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August 2013

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Impact Of Healthcare Delivery

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August 2013

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## Developing A Vaccine Business:
# The Takeda Approach

"There has to be a sense of commitment to helping the country as a partner, not just extracting resources and revenues and walking away." p. 24

Tadataka Yamada, M.D.
Chief Medical and Scientific Officer, Takeda

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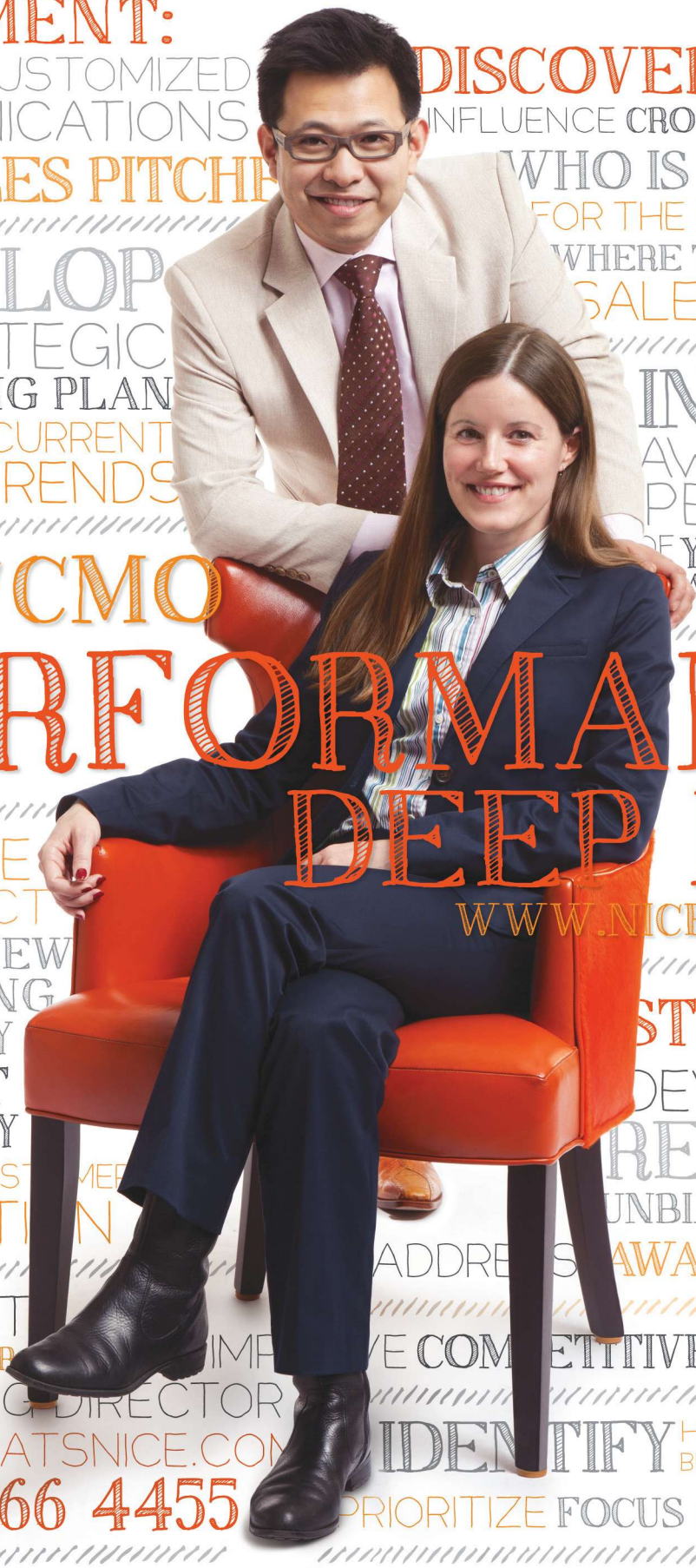

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# 24 FEATURE: TAKEDA

Tadataka (Tachi) Yamada, M.D., chief medical and scientific officer at Takeda, explains why vaccines play a pivotal part in making Takeda a truly global pharmaceutical business, and how the company is building its vaccine franchise in order to do so.

August 2013

## DEPARTMENTS



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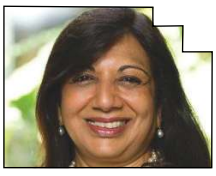

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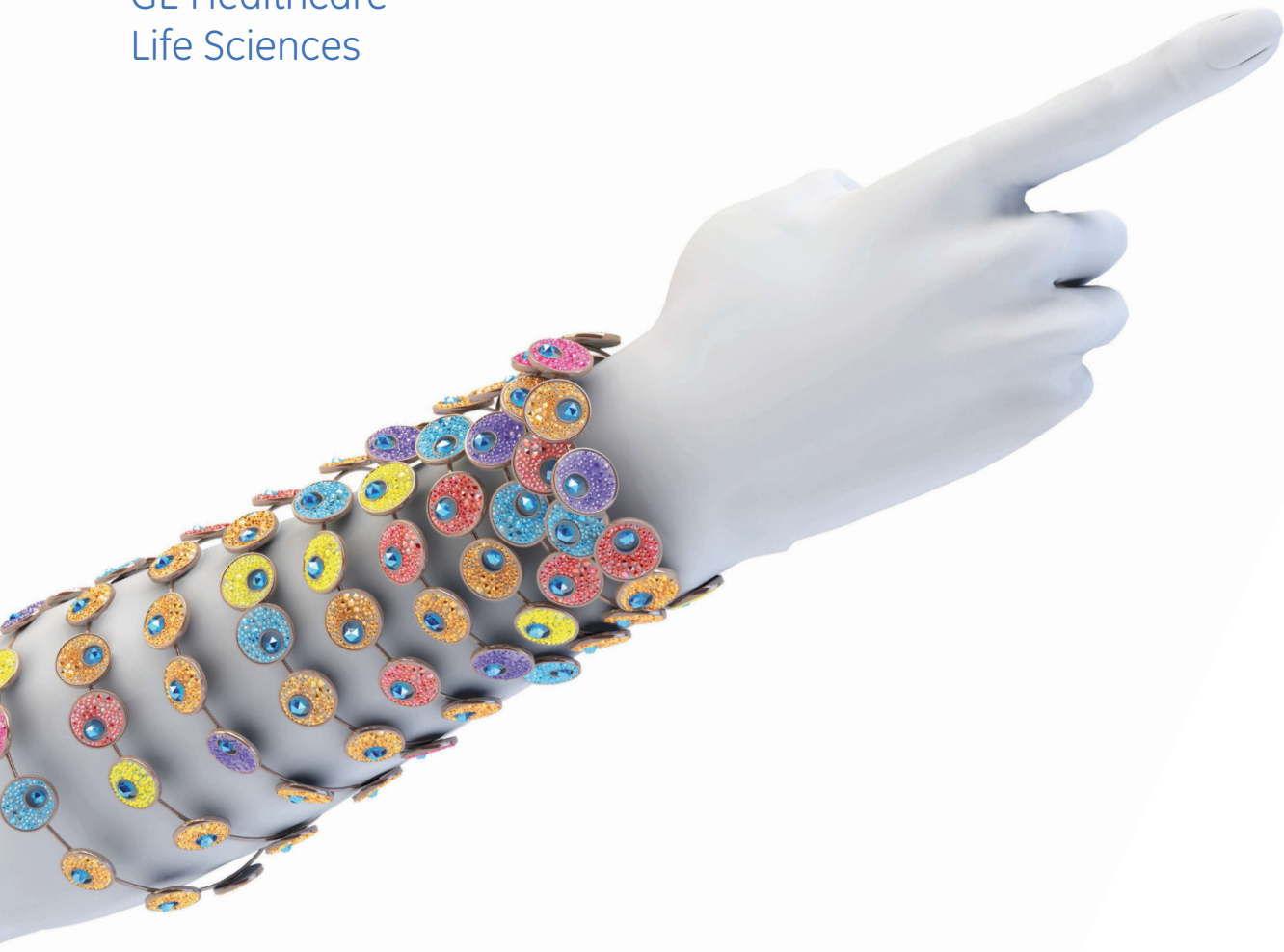

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## EDITOR'S NOTE

# Can India Achieve cGMP For Vaccines? Does It Matter?

In May, amid much fanfare, the Indian government announced the development of a new low-cost vaccine proven effective against the diarrhea-causing rotavirus — one of the leading causes of death across the developing world. According to reports, the Phase 3 clinical trial results of Rotovac, being developed by India-based Bharat Biotech, indicated it was safe and effective in the 6,799 infants who were injected with the vaccine. This news came just one week after GlaxoSmithKline (GSK) and Merck agreed to offer a 95 percent discount off the purchase price for their respective HPV vaccines (Cervarix and Gardasil) to the Global Alliance for Vaccines and Immunizations (GAVI Alliance), which delivers immunizations to the developing world. Interestingly, both GSK and Merck also make rotavirus vaccines (Rotarix and RotaTeq), which the GAVI Alliance is able to acquire for $2.50 a dose. If approved, Bharat Biotech has pledged to sell Rotovac for $1 a dose. Here are the problems I have with this news.

First, in December 2011, WHO suspended Bharat Biotech from being able to supply the hepatitis B vaccine (Revac-B+) as a result of a failed site audit of the company's Hyderabad, India, facility during a prequalification evaluation for possibly manufacturing two different vaccine types. Apparently the audit found deficiencies in the implementation of cGMP, as well as in the company's quality management systems. The company's website claims to have manufacturing, quality, and control procedures conforming to stringent standards set by national and international authorities, including the USFDA, and to be the first biopharma facility in India to be audited and approved by the Korean Food & Drugs Administration (KFDA). The company claims to have been audited by a number of other regulatory authorities but doesn't list the two most respected in the world, the European Medicines Agency (EMA) and the USFDA. So perhaps Bharat can make it cheaper, but can it make it safer?

The second problem I have with this news revolves around a statement by India's secretary of the Department of Biotechnology, Dr. K. Vijay Raghavan, quoted as saying, "The clinical results indicate that the vaccine, if licensed, could save the lives of thousands of children each year in India." I fully expect the Indian government will approve the license as it has shown favoritism towards Indian manufacturers for years under the guise of bringing cheaper drugs to the Indian people (e.g. see the Supreme Court of India denying Novartis patent protection for Gleevec). But it's that statement, "saving thousands of lives," that really bothers me.

That's because, no matter if the vaccine is approved and offered at $1.00 a dose, it's how the medicine is administered that really matters. A study by the International Clinical Epidemiology Network (INCLEN), an international network of healthcare professionals, found 62 percent of the injections administered in India to be unsafe. It is estimated that more than three billion injections are administered annually in India, meaning 1.89 billion are unsafe — primarily the result of healthcare providers reusing needles and syringes intended to be single use. But whether it be hepatitis, the rotovirus, cervical cancer, or some other type of serious ailment, it seems to me that India should focus as much effort on safely administering drugs as it is on making drugs for less money.

**Rob Wright**
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## ASK THE BOARD

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### Q: What was your most interesting experience as a CEO, and why?

I was in Uppsala, Sweden, in 1997 talking to front-line executives as the new CEO of Pharmacia and Upjohn. I was surprised to learn that a new product launch opportunity, Detrol, had been compromised to Forest Labs by a relatively junior person in the previously "decentralized" Pharmacia. This resulted in arbitration hearings. Our strategy required unfettered rights to Detrol. I had known Forest CEO, Howard Solomon, for a long time. We had developed mutual respect and trust. I played my trust card with Howard, enabling us to strike a $25 million deal for the unfettered rights to Detrol prior to the arbitration decision. What I learned, first, was to not delegate strategic asset decisions to managers who are beyond your line of sight. Second, always be respectful and kind to people. You never know when someone may be across the table from you.

**Fred Hassan**
Hassan is the chairman of Bausch + Lomb and senior advisor with the private equity firm Warburg Pincus. In addition, he serves on the boards of Avon and Time-Warner.

### Q: How can a small start-up biotech get help?

Nearly all states have one or more industry-driven organizations focused on supporting life sciences companies. These groups can be excellent resources for advice, mentorship, and introductions, as well as cost-saving purchasing groups, educational resources, and information about government programs and regulations. BIO's page for the Council of State Bioscience Associations provides a listing of most state biotech associations. Another effective avenue for connecting with state assistance is speaking with your elected officials. Few things excite legislators as much as helping companies grow and create well-paying jobs in their districts. Legislators have direct connections with their capitals, state agencies, and economic development programs, and often know where the best assistance is hiding. Government resources may seem unintelligible but can be worth the effort.

**Heather Erickson**
Erickson is president & CEO of the Life Sciences Foundation, the independent steward of biotech heritage. Previously, she was founding president of MedTech Association, serving New York's bioscience community.

### Q: What are the challenges and opportunities around Big Data?

Some include managing data at massive scale, integrating very diverse data sets, accessing distributed data across the globe, machine learning and mining techniques to identify patterns, and decision support environments which translate data into effective and timely decisions. These challenges have found their way into the umbrella term "Big Data" and are real challenges that appear in multiple phases of the pipeline — the complexity of phenotypic screening, the volume of next-gen sequencing data, the diverse data brought together in composite biomarkers, or classes of real-world evidence for on-market products. Big Data is not a silver bullet. Avoid the temptation to assemble Big Data platforms in the hope of self-emergent insight. In my experience, Big Data yields the most value when the system's design and development are driven by well-constructed scientific hypotheses.

**John Reynders**
Dr. Reynders is the CIO for Moderna Therapeutics. He has held senior R&D and technology leadership positions at AZ, J&J, Lilly, Celera Genomics, and Los Alamos National Laboratory.


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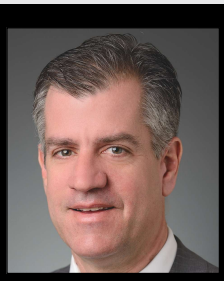
# Healthcare Delivery Consolidation Spells Higher Costs And Less Competition

The consolidation of healthcare delivery over the past several years has been substantial and is accelerating with the implementation of Obamacare. But what are the implications for patients and those paying the bills — employers and taxpayers?

A survey by the Medical Group Management Association shows a nearly 75 percent increase in the number of active physicians employed by hospitals since 2000, while 74 percent of hospital leaders planning to increase physician employment within the next 12 to 36 months.

Medicare payment cuts on certain procedures in physician offices have resulted in increased hospital acquisition of particular specialties, notably cardiology and oncology. For example, the percentage of cardiology practices employed by hospitals more than tripled from 2007 to 2012, rising from 11 percent to almost 35 percent in that time.



John McManus,
The McManus Group
jmcmanus@mcmanusgrp.com

Similarly, hospitals are acquiring ambulatory surgery centers (ASCs), which provide outpatient surgical care, at a rapid pace. Analysis by the Ambulatory Surgery Center Association found half of the 150 ASCs that closed since 2009 were purchased by a hospital and are now operating under hospital license and billing at the substantially higher Medicare payment rate of hospital outpatient departments. Hospitals often retain the center's physicians, nurses, and even the name on the building (e.g. The Louisville Endoscopy Center), but bill 78 percent more for the identical procedures it delivered before.

Proponents of this consolidation claim that it has the potential to improve care coordination and better lends itself to bundled payments and capitation, which can contain costs. They argue salaried physicians who are no longer paid by the procedure will be discouraged from ordering unnecessary tests and procedures. The narrative for years in the health policy community has been that physician ownership and independent, uncoordinated physician practices have incentives to overutilize care.

Obamacare fully subscribes to this line of thinking through promotion of so-called "Accountable Care Organizations," where care would be delivered through consolidated health systems that would be responsible for the continuum of care provided to patients. If treatment costs less than set targets and established quality measures are met, the ACO health care providers would share in the savings.

However, it is worth noting that the proposed ACO regulation would have penalized ACO providers that exceeded the target. But that proposal was quickly scrapped after vocal protests by the hospital industry. As a result, the ACO model provides only an upside if costs come in below targets but absolutely no downside if costs exceed expectations. Heads I win, tails you lose.

The ACO roll-out has expedited hospital acquisitions of physician practices, ASCs, and other free-standing centers, in part because physician practices and other providers are being told they could be frozen out of the market and denied access to patients if they do not join up now as part of a hospital-based ACO.

But does hospital acquisition actually reduce costs? And what are the impacts on patient care?

## WHAT DOES MEDPAC HAVE TO SAY?

In an interesting turn of events, the Medicare Payment Advisory Committee (MedPAC), which advises Congress on payment policy, has taken notice of this rapid consolidation and noted that hospitals are being paid substantially more for identical procedures that can be provided in the physician's office.

In its June 2013 report, MedPAC stated, "If the same service can be safely provided in different settings, a prudent purchaser should not pay more for that service in one setting than another. Payment variations across settings may encourage arrangements among providers that result in care provided in higher-paid settings, thereby increasing total Medicare spending and beneficiary cost sharing."

MedPAC goes on to recommend reducing hospital payment rates to the physician office level for "Evaluation & Management (E&M)" procedures commonly performed in physician offices, which would save Medicare more than $10 billion over the next 10 years. A similar policy applied to hospital-based cardiac medical imaging, where echocardiograms are as much as 141 percent more expensive in the hospital than in physician offices, could result in more than $1.7 billion in savings per year.

The hospital lobby is aggressively pushing back on these proposals, arguing that hospitals need this revenue to offset their uncompensated care and poor Medicaid payments, notwithstanding they get special payments exclusively available to hospitals and not physician practices (e.g. Medicare and Medicaid disproportionate share and bad debt). Last Congress, the Senate blocked a House-passed proposal to equalize E&M payments for hospitals and physician offices.

While Medicare payments are set by statute and depend heavily on the lobbying prowess of the competing industries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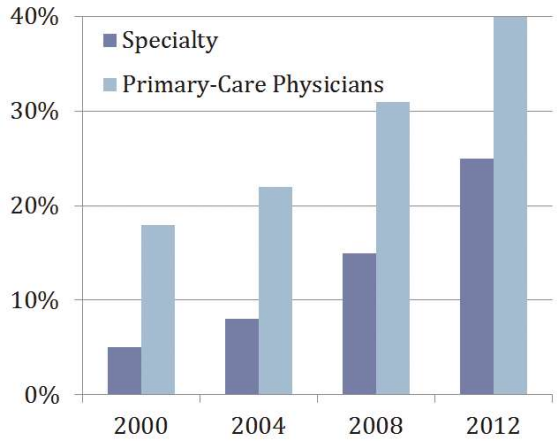
## Spike In Doctors Employed By Hospitals




- **Specialty physicians** employed by hospitals jumped from 5% to 25%
- **Primary care physicians** employed by hospitals doubled to about 40%

Source: The Advisory Board, "The power of joining a hospital network: Physician clinics raise rates," August 2012

and Congress's interest and ability to enact reforms, perhaps the more fundamental impact of this consolidation is on the commercial market.

Hospitals are merging into megasystems and purchasing physician practices to eliminate competition and secure referrals. In a seminal synthesis report issued in June 2012, the Robert Wood Johnson Foundation made three key findings with respect to consolidation:

1. Hospital consolidation results in higher prices.
2. Hospital *competition* improves quality of care, whether under administered pricing or private insurance.
3. Hospital-physician consolidation has not led either to improved quality or reduced costs. Indeed, studies find that consolidation was primarily for the purpose of enhanced bargaining power with payers.

Similarly, the basic economic principle of competition resulting in lower prices is also evident in Medicare's Part D prescription drug program. The Congressional Budget Office found lower bids were submitted in the Part D regions with more prescription drug plan sponsors. Between 2007 and 2010, each additional plan sponsor in a region correlated with a 0.5 percent reduction in the average bid for that region.

Unfortunately, the Obama administration would exacerbate this consolidation phenomenon by advancing its proposal to prohibit physician practices from integrating so-called "ancillary services" — advanced medical imaging, radiation, and physical therapy — into their practices. The result is that these services would be provided primarily in hospitals, which are more expensive and less convenient for patients. More importantly, the proposal would undermine the independent physician practice, and many of these physicians would throw their hands in the air and conclude that staying independent of hospitals is economically unfeasible and join many of their colleagues as employees of mega-hospital systems.

The reaction to this proposal of the House physician caucus (i.e. members of Congress who were physicians before they became Congressmen) has been unified and alarmed. The letter signed by 17 members of the caucus states, "We hope you will reject this unwise policy that will legislatively undermine the important counterbalance provided by integrated physician groups that provide ancillary services, which we believe is essential to America's patients and taxpayers alike."

If MedPAC, the Robert Wood Johnson Foundation, and knowledgeable physician members of the House of Representatives are waving red flags about the negative implications of this health delivery consolidation, why is the Obama administration aggressively pursuing policies that accelerate this phenomenon?

Answer: Centralization of fewer, powerful entities is easier for big government to regulate and control than thousands of independent, free-thinking physician practices with their own ideas about how best to deliver care to their patients.

John McManus is president and founder of The McManus Group, a consulting firm specializing in strategic policy and political counsel and advocacy for healthcare clients with issues before Congress and the administration. Prior to founding his firm, McManus served Chairman Bill Thomas as the staff director of the Ways and Means Health Subcommittee, where he led the policy development, negotiations, and drafting of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. Before working for Chairman Thomas, McManus worked for Eli Lilly & Company as a senior associate and for the Maryland House of Delegates as a research analyst. He earned his Master of Public Policy from Duke University and Bachelor of Arts from Washington and Lee University. He can be reached at jmcmanus@mcmanusgrp.com.

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atf SYSTEM

By Wayne Koberstein, executive editor

# CogRx (Cognition Therapeutics)

***Stay small, pick your target, and prove your concept — the simple game plan of this tiny but tough player in the rough-and-tumble neurology area.***

## SNAPSHOT

A tough cookie in a tough area — a good way to describe Cognition Therapeutics (CogRx) and its quest for innovation in neuroscience. CogRx is a small, early-stage developer of new drugs intended to treat Alzheimer's disease and possibly other conditions such as Parkinson's and ALS. The company believes it has a novel, potentially effective mechanism for blocking beta-amyloids and other misfolded, neurotoxic proteins. It is built on a lean-staffed but scientifically heavy model, focused on funding proof-of-concept studies in a Phase 1 trial of a novel small-molecule Alzheimer's drug, with a targeted launch of 2014.

Hank Safferstein, Ph.D., CogRx

## LATEST UPDATES

• January 2013: Company begins raising funds in its $14 million Series B round, set to close in 2014 to pay for the Phase 1 Alzheimer's trial.

## WHAT'S AT STAKE

CogRx is especially interesting for three reasons: its tiny size and scaled-down funding model, dense concentration of scientific expertise, and ambitious agenda in neuroscience, a field where much larger players have met with defeat. And the backdrop to the company's courageous quest is the cruel environment for early-stage contenders. Its singular survival strength is simple but amazingly overlooked by many start-ups: Take your science from bench to human as quickly as possible, understand the disease mechanism and pick your therapeutic target, define and refine your drug modality, and pursue proof-of-concept with maximum speed and efficiency.

"The discovery and development program has delivered first-in-class receptor antagonists against the toxic forms of the Abeta protein. No other company has this asset at this time. And while the science has gone very well, the funding remains our biggest challenge," says CEO Hank Safferstein, Ph.D.

CogRx has placed its chips on the beta-amyloid theory of Alzheimer's and on similar protein-folding mechanisms for other CNS conditions such as Parkinson's. The Abeta protein consists of "oligomers," a specific shape of accumulated beta-amyloid that binds with and destroys neurons in the brain. The company has developed several small molecules that block abeta at a particular spot in the binding site its scientists have identified as critical to toxicity. It has developed and used its own novel screening and chemistry platforms to select candidates based not only on binding ability but also on resulting improvement in neural function. "We have been able to achieve this with approximately 70 percent less funding than our venture-backed peer groups," Safferstein says.

So far, CogRx has raised only about $8 million and estimates it needs another $14 million "to advance the IND (investigational new drug) candidate from our lead series to clinical proof of concept, complete optimization of the backup series to IND candidate stage, and further define the signaling pathway's downstream from receptor binding," says Safferstein. "We believe these pathways may be implicated in other CNS proteopathies. The company is putting together a Series B to cover that amount by Phase 1 launch and eagerly seeking a commercial partner." With a large field of potential competitors in Alzheimer's and other neurodisorders (more than a half-dozen already have signed with major companies), CogRx must surely be getting Big Pharma's attention.

As large pharmas "externalize" their R&D, Safferstein suggests the picture can get even more challenging for companies with novel approaches. "Without people within R&D to vet the technology, it becomes increasingly hard to foster innovation using this partnered external development model," he says. He believes pharma venture funds can help bridge the "funding and diligence gap" to position companies such as CogRx as external development partners.

It may also help to have a simple plan — the company's next move is to fund the advancement of its Alzheimer's program to proof-of-concept in the clinic. "We can discuss preclinical validation until we are blue in the face, but the only validation that counts is clinical validation," Safferstein concludes. It's a big jump to make.

## VITAL STATISTICS

• Employees: 6; Headquarters: Pittsburgh

• Finances: Series A: $1.5 million in July 2009. Ogden CAP, LLC, M5Invest Partners, Pittsburgh Life Sciences Greenhouse, Innovation Works (Pittsburgh)

Series A1: $2.1 million in January 2011. Golden Seeds. New: The Breedlove Limited Family Partnership

Series A2: $3 million in January 2012

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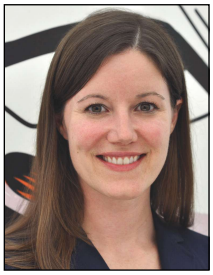

# OUTSOURCING INSIGHTS

## Using 2013 Trends By Buyer Group To Plan Your Outsourcing Initiatives

*By Kate Hammeke, director of marketing intelligence, Nice Insight*

Outsourcing has proven to be valuable to biopharmaceutical companies of all sizes. And different types of drugmakers, from virtual biotechs to Big Pharma, have implemented outsourcing programs for a plethora of reasons. There are commonalities in both outsourcing motivations and practices across the different buyer groups, as well as differences. Knowing which services are outsourced by your peers, as well as which factors are most relevant to their outsourcing strategy, may add value to your organization's 2014 planning and future outsourcing initiatives. For CMOs and CROs pitching their services to drug innovators, understanding which services are outsourced and why sponsor companies engage outsourcing partners can help your business refine its sales approach and present it as the right type of partner for the project.

According to the results of Nice Insight's 2012-2013 biopharmaceutical outsourcing study, the top three services outsourced for each buyer group included the same three services — analytical testing, bioanalytical testing, and clinical research — yet in slightly different order and with varied frequencies. For both biologics companies and emerging pharma companies, analytical testing was the service most likely to be outsourced, at 43 percent and 27 percent respectively. Big Pharma and specialty pharma respondents reported outsourcing clinical research in the greatest numbers, with 36 percent and 34 percent respectively. The most likely service outsourced among emerging biotechs was bioanalytical testing, at 34 percent.

### REASONS VARY FOR CMO/CRO USE

In addition to the top three services outsourced, the data starts to show how different types of drug developers rely on CMOs and CROs for different needs. For example, biologics companies are more likely than pharmaceutical companies to outsource custom synthesis. Custom synthesis was the fourth most outsourced service among both established and emerging biotechs (26 percent and 27 percent respectively); whereas custom synthesis was not in the top five for Big Pharma (sixth, at 22 percent) or emerging pharma (ninth, at 13 percent). Among specialty pharma respondents, custom synthesis tied with data management in popularity for outsourcing, each at 18 percent — the fifth most-popular service outsourced by the buyer group. This information can be particularly useful for CMOs pitching their custom synthesis offering — 1 in 4 respondents from biologics companies are outsourcing this service as compared to approximately 1 in 10 respondents from emerging pharma companies.

While the data shows that biotechs are more likely to lean on CMOs for chemical synthesis, it also shows that traditional pharmaceutical companies seek out regulatory support from contract organizations in greater percentages. This bodes well for companies that offer regulatory support — approximately 70 percent of the CMOs and 72 percent of the CROs included in Nice Insight's annual research. Regulatory support was the fourth most frequently outsourced service among the specialty pharma respondent group (21 percent) and fifth among Big Pharma (22 percent) and emerging pharma (18 percent). With roughly one in five respondents from traditional pharmaceutical companies seeking this service from their outsourcing partner, it makes sense for contract service providers to refer to this service offering each time they pitch a project.

In addition to similarities across the top services outsourced, there was a common motivation for outsourcing that rose to the top three reasons across each of the five buyer groups — improving quality. In fact, improving quality was the number one reason for engaging a CMO or CRO as reported by emerging biotechs (45 percent), specialty pharma (58 percent), and emerging pharma (67 percent). Among established biotech respondents, it placed third (47 percent) behind gaining a competitive advantage (53 percent) and gaining access to scientific capabilities (50 percent). It placed second among Big Pharma respondents (55 percent), after gaining access to technologies (65 percent). Big Pharma happened to be the only group that included access to technologies in the top three reasons for engaging outsourcing partners.

Whether you are new to outsourcing or the company you work for has well-established processes, knowing which services are outsourced by similar businesses as well as their outsourcing goals may be helpful in planning your outsourcing initiatives for the coming year.


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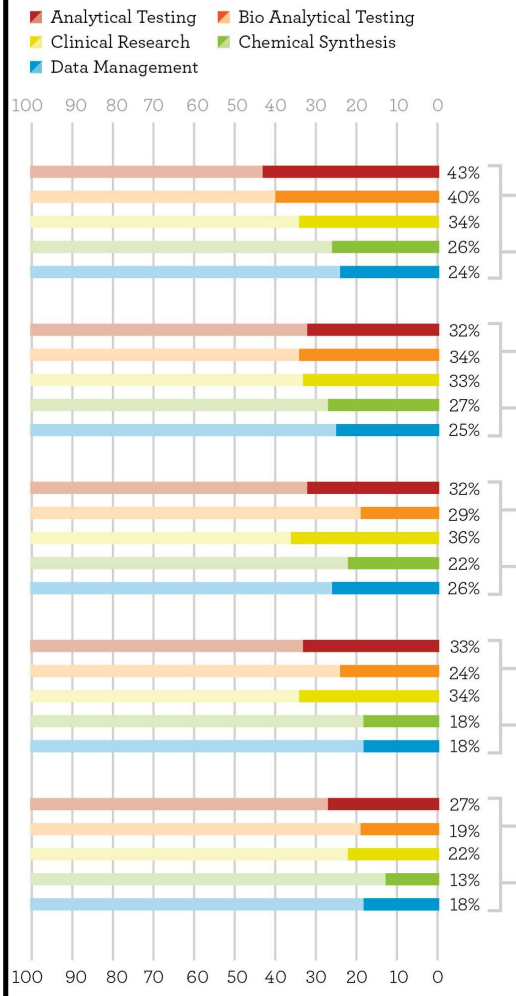
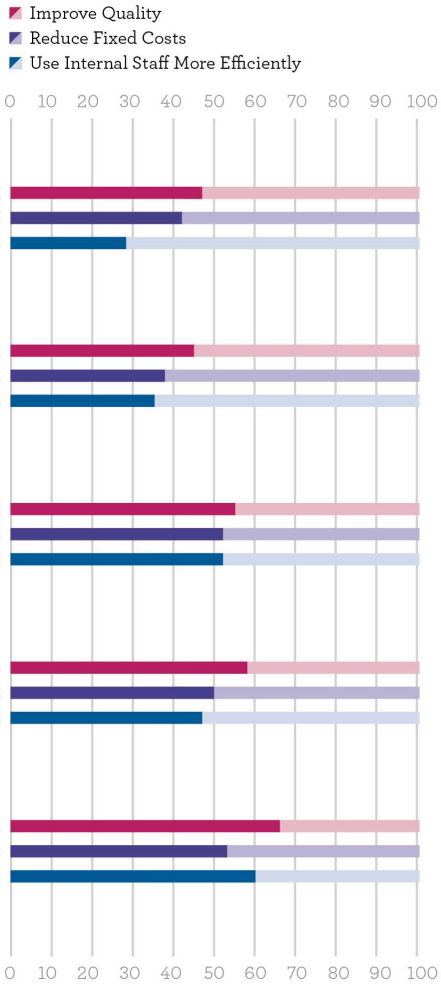
## Top Services Outsourced by Buyer Group



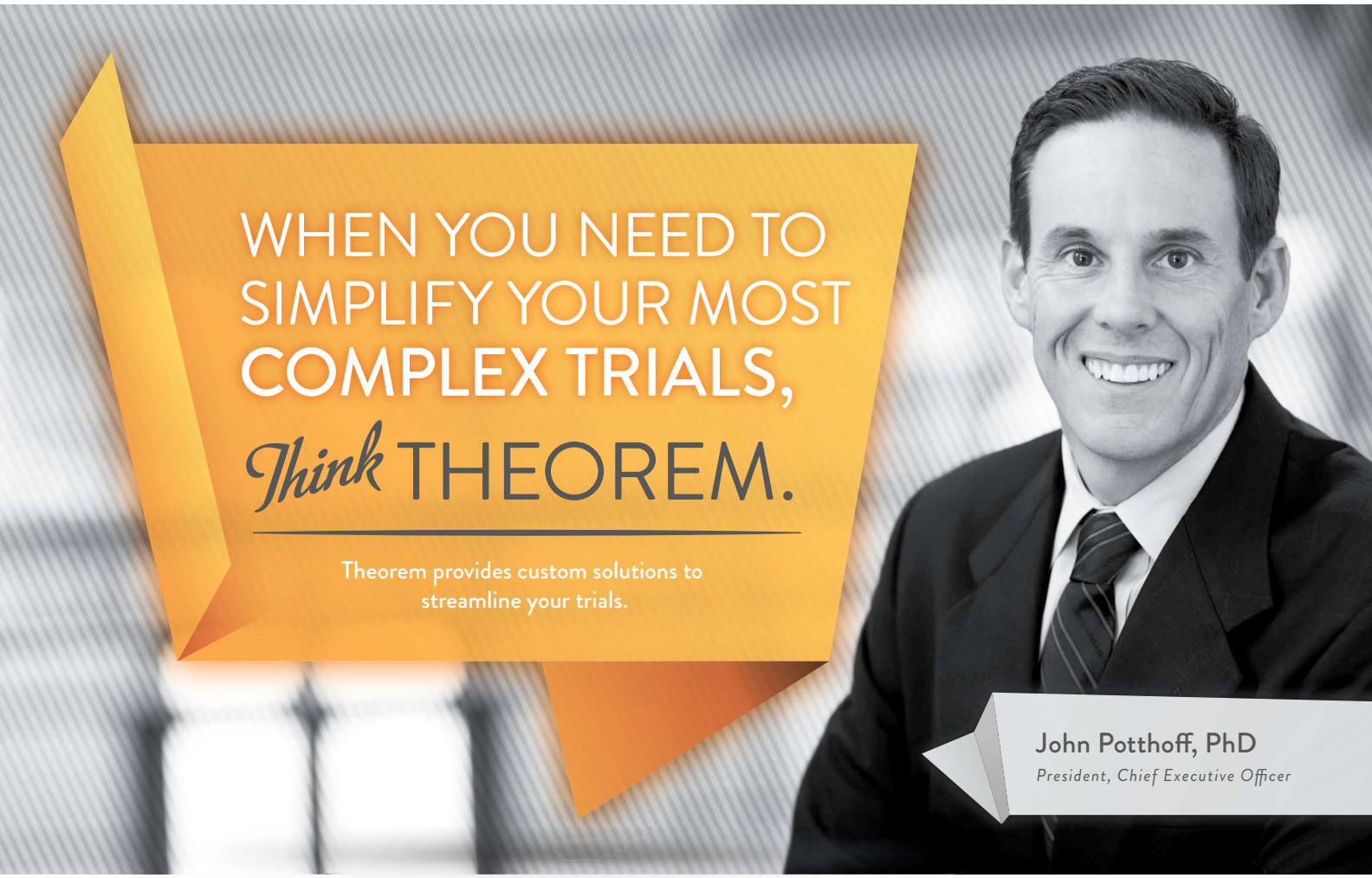

## Top Motivations for Outsourcing by Buyer Group




Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2012 sample size is 10,036 respondents. The survey is composed of 500+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions on 170 companies that service the drug development cycle. More than 800 marketing communications, including branding, websites, print advertisements, corporate literature, and trade show booths, are reviewed by our panel of respondents. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer-awareness score. The customer-perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory Track Record, Affordability, Productivity, and Reliability.


Walker

If you want to learn more about Nice Insight's CRO/CMO report or to participate in the survey research, please contact Managing Director Nigel Walker of That's Nice at nigel@thatsnice.com. If you have a question about the data or are interested in custom market research, contact Kate Hammeke at kate.h@thatsnice.com.

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# BIO INNOVATION NOTES

## Innovation In Disposable Connectors

*By Eric Langer, president and managing partner, BioPlan Associates, Inc.*

The single-use application market in biopharmaceutical manufacturing is rapidly expanding and highly innovation-driven. Adoption of single-use equipment in early manufacturing has reached a level of maturity that will spill into commercial scale manufacturing in the near term. Indeed, results from our *10th Annual Report and Survey of Biopharmaceutical Manufacturers* (www.bioplanassociates.com/10th) indicate that nearly half of biopharmaceutical manufacturers and CMOs either strongly agree (18 percent) or agree (28 percent) that they expect to see 100 percent single-use facility in operation within five years.

Those are big expectations — and if they are to be met, some critical hurdles may need to be crossed. One of them is developing standardized applications and connectors. Connectors are needed because they permit interconnectability between various components and between different vendors' devices. This plug-and-play approach ultimately enables further adoption of disposable devices and reduces the risk of being locked into a single component supplier.

It's no surprise, then, that disposable bags and connectors top the areas in which the industry is demanding innovation and better products. When we asked respondents where they want their suppliers to focus their new product development efforts, a leading 44 percent pointed to basic devices such as disposable bags and connectors. This response ranked 4 percent above the next most-desired innovation (disposable probes and sensors, at 40 percent). Other disposable devices also appear near the top of the list, including innovation in disposable bioreactors and disposable purification products.

Interest in disposable-bags-and-connectors innovation is higher in established biomanufacturing hubs, with U.S. respondents and Europeans leading the way (47.7 percent and 45.7 percent, respectively). Respondents from the rest of the world have expressed less interest in innovation in this area (26.1 percent) — this year they're more concerned with process development services. This difference is likely due to the fact that early pipeline products in the U.S. and EU, made using single-use devices, are now reaching later-stage production. As such, the need for better products for commercial scale production is now becoming more acute.

### INCREASED INTEREST IN CONNECTIVITY OVER TIME

The biopharmaceutical manufacturing community's interest in innovative disposable connectors appears to have risen over the past couple of years, perhaps as the industry recognized what a crucial role the devices can play by introducing them into existing single-use product lines (e.g. substrate feeds via novel bags, molded manifolds, and plastic connectors to enable fed-batch, repeated batch, or perfusion modes of bioreactor operation). This year's 44 percent expressing an interest in connectors innovation is a step up from 40 percent last year and 37 percent in 2011.

Interest in connectors innovation is increasing alongside adoption of these devices. Among respondents to our study who use disposables, 8 in 10 already say they're using connectors and clamps at some stage of manufacturing. The data in the study shows these devices have become more critical over time, growing from 68.3 percent adoption in 2007 and 47.6 percent in 2006, the early years of single-use product introduction. In fact, the compound annual growth rate in adoption for these products between 2006 and 2013 stands at a healthy 7.5 percent, the fifth-fastest growth rate of the 14 single-use products we identified in our study.

### LOOKING FORWARD

When we evaluated the importance of single-use connectors, we found that nearly all bioprocessing professionals (84 percent) are relying on their suppliers to develop and standardize better connector compatibility (See Fig 2). This demand is likely to push suppliers to consider more "open" designs that do not lock end users into a single format or supplier.

Growing adoption of and interest in disposable connectors means that vendors will likely enjoy a healthy demand for their new products. However, these small devices also command only small budgets: When we estimated the average budget per facility on different single-use components, we found that the average respondent budgets just over $25,000 for connectors and clamps. That's far below other more complex single-use applications such as filter cartridges, depth filters, bioreactors, and buffer containers. While that may suggest that vendors may find better margins with other innovative products, it also means that connectors — as smaller line-items — may find an easier path into the budget. Indeed, effective integration into both process and business systems

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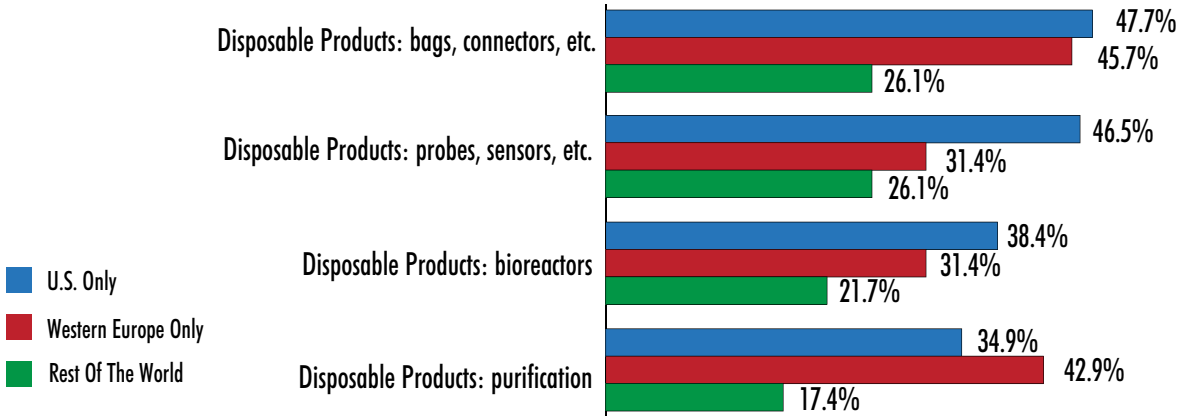
defines successful applications of single-use systems versus unsuccessful ones, and so far at least, most of the focus has been on physical connections such as tubing and connectors, giving them a leg up on other products.

Given healthy penetration of disposable connectors — and growing end user desire for innovation — it's likely that the industry will continue to see a number of innovations in this area. Vendors will need to consider standardizing these devices to satisfy end user demand. With disposable devices continuing to make inroads into commercial biomanufacturing, we can expect that the importance of connectors and clamps will only rise over time. These devices enable the shift towards disposable usage, and innovation should continue as vendors recognize that their use (and standardization) is crucial in the continued maturation of the disposables market.

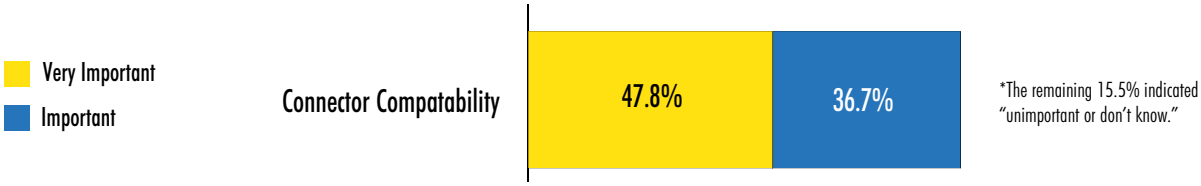
## Figure 1: Selected New Product Development Areas Of Interest

U.S. vs. Western Europe vs. Rest Of The World




## Figure 2: Single Use/Disposables Standardization Factors

"In my opinion, single use/disposables vendors need to work harder to standardize."




**Survey Methodology:** The 2013 10th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production is an evaluation by BioPlan Associates, Inc. that yields a composite view of and trend analysis from 300 to 400 responsible individuals at biopharmaceutical manufacturers and CMOs in 29 countries. The respondents also include more than 185 direct suppliers of materials, services, and equipment to this industry. Each year the study covers issues including new product needs, facility budget changes, current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring, and employment. The quantitative trend analysis provides details and comparisons of production by biotherapeutic developers and CMOs. It also evaluates trends over time and assesses differences in the world's major markets in the U.S. and Europe.

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imagination at work

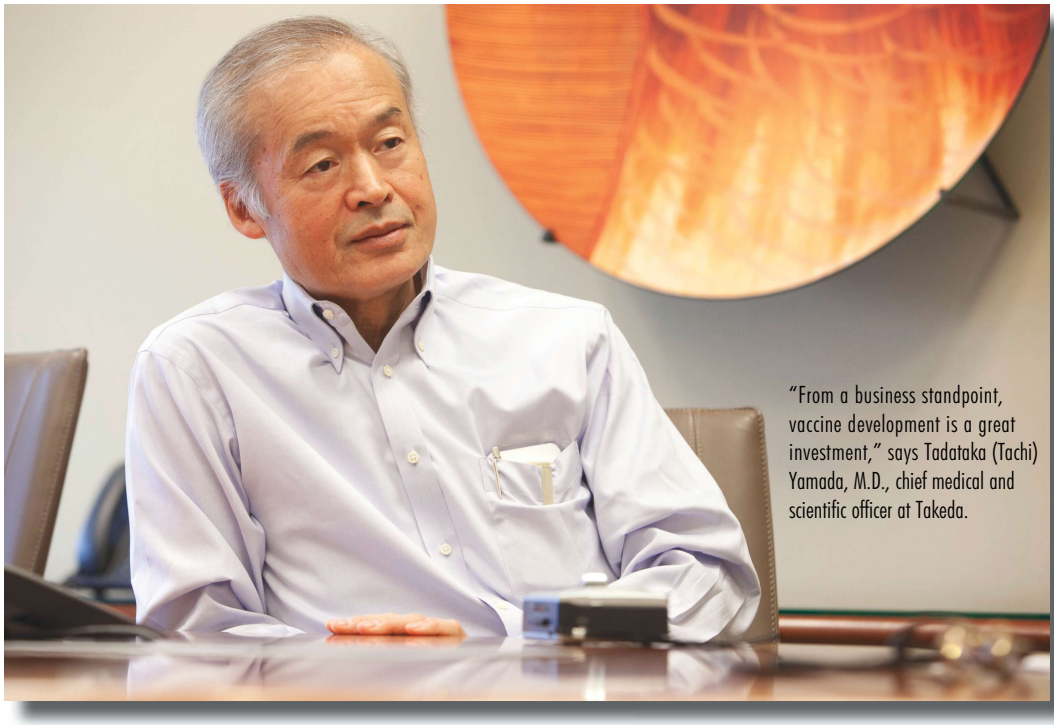
Tadataka (Tachi) Yamada, M.D., chief medical and scientific officer, Takeda

# Takeda's Approach To Becoming A Global Player In The Vaccine Market

By Rob Wright, chief editor

In 2008 Takeda Pharmaceuticals took aim at becoming a global pharmaceutical company by making a number of strategic moves, such as the dissolution of the 23-year, 50/50 joint venture with Abbott, known as TAP Pharmaceuticals, and acquiring Millennium Pharmaceuticals (2008) and Nycomed. These changes strengthened Takeda's position in two of the largest pharmaceutical markets outside of Japan (U.S. and EU), placing it on the verge of being the first Japanese company to be listed among the 10 largest pharmaceutical companies in the world. With 2012 net sales of $18.4 billion, Takeda ranks twelfth, up four spots from the previous year. What will get them to the next level?

According to Tadataka (Tachi) Yamada, M.D., Takeda's chief medical and scientific officer (CMSO), the answer lies first in advancing Takeda's very strong late-stage pipeline and second in developing a successful vaccine business that has the potential to be commercially attractive while at the same time creating low-cost health solutions (i.e. vaccines) for some of the poorest countries in the world (i.e. emerging markets). Yamada, who previously served as the president of the Bill and Melinda Gates Foundation global health program (2006 to 2011), explains why vaccines play a pivotal part in making Takeda a truly global pharmaceutical business, and how the company is building its vaccine franchise in order to do so.



"From a business standpoint, vaccine development is a great investment," says Tadataka (Tachi) Yamada, M.D., chief medical and scientific officer at Takeda.

## THE STRONG BUSINESS CASE FOR VACCINES

"We are not in the business solely to make money or to make a return on investment for our shareholders," Yamada says. "Certainly we have to do that. But if we forget we are in the business of helping people with unmet medical needs, we are going to fail." That mindset was first honed in Yamada while he was in medical school and then was rekindled during his tenure at the Gates Foundation. He brought this mindset with him to Takeda, as well as the business case as to why creating a global vaccine franchise makes sense.

Indeed, the vaccine market is in a significant growth mode. In 2002 the global vaccine market was approximately $5.7 billion, but today it is near $27 billion and expected to increase at a compound annual rate of 10.3 percent through 2015.

Vaccines represent very low-cost health solutions which prevent disease. The measles vaccine costs about six cents. WHO estimates global immunization campaigns save more than 2.5 million lives every year, and protect millions more from disease and disability. "From a business standpoint, vaccine development is a great investment," states Yamada. "For a pharmaceutical company, it presents a product line which is not as dependent upon the life cycle of intellectual property as most small molecules. It is very difficult to create a generic vaccine without doing a set of clinical studies to prove it has the same human response as the branded vaccine." Yamada believes the need to conduct clinical trials to gain approval of a generic vaccine provides companies with better IP protection, serving as a barrier to entry by smaller generic companies.

However, because vaccines are developed from biological organisms, they can be harder to work with, are less predictable than their chemical counterparts, and thus, have to be tested in more people before being licensed. As a result, it can take 15 years or more to develop a vaccine, and at an estimated cost between $163 million and $518 million.

Once developed, their biological nature makes them more difficult to consistently manufacture on a commercial scale. Another challenge revolves around the shipping and storage of vaccines. For example, temperatures for refrigerated and frozen vaccines need to be maintained between 2° C and 8° C and -50° C and -15° C.

These challenges aside, for big pharmaceutical companies the vaccine business remains a very worthwhile investment. Consider this: Of the 10 bestselling vaccines presently on the market, all are produced by five Big Pharmas — GSK, Merck, Novartis, Pfizer, and Sanofi. Total sales of the Top 10 are nearly $6 billion, with Pfizer's Prevnar 13 (pneumococcal vaccine) topping the list. Available in 120 countries, and with sales totaling $3.72 billion in 2012, Prevnar 13 accounts for nearly 14 percent of the total vaccine pie. Merck's chicken pox vaccine, VARIVAX, first received FDA approval in 1995, and still generates $392 million in annual sales.

## THE VACCINE VISION

For Yamada, creating a global vaccine business first involved devel-

oping a vision that fit within the company's current corporate philosophy. At Takeda this is referred to as Takeda-ism and consists of four pillars — integrity, fairness, honesty, and perseverance. To come up with the vision, Yamada and his staff first asked the following questions:

- What is it going to do?
- What is its purpose in the company?
- How is it going to be consistent with the rest of the company?
- Why is it important to the company to invest in it?

To be successful in these developing markets, Yamada believes pharmaceutical companies need to be part of the solution to those nations' problems, in addition to providing new drugs and vaccines. "There has to be a sense of commitment to helping the country as a partner, not just extracting resources and revenues and walking away," he attests.

Yamada then recruited a former Gates Foundation colleague, Dr. Rajeev Venkayya, to head up Takeda's vaccine business. While at the foundation, Venkayya oversaw the organization's top two priorities — eradication of polio and new vaccine introduction. Once on board, Yamada then gave

## THE MOST COMMON LEADERSHIP MISTAKE

Fifty years ago when Tachi Yamada was living in Stanford, CA, he invited his girlfriend from Ohio for a visit. Today, she is his spouse of 46 years. During her visit, she taught him a valuable leadership lesson. "It was a sunny day, and I suggested we wash the car," he recalls. "After about 10 minutes of washing, she throws down the sponge and says, 'If you want me to help you wash your car, let me help you. If you want to wash your car yourself, why don't you do it yourself?'" Evidently, he was washing the car as fast as he could, assuming she couldn't wash the car as well as he. "That was a very important lesson to me," he attests. "I have carried it with me my whole career. If you are in a position of leadership, you have to remember that you can't do everything. You have to depend on others and delegate authority. I think where CEOs get in the way of their own success is by assuming they can do tasks better than anybody else, and therefore should only do those tasks themselves." Yamada believes this kind of thinking is unmotivating to the people working with you, not a sustainable leadership model, and impedes the attainment of objectives. His advice, "Take the fullest advantage of everybody around you who can help you do what needs to be done." Though the car washing example may seem simplistic, everywhere Yamada has gone he has seen examples of leaders making the same mistake — only on a bigger scale.

Venkayya the autonomy to build his own team, rather than micromanage the process, a common leadership mistake (see sidebar on page 27). In addition to recruiting talent, Takeda needed to acquire additional vaccine capabilities.

## ADDING COMPETENCIES VIA ACQUSITION

In October 2012, Takeda acquired LigoCyte, a small biopharmaceutical company in Bozeman, MT, that manufactures a vaccine to prevent norovirus gastroenteritis. "Norovirus is the largest cause of epidemic diarrhea in the United States," says Yamada. The CDC estimates 1 in 15 Americans come down with norovirus each year. Because it is highly contagious and presents with highly debilitating symptoms (i.e. vomiting, diarrhea, stomach cramps), there is significant lost productivity. Norovirus is estimated to affect 267 million people globally, causing more than 200,000 deaths annually, most occurring in less-developed countries.

The second acquisition occurred in May of this year when Takeda bought Inviragen. With this acquisition, Takeda picked up competencies for creating innovative vaccines for emerging infectious diseases, including dengue fever, a mosquito-spread illness primarily found in tropical and subtropical climates. "Half a billion people or more will get dengue each year," states Yamada. Inviragen's lead candidate, DENVax, a four-strain recombinant viral vaccine for the prevention of dengue, is currently in Phase 2 clinical trials.

With these two acquisitions, the company picked up the ability to manufacture subunit vaccines via LigoCyte's proprietary, virus-like particle platform (VLP) technology, as well as live vaccines. "These two important technologies shore up our ability to produce vaccines of the future," states Yamada. "We are particularly interested in combination vaccines, including the Sabin-inactivated Polio virus, so-called sIPV. Oral polio vaccines are live strains, which can be shed. Once you've eradicated polio from the world, you really don't want that around." As a consequence, Yamada believes the world will soon turn solely

## KEY LESSONS LEARNED FROM WORKING AT THE GATES FOUNDATION

Prior to joining Takeda Pharmaceuticals as the chief medical and scientific officer, Tachi Yamada, M.D., spent five years working as the president of the Bill and Melinda Gates Foundation's global health program. There, he directed projects geared toward solving some of the health challenges of the developing world. These included TB, HIV, malaria, other infectious diseases, malnutrition, and maternal and child health. As a former academic and pharmaceutical executive, Dr. Yamada was asked what was the most valuable experience he gained from working at the Gates Foundation. Instead of one experience, he explained he learned a lot about urgency, innovation, partnership, and measurement. "The sense of urgency we have in the pharma industry is not the same as that which I felt when I was in the field at the foundation," he explains. "I would come into contact with mothers holding babies on the verge of dying or already dead. This happens seven million times a year unnecessarily or from preventable causes." This experience gave Yamada a heightened sense of urgency about the work he was doing, and he brought that sense of urgency to Takeda. "If we don't work with urgency, then we can't meet people's unmet medical needs, and they will suffer or die unnecessarily," he states.

Regarding innovation, Yamada describes it this way. "We worked on problems at the Gates Foundation that didn't seem to have any viable solution and required more than just the usual everyday pharmaceutical effort to solve. They require true innovation, which means more than just a little tweak or a little 'smart' move." According to Yamada, the pharmaceutical industry is primarily involved in evolutionary innovation, which advances but does not significantly change the field. "Revolutionary innovation is where something absolutely transforms the field, and often it involves some crazy idea or something never thought of before," he explains. "Take the example of peptic ulcer disease. It was treated with antacids, then with H2 Blockers, and then Proton pump inhibitors. All of these just treat the disease, but don't cure it. The finding that Helicobacter pylori causes peptic ulcer disease — and if you treat with antibiotics, you can actually cure people from the ulcer and from ever having the ulcer again — is an example of revolutionary innovation." To create revolutionary innovation, Yamada says you need to take chances, be willing to take risks, be willing to fail, and create an ecosystem of challenging dogma.

He also learned the importance of partnership, essential for executing global health initiatives. "You can't do it alone," he affirms. "We worked very closely with WHO, UNICEF, and other international agencies in the developing world to get things done," he says. "Our closest partners were with the department for international development in the United Kingdom or USAID in the United States."

Finally, there is the concept of measurement. "It is easy when you are giving a lot of money away to assume you are doing good," he states. "But, in fact, you have to measure the impact of what you are doing." This is something the pharmaceutical industry could do better. Recent policy makers are in agreement, as are payers, who are seeking outcomes-based data from patients taking medicines and the real impact those medicines are having on society and patients.

According to Yamada, these four concepts — urgency, innovation, partnership, and measurement — are critical concepts. "I worked with these every day at the Gates Foundation and brought them back with me to the pharmaceutical industry," he concludes.

to combination-inactivated polio vaccines, and he intends for Takeda to be ready for that trend.

As Takeda builds its global vaccine business, it strives to capitalize on the entrepreneurial and innovative thinking of the companies it has acquired. "Small companies are able to move more quickly and address opportunities in the most efficacious way, because there is less bureaucracy," he says. "Hopefully, we can learn from these cultures and gain some competitive advantages and insights against the backdrop of what is a very important Japanese culture," he states. Takeda should have plenty of learning opportunities to do so. Since 2010, the company has grown from around 20,000 employees to 30,305, adding more than 10,000 overseas-based staff, and operating in nearly 70 countries. For the first time in the company's 232-year history, Takeda has more employees working and living outside of Japan than within — a testament to Takeda moving forward in becoming a truly global player.

## AN IMPORTANT LEADERSHIP SKILL TO FOCUS ON

Ever meet people who make leadership look effortless and wonder how they do it? Perhaps you can't quite put your finger on what makes them good leaders, but you view them as a leaders, not just managers. If you asked Takeda's Tachi Yamada what his most valuable leadership skill is, and how he acquired it, he would say being able to extract the best out of the people who work for him. "I think you can walk into organizations and find a group of people who say, 'These people are bad, let's get rid of them all and bring in new people,'" he explains. "Or, you can walk into an organization and say, 'These people are not perfect, but they are good, so let's get the best out of the people we have.' I get the most out of employees' strengths and try to shore up their weaknesses. Every organization I have walked into I have been able to get the people to perform better than they probably imagined they could."

How does he do it? Listening. According to Yamada, one of the keys to becoming a leader is listening to what is important to people. "Often people are good at what they consider to be very important," he explains. "People's feet take them to where their hearts want to go. Some people will say, 'I really like this,' but you see them every day demonstrating they don't like what it is they say they do." Yamada believes ferreting out what is really important to people is the difference between excellent and average performance. "You've got to make sure people are doing what they really love, and you'll find they are good at it," he affirms.

Elias Zerhouni, M.D., president of global R&D, Sanofi

# At Sanofi, The Case For Change Was Not Hard To Make

By Cathy Yarbrough, contributing editor

Sanofi will be the most productive and profitable R&D operation in the bio-pharmaceutical industry in 2015. That's the vision of Elias Zerhouni, M.D., the company's president of global R&D, and Sanofi CEO Chris Viehbacher, who persuaded Zerhouni, the former NIH director, to leave the world of academia where he had built a reputation as an innovative, successful, and charismatic leader.

Zerhouni, who joined Sanofi in 2011, said he viewed the position, his first in industry, as an opportunity to transform biopharmaceutical research and development from the inside. "Clearly we need to reinvent. We have to change the culture of the industry, which needs new ways of doing things," he said.

Zerhouni has long been aware of the role biopharmaceutical companies play in combating disease and improving human health. His views about why pharmaceutical R&D has become sluggish and how it can be reinvigorated were shaped by his experiences at NIH and Johns Hopkins University School of Medicine. At the latter, he not only was a professor and chair of radiology and radiological science and executive vice-dean, he also founded and co-founded five start-ups.

But more than anything, at both places, Zerhouni was a

## TIPS FOR SUCCEEDING AS A "CHANGE AGENT"

Although "change agent" has become an overused term, it aptly describes the career of Elias Zerhouni, M.D. Before joining Sanofi as president of global R&D, Zerhouni was a professor and chair of radiology and radiological sciences and executive vice-dean at Johns Hopkins School of Medicine and director of NIH. "I've had the opportunity to be put in the middle of circumstances in which things were not going well, and the organization's leaders recognized that they had to find a new direction," he said.

To reinvent Sanofi's R&D culture, Zerhouni took advantage of his perspective as an outsider, a native of Algeria, and a newcomer to the executive suite of a major pharmaceutical company. He came to the U.S. from Algeria in 1975 for his residency in diagnostic radiology at Johns Hopkins.

"Being an outsider has been a huge benefit for me at Johns Hopkins, NIH, as well as Sanofi," he said. An outsider is more willing to question an organization's way of doing things. "Also being an immigrant has helped me to understand different points of view that exist in any complex organization, because today, all great institutions are multi-disciplinary and multicultural by nature," he said. "Part of my ability to succeed in the U.S. may be that I can bring a viewpoint that many people feel is sometimes surprisingly different and constructive in showing there is a different way."

### Believe In Your Vision

Zerhouni learned how to make things happen even when many of his colleagues thought it was impossible to do so or did not agree with his vision. For example, NIH leaders did not uniformly embrace his vision for the agency, outlined in the NIH Roadmap for Medical Research, published in 2003. Their attitude was, "Who is he to tell us what to do? What does he know?" recalled Zerhouni, whose first government job was the NIH director position.

The road map called for greater collaboration among the 27 institutes and centers of NIH, a substantial investment in translational research, and the awarding of research grants to support the high-risk innovative studies that, if successful, typically have the most significant impact on medicine. Because he believed these and other initiatives would strengthen not just NIH but the entire R&D ecosystem, Zerhouni turned to the U.S. Congress to enact legislation. The result was the NIH Reform Act of 2006.

"I wanted to make sure the change we implemented at NIH would be institutionalized," he said. "When I set out to change the law governing NIH, due to the very partisan Congress, very few thought it would happen, and yet it did, despite great opposition, thanks to a lot of strategic preparation with the relevant senators and congressmen over the preceding three years."

### You Will Become Unpopular

A successful change agent must not be afraid of becoming unpopular. Because change is uncomfortable for some people, you will likely become unpopular. "Twenty percent [of the people you are working with] will be rabidly against you." Zerhouni said.

However, if the change makes sense to them, most people will not oppose it even if it is unpopular. "Twenty percent will agree with you and will say, 'He's right, we need to move on to do things differently if we're going to adapt.' Sixty percent will be in the middle. Their attitude will be, 'I want to see more. Let's see how things go.' They may not like the change, but will respect it."

### You Can't Do It By Ordering People Around

In his past and current leadership positions, Zerhouni could have mandated that his vision be implemented. "But that would not have changed anything," he explained. "You must understand that you can't bring people to the same passion and vision that you have because of your position of authority. You can't do it by ordering people around."

Change agents should not compromise their vision to win the support of staff, he noted. "You must believe in your vision totally and have a deep understanding of what you want to accomplish and what makes you, as the leader, excited about it in a genuine way."

Rather than order staff members to change, Zerhouni persuades them. "You first have to persuade others of the need for change, and then organize a fair, open process for all to participate in earnest and have the resilience and courage to implement what was agreed upon."

Zerhouni also said that change agents should be transparent. "You can't motivate others by not being genuine," he said. "You want colleagues and staff to realize that you're not initiating change for your own self-interest."

change agent. During his six-year tenure at the federal agency, he initiated translational medicine, multidisciplinary research collaborations, and other programs, all to accelerate the progress of medical research. Although his campaign at NIH focused on the agency's support of scientists at universities and government labs, Zerhouni said that he has long regarded academic and industry R&D as a highly interconnected and interdependent ecosystem.

Despite his ecosystem connections, Zerhouni's ability to influence biopharmaceutical R&D was limited before 2011. The Sanofi position has enabled him to reinvent R&D from the inside of one of the major players in the biopharmaceutical industry. Under his leadership, Sanofi's R&D now emphasizes the biology of disease, translational research, and open innovation.

"R&D in pharma has been isolating itself for 20 years, thinking that animal models would be highly predictive."

Elias Zerhouni, M.D., president of global R&D, Sanofi

Zerhouni felt that Sanofi leaders and scientists readily embraced his new initiatives. "The case for change was not hard to make," he said. "In the industry, we fail a lot, and we fail really late." Many failures in pharmaceutical development can be attributed to the lack of a deep understanding of disease biology during identification of drug targets, he added. "We don't understand the language of biology as well as we should to effectively translate it into real innovation."

## "IT'S THE BIOLOGY, STUPID"

In a speech earlier this year on the future of genomic medicine, Zerhouni adapted the unofficial motto of President Bill Clinton's first presidential campaign, "It's the economy, stupid," to underscore his comments about the real reason for failures in drug development. "It's the biology, stupid," he said.

Viehbacher recently echoed Zerhouni's comments when asked by Bloomberg News to explain why Sanofi wasn't investing resources in clinical studies on Alzheimer's disease, in contrast to several of the company's competitors. "I think we have to do a lot more basic science work to understand what's going on," said the Sanofi CEO. "We really, at best, partially understand the cause of the disease. It's hard to come up with meaningful targets."

Sanofi's new commitment to the biology of disease does not signal the company's evolution into a basic sciences company or elimination of internal research. "Instead, we are getting closer to the basic sciences in academia," Zerhouni explained.

To get closer to academic basic sciences, Sanofi has been establishing an external innovation network of research partnerships with major academic institutions. "Our goal is to create synergies and intellectual collaboration that are of mutual benefit," he said.

Sanofi's external innovation network "is fundamentally different from what pharma companies have done in the past," Zerhouni pointed out. Rather than paying the university for access to a particular lab's research data and then walking away, the company is establishing "non-mercenary" collaborations between the "best and brightest scientists at Sanofi and the best and brightest in academia," he said.

The company's diabetes partnership with University of California at San Francisco (UCSF) is one example of Sanofi's approach to external innovation. "This is a true partnership between scientists with very different strengths," said Matthias Hebrok, Ph.D., director of the UCSF Diabetes Center. "UCSF is known for its deep understanding of the underlying biology of diabetes, while Sanofi has great expertise in screening compounds, identifying which molecules have potential, and moving them along to develop a new drug. Such an endeavor is almost impossible to accomplish in a single academic laboratory. Thus, both partners profit from the expertise of the other group."

Partnerships with academic labs are not unique to Sanofi or the industry. In fact, they once were much more commonplace but vanished when the industry turned inward, adopting a culture of secrecy, Zerhouni said. "The secrecy came from an era when R&D was taken over by considerations such as intellectual property and the sense that biology would be understood in isolation," he explained.

"R&D in pharma has been isolating itself for 20 years, thinking that animal models would be highly predictive," he explained. In addition, the entire ecosystem, not just industry researchers, became arrogant as a result of the "phenomenal breakthroughs that occurred in the early 1990s," he said. These breakthroughs "gave us the impression that we could cure human disease in animal models."

## SECRECY NOW SIGN OF WEAKNESS

Zerhouni stressed what many people in the industry have been saying recently — there needs to be more collaboration, partnerships, and open innovation throughout the industry. That secrecy he referenced earlier is now considered a sign of weakness because it impedes progress. "Times have changed, and it is no longer about who owns the data, but how to solve the problem faster," he explained.

To eliminate the barrier of secrecy and stimulate open innovation, Zerhouni has hired several academic "stars" who bring their culture of open inquiry and their networks. Zerhouni and the other scientists whose reputations were made in academia tap their own professional networks to establish Sanofi's innovation partnerships with government and university labs.

While the Sanofi scientists who have devoted their careers to pharmaceutical R&D are expected to replace secrecy with open inquiry, the academic researchers who have joined Sanofi must adapt to a corporate culture and learn the rigor of the translational process with their new colleagues. "It is an enormous challenge with a steep learning curve, but it can provide the joy of seeing the research 'translated' to a potential and even possibly an actual treatment," he said.

Those researchers are not abandoning academia, he pointed out. "Sanofi scientists who left academia to join the company still have the opportunity to work with academic researchers as part of the company's external partnerships," he said.

Zerhouni said he does not regard Sanofi's new approach to R&D as a model for the biopharmaceutical industry. "I don't have the ambition to develop an R&D model to guide the whole industry. If what I do works at Sanofi, it will be adopted. If it doesn't, it will be forgotten."

## TARGET DISCOVERY TO PHASE 3: 10 YEARS

Soon after joining Sanofi as its president of global R&D in 2011, Elias Zerhouni, M.D., said he evaluated and then trimmed the company's list of compounds under development to ensure that the company's resources were being applied to the most promising projects with the highest likelihood of success. He also accelerated the pace of the company's development of one of the most promising projects: the PCSK9 antibody, a cholesterol-lowering agent that he described as the prototype example of "terrific science leading to a terrific product."

Because the project was accelerated, PCSK9's development from target discovery to Phase 3 has required only 10 years. If proved safe and effective and approved by the FDA, the PCSK9 antibody, a fully human monoclonal antibody drug, will be a first-in-class therapeutic agent.

The antibody is based on the 2003 discovery of a physician-geneticist in France who studied the genetics of family members who died from cardiovascular disease at an early age. The physician linked the family's high blood-cholesterol levels to a "gain-of-function" variant of the PCSK9 gene, which encodes a protein whose actions influence blood levels of low-density lipoprotein (LDL), the so-called "bad cholesterol." Subsequently, a U.S. researcher identified a "loss-of-function" variant of the same gene in a subset of 300 African-Americans with very low levels of blood cholesterol.

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# Pushing India's Biotechnology Industry To New Heights

By Cliff Mintz, Ph.D., contributing editor


Kiran Mazumdar-Shaw, chairman & managing director, Biocon

Biotechnology is one of the newest entrants to India's life sciences sector and is expected to drive future growth of its burgeoning pharmaceutical industry. The company largely responsible for jumpstarting India's biotechnology is Biocon Limited, a 35-year-old company founded and operated by Kiran Mazumdar-Shaw. Mazumdar-Shaw is one of India's most influential women. Biocon currently employs 7,000 people and is one of the world's top 20 biotechnology companies.

Under Mazumdar-Shaw's stewardship, Biocon evolved from its humble beginnings in 1978 as an industrial enzyme manufacturing company into one of the most recognized biotechnology companies in Asia. During her tenure at Biocon, she created two subsidiaries: Syngene (1994), that supplies contract development support services for discovery research, and Clinigene (2000), that caters to companies interested in clinical drug development. To date, she is one of the only women in the world to control and lead a publicly traded biotechnology company.

Named among *Time* magazine's 100 most influential people in the world, Mazumdar-Shaw is frequently credited with launching India's emerging biotechnology industry.

Despite her hectic schedule, she sat down with me during a recent visit to New York City to discuss Biocon, the challenges of doing business in India, and the emergence of India as a contender on the world's life sciences stage.

**Q: How did you manage to build Biocon into one of Asia's leading biotechnology companies?**

**Mazumdar-Shaw:** As you may imagine, India was a very different country in 1978 as compared with today. At that time, India was underdeveloped, financially challenged, and overly bureaucratic. And starting a business (especially a joint venture with a foreign company) was extremely difficult because India was going through a nationalistic phase.

At age 25, I started Biocon India with roughly $1,000 (10,000 rupees) I had earned and saved. I retained 70 percent ownership of the company because foreigners, according to Indian regulations at the time, could only own up to 30 percent of a joint venture. Not surprisingly, in the late 1970s, there was no venture funding in India, and new businesses depended upon high interest debt funding to start up operations.

After talking with countless numbers of Indian bankers — most did not want to give money to a young woman with no business experience in an industry they had never heard of — I was able to convince one to give me a small line of credit to start up operations. I rented space in an industrial part of Bangalore and used my garage as an office to conduct business.

Biocon India's plan was to produce industrial-scale enzymes for beer, wine, paper, animal feeds, and detergents, and by the late 1980s we were profitable. In 1989, Unilever bought out the 30 percent stake in Biocon India that was owned by my Irish partners. This was a very transformative period for Biocon because Unilever's multinational business model forced me to conform to global best practices, which, to this day, continue to differentiate Biocon from most other Indian life sciences companies. It is our commitment to global best practices that enables us to maintain our status as a world-class biotechnology company.

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By the late 1990s, I decided Biocon's enzyme business was a self-limiting one. Biocon was profitable, and things were going great, but I realized that remaining in the enzyme business would not provide me with the exponential growth I was looking for. Consequently, I turned my attention to biopharmaceuticals, which I believed was a good business opportunity for Biocon given our expertise in recombinant DNA technology and bacterial and fungal fermentations. Interestingly, Unilever had no interest in pursuing biopharmaceutical drug discovery, and in 1998, my husband, John Shaw, and I bought Unilever's share of Biocon India and became fully independent.

After the buyout, we were able to transform our enzyme business into biopharmaceuticals by leveraging our proprietary fermentation platforms and recombinant DNA technologies into statin and insulin production. However, I realized there was one technology platform that was missing — monoclonal antibody (mAb) production. Biocon acquired that capability in 2001 by in-licensing Cuban mAb production technology and bringing it to India. This gave Biocon its foundation in biopharmaceuticals.

In 2004, we took Biocon public (India's first publicly traded biotech company) and decided in 2007 to sell the company's enzyme business to Novozymes A/S of Denmark. Prior to going public, all of Biocon's manufacturing and R&D activities were self-financed. Getting listed on the Indian markets helped Biocon to become a fully integrated biopharmaceutical company, which today is one of Asia's largest mAb and biologics manufacturing facilities.

> "I often say that I can afford to innovate and possibly fail because the cost of failure in India is very affordable."
>
> Kiran Mazumdar-Shaw, Biocon

**Q: What are some of the important lessons you learned during your 35-year tenure as a biotechnology executive?**

**Mazumdar-Shaw:** I think taking risks and managing them successfully is my main strength and one of the main ingredients responsible for my success in the biotech industry. Also, I am passionate about innovation, which helps to differentiate a successful company from an unsuccessful one. Innovation is something that cannot be taught; it must be in one's DNA. And a strong innovative spirit is critical for positive leadership. Also, throughout my career, I have surrounded myself with others who share this innovative spirit and are willing to take risks with me. Of course, as an organization grows larger, the ability to take risks decreases because much more is at stake. However, I continue to promote risk-taking at Biocon, and we are very aggressive both scientifically and in execution of our IP and patent strategy.

Finally, I believe investment in R&D is going to yield huge value for Biocon, and we are going to continue to pursue that path. For example, Biocon is currently developing two innovative products we are very excited about: oral insulin (partnered with Bristol-Myers Squibb for clinical development), and an anti-CD6 monoclonal antibody (itolizumab) recently approved in India to treat autoimmune diseases like psoriasis, rheumatoid arthritis, multiple sclerosis, and inflammatory bowel disease. The next step for itolizumab is to develop and get it approved (by partnering with a larger company) in the U.S. as a treatment for certain autoimmune disease indications.

**Q: Do you think Indian drug manufacturers are ready to compete in the innovative drug discovery and development space?**

**Mazumdar-Shaw:** India has emerged as a significant global player in the low-cost manufacture of generic prescription drugs. I think Indian companies continue to focus on generic drug development business, as compared with innovative drug development, because Indian investors are extremely risk averse. This attitude is what drives the whole business ethos of the Indian pharmaceutical sector. But there are early signs that innovative drug development is beginning to take hold in India.

India offers the world an affordable platform for cost-effective drug innovation. I often say that I can afford to innovate and possibly fail because the cost of failure in India is very affordable. When other biopharma entrepreneurs realize this, I believe there will be an innovation explosion in India.

While many Big Pharma and biotech companies are getting out of R&D because "innovation is too expensive," India offers a unique opportunity to show the rest of the world that affordable innovation is possible and can help to deliver much-needed new drugs to address unmet medical needs.

**Q: What are your views on the future of the global biosimilar market?**

**Mazumdar-Shaw:** I believe biosimilars are the future, but

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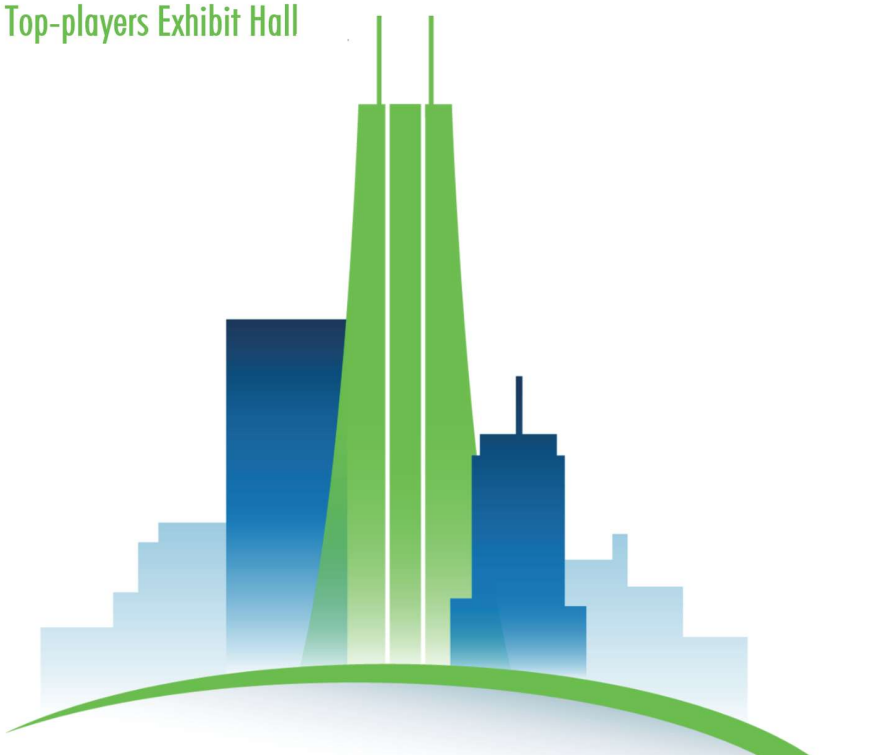

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they will go through a painful period of slow acceptance over the next 10 years or so. But it is only a matter of time before biosimilar products will penetrate global markets as aggressively as small-molecule generics have in recent years. This is because national healthcare systems must seriously begin to address the escalating costs of prescription drugs. However, unlike generic small-molecule drugs, biosimilars face many tough challenges.

First, some of the regulatory requirements for approval of biosimilars in the U.S. don't make rational sense. For example, the stipulation of using a U.S. reference product only to establish biosimilarity begs to be questioned. This regulatory requirement will undoubtedly raise the costs of developing biosimilar molecules for the U.S. market, which in turn may likely lead to higher prices for biosimilar drugs in the U.S.

Another big challenge is physician education. Until physicians are clearly convinced of the safety and efficacy of biosimilars, they are unlikely to prescribe them to patients. Physicians need to be convinced of the quality of a biosimilar as compared with its branded counterpart.

Perhaps one of the greatest challenges for biosimilars will be whether or not these molecules are substitutable or interchangeable with innovator products. While this is still a very contentious and a hotly debated topic, I believe biosimilars will ultimately be interchangeable or substituted for branded products and become part of standard medical practice in the future.

Another challenge is one of development cost. Current guidelines mandate extensive comparative clinical studies, often larger in size than the innovator drug. It is imperative regulators evolve an abbreviated path that shrinks both the size and timeline to commercialize biosimilar drugs, or else the objective of affordability will not be met.

Finally, biosimilar products are already quite prevalent in many emerging markets. However, unlike the past, the countries that represent these markets are aggressively establishing regulatory guidelines for development and approval of biosimilar products. To that end, we recently submitted draft biosimilar guidance to the Indian regulatory authority that includes mandatory comparator clinical trials for approval of biosimilars in India. Our goal is to ensure biosimilars manufactured in India are safe, efficacious, and of high quality.

> "I am concerned about India's willingness to implement compulsory licensing for certain drugs."
>
> Kiran Mazumdar-Shaw, Biocon

**Q: What are some of the major challenges foreign drug makers must overcome to successfully compete in the Indian life sciences market?**

**Mazumdar-Shaw:** One of the most challenging aspects of the Indian pharmaceutical market is drug pricing. Most of the drugs being developed by Western companies will simply be too expensive to sell on the Indian market. This is forcing many multinational companies to consider dual pricing and branding strategies; that is, they offer a lower price for India and other emerging markets as compared with the rest of the world. While the sheer size of the Indian market suggests this may be a viable strategy going forward, many multinational pharmaceutical companies are still weighing their pricing-strategy options.

Fragmentation of Indian supply and drug distribution chains is another huge challenge for foreign drug makers. For example, every state in India has a different set of regulations for drug distribution. Also, the current system literally supports hundreds of thousands of pharmacies and physicians with different local and regional needs. The Indian market is extremely complex and the one-size-fits-all drug distribution model favored by Western drug companies would be impossible to implement in India.

Finally, penetration of the different markets that exist in India is also extremely challenging. For example, the needs, infrastructure, and dynamics of Indian urban markets are very different from those of the semi-urban markets, which are again markedly different from those of rural Indian markets. To be successful, foreign drug companies must understand and embrace the differences of these markets and determine the best way forward for each of them.

**Q: What are your thoughts on the recent patent rulings that many multinational pharma and biotech companies claim are making it increasingly difficult for foreign companies to compete in India?**

**Mazumdar-Shaw:** The Indian government has been very clear from the beginning that it will not accept "evergreening" of patents. The recent Indian court decision not to honor Novartis' Gleevec patent extension, in my opinion, was a clear example of

"If the Indian government continues to refuse to respect IP, then it is very likely that multinational drug companies will not choose to launch new products in India."

Kiran Mazumdar-Shaw, Biocon

evergreening. So the decision not to honor the Gleevec patent was consistent with previous court opinions and its stated intentions.

I am concerned about India's willingness to implement compulsory licensing for certain drugs. IP is vital for innovation, and the Indian government must respect it (and protect it) if it wants India to play on the world life sciences stage.

I frequently tell Indian compulsory licensing advocates that there is a big difference between the costs of innovation and imitation. Consequently, India should not frivolously grant compulsory licensing of multinational drugs to Indian generic companies that have invested nothing in drug development. Innovative companies must be compensated to continue to be able to innovate. Further, there are lots of avenues open to the Indian government to subsidize purchasing-price parity for multinational drugs in India short of compulsory licensing.

In addition, the Indian government has completely abdicated its responsibility for providing access to potentially life-saving drugs for patients; in India everyone pays out-of-pocket for their drugs. The government should be buying these drugs at negotiated discounted prices and providing them to patients. Instead, Indian companies are looking for loopholes in trade agreements to induce the government to declare compulsory licensing for certain drugs. I think this approach is wrong-headed because the quantities of "cheap" drugs that will actually be sold in India will be quite small, and India's reputation as a place where IP is protected and innovation can take place will be seriously damaged globally.

Unfortunately, the Indian government continues to attempt to protect its generic drug industry and, in my opinion, needs to be much more respectful of IP. If the Indian government continues to refuse to respect IP, then it is very likely that multinational drug companies will not choose to launch new products in India, which could have very devastating healthcare consequences for its people. As far as I am concerned, India should respect IP, encourage innovation, and negotiate drug pricing from a position of strength, not weakness.

## Global Business Update

# Israel Drives Middle East Biotech

By Gail Dutton, contributing editor

Israel has been called, accurately, a nation of start-ups. With its scientifically oriented population and entrepreneurial drive, the nation is driving Middle East biotech. Approximately 60 percent of Israel's life sciences companies focus on medical devices, while about 35 percent focus on biopharmaceuticals. Typically, 40 to 60 biotech companies are founded each year.

Per capita, Israel has the most biotech start-ups in the world. Entrepreneurs make up 6.4 percent of the population. Israel has one of the highest concentrations (1.45 percent of its population) of scientists in the world — a percentage that was enhanced by the 1990s' influx of Soviet-trained scientists and engineers. To put this in context, the percentage for the U.S. is 0.81, according to CORDIS, the EU's Community Research and Development Information Service.

## BIOPHARMA PRESENCE GROWS

Benny Zeevi, co-chairman of the Israel Advanced Technology Industries (IATI), characterizes the Israeli life sciences industry as "relatively young, rapidly growing, and exuberant." Currently, more than 800 life sciences companies operate in Israel, and nearly two-thirds are less than 10 years old. More than a third already generate revenue. The Israeli life sciences industry is dominated by the medical technology industry, but the pharmaceutical field is growing. In March, ClinicalTrials.gov reported 4,013 clinical trials were currently underway, up from 3,000 a few years ago. (This figure includes trials conducted in Israel by international companies.) That's 70 percent of all the clinical trials conducted in the Middle East.

TEVA Pharmaceutical Industries dominates Israel's list of biotech success stories. Founded in 1901, TEVA has become one of the world's leading pharmaceutical companies, developing innovative specialty medicines as well as generic and OTC products, active pharmaceutical ingredients, and new therapeutic entities. It actively partners with the growing number of biotech start-ups.

Many of Israel's biopharma companies have grown beyond the one-man-and-a-lab stage. About 30 of the companies are midsized and are beginning to make their marks. For example, Protalix Biotherapeutics is using its proprietary plant-based expression system to develop enzymes used in treating Gaucher disease. Its product, Elelyso, recently received regulatory approval in the U.S. and Israel. Five other compounds are in the pipeline. The most advanced is entering Phase 2 trials. Another firm, Gamida Cell, expects to launch its stem-cell-based leukemia therapy, StemEx, in 2013. Five products are in its pipeline. Cell Cure Neurosciences is working to develop OpRegen for age-related retinal degeneration. Human trials are ongoing.

Medical device patents comprise the largest segment of Israel's life sciences portfolio. Overall, drugs discovered in Israel — though often developed elsewhere — account for approximately $25 billion in annual sales, notes Ruti Alon, general partner at the venture capital firm Pitango and IATI conference co-chair.

## LATE-STAGE FINANCING NEEDED

Funding is, perhaps, the biggest challenge for biopharmaceutical companies in Israel and throughout the world. Israel boasts 25 to 30 active VC firms but only about 10 actively invest in biopharma. One, Pitango, has $1.4 billion under management and includes 16 life sciences companies in its broad portfolio. Additionally, in 2011, Merck Serono launched the Merck Serono Israel Bio-incubator Fund. The purpose, according to Merck, is to "accelerate the successful development of entrepreneurial start-up companies." It offers seed financing and the opportunity for researchers to use a dedicated part of Merck Serono's Israeli research and development center, Interlab, for their own projects. Over a seven-year time span, Merck Serono plans to invest a total of 10 million EUR into this fund.

To help bridge the funding gap, the Israeli government established the Heznek venture capital fund in 2002, with a focus on life sciences, software, and communications. The organization matches the capital funding secured from

outside investors or investment entities, providing matching funds peak at 50 percent of the total capital requirements, and do not exceed 5 million NIS (New Israeli Shekel, the currency in Israel) — about $1.3 million. The fund invests in companies that are less than six months old with less than 1 million NIS in expenses. The government's investment is exchanged for shares in the company, which the matching investor may purchase at the original price (plus interest) during the first five years of the investment.

Nonetheless, like most young biotech companies, Israeli firms need additional financing. As Zeevi says, "To become a global company takes time and a lot of money. We have almost no late-stage funding." Companies need this influx of cash to take them all the way to commercialization or, at least, to the point at which licensing or mergers or acquisitions become feasible.

Among firms funded by venture capital, "For pharma/biotech companies, licensing is the most probable funding and exit strategy," Alon says. "For medical device companies, the most common exit is via mergers and acquisitions."

The exit strategy for medical devices, however, is shifting to licensing as the costs of trials leading to commercialization increase. "The structure of licensing deals gives the acquirer better control in validating the value of the assets it is interested in buying," Zeevi explains. Acquisitions may evolve from those licensing agreements.

For relatively young companies, the stock markets are virtually closed, Alon says. Currently, NASDAQ lists nine Israeli biotech or pharmaceutical companies. The Tel Aviv Stock Exchange (TASE) lists approximately 60 biotech companies.

## GOVERNMENTS OFFER INCENTIVES

The Office of the Chief Scientist (OCS) is a good starting point for companies interested in investing in Israeli biotech. That office is a function of Ministry of Industry, Trade, and Labor, which is charged with executing government policy to support industrial R&D. To attract biotech specifically, the government is establishing a new biotech incubator to help attract large, international pharmaceutical companies to Israel. This bio-incubator will join the more than 20 incubators or accelerators in Israel. "But not all include biopharma," Alon points out.

Israeli biotech can count on "significant government support" from that office, Zeevi says. Multiple programs and incentives are available. "But," Alon cautions, "that is mainly initial funding. Companies must develop additional funding sources."

Much of the support comes in the form of tax incentives for local and foreign investment that significantly reduce the corporate tax rate. "These incentives for approved enterprises are included in the Encouragement of Capital Investments Law, which took effect January 1, 2011," Alon says.

As in the United States, Israel levies taxes on the global income of companies incorporated there, and on the income of foreign companies operating there. However, it has tax treaties with many nations, including the U.S., to avoid double taxation. The corporate tax rate for 2013 is 25 percent. Income tax rates on individuals increased January 1, 2013, and the tax burden for individuals and corporations appears to be in flux.

## STRONG INDUSTRY/ACADEMIC PARTNERSHIPS ARE NORMAL

Israel's young biotech industry is supported by strong research institutions. The seven universities there excel in neurology, oncology, vaccine, and stem-cell work. Israeli scientists pioneered the in-vitro differentiation of human embryonic stem cells (hESCs) and their genetic modification, which led to a cell line representing Lesch-Nyhan disease. "We don't have legal issues that halt stem-cell research in Israel," Zeevi points out.

Most of the universities have ties to the industrial parks that are home to R&D centers and laboratories for some of the world's leading life science companies. Additionally, an OCS magnet program forms consortia composed of university research departments and high tech companies in multiple fields, including biotech. Consequently, investigators are cognizant of requirements for scale-up and commercialization and are likely to consider them during the early stages of project design.

Each university handles its own technology transfer program. The Hebrew University of Jerusalem, Tel Aviv University, Technion Institute of Technology, and the Weizmann Institute of Science are most active in research. "The Weizmann Institute of Science and Hebrew University are very successful," Alon says. Hebrew University, for example, has discovered several blockbuster drugs. They include Exelon, developed by Novartis to target Alzheimer's disease, and Doxil, commercialized by Johnson & Johnson to target cancer. At the Weizmann Institute, scientists have developed drugs to treat multiple sclerosis, Alon says. The Weizmann Institute has registered approximately 1,400 families of patents since 1959 and spun out 42 companies — half of them since 2000.

According to the Worldwide Intellectual Property Organization's (WIPO) list of educational institutions filing patents, Hebrew University ranks 23rd in the world in the number of total patent filings in 2011, with 52. Tel Aviv University holds 33rd place, with 43 patent filings. In terms of academic ranking, Hebrew University, Tel Aviv University, Technion, and Bar-Ilan University are among the world's top 400 universities, according to the British weekly magazine, *Times Higher Education*. Consequently, corporations working in Israel have ready access to innovative employees trained at world-class institutions.

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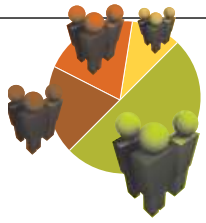

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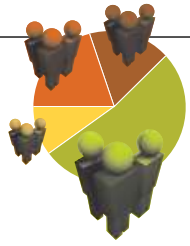

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# Global Pricing Data, Analytics Enable Better Decisions And Competitive Edge

Increasing price transparency and global competition are key challenges faced by companies across all industries, and pharma manufacturers are no exception. Today's pricing decisions cannot be based on instinct or informal methods, due to the high level of risk incurred through inaccurate practices.

Analytical pricing strategies are used worldwide. For example, in the financial industry, decisions based on pricing data and advanced analytics have been long-established and are an integral part of price setting. For the travel industry, benchmarking competitor prices hourly and ensuring pricing decisions are optimized are recommended practices. The question is: Why not apply the same principles to pharma pricing? Basing decisions on data and analytics empowers the decision maker and allows full confidence in the choices made.

Data and analytics have become powerful tools for pharmaceutical organizations in their endeavor to stay ahead of competitors. Best practice shows that better data and analytical models improve decision making and provide better business outcomes. Within the pharma industry, data forms the basis of many decisions: Clinical data defines whether or not a drug is effective, sales data defines market share, and advanced data models drive cost-effectiveness decisions made by health-technology authorities.

Opportunities exist for pricing data to play a part in strategic pricing and market access. With so many innovative pricing schemes and tactics, pharmaceutical competitor price intelligence is crucial in optimizing prices and gaining a competitive edge. The use of data analytics can help to move pricing behavior from reactive to proactive decisions based on predicted market conditions.

## HOW TO USE PRICING DATA AND ANALYTICS IN PHARMA

***Test For Competitor Response:*** Competitors do not evolve in isolation — they are responding to the relevant companies in the industry, if they have the freedom, knowledge, and capability to do so. Knowing how the launch of a direct competitor affects the price of a product across markets is essential in knowing how to react.

***Business Transformation:*** Data allows you to visualize what is happening in the outside world and to shape competitor actions. Modeling allows manufacturers to make the best use of the data to help predict competitor actions and optimize business strategies. Transforming business decisions based on data and models also enables organizations to keep ahead of competitors and make business processes more efficient. This is particularly essential in emerging markets where policy and pricing are not clear.

***Internal Transparency:*** Internal transparency of the entire price waterfall, from list price to reimbursement price, including all discounts and rebates, is essential in understanding distribution chains across markets and analyzing the impact of pricing decisions. For example, some organizations have attempted to increase the list price only to find that, because of additional discounts and rebates, the pocket/net price did not actually go up, translating into considerable internal and external hassle for little financial reward. Successful companies focus on the full price waterfall when implementing price increases, ensuring that the uptick in profit is a worthwhile result. In some markets where regional purchasing power is important, such as Spain or Italy, it may be necessary to consider price waterfalls at local and regional levels.

Preeti Patel

Patel is VP of strategic consulting at Alliance Life Sciences. She is a PRINCE2 practitioner and clinical pharmacist with more than 10 years of experience in pricing and reimbursement.

***Analytics and Simulation Capabilities:*** Best practices include established price trending simulation capabilities, often combined with product differentiation and the capability to model multiple scenarios. Simulating the impacts of prices and trending improves the predictability of pain points.

***Legislative Changes:*** Tracking the impact of country legislative changes for medicines at a time when cost-containment pressures are being faced by healthcare systems everywhere is important. If prices go up in one country, but the price for the same or similar product remains unchanged in a neighboring country, parallel imports and international referencing are often the result. Studying the impact of price changes on referenced markets is critical for making informed decisions, such as price cuts or removing products from the market. Understanding the impact legislative reforms have on product pricing is important in making the most appropriate decisions.

A number of tactics can be used to ensure price and portfolio optimization other than changing the price — ranging from introducing unique pack definitions in some markets to ensuring a strategic launch sequence to maximize achievable prices. Having the ability to map out the implications of each scenario is important in establishing which direction to take.

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# How To Achieve More When Resources Are Tight

Gaurav Gupta (right), principal and Corey Pappel, consultant; Stroud Consulting

Opportunities exist in every business that are not being realized; in fact, you can probably name 10 valuable initiatives not being persued in your business before you've had your morning coffee. The problem is that even short lists of goals often generate long lists of opportunities, all competing for the same limited resources. As many have found through experience, sometimes less is indeed more. When resources are constrained, as they almost always are, you're forced to make tradeoffs to decide what priorities to focus on, and these tradeoffs can leave good opportunities on the table.

But what if you could increase the effectiveness of your existing resources? What if your resources could realize an opportunity in a matter of weeks instead of months, with increased certainty that they would meet or exceed their targets for each opportunity?

Here are four potential opportunities to help limited resources achieve more than previously believed possible.

## 1. TAKE A RELENTLESSLY RIGOROUS APPROACH TO PROBLEM SOLVING.

Many methods exist for solving problems, from guess-and-check solutions to brainstorming to thorough, fact-based analysis. Approaching every problem with a rigorous problem-solving approach, though seemingly time-intensive, will dramatically increase the likelihood of solving a problem the first time. This will ultimately free up precious resources to tackle the next big challenge.

## 2. TRAIN LESS — IMPLEMENT AS-NEEDED TRAINING.

With more and more training programs available to businesses and with the perceived scalability of these programs, many organizations have taken the approach of wide-scale training, believing that 10,000 black belts are better than 1,000. However, training that is not directly applied is most often wasted — people only retain a fraction of what they learn if they don't use it immediately. Establishing a training program that is targeted and just-in-time frees up resources to execute top-priority opportunities.

## 3. IMPROVE RESOURCE ALLOCATION.

Resource allocation can be tricky, and by closely examining roles and responsibilities and looking for ways to create leverage, you may be surprised at how much opportunity you find in improving your organization's effectiveness. For example, ask yourself the following questions:

**Have you engaged the broader organization in improvement activities?**

Everyone from the shop floor to company leadership can have a role in improvement. Finding ways to leverage specific skills in your organization can help increase bandwidth of other resources and increase engagement across the organization. Finding ways to simplify or segment tasks might allow you to better utilize shop-floor operators in data collection, problem identification, and testing.

**Is your accountability structure set up to minimize non-value-added work?**

Ensure that the person accountable for delivering an improvement is positioned to make the necessary change. Too often the improvement resources are tasked with driving a change but lack clear stakeholder support. Excess time and energy is then spent either resetting expectations or gaining alignment. This non-value-added work could be prevented with the right expectation and accountability of all involved business functions.

**Do individuals have too many prioirities?**

Just as organizations lose effectiveness when addressing too many opportunities at once, so do individuals. Advancing multiple opportunities at once can provide an illusion of urgency and progress; however, it is often a false sense of urgency with more activity than progress. Working on fewer parallel tasks allows your team to focus on delivering specific results quickly, creating a continuous sense of accomplishment and freeing them up to tackle the next big challenge. The path to greater individual effectiveness is to accelerate the rate of completion, not expand the number of priorities.

## 4. REEVALUATE WHETHER YOU ARE TRULY WORKING ON THE MOST IMPORTANT PROBLEMS.

This sounds obvious, and most people believe they are already doing so. But, while most organizations have a system for prioritizing opportunities, there is hidden opportunity in challenging the perception of the value of specific opportunities and the complexity of realizing them. Taking a data-driven, rigorous approach to understanding the value and complexity may present priorities that you did not initially expect — you may find that the opportunities that have been deemed to be hard are not so.


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# Building A Talent Pipeline

Teresa Shaffer

As a senior executive, you have myriad professional responsibilities. Although most are tangible and driven by your place within your organization, there are silent others that are just as important to your organization, such as sponsoring the professional development of a junior executive.

## Sponsors vs. Mentors

Sponsorship is more strategic and less developmental than mentoring. Sponsors leverage relationships, power, resources, and business savvy. They demonstrate leadership competence and are genuinely willing to help others in order to grow future leaders. A good sponsor also builds awareness with other influential executives on the importance of being a sponsor.

I was coaching Ted, who was a highly talented director of a large financial institution. He enjoyed leading his team, and was very committed to the organization. His goal was to move to a VP position, but he was never recognized when the opportunity arose.

After meeting with Ted and learning what he had accomplished, it became apparent he needed stronger sponsorship to help him get to the next level. I worked with Ted to help him identify an executive in his company, whom he respected and admired, that he could ask to be his sponsor. Even though Ted knew the executive and they had a collegial relationship, he needed a sponsor to champion him in executive meetings and talent reviews, so he could gather more support from other influential executives for the VP position. Ted was honored when the executive agreed to sponsor him.

Ted's sponsor helped him gain visibility and credibility with the executive team by having him lead a critical companywide project. Together, we implemented the five tips below. Now, Ted is well on his way to his goal of a vice presidency.

I have sponsored many individuals over the years, and I always thought it was important to use my most precious resource, my time, as wisely and as effectively as possible. Here are some practical tips I've successfully applied as a sponsor that were an efficient use of time but also had the greatest benefit for the person and company I was sponsoring:

- Champion the protégée in talent reviews and executive meetings.
- Help the protégée identify lead projects that offer visibility with the executive team.
- Set up regular meetings with them to identify and help overcome obstacles, offer advice through the process and before their next interview.
- Introduce them to key decision makers.
- Recognize and reward their achievements at a regional and national level.

Take a look around your organization. Like so many, yours may be losing its top talent to retirement in the next few years. Who is in the pipeline to take their place — to take your place? Having a hand in choosing the next generation of top talent can be one of your most rewarding responsibilities yet.

Teresa Shaffer is a certified executive coach and professional coach. Prior to founding Shaffer Executive Coaching, she built a highly successful, award-winning corporate career that included progressive responsibility in sales, senior management positions, and leadership training. Prior to her corporate positions, Teresa worked within one of the nation's top 10 U.S. healthcare systems.

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