shape Your Cost with Hard and Soft Coverage Analysis Trends

TRACK 01B LEVEL: ■
Trials, Studies and Programs: Diverse Operational Approaches to Generating Evidence in the Late-phase Environment

TRACK 02A LEVEL: ■
Stage Gate Decision-making Workshop, Part 1 of 2

TRACK 02B LEVEL: ■
Portfolio Management Symposium

TRACK 03A LEVEL: ■
The State of Clinical Outsourcing: Managing Risk in Outsourced Clinical Trials

TRACK 03B LEVEL: ■
Innovative Partnerships for mHealth

TRACK 04 LEVEL: ■
Global Symposium

TRACK 06 LEVEL: ■
Finessing Scientifically Accurate, Comprehensible, Compliant, Clinically-focused Module 2 Summaries of an eCTD-based Submission

TRACK 07A LEVEL: ■
Managing Data at Arms' Length: China

TRACK 07B LEVEL: ■
Evaluation and Selection of the Optimal Endpoints for Clinical Studies

TRACK 08A LEVEL: ■
Pediatric Drug Development: A New Paradigm Under FDASIA

TRACK 08B LEVEL: ■
Is There a Disagreement? We Can Help - Dispute Resolution between Industry and US/EU Regulators

TRACK 09 LEVEL: ■
Regulatory Environment in the US: CDRH Panel Discusses What's on the Horizon

TRACK 10 LEVEL: ■
Clinical Trials on Trial: Potential Legal Liability Arising from Clinical Trials

TRACK 11A LEVEL: ■
Vendor Management Using Quality by Design and Risk Management Strategies

TRACK 11B LEVEL: ■
Practical Considerations for GCP Audits in a Risk-based Environment

TRACK 12 LEVEL: ■
Chemistry, Manufacturing and Controls (CMC) Regulatory Landscape in Emerging Markets

TRACK 14A LEVEL: ■
Narrative Medicine and Pharmacovigilance

TRACK 14B LEVEL: ■
Electronic Health Records (EHRs) in Signal Detection and Evaluation

TRACK 15 LEVEL: ■
Hot Topics in Statistics: Working Together Effectively to Transform Our Science

TRACK 16 LEVEL: ■
Challenges and Solutions for Professional Development and Training of Clinical/Nonclinical Staff

TRACK 18 LEVEL: ■
European Town Hall: Implementation of New Safety Legislation and Other Hot Topics

TRACK 19 LEVEL: ■
How Can Translational Medicine Fill the Gaps in Life Sciences Industries?

TRACK 22 LEVEL: ■
Next Generation Medical Information Call Center

MONDAY, JUNE 24 2:30-4:00 PM

TRACK 01A LEVEL: ■
Implementing Performance Metrics: How Investigator Sites Can Pave the Way for Running Successful Clinical Trials

TRACK 01B LEVEL: ■
Global Clinical Trials: The Role of Emerging Markets

TRACK 02A LEVEL: ■
Stage Gate Decision-making Workshop, Part 2 of 2

TRACK 02B LEVEL: ■
Bridging the Gap Between Strategy and Execution

TRACK 03 LEVEL: ■
Implementing Regulatory Outsourcing Partnerships: New Trends and Practices

TRACK 04 LEVEL: ■
Drug-induced Vasculitis: A Dilemma in Translational Medicine

TRACK 07A LEVEL: ■
That Awkward Stage: Transition from Paper Trial Master File to eTMF

TRACK 07B LEVEL: ■
CDISC SHARE: A Promising Approach to Therapeutic Area Standards Development

TRACK 08A LEVEL: ■
Roundtable on Personalized Therapy Innovation in Rare Disease: Focus on Public Policy

TRACK 08B LEVEL: ■
Navigating the Regulatory Pathway for Advanced Therapy Medicinal Products (ATMPs) and Combined ATMPs

TRACK 10A LEVEL: ■
Cooperation Among Regulators: Impact on Stakeholders

TRACK 10B LEVEL: ■
Legal Jeopardy from the Conduct of Clinical Trials

TRACK 11A LEVEL: ■
Quality Risk Management: An Old Hat?

TRACK 11B LEVEL: ■
Effectiveness Checks in the Clinical Research Setting

TRACK 12 LEVEL: ■
Update on Submission and GMP Expectations for Part 3 Combination Products

TRACK 13 LEVEL: ■
Using Epidemiologic Methods to Advance Comparative Effectiveness Research

TRACK 14A LEVEL: ■
The New Standards for the Identification of Medicinal Products and Individual Case Safety Reporting Applied in Pharmacovigilance

TRACK 14B LEVEL: ■
Characterizing Drug Shortages and Their Causes: Anticipating Future Trends

TRACK 15 LEVEL: ■
Key Multiplicity Issues in Clinical Trials

TRACK 16 LEVEL: ■
The Secret of Stellar Careers: Serendipity plus Planning = Success

TRACK 18 LEVEL: ■
CBER Town Hall

TRACK 19 LEVEL: ■
Defining Clinical Trial Innovation: Challenges and Opportunities for 2013

TUESDAY, JUNE 25 8:00-9:30 AM

TRACK 01A LEVEL: ■
Is This Trial Worth It? A Panel Discussion for Sites and Project Managers

TRACK 01B LEVEL: ■
Leveraging In-Pharmacy Education to Improve Patient Comprehension and Access to Clinical Trials

TRACK 02A LEVEL: ■
Careers Beyond Project and Portfolio Management: A Panel Discussion

TRACK 02B LEVEL: ■
The Financial, Resource and Planning Challenges of Incorporation of Mandatory Language into Protocols

TRACK 03 LEVEL: ■
Making CRO-Sponsor Partnerships Work: Executive Roundtable

TRACK 04 LEVEL: ■
The Thorough QT Study: Isn't There a Better Way to Do This?

TRACK 05 LEVEL: ■
Prescription Drug Marketing Regulatory Primer

TRACK 06A LEVEL: ■
Regulatory Writing Jeopardy

Track 06B Innovation and Evolution Within the Medical Science Liaison Role

TRACK 07A LEVEL: ■
Development of a New Patient-reported Outcome (PRO) Measure for Depression: Progress and Results from the PRO Consortium

TRACK 07B LEVEL: ■
Data from Everyone: Using Smartphones and the Internet to Connect with Subjects

TRACK 08A LEVEL: ■
FDA's Expedited Drug Development and Review Programs

TRACK 08B LEVEL: ■
A Regulatory Perspective of Biosimilars in Emerging Markets

TRACK 09 LEVEL: ■
Postmarket Surveillance Issues for Medical Devices

TRACK 10 LEVEL: ■
Ethical Issues in Clinical Trials

TRACK 11 LEVEL: ■
GCP and Inspection Readiness

TRACK 12 LEVEL: ■
Developing and Embracing a Culture of Quality in the Pharmaceutical Industry

TRACK 13 LEVEL: ■
Payer Collaborations with Pharma: Real-world Evidence to Improve Patient Outcomes and Influence the Pipeline

TRACK 14A LEVEL: ■
Social Media, Mobile Applications and Patient Support Programs: Challenges and Solutions for Handling Drug Safety Information

TRACK 14B LEVEL: ■
Aligning Statistical Science and Regulatory Practices for Expedited Safety Reporting

TRACK 15 LEVEL: ■
Biomarkers for Drug Development: How Are We Dealing with the Challenges?

TRACK 16 LEVEL: ■
DNA of Entrepreneurs: Calculated Risk-taking and Bringing Game-changing Technology to the World

TRACK 17 LEVEL: ■
Research Advances for Rare Diseases and Orphan Products

TRACK 18 LEVEL: ■
Pharmaceuticals and Medical Devices Agency (PMDA) Town Hall

TRACK 19 LEVEL: ■
Using Risk-based Signal Detection Methods to Identify Sites with Potential GCP Problems: Better Than a Crystal Ball

TUESDAY, JUNE 25 10:15-11:45 AM

● *Basic-level content;* ■ *Primarily intermediate-level content;* ◆ *Primarily advanced-level content*

TRACK 01A LEVEL: ■
Domestic and Global Trends in Clinical Trial Budgeting

TRACK 01B LEVEL: ■
Optimizing Trial Feasibility by Leveraging Electronic Health Record Data and Engaging Investigators and Patient Advocacy Groups

TRACK 02 LEVEL: ■
Effective Diverse Team Collaboration and Management for Drug Development: Key Commonalities and Differences among Korea, China and Japan

TRACK 03A LEVEL: ■
Developing and Maintaining Sponsor/CRO Partnership Regulatory Submissions Processes: Challenges and Successes

TRACK 03B LEVEL: ■
Change Order Panel Discussion and Brainstorming Session: Can We Be More Efficient?

TRACK 04 LEVEL: ■
Measuring the Impact of Subject Dual Enrollment on Study Data Validity and a Web-based Tool to Avoid Simultaneous Participation in Multiple Concurrent Clinical Trials

TRACK 05 LEVEL: ■
FDA Enforcement Update: Advertising and Promotion

TRACK 06 LEVEL: ■
Preparation of Clinical Study Reports and Summary Documents: Maximize Efficiency and Minimize Redundancy

TRACK 08 LEVEL: ■
Innovative Approaches to Ensure Safety and Efficacy in the Real Life Population

TRACK 12 LEVEL: ■
Strategies for the Development and Registration of Antibody Drug Conjugates

TRACK 13 LEVEL: ■
Big Data: Impact on Innovation

TRACK 14 LEVEL: ■
EU Update: PROTECT and EnCePP

TRACK 15 LEVEL: ■
Statistical Considerations When Developing Antibacterial Treatments

TRACK 16A LEVEL: ■
Advanced Presentation Skills

TRACK 16B LEVEL: ■
DIA 2013 Student Forum: Getting a Job and Developing a Career

TRACK 19 LEVEL: ■
Achieving Innovative Technology Results

TUESDAY, JUNE 25 1:45-3:15 PM

TRACK 01A LEVEL: ■
Enrollment Analytics: Moving Beyond the Funnel

TRACK 01B LEVEL: ■
Taking the Measure of Metrics

TRACK 02A LEVEL: ■
Regulatory, Clinical, and Quality Challenges in Contracting and Due Diligence: The Forgotten Keys to Biopharma Transactions

TRACK 02B LEVEL: ■
Approaches to Quality Risk Management: Understanding What Matters

TRACK 03A LEVEL: ■
Pharma, Academia and CRO Preferred Partnerships: Why Collaboration Makes a Better Global Trial

TRACK 03B LEVEL: ■
FDA Collaborations Broaden the Reach of Health Care Messages to Effectively Communicate with the Public

TRACK 04 LEVEL: ■
Human Abuse Liability Testing in CNS Drug Development

TRACK 05 LEVEL: ■
Drug Development for Commercial Success

TRACK 06 LEVEL: ■
The New European Pharmacovigilance Legislation: Guiding Medical Writers Through the Risks and Benefits

TRACK 07A LEVEL: ■
Innovative Computerized System Validation and Auditing

TRACK 07B LEVEL: ■
Changing View of Electronic Data Capture (EDC) and Implications for Data Quality

TRACK 08A LEVEL: ■
Electronic Submissions in PDUFA V

TRACK 08B LEVEL: ■
Implementing an Internationally Acceptable Framework for the Benefit-risk Assessment of Medicines: How Close Are We to This?

TRACK 08C LEVEL: ■
US and EU Regulatory Update of Clinical Trial Disclosure

TRACK 09 LEVEL: ■
Co-development of Targeted Therapies and Companion Diagnostics: Identifying Regulatory Strategies to Overcome Challenges

TRACK 11 LEVEL: ■
GCP Risk-based Monitoring

TRACK 14A LEVEL: ■
Quality Assurance for Signal Detection Programs

TRACK 14B LEVEL: ■
Periodic Reporting in Drug Safety: From Safety Updates to Continuous Signal Monitoring and Benefit-risk Evaluations

TRACK 15 LEVEL: ■
Looking Closer into the Utility of Adaptive Approaches

TRACK 17 LEVEL: ■
Is There a Recipe for Successful Implementation of Registries for Rare Diseases?

TRACK 18 LEVEL: ■
Convergence in Regulatory Science Across the Strait

TRACK 19 LEVEL: ■
First-in-Human Studies: How Much Complexity Is Too Much?

TRACK 20 LEVEL: ■
Reinventing the R&D Business Model: Heeding the President's PCAST Report on Innovation

TRACK 22 LEVEL: ■
Learning to Share-Sharing To Learn: How an Industry Learns to Honor it's Volunteers

TUESDAY, JUNE 25 4:00-5:30 PM

TRACK 01A LEVEL: ■
Approaches to Risk-based Monitoring

TRACK 01B LEVEL: ■
Evaluating Sites for Optimum Site Selection and Performance

TRACK 02 LEVEL: ■
Strategic Planning of the Global Program to Facilitate Regulatory Approval and Market Access

TRACK 03 LEVEL: ■
Investigator Budgets Impact on Patient Enrollment and Retention: How to Improve Sponsor/CRO/Site Processes to Increase Productivity

TRACK 04 LEVEL: ■
Optimizing the Transition from Preclinical to Clinical Research

TRACK 05 LEVEL: ■
Product Communications in the Preapproval Phase

TRACK 06 LEVEL: ■
Protocol Trends and Strategies for Quality

TRACK 07A LEVEL: ■
Real, Transparent Dialogue from Three Sponsors: Destination eTMF - Are We There Yet?

TRACK 07B LEVEL: ■
Real-world Electronic Health Records Data and Informatics Technology in Drug Development and Life Cycle Management

TRACK 08A LEVEL: ■
Labeling and Patient Medical Information (PMI)

TRACK 08B LEVEL: ■
Bringing the Views of "Payer Regulators" into Product Development to Align Label Outcomes and Safety with Patient Access

TRACK 09 LEVEL: ■
Diagnostic Biomarker Verification and Validation: A Cost-efficient, Speed to Market Adaptive Design Clinical Trial Model

TRACK 10 LEVEL: ■
Breakthrough Therapy: One Candle on the Birthday Cake - Are Innovators Enjoying Sweet Success or Is the Pathway Not Baked Yet?

TRACK 11 LEVEL: ■
GCPs in Emerging Countries

TRACK 12 LEVEL: ■
Lessons Learned from the EMA-FDA Quality by Design (QbD) Pilot

TRACK 13 LEVEL: ■
Utilizing Electronic Medical Records as an Innovative Methodology for Evaluating Therapeutic Effectiveness

TRACK 14 LEVEL: ■
Risk Management in the US, EU and Japan: The Challenges of Diversity

TRACK 15 LEVEL: ■
Analysis Data Standards: Developing, Applying, Submitting and Reviewing

TRACK 16A LEVEL: ■
So You Want to Foster Innovation: A Neuroscience Primer on How Creative Ideas Arise from the Brain

TRACK 16B LEVEL: ■
Advanced Presentation Skills

TRACK 17 LEVEL: ■
Development for Rare Disease Treatments

TRACK 18 LEVEL: ■
"Korea Forum: Introduction to the Korean Ministry of Food and Drug Safety (MFDS) and Government R&D Program"

TRACK 19 LEVEL: ■
The Evolving Clinical Trial Disclosure Global Landscape

TRACK 20 LEVEL: ■
Where Research, Medicine and Care Converge: A CMO Roundtable Discussion

POSTERS

STUDENT POSTERS

Monday, June 24 | 10:00 AM-5:30 PM

The Student Poster Program is an opportunity for students from around the world to present their research results to a diverse group of scientific professionals who are actively involved in the discovery, development, and life cycle management of medical products.

PROFESSIONAL POSTERS

Tuesday, June 25 | 11:45 AM - 4:00 PM
Wednesday, June 26 | 11:45 AM-4:00 PM

Professionals from all fields related to the mission of DIA will present their original research to a diverse group of professionals who are involved in the discovery, development, and life cycle management of medical products.

WEDNESDAY, JUNE 26 8:00-9:30 AM

● *Basic-level content;* ■ *Primarily intermediate-level content;* ◆ *Primarily advanced-level content*

TRACK 01A LEVEL: ■
Clinical Trial Design for Optimal Patient Recruitment and Retention

TRACK 01B LEVEL: ■
Understanding Operational Feasibility: A Discussion of Current Methodologies, Primary Research Limitations and Opportunities

TRACK 02A LEVEL: ■
Cost Management for Global Drug Development Projects

Track 02B Stop Moving the Goalposts: A Life Cycle Approach to Risk-based Quality Management in Clinical Development

TRACK 03A LEVEL: ■
Evolving to Functional Service Providers (FSP): Successfully Transforming Existing Partnerships into FSP Relationships

TRACK 03B LEVEL: ■
Unique Nonprofit-Industry Partnerships to Develop or Disseminate Novel Virtual Population Simulation Technology

TRACK 04 LEVEL: ■
Molecular Imaging: Utilizing It as an Effective Drug Development Tool

TRACK 06 LEVEL: ■
Tethering the Channels of Scientific and Medical Content

TRACK 07A LEVEL: ■
Enhancing Regulatory Science and Expediting Drug Development: eClinical and eHealth Tools

TRACK 07B LEVEL: ■
Challenges and Recommendations Related to the Use of ePRO Instruments in Clinical Trials

TRACK 08A LEVEL: ■
FDASIA: Impact of New Legislative Provisions on Innovative Drug Development

TRACK 08B LEVEL: ■
Regulatory Operations: Types and Industry Trends of Outsourcing the Life Cycle Management of Your Electronic Submissions

TRACK 09 LEVEL: ■
How to Convert a New Device (PMA) into an Old (510(k)) Device: The De Novo 510(k)

TRACK 10 LEVEL: ■
Using Legislation to Advance Regulatory Science: "I'm Just a Bill..."

TRACK 11 LEVEL: ■
How Will Risk-adapted Clinical Trials Be Inspected?

TRACK 12A LEVEL: ■
How to Prepare for Meetings, Both Internal and with the FDA

TRACK 12B LEVEL: ■
Current Developments in the Automated NDA Field Alert Reporting Project

TRACK 13 LEVEL: ■
The Environment for Health Care Decision-making: Collecting, Using and Understanding Comparative Effectiveness Research

TRACK 14A LEVEL: ■
Molecular Predictors of Drug-induced Harm: From Clinical Development to Postmarketing Surveillance

TRACK 14B LEVEL: ■
Pharmacovigilance Update for Japan, Developing Asia and Latin America

TRACK 15 LEVEL: ■
Structured Benefit-risk in the Current Regulatory Environment and the Implications for Clinical Statisticians

TRACK 16 LEVEL: ■
How Economic and Technological Change Can Affect Professional Expectations: Case Studies in Succeeding in the Midst of Change

TRACK 17 LEVEL: ■
Models for Genomic Research Success: How a Patient-Researcher Relationship Led to the Discovery of a Norepinephrine Transporter Deficiency and the Emerging Role of Crowd Sourcing in Rare Disease Research

TRACK 18 LEVEL: ■
FDA-Health Canada Regulatory Cooperation Council (RCC) Town Hall

TRACK 19 LEVEL: ■
Bringing SPIRIT into Protocols, Structuring Content and Expanding This Work to Noninterventional Postmarketing Protocols

TRACK 21 LEVEL: ■
Collaborating to Streamline Drug Development: Are We Making Progress?

WEDNESDAY, JUNE 26 10:15-11:45 AM

TRACK 01A LEVEL: ■
Driven by Data: More Effective Strategies to Reach Your Patient Recruitment Goals

TRACK 01B LEVEL: ■
Study Startup Symposium

TRACK 01C LEVEL: ■
Meeting the Operational Challenges of Risk-based Monitoring: Investigator and Sponsor Perspectives

TRACK 02 LEVEL: ■
So You Want to Be a Project Manager: How to Find Your Way to a Challenging and Rewarding Career

TRACK 03A LEVEL: ■
Innovative Strategies for Evolving Sponsor, CRO and Site Alliances

TRACK 03B LEVEL: ■
Project Data Sphere: Clinical Trial Data-sharing in Cancer to Accelerate Innovation and Enhance Patient Health

TRACK 04 LEVEL: ■
Pharmacometrics: Implications and Impact in Preclinical to Early Phase Clinical Development

TRACK 06 LEVEL: ■
Globalization of Medical Communications/Medical Science Liaisons: A Comparison of Guidance and Practice Differences

TRACK 07A LEVEL: ■
EDC Insights: Before, During, and After

TRACK 07B LEVEL: ■
Advancing Endpoint Adjudication

TRACK 08A LEVEL: ■
Advancing Alzheimer's Innovation: A Call to Action

TRACK 08B LEVEL: ■
A Comparison of Study Startup Regulations and Timelines in Several Major Emerging Markets and the Decision Process for Selection

TRACK 10 LEVEL: ■
Enforcement Trends and Public Policy: Lessons Learned and Practices to Follow

TRACK 12 LEVEL: ■
Drug Shortages: Causes, Current State and Path Forward

TRACK 16 LEVEL: ■
Successful Mentoring Relationships

WEDNESDAY, JUNE 26 1:45-3:15 PM

● *Basic-level content;* ■ *Primarily intermediate-level content;* ◆ *Primarily advanced-level content*

TRACK 01 LEVEL: ■
Using Big Data to Design Smarter Studies

TRACK 02A LEVEL: ■
Using Competence Models to Drive High Quality Drug Project Management

TRACK 02B LEVEL: ■
Challenges and Strategic Approaches to Biosimilar Development

TRACK 03 LEVEL: ■
Towards an Effective Virtual R&D Team for Faster Accessing of the East Asian Market

TRACK 06 LEVEL: ■
Recent Corporate Integrity Agreements: Impact on Industry-sponsored Publications and Medical Communications Activities

TRACK 07A LEVEL: ■
Coalition for Accelerating Standards and Therapies (CFAST): The Ultimate Drug Development Drivers

TRACK 07B LEVEL: ■
Cloud Technology for Decision Makers: What's Real and How to Validate It

TRACK 08A LEVEL: ■
Advancing Alzheimer's Innovation: Patient Advocacy, Caregiver Support and Health Care System Impact

TRACK 08B LEVEL: ■
FDASIA Patient Provisions: One Year Later

TRACK 08C LEVEL: ■
eSubmission Outsourcing and Mergers and Acquisitions: Now This Is an Intriguing Equation

TRACK 09 LEVEL: ■
Developing Effective Policy Strategies for Coverage and Reimbursement of Companion Diagnostics

TRACK 10 LEVEL: ■
The Science of Compliance

TRACK 11 LEVEL: ■
FDA CDER's Office of Scientific Investigations and European Medicines Agency Collaboration on Good Clinical Practice (GCP), Bioequivalence (BE) and Pharmacovigilance (PV) Inspections

TRACK 12 LEVEL: ■
Implementation of Quality by Design: Progress, Challenges and Opportunities - Industry Perspective

TRACK 13 LEVEL: ■
The 2012 US Payer Landscape: Results from a Survey of Medical and Pharmacy Directors on Comparative Effectiveness Research

TRACK 14 LEVEL: ■
An Interactive Course on Likelihood Ratio Test-based Method for Signal Detection

TRACK 15 LEVEL: ■
Clinical Trial Simulations and Modeling

TRACK 16A LEVEL: ■
Transition from Subject Matter Expert (SME) to Subject Matter Educator Extraordinaire (SMEE)!

TRACK 16B LEVEL: ■
Submitting an Abstract for the DIA 2014 50th Annual Meeting

TRACK 17 LEVEL: ■
Rising to the Challenge of Developing Novel Orphan Medicines for the Global Market

TRACK 18A LEVEL: ■
Canadian Approaches to Regulatory Modernization and International Engagement

TRACK 19 LEVEL: ■
Clinical Outcome Assessment (COA) for Clinical Trials: PROs, ClinROs, and ObsROs

TRACK 21 LEVEL: ■
TransCelerate's Collaborative Approach to Risk-based Monitoring: The Methodology

WEDNESDAY, JUNE 26 4:00-5:30 PM

TRACK 01A LEVEL: ■
Innovative Ways of Working with Patients to Make Clinical Research More Productive, Less Costly and Less Burdensome for the Patient

TRACK 01B LEVEL: ■
Overcoming Unique Challenges of Pediatric Studies

TRACK 02A LEVEL: ■
Pharmaceutical Project Management: What's Really Important and How Can We Do Better?

TRACK 02B LEVEL: ■
Pharmacometric Methods: Essential for Optimal Drug Development Strategy

TRACK 03 LEVEL: ■
Partnering and Outsourcing Challenges in India: The New Paradigm Shifts

TRACK 06 LEVEL: ■
Learnings from Safety Communications Across the Industry: Patients and EMA, REMS, and FDA, Physicians, and Medical Information Groups

TRACK 07A LEVEL: ■
Clinical Trial Visit of the Future: Leveraging Emerging Technologies to Crack the Patient Recruitment Challenge

TRACK 07B LEVEL: ■
Data Standards Strategy

TRACK 08A LEVEL: ■
Advancing Alzheimer's Innovation: Clinical Development Successes and Challenges

TRACK 08B LEVEL: ■
Electronic Regulatory Submission (ERS) Development and the Impact on the Sponsor's Organization: Retooling R&D for ERS

TRACK 08C LEVEL: ■
Global Pediatric Development: Next Steps

TRACK 09 LEVEL: ■
Global Development of Novel Combination Products: Regulatory and Clinical Case Studies from Biotech and Pharma Sponsors

TRACK 10A LEVEL: ■
Meeting the Challenges of Health Care Disparities and Clinical Trial Requirements in the Global Environment

TRACK 10B LEVEL: ■
Ethical Issues in Clinical Trials

TRACK 11 LEVEL: ■
Innovations in Proactive Quality Management: Best Practices and Variability in Approaches to Proactive Quality Management

TRACK 12 LEVEL: ■
Implementation of Quality by Design: Progress, Challenges and Opportunities - FDA Perspective

TRACK 13 LEVEL: ■
Informing Regulatory and Health Technology Assessment (HTA) Decision-making Processes: An Integrated Approach to Life Cycle Management

TRACK 14A LEVEL: ■
Developing a Patient Aid to Make Information about Treatment Benefits, Harms and Uncertainties Meaningful to Individual Patients and Enhance Their Decisions

TRACK 14B LEVEL: ■
Herbal-induced Organ Toxicity (HILI): How That May Impact Rx Benefit-risk

TRACK 15 LEVEL: ■
Noninferiority Trials in Drug Development: Clinical, Statistical and Regulatory Perspectives

TRACK 16 LEVEL: ■
Ensuring Patient-centered Care: Partnering with Patient Advocacy

TRACK 17 LEVEL: ■
Rescuing and Repurposing Drugs: Challenges and Opportunities

TRACK 18A LEVEL: ■
Challenges for Stable Supply of Drugs and International Cooperation

TRACK 18B LEVEL: ■
Latin America Town Hall

TRACK 19 LEVEL: ■
Current Regulatory Landscape Impacting Medical and Scientific Communications

LIFE SCIENCES INTEROPERABILITY SHOWCASE℠

HIMSS

June 25-27 | Exhibit Hall

DIA is proud to partner with HIMSS® and IHE to once again offer the Life Sciences Interoperability Showcase℠. The Showcase will demonstrate standards-based IT solutions to improve health data information exchange between systems, providers, and organization to optimize clinical research. For additional information contact **Shannon.Lewis@diahome.org**.

THURSDAY, JUNE 27 9:00-10:30 AM

● *Basic-level content;* ■ *Primarily intermediate-level content;* ◆ *Primarily advanced-level content*

TRACK 01A LEVEL: ■
Parents as Partners: Engaging Caregivers for Pediatric Trials

TRACK 01B LEVEL: ■
Hot Topics in Clinical Supplies

TRACK 02 LEVEL: ■
Orphan Drug Development Strategy by Big and Medium/ Small Pharmaceutical Industries

TRACK 03 LEVEL: ■
Strategic Partnerships: Emerging Models and Their Impact on Drug Development

TRACK 06 LEVEL: ■
Key Learnings from the Approval and Launch of a 505(b)(2) Product from a Medical Communications Perspective

TRACK 07A LEVEL: ■
eDM From Three Sponsors

TRACK 07B LEVEL: ■
Changing Landscape of IT in the Pharmaceutical Industry

TRACK 08A LEVEL: ■
FDA's Electronic Drug Registration and Listing System: Updates

TRACK 08B LEVEL: ■
NDA Submission Strategy for New Chemical Entity (NCE) Products in Asia Pacific Countries to Reduce Drug Lag

TRACK 09 LEVEL: ■
Medical Devices Global Symposium

TRACK 11 LEVEL: ■
eSource Symposium

TRACK 12 LEVEL: ■
Postapproval Change Management: Challenges and Opportunities

TRACK 13 LEVEL: ■
Patient-centered Predictive Modeling and Its Role in Creating a Learning Health System

TRACK 14A LEVEL: ■
Coding with Confidence

TRACK 14B LEVEL: ■
Tracking Misuse and Abuse of Marketed Products: Is Pharma Doing All that It Can?

TRACK 15 LEVEL: ■
Some Innovative Approaches to Handling Missing Data Problems in Clinical Trials

TRACK 16 LEVEL: ■
Mobile Learning and Social Media Symposium

TRACK 17 LEVEL: ■
The Not So Rare Challenge that Faces Rare Disease Development: Demonstrate Value

TRACK 18 LEVEL: ■
CDER Town Hall: Part 1 of 2

THURSDAY, JUNE 27 10:45 AM-12:00 PM

TRACK 01A LEVEL: ■
CRA's Knowledge and Adaptability Required to Monitor Informed Consent Process in an Evolving Regulatory Environment

TRACK 01B LEVEL: ■
Impact and Interventions Related to FDASIA: Increasing Diversity in Clinical Trials

TRACK 02 LEVEL: ■
The Importance of Country Selection in Clinical Study Design

TRACK 03 LEVEL: ■
Transforming Relationships to Adapt to Evolving Organizational Strategic Goals

TRACK 06 LEVEL: ■
Insights into China: Practical Tips for Writing Publication and Regulatory Documents

TRACK 07A LEVEL: ■
Implementing a Paperless Trial for Phase 3: A Biotech's Lessons Learned

TRACK 07B LEVEL: ■
What's the Point? Can Point of Care Devices Enhance Clinical Trials?

TRACK 07C LEVEL: ■
Emerging Electronic Tools in Cardiovascular Outcomes Studies

TRACK 08 LEVEL: ■
Certificate of Pharmaceutical Product (CPPs): How Can the Process for Obtaining from and Submitting to Health Authorities Be Made More Efficient? Moving from Ribbons and Wax to Electronic Solutions

TRACK 11 LEVEL: ■
Protocol Deviations: Avoidable Problems or an Unavoidable Risk

TRACK 14 LEVEL: ■
Off-target Blood Pressure Changes and Evaluation in Drug Development: Safety,Clinical and Regulatory Considerations

TRACK 15 LEVEL: ■
Bayesian Methods in Medical Product Development and Comparative Effectiveness

TRACK 16 LEVEL: ■
Cultural Awareness and Collaboration

TRACK 18 LEVEL: ■
CDER Town Hall: Part 2 of 2

PATIENT ADVOCATE FELLOWSHIP PROGRAM

Various patient groups will be in attendance at DIA 2013 to develop, strengthen and support their collaborations with policy makers, health professionals, industry representatives and academia. Engage in conversation with these organizations and help to advocate for change.

For more information, contact **Donna.Mayer@diahome.org**.

Preliminary Program Now Online!

For more information visit **www.diahome.org/DIA2013Prelim**

PRECONFERENCE PROGRAMS AND TUTORIALS — Sunday, June 23 (as of April 5, 2013)

Receive **$100 off** of your DIA 2013 meeting registration by registering for two half day tutorials or one full day tutorial. Visit **www.diahome.org/dia2013** for more information.

Morning Tutorials, Half-day — 8:30am-12:00 PM Tutorial Fee: $405

Tutorial 20	Japan's Regulatory Environment: Overview of the Organization, Processes, Systems and Changes Affecting Pharmaceutical Development
Tutorial 21	FDA Enforcement: Understanding the Agency's Authority, How Violations Occur, How to Prevent Them and How to Respond if Violations Do Occur
Tutorial 22	Global Reimbursement Systems: A Market Access Perspective
Tutorial 23	A Device Primer: 510(k)s, PMAs, IDEs
Tutorial 24	Designing, Operating, and Evaluating Patient Registries
Tutorial 25	Leadership: How to Organize and Lead People in Group Work

Afternoon Tutorials, Half-day — 1:00-4:30 PM Tutorial Fee: $405

Tutorial 30	Analysis of Safety Data from Clinical Trials
Tutorial 31	Highlights of the New Pharmacovigilance Legislation in the EU: Key Points to be Taken into Account for Successful Implementation and Lessons Learned
Tutorial 32	Understanding Translational Medicine: Benefits and Innovative Approaches
Tutorial 33	Understanding Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA) in the Biopharmaceutical Industry
Tutorial 34	Fourteen Steps from Research to Development
Tutorial 35	Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions and Regulatory Document Writing
Tutorial 35	Successful Drug Development: Best Practices for Clinical Trial Design, Agency Interactions and Regulatory Document Writing
Tutorial 40	Investigative Site Boot Camp: Innovative Solutions to your Operational Challenges
Tutorial 41	The DIA - HBA Skill Building Series: A Custom-Fit Leadership Approach for Women in Middle Management in the Regulatory, Medical, Legal and Compliance Functions

Full-day Tutorials — 9:00-5:00 PM *Tutorial Fee: $755

Tutorial 50	Understanding and Navigating the Regulatory System in China
Tutorial 51	Quality Oversight of CROs-Clinical Vendors
Tutorial 52	Regulatory Affairs for Biologics
Tutorial 53	Clinical Statistics for Nonstatisticians
Tutorial 54	Art of Writing a Clinical Overview
Tutorial 55	Overview of Drug Development
Tutorial 56	Risk Communications
Tutorial 57	Preparing for a US FDA Advisory Committee Meeting

DIA 2013 REGISTRATION FEES

Member Standard	$1350
Nonmember Standard	$1490
Government Member	$480
Government Nonmember	$620
Charitable Nonprofit/Academia Member	$875
Charitable Nonprofit/Academia Nonmember	$1015
One-day Member	$825
One-day Non-member	$965

For student rate application form contact Donna Mayer +1 215.293.5817 or Donna.Mayer@diahome.org

DIA 2013
49th Annual Meeting
Advancing Therapeutic Innovation and Regulatory Science

SCHEDULE AT-A-GLANCE

SATURDAY, JUNE 22

Registration Hours:

9:00 AM-5:00 PM	Exhibitor Registration

SUNDAY, JUNE 23

Registration Hours:

8:00-9:00 AM	Registration for Full-day, Morning Preconference Tutorials*
12:30-1:00 PM	Registration for Afternoon Preconference Tutorials*
8:00 AM-6:00 PM	Exhibitor Registration
3:00-6:00 PM	Attendee and Speaker Registration

Schedule:

8:30 AM-12:00 PM	Half-day Preconference Tutorials*
9:00 AM-5:00 PM	Full-day Preconference Tutorials*
1:00-4:30 PM	Half-day Afternoon Preconference Tutorials*

**Space is limited for Preconference Tutorials, therefore preregistration is strongly recommended. Availability for onsite registration is not guaranteed.*

MONDAY, JUNE 24

Registration Hours:

7:00 AM-5:30 PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:45-8:30 AM	Orientation/Networking and Coffee for DIA 2013 49th Annual Meeting First Timers
7:45-8:30 AM	Coffee and Breakfast Breads
8:30-10:00 AM	Opening Plenary Session
9:30 AM-5:30 PM	Exhibition Hall Open
10:00-11:00 AM	Coffee Break
10:00-11:00 AM	Orientation and Coffee for DIA 2013 49th Annual Meeting First Timers
10:00 AM–5:30 PM	Student Poster Session
11:00 AM-12:30 PM	Concurrent Educational Opportunities
12:30-2:30 PM	Extended Lunch
2:30-4:00 PM	Concurrent Educational Opportunities
4:00-5:30 PM	Welcome Reception
4:30 PM	Student Poster Award Ceremony

TUESDAY, JUNE 25

Registration Hours:

7:00 AM-5:30 PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:15-8:00 AM	Coffee and Breakfast Breads
8:00-9:30 AM	Concurrent Educational Opportunities
9:00 AM-5:30 PM	Exhibition Hall Open
9:30-10:15 AM	Coffee Break
10:15-11:45 AM	Concurrent Educational Opportunities
10:15-11:45 AM	Student Forum
11:45 AM-1:45 PM	Extended Lunch
11:45 AM-4:00 PM	Professional Poster Session
1:45-3:15 PM	Concurrent Educational Opportunities
1:45-3:15 PM	Exhibit Guest Passes
3:15-4:00 PM	Refreshment Break
4:00-5:30 PM	Concurrent Educational Opportunities

WEDNESDAY, JUNE 26

Registration Hours:

7:00 AM-5:30 PM	Attendee, Speaker, and Exhibitor Registration

Schedule:

7:15-8:00 AM	Coffee and Breakfast Breads
8:00-9:30 AM	Concurrent Educational Opportunities
9:00 AM-4:00 PM	Exhibition Hall Open
9:30-10:15 AM	Coffee Break
10:15-11:45 AM	Concurrent Educational Opportunities
11:45 AM-1:45 PM	Extended Lunch
11:45 AM-4:00 PM	Professional Poster Session
1:45-3:15 PM	Concurrent Educational Opportunities
1:45-3:15 PM	Exhibit Guest Passes
3:15-4:00 PM	Refreshment Break
4:00-5:30 PM	Concurrent Educational Opportunities

THURSDAY, JUNE 27

Registration Hours:

8:00-10:45 AM	Attendee and Speaker Registration

Schedule:

8:15-9:00 AM	Coffee and Breakfast Breads
9:00-10:30 AM	Concurrent Educational Opportunities
10:30-10:45 AM	Coffee Break
10:45 AM-12:15 PM	Concurrent Educational Opportunities